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Item 5.2 of the Draft Provisional Agenda

COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Eleventh Regular Session

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GUIDING PRINCIPLES FOR THE DEVELOPMENT OF CGIAR CENTRES' POLICIES TO ADDRESS THE POSSIBILITY OF UNINTENTIONAL PRESENCE OF TRANSGENES IN *EX SITU* COLLECTIONS

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GUIDING PRINCIPLES FOR THE DEVELOPMENT OF CGIAR CENTRES' POLICIES TO ADDRESS THE POSSIBILITY OF UNINTENTIONAL PRESENCE OF TRANSGENES IN *EX SITU* COLLECTIONS

I. INTRODUCTION

1. At its Tenth Regular Session, the Commission considered a *Report on the International Network of Ex Situ Collections under the auspices of FAO*[1] which included information on an Expert Workshop on "Technical issues associated with the Development of CGIAR policies to address the possibility of adventitious presence of transgenes in CGIAR *ex situ* collections". The purpose of the workshop had been to provide technical inputs to the CGIAR Centre genebanks in drawing up their policies to prevent unintentional transgenic introgression. A set of draft guiding principles developed by the CGIAR was made available informally to the Commission during the session. The Commission was informed that the final version of the *Guiding Principles for the Development of CGIAR Centres' Policies to Address the Possibility of Unintentional Presence of Transgenes in Ex Situ Collections,* would be issued by April 2005, after consultation with all relevant stakeholders. The Commission then requested its Intergovernmental Technical Working Group on Plant Genetic Resources for Food and Agriculture to consider the draft Guiding Principles.

2. At its third session in October 2005, the Working Group recognised the importance of the Guiding Principles in avoiding the unintentional introgression of transgenes into other accessions, and noted that the Guiding Principles would help maintain the integrity of genetic resources, in particular in centres of origin, and in the collections of the CGIAR Centres. The Working Group stressed that the integrity of accessions is not only threatened by transgenes, but also by unsuitable genebank management practises and genetic erosion. It reaffirmed that the integrity of genetic resources is important and noted the proactive approach taken by some of the CGIAR Centres to address the risks associated with transgenes. It noted that the Guiding Principles arose from extensive expert consultation and guidance, and that this approach should be continued. The Working Group agreed on the relevance of the Guiding Principles as a good basis for crop-specific guidelines. It acknowledged the need to take existing national law and regulations, as well as international agreements, in particular the Biosafety Protocol, into account in developing guiding principles or guidelines. It noted that each country is responsible for managing its *ex situ* collections.

3. This document contains the Guiding Principles in its *Appendix*. It briefly summarizes the development of the Guiding Principles and the state of their implementation. The Commission's guidance is sought as to how it wishes to proceed with the Guiding Principles.

II. DEVELOPMENT OF THE GUIDING PRINCIPLES

4. Following the Tenth Regular Session of the Commission, the draft Guiding Principles were developed through the expert workshop mentioned on paragraph 1 above. The draft Guiding Principles were widely circulated for further consultations with various stakeholders. They were also distributed to National Agriculture Research Systems, civil society organisations, and farmers' organisations, the Global Forum for Agricultural Research, and through the Bio-IPR list-server of GRAIN, for input and comments. The guiding principles were also presented by IPGRI (now Bioversity International) at the FAO Expert Consultation on "Genetically modified organisms in crop production and their effects on the environment: methodologies for monitoring and the way ahead" held in January 2005. The Genetic Resources Policy Committee of the CGIAR revised the Guiding Principles based on the feedback received, and forwarded them to

[1] See document CGRFA-1-/04/06.

the May 2005 joint meeting of the Center Board Chairs (now the Alliance Board) and Centre Directors' Committee (now the Alliance Executive)[2] which adopted them. The Centres were requested to post the Guiding Principles on their websites.

III. IMPLEMENTATION OF THE GUIDING PRINCIPLES

5 By paragraph 6 of the Guiding Principles, Centres should develop, document and communicate crop-specific guidelines for the best genebank management practices. These guidelines should include crop-specific risk analysis procedures (*i.e.,* risk assessment, management, and communication) addressing critical control points. The Alliance Executive of the CGIAR Centres requested the System-wide Genetic Resources Programme (SGRP) to develop crop-specific guidelines. Within the larger context of the SGRP-coordinated Global Public Goods 2 project (GPG2) CIMMYT is coordinating Centres' inputs into the development of such guidelines for maize, rice and potato

6. By paragraph 12 of the Guiding Principles, the Centres should establish and maintain a database on the global status of GM research and development for the crops within their collections, in order to facilitate risk analysis. The database should be posted on a publicly accessible website. As a first step, the Genetic Resources Policy Committee has recommended an expert meeting to develop the database.

IV. GUIDANCE SOUGHT FROM THE COMMISSION

7. The Commission may wish to:

- welcome the Guiding Principles for CGIAR Centres and encourage the CGIAR to bring the guidelines to the attention of relevant international institutions;
- consider, as its Working Group recommended, relevant sections of these Guiding Principles in the development of the draft *Code of Conduct on Biotechnology* and in the review of the *Code of Conduct on Plant Germplasm Collection and Transfer,* if and when it is updated;
- recommend to national, regional and international genebanks to consider using the Guiding Principles; and
- consider, as its Working Group recommended, whether the database on the global status of research and development in genetic modification, described in paragraph 12 of the Guiding Principles, should be placed under international auspices, so that it will be publicly accessible internationally.
- review the crop-specific guidelines for potato, rice and maize currently under development at its Twelfth Session .

