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Agenda item 16

THEMATIC PROGRAMMES OF WORK—PROGRESS REPORTS ON IMPLEMENTATION: AGRICULTURAL BIOLOGICAL DIVERSITY

Potential impacts of genetic use restriction technologies (GURTs) on agricultural biodiversity and agricultural production systems

Note by the Executive Secretary

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

(a) Invited the Food and Agriculture Organization of the United Nations (FAO), 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; and

(b) Invited FAO 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. The attached document has been submitted by the Food and Agriculture Organization of the United Nations, in response to decision V/5 of the Conference of the Parties.

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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

CONSIDERATION BY THE FAO COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE OF THE POTENTIAL IMPLICATIONS OF GURTS FOR THE CONSERVATION AND SUSTAINABLE USE OF AGRICULTURAL BIOLOGICAL DIVERSITY

1. In 1999, the Committee on Agriculture of the Food and Agriculture Organization of the United Nations (FAO) identified the 'terminator technology' 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'.[1]

2. Within the context of the Convention on Biological Diversity, FAO provided inputs to the consultant study on genetic use restriction technologies (GURTs) that was reviewed by SBSTTA in 1999.[2] The Conference of the Parties, in decision V/5, then invited FAO, in close collaboration with the members of the Ecosystem Conservation Group, to 'further study the potential implications of GURTs 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'. It invited 'the Food and Agriculture Organization 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'.

3. A study on *Potential impacts of genetic use restriction technologies on agricultural biodiversity and agricultural production systems*[3] was subsequently prepared, with technical advice from consultant experts, following consultation with all members of the Ecosystem Conservation Group and comments from stakeholders, and submitted to the 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 2001. It discussed various technical aspects of GURTs, their potential impacts on agricultural biodiversity, biosecurity implications and impacts at farming system level (especially seed systems) as well as economic implications, and identified policy issues that governments might wish to consider. The study identified and discussed three aspects of GURTs that needed to be considered: (1) use restriction, (2) environmental containment, and (3) agricultural productivity contributions.

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1 FAO CL 116/9, para. 44 to 53.

2 UNEP/CBD/SBSTTA/4/9/Rev.1.

3 CGRFA/WG-PGR/1/01/7.

4. The Working Group:[4]

> ' 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. 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. Discussion was held on the flow of material in further breeding and of seed-saving practices used by farmers in traditional low-seed replacement systems and the consequences of this for the diffusion of improved varieties by farmers. Some members highlighted the potential for encouraging innovation and increased investment by the private sector. The Working Group noted that food security aspects should also be introduced in the document. The Working Group also noted that the report should make it clear that definitive analyses and conclusions on possible impacts required more information and such information might become available if and when products incorporating GURTs are submitted to regulatory bodies prior to commercialization.
>
> ' Some members of the Working Group supported the step-by-step and case-by-case approach, which was consistent with the regulatory frameworks in place in many countries. The need for capacity-building on biosafety at national level was highlighted by countries, as essential in following this approach. Some also suggested that this approach be complemented by a more strategic assessment, taking into account the precautionary approach, in view of potential cumulative effects. Some members were of the opinion that the use of GURTs was not justified, whereas some others highlighted scenarios where the use of GURTs might be advantageous'.

5. The Working Group therefore agreed that the document should be modified by FAO and submitted for the consideration of the Commission at its Ninth Regular Session. The results of the Commission's consideration would then be submitted to the Convention on Biological Diversity.

6. In the event, the Ninth Regular Session of the Commission was not held in 2001as planned, due to the priority that the Commission had given to completing the negotiation for the revision of the International Undertaking on Plant Genetic Resources, in time for its consideration at the Thirty-first Session of the FAO, in November 2001. These negotiations have now been crowned with success, with the adoption by the FAO Conference on 3 November 2001 of the International Treaty on Plant Genetic Resources for Food and Agriculture.

7. The Ninth Regular Session of the Commission will accordingly be convened in late 2002, and the Commission will at that stage consider the question of GURTs, and address itself to the Conference of the Parties to the Convention.

8. The document presented to the Inter-governmental Technical Working Group on Plant Genetic Resources for Food and Agriculture of the Commission on Genetic Resources for Food and Agriculture, *Potential impacts of genetic use restriction technologies on agricultural biodiversity and agricultural production systems*, is attached to this report, for information.

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4 CGRFA/WG-PGR-1/01/REPORT: Report of the Intergovernmental Technical Working Group on Plant Genetic Resources for Food and Agriculture (FAO Commission on Genetic Resources for Food and Agriculture), para. 34-37.

March 2001

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 6 of the Draft Provisional Agenda

COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

WORKING GROUP ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

First Session

Rome, 2 - 4 July 2001

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

CONTENTS

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

1. INTRODUCTION

1. In 1999, the Fifteenth Session of the FAO Committee on Agriculture noted that biotechnology in general offered considerable potential and opportunity, also presented risks, and was an area where there was a growing gap between developing and developed countries. The Committee recommended that FAO develop a strategic approach to biotechnology and a coordinated cross-sectorial programme. It also recommended that FAO undertake activities in the various areas of its mandate — including information exchange, capacity building and policy advice to Members — which were important in helping developing countries realize the potential benefits of biotechnology, while managing risks. In this context, it reported to the Hundred and Sixteenth Session of the FAO Council that "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".[1]

2. The independent Panel of Eminent Experts on Ethics in Food and Agriculture, established by the Director-General to advise the Organization and raise public awareness of ethical considerations, discussed GURTs at its first session in September 2000, and unanimously stated that " 'terminator seeds' are generally unethical as it is deemed unacceptable to market seeds whose offspring a farmer cannot use again because the seeds do not germinate". It added that "there are situations were the assessment can be different, however. Where the concern is with possible outcrossing of crops, for example, genetically modified organisms that could damage wild plant populations, GURTs might be justified". [2]

3. The potential impacts of these technologies and related policy issues have also