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Item 17 of the provisional agenda*

THEMATIC PROGRAMMES OF WORK: PROGRESS REPORTS ON IMPLEMENTATION AND CONSIDERATION OF PROPOSALS FOR FUTURE ACTION: AGRICULTURAL BIOLOGICAL DIVERSITY

Potential impacts of genetic use restriction technologies (GURTs) on agricultural biodiversity and agricultural production systems: report submitted by the Food and Agriculture Organization of the United Nations

Note by the Executive Secretary

1. In paragraphs 20 and 21 of its decision V/5, the Conference of the Parties:

(a) Invited the Food and Agriculture Organization of the United Nations, in close collaboration with the United Nations Educational, Scientific and Cultural Organization, the United Nations Environment Programme and other member organizations of the Ecosystem Conservation Group, and other competent organizations and research bodies, to further study the potential implications of genetic use restriction technologies for the conservation and sustainable use of agricultural biological diversity and the range of agricultural production systems in different countries, and identify relevant policy questions and socio-economic issues that may need to be addressed;

(b) Invited the Food and Agriculture Organization of the United Nations and its Commission on Genetic Resources for Food and Agriculture and other competent organizations to inform the Conference of the Parties at its sixth meeting of their initiatives in this area.

2. In response to the request the FAO had submitted an information document (UNEP/CBD/COP/6/INF/1/Rev.1) informing the sixth meeting of the Conference of the Parties that the Commission on Genetic Resources for Food and Agriculture would consider the questions of GURTs at its ninth meeting, in October 2002.

3. The attached document has been submitted by the FAO on behalf of the Commission, which considered the technical study at their ninth meeting held from 14 to 18 October 2002.

4. The document is being circulated in the language and the form in which it was received.

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* UNEP/CBD/COP/7/1 and Corr.1.

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Potential Impacts of Genetic Use Restriction Technologies (GURTs) on Agricultural Biodiversity and Agricultural Production Systems

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INTRODUCTION

CONSIDERATION OF THE TECHNICAL STUDY BY THE NINTH REGULAR SESSION OF THE FAO COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

The Ninth Regular Session of the FAO Commission on Genetic Resources for Food and Agriculture met in Rome, from 14 to 18 October 2002. As part of its consideration of cooperation between FAO and the Convention on Biological Diversity, the Commission considered document CGRFA-9/02/17 Annex,[1] a technical study that had been prepared by the FAO Secretariat, on the *Potential Impacts of Genetic Use Restriction Technologies (GURTs) on Agricultural Biodiversity and Agricultural Production Systems*. This study responds, *inter alia*, to the request of the Conference of the Parties to the Convention on Biological Diversity, in decision V/5, that FAO "*further study the potential implications of genetic use restriction technologies for the conservation and sustainable use of agricultural biological diversity and the range of agricultural production systems in different countries, and identify relevant policy questions and socio-economic issues that may need to be addressed*".

Work on GURTs in FAO started from a recommendation by its Committee on Agriculture in 1999, that FAO develop a strategic approach to biotechnology and a coordinated cross-sectorial programme. In this context, "*the 'terminator technology' was mentioned as an example of a biotechnology that may have wide implications for agriculture, and that needed careful attention. The Committee stressed FAO's role in providing a forum for countries to monitor food and agriculture biotechnologies*".[2]

The technical study considered by the Commission at its Ninth Session was developed in consultation with a wide range of interested parties. An outline was made available for comment to the second meeting of the Liaison Group on Agricultural Biodiversity, in January 2001. A first draft was submitted in April 2001 to peer review by independent experts in relevant disciplines, including members of the Ecosystem Conservation Group, and a revised draft was sent for comments to a wide range of stakeholders in May 2001.[3] The document took into account the comments received.

The Technical Study was reviewed by the subsidiary Inter-governmental Technical Working Group on Plant Genetic Resources for Food and Agriculture of the Commission on Genetic Resources for Food and Agriculture in July 2002. The Working Group "*acknowledged the overall accuracy of the technical section of the report on GURTs and that the analysis of potential impacts needs to be well balanced.*

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[1] It also considered document CGRFA-9/02/17, which described the process by which the technical study had been developed. Both document CGRFA-9/02/17 and the technical study itself (CGRFA-9/02/17 Annex) are available on the internet at http://www.fao.org/ag/cgrfa/docs9.htm.

[2] Document CL 116/9 para. 44 to 53.

[3] FAO prepared this document based on a background study undertaken by Plant Research International, on a consultancy basis, available on the internet at ftp://ext-ftp.fao.org/ag/cgrfa/BSP/bsp15e.pdf. It also consulted all the members of the Ecosystem Conservation Group (IUCN, UNDP, UNEP, UNESCO, the World Bank, WWF and WRI); experts who undertook a peer review; and invited comments from stakeholders (Cambia, CBD Secretariat, Centro Internazionale Crocevia, Eubios Ethics Institute, FIS/ASSINSEL (now ISF), GFAR, GRAIN, IFAP, International Agri-Food Network, IATP, IPGRI, ITDG, NGO CGIAR Committee, NGO SAFS Caucus Quaker UN Office, RAFI (now the ETC Group), Solagral, SIDA, UPOV, WIPO), not all of whom commented.

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Detailed comments on the document, stressing both the potential advantages and disadvantages of GURTs were provided by many delegates with the aim of improving the report's balance". The Working Group agreed that the study should be modified, in the light of the comments made (some of which were subsequently submitted in writing), and submitted to the Commission at its Ninth Regular Session. The results of the Commission's consideration would then be submitted to the Conference of the Parties to the CBD. In the event, the Ninth Regular Session of the Commission was not held in 2001 as planned, due to the priority that the Commission had given to completing the negotiations that led to the adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture by the Thirty-first Session of the FAO Conference, on 3 November 2001. A report was accordingly sent to the Sixth Meeting of the Conference of the Parties in April 2002, noting that the Commission would not consider the question of GURTs until its Ninth Regular Session.[4]

Following consideration of the Technical Study at its Ninth Regular Session, the Commission decided that it "*should be forwarded to the next Conference of the Parties, for information. Some Members stressed that, in doing so, it should be made clear that genetic use restriction technologies are currently in a period of research and development, are not currently available commercially, and may never be. One Member expressed concern at the lack of balance in the updated study, requested to append additional written comments to the study, and was invited to do so*."

