PRO-GRACE

PROMOTING A PLANT GENETIC RESOURCE COMMUNITY FOR EUROPE

DELIVERABLE 2.2

Blueprint for a Genebank Quality Certification System

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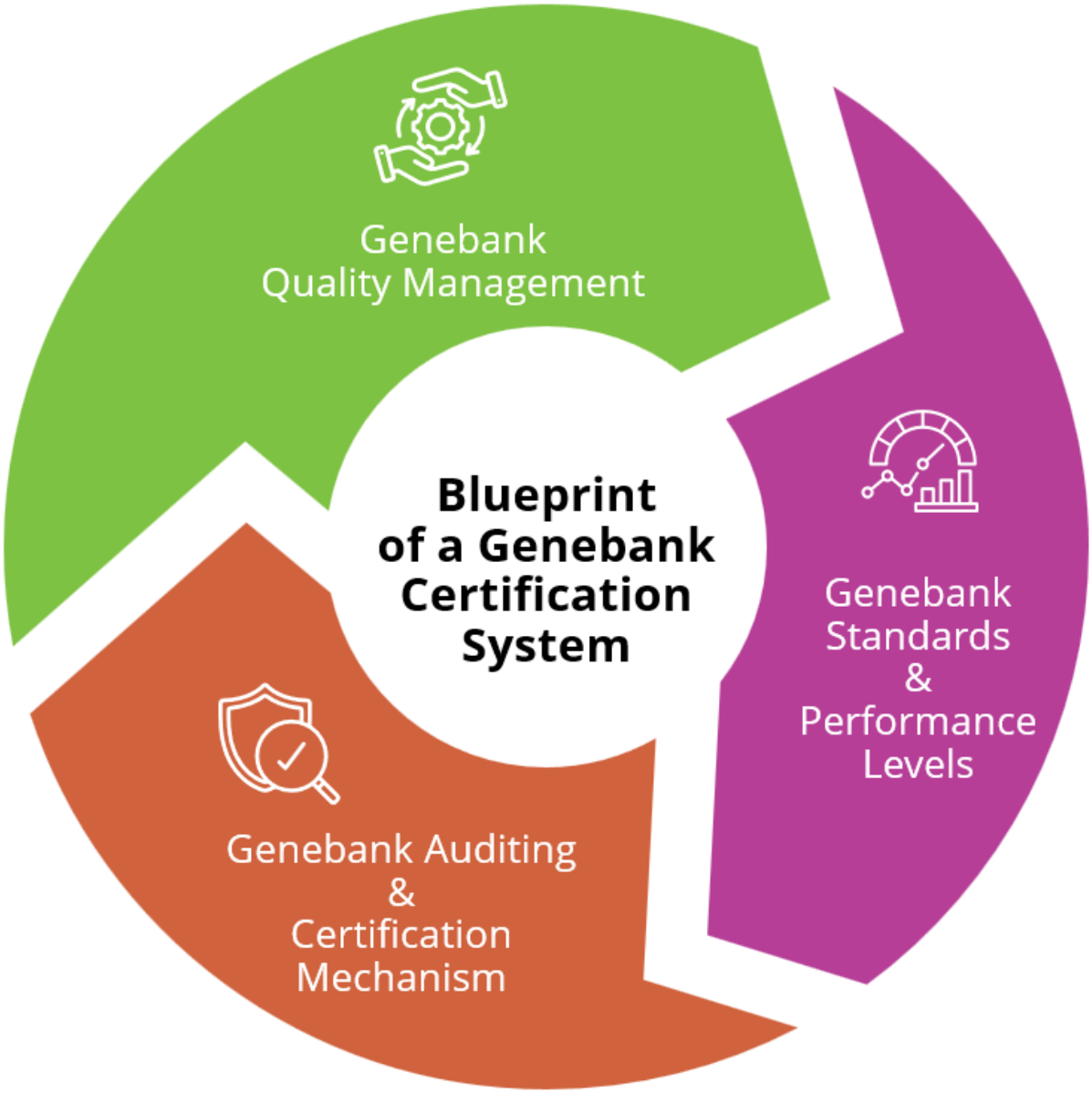
Genebank
Quality Management
Blueprint
of a Genebank
Certification
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Genebank
Standards
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Certification
Mechanism

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1. Executive summary

The conservation of Plant Genetic Resources (PGR) is crucial for global food security and agricultural resilience in the face of environmental and societal challenges. Effective PGR conservation relies on various methods including *in situ*, on-farm, and *ex situ* approaches. Global cooperation is essential, as no single genebank or country can manage the world's plant genetic diversity alone. A certification system for genebanks would strengthen collaboration, ensure quality, prevent duplication, and secure funding for sustainable PGR conservation. This blueprint for a certification system has been designed for long-term *ex situ* conservation of orthodox seeds in genebanks but it could be expanded to other methods like *in vitro* or cryogenic storage over time.

A robust certification system would include three key components:

- Quality Management Systems (QMS) in genebanks to ensure operational transparency.
- Minimum Standards and Performance Indicators that establish benchmarks for genebank operations.
- Independent Auditing and Certification to verify adherence to these standards and ensure consistency in operations.

A Genebank QMS is crucial for maintaining and improving quality and creating transparency in operations. While the globally recognized ISO 9001 standard provides a comprehensive quality management approach, it may be challenging for some genebanks to implement due to cost. The Global Crop Diversity Trust (GCDT) offers a specialized Genebank QMS that aligns with the FAO Genebank Standards. It includes standardized processes, comprehensive documentation, quality assurance through audits, risk management, continuous improvement, and staff training.

Regarding the minimum standards, the certification system can draw on the FAO Genebank Standards and CGIAR's Genebank QMS, focusing on the various areas of genebank management. In addition it should also incorporate continuity to ensure that another genebank can take over operations if one fails, preventing disruptions in access to resources.

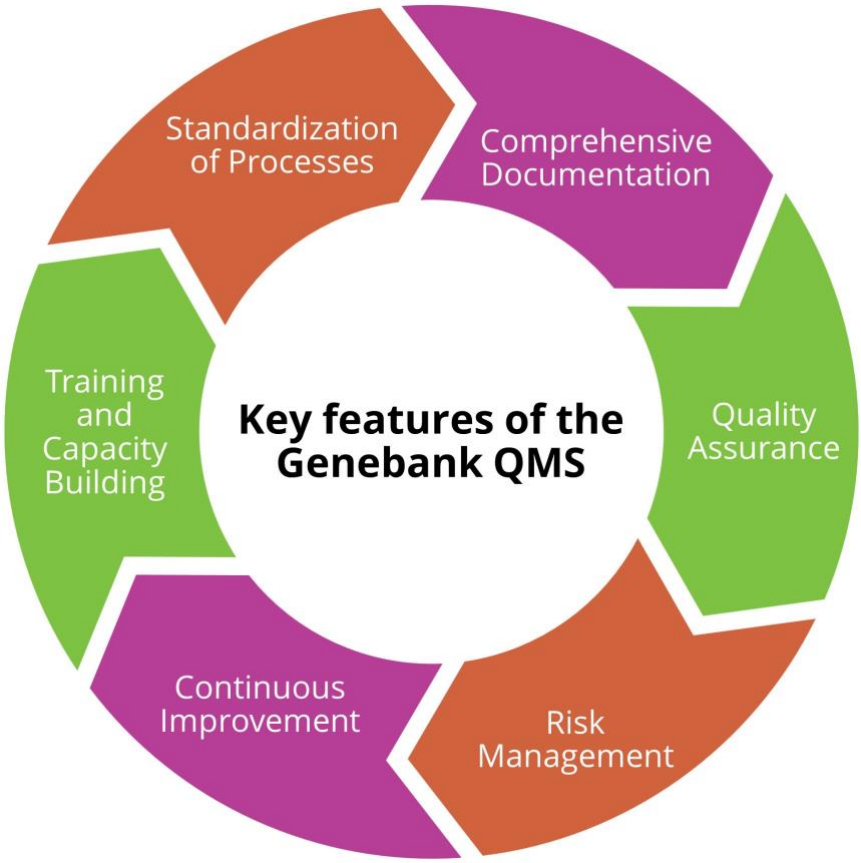
Finally, the auditing and certification mechanism would involve a certifying agency that develops a verification system to ensure compliance with procedural standards. This agency would establish reporting, auditing, and certification processes, potentially offering tiered certification levels to recognize varying degrees of excellence in genebank operations.

Genebank Quality Management

Genebank Quality Management (GQM) refers to the structured processes, tasks, and activities designed to ensure the quality and transparency of genebank operations. This includes quality planning, assurance, control, and improvement, aiming to align genebank activities with agreed standards.

A widely recognized framework for quality management is ISO 9001, a global standard that emphasizes process management, risk-based thinking, leadership, and continual improvement. ISO 9001 is applicable to any organization seeking to demonstrate its efficiency, transparency, and capacity for

quality. The standard prioritizes understanding customer needs, enhancing satisfaction, and embedding quality management into the organization's processes. Certification under ISO 9001 requires an audit by an independent body, ensuring that the genebank consistently meets the criteria. While beneficial in terms of efficiency, customer satisfaction, and reputation, implementing ISO 9001 can be resource-intensive, which might not be feasible for all genebanks. Thus, an alternative QMS that maintains core quality management principles might be needed.



