Table of addressed changes in the ISO feasibility document preparation process - Updated 17 December 2008

Content (Title/section)	Need for improvement or change	Author	Proposed action & approach
Initial comments to first draft (wiki space platform where information about ISO was first gathered, with initial inputs from genebank examples – CIP, CIMMYT, IRRI, CGN, IPK, Nordic Gene bank and Plant Gene Resources of Canada) (April - June 08)			
Technical content	There was a need to better define and explain what ISO are and distinguish between certification and accreditation. Several definitions and clarifications were given, mainly about: - Practicalities between certification and accreditation - Cost related issues - Considerations about genebanks at different developmental stages - Compatibilities amongst QMS and certification bodies - Stepwise recommendations for further steps	M. Mezzalama (CIMMYT)	The useful information was incorporated into the wiki document.
Structure and expected audience	The first half of the document it is too much of Google cut and paste, and as a result the reader will start reading the next thing on his pile. I think you should concentrate on the questions that your audience (who exactly is it?) is interested in: why would I be interested in QM, what is it (in a genebank context), how do I use those methods, what are the experiences of others. Much of the current document can be used as input, but I strongly doubt if anyone is interested in the history of ISO (I do not see the relevance), nor is your audience waiting for a philosophical study of quality or a list of definitions. Concerning the audience, I think that aiming at the ones who know little, telling them about the experience of the others could	Theo van Hintum (CGN)	These points were considered and the literature review was shortened a bit and added only as an annex (these was still considered important to keep, for people less familiar with the ISO) at the bottom of the wiki document. A different structure was done for the second version (Sep08) and further updated on the third version (Oct08)

	do the job. For the ones with some experience it could also be good to read about what they actually did (here at CGN it certainly was an experience of 'doing and than thinking' for most of us) I suggest another approach to it.		
Structure	The document should be re-done with a different layout, following more the structure of a feasibility study. Current examples from genebanks should be included as 'study cases' boxes where relevant, for better clarity.	J. Hanson (ILRI)	A few examples of feasibility reports were studied and a new layout was made, fitting the previous information into the various sections and filling in the remaining gaps. Major changes included: - The choice of four solutions and the comparison of their characteristics and how are they fit for each purpose. - For the comparison of advantages and disadvantages a SWOT and PEST analysis were also included, as per literature recommendations for feasibility studies. - Socio cultural and ethic issues were also incorporated into the comparisons as well as risk assessments.
Examples from genebanks	The example of AEGIS should be incorporated into this study	J. Engels (Bioversity International)	This case was added to the other examples
Comments to second draft (Sep - Oct 08)			
Purpose of document	Use the document as a road map for genebanks, explaining what are the ultimate outcomes to expect in the future	J. Hanson (ILRI)	These new points of view were added into the third draft (Nov08)
Purpose of document	One of the objectives of the GPG2 is to learn from each other and to have a more system wide thinking, these was one of the reasons for the development of this document, to elucidate and describe the existent viable options for QMS. The mitigation of the risks in genebank management was another motivation for this study; this together with the need to check compliances and the own conscience of genebank curators will influence the decision on which QMS to use in order to upgrade the CG	J. Hanson (ILRI)	These new points of view were added into the third draft

	genebanks into a further level of recognition.		
General editing and methodology	Several clarifications were required about the terms used, titles, tables, paragraphs and methodology. A few corrections were suggested.	J. Engels (Bioversity International)	Clarifications were made to relevant issues and explained better
Methodology	Reformulate the possible options so that the absolute key aspects that genebank need to have in place are covered	D. Galsworthy (CSL)	Options to be discussed were adjusted
Structure	Add a footnote with the pagination, date and title of the article	D. Galsworthy (CSL)	Changes inserted
Structure	Purpose a model for genebanks, with specific procedures (used by each genebank) plus overarching policies (common for all genebanks)	D. Galsworthy (CSL)	A decision tree with the list of procedures and distinctions between the ISO 9001 and ISO 17025 were included in the new document
Comparison analysis and explanation of options	Explain better the difference between certification and accreditation, at the beginning of the document Explain better the PEST and SWOT analysis (put tittles for the tables) and the methodology and make it more clear Organize/readjust better the case studies and the related text (left or top box)	J. Engels (Bioversity International)	Points taken and addressed in the third draft
Content	Technical editing was made and several additions about costs were suggested	D. Galsworthy (CSL)	New tables of detailed costs for each option were made and the technical clarifications better organized by various sections
Content	ISO 14001 is not relevant for this discussion so it should be removed from the document.	D. Galsworthy (CSL)	Item discussed and removed
Table 1	Most genebank curators or representatives made corrections or updates into the data about their genebanks	M. Mezzalana (CIMMYT) D. Galsworthy (CSL, CIP) B. Marichu (IRRI) A. Lezar (South Africa) Argentina Australia China J. Honsa (Rtech labs)	Changes/updates accepted
Genebank network	Shall we incorporate the issue of collaboration, facilitation and sharing responsibilities into the	J. Engels (Bioversity International)	Issues were incorporated into the third draft discussion