"Some Members of the Commission expressed the concern that GURTs are in contradiction to the spirit of the International Treaty and the sharing of genetic resources. Members of the Commission also expressed concern regarding the possible effects on developing countries and their farmers, and on food security and rural development. They indicated the need to better understand any possible adverse impacts on the environment, and the implications for agriculture. The Commission agreed that FAO should play a role in sharing information and experience regarding genetic use restriction technologies, particularly by inviting Members to provide information on any relevant national regulatory decisions, and making them available".

The current document contains the technical study, and the comments on it that were provided by the United States of America.

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4 UNEP/CBD/COP/6/INF/1/Rev.1.

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September 2002

منظمة الأغذية والزراعة للأمم المتحدة | 联合国粮食及农业组织 | Food and Agriculture Organization of the United Nations | Organisation des Nations Unies pour l'alimentation et l'agriculture | Organización de las Naciones Unidas para la Agricultura y la Alimentación

Item 7 of the Draft Provisional Agenda

COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Ninth Regular Session

Rome, 14-18 October 2002

POTENTIAL IMPACTS OF GENETIC USE RESTRICTION TECHNOLOGIES (GURTs) ON AGRICULTURAL BIODIVERSITY AND AGRICULTURAL PRODUCTION SYSTEMS: TECHNICAL STUDY

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* Note by the Secretariat: At the Ninth Regular Session of the Commission on Genetic Resources for Food and Agriculture, the Commission considered document CGRFA-9/02/17 Annex and agreed to forward it for information to the next meeting of the Conference of the Parties to the Convention on Biological Diversity, with the original paragraph 50 removed. This has been done, and the remaining paragraphs have been renumbered accordingly, in this revised version (CGRFA-9/02/17 Annex Rev. 1).

POTENTIAL IMPACTS OF GENETIC USE RESTRICTION TECHNOLOGIES ON AGRICULTURAL BIODIVERSITY AND AGRICULTURAL PRODUCTION SYSTEMS: TECHNICAL STUDY

1. TECHNICAL ASPECTS OF GURTs TECHNOLOGIES

1. Biotechnology-based switch mechanisms to restrict the unauthorized use of genetic material have been described in a number of patent applications. These have been grouped under the collective term, Genetic Use Restriction Technologies (GURTs). The use of GURTs *per se* results in a genetically modified organism (GMO) even if applied to non-genetically modified material.

2. Two types of GURTs can be distinguished: variety use restriction (V-GURTs), rendering the subsequent generation sterile; and use restriction of a specific trait (T-GURTs), requiring the external application of inducers to activate the trait's expression.

3. The use restriction aspect of these technologies has some parallels in classical genetics. Similar to offspring from V-GURTs products, sterile triploid[1] fish, seedless triploid fruits such as watermelon or parthenocarpic[2] fruits are not fertile. In F_1 hybrid breeding, while subsequent reproduction of hybrid plants and animals remains possible, wide segregation occurs and certain useful characteristics are not maintained in the offspring, as in the case of T-GURTs. Whether applications derive from classical or molecular genetics, farmers are obliged to re-purchase new growing stock for these organisms in order to overcome the sterility or poor performance of the hybrids' offspring.

4. However, such applications of classical genetics are commercially used to add value to the product, so that seedless fruits, sterile fish or hybrid maize have been widely accepted by both farmers and consumers and caused little or no controversy, whereas GURTs, used as a technology protection system,[3] (particularly V-GURTs) are perceived as restricting access without themselves adding value, and as raising concerns through potential impacts on biodiversity, agricultural practices, seed security and rural economies.

Functional mechanism of GURTs

5. At least three V-GURT strategies can be distinguished. *Strategy 1* uses the induced activation of a disrupter gene[4] which, if expressed, results in a product that inhibits germination.[5] This gene is held inactive by a transcriptional block that allows normal embryo development. However, when sold, the seeds are treated with a chemical inducer,[6] leading to expression of the disrupter gene in the second-generation seed. Consequently, the second-generation seed is fit for consumption, but infertile.

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1 Having three chromosome sets instead of the normal two.

2 Seedless fruits produced from unfertilized ovaries.

3 The analysis in this document distinguishes three distinct aspects of GURTs that need to be considered: use restriction ("technology protection"), environmental containment, and agricultural productivity contributions.

4 A gene interrupting the normal functioning of one or more other genes.

5 Delta & Pine Land/USDA concept.

6 A chemical that enables expression of a gene's activity.

6. *Strategy 2* differs in that the breeder applies a chemical in all generations, but ceases before selling the seed.[7] Here a disrupter gene expresses in the seed by default, resulting in sterile seed. Expression is prevented by application of the chemical, which provides a restorer protein to safeguard fertility.

7. *Strategy 3* focuses on crops reproduced vegetatively, like roots and tubers and many ornamentals, to prevent growth during storage, and extend shelf life.[8] Here a gene blocking growth is expressed by default, which can be suppressed by application of a chemical that induces a second gene.

8. In the T-GURT concept, a trait is switched on or off at will through inducible promoters regulating the expression of the transgene, by induced gene silencing,[9] or by excision of the transgene using an enzyme.

9. Whereas these concepts have been mainly described for plants, analogues could be developed for farm animals. For example, a technically possible V-GURT strategy based on sex chromosome modifications has been identified, especially for meat production in mammals. This requires the development of pairs of gene constructs that induce sex-linked sterility, with compensating elements that can restore fertility in the initial-breeding animals. Control of the process to overcome infertility would remain with the breeder.

State-of-the-art of GURT applications

10. *Strategy 1* has not yet been implemented, although several components of the concept have been demonstrated to work. *Strategy 2* has recently been shown to function in the laboratory but needs further improvements before field applications.

11. To be fully functional, GURTs need the timely, perfectly active operation of the various components of the chain, including tissue- and stage-specific promoters, disrupter and restorer genes, inducible promoters and their inducers, and recombinases:[10] many technical problems remain to be solved. Many promoters active in reproductive organs or during germination have been described, but their specificity may be less than the 100% necessary for V-GURT applications. The disrupter genes known so far may function, but counter-acting restorers are not known for all suggested disrupter genes. The timely control of the recombinase, to prevent expression of disrupter genes when desired, is not fully proven, although some satisfactory recombinases seem to be available. Inducer chemicals must also be efficiently applied to the seed: alcohol and steroids are the most promising candidates, but the final choices are as likely to be affected by biosafety and intellectual property rights (IPR) considerations as by technical considerations.