A functional alternative is the Genebank Quality Management System (GQMS) developed by the Global Crop Diversity Trust (GCDT). This system, utilized by CGIAR+ genebanks, offers a tailored approach to managing PGR focused on food security. The GQMS incorporates mechanisms for online reporting, performance monitoring, auditing, and validation. Key elements of the GQMS include:

1. Standardization of Processes: The system sets guidelines based on FAO Genebank Standards for collection, storage, documentation, and distribution of genetic material.
2. Comprehensive Documentation: It requires detailed record-keeping for each sample, including its origin, genetic traits, and storage conditions, ensuring traceability and accountability.
3. Quality Assurance: The system employs internal and external audits to evaluate compliance with standards and pinpoint areas for improvement.
4. Risk Management: Procedures are in place to assess and mitigate risks such as environmental threats, equipment failure, or human errors that could affect genebank operations.
5. Continuous Improvement: The system encourages ongoing review and refinement of processes to optimize genebank efficiency and effectiveness.
6. Training and Capacity Building: The GQMS emphasizes staff training to ensure personnel are equipped to maintain the security and integrity of PGR.

Although the GQMS shares principles with ISO 9001, it is more specialized for the conservation of PGR. Thus, the GQMS blends quality management with minimum performance standards for genebanks.

For Genebank Certification, genebanks must, in any case, demonstrate adherence to quality management principles through a series of minimum requirements:

- A description of the quality management system (QMS), detailing scope, roles, and responsibilities.
- Documented procedures, typically in Standard Operating Procedures (SOPs), covering key activities related to PGR conservation and accessibility.
- Evidence of SOP compliance through records.
- Documentation of staff training and competence to perform SOPs.
- Active feedback collection from users and responsive actions.
- Evaluations of performance, including non-conformances, updates to SOPs, and user feedback, reported to the certifying body.

Genebank Standards and Performance Levels

The Genebank Certification System aims to ensure that PGR are reliably conserved and available, with continuity guaranteed for future generations. It emphasizes flexibility for genebanks to develop their own operational solutions while adhering to essential conservation and accessibility standards. Two major frameworks guide this system: the FAO Genebank Standards and the CGIAR Genebank Quality Management System (QMS), both focusing on seed conservation. However, neither includes a continuity element, which has been added in the proposed certification system.

The FAO standards, established in 2014, outline operational guidelines for genebanks. These standards cover key conservation activities and seed storage (but do not address continuity in conservation). The CGIAR's QMS expands upon the FAO standards by making them more practical and operational. The QMS focuses on the full lifecycle of seed management, from acquisition to distribution and safety duplication. While it is aligned with FAO guidelines, it places a stronger emphasis on the operational aspects of seed conservation, ensuring that genebanks adhere to quality management throughout their processes.

The proposed certification system integrates the core principles from both the FAO and CGIAR standards, while also introducing additional requirements for continuity in conservation efforts. Below are some of the fundamental principles outlined for the certification system:

- Acquisition: All germplasm should be acquired in compliance with national and international laws. Each accession must be legally obtained, with a clear "paper trail" documenting its origins and acquisition terms.
- Seed Storage: Seeds should be stored under conditions that maximize their longevity and minimize the need for regeneration. Optimal storage involves maintaining a temperature of -18°C and appropriate moisture levels.
- Viability Testing: The viability of seeds must be regularly monitored to ensure they remain viable. The frequency of testing should balance reliability with cost-effectiveness, taking into account the species and its characteristics.

- Regeneration: Accessions should be regenerated periodically to ensure sufficient seed availability. The process should aim to maintain genetic integrity and avoid contamination. Regeneration methods should be customized to each species' needs but must follow basic principles such as adequate population size and proper isolation techniques.
- Characterization and Evaluation: Characterization helps confirm the identity of accessions during regeneration. While evaluation is encouraged to enhance the usefulness of materials, it is not mandatory for certification.
- Documentation and Information Management: Genebanks must maintain comprehensive records on each accession, including passport data and management history, in an accessible, secure, and well-organized database.
- Distribution: Accessions should be readily available for distribution, with clear criteria for handling requests. Requests should be processed efficiently, and distribution should follow the conditions outlined in the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).
- Safety Duplication: Each accession should be duplicated in another genebank, and preferably also in the Global Seed Vault, to ensure backup in case of disaster.
- Germplasm Health: Genebanks must ensure that their materials meet phytosanitary standards to prevent the spread of plant diseases.
- Continuity: In the event of a genebank discontinuing its operations, certified genebanks should be able to take over the conservation and distribution responsibilities, ensuring that no material is lost.

This certification will ultimately enhance the reliability, accessibility, and longevity of PGR globally.

Genebank Auditing and Certification Mechanism

A certifying agency plays a key role in developing a verification mechanism to ensure compliance. The certification system includes procedural standards, verification mechanisms, and a process for reporting, auditing, and certification, with potential levels (e.g., bronze, silver, gold). The certifying agency has the flexibility to tailor the system to meet specific genebank needs.

2. Introduction

Plant genetic resources (PGR) form the raw material for plant breeding; without PGR no new crop varieties can be developed, and agriculture will not be able to adapt to changes in the environment, agricultural practices or consumer demands. The world needs to conserve its PGR, since otherwise they will disappear due to genetic erosion and/or extinctions caused by anthropization, climate change, changes in agricultural practices and other deleterious causes.

There is a range of synergistic approaches for conserving PGR. For example, crop wild relative populations can best be conserved in their original environment (*in situ,* often in nature) provided that they are well protected against land conversion, climate change and other threats; fruit trees are best conserved in the orchards where they are generally grown (on-farm), and field and horticultural crop orthodox seeds best in genebanks where they can be dried, frozen and maintained for many decades (*ex situ*) (Engels & Visser 2003). To increase the security of the fruit trees on-farm, it is advisable to also store some buds in liquid nitrogen *ex situ*. Similarly, *in vitro* conservation of crops which don't produce seeds, can be necessary. Moreover, to rescue and increase access to the crop wild relatives in nature and traditional crop varieties on-farm before they are lost forever due to multiple threats, the infrastructure of genebanks can be used to back up this crop diversity and link it to germplasm users (Hintum *et al*. 2021). As far as the reliability of the conservation and access to the germplasm for the professional user community is concerned, *ex situ* seed collections are generally considered to be the most efficient approach, as long as they are stored in dried and frozen form. Luckily, most of our field and horticultural crops can be stored in that way (FAO 2014).

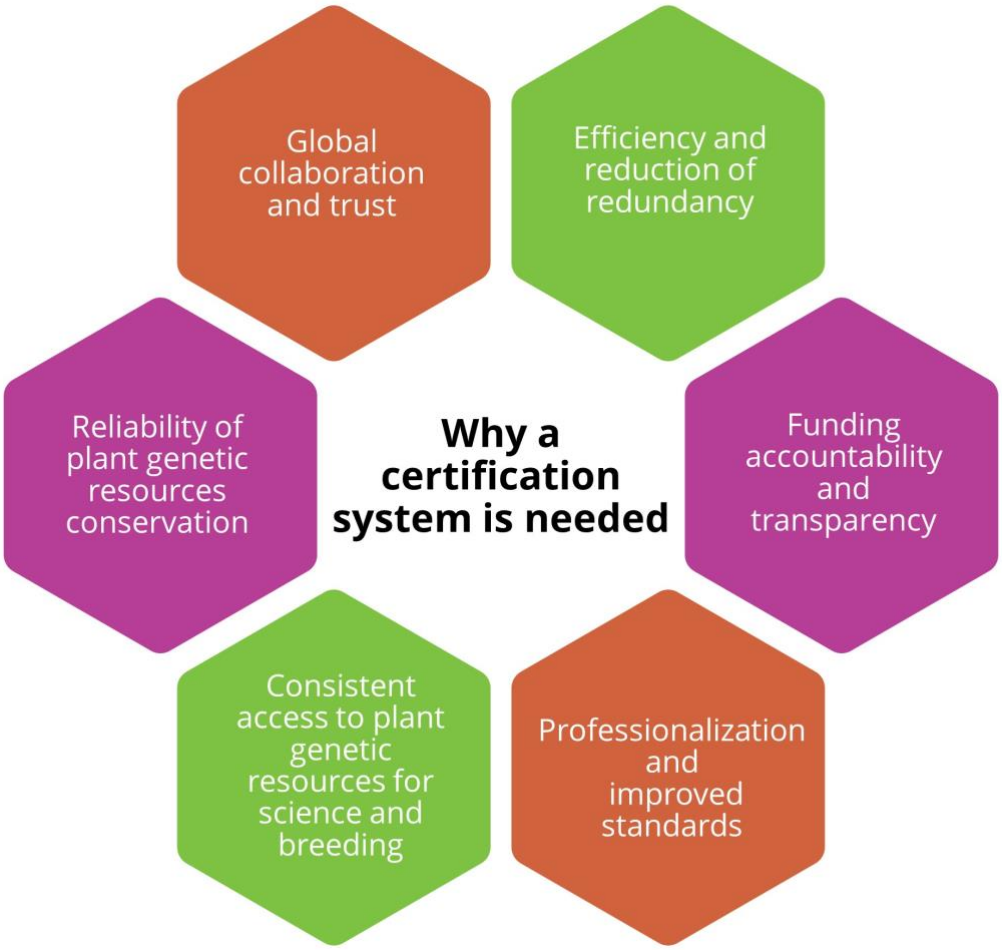
Why a certification system is needed

No single genebank or single country can conserve the world's PGR alone. Countries interdepend on each other for genetic resources, and national, regional, and international genebanks are tasked to conserve the world's PGR and make it available to relevant users. Collaboration and division of tasks is crucial to get the work done collectively. However, this requires mutual trust. Genebanks will be able to rely on each other if they use mutually agreed standards and reach a mutually agreed quality level.

