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Quality management in a genebank environment: Principles and experiences at the Centre for Genetic Resources, The Netherlands (CGN)

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Abstract: To enhance the management of plant genetic resources by genebanks, implementing a quality management system is essential. Such a system ensures the consistent quality of genebank operations through the establishment of a quality policy, the integration of quality planning and assurance, and the execution of continuous quality control and improvement measures. This structured approach also supports alignment with globally recognized standards, such as those established by the UN Food and Agriculture Organization (FAO). The Centre for Genetic Resources, The Netherlands (CGN), with its significant experience in quality management, is presented as a case study to illustrate the methodology and its impact on genebank operations. By detailing operating procedures, a quality management system provides transparency, fostering trust and facilitating collaboration between genebanks. Additionally, the potential for developing a certification system for genebanks – wherein an authorized body formally certifies that a genebank adheres to specific standards – is examined.

Keywords: ex situ genebank, genebank collaboration, quality management, certification system

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Introduction

Genebanks play a vital role in safeguarding plant genetic resources (PGR) for future generations, ensuring that these resources remain accessible for developing crops essential to feeding the global population (FAO, 2010). In addition to their long-term conservation efforts, genebanks also provide crucial materials to crop scientists and plant breeders, supporting their research and breeding programmes. These responsibilities are significant and demand a high level of commitment. Consequently, it is essential that genebank operations maintain a high standard of quality, which must be consistently assured. Effective quality management is therefore critical to ensure that genebanks fulfil their responsibilities and operate at the appropriate level to meet global food security needs.

The Centre for Genetic Resources, The Netherlands (CGN) holds the statutory responsibility for managing PGR on behalf of the Dutch government. When this mandate was assigned by the Dutch Ministry of Agriculture in 2004, the ministry also required CGN to implement a quality management system to ensure that public funds were being used effectively and that the Dutch public could have confidence in CGN's ability to perform its duties at a high standard. As a result, CGN became the first genebank in the world to achieve ISO 9001 certification. As stated on the website of the International Organization for Standardization (ISO, 2015), "ISO 9001 is a globally recognized standard for quality management. It helps organizations of all sizes and sectors to improve their performance, meet customer expectations and demonstrate their commitment to quality. Its requirements define how to establish, implement, maintain, and continually improve a quality management system (QMS). Implementing ISO 9001 means your organization has put in place effective

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processes and trained staff to deliver flawless products or services time after time."

Each genebank holds unique collections that often reflect regional crops and wild relatives adapted to specific climates and conditions. Preserving PGR is a shared responsibility that transcends borders. To fulfil this mission, genebanks must collaborate, sharing resources, data and expertise to prevent unnecessary duplication and ensure no vital genetic material is overlooked. Working together also enables coordinated efforts to store, regenerate and monitor seed viability over time. Successful collaboration relies on mutual trust, which in the context of genebanks means adhering to agreed-upon operating procedures and standards for managing PGR effectively. It is therefore not surprising that when the Global Crop Diversity Trust (GCDT) took on the coordination of the CGIAR Genebank Platform and began contributing to the funding of CGIAR genebanks, it recognized the need for a mechanism to monitor the performance and quality of these institutions. Transparency in the operations of the genebanks was essential to assess their effectiveness and to identify areas for investment. Consequently, the GCDT developed the 'Genebank Quality Management System' and provided support to the CGIAR genebanks in its implementation (Lusty *et al*, 2021).

The various elements of quality management within a genebank context are described and illustrated through the experiences of CGN. Additionally, this discussion will introduce and explore certain aspects of the potential establishment of a Genebank Certification System.

Quality management in a genebank environment

Quality management

Quality can be managed, although it is difficult to define. According to the ISO 9001 standard for quality management systems (ISO, 2024), quality is defined as the "degree to which a set of inherent characteristics [or distinguishing features] of an object fulfils requirements". An object is defined as "anything perceivable or conceivable, such as a product, service, process, person, organization, system or resource". Based on this definition the quality of a genebank can be defined as 'the degree to which the genebank fulfils its objectives'.

The objectives of a genebank are relatively well-defined and encompass two primary elements: the conservation of PGR for future generations and providing access to these PGR for the current generation of users (FAO, 2014). While these elements are broadly agreed upon, interpretations of what constitutes 'conservation' and 'access' can vary among genebanks. Discussions surrounding 'conservation' often focus on technical aspects, such as the required frequency of seed viability testing or the appropriate number of plants in a regeneration plot. In contrast, the concept of 'access' is more heavily influenced by policy considerations, addressing questions like who should have access to the material and under what conditions.