12. In addition, GURT applications are confined to crops for which technologies for genetic modification are available, such as the currently cultivated transgenic crops. Long breeding schemes may be required to introgress GURT into some difficult-to-transform elite lines. Current constraints may prevent imminent application of V-GURTs, but the pace of biotechnology and genomics development should allow the production of functional GURT prototypes for crops within five to ten years. T-GURTs seem nearer application.

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7 Zeneca concept.

8 Syngenta concept.

9 *E.g.*, by anti-sense suppression.

10 An enzyme catalizing recombination between specific target sequences resulting in addition, deletion or inversion of the fragment targeted by the flanking sequences.

13. While technically feasible, practical GURTs applications in forestry will be less likely, due to differences in management practices. For animals, technical problems will further delay practical applications.

Targets and applications of GURTs

14. Three distinct aspects of GURTs need to be considered: use restriction, environmental containment[11], and agricultural productivity contributions.

15. As a use restriction strategy, in the crop sector, species for which hybrid technologies or other natural control mechanisms are not well developed may be primary targets for V-GURTs, including inbreeding crops (*e.g.*, wheat, soybean and cotton), and vegetatively multiplied horticultural crops and ornamentals. T-GURTs could be applied to all crops. GURTs could also be utilized as a use restriction strategy to prevent farmers from resowing apomictic[12] seed, including of hybrids.

16. Functional GURTs, once developed, could be used for the environmental containment of transgenic seed (V-GURTs) or transgenes (T-GURTs). The probable focus will be species for which ecological niches and wild relatives exist locally, such as in crop diversity centres, and the containment of traits posing possible human health risk, such as transgenic crops for drug or vaccine production, or biodiversity-threatening traits.

17. Possible direct productivity gains from GURTs include T-GURTs enabling a producer to restrict trait expression, when there is a production advantage to doing so in a specific phase of plant or animal development, or during drought or pathogen attack, and V-GURTs used to control farm animal reproduction, in order to safeguard the integrity of adapted maternal breeds, or to prevent pre-harvest sprouting, particularly useful in tropical countries.

2. POTENTIAL IMPACT OF GURT APPLICATIONS: AGRICULTURAL BIODIVERSITY AND BIOSECURITY[13] ASPECTS

Potential impact on agricultural biodiversity

18. Agricultural biodiversity encompasses the genetic, species and ecosystem levels. In assessing the impact of GURTs on agricultural biodiversity and key ecosystem functions, a holistic perspective that takes into account all these levels is necessary, but is hampered by currently insufficient data.[14]

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11 A mechanism to prevent unwanted escape of genetic material into neighbouring individuals.

12 The asexual production of diploid offspring without the fusion of gametes. (*adj*: apomictic).

13 In this document, "Biosecurity encompasses all policy and regulatory frameworks (including instruments and activities) to manage risks associated with food and agriculture (including relevant environmental risks), including fisheries and forestry" (FAO Committee on Agriculture document COAG/01/8, *Biosecurity in food and agriculture*).

14 During the Working Group, it was stated that plants containing GURTs had not yet been grown outside research laboratories or greenhouses, and had certainly not been commercialized: assertions about such impacts were speculative. However, some considered it important to consider in detail, even if speculatively, the positive and negative potentials of such powerful new transgenic technologies. It was noted that definitive analyses and conclusions on possible impacts required more information and such information might become available if and when products incorporating GURTs were submitted to regulatory bodies prior to commercialization

19. The scale and type of farming system in question is an important consideration. In low-input farming systems (LIFS), farmers continuously breed and improve local seed, and depend on the contribution of new genes to this dynamic process to maintain local adaptive fitness and productivity. A first major effect may result from the widespread adoption by such farmers of GURTs containing desirable new traits, which — as with other modern varieties — would imply the displacement of locally-adapted genetic material through a process of substitution, with potential negative consequences for agricultural biodiversity, rather than integration of genes from the new material, as usually happens in the case of non-GURT commercial varieties.[15] The loss of traditional, dynamically locally adapted varieties could significantly affect the resilience and long-term productivity of LIFS, particularly in marginal environments or in extreme events. The magnitude of such impacts may depend primarily on the degree of interaction of the local farming systems with the commercial seed industry, both local and international: where GURTs varieties target farmers already using modern cultivars, effects on crop genetic diversity may be minimal.

20. Incentives for farm-level breeding may be reduced if desirable traits in GURT varieties cannot be accessed.[16] Genepools used by international breeding companies, private national breeders and local farmers, where there is now some genetic exchange, may become more isolated. The limitations to local farmers improving their germplasm may reduce the value of such germplasm as an input to formal breeding, to its long run detriment.

21. For equity, and to safeguard the long-term on-farm maintenance of plant genetic resources, increased investments in public — including participatory — plant breeding may be needed, to correct an increasing innovation-absorption gap. Similar assumptions can be made for the farm animal sector. Germplasm use and exchange between the industrial sector and LIFS is rather limited in forestry and fisheries, and therefore, negative agricultural biodiversity effects less likely to occur.

Biosecurity implications

22. It has been argued that second generation V-GURT sterility renders this technology particularly useful to prevent unwanted escape of genetic material into the wild.[17] However, this mechanism may not work adequately. For open-pollinated species, potential outcrossing of V-GURT varieties could reduce yield in the subsequent year due to occurrence of sterile seeds in neighbouring stands. The probability may be low, given the multiple gene recombination events that would need to accompany outcrossing. There is, however, as yet inadequate information to evaluate the potential negative effects.

23. The impact of outcrossing of T-GURT constructs may be limited in most cases. Most GURT-protected traits will be under positive inducer control. If unplanned outcrossing occurs, inducers will not be applied, and the constructs will usually remain unnoticed. However, a trait may be inducible by related substances or by naturally occurring trigger events (*e.g.*, steroids, pest and disease infestations), with such effects as yield drop and the production of undesirable substances, depending on the inadvertently triggered trait. Highly specific inducing substances appear necessary to avoid such undesirable effects. Moreover, and more importantly, the outcrossing of GURT constructs negatively controlling a trait could not only affect domestic species — with potential impacts on yield and quality — but confer unwanted properties on wild

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15 During the Working Group, it was noted that farmers are pragmatic, and will adopt or reject varieties according to their merits in their specific farming systems. It was stated that loss of traditional varieties does not necessarily accompany introduction of modern varieties.