Agreement on a minimum genebank quality level will increase reliability of access and conservation, it will also avoid unnecessary duplication of material and activities. The current level of redundancy between genebanks is large as many genebanks conserve the same material, especially for crops like wheat and barley (Hintum 2000, Singh *et al.* 2019). This redundancy will only be reduced if genebanks can rely on each other: 'If you do it, I do not need to do it.' The introduction of a system of certified collaborating genebanks is expected to reduce the costs for long-term conservation, and will allow spending more resources to fill the gaps in the joint PGR collections, and enhance the use of the collection through characterization, documentation, and distribution, hereby increasing the overall relevance and impact of the genebanks involved.

In Europe, the PGR community, as organized in the European Cooperative Programme for Plant Genetic Resources (ECPGR), agrees that this is the way forward: support genebanks in reaching an appropriate quality level and create a mechanism to ensure that it is sustained over time. In its 'Plant Genetic Resources Strategy for Europe', published by ECPGR and launched on 30 November 2021 for the EU in Brussels, the community formulated as an objective the establishment of 'a certification system, that is economically sustainable and accessible to genebanks and collection holders' (ECPGR 2021). Also, the FAO Intergovernmental Technical Working Group on Plant Genetic Resources for Food

and Agriculture in 2023 formulated the need for a system to ensure the quality of genebanks (FAO 2023). This FAO Working Group preferred the term 'acknowledgement system' over 'certification system'. In their view, the quality assurance system should be based on the FAO Genebank Standards (FAO 2014). They stated: "The Working Group also recommended that FAO look into options on how and which capacity-building and evaluation mechanisms could be created to support genebanks in reaching the Genebank Standards and explore the possibility for creating an acknowledgement system" (FAO 2023).



Another reason for creating a certification system is to ensure that the support of funding agencies for genebanks is used effectively. Many national governments, but also organizations such as the Global Crop Diversity Trust (GCDT), must ensure that the public money used for genebank management is well spent. For this reason, the GCDT created a quality management system, not only to manage and improve the quality in collaborating genebanks, but also to provide the transparency necessary to assess if funds are well spent. At a national level, The Centre for Genetic Resources, The Netherlands (CGN) became the first genebank with an ISO 9001 certification in 2004 when their funding organization, the Dutch Ministry of Agriculture, required them to implement proper quality management. The Dutch government outsourced the genebank task and their legal obligations in PGR conservation to CGN, which introduced the quality management requirement to prove that they were operating effectively.

In addition to these funding and efficiency related arguments, it is important to note that a framework for quality certification of genebanks will help to professionalize the current genebank system, making it possible to identify and close gaps and thus ensure complete coverage of the targeted gene pools, and organize optimal conservation and characterization of the accessions maintained. It would support a dynamic community of users, creating more impact to healthy and affordable food, a higher return of investment for socio-economic gains in the seed and food sector, and contributing to various policies to transition towards a fair, healthy and environmentally-friendly food system.

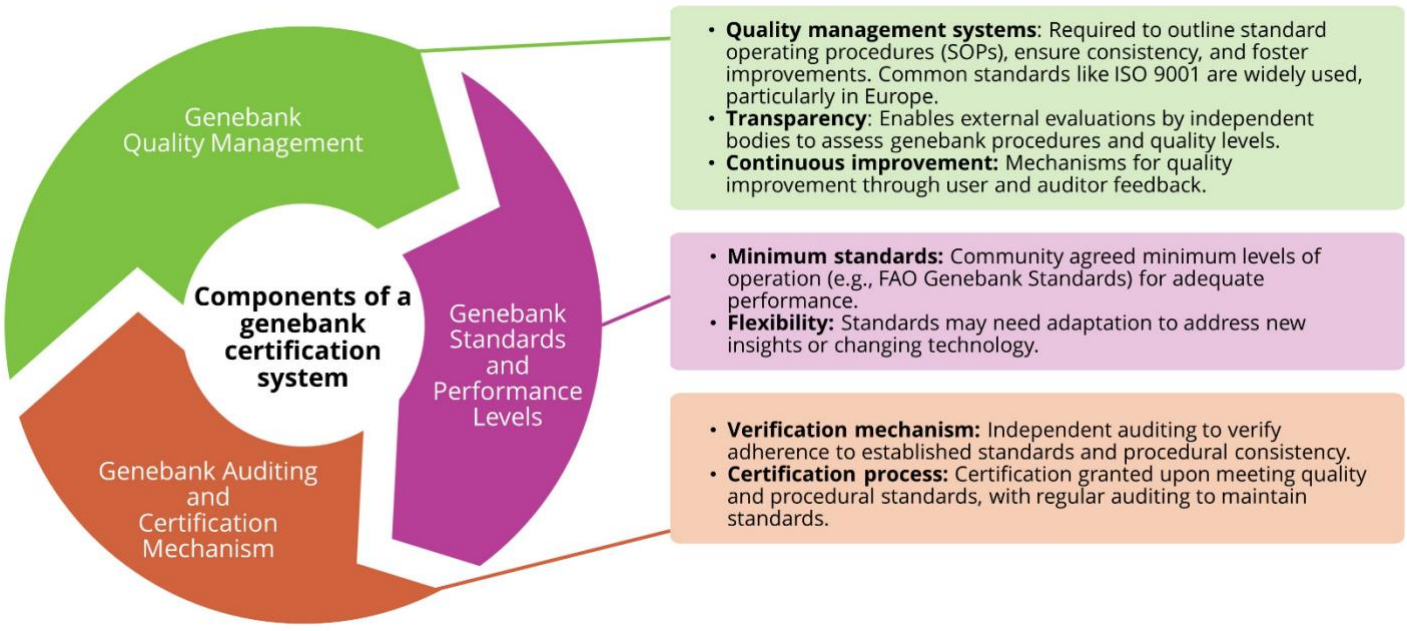
Thus, a system that guarantees an adequate quality level of genebanks to ensure access to the current generation and proper conservation for future generations of users, is needed for increased efficiency, reliability, transparency and fiduciary responsibility.

Since the conservation of and access to PGR is a global responsibility, a system guaranteeing this should be applicable to all qualified actors in the world, including international, regional and national genebanks.

The components of a genebank certification system

A system that ensures genebank quality through certification requires various elements: quality management systems in genebanks, clear quality standards and performance indicators, and a mechanism for auditing and certifications. These will be briefly introduced below and elaborated on in the subsequent chapters.

First, genebanks need to *implement a quality management system* which describes how procedures and processes are executed and how improvements are planned and achieved. The inherent transparency of the quality management system will allow an independent body to evaluate the genebank methodologies and assess the level of quality at which they function. Furthermore, an important element of most quality management systems is the quality improvement, i.e., mechanisms are built in to ensure that the procedures applied continue to improve on the basis of feedback from the users, auditors and other sources.



There are several standards that can be used in the implementation of a genebank quality management system; the ISO 9001 standard is the best known and most widely adopted in the European genebank community. A recent survey of European genebanks (Hintum *et al* 2024) showed that 11 respondents representing 14 genebanks in 7 countries, out of 43 responses representing 60 genebanks in 31 countries, indicated that there was active quality management in their genebank(s), always applying the ISO 9001 standard. In a few cases, the genebank contacts indicated that they had used other quality management standards (the French NFS 96-900 or the laboratory-oriented ISO 17025) but had stopped doing so for various reasons. Other genebanks indicated that they were working towards ISO 9001. Thus, nearly a quarter of the European genebanks that responded to the questionnaire is already actively managing their quality and is using ISO 9001.

Independent of ISO 9001, the CGIAR and WorldVeg Genebanks, under guidance of the Crop Trust, have developed and adopted a Genebank Quality Management System. It is a combination of a quality management system and the essential element of a genebank certification system: minimum levels of performance.

The second element of a genebank certification system are the minimum levels of specific performance indicators: *it should be clear what is considered an adequate level of operation*, the minimum quality standards for genebank operations. Hintum *et al* (2024) showed that the FAO Genebank Standards (FAO 2014) provide a good basis for these standards, but need to be specified, generalized or extended on various aspects to provide a sufficient quality level in the operations. For example, the viability testing protocols might be too complicated to be adopted and therefore require generalization, whereas the regeneration protocols might be too general and more specific guidelines might be needed. Furthermore, standards for ensuring access and continuity are lacking altogether. The appropriate level of specificity is important in providing clear guidelines to the genebanks without limiting the possibility to best accommodate to local situations and take crop or species-specific aspects into account.