	document (e.g. AEGIS?). This will also force the EU genebanks to achieve a certain standard. Will this mean that genebanks will be forced to share some responsibilities and 'give up' same of their activities and trust others to carry them out?		
The meaning of SOPs	Are published genebank manuals a requirement for the SOP to function? Explain different levels/types of SOP Explain better the difference between certification and SOPs, for ensuring quality, since they seem quite similar in many ways	J. Engels (Bioversity International)	The use of SOP terminology was discussed with D. Galsworthy and we decided to call the third option for QMS, Documented Procedures instead. These can be published or not. We also agreed that if a genebank has a published manual, it means they have their procedures documented. Issues were re-phrased for better clarity.
The meaning of SOPs	Re-define the 4 options, particularly the SOP	D. Galsworthy (CSL)	Same as above
The meaning of SOPs	Explain better what SOP are, that are custom done and not one size fits all	N. Mutio (ICRAF)	Further clarification made
The meaning of SOPs	Possibility to have a hybrid with SOP, certification and accreditation	J. Engels (Bioversity International)	This was indeed one of the possible options, and this was made more clear in the new document
Study cases	The Kew example is not relevant for the implementation of quality systems for genebank, because ISO 14001 is for the overall management of the facilities.	D. Galsworthy (CSL)	The Kew study case was discussed (it was chosen as an example of methodology to follow and also because IRRI adopted an environmental ISO) and agreed that it was not relevant for this document and was therefore removed
Study cases	Most genebank curators made detailed changes to their study cases	M. Mezzalana (CIMMYT) D. Galsworthy (CSL, CIP) B. Marichu (IRRI) A. Lezar (South Africa) J. Honsa (Rtech labs)	Additions accepted
Study cases	What is the utility of including the cases from South Africa (not finished, still deciding what to do next)?	J. Engels (Bioversity International)	This was also discussed and it was decided it was useful to show here cases of genebanks that are concern about the QMS issue, although have not made their decisions yet.
Study cases	Recent contacts established with Australian genebanks opened the possibility to include one	M. Jorge (Bioversity International/ILRI)	More details were requested and an additional study case was incorporated into the third

	more study case		draft
General discussion	Incorporate more detail about the social and political risks some genebanks are exposed if superior staff imposes less adequate SOP	L. Bongo (kuluk consult; links to Balkan genebanks)	Point taken and addressed in the third draft
General discussion and other comments	Need for genebanks to follow certain quality standards to: - share responsibilities - create international standards for varieties - separate characterization from regeneration	L. Bongo (kuluk consult; links to Balkan genebanks)	Relevant points addressed in the third draft
General discussion	The paper needs to emphasize that continual updating is required with new innovations and software (4 bullet points suggested…)	B. Redden (ATFCC)	The 4bullets points suggested were incorporated into the recommendations (under 'Other genebanks networks') section
General discussion	Emphasize the difficulty to have the discipline to achieve a high level of quality system and maintain it without some type of external review or audit	J. Honsa (Rtech labs)	Point taken and addressed in the third draft
Other comments	Mention problematic to have plant breeders (wishes to do selection) running genebanks with opposite approach (genebanks should never do selection but save germplasm according to genetic distribution)	L. Bongo (kuluk consult; links to Balkan genebanks)	Irrelevant for this document
Questions	Use or not the term 'best choice'?	J. Engels (Bioversity International)	This was also discussed and remained in the document but referred to as best options.
Questions	Can ISO cause a certain loss of flexibility that could be disadvantageous sometimes limiting the scope of decisions about unexpected issues? (e.g strict rules to follow deadlines or techniques that could be alternatively used in a few cases)	M. Jorge (Bioversity International/ILRI)	It is possible but it all depends of the practical sense of the executors and people involved. There is a possibility for the unexpected to occur, as long as all procedures and actions are documented and justified
Questions	How does the ISTA accreditation relates to the ISO?	M. Jorge (Bioversity International/ILRI)	Issue discussed and its inclusion into the document dismissed as it would complicate issues even more
Questions	Did CGN ever considered other options than certification?	J. Engels (Bioversity International)	Ask T. van Hintum about it.
Questions	Ask for clarification about the issue of peer assessment of competence (risk of assessment not done appropriated)	D. Galsworthy (CSL)	These need was better emphasized through the third draft
Questions	What would be the process to	J. Hanson (ILRI)	This is a very good point and it