16 During the Working Group, it was stated that this was speculative, and that such a cause and effect relationship had not yet been observed.

17 A number of stakeholders, however, were of the opinion that the use of GURTs was not justified, even for this purpose. During discussion by the Working Group, it was also stated that the present technical report was biased, in that it appeared to give a cloak of respectability to GURTs. The immediate banning of GURTs was called for.

relatives.[18] Such possibilities require further research, and raise important policy questions. In addition, some inducer substances (*e.g.*, steroids) could affect the target organisms, the environment, and human appliers and consumers. Existing regulations, for example, for pesticides and veterinary medicines, may apply.

24. For farm animals, potential negative environmental effects may be more easily containable, given the high level of domestication and current reproduction control practices. In forestry, direct negative economic impacts due to yield drops may be less, since seeds are not typically an important product. In contrast, given the high probability of escapes of aquatic species, varieties containing GURT constructs may negatively impact on wild populations if they pass into the wild genepool, thus affecting the reproductive ability of wild populations. The possibility of negative effects on aquatic populations should become an active and necessary study area.

25. Governments are moving to set up regulatory systems for modern biotechnologies, including GURTs, with a concomitant need for technical assistance to build national capacity in developing countries, including for risk assessment, management and communication. Governments may also need to consider liability issues for negative environmental impacts, including on biodiversity, resulting from GURTs.

3. POTENTIAL SOCIO-ECONOMIC IMPACTS OF GURTS IN FARMING SYSTEMS

26. Agricultural production systems are very diverse, and detailed analyses would require consideration of hundreds of crop and livestock production patterns, and seed and germplasm market linkages. The effects of GURTs on farming systems will depend on their level of input use. Intensive systems tend towards high dependence on the formal seed sector, with a high rate of seed replacement. Low-intensity systems tend towards low seed replacement levels and a higher reliance on informal seed supply. Many LIFS are in remote areas, without the option of seasonal seed or fertilizer purchase, and it seems unlikely that GURTs will be adopted by such farmers (it is likely that GURTs will first be applied to elite germplasm grown in developed nations): the poorest farmers in these farming systems, however, who often sow grain channeled for consumption instead of seed, risk significant yield drops if V-GURT grain enters local markets through trade or relief channels. T-GURT escapes, however, will remain unnoticed.

27. High-intensity farming systems currently account for a small proportion of farmers in developing countries. Some integrated low input intensive farming exists, such as smallholder hybrid maize and cotton growing, but most intensive and semi-intensive production is in relatively specialized commercial farms, such as for salmon and shrimp. High-value produce often dominates, including vegetables, fruit, specialized poultry and fish, and productivity often depends on the quality of purchased seed and animals. Cultivar or animal breed characteristics, as well as the changing environment, condition the responsiveness of crops and livestock to other purchased inputs (*e.g.*, fertilizer and feed). In these circumstances, T-GURTs may facilitate production management decisions, and the production and income on high-intensity developing country farming systems might increase. V-GURTs may be accompanied by increased breeding investments for such systems,[19] particularly in countries with weak IPR regimes. GURTs — like other modern technologies— may support a shift from medium-intensity farming to high-intensity, market-oriented systems.

28. Medium-intensity farming accounts for a substantial proportion of production in developing countries. Most are mixed staple and cash crops farms, often with livestock and significant off-

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[18] During the Working Group, it was requested that it be noted that such effects could also result from introduced non-GURT varieties.

[19] During the Working Group, it was stated that this is speculative, given that this technology is yet to be commercialized.

farm cash income. A minority are specialist producers. Such farmers are likely to be most vulnerable to GURTs, as they are partially integrated into the formal seed sector, but often could not afford V-GURTs seed or T-GURTs inducer purchase each season. Such farmers generally obtain lower yields with the same germplasm than intensive farms, and annual seed purchase may not be economic. The large-scale introduction of GURTs might force them to spend a larger proportion of their budget on seed, or cut them off from technology advances. . The introduction of GURTs, in the absence of substantial additional public investment in crop and livestock breeding for low- and medium-intensity, resource-poor farming systems, could widen the income gap between resource-poor and commercial farmers, with, as possible results, a concentration of land ownership, a shift in responsibility from women to men, large differences between early and late adopters, greater total output, and greater environmental problems due to the loss of biodiversity.

29. GURTS may have diverging effects on farmers' access to improved genetic resources. On the one hand, current practices of lateral multiplication of improved materials for local markets, including of local varieties that have introgressed genes from commercial varieties, will be hampered by V-GURTs, which could seriously effect medium- and low-intensity farmers who depend on informal local markets for their seed needs. On the other hand, if GURTs create greater incentives for research and development of a wider diversity of crops, and result in the availability of a more diverse set of improved cultivars, this could increase options for commercialized high-intensity producers, and possibly encourage greater specialization. This will depend on whether such markets are attractive for GURTs producers. The relative weight of these processes will vary across farming and seed systems.

4. POTENTIAL ECONOMIC IMPACTS OF GURTS

30. The enhanced control over future generations of improved material that GURTS offers has potentially diverse economic impacts on breeders and farmers, with sectorial, national and international policy implications.

Impacts on research and development

31. V-GURTs will only be commercially viable if they are applied to new breeds and cultivars with considerable productivity improvements. They are likely to be used in conjunction with other high value GM products. Embedding V-GURTs in these will require additional investments and may result in higher product prices, but wide adoption of these products, and a significant reduction in developers' transaction costs, due to additional biological (rather than intellectual property) protection, may together lower product prices.

32. Serious possible short-term constraints relate to consumer acceptance of GURTs as GMOs,[20] costly measures to ensure the segregation of GMO and non-GMO products in the food chain, and related liability costs.

33. Initially, much investment in GURTs will target crops and cultivars for richer markets of industrialized and middle-income countries, with little investment for least-developed countries and marginal and poor areas, where farmers' purchasing power is limited.