The ISO 9001 standard for quality management doesn't contain such domain-specific standards and leaves it to the implementing organization to define them. In contrast, the CGIAR Genebank Quality Management System is genebank specific and contains many Key Performance Indicators (KPI's) for genebank operations and targets for these indicators (Lusty *et al* 2021). For example, it states that a minimum of 90% of accessions should be readily available for distribution.

Finally, the last step towards a certification system would require *an independent mechanism to (a) verify that the procedures comply to the standards and (b) that these procedures are followed*. If these two requirements are met, the genebank can be certified. This independent mechanism needs to have access to 'genebank expertise' to be able to verify that the procedures used by the genebanks comply to the standards as that will often be a difficult matter of judgement, i.e., comparing the Standard Operating Procedures (SOPs) of the genebank with the agreed community standards. The second aspect of the mechanism, the verification that the procedures are followed requires an auditing system that can be part of the quality management system (such as ISO 9001) or organized additionally.

Obviously, no genebank certification system will function without appropriate support to the candidate genebanks, helping them to set up a quality management system and to improve their facilities and procedures to comply to the agreed standards, but that is outside the scope of this blueprint. This blueprint will elaborate the three elements jointly defining the Genebank Certification System: (1) Genebank Quality Management, (2) Genebank Standards and Performance Levels, and (3) Genebank Auditing and Certification Mechanism.

The scope of this blueprint

Since assuring the conservation of, and access to, PGR is a global responsibility, a system guaranteeing the effectiveness and quality of activities should be applicable to all serious actors in the world, including international, regional, national genebanks and genebanks of NGO's. Therefore, this blueprint is not limited to seeds, Europe or the CGIAR, but should be applicable to any genebank conserving PGR for the future and making these available to the world.

Since by far most of the PGR conserved in genebanks are conserved as orthodox seeds, this blueprint will focus on these crops. However, it should be relatively easy in time to expand the scope to also include conservation of crops *in vitro*, *in cryo*, or in field collections. Quality management of *in situ* conservation and use activities is a very different issue, given the width of the range of actors and methodologies and will require quite different approaches.

This blueprint will only cover issues directly relevant to the conservation of, and access to, the PGR in the genebank. It does not cover other important issues related to the management of a genebank, such as working conditions of the staff, the composition of the collection, international collaboration, etc. Although these are essential components in the management of a genebank, and can add a lot of quality to the management, they do not directly influence the material conserved and, since the system should be 'lean and mean' they were kept out of the scope.

Relation to the GRACE research infrastructure

This blueprint was developed within the framework of the EU project 'Pro-Grace' which aims, in its own words to "prepare GRACE-RI, a proposed novel, pan-European Research Infrastructure that aims to bring together the European institutions working actively on the conservation and characterization of plant genetic resources." (Pro-Grace 2024).

Pro-Grace will produce a series of valuable concepts, blueprints, tools, and analyses designed to support a potential Research Infrastructure, including elements critical to the development of a Genebank Certification System. Among these, Deliverable No. D2.2, "Blueprint for a Genebank Quality Certification System," serves as a foundational document. Additional deliverables, such as the capacity-building blueprint and standards for genebank data exchange, may also contribute to establishing a certification system. Furthermore, once GRACE-RI is operational, it could play a key role in supporting European genebanks to qualify for certification, set 'European KPIs' (that obviously should meet the levels required for certification), or even serve as the certifying agency within Europe. However, this blueprint is an independent product, crafted to be implementable regardless of GRACE-RI's development status.

3. Genebank Quality Management

Quality management is the act of overseeing all activities, tasks and processes that are required to maintain a desired level of quality of products and/or services. It generally includes quality planning, quality assurance, quality control and quality improvement.

The purpose of a Genebank Quality Management system, in the context of genebank certification, is to ensure that the processes in the genebank are transparent, allowing them to be compared to the agreed Genebank Quality Standards, and that it is assured that these processes are applied in the genebank.

The international basic standard for quality management systems is ISO 9001. It is a widely adopted standard for organizations that not only want to show their partners and funding agencies that they are well organized, but possibly more importantly, that they have a system in place that ensures quality and transparency, certified by an independent auditing organization.

ISO 9001, a possible standard for quality management

ISO 9001:2015 is the latest version of the ISO 9001 standard, which sets out the criteria for a quality management system (QMS). It is part of the ISO 9000 family of standards, and it is the only standard in the ISO 9000 family that can be certified (although this is not a requirement). The standard is based on several quality management principles including a strong customer focus, the motivation and implication of top management, the process approach, and continual improvement.

It has a few key aspects. First, ISO 9001:2015 uses a *process approach*, i.e., it emphasizes understanding and managing interrelated processes as a system to contribute to the organization's effectiveness and efficiency in achieving its quality objectives. It also uses *risk-based thinking* to improve the likelihood of achieving set objectives, output consistency, and customer satisfaction. Another focus is on *leadership*, with a stronger focus on the top management's role in integrating the QMS into business processes and taking accountability for its effectiveness. Furthermore, there is a strong *customer focus*; the standard highlights the importance of understanding customer needs and meeting or exceeding their expectations. In addition to these key aspects, there is the aspect of *continual improvement*, requiring the organization to continually improve its quality management systems and adapt to changes in the environment of the organization. Regarding the *documentation requirements,* ISO 9001:2015 is less prescriptive about documentation than previous versions, allowing organizations greater flexibility in how they maintain documented information.

Organizations can choose to get certified by undergoing an audit from an external certification body. These audits are based on the documents that the organization provides, defining its objectives and procedures, i.e., they do not refer to external quality standards or minimum levels of performance indicators. This certification is valid for three years, after which a re-certification audit is required.

Implementing and maintaining ISO 9001 in an organization requires substantial effort, but does generally pay off. The benefits of ISO 9001 are seen to be increased efficiency, improved customer satisfaction, better decision making and in addition, enhanced reputation through global recognition of this standard and thus the organization applying it. However, this investment might be limiting to

some genebanks, and therefore ISO 9001 certification should not be a requirement for genebank certification. Therefore, an alternative route to certification should be presented to genebanks. This route, however, needs to have the basic elements of quality management. An existing and functioning alternative system in the genebank community has been developed by the Global Crop Diversity Trust (GCDT) and is used in the CGIAR and WorldVeg genebanks (CGIAR+ genebanks).

The Genebank Quality Management System as developed by the GCDT

The CGIAR+, the large global partnership that unites international organizations generally located in the global south that are engaged in research for food-security, hosts eleven genebanks worldwide, conserving nearly 800 000 accessions of mainly staple crops. These very important genebanks were, at some stage, coordinated by the Global Crop Diversity Trust (Crop Trust). An overview of the performance of these genebanks and assurance of the quality of their performance was only possible by developing and implementing a quality management system. This Genebank Quality Management System "put in place a number of mechanisms that enabled effective online reporting, performance management, quality management, audit and external review and validation" (Lusty *et al* 2021).

The first key feature of the Genebank QMS is the *standardization of processes*; the system provides the standards, based on the FAO Genebank Standards, for procedures for collection, storage, documentation and distribution of the genebank material. The second key feature is *comprehensive documentation*, emphasizing the importance of detailed documentation at every stage of the genebanking process. This includes recording the origin, genetic characteristics, and conditions of storage for each sample, ensuring traceability and accountability. A third feature is *quality assurance*, incorporating rigorous measures to monitor and evaluate the genebank's operations. Regular audits, both internal and external, form part of the system to ensure compliance with established standards and to identify areas for improvement. *Risk management* is another important feature of the system; including protocols for assessing and mitigating risks that could impact the genebank operation. These include potential threats, such as environmental changes, equipment failure, or human error. *Continuous improvement* is also an important feature of the Genebank QMS, encouraging ongoing evaluation and refinement of processes to enhance the efficiency, effectiveness, and reliability of genebank operations.

The Genebank QMS places a strong emphasis on *training and capacity building* for genebank staff. This ensures that personnel are well-equipped with the knowledge and skills needed to maintain the quality and security of the genetic resources in their care.

The Genebank QMS shares important principles with the ISO 9001:2015 standard like process management, risk management and continuous improvement. However, where ISO 9001:2015 is a broad, sector-independent standard aimed at improving overall quality management and customer satisfaction, the Genebank QMS is a highly specialized system designed to ensure the effective conservation and management of PGR. ISO 9001:2015 is a quality management system that can be adopted by a genebank, the Genebank QMS is a combination of a quality management system and the second element of a genebank certification system: minimum levels of performance.

Minimum requirements of a Genebank Quality Management System

In the end, a genebank seeking to be certified will need to implement a quality management system that allows an auditor to assess whether the genebank operates at an adequate quality level and complies with the requirements as formulated in the Genebank Quality Standards. It can be based on an established system such as the described ISO 9001:2015, the GCDT developed Genebank QMS or any other QMS that meets the following criteria:

- A general description of the QMS, the scope, roles and responsibilities, procedures, etc.
- All procedures relevant to the conservation and availability of the PGR are documented in Standard Operating Procedures (SOPs) or similar documents.
- Records regarding these activities are kept, i.e., evidence is provided that the procedures documented in the SOPs are being followed.
- Staff members have met training and competence requirements to perform the SOPs.
- Feedback from users is actively sought and addressed.