	turn SOP into certification? Is it really that difficult?		will just depend how much of the procedures would be described in the SOP
Questions	Would it be appropriate to add the ideas of best practice transfer, vehicle for improvement, ability to share resources; best value	D. Galsworthy (CSL)	These ideas were incorporated into various parts of the third draft
Questions	How to incorporate/relate the upcoming CGIAR changes into genebank management? Will they affect the outcomes of this study? How to consider them?	M. Jorge (Bioversity International/ILRI)	Issue discussed and a few points mentioned in the discussion and recommendations
Questions	Questions arise about a possible revision of genebank guidelines by FAO or Bioversity International as well as future obligation to go under certification or accreditation following possible recommendations from the ISO document.	A. Diederichsen (Plant Gene Resources of Canada)	Neither Bioversity International or FAO are thinking about publishing new guidelines. The actual trend is moving from very precise implementation standards into more viable/flexible options (some of them crop specific), looking more at the best practices point of view, than rigid standards that need rigorous implementation. There is an increased focuses on the positive outcome of the standard than following a prescribe standard (e.g. best practices knowledge base). There will be no imposition regarding the ISO implementation. The document being prepared is the first feasibility study that will evaluate and discuss how much it would take/what it would be expected if ISO are to be implement it in the future for genebanks. It is also a document aiming at improving/creating awareness about the level of QMS currently in place in various genebanks and what would be the minimum requirements that should be achieved to mitigate current (and potential) risks in genebank collections. It will be a useful background document for genebank curators and administrators to

			better understand the practical implications as well as the advantages and disadvantages to implement the various levels of QMS in their genebanks.
Comments to third draft (Oct - Nov 08)			
Structure	Insert very clear recommendations	J. Hanson (ILRI)	Relevant points addressed in the forth draft
Layout	Use a more structured heading styles and format Indicate the information source for each study case directly in each one Re-arrange similar cases in the same rows of table 1, grouping them by similar QMS and re-allocate the table after the description of each of the 4 QMS options selected for this study Add an executive summary after final comments and changes Put the author names at the end of the document	J. Hanson (ILRI)	Relevant points addressed in the forth draft
References and Acronyms	Complement the list of references and acronyms	M. Jorge (Bioversity International/ILRI)	Relevant points addressed in the forth draft
Comments to forth draft (Nov - Oct 08)			
General question	What is the advantage of turning into an ISO system of quality control *versus* the periodical reviews currently in place? If the advantage of turning to ISO norms is compelling, then this means that there will be no need for reviews, and that the costs of the periodical controls of the ISO system are fully budgeted.	D. Debouck (CIAT)	This depends of what is in place in each genebank. Different opinions were shown with the trends and opinions from each case study, where some genebanks have their own quite good system in place and do not think it is worth the ISO upgrade, while others felt the need for a better quality system and moved upward. The main advantage of the ISO system is that it forces the adequate implementation of defined procedures and detailed recording of all procedures
General question	When there are climatic uncertainties that can affect the amount and quality of seeds harvested, what can be done if a genebank is applying ISO? If the appropriate numbers of quality seeds are not harvested in due	D. Debouck (CIAT)	Deviations from pre-defined protocols can be explained and justified, as it may happen with regeneration processes in the field per example. The main point of the ISO is to have all procedures documented and to