34. While V-GURTs may lead to increased investment for some crops, their permanent protective nature may affect the long-term innovative capacity of these investments, and lead to

[20] During the Working Group, it was noted that the acceptance or non-acceptance of GMOs may be strongly impacted by local or national political factors, as well as consumer acceptance and other variables.

increased segmentation of the genepools used by private and public sector breeders.[21] Such potential impacts must be assessed on the basis of breeders' current access to genepools, which varies according to the plant variety protection regime, as well as by crop. In countries with plant variety protection, such as the UPOV system, protected varieties are available for further breeding, under the breeder's exemption. However, where patents protect plant varieties, there is no breeders' exemption. Also, for some crops, F_1 hybrids mean that elite parents are typically not available to breeders, so the incremental impact of GURTs introduction on genepool segmentation may be minor.

35. However, in many developed and most developing countries, many breeding enterprises, especially the public sector, regularly use elite lines developed elsewhere: with GURTs, particularly V-GURTS, this would be impossible or very difficult, which could disrupt breeding research, with resultant increased productivity lag, particularly in developing countries.

36. In general, GURTs will tend to move agricultural research and development (R&D) further into the private sector, with two important policy implications: first, policy-makers will need to explore new ways to facilitate a positive spill-over throughout the agricultural sector from private sector innovations; and, second, they will need to assess the degree to which private sector innovations could widen the productivity gap between formal and informal sector producers, and identify the amount and type of publicly funded R&D needed to address this gap. In practise, there may be few effective measures available to policy makers, especially in developing countries, to address such problems.

Market power

37. Horizontal concentration and vertical integration in the seed breeding and agrochemical sectors has recently been the subject of considerable attention. GURTs could further concentrate market power in the formal seed sectors for some crops, due to economies of scale. This has lead to concern that firms may have the capacity to set prices non-competitively. If seed suppliers attempt to exploit their market power and appropriate a greater share of revenue from farmers, this will probably be an incremental process, that over time allows for adjustments in other markets, including those for farm products. Whether GURTs raise concern over the development of possible monopoly power in the sector will partly depend on the extent to which firms or other entrants can develop competing or alternative products, with or without their own GURT technologies.[22]

38. With monopoly concentration, seed supply may become a particular problem, if farmers become dependent on GURT seed and lose the safety margin of being able to save seed for the next season. If the supplying company collapses or abolishes the product line, this could, in extreme situations, leave the farmer without seed. Such problems with corporate insolvency are not unique to GURTs, but could be greatly exacerbated when the product of the harvest is sterile, and useless as seed. This could have immediate consequences for food security.

39. In this context, it should be noted that anti-trust laws and regulation are national, and that no international institutions support countries lacking relevant regulatory capacity. Although some developments within the WTO address this issue, significant difficulties and delays are likely in agreeing international standards.

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21 During the Working Group, it was stated that the effects might be relatively minor, if GURTs were implemented only in highly bred, uniform, elite materials. Moreover, influxes of funds towards private breeding need not necessarily result in reduced funding for public sector programmes.

22 During the Working Group, it was stated that licensing regimes, rather than the technology itself, may be a more important determinant of the scope of the technology's availability.

Agricultural input and output markets

40. In terms of inputs, the most likely effect of GURTs is an increase in farmers' seed replacement rate, and thus increased demand. In time, similar processes may occur in the farm animal and aquaculture sectors. This implies a shifting in benefits from seed consumers (*i.e.*, farmers) to the producers (*i.e.*, seed suppliers). The degree of this shift will depend on current seed replacement rates, the degree of competition in the market, and the rate at which yields deteriorate with replanted seed.

41. In the formal seed sector in industrialized countries, the private sector dominates, while government institutions dominate in most developing countries, as part of policies to increase agricultural output.[23] Recent structural adjustment policies have led to privatization in the seed sector in many developing countries: mixed systems have developed, with a private seed industry for some crops, leaving less profitable crops to the public sector. In both developing and developed countries, some seed markets are dominated by one or a few suppliers, although the characteristics of these suppliers vary.

42. Some commentators have expressed concern that GURTs will narrow farmers' choices, by reducing the number of suppliers, through effectively increasing the cost to competitors of using their genepool. However, this reflects the current structure of the formal seed sector, and current demand distribution between the formal and informal sectors. In the formal sector, GURTS could increase competition by stimulating private sector suppliers to enter markets previously dominated by government monopolies. However, by reducing the informal sector breeders' ability to access and distribute improved genetic materials, GURTS may reduce producers' options, and the sector's capacity to supply farmers. This is particularly important where informal sector breeding is more responsive to the needs of diversified and low-income farmers: the impact of GURTs not only on the number of suppliers, but on the diversity and characteristics of the seeds supplied, must be considered when assessing potential impacts on farmers' choices.

Intellectual property rights considerations

43. IPRs can protect cultivars either through patents, based on novelty, non-obviousness and industrial application, or Plant Breeders' Rights (PBR), based on distinctness, uniformity and stability, as well as novelty. GURTs, particularly V-GURTs, allow technological control over the use of genetic materials, whether or not these are themselves subject to legal protection through IPRs.[24] Moreover, IPRs are time-limited,[25] and subject to the principle of territoriality, which is not the case with GURTs.

44. GURTs, by increasing the level of technological protection over the product, may result in a significant lowering of transaction costs that would otherwise have been required to enforce the intellectual property protection through legal channels, and may ensure such protection in countries with no IPR systems in place. This could ensure a higher return to breeders and thus incentivate increased R&D investments. If the higher returns were passed on to the farmer, this might result in cheaper seed. The policy question facing governments is whether increased technological protection to genetic resources by GURTs is desirable, and how this would interface with IPR regimes. In this, governments may wish to distinguish between GURTs applications that offer intrinsic production increases, and those that serve merely as use restriction strategies.

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23 During the Working Group, it was stated that, while, in some developing countries, the public sector dominates the breeding of certain crops, especially in the horticultural or niche crops area, in some developing countries, private sector breeding programmes may be relatively stronger than public.

24 During the Working Group, it was noted that the denial of patent protection to technologies involved in creating GURTs might therefore result in making them more widely available.

25 Trade secrets are a form of IPR that is not time-limited, in that a secret remains a secret until it becomes a matter of public knowledge.

45. In developing countries, a major factor may be the relative inability of GURTs, compared to legislation, to discriminate between permitted uses of genetic resources. UPOV-like plant variety protection allows countries to regulate the roles of breeders and farmers, according to their diverse farming systems and needs, through the breeder's exemption and farmer's privilege. Through IPRs, Governments may fine-tune the use of genetic resources which require authorization by the rights-holder, and of exemptions to such rights.