Regardless of differing perspectives on these definitions, it is essential to ensure that the objectives established for a genebank are met in the most effective manner possible. A quality management system serves as a valuable tool to assist genebanks in achieving these goals optimally.

Quality management, and this will appear obvious, involves overseeing all activities and tasks necessary to sustain a desired level of excellence, specifically to achieve established objectives. This process typically encompasses several key components, including quality planning, quality control and quality improvement.

Quality planning

In the context of a genebank, quality planning involves establishing methods to measure or assess the achievement of objectives using Key Performance Indicators (KPIs), defining and updating Standard Operating Procedures (SOPs), and ensuring that the desired quality level is maintained through an annual Quality Improvement Plan (QIP). These elements will be detailed below.

After clearly defining objectives, methods need to be established to quantify or otherwise assess the achievement of these goals. This is typically accomplished through the identification of KPIs, that can differ from genebank to genebank as they need to be tuned to the genebank's organization and operations. The KPIs may include metrics such as the number of accessions, the quantity of samples distributed, the number of regenerations conducted, the percentage of successful regenerations, and the number of viability tests performed. It is important to view these KPIs as monitoring tools rather than strict performance assessments, as an overemphasis on these indicators could lead to unintended consequences. For example, a curator might feel compelled to distribute accessions solely to increase the number of samples sent out, potentially undermining the integrity of the genebank's operations. The indiscriminate distribution of seed samples – such as fulfilling requests like "please send the entire lettuce collection" – can deplete inventory, necessitating earlier regeneration of the accession, which incurs additional costs and may impact the genetic integrity of the collection. Therefore, in cases of large requests, a genebank should work collaboratively with the requester to identify an optimal selection of accessions that meets their needs while preserving the collection's resources.

The quality planning phase also encompasses the formulation of SOPs, which detail how essential operations are to be conducted. This is a critical component of effective genebank management and includes various elements such as protocols for acquisition, regeneration, seed processing (cleaning, drying, seed moisture content determination, viability testing, etc.), seed storage, distribution, information management and other

operational procedures. By clearly defining these SOPs, genebanks can ensure consistency and quality in their practices, thereby enhancing their overall effectiveness in achieving their objectives.

The FAO Genebank Standards for Seed Conservation (FAO, 2014) categorize genebank operations into ten key areas: 1) acquisition of germplasm, 2) drying and storage, 3) seed viability monitoring, 4) regeneration, 5) characterization, 6) evaluation, 7) documentation, 8) distribution and exchange, 9) safety duplication, and 10) security and personnel. Each of these essential elements can be associated with its own SOP. However, depending on the scope of the quality management system, this framework can be expanded to encompass the promotion of use, research activities and other genebank-related functions.

The level of detail in SOPs can vary significantly. In some instances, SOPs can serve as comprehensive guides, offering precise instructions on which actions to take and controls to operate in specific situations. In contrast, other SOPs may outline the principles and objectives of an operation without delving into the details of the actions required to achieve those goals. For example, a SOP for the acquisition of germplasm typically emphasizes the need to adhere to all legal and phytosanitary regulations and specifies certain criteria for selecting materials suitable for inclusion in the collection. However, it may not detail where and how the material should be obtained (although it could be beneficial to include guidelines on handling materials during collection missions).

SOPs not only clarify the processes involved but also serve as valuable resources for new staff members, helping them understand important considerations when performing genebank tasks.

It is essential that these SOPs are not created in isolation but rather reflect existing practices and the current operational reality. During the documentation of procedures, it may become evident that certain practices are not 'fit for purpose' and require improvement. The previously mentioned FAO Genebank Standards for Seed Conservation (FAO, 2014) can often serve as a valuable reference point, providing guidance on what constitutes a high standard and an appropriate level of operation for genebanks. This alignment ensures that the SOPs are not only functional as a reference and training material but also effective in enhancing the overall quality of operations.

Quality planning is an ongoing process rather than a one-time task. It is typically conducted annually, producing a QIP that is implemented throughout the year to achieve the desired quality standards. The QIP incorporates elements such as user feedback, non-conformities, assessment of evolving policies, application of new technologies, and potential risks.

Quality control

Once the KPIs and SOPs have been established, the genebank can implement a quality control mechanism. This process involves generating evidence that demonstrates compliance with the defined protocols, staff competency and user satisfaction. Documenting this evidence should be integrated into the SOPs and may, for example, include maintaining logbooks for regenerations, which could record instances where protocols could not be adhered to, accompanied by justifications and approvals from a supervisor.