Regularly, e.g. at least once a year, the genebank should evaluate its performance and report to the responsible certification agency on achievements, deviations and changes in SOPs, and feedback from users.

All documents (the SOPs and the reports) should be readily available to an auditor, if necessary, translation tools can be used.

4. Genebank Standards and Performance Levels

The genebank quality standards should be such that if a genebanks complies to these standards, it ensures that the PGR handled by this genebank are reliably conserved and readily available. Furthermore, continuity of the conservation and availability for future generations is guaranteed. The standards should not go beyond ensuring these basic requirements, and genebanks should retain the flexibility to find their own solutions in reaching these goals.

In defining the operational standards, two existing systems should be considered: the FAO Genebank Standards and the CGIAR Genebank Quality Management System on Seed Conservation. These sets of standards will be described and the elements to be included in the Certification System will be listed.

The FAO Genebank Standards

As was shown by Hintum *et al* (2024), the FAO Genebank Standards are a set of well-known and generally adopted standards for the basic operations of a genebank. They cover the conservation part of the activities quite well, and to some extend the availability part. However, the continuity part is completely lacking.

The FAO Genebank Standards for Seed Conservation (FAO 2014) have been grouped in the following ten categories:

1 Standards for acquisition of germplasm
2 Standards for drying and storage
3 Standards for seed viability monitoring
4 Standards for regeneration
5 Standards for characterization
6 Standards for evaluation
7 Standards for documentation
8 Standards for distribution and exchange
9 Standards for safety duplication
10 Standards for security and personnel

The standards are formulated in the FAO Genebank Standards as follows (quoted verbatim, in the FAO publication their numbering is preceded by a '4.' since they are part of Chapter 4 'Genebank standards for orthodox seeds'):

1 Standards for acquisition of germplasm

1.1 All seed samples added to the genebank collection have been acquired legally with relevant technical documentation.

1.2 Seed collecting should be made as close as possible to the time of maturation and prior to natural seed dispersal, avoiding potential genetic contamination, to ensure maximum seed quality.

1.3 To maximize seed quality, the period between seed collecting and transfer to a controlled drying environment should be within 3 to 5 days or as short as possible, bearing in mind that seeds should not be exposed to high temperatures and intense

light and that some species may have immature seeds that require time after harvest to achieve embryo maturation.

1.4 All seed samples should be accompanied by at least a minimum of associated data as detailed in the FAO/Bioversity multi-crop passport descriptors.

1.5 The minimum number of plants from which seeds should be collected is between 30-60 plants, depending on the breeding system of the target species.

2 Standards for drying and storage

2.1 All seed samples should be dried to equilibrium in a controlled environment of 5–20 °C and 10-25 percent of relative humidity, depending upon species.

2.2 After drying, all seed samples need to be sealed in a suitable airtight container for long-term storage; in some instances where collections that need frequent access to seeds or likely to be depleted well before the predicted time for loss in viability, it is then possible to store seeds in non–airtight containers.

2.3 Most-original-samples and safety duplicate samples should be stored under long-term conditions (base collections) at a temperature of –18 ± 3 °C and relative humidity of 15 ± 3 percent.

2.4 For medium-term conditions (active collection), samples should be stored under refrigeration at 5–10 °C and relative humidity of 15 ± 3 percent.

3 Standards for seed viability monitoring

3.1 The initial seed viability test should be conducted after cleaning and drying the accession or at the latest within 12 months after receipt of the sample at the genebank.

3.2 The initial germination value should exceed 85 percent for most seeds of cultivated crop species. For some specific accessions and wild and forest species that do not normally reach high levels of germination, a lower percentage could be accepted.

3.3 Viability monitoring test intervals should be set at one-third of the time predicted for viability to fall to 85 percent of initial viability or lower depending on the species or specific accessions, but no longer than 40 years. If this deterioration period cannot be estimated and accessions are being held in long-term storage at – 18°C in hermetically closed containers, the interval should be ten years for species expected to be long-lived and five years or less for species expected to be short-lived.

3.4 The viability threshold for regeneration or other management decision such as recollection should be 85 percent or lower depending on the species or specific accessions of initial viability.

4 Standards for regeneration

4.1 Regeneration should be carried out when the viability drops below 85 percent of the initial viability or when the remaining seed quantity is less than what is required for three sowings of a representative population of the accession. The most-original-sample should be used to regenerate those accessions.

4.2 The regeneration should be carried out in such a manner that the genetic integrity of a given accession is maintained. Species-specific regeneration measures should

be taken to prevent admixtures or genetic contamination arising from pollen geneflow that originated from other accessions of the same species or from other species around the regeneration fields.

4.3 If possible, at least 50 seeds of the original and the subsequent most-original-samples should be archived in long-term storage for reference purposes.

5 Standards for characterization

5.1 Around 60 percent of accessions should be characterized within five to seven years of acquisition or during the first regeneration cycle.

5.2 Characterization should be based on standardized and calibrated measuring formats and characterization data follow internationally agreed descriptor lists and are made publicly available.

6 Standards for evaluation

6.1 Evaluation data on genebank accessions should be obtained for traits that are included in internationally agreed crop descriptor lists. They should conform to standardized and calibrated measuring formats.

6.2 Evaluation data should be obtained for as many accessions as practically possible, through laboratory, greenhouse and/or field analysis as may be applicable.

6.3 Evaluation trials should be carried out in at least three environmentally diverse locations and data collected over at least three years.

7 Standards for documentation

7.1 Passport data of 100 percent of the accessions should be documented using FAO/Bioversity multi-crop passport descriptors.

7.2 All data and information generated in the genebank relating to all aspects of conservation and use of the material should be recorded in a suitably designed database.

8 Standards for distribution and exchange

8.1 Seeds should be distributed in compliance with national laws and relevant international treaties and conventions.

8.2 Seed samples should be provided with all relevant documents required by recipient country.

8.3 The time span between receipt of a request for seeds and the dispatch of the seeds should be kept to a minimum.

8.4 For most species, a sample of a minimum of 30–50 viable seeds should be supplied for accessions with sufficient seeds in stock. For accessions with too little seed at the time of request and in the absence of a suitable alternative accession, samples should be supplied after regeneration/ multiplication, based on a renewed request. For some species and some research uses, smaller numbers of seeds should be an acceptable distribution sample size.

9 Standards for safety duplication

9.1 A safety duplicate sample for every original accession should be stored in a geographically distant area, under the same or better conditions than those in the original genebank.

9.2 Each safety duplicate sample should be accompanied by relevant associated information.

10 Standards for security and personnel

10.1 A genebank should have a risk management strategy in place that includes inter alia measures against power cut, fire, flooding and earthquakes.

10.2 A genebank should follow the local Occupational Safety and health requirements and protocols where applicable.

10.3 A genebank should employ the requisite staff to fulfil all the routine responsibilities to ensure that the genebank can acquire, conserve and distribute germplasm according to the standards.

The standards of the CGIAR Genebank Quality Management System on Seed Conservation

The CGIAR Genebank Quality Management System on seed conservation is clearly based on, or inspired by these FAO Genebank Standards, but tried to make them more operable. On the website about quality management in the CGIAR Genebanks (CGIAR 2024) the 'Fundamentals of Genebank Operations' are described (quoted from the website):

> The QMS addresses all aspects of genebank operations, from the acquisition of accessions to distributing to users and safety duplicating the collections offsite.
>
> During *acquisition* and the preparation of a sample for conservation, the genebank demonstrates that its procedures comply with relevant national and international laws, that they are in accordance with CGIAR and genebank policy, and that technical aspects meet international standards.
>
> *Conservation* procedures ensure maximum longevity and minimum frequency of regeneration, with suitable monitoring and safeguards, and effective strategies for allocating samples to active and base collections.
>
> *Regeneration* takes place to ensure that the genebank has enough seed of adequate viability, using best practices to ensure genetic integrity and maintain seed longevity.
>
> *Characterization and evaluation* procedures provide vitally useful information to complement an accession's passport data. The genebank has methodologies for characterising accessions using standardised formats and recognised descriptors. Genebanks also engage in partnerships to evaluate the performance under different environmental conditions, including agronomic traits such as yield, pest and disease resistance, nutritional qualities and tolerance of abiotic stressors.
>
> *Distribution* takes place in accordance with international legislation, so that on request genebanks can supply an adequate sample of seeds or other planting material, free of

quarantine diseases. Genebanks keep records of distribution, report to the Secretariat of the ITPGRFA, and follow up to gather information generated from the use of accessions.

Safety duplication offsite is essential for all accessions, and procedures are in place to renew safety duplicates when necessary.

Information management is a crucial aspect of genebank operations, requiring detailed policies and procedures to ensure the integrity of all data associated with the genebank and its accessions. Backup, recovery and restoration are as important for information about accessions as they are for the accessions themselves.

Germplasm health is maintained in conserved accessions and ensures that distributed samples meet requirements for international phytosanitary certification.

