

CIP GENETIC RESOURCES RISK MANAGEMENT
(Draft version)

Overall Objective: Protection and effective use of the Center’s global collections and safety backups kept for other Centers and institutions

<i>Sub-Objectives</i>	<i>Associated Risks</i>	<i>Processes/ systems and activities</i>	<i>Manager(s) responsible</i>	<i>Policy, Procedure Document References</i>	<i>Recent/ planned reviews</i>	<i>Risk –Potential Impact</i>	<i>Risk – Likeli hood</i>	<i>Potential mitigations</i>
	<p>Genebank conserves in a timely way endangered genetic material before it is lost forever</p> <p><i>Genetic erosion is moving apace. At the same time that collection activities could be stalled by insufficient funding, there are increasingly restrictive national bioprospecting laws or national reluctance to grant appropriate approvals</i></p>							

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	Genebank fails to collect genetic material before it is lost due to such factors as mining, road construction, urbanization, land use change, climatic events, agricultural intensification and the replacement of traditional varieties with modern ones	Collecting missions	Genebank staff with crop project scientists;	SGRP policy; FAO Code of Conduct; ITPGRFA, regional legislation (D-391, CAN);	EU review 2007	H Wild populations erosion; potential for traditional varieties	High	<p>Prioritize collection activities, by analysis of gaps in the genebank and analysis of remaining distribution of traditional varieties and wild relatives <i>in situ</i>.</p> <p>Engage national authorities in selected target countries to establish mutually agreeable terms for collecting.</p> <p>Engage donors for funding.</p> <p>Engage international developments and agreements on ABS (Access and Benefit Sharing) under the ITPGRFA and the CBD, to optimize the negotiation process.</p>
	Genetic material is collected for Genebank without appropriate national permits	Collecting missions	Genebank Head; Project Leaders of collection projects	SGRP policy; FAO Code of Conduct; ITPGRFA, D-391		H Institutional image damaged	Nil	<p>Maintain awareness of national contact points and follow national procedures for obtaining relevant permits, under CBD or under ITPGRFA, and D-391.</p> <p>Undertake collections in partnership with national relevant institutions.</p>

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	Genetic material is collected by non-genebank Center staff without appropriate national permits	Collecting missions	Center senior mgt; Seed Health Unit (or equiv)	GADC, CIP Guidelines on Plant Genetic Resources and Related Intellectual Property Rights		H Institutional image damaged	Low	All institute staff wishing to bring in material are made aware of the absolute necessity to conform with internationally agreed protocols, and to consult with Genebank or other Center authorities to ensure they follow the right procedures (IP Management Unit has similar responsibility for bred materials that are the property of other breeders and subject to different laws)
	Long term financial unsustainability of genebank operations (in the past this has relied on unrestricted funding to the Center. However this form of funding has significantly shrunk compared with restricted project funding.) But matching funding is needed	Finance	Center senior mgt; Genebank Head	Annual meeting, Budget hearing, PNMs and proposals		M Germplasm viability reduced	Low	Prepare submissions in anticipation of funding from the Global Crop Diversity Trust, which has been recently established to provide long-term financial support to the CGIAR, Centers' international genebanks and selected regional genebanks. (The final terms of access to endowment funding are not yet in place).
	Failure of stakeholders relationships jeopardizes Genebank germplasm collecting mission activities	Partnership Management	Center Senior mgt	Agreements with NARs		Potential erosion in situ	Very low	This is closely related with Center institutional activities to foster effective partnership relations
Genebank conserves the broadest inter- and intra-species diversity in the collections								
	The crop genetic diversity not well represented in the collections	Conservation	Genebank staff		Global Trust Potato Curators Workshop	Demand for important traits not covered	Low	Organize targeted (geographically and traits) collecting missions.

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Genebank samples are safeguarded from loss due to diseases or pests								

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	Introduction of diseases and pests (to genebank, or, in the case of imported samples, to host country) through incoming samples	Receiving process – introduction and quarantine (<i>preventive controls</i>) Safety backups (<i>recovery measure</i>)	Head, Seed Health Unit (or equiv); Head ADU	Host country quarantine regulations National Classification of phytosanitary risks (SENASA)	Safe germplasm movement workshop (Nov-2007)	H (could result in revocation of Govt permits; damage to genebankssamples)	Low	Require incoming material to be accompanied by phytosanitary certificates recognized by host country Seed health testing by Seed Health Unit (SHU) follows International Seed Testing Association (ISTA) and US National Seed Health System protocols or equivalent To minimize errors in health unit laboratory techniques for detection of pathogens, pathology labs are subject to periodic inspection and equipment calibration tests Depending on the material and results of tests, incoming samples may be subject to treatment and outgrowing in isolation units before permit granted Non-permitted material is destroyed in accordance with quarantine regulations Logs documenting compliance are kept by health testing unit Physical separation of processing areas (drying cleaning, propagation) from collection storage areas. Procedures for producing pathogen-tested materials in accordance to ISO certification