Additionally, the quality control mechanism may involve maintaining an overview of all requests for material, documenting the dates of the requests, the actions taken, the shipment dates of seeds, and potentially including feedback from the requestors of seeds. This systematic approach to evidence production not only ensures accountability but also fosters continuous improvements in the operational efficiency of the genebank.

In addition to the user feedback, a significant and regular form of quality control comes from staff observations of potential deviations from established SOPs. These observations should be documented, processed and, together with other quality-related information, reviewed during internal audits to ensure comprehensive quality evaluation and drive continuous improvement through QIPs.

Ultimately, it should be feasible for an independent observer to assess and verify that the genebank is adhering to its established protocols. More critically, this observer should be able to ascertain that the staff possesses the requisite knowledge and skills to perform their duties as outlined in the SOPs. This principle is central to the certification process for the ISO 9001 standard for quality management systems.

As part of this ISO 9001 certification, an auditor, selected by the certifying agency, will conduct an annual evaluation of the genebank. During this assessment, the auditor will verify that the genebank is operating in accordance with its SOPs and that management effectively oversees organizational operations, including initiatives for quality improvement. This external validation not only reinforces accountability but also enhances confidence in the genebank's quality management practices.

Quality improvement

The final component of quality management to be addressed here is quality improvement, which focuses on identifying operational flaws and implementing corrective measures. Staff observations and feedback from genebank users play a crucial role in this process. When activities deviate from established SOPs, these non-conformities necessitate a thorough analysis to identify their root causes and facilitate appropriate adjustments to improve the protocols. User reports that highlight issues such as not receiving requested materials, receiving incorrect materials, or experiencing difficulties in germination of the received material are critical indicators that something is amiss. These signals may suggest problems with the ordering system,

documentation errors, or seed viability concerns – all of which require immediate attention and action. This type of feedback from users can be asked when handling seed requests, but can also be collected in targeted questions and interviews.

It is vital that all forms of feedback are taken seriously and addressed promptly. Additionally, maintaining records of feedback and subsequent actions provides valuable information for auditors assessing the performance of a genebank. Also here, the presence of SOPs detailing procedures of how complaints and issues are identified, addressed and improvements implemented makes sure that the QMS itself fosters improvement.

Together, these elements constitute the quality management system of a genebank. Given that each genebank is unique and the implementation of quality management practices remains relatively uncommon in this sector, there is currently no standardized model for a genebank quality management system. A standard of potential interest was published in 2018 for the biobanking community (ISO 20387:2018) that through its focus on handling and storage of biological material, technical competence, risk management and data integrity may be of relevance to genebanks, albeit, to the best of our knowledge, no genebank currently uses this standard (ISO, 2018).

Genebanks that have adopted quality management are often hesitant to publish their SOPs and related documentation. To date, CGN is one of the few genebanks that has made its complete quality management system publicly available (ECPGR, 2024). In the introductory text accompanying the SOPs, CGN states:

"With these documents, CGN gives complete transparency regarding the reality of its genebank. As you will see, it is far from perfect. We hope this material will help others in setting up their quality management systems, and in providing transparency regarding their genebank operations. We also hope that it will start discussions and generate constructive feedback regarding our methods helping us to improve. In the end, we all want to conserve plant genetic resources as efficiently as possible, for the generations to come, and provide access to these resources for the current generation of users."

Quality management at the Centre for Genetic Resources, The Netherlands (CGN)

An important reason for implementing quality management, already referred to in the introduction section above, is to ensure the effective use of funding provided by supporting agencies. In 2004, CGN became the first genebank to achieve ISO 9001 certification when their funding body, the Dutch Ministry of Agriculture, mandated the establishment of a formal quality management system. PGR management was recognized by the Dutch government as a key responsibility arising from international commitments, such as the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). The important responsibility of managing genetic resources was delegated to CGN, a division of Wageningen University and Research, which had been responsible for operating the genebank for Wageningen's agricultural institutes already since 1986. To ensure that CGN was fulfilling this statutory role effectively, the Ministry required the implementation of a robust quality management system.

Setting up CGN's quality management system

Already in 1993, CGN had produced an internal report titled CGN Genebank Protocol, which compiled the protocols followed by various curators, the seed manager and the documentation manager (van Hintum and Hazekamp, 1993). This report garnered considerable attention within the genebank community, as many institutions were keen to learn how a colleague genebank, CGN, conducted its operations. However, when the time came to formalize the SOPs for the quality management system, it became evident that the published CGN Genebank Protocol had outlined the procedures for an idealized scenario. For instance, the protocol might specify regenerating on the basis of a minimum of 50 plants, but in reality, if 55 were sown and 8 died, how should the curator proceed? The SOPs had to account not only for the ideal procedures but also specify the decision-making required in less-than-perfect circumstances. The process of drafting the SOPs sparked significant internal debate, curators learning from each other, asking the questions they never asked themselves, and ultimately leading to substantial improvements in quality.