46. Patents regimes are local, and take into account a country's engagements under relevant international instruments. For patents over GURTs inventions, the question arises of whether governments might wish to investigate relevant aspects of Article 27.2 of the WTO TRIPS agreement, which enables exclusion from patentability of inventions that threaten the *ordre public* or morality, in order to protect human, animal or plant life or health, or avoid serious prejudice to the environment, provided that such exclusion is not merely because the exploitation is prohibited by their law. Scientific evidence that GURTs represent a danger to the environment or human, animal or plant health might be a basis to deny patent protection, provided that this clause has been included in the country's patent law.

47. The GURTs process itself may or may not be patented, and still be used as a use restriction strategy. Rejection of patent applications claiming GURTs processes or products would make GURTs technology publicly available, and encourage wide adoption by competitors, to protect their innovations. If the intention of a country is to prohibit the commercialization of GURTs varieties, other regulatory measures may need to be applied.

Other regulatory aspects

48. Governments may wish either to regulate the impacts of the use of certain GURTs products in their countries, or to forbid their use, depending on their assessment of potential socio-economic and environmental impacts, including on biodiversity. There are considerably more options available in the former case than in the latter. Biosecurity regulations apply to organisms containing GURTs, but such regulations cannot simply be used to prohibit GURTs, if the organisms containing GURTs cannot be shown to pose a specific threat to food or environmental safety.

49. Some seed legislation may offer opportunities for regulating GURTs. Variety release procedures often require registration procedures and performance testing. Where variety release includes compulsory performance testing, it may be possible to regulate release of V-GURT varieties, even if they include agronomic improvements, on the basis of their not producing a viable second generation.[26] However, the benefits of such a measure must be considered against its potential impact on industry concentration, as costs associated with compulsory performance testing may raise the capital entry point and reduce competition. In fact, many countries have dispensed with such seed provisions in their national legislation or limit the scope of such provisions to certain crops.

5. CONCLUSIONS

50. GURTs could have considerable impacts, both positive and negative, on agricultural biodiversity and agricultural farming systems: these impacts, together with possible policy considerations, are summarized in this section.

[26] A number of stakeholders consulted called for the outright banning of what they called "terminator" technologies (that is, Technology Protection Systems, or GURTs), on the basis of producing a sterile second generation. During discussion by the Working Group, it was noted that compulsory registration systems exist only in certain nations, and that the registration of hybrids is permitted, despite the inability to test their agronomic aspects in the second generation.

(i) *Targets of GURTs.* Three aspects of GURTs need to be considered: use restriction, environmental containment, and agricultural productivity contributions., which have different implications, and need to be considered separately. In terms of use restriction, the most likely targets for V-GURTs are species for which hybrid technology is not yet well developed, including inbreeding seed crops and vegetatively multiplied horticultural crops and ornamentals. T-GURTs could be applied to all crops.[27] GURTs could also be utilized as a use restriction strategy to prevent farmers from resowing apomictic seed, including of hybrids. Functional GURTs could be used for the environmental containment of transgenic seed (V-GURTs) or transgenes (T-GURTs), including where wild relatives exist locally, and of traits posing possible human health risks, or threatening biodiversity. Possible direct productivity gains include T-GURTs enabling a producer to restrict trait expression, when there is a production advantage to doing so in a specific phase of plant or animal development, and V-GURTs, to safeguard the integrity of adapted maternal breeds in farm animal reproduction, or to prevent pre-harvest sprouting.

(ii) *Timeframe for GURTs application*. The pace of biotechnology development should allow GURTs and their products to become functional in the next five to ten years. While technically feasible, practical GURTs applications in forestry will be less likely, due to differences in management practices. In the case of animals, technical barriers will further delay their practical applications. Countries may wish to note this timeframe, in the context of possible policy and regulatory measures for the use of these technologies.

(iii) *Agricultural biodiversity aspects.* Impacts on agricultural biodiversity will vary in different farming systems. In LIFS and medium-intensity farming systems a change from local to GURT varieties may imply a loss of the agricultural biodiversity,[28] in high intensity farming systems the impact may be minor.

(iv) *Environmental impact.* While the environmental containment aspect of GURTs may reduce potential risk associated with their eventual out-crossing, there remains a possibility of pollination of neighbours with GURTs pollen, leading to yield drops in cultivated areas,[29] as well as to alteration of wild ecosystems. Further studies are required to assess the likelihood of such effects. The use of some substances as inducers (*e.g.*, steroids) may be regulated as pesticides and veterinary medicines. The effects on the target organisms, as well as the environment and human appliers and consumers, need to be assessed.

For farm animals, potential negative environmental effects may be more easily containable, given the high level of domestication and current reproduction control practices. In contrast, given the high probability of escapes of aquatic species, varieties containing GURT constructs may negatively impact on wild populations if they pass into the wild genepool, thus affecting reproductive ability of the wild populations. The probability of negative effects on local aquatic populations is a necessary and active area of study.

(v) *Impact on research and development.* By stimulating further investment, GURTS may increase agricultural productivity in certain farming systems. However, restricted introgression of genes from GURTs into local genepools may reduce incentives for farm-level breeding, if desirable traits in introduced GURTs varieties cannot be accessed, widening the technological and income gap between resource-poor and better-off

27 V-GURTs were likely to be applied for use restriction purposes to self-pollinated crops, and to cross-pollinating crops for environmental purposes.

28 During the Working Group, it was stated that this was speculative.

29 During the Working Group, it was stated that such effects might be highly localized.

farmers. This may call for a corresponding strengthening and readjustment of public agricultural research, as well as innovative ways to promote public access to private sector innovations, in order to mitigate any direct and indirect negative consequences on agricultural productivity in farming systems that fall outside the target areas for private investment.

(vi) *Socio-economic impacts.* While strengthened control over the use of GURTs products may likely increase investment in further breeding, GURTs may well reinforce the concentration and integration trends in the breeding sector in such a way as to lead to possibilities for misuse of monopoly power, rendering farmers fully dependent on formal seed supply systems. GURTs could also increase seed insecurity of resource-poor farmers who cannot afford purchase of seed and who depend on the local grain market for their seed needs. This may generate a low level of acceptance by low-income farmers in developing countries. This issue requires continuous monitoring of the situation on a case-by-case basis, and probably strengthening of competition and anti-trust institutions in developing countries and at the international level.