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	Introduction of diseases and pests present in host country to the genebank through regeneration process	Regeneration process (<i>preventive controls</i>)	Genebank staff	Workflow , CIP Guidelines on Genetic Resources , Biotechnology and Intellectual Property Rights.		Germplasm viability reduced	Low	Regenerated material is also subject to phytosanitary testing as described above. Genebank staff can draw on expertise of Center pathologists and virologists working on the same commodity crops. Procedures documented and staff well trained.
Genebank in vitro accessions are safeguarded from loss due to microbial contamination								
	Low viability and loss due to presence of microbial contaminants	Acquisition regeneration (subculturing) & multiplication	In vitro bank staff	GADC guidelines		M Viability reduced of particular accessions in the collection		Increase the number of replicates. Protocols developed for eliminating contaminants.

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<p>Genebank samples are safeguarded from losing genetic integrity due to unintentional introduction of genes of other varieties or species</p> <p><i>Genetic integrity loss can occur through regeneration, but also in many ways and at many points in sample handling, e.g. accidental mixing of different samples, accidental mixing of labels. Protection must be implemented against all of these.</i></p>								<p>The ultimate detection mechanism relies on the “seed file” – a small sub-sample of the original incoming sample of each accession, put aside and permanently stored in a safe purpose-built cabinet. It serves as the reference sample definitively identifying that accession. Every new seed sample produced in the field is cross-referenced against its seed file, and is accepted for storage only if it matches.</p> <p>This measure is not practical. Most genebank accessions were collected in the 60-70’s; at that time this vision was not taken in to account. However, CIP genebank has initiated systematic integrity assessment of seed populations stored at –20°C. This work will provide information for planning targeted new collecting missions in particular in the “type localities”.</p>

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	Genetic integrity loss due to mixture with exotic seed during seed multiplication	Regeneration process (<i>preventive controls</i>)	Genebank staff	Workflow and guidelines for seed regeneration		M Genetic integrity loss for particular accessions or genotypes	Low	<p>Genebank quality control measures ensure that the seed samples are not mixed and that their collection histories are preserved. All seed operations are undertaken with procedures to minimize risks of inadvertent admixture of seed or mixing of labels, e.g. cleaning between samples, sealed containers, fixed labels inside and out.</p> <p>Use of bar-coding for additional quality control and quality assurance.</p> <p>Regeneration planting plans designed to minimize risk – can track what was planted in plots for past years, avoid using same plots for regeneration of different samples where potential risk of out-crossing with survivors of past plantings.</p> <p>Plots are monitored for off-types, which are manually removed.</p> <p>Harvested seed populations are processed manually and individually, and examined to remove off-types</p> <p>Establishment of safety back-ups.</p>

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	Integrity loss due to introgression with pollen from other germplasm during regeneration	Regeneration process (<i>preventive controls</i>)	Genebank staff	Workflow and guidelines		L Genetic integrity loss for particular accessions or genotypes	Low	<p>Conduct research on outcrossing rates in crop and use results to design standards for plot sizes, distances and harvesting protocols, creating a minimum level of “contamination”.</p> <p>Establishment of safety back-ups.</p> <p>Seed heads are bagged. Wild species are regenerated inside a secure screenhouses. Plots of different species are interspersed to minimize outcrossing.</p>
Genebank samples are safeguarded from genetic introgression with transgenes of other varieties or species			Genebank Head ABLs Head	Biosafety regulations CGIAR and CIP guidelines		L	Low	<p>Genetic introgression with transgenes is in many respects similar to the loss of genetic integrity. Therefore similar risk-prevention measures apply.</p> <p>However, transgenes require special attention because of their political sensitivity, and may require a higher level of risk control. Some recipients of seed require a special declaration that seed samples they receive contain no transgenes.</p> <p>Transgenes also introduce an additional risk that needs to be addressed, namely the risk of accidentally introducing transgenes through new acquisitions that may have unknowingly acquired through unintentional introgression.</p>