The establishment of an ISO 9001-compliant quality management system at CGN was facilitated by an external consultancy firm. This firm provided expertise in the methodology, offering guidance on how to logically segment genebank activities, describe processes through flowcharts, and formulate the SOPs. As CGN was the first genebank to adopt a formal ISO 9001 quality management system, there was no pre-existing standard to follow. This allowed CGN to analyze its activities and make a system that was 'fit to purpose' to its circumstances and reality. However, when compared to the quality management systems now used by other genebanks, the terminology employed by CGN is somewhat unconventional, and the level of detail is occasionally either excessive or insufficient, as compared to other systems. Additionally, after two decades of operation and considerable evolution, the system's internal coherence has eroded, suggesting that a comprehensive revision may be necessary. Nevertheless, the system has significantly contributed to CGN's success as a genebank, and still does. It enabled CGN to maintain consistent quality, as reflected by user feedback.

The ISO 9001 standard mandates that the CGN conduct annual external audits, carried out by an ISO accredited conformity assessment agency. These audits generate reports that highlight areas requiring attention, including opportunities for improvement and, when applicable, instances of nonconformity with the ISO

standard. In cases of nonconformity, CGN must submit an improvement plan, complete with a timeline and supporting evidence.

In addition to the external audit, an internal audit is conducted annually. While CGN outsources this process to a specialized company, it retains the option to perform it in-house. The report of the internal audit serves as input for the subsequent external audit.

Every three years, recertification is conducted through a more comprehensive audit performed by the accredited auditing agency.

Costs and benefits

Estimating the costs of ISO 9001 certification is nearly impossible. A general rule of thumb exists, but has very limited value. It suggests that establishing the system typically requires approximately €1,000 to €3,000 per employee, and to maintain it, 10–20% of the initial costs annually (personal observation). In the case of CGN, the estimate for the initial costs probably is conservative. The actual costs were never calculated and strongly depended on the significant staff time invested in drafting, revising and editing the SOPs. Conversely, now that the system has been in place for an extended period, the annual maintenance cost is likely on the low side of the rule of thumb estimate. In fact, when accounting for the cost savings achieved through more efficient operations, it could be argued that CGN is actually realizing financial savings as a result of its quality management system.

Another important aspect to consider is staff perception and acceptance. At CGN, initial resistance to the introduction of quality management was significant, as it was viewed as a constraint on creativity, reducing employees to mere components of a mechanized system. Additionally, the use of KPIs to monitor processes was perceived as akin to 'Big Brother' surveillance. However, over time, staff members came to recognize and appreciate the benefits of a structured organization, and the importance of well-documented procedures became particularly evident during instances of succession, such as when retiring employees were replaced by new hires.

A Genebank Certification System

Rationale for a Genebank Certification System

Effective collaboration and division of responsibilities are vital for the conservation of PGR required by future generations. However, successful collaboration necessitates mutual trust among genebanks. By adopting standardized practices and achieving a shared quality level, genebanks can establish reliance on one another's efforts, thereby facilitating efficient collaboration. This partnership not only enhances the secure conservation and accessibility of PGR for users but also improves management efficiency by minimizing unnecessary redundancy; many genebanks currently conserve overlapping collections. The establishment of mutual trust enables the principle that 'if you undertake this task, I do not need to do so', thereby reducing long-term conservation costs and reallocating resources to address gaps in collective PGR collections and investments in quality improvement. This, in turn, enhances PGR utilization through improved characterization, documentation and better user interfaces.

In Europe, the PGR community, organized under the European Cooperative Programme for Plant Genetic Resources (ECPGR), recognizes the necessity of implementing a genebank certification system. In its *Plant Genetic Resources Strategy for Europe*, launched on 30 November 2021, the European PGR community calls on the establishment of an economically sustainable certification system accessible to genebanks (ECPGR, 2021). Also, the FAO Intergovernmental Technical Working Group on Plant Genetic Resources for Food and Agriculture has underscored the importance of a quality assurance system, preferring the term "acknowledgment system" aligned with the FAO Genebank Standards (FAO, 2014). They have recommended that the FAO investigate capacity-building and evaluation mechanisms to support genebanks in adhering to these standards (FAO, 2023).