(vii) *Regulatory aspects.* Depending on their assessment of the potential impact of GURTS on the future development of their agricultural sectors and the welfare of farmers, governments may wish to consider regulating the commercial use of GURTs. This may require new legislative measures, such as compulsory varietal registration requiring yields in the second generation. In addition, the concept of *ordre public* of Article 27.2 of TRIPS may be used to exclude GURTs technologies and products from patentability, although the potential wider economic implications of such a measure needs further consideration. Countries may wish to consider these regulatory aspects in the further development of the *Code of Conduct on Biotechnology as it Affects Genetic Resources for Food and Agriculture.*

Governments are moving to set up regulatory systems for modern biotechnologies, including GURTs, with a concomitant need for technical assistance to build national biosecurity capacity in developing countries, including for risk assessment, management and communication. Liability for negative environmental impacts may need to be considered.

51. Governments may wish to consider adopting a systematic step-by-step and case-by-case approach in considering the possible impacts of GURTs, and take appropriate measures accordingly. In analysing the risks and benefits of GURTs, alternative technologies should be considered in the decision-making process.

U.S. MISSION TO THE U.N. AGENCIES
FOR FOOD AND AGRICULTURE
via Sardegna, 49
00187 Roma
Tel: (39-06) 4674-3506   Fax: (39-06) 4788-7048
January 10, 2003

Louise Fresco
Assistant Director General
Agriculture Department
The UN Food and Agriculture Organization
Rome

Dear Ms. Fresco:

In accordance with the decision reached at the Ninth Regular Session of the FAO Commission on Plant Genetic Resources, I am pleased to forward the U.S. comments to document CGRFA 9/02/17 Annex, *Potential Impacts of Genetic Use Restrictions Technologies (GURTS) on Agricultural Production Systems : Technical Study*. As noted in the Commission Report, the U.S. comments are to be appended to the report which FAO will forward to the next Conference of the Parties of the Convention on Biological Diversity.

The U.S. comments have also been forwarded by e-mail to the Secretary of the Commission.

Yours truly,

Carolee Heileman

Carolee Heileman
Acting Permanent Representative

Attachment: as stated

U.S. Comments on CGRFA 9/02/17 Annex, *Potential Impacts of Genetic Use Restrictions Technologies (GURTS) on Agricultural Production Systems: Technical Study*

During the October 2002 meeting of the FAO Commission on Genetic Resources for Food and Agriculture, (Ninth Regular Session) the U. S. was invited to prepare the following addendum to the FAO CGRFA Secretariat's report on GURTs for the Convention on Biological Diversity (CBD) that outlined the U. S.'s reservations about that report.

1) General comments: Biotechnology in the broad sense has played a critical role in the dramatic gains in crop productivity during the last fifty years. Modern genetic engineering of crops, a relatively new biotechnology, has already begun to contribute to these continuing productivity gains. GURTs use genetic engineering methods, still in very early developmental stages, to regulate gene expression. Possible commercialization is several years in the future. Consequently, at present, few if any reliable scientific data exist about the potential impact of GURTs on agriculture, and about the potential societal or economic impact of GURTs.

The United States believes that any report on GURTs must underscore this current lack of reliable scientific, economic, and social data. Moreover, such a report must be balanced, reflecting both possible concerns, and potential benefits, associated with the development and deployment of GURTs. The current draft of the report does not adequately convey the lack of scientific and socioeconomic information about GURTs, and frequently downplays that limitation by mentioning it only in footnotes to the report. At the same time, the report engages freely in speculation about hypothetical risks associated with this technology, often ignoring, or minimizing, the magnitude of some of this technology's potential benefits.

The United States understands that, initially, new, innovative "breakthrough" agricultural biotechnologies, such as GURTs, may elicit as much or more overstated concern for their potential negative aspects, as unbridled optimism for their potential benefits. This imbalanced view was also seen during early experiments in the mid-1970s with transgenic bacteria--now the source of nearly all of the insulin consumed by diabetics worldwide. Again, in the mid-1990s, with the first commercialized herbicide-resistant and insect-protected transgenic crops, there was speculation about associated negative impacts. With the latter, some feared that transgenic crops would endanger food safety, and lead to increased agrichemical use, accompanied by serious environmental damage. But, the opposite scenario has occurred. Following exhaustive regulatory testing and review by "sound scientific" methods, transgenic herbicide-resistant and insect-protected crops are now grown on millions of hectares. Furthermore, many farmers in developing nations are now using these technologies. They have tangibly reduced the application of agrichemicals, substantially reduced farmer/producer costs, increased productivity, simplified crop management, and mitigated negative environmental effects. No adverse health effects from consumption of food derived from transgenic plants have been reported.

Varietal Genetic Use Restriction Technology ("V-GURTs") and Trait Genetic Use Restriction Technology ("T-GURTs") represent novel applications of agricultural biotechnology. The U. S. strongly supports the careful, sound, scientific, case-by-case assessment of these technologies' risks and benefits. But, the FAO report on GURTs technology prepared for the CBD does not employ a balanced, scientifically based risk/benefit analysis framework. Indeed it cannot, given that the technology is not even ready for the most preliminary field assessments, let alone commercialization. Consequently, the FAO report's conclusions, especially the forecasts about the socioeconomic impact of such technology, are speculative and premature. Until such scientific assessments provide the evidence needed for sound risk-benefit assessments, and informed choices, sweeping conclusions about such technologies or their applications should not be drawn, nor should unwarranted restrictions be placed on research involving these technologies.

At a minimum, early in its text the report should have listed some of the potential benefits associated with GURTs. These include i) increasing the amount of research and development efforts devoted to "value-added crops;" ii) improving the ability to reduce unintended gene flow from transgenic crop varieties to non-transgenic varieties and wild relatives of crops; and iii) contributing important new basic knowledge of plant genomes and reproductive biology overall.

The report also ignores the reality that seed trade is generally market-driven. Availability of GURTs varieties will depend on farmer and consumer acceptance and demand. If farmers or consumers do not want these technologies, they will not purchase or plant the seed. Then developers will not produce or distribute the technology. Acceptance would depend on many factors that cannot be assessed now, such as cost of goods, quality, distribution networks, etc. Notably, farmers and consumers in the developing and developed world have readily accepted new plant varieties that could not be propagated directly from seed (seedless fruits or vegetables), or which do not retain their original value when seed-propagated (hybrids), because those varieties were more attractive than alternatives. The report should have recognized this central attribute of seed trade. Instead, the report suggests that the seed producers can—or would want to—somehow force farmers and consumers to accept a product that they actually did not want or did not find valuable.