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	Introgression of transgenes into genebank accessions during genebank management	Quarantine Conservation Regeneration	Genebank staff Health Quarantine Unit ABLs staff	Host Country quarantine (SENASA) and biosafety regulations (national and CIP's) CIP guidelines		H Institutional image damage	Low	<p>Although reproductive methods are such that introgression is probably a low risk, it is still a potential risk with major consequences if it occurs. The possibility of accidental mixture of material needs to be minimized</p> <p>No transgenic samples are included in Genebank collections or stored in Genebank building. Facilities and staff handling transgenics are physically separated.</p> <p>Testing protocols for the detection of transgenes are being developed jointly with other CGIAR Centers (complex issue, work in progress)</p> <p>Management of transgenic clones in biosafety facilities.</p> <p>Establishment of safety back-ups.</p>

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	Introduction of transgenes into the collection in new germplasm acquisitions	Receiving process – introduction and quarantine (preventive controls)	Genebank staff, Health Quarantine unit	Host Country quarantine and biosafety regulations (national and CIP's) Center biosafety committee procedures GADC guidelines		H Institutional image damage	Very low	Possible introduction of transgenes is increasing. Future collecting trips and seed donations will need to include an assessment of risk level. Testing protocols for the detection of transgenes are being developed jointly with other CGIAR Centers (complex issue, work in progress) Establishment of safety back-ups.
Genetic integrity of genebank samples is safeguarded								Loss of genetic integrity by “contamination” with exogenous genes is covered above. Even in the absence of “contamination”, genetic integrity can be altered by genetic drift in the case of outcrossed species. Loss of genotypes could also become a source of genetic integrity reduction. Risk is higher in more genetically variable accessions (wild species, especially the outcrossing, and traditional varieties). Drift is reduced by using appropriate number of plants per accession for hand pollination and seed production.

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	Loss of integrity of samples due to uncontrolled drift or selection during seed multiplication (wild species)	Seed regeneration	Genebank staff	Workflow for seed regeneration		M Genetic integrity loss for particular accessions or genotypes	M	Use of standard large plot sizes ensures minimal drift. Labour-intensive nature of seed multiplication precludes the maintenance of large population sizes. Procedures documented and staff well trained. Genetic integrity assessment of seed populations.
Genetic integrity of in vitro genebank samples is safeguarded								
	Mislabelling or misidentifications occur during in vitro multiplication process	Multiplication processes	Genebank staff	Workflows Guidelines		M Genetic integrity loss for particular accessions or genotypes	L	Effective use of a computerized labeling system of accessions in long-term storage. Use of bar coding only, scanners and pocket PCs.
	Missidentifications occurred during database management	Database management	Genebank staff ; Bioinformatics Unit			M Genetic integrity loss for particular accessions or genotypes	L	
	Genetic integrity loss due to genetic changes induced by use of non-appropriate culture medium (mutations, somaclonal variation)	Multiplication, regeneration and conservation processes	Genebank staff	Guidelines Workflows		M Genetic integrity loss for particular accessions or genotypes	L	Use of appropriate medium to assure genetic stability of in vitro collections. Quality control routinely

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Genebank samples are safeguarded from loss due to inappropriate seed multiplication procedures								
	Poor plot management	Genebank Infrastructure (<i>preventive controls</i>)	Genebank Head	Guidelines Workflows		Medium Loss of particular accessions or genotypes	Low	Standard procedures for plot management – preparation, sowing, transplanting, fertilizers, water, pesticides, harvesting, developed. Establishment of safety back-ups.
Genebank samples are safeguarded from loss due to inadequate storage conditions								

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	Storage conditions at genebank not suitable (temperature, humidity, exposure to pests, exposure to other damage to samples)	Genebank Infrastructure (<i>preventive controls</i>) Safety backups	Genebank Head Maintenance Unit Head	FAO/IPGRI Genebank Standards Design of Seed Storage Facilities for Genetic Conservation (DSSF) specifications CIP' protocols, workflows		H Loss of collections	L	Dried seed samples are carefully sealed in aluminium foil bags against humidity and pest attack. Samples stored in multiple containers to minimize container-specific risks Alarm systems for temperature/humidity changes in storage areas and security system for Genebank building exist Long-term cold store built inside medium-term cold store for improved efficiency. Establishment of safety collection back-ups
	Cold store compressors fail	Genebank Infrastructure (<i>preventive controls</i>)	Genebank Head Maintenance Unit Head	Guidelines		M Viability decrease of collections	Low	Cold store compressors are backed up and alarmed. Temperature is permanently monitored Cold store compressors back-ups. Establishment of safety collection back-ups