	time per example, then there are delays against planned milestones in other steps of the gene bank operations. How does an ISO system cope with this type of problems? this could explain the reluctance by gene bank managers to move swiftly to ISO norms		follow them as they are described or else, justify necessary deviations from the protocols or detailed documented procedures
General question	What are the long-term implications of an ISO accreditation or certification? What is the exact scope of such an accreditation/ certification? It might be useful to indicate, among the multiple activities of a gene bank, which are covered by this process and which are not, specially if it is to move during a transient period into a mixed system of partial accreditation and documented procedures.	D. Debouck (CIAT)	The definition of the areas of a genebank to be covered by ISO (if this choice is opted for) is entirely dependent of each genebank criteria, based on their priorities and risk areas.
Specific questions/concerns	Page 3 line 13 and line 24: if you introduce the words 'accreditation' and 'certification', your reader expect you start with a definition, showing the difference between the two, rather than referring to norms, whatever norm. On the other hand, it is a bit puzzling, namely in relation to the above text of pages 1-2 (and in line with 'rationalization'), that two well-known gene banks adhere to different norms. Why is that? Either there is one single norm for gene banks (independently from the materials they are handling), or there are a couple of norms for the different operations they are performing, but it does not look good if one gene bank sticks to one set of standards and another gene bank is sticking to another set.	D. Debouck (CIAT)	Point taken and definitions were explained in more detailed in the updated document. It is truth that genebanks adhere to different norms. It means there one solution does not fit all (this is also truth for many similar procedures of genebanks). There are different ways to reach a similar output, depending on the circumstances. In fact, this document is suppose to help to consider the various options and facilitate individual or even collective decision for further action towards a common QMS
Criteria and requirements for QMS in genebanks (page 5)	What are we suppose to control on equipment and supplies? It does not tell us much.	D. Debouck (CIAT)	Clarifications added in the text
Page 5 question	is not it rather any audit procedure, be internal or external?	D. Debouck (CIAT)	Correction made

Page 5 line 37: "materials of the wrong genetic source":	The wording might be misleading, and not truly reflecting the two risks here. First, the client asks for a particular material and gets another one, because simply another number was sent, or the material has been mislabeled. Second, the client asks for a particular material because it possesses a particular trait (for instance, as announced on the institutional web site), and gets the right material but without the trait. Controlling risk B is much more tricky than controlling risk A, and if the final purpose of an ISO certification is a true quality control, then risk B must be considered (specially if the gene bank is accredited).	D. Debouck (CIAT)	More detailed explanation was included as a footnote
Page 6, Table 2 (not mentioned in the main text)	It is unclear why the fourth column is documented only for "Documented Procedures".	D. Debouck (CIAT)	Insert reference to all tables and explain better the content in the tables within the document
Page 6 question	from funding opportunities, the benefit is unclear: on the one hand, the adoption of ISO norms practically means obligation to continuously stick to higher quality standards (and what if there is a funding shortfall?), and on the other hand, such an adoption may mean higher costs of operations.	D. Debouck (CIAT)	Explain better in the text
Page 6 lines 18-19:	the sentence is built as a relative, is there something missing?	D. Debouck (CIAT)	Corrected
Page 6, Table 3 (not mentioned in the main text),	It is unclear why costs of labour are not considered in the Economic Influences, since many gene bank operations are labour intensive. Again, it is unclear why the fourth column is not fully filled in.	D. Debouck (CIAT)	Insert reference to all tables and explain better the content in the tables within the document
Page 7, Table 4 (not mentioned in the main text),	it is unclear why Staff attitudes can simultaneously be strong factors towards and against adoption of accreditation and certification.	D. Debouck (CIAT)	Explain better in the text
Page 8, line 3:	typo: "… certification does not **necessarily** guarantee …".	D. Debouck (CIAT)	Corrected