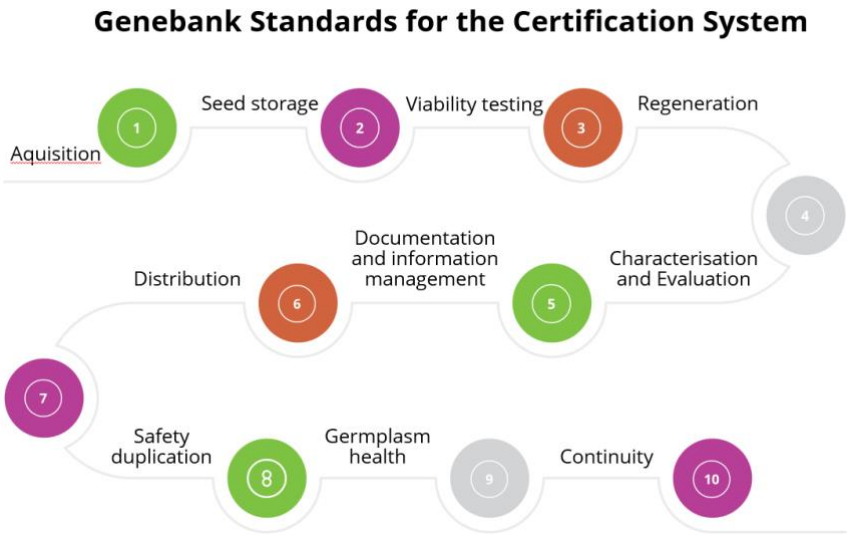
In addition, it is indicated that the genebank should abide by a number of legal instruments and standards (including the FAO Genebank Standards), have proper risk management, monitor user satisfaction and allow for verification and certification.

The Genebank Standards for the Blueprint

The two systems described above provide the basis for the standards to be used in a Genebank Certification System. They are discussed below in some detail. The element of continuity however is missing in both systems and has been added.

No absolute performance levels are mentioned in the list, determining these levels will be either a responsibility of the genebank ensuring that the principle is met, or the responsibility for the Certifying Agency in discussion with the genebank community, and might change over time. For example, when the principle for distribution says: “The time necessary for processing the request should be minimised.”, it doesn’t give the maximum number of days between receiving the request and answering it. This should be determined once the Certification System is defined.

The standards as discussed below do not incorporate the institutional requirements that a genebank should meet for certifications (see Annex 1). In addition, they only focus on seed-propagated material. Once established. they can relatively easily be extended to also incorporate other methods of PGR conservation.



Acquisition

Principle: All material in the collection has been acquired in accordance to national and international laws, allowing exchange and use of the material under standard conditions.

Each accession in a certified genebank should be available for distribution under SMTA (irrespective of their status regarding Annex 1 of the ITPGRFA). This implies that these accessions should have been 'legally obtained' and it should be possible to demonstrate this. Therefore, for each accession in the collection there should be 'a paper trail' showing that the accession was obtained in accordance to national and international laws. This 'paper trail' can consist of documents showing that the accession was included prior to the Convention on Biological Diversity (CBD), was obtained with an SMTA, obtained with proper Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) of the country where it was collected, etc. In case of an audit, it should be possible to present this evidence on demand.

On the technical aspects of the actual collecting activity (time of collecting, seed processing during collecting, number of plants, etc.) no standards will be included in the certification system.

Seed storage

Principle: The seeds are stored in a way that ensures maximum longevity and minimum frequency of regeneration.

The genebank should be equipped with appropriate facilities to check, clean, dry, pack and store the seeds under optimal conditions.

Incoming seeds from regeneration or donations should be checked for being the correct species and the seed lot should be cleaned before packing and storage to ensure purity.

The optimal conditions for drying the seeds were described in the FAO Genebank Standards: 5–20 °C and 10-25 % RH via equilibrium drying. The genebank should be able to ensure proper drying conditions and measure the moisture status of the seeds.

For packing the seeds different options are available. Some genebanks use metal cans, plastic or glass jars or other containers, but most use bags of laminated aluminium foil that can be heat-sealed. The number of bags per accession and their size differ. Some genebanks use one large bag for a seed lot, others use many pre-packed bags avoiding the necessity to open the bag when a sample is needed for distribution or viability testing. Initially no standard method will be required for certification.

Seeds in genebanks should be stored in cold conditions, i.e., –18 ± 3 °C. Medium-term storage, as described in the FAO Genebank Standards, should be avoided since above zero temperatures are not effective in maintaining the seed quality over longer periods of time. However, if the use of medium-term storage is part of a strategy that sufficiently ensures the secure conservation of the accessions, it can be used as well.

Viability testing

Principle: The viability of the seeds is determined after regeneration and monitored during storage to minimise the chance of loss of (parts of) accessions during storage.

New seed, after regeneration, should always be tested to assure that the viability is sufficiently high. The viability should also be regularly monitored during storage. Frequency and (general) methodology of these tests need to be part of the standard.

The frequency of the viability monitoring tests needs to be sufficient to minimise the chance of losing accessions due to decreased viability, however the viability testing should not be unnecessary frequent generating unnecessary costs and depletion of seeds. The period between viability tests can be determined based on the result of the tests.

The method of viability testing is highly dependent on the species, crop or even the domestication level: modern varieties are bred to geminate promptly and with high percentages, whereas wild material has strategies to delay its germination and spread it over time. Knowledge in this field is developing and standardisation is not possible yet. However, the number of seeds to use in the tests, and the type of viability tests can be standardised and should be sufficient to reliably draw a conclusion regarding the viability of the seed.

Regeneration

Principle: Accessions are regenerated to ensure that the genebank has enough seed of adequate viability, using best practices to ensure genetic integrity and maintain seed longevity.

The topic of ‘regeneration’ has several aspects. First there is the threshold that determines the need for regeneration: how many seeds should always be available and what viability should they have? The other aspect is the method of regeneration; how can the accession be regenerated to ensure its genetic integrity?

Threshold for regeneration

The threshold for the number of available seeds should be determined by the ability to regenerate, distribute and determine the viability of the material. A genebank can define these numbers themselves as long as these requirements are met.

When the monitoring of the viability indicates that the seeds are losing their ability to contribute to the next generation in a regeneration, they should be regenerated. The viability threshold is difficult to define given the often low reliability of the viability tests and the specificity of the samples (in terms of species, crop or domestication level). Also here, the genebank can define its own protocols as long as they are sufficient to guarantee a timely regeneration.

Method of regeneration

Regeneration should maintain the genetic integrity of the accessions as much as possible, i.e., it should avoid genetic drift, pollen- and seed-contamination. Furthermore, it should generate sufficient quantities of seed for the next generation of the accession.

Maintaining the genetic integrity of the accessions implies, depending on the reproductive system of the accession:

- sufficiently large populations,
- appropriate environment, limiting selection, especially for photoperiodism, thermoperiodicity and seed germination traits
- balanced contribution of different parent plants to the next generation, for example by harvesting equal amounts of seed from every mother plant and/or controlling pollination,
- isolation methods for cross pollinating populations to avoid pollination with pollen from another accession, possibly in combination with insects or other means to assure sufficient pollination,
- careful treatment of harvested seeds to avoid contamination of seeds and finally
- proper identification of seed batches to avoid switching of identity.

To ensure production of sufficient seeds, there should be sufficient plants that are cultivated in an appropriate way and a suitable environment (think of vernalisation, pest control, etc). Obviously, this requires a good knowledge of the species' biology, as well as expertise of the involved staff and access to locations and facilities.

Defining regeneration protocols as part of the standards is not desirable, due to the specific requirements of each crop or species, and due to the local specificities of facilities. However, standards for the minimal required population size and guarantees for avoidance of contamination, can be demanded. Specific indications can be derived from the crop-specific standards agreed by the ECPGR Working Groups (ECPGR 2024).

Characterisation and Evaluation

Principle: Accessions are characterised during regeneration to confirm their identity. Evaluation is facultative.

The genebank certification system should be 'lean and mean', and only the minimum activities will be required that contribute to reliable conservation and easy access. Characterisation during regeneration can help in identifying contaminations and is therefore recommended unless there are other measures in place to verify the identity of the accessions.

Phenotyping in general, including both characterisation and evaluation, support the selection of material by the user of the PGR and should therefore be encouraged strongly. However, this is not a requirement for reliable conservation nor easy access.

Genebanks are encouraged, but not required, to participate in research projects or other phenotyping (or genotyping) activities and make the resulting information available to the public.

Documentation and information management

Principle: Each accession has full documentation regarding its identity and its management; this information is properly managed making it accessible and secure.

Every accession should have documentation about its identity (passport data) recorded, using FAO/Bioversity multi-crop passport descriptors or a structure that is easily mapped on these descriptors.

All available relevant passport, phenotypic and management information about the accessions is managed in an integrated database or other information management structure that allows easy retrieval, i.e., different types of information can be queried simultaneously. The access to the data should be well organised allowing those who need to have access to the data can access them, but also secure, avoiding accidental loss of information due to mistakes or technical issues. This can involve the definition of roles and will always involve proper back-up protocols.