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	Power supply cut-off	Genebank Infrastructure (<i>preventive controls</i>)	Genebank Head Maintenanc e Unit Head	Guideline s		M Viability decrease of collections	Low	Back up generators in place, regularly checked and maintained to ensure good working order. Backup power supply is independent of the backup to the rest of Center Establishment of safety collection back-ups
Genebank samples are safeguarded from loss due to theft, vandalism or disaster								
	Theft or vandalism by intruders	Genebank Infrastructure (<i>preventive controls</i>)	Institution’s security staff	Security procedure s		H Institutional image damage Loss of particular accessions		Genebank benefits from Center 24 hours perimeter security Control of access to genebank facilities, only for authorized personnel. Establishment of safety back-ups
	Theft during germplasm shipment in vitro to other genebanks (i.e. black boxes as safety duplicates) and apply of regulations.	Safety Backups Distribution	Genebank Head ADU Logistics Unit			H Institutional image damage		Use the safest shipment services.
	Damage due to weather elements	Genebank Infrastructure (<i>preventive controls</i>)	Genebank Head			H	L	Genebank building designed and built to ensure weather protection – subject to periodic maintenance checks Establishment of safety back-ups

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	Damage due to fire	Genebank Infrastructure (<i>preventive controls</i>)	Genebank Head Institution's security staff	Security procedure s		H Loss of collections	Very low	Genebank building rated for fireproofing; fire suppression measures – subject to periodic fire safety checks Trained genebank staff with fire suppression techniques. Establishment of safety back-ups
	Damage due to earthquakes	GRC Infrastructure (<i>preventive controls</i>)	Institution's security staff	Security procedure s		H Loss of collections	Low	Genebank building designed and built to earthquake proof standards adequate for location. Establishment of safety back-ups
	Damage due to other catastrophic events (e.g. aircraft crash on flight path to/from airport)	Safety backups shipment Distribution shipment	Institution's security staff	FAO/IPG RI Genebank Standards		H Loss of collections	Very low	Safety backup arrangements are in place. However there are sub-risks such as reliability of partners hosting safety backups, backlogs of safety duplication for new accessions, which need to be carefully monitored. GPG1 is assisting in backlog of safety backup duplication and regeneration.
Viability of samples in collection is maintained								

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	New material in collection is not viable	Receiving process – introduction and testing (<i>preventive controls</i>)	Genebank Head, and staff	Guidelines		M Loss of particular accessions or genotypes	Low	Viability testing regularly
	New material in cryo-collection is not viable	Cryopreservation procedures	In vitro genebank staff	Protocols		M Loss of particular accessions or genotypes	Low	Viability testing regularly
	Loss of viability due to backlogs in regeneration (equipment, manpower limitations) <i>The continuous collection and acquisition of genetic resources can present a challenge for the Genebank to keep up with some of the regeneration requirements.</i>	Storage (monitoring) processes (<i>preventive controls</i>)	Genebank staff	Guidelines		H Loss of particular accessions or genotypes	Low	Monitoring of viability according to (or within) recommended intervals. GPG1 Project is helping to fund reduction in backlogs in viability testing and regeneration of ageing accessions. There is a need to re-assess the viability monitoring regime. The current regime is based on theoretical predictions. Now with many years of accumulated data available, including sufficient data to analyse differences among types of variety, it will be possible to improve the regime based on actual viability data.
Only healthy germplasm is distributed from Genebank								

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	Germplasm distributed from genebank es diseased.	Distribution processes (<i>preventive controls</i>)	Genebank staff Head, Health Unit	Protocols		H Institutional image damage	Low	Distributed material also subject to phytosanitary testing as described above. Make the appropriate seed health checks according to the phytosanitary standards of the importing country. All outgoing material must be accompanied by a phytosanitary certificate Quarantine officials visit seed multiplication plots during growing out. Introduce quality control ISP systems in the process for distribution of healthy materials
Mitigate environmental risks associated with Genebank activities								
	Non-native wild species may escape into the environment	Genebank Infrastructure	Genebank staff			L	Low	Wild species are grown only in pots inside a contained screenhouse. After harvest, all remaining materials are destroyed, including the soil.
Genebank complies with international undertakings and agreements with providers concerning the distribution of germplasm								