[2] See summary record of Proceedings of this joint meeting at: http://www.cgiar.org/pdf/cbc_ae_jointSOP_200505.pdf.

Appendix

GUIDING PRINCIPLES FOR THE DEVELOPMENT OF CGIAR CENTRES' POLICIES TO ADDRESS THE POSSIBILITY OF UNINTENTIONAL PRESENCE OF TRANSGENES IN *EX SITU* COLLECTIONS

BACKGROUND

1. In the management of germplasm, the CGIAR Centres embrace the following overarching principles: ethics, transparency, accountability, risk analysis and quality control.

2. The purpose of genebanks is to collect, conserve and make genetic resources available. The maintenance of the genetic identity of the accessions is an overriding objective of genebanks. The Centres take proactive steps that aim to prevent the unintentional introgression of exotic genes, including transgenes, not already present into samples conserved in their genebanks. Proper germplasm management procedures and genebank practices and protocols to ensure quality and integrity of accessions must be followed.

3. Transgenes and conventional genes are subject to the same underlying biological processes of mutation, geneflow, introgression, recombination and natural selection. Therefore, best practices for preventing introgression of conventional genes provide an appropriate basis for preventing introgression of transgenes.

4. Germplasm management procedures and practices should conform to best practices. Best practices and appropriate technologies vary with the crop, influenced, for example, by its breeding system, pollination system, and whether it is an annual/perennial. These best practices include procedures and practices that aim to prevent the transfer of genes from sources other than the accession in question. Routes for transfer by other sources include admixture of seeds and pollination.

5. It is recognized that available technical means do not permit the complete exclusion of unintentional presence of exotic genes, including transgenes, in genebank accessions. It is also recognized that available testing techniques do not provide an absolute guarantee, without testing every single seed or plant that any given accession is free of transgenes. However, best practices in genebanks will achieve a high degree of statistical probability that an accession does not include unintentionally present transgenes.

GUIDING PRINCIPLES

6. The Centres should take proactive steps to determine the risk of the unintentional presence of exotic genes, including transgenes, in their *ex situ* collections.

7. The Centres should develop, document and communicate crop-specific guidelines for best gene bank management practices. These guidelines should include crop-specific risk analysis procedures (*i.e.,* risk assessment, management, and communication) addressing critical control points.

8. The major genebank operations that need to be evaluated are collecting, acquisition, regeneration, characterization, delivery, conservation, testing health and viability, evaluation and documentation (genebanks are most open to unintentional introduction of transgenes at the collecting and acquisition stage, because germplasm may have been exposed to geneflow outside the control of the genebank). The guidelines must aim to minimize geneflow at these stages, for transgenes and for conventional genes.

9. As part of their risk analysis, when collecting or acquiring new accessions by other means, Centres should consider the following regarding testing:

a. whether transgenic events (commercial and research) in the relevant taxa are likely to be present in the area of collecting or acquisition;

b. the distance between the collecting site and areas where transgenic events (commercial and research) are situated; or

c. whether germplasm providers can provide adequate documentation of their germplasm management practices with respect to the material in question.

10. With respect to existing accessions, Centres' testing procedures should be guided by the following criteria:

a. No testing would be required when:

i. there are no transgenic events (commercial or research) in the relevant taxa at the present time;

ii. there were no transgenic events (commercial or research) in the relevant taxa at the time of acquisition (*e.g.*, maize prior to 1996);

iii. it is determined that, unless there are other factors, there is no presence of transgenic events within a distance that would allow for introgression; or

iv. there are transgenic events (commercial or research) present, however, proper management practices have been followed and documented in the management of the accession,

b. Tests should be undertaken when there are transgenic events (commercial or research) present and good management practices cannot be demonstrated.

c. Once an accession has been determined to either not require testing or has tested negative, the Centre will follow best practice regeneration and maintenance procedures to maintain the genetic integrity, as for all accessions.

11. If and when transgenes are detected in an accession, in following best practice management procedures, the Centres will take appropriate steps to prevent introgression of those transgenes to other accessions.

12. The Centres should establish and maintain a database on the global status of GM research and development for the crops within their collections in order to facilitate risk analysis. The database should be posted on a publicly accessible website.

13. The Centre should bear the costs of the procedures, including tests when necessary, set out above. Requests for additional assurances above those established by the Centre should be met through additional funds on a case-by-case basis from outside sources.

14. Upon request by the recipients of materials, the Centre will provide information describing procedures and tests that the Centre has followed for the accession concerned.

15. All data resulting from any testing should be properly documented and made publicly available as soon as it is considered scientifically reliable (*e.g.*, by posting on the Centre’s web site). All procedures and supporting information should be presented at the same time. The Centre will also inform the relevant authority of the country of collecting or acquisition of the material in question when transgenes are found; the Centre will also inform the relevant authority of the country in which the Centre is located.