Page 8, line 3:	This kind of statement should be made with care, because it could turn into a 'killing argument': if certification and accreditation do not lead to improved quality, then why to take the burden? Worse, it can be a serious public offense towards the donors if a certified gene bank is not working along the ISO approved standards.	D. Debouck (CIAT)	This is a fact (only for certification) and this is why this document might be very useful for people to have a broad perspective of all options. This is also why, some genebanks have decided so far it was not useful to do certification (see study cases in the document) This statement is not correct, a certified genebank would follow its ISO procedures, but that does not guarantee that those ISO procedures were the most adequate.
Page 8, Table 5 (not mentioned in the main text),	It is unclear why 'Research funding' is listed here and not in the 'Economic influences' of Table 3. Similarly, some social aspects of technological innovation may be moved to Table 4.	D. Debouck (CIAT)	Explain better in the text.
Page 9, Table 6:	The 'copy-and-paste' (typo on line 16) from Accreditation is not clear; would Accreditation and Certification eventually mean the same thing?	D. Debouck (CIAT)	Typo corrected. They have many similarities but a few differences (listed at the bottom of the rows in Table 6)
Page 10 line 28,	typo: "lack **of** peer review". Is it the case of the CGIAR gene banks?	D. Debouck (CIAT)	Corrected It is in many of them
Page 16 line 15, typo:	"Case study 6 - Deciding **where** to go from partial …". Same in Case study 7 and 8 on page 17.	D. Debouck (CIAT)	Corrected
Page 20 line 2,	the sentence does not read well; possible typo: "… to **improve** compliance …", or "… issues **related** to improved compliance …".	D. Debouck (CIAT)	Corrected
Page 21 line 18,	a better word than 'Although' (that right now leaves the sentence unconcluded) would be 'Nevertheless'.	D. Debouck (CIAT)	Corrected
Page 21 line 48, Page 23 line 53, typo: "…	'disadvantageous' is an adjective not a substantive; a possible replacement is 'mishap'. view, **as** long as financial …".	D. Debouck (CIAT)	Corrected

Page 25 line 1: Page 25 line 30, typo:	the word 'personal' is not adequate; human should be preferred since it refers to 'human resources'. "what the quality standard**s** are asking for … ".		
Page 26 line 12,	one would rather expect "Production of audit records"; is it correct?	D. Debouck (CIAT)	This is correct
Page 29 lines 9-10: (recommendation 1) Page 29 line 14: (recommendation 2)	this recommendation is rather vague and might apply equally to an ISO norm, or a storage system, or a documentation software. this recommendation should better take into account whether the gene banks are responsible for seed collections, *in vitro* collections or field collections, in order to go to the specifics, since there is common consensus to document operations	D. Debouck (CIAT)	Corrected for better understanding
Page 33 line 21, typo: Page 37 line 21,	"… (Quality World **articles**) …". "… **third** party verification …".	D. Debouck (CIAT)	Corrected
General comments	General concerns about high costs and doubts about the need to implement ISO as well as about the applicability of ISO for genebanks. Limited opportunity to read and comment about the feasibility document being discussed.	GPG2 side meeting at Bioversity (26 Nov08) Representatives from various CGIAR genebanks (IRRI, WARDA, IITA, ICARDA, ICRISAT, ILRI, CIP, CIMMYT)	In general genebank managers are quite unfamiliar with the ISO implications, vantages or disadvantages. Most people have a pre-conceived idea that the ISO implementation is difficult, costly and perhaps irrelevant/inadequate for the particular activities of a genebank. This is part of the reason this document was compiled and developed, to elucidate genebanks managers and decision makers with an independent opinion about the possible options and general preliminary recommendations on how to move forward.
Additional information for table 1	Incorporate information about two genebanks in Portugal that were certified since 2006. Additional information received from one of the genebank	M. Veloso (INRB, Portugal) Elvio Nunes (Isoplexis, Madeira)	Information added and contacts established with genebanks. Details added
Additional information	Additional estimates on costs were given from CIP	E. Rojas (CIP)	Information added

Final revisions for better clarity	Accreditation and certification are not mentioned in the same order through the document/tables, it is inconsistent.	M. Jorge (Bioversity International/ILRI)	Refer to certification before accreditation (options for QMS), as well as on Table 1, PEST (this one was already like that), SWOT, cost estimative and study cases.
Structural adjustments	Some subtitles do not read very well, must be more logical	M. Jorge (Bioversity International/ILRI)	Changing the previous *Discussion* into **Feasibility analysis,** *e) test for strategic fit* into **Discussion** and *f) risk assessment* into **Risks**.
General information	Incorporate list of collaborators and respective contacts	J. Hanson (ILRI)	List compiled and annexed
General information	General revision and corrections	E. Dulloo (Bioversity International)	Suggestions accepted