In sum, the United States underscores that domestic and international technology policy should be based on science rather than speculation. The United States strongly cautions CBD readers that the opinions and conclusions in the FAO report are, for the most part, not science-based but, rather, often represent conjecture derived from "fear of the unknown." The FAO report focuses overwhelmingly on the potentially negative, rather than the potentially positive, contributions of this technology.

The United States believes that some, but relatively little, useful technical literature about GURTs exist, including the assessment commissioned by the CBD SBSTTA (Jefferson, R. A., Byth, D., Correa, C., Otero, G. Qualset, C. 1999. "Genetic Use Restriction Technologies, Technical Assessment of the Set of New Technologies which Sterilize or Reduce the Agronomic Value of Second Generation Seed, as Exemplified by U. S. Patent No. 5,723,765 and WO 94/03619. UNEP/CBD/SBSTTA/4/9/Rev. 1 Annex). To communicate the actual paucity of reliable information about GURTs, the report should include an annex that indicates what little information currently is available. Furthermore, periodic updates of Jefferson et al.'s assessment would be warranted as more technical information and relevant data accumulate.

<u>2) Specific concerns:</u> The FAO report contains many premature conclusions, imbalanced discussions, speculations unsupported by data, and technical inaccuracies. The United

States is compelled to highlight these to try to ensure that development of a potentially valuable technology for agriculture worldwide is not prematurely aborted before the appropriate, science-based, case-by-case risk/benefit assessments occur.

- Major sections of the FAO report, e.g., "2. Potential Impacts of GURT Applications, "3. Potential Socio-economic Impacts…," "4. Potential Economic Impacts..," and "5. Conclusions" are imbalanced and speculative. Specific examples include:
    - Paragraph 4 states that "…GURTs, used as a technology protection system, (particularly V-GURTs) are perceived as restricting access without themselves adding value…" Actually, GURTs technology will add value, either directly or indirectly; its added cost would preclude its being incorporated into varieties if it did not add value. The statement itself is later contradicted in Paragraph 19 which mentions that "…a first major effect may result from the widespread adoption by such farmers of GURTs containing desirable new traits…", i.e., value-added varieties. Furthermore, GURTs (especially T-GURTs) may add value to varieties by providing a biological mechanism that links expression of specific traits to specific "targeted" environmental conditions, while simultaneously protecting the trait under unfavorable environmental conditions. Finally, GURTs could add value by reducing the occurrence of "volunteer" follow crops or preventing unintended cross-pollination and geneflow with weed species or other varieties.
    - Paragraph 19, 28, and 51 iii state that introduction of improved varieties with GURTs technology may reduce biodiversity by displacing traditional varieties in traditional farming systems, or may widen the income gap between farmers in different socioeconomic circumstances. Actually, because no varieties with GURTs exist outside of the laboratory, there are no data available to test the preceding speculations. If and when this technology is deployed in products, it will have undergone risk assessment and risk management analyses similar to those for other products of genetic engineering. As noted in paragraph 26, traditional farmers are unlikely to use, or even to have initial access, to such products. Moreover, the report hypothesizes that biodiversity might be lost if such farmers cultivate GURTs varieties instead of traditional varieties. Such statements are misleading, because any type of crop substitution, not only involving GURTs varieties, may contribute to abandonment of earlier varieties. Furthermore, studies of traditional farming systems, such as traditional Mexican maize agriculture, indicate that landrace varieties with specialized, culturally valuable traits generally do persist when improved varieties are introduced.
    - Paragraph 36 states that "In general, GURTs will tend to move agricultural research and development (R & D) further into the private sector…" Actually, the global trend for the private sector to conduct an increasing proportion of such research preceded the concept of GURTs by some years, and has been determined more by national and local political decisions regarding allocating public-sector funding for such research.
    - Paragraph 37 states that "GURTs could further concentrate market power in the formal seed sectors for some crops, due to economies of scale. This has lead to concerns that firms may have the capacity to set prices non-competitively" (Paragraph 51 vi essentially repeats this concern).

Actually, because no varieties with GURTs exist outside of the laboratory, there are no data available to test the preceding speculation. But, because of the diverse global sources of agricultural products, and the ease whereby additional production can begin, monopolistic pricing of such agricultural commodities, including planting seed, is highly unlikely and in fact has not occurred with the biotechnologies adopted to date.

- Examples of technical inaccuracies:
  - Paragraph 10 states that "Strategy 1 has not yet been implemented, although several components have been demonstrated to work…" and Paragraph 12 states "T-GURTs seem nearer to application." Actually, "Strategy 1" (V-GURTs) has already been implemented in tobacco in the laboratory.
  - Paragraph 44 recommends that, when considering whether to grant intellectual property rights, governments may want to consider categorizing applications of GURTs technology according to whether they would intrinsically enhance agricultural production, versus whether they would primarily serve to restrict use of specific genes or varieties. But the paragraph does not mention that Article 27.1 of the TRIPs Agreement requires that WTO nations make patents available and patent rights enjoyable, without discrimination on the basis of field of technology. Consequently, discriminating between the different rationales for patent protection in this manner may be a violation of TRIPs Article 27.1.
  - Paragraph 46 states that "Scientific evidence that GURTs represent a danger to the environment or human, animal, or plant health might be a basis to deny patent protection, provided that this clause has been included in the country's patent law." Actually, the current regulatory framework of the United States and of other nations would prohibit deployment of that type of trait. It must also be stated that there is no scientific evidence, to date, that GURTs represent such a danger.
  - Footnote 26, referring to Paragraph 49, states: "A number of stakeholders consulted called for the outright banning of what they called "terminator" technologies (that is, Technology Protection Systems, or GURTs) on the basis of producing a sterile second generation." Actually, this summary of nations' remarks about this topic is incomplete. Although some nations did call for prohibiting V-GURTs technology (but not specifically T-GURTs), other nations called for this technology to be carefully assessed, like any transgenic technology, before crops with V- or T-GURTs are approved for production.