There should be sufficient technical support to solve technical issues and manage the documentation system.

Distribution

Principle: Every accession is available for distribution to bona fide users, and requests are handled swiftly and according to clear criteria.

Every accession in the genebank should be readily available for shipment, implying that there are sufficient seeds available. Obviously, this will not be possible for example when stock has depleted due to unexpected high demand for a certain accession, or when regeneration of material failed and must be repeated.

Seeds are distributed under the conditions of the ITPGRFA, i.e., access shall be accorded expeditiously and free of charge, or, when a fee is charged, it shall not exceed the minimal handling costs involved.

The number of distributed seeds per accession can depend on the crop or species, but should sufficiently represent the genetic composition of the accession. To avoid unnecessary seed depletion this amount can be kept minimal, when necessary the user should multiply the material after receipt and before use.

The time necessary for processing the request should be minimized. Preferably the SMTA should be signed on-line by the requestor. Otherwise, the process of sending the SMTA and processing it when it returns should be optimized, avoiding unnecessary delay.

The material should be routinely packed and sent, taking into account the requirements of the receiving country in terms of statements, declarations and certificates (phytosanitary, non-GMO, etc.). When these requirements are not reasonable, the request can be denied.

When the request involves more than a certain number of accessions (e.g. 50) the request can be denied and contact should be sought with the requestor to either limit the request or make an arrangement with the requestor, e.g. regarding access to the data generated.

Criteria for the evaluation of requests should be transparent. In all cases that access was denied, a record with the details of the request and the reason for rejection should be recorded. A mechanism for users to provide feedback needs to be available and presented to the user at every request. Mechanisms for processing and using the feedback need to be operational.

Safety duplication

Principle: Every accession should be duplicated in a black-box construction at a genebank in another country and, if possible, in the Global Seed Vault in Svalbard.

Of all elements in this list, this is the simplest: every accession should be safety duplicated in a colleague genebank outside the country where the genebank is located, if possible supplemented with triplication in the Global Seed Vault in Svalbard. Details about the shipments of safety duplicates should be agreed between the sending and receiving genebank in a contract or MoU.

Germplasm health

Principle: Genebank material should be, as far as possible, free of known plant diseases and meet the national phytosanitary requirements.

Accessions in certified genebanks should be ready for shipment to users, however phytosanitary issues can hinder this process. Therefore, national rules should be followed regarding the prevention of the spread of diseases; material should, in principle, always be ready for shipment within the country.

Since phytosanitary requirements differ per country, the sending genebank should try to comply with the phytosanitary requirements of the receiving country. If this is not possible, the genebank should seek other ways to obtain permission to import for example on the basis of Post Entry Quarantine regulations. Since phytosanitary requirements differ per country and change rapidly with new emerging diseases, users should provide this information for efficient distribution.

Continuity

Principle: In case the genebank has to discontinue its activities, other certified genebanks should be able to take over.

If for whatever reason, the genebank is no longer able to maintain its certification, there should be a mechanism for other certified genebanks to take over the activities. For example, if due to a natural disaster a genebank is destroyed, the backed-up material should be available for ‘re-activation’ by another certified genebank – irrespective of the location of this genebank. Obviously, this should be discussed with the ‘original genebank’ if that is possible. If this genebank can offer another solution

this can be considered. The objective remains that the material in the ‘system of certified genebanks’ remains well conserved and available to users.

5. Genebank Auditing and Certification Mechanism

The establishment of a certification system for genebanks is essential to ensure the reliable conservation and accessibility of PGR, both now and in the future. The necessary components of such a certification system have been outlined in the previous chapters of this blueprint. In this chapter, we will discuss the essential elements of the certification mechanism, with particular attention to the independent role of the certifying agency within this process.

At the highest level, we outline the "general requirements for the competence of genebanks." These requirements are detailed in a model provided in Annex 1, which serves as a guideline for the basic standards that a genebank must meet to function effectively. These standards should reflect the collective agreement of the scientific and genebank communities. However, they are defined at a broad level, indicating what should be achieved rather than prescribing how it should be accomplished.

Building on these general requirements, a certifying agency is tasked with developing a verification mechanism to ensure compliance. Annex 2 presents an example of such a system. This mechanism must specify how the general requirements will be fulfilled and how their fulfilment will be verified. The certification system should incorporate the following key elements:

- *Procedural Standards:* These are the standards that genebanks must follow, which may reference internationally recognized standards (with potential modifications), standards established by the certifying agency, or alternative approaches by which the genebank can demonstrate its adherence to the general requirements.
- *Verification Mechanisms:* Genebanks must implement mechanisms to ensure that these procedures are correctly applied and that any non-conformities are addressed appropriately.
- *Reporting, Auditing, and Certification:* This aspect of the system outlines how reporting, auditing, and certification processes will be conducted. It may also include the option to differentiate between various levels of certification (e.g., bronze, silver, and gold) and/or the ability to certify specific procedures (such as long-term storage, distribution, regeneration, etc.).

Ultimately, it is the responsibility of the certifying agency to design its certification system, which obviously may differ from the example provided in Annex 2. The agency has the autonomy to tailor its approach to meet the specific needs of the genebanks it certifies, while being open for feedback from the stakeholder community. The requirements should be clearly communicated to the target genebanks (see for an excellent example Bartholomew *et al*., 2024), including elaboration of the procedures for obtaining certification, to become a ‘Trusted Genebank’.

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ANNEX 1 General Requirements for the Competence of Genebanks

1. General requirements

1.1. Sustainability

- The genebank must maintain a stable and reliable organizational foundation, along with a secure source of funding, ensuring its ability to continue operations in the foreseeable future.

1.2. Transparency

- The genebank must operate with transparency, free from confidentiality obligations regarding its operations (except as mandated by general privacy protection regulations). It should be prepared to provide all relevant data for review or auditing processes when required.

2. Structural requirements

2.1. Organisational structure

- The genebank must be a legal entity or a defined part of a legal entity, with clear legal responsibility for its activities.
- The management responsible for the overall operations of the genebank must be clearly identified.

2.2. Quality management system

- The genebank must define and document the scope of activities that comply with the requirements outlined in this document.
- Activities must be conducted in a manner that meets the standards set forth in this document, as well as the expectations of customers, regulatory authorities, and accrediting organizations.
- The genebank must document its procedures to the extent necessary to ensure consistent execution of its activities.
- The genebank must employ personnel who, irrespective of other duties, possess the authority and resources necessary to:
    - Implement, maintain, and enhance the management system.
    - Identify deviations from the management system or established procedures for its activities.
    - Initiate corrective actions to prevent or mitigate such deviations.
    - Report to management on the performance of the management system and any areas requiring improvement.
- Management must ensure that:
    - Communication occurs regarding the effectiveness of the management system and the importance of meeting customer and other relevant requirements.
    - Customer feedback must be appropriately documented and utilized, when feasible, to enhance the system.
    - The integrity of the management system is preserved when changes are planned and implemented.

3. Resource requirements

3.1. General

- The genebank must have access to the personnel, facilities, equipment, systems, and support services necessary to manage and execute its activities.

3.2. Personnel

- All personnel, whether internal or external, who could influence the genebank's activities, must act impartially, possess the required competence, and work in accordance with the management system.
- The genebank must ensure that its personnel are competent to perform their designated activities and capable of assessing the significance of any deviations.

3.3. Facilities and environmental conditions

- The facilities and environmental conditions must be appropriate for the genebank's activities and must not negatively impact processes.
- The genebank must monitor, control, and record environmental conditions in alignment with relevant specifications, methods, or procedures, particularly where these conditions may affect stored items.
- When utilizing sites or facilities outside of its direct control, the genebank must ensure that all requirements related to facilities and environmental conditions, as stipulated in this document, are met.

3.4. Equipment

- The equipment used must be suitable for the genebank's activities and must not adversely affect these activities.
- The maintenance of equipment must ensure its safe and reliable operation for the intended activities.
- Maintenance activities must be appropriately documented.

3.5. Externally provided services

- If the genebank outsources services, it must ensure the quality of these services and document the actions taken to guarantee this quality.

4. Process requirements

4.1. General

- The genebank must employ processes that ensure (1) the reliable conservation of the plant genetic resources in its collection and (2) full access to the material for both internal and external users.
- Any deviations from standard processes must be recorded, and these records must be available for review or audit when required.

4.2. Acquisition

- The genebank must ensure that all material in its collection has been acquired in compliance with national and international laws, allowing for the exchange and use of the material under standard conditions.

4.3. Seed storage

- Seeds in the collection must be stored under conditions that maximize their longevity and minimize the need for regeneration.

4.4. Viability testing

- The genebank must regularly test seed viability to minimize the risk of losing accessions or components thereof during storage.

4.5. Regeneration

- The genebank must regenerate accessions to maintain an adequate supply of seeds with sufficient viability, using best practices to preserve genetic integrity and seed longevity.

4.6. Characterisation and evaluation

- The genebank must characterize its accessions during regeneration to confirm their identity.

4.7. Documentation and information management

- The genebank must collect comprehensive documentation on each accession concerning its identity and management.
- The genebank must manage accession-related information in a manner that ensures both access and security.