Beyond the benefits of quality management for individual genebanks, certification will provide a framework to ensure that these institutions meet community-agreed standards for conservation and access, and that continuity is guaranteed. The FAO Genebank Standards (FAO, 2014) are well accepted for the operating procedures concerning handling material and the Standard Material Transfer Agreement (SMTA) of the ITPGRFA could provide the basis for the distribution of PGR (FAO, 2024). In addition, procedures for guaranteeing continuity will need to be set up. Should a genebank lose its certification, another certified genebank should be able to assume responsibility for the material from the 'lost' institution, thereby ensuring that PGR once integrated into the system remains preserved and accessible. Consequently, a certification system is essential for enhancing efficiency, reliability, transparency and accountability, given that the conservation and accessibility of PGR represent a global responsibility that must be upheld by all credible stakeholders, including international, regional and national genebanks.

Components of a certification system

Implementing a certification system for genebanks necessitates several key elements. Firstly, the genebanks seeking certification must establish a robust QMS that enables an external auditor to assess both the activities undertaken and the methodologies employed. Secondly, the SOPs utilized within the genebanks must align with community-agreed standards. Lastly, a certification mechanism must be developed and administered by an organization endowed with adequate authority.

An increasing number of genebanks are in the process of establishing QMS; however, international support and coordination remain limited. The absence of coordinated

international oversight for PGR activities has resulted in a lack of responsibility for guiding genebanks in these critical advancements. Consequently, there is a risk that genebanks will repeatedly reinvent processes and protocols. The establishment of a central hub to provide training materials, templates and examples of effective QMS tailored to various types of genebanks and operations could significantly expedite this process.

The FAO Genebank Standards (FAO, 2014) serve as an excellent foundation for defining minimum operational quality levels. While some adaptations will be necessary to incorporate current technology and evolving insights, the fundamental objectives – namely, to conserve plant genetic resources for future generations while ensuring their availability to present users – are clearly articulated. Moreover, details concerning access provision to PGR must be formulated, alongside procedures to ensure continuity. The groundwork has already been laid through the initial set of Genebank Standards (FAO, 2014).

A critical element still to be finalized in the development of a genebank certification system is the appointment of a Certifying Agency. This agency would have several key responsibilities. Firstly, it would need to establish the general competency requirements for genebanks, reflecting the consensus of both the scientific and genebank communities. Secondly, it would be tasked with creating a verification process to ensure these requirements are met. This process should outline how the requirements are to be fulfilled and how their fulfilment will be assessed. Typically, this includes certification audits every three to five years, along with intermediate audits to monitor ongoing quality management within the genebank. Several organizations are currently under consideration for the role of Certifying Agency, with the goal and expectation of arriving at a suitable solution.

Discussion

The QMS of CGN was developed independently, without following a predefined standard, leaving scope for further improvement. Rather than positioning this QMS as an exemplary model, it has been made publicly accessible to provide transparency and encourage constructive feedback (ECPGR, 2024). An open dialogue regarding quality management practices and procedures in genebanks would benefit all involved by providing exposure to actual QMS approaches in genebanks and stimulating discussion about SOPs. Furthermore, it will inspire the harmonization of these systems and enhance the quality of all genebanks involved.

Recently, CGN initiated an evaluation of the alignment of its procedures with the FAO Genebank Standards (FAO, 2014), revealing certain divergences in practice. For instance, CGN's approach to seed viability testing, which employs fixed thresholds, contrasts with the FAO's recommendation to test for specific declines in viability (Wijnker *et al*, 2024). While CGN's alternative approach is obviously based on a considered rationale, feedback from the genebank community and possibly a certifying body could provide valuable input for further improvement.

In its commitment to ensuring the accessibility of PGR, CGN currently lacks a formal contingency plan should it cease operations or be unable to provide access to the genetic resources in its collections, thus jeopardizing access to PGR. A network of certified genebanks could play a critical role in these circumstances, taking over and potentially keeping the PGR currently in CGNs collection conserved and accessible. A genebank certification system would provide the credibility needed. Moreover, in combination with the legal assurances provided by the SMTA, it could provide a robust foundation for continued access to these resources in an open network of certified genebanks.

Conclusions

Quality management serves as a crucial instrument for enhancing the effectiveness and efficiency of genebanks, establishing a foundation for collaboration. The experiences of various genebanks, particularly those of CGN, demonstrate the positive impacts of implementing quality management practices. By integrating quality management with community-agreed minimum standards for genebank operations, a foundation is established for genebank certification. This certification would represent a significant advancement toward ensuring the proper conservation of, and access to, PGR for both present and future generations of users, ultimately contributing to global food security.

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Conflict of interest statement

The authors declare that they have no conflicts of interest.

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