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	Recipients of “designated” germplasm or Center-created “non-designated” germplasm attempt to claim IP rights over the germplasm	Distribution processes (<i>preventive controls</i>)	GADC Head IP policy committee chair	Center Policy on MTAs Guidelines		H Institutional image damage	Low	<p>Standard MTAs for “designated” and Center-created “non-designated” germplasm. MTA for “designated” material developed in collaboration with FAO and other CGIAR Centers. As set forth in the MTA, all recipients must agree: - not to claim legal ownership or seek intellectual property protection over the designated germplasm or related information; and - to make any subsequent transfer of the designated germplasm or related information subject to these conditions.</p> <p>Require positive confirmation of acceptance of MTA provisions from recipients before material is shipped</p> <p>Standard MTA for “designated” germplasm is printed as a reminder on wrapper covering shipped samples</p> <p>Standard MTA is expected to change in 2006, with new text established by the Governing Body of the ITPGRFA</p> <p>Establish an IP-aware component of its comprehensive germplasm database, to ensure that all incoming and outgoing germplasm is transferred legally, and accompanied by the appropriate MTA and other documents.</p>

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	Non compliance with restrictions placed on non-Center “Non designated” germplasm – distribution or subsequent use by recipients in contravention of restrictions	Distribution processes (<i>preventive controls</i>)	GADC Head			H Institutional image damage	Low	Center MTA requires compliance of recipient with IP restrictions layed out by the Center and the CGIAR.
Genebank accession data is complete, accurate and in a form that can be widely accessed as a global public good by those who can productively use the data in the furtherance of the Center’s mission								

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	Incorrect classification of accessions (risk highest for wild relatives)	Accession processing Acquisition process Database management Labelling	Genebank staff	Guidelines		M Loss of genetic integrity of particular accessions	Low	Reference herbarium Where there is doubt about the identity of an accession, voucher specimens are sent to taxonomists working on that group of plants In process of putting digital images of voucher specimens on the website so any taxonomist in the world can see what is identified and can advise if this is incorrect The GPG1 project is comprehensively helping to upgrade database management to ensure their accurate classification
	Incorrect data on original location of accessions (risk highest for old accessions)	Accession processing Collecting Acquisition process Database management Labelling	Genebank staff	Guidelines		M Loss of genetic integrity of particular accessions	Low	Especially for old accessions, data on their origin is often sparse, inaccurate, unvalidated and inconsistent. Yet these data are increasingly important, both for scientific analysis of diversity by GIS, and for implementation of global agreements e.g. ITPGRFA, CBD etc The GPG1 project is comprehensively reviewing all locational data, with a redesigned database format for better data validation and organization, cross-referenced with GIS digital gazetteers.

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	Incorrect data on country of origin (risk highest for old accessions)	Registering data of accessions Acquisition Collecting	Genebank staff			M Loss of genetic integrity of particular accessions	Low	Especially for old accessions, there may have been confusion between (a) the country that donated an accession to the Center and (b) the country where the accession was originally bred or collected. The country of origin, in particular, could be incorrectly recorded. The GPG1 project is comprehensively reviewing all data on accessions history and procedence.
	Delays in recording of accessions and declaring them to FAO & SINGER	Accession processing (<i>preventive controls</i>)	Genebank staff			M Delays in utilization of particular accessions	L	Potential backlogs in recording accessions can occur at two levels – upon entry and later on when designating the materials to FAO and SINGER. With regard to the first, there will be pressure from collection exploration partners to speed up introduction and multiplication processes and have the material entered and access available. Use of informatics tools for developing control systems and detect backlogs in recording new accessions and FAO designation. With regard to the second, Genebank can readily reconcile total numbers of material currently kept versus what has been declared to FAO, to monitor any backlogs.

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	Inflation of accession numbers	Database management	Genebank staff			M Institutional image damage	Low	Risk relates to multiple counting of identical samples as multiple accessions. Use of modules for providing on-line inventories according FAO designation, biological status, plant health, etc. Use of barcoding reduces mistakes.
	Limited ICT capacity constrains accessibility of germplasm and related data to potential users	Database management	Genebank staff			M Delays in utilization of germplasm	Low	May still be substantial work to do to document “institutional memory” – data on evaluation on such aspects as diseases, pests and abiotic stresses collated during Center’s life. There is an opportunity to address centrally through the centralization of such information with the Genebank germplasm information. What would be needed is a “data curatorship” type position to handle this.

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