4.8. Distribution

- Every accession in the genebanks collection must be available for distribution to bona fide users.
- Seed requests from external users must be handled promptly and according to clear criteria.
- The genebank must strive to meet all import requirements of the receiving country.

4.9. Safety duplication

- The genebank must ensure that every accession is safety duplicated at a genebank in another country and, if possible, at the Global Seed Vault in Svalbard.

4.10. Germplasm health

- The genebank must ensure that all material meets national phytosanitary requirements.
- The genebank must endeavour to meet the phytosanitary requirements of the receiving country.

4.11. Continuity

- The genebank must ensure that, in the event of discontinuation of its activities, other certified genebanks are able to take over its responsibilities.

ANNEX 2 Requirements of a Certifying Agency for Recognition of Genebanks

1. Description of the Certifying Agency

1.1. Sustainability

- The Certifying Agency must maintain a stable and reliable organizational foundation, along with a secure source of funding, ensuring its ability to continue operations in the foreseeable future.

1.2. Legal status

- The Certifying Agency must be an independent and impartial legal entity or a defined part of a legal entity to assure its liability.

1.3. Organization

- The Certifying Agency should include a certification board that grants certificates to competent genebanks and an executive part that is responsible for its operation (see activities)
- The Certifying Agency pays responsibility to a steering committee
- A user board guarantees a support base from the genebank community.

The organizational structure of the Certifying Agency enhances an impartial and independent certification process as the assessment of the genebanks and the assignment of certificates are separated. The certification board is responsible to define and continuously improve activities and requirements for certification of genebanks and the certification process, in line with input of the user board.

A steering committee ensures the continuity of the Agency e.g. by verifying that activities and requirements have sufficient support from the genebank community. It should be populated by experts on genebank operations, quality management, and policy development.

To maintain continuous support in the field, a user board should include representatives from a diverse group of certified and non-certified genebanks. The user board should meet periodically to evaluate requirements for certification, to discuss new developments in the field and to propose best practices to be considered as acceptable procedures/way of working.

2. Resources (people)

- The Certifying Agency must have sufficient, competent personnel to fulfil its tasks
- The Agency must ensure that its personnel is competent to perform their designated activities. Specific tasks may be done by external personnel under the responsibility of the Agency. In that case the Agency must also ensure the competence.
- Personnel may have different roles as long as any conflict of interest is avoided.

- Required competences must be defined for each relevant task.

Considering the foreseen activities and the proposed certification process, it is assumed that the Agency itself is limited in personnel. The larger part of personnel is expected to be insourced from other organizations e.g. by creating a pool of “approved auditors”. To maximize and maintain trust in the impartiality and competence of the Agency, the competence requirements and the methods to supervise personnel are essential and must be available to stakeholders.

3. Activities/tasks of the Certifying Agency

3.1. Define and publish scopes of activities of genebanks that can be certified/acknowledged, and levels of certification.

- The scope of the certification can be “full” for certification of all genebank activities, or limited to a (set of) genebank operations such as “seed processing and storage”, “regeneration” or “distribution”.

Also, for acknowledging partial qualification levels (such as bronze, silver and gold), minimum requirements for each level must be defined and made available to interested parties.

3.2. Define and publish requirements for certification

- Requirements for certification of genebanks are described in the “general requirements for the competence of genebanks” (Annex 1 of this Blueprint).

The Certifying Agency publishes these requirements and gives, where possible, details regarding the standards that the SOP’s of the genebanks should comply with to meet the requirements. These standards should be widely accepted by the genebank community and kept up-to-date.

Genebanks own procedures can be accepted when they are demonstrably effective, i.e., comply to the standards or are otherwise sufficiently effective. To assess if these procedures are effective, the assessment team of the Agency must include assessors that have sufficient knowledge and experience in the matter. Additionally, an appeal mechanism must be operational (see 5.6).

3.3. Coordinate the (re)certification and certification process

The Certifying Agency, after receiving a request to certify a genebank, assigns a coordinator to guide the certification process. The coordinator plans relevant activities, selects competent personnel to perform the activities, manages relevant information and documents, and keeps track of the process timing.

3.4. Receipt and registration of complaints and remarks from users of certified genebanks

One of the benefits of certification is the enduring trust in certified genebanks. For this, feedback, both positive and negative, adds to this trust if that feedback is used as input in the (re)certification process. The Certifying Agency must be able to receive and register feedback from 3rd parties and to share that feedback to the assessment team in due time.

3.5. Assure proper communication with stakeholders

For the Certifying Agency it is key that the genebank community recognizes the added value of the Agency. The continuous support is discussed during periodic meetings with the user board. These meetings should address topics such as:

- Evaluating the requirements for certification
- Discussing the acceptability of standards/review standards
- (Technological) developments

Besides, the Certifying Agency must also be available for stakeholders to address the needs for capacity building for genebanks on the certifying process.

4. The certificate

- Certificates are valid for a period of 5 years after granting the certificate (see 5.3). At midterm, the continuous competence must be confirmed by an audit on-site (see 5.4). After re-assessment of the competences, the validity of the certificate can be extended for another 5 year period (see 5.5).
- Certificates include the scope of activities for which the genebank is certified,
- Acknowledgement of partial qualification indicating the level of process for relevant activities towards certification (silver/bronze).
- Only genebanks that are certified may use the certificate for publicity, marketing, etc.
- The Certifying Agency maintains a publicly accessible list of certified genebanks indicating the scope and level of certification.

5. The Certification process

5.1. Handling requests for initial certification and scope-extensions

A procedure is defined describing how a genebanks can ask for certification or extension of the scope; what information is needed and how to proceed. The request should include:

- Certification request, including desired scope and expected level for certification of the genebank
- Documents/procedures to assess

  1 evidence that the genebank fulfils the requirements listed in annex 1 “general requirements for the competence of genebanks” and specified in the standard requirements.

  2 evidence that the genebank uses methods for the desired scope of certification that are accepted by the genebank community or that are demonstrably effective and fit-for-purpose.

5.2. Assessment of genebanks

After receiving a request for certification or scope extension, the coordinator appoints a competent assessor or an assessment team. First, the completeness of the request and the

compliance with stated requirements is verified (5.2.1), second the fulfilment of the genebanks own procedures is assessed on the genebanks site (5.2.2) and a follow-up is defined when necessary (5.2.3). The findings of each stage are reported to the genebank within a time that is realistic and acceptable for both the assessor and the genebank.

5.2.1. Desk study/initial assessment

Verification of the requests completeness and compliance to requirements stated in 5.1 should be done by an assessor with sufficient knowledge of genebanks operations and methodologies. The verification is expected to be done by desk-study. Within an agreed timeframe, the findings shall be reported to the genebank.

5.2.2. Audit on site

After a positive initial assessment, the compliance of the genebanks operations and structure to its documented procedures is verified at the genebanks premises under supervision by the lead-assessor. The time needed for the audit, should be set before the actual audit. A summary of findings and all non-conformities must be shared with and accepted by the audited genebank at the end of the audit. The assessor and the genebank must agree upon the timeframe to solve or mitigate the non-conformities and the way to demonstrate its effectiveness. Findings and eventual solved non-conformities must be summarized in a report. The audit findings report, including the required improvements and an advise regarding certification are shared with the genebank and the certification board.

5.2.3. Follow-up

When improvements are required to meet the set criteria for certification (non-conformities), these shall be clearly communicated by the assessor including a time plan for implementation of the required improvements. The genebank will report and provide evidence about the implementation of the improvements.

5.3. Decision on certification

The certification board decides on certifying the genebanks scope after completing the activities described in 5.1 and 5.2. In case the genebank disagrees with the decision, an appeal system must be in place (see 5.7).

5.4. Midterm confirmation

The continuous competence of the genebank must be verified by assessing the compliance of the genebanks operations and structure to its documented procedures during an audit on the premises of the genebank. A summary of findings and all non-conformities must be shared with and accepted by the genebank at the end of the audit. The assessor and the genebank must agree upon the timeframe to solve or mitigate the non-conformities and the way to demonstrate its effectiveness. Findings and eventual solved non-conformities must be summarized in a report.

5.5. Renewal of certificate

For renewal of the certificate, compliance to requirements must be verified similar to the process stated in paragraph 5.2 and 5.3.

5.6. Extension of certified scope

If the genebank desires to extend its certified scope with more activities (see 3.1), a request should be sent to the Certifying Agency. Depending on the requested extension, a competent assessor will propose on how the genebanks competence for these activities should be assessed (e.g. desk study or on-site audit; required documentation and registrations). Findings and eventual solved non-conformities must be summarized in a report. The report and an advise upon certification are shared with the genebank and the certification board. The certification board decides on certifying the genebanks scope extension.

5.7. Handling of complaints and appeals

The Certifying Agency must be able to receive complaints and appeals, and to treat these impartial and independent. The Agency shall acknowledge the receipt of the complaint or appeal and a provide a timeframe in which the outcome (e.g. decision) will be provided to the complainer or appellant. Any decision shall be made by persons that were not involved in the subject of the complaint or appeal in question. Investigation and decisions on complaints and appeals shall not lead to any discriminatory actions. The complainer or appellant shall be informed on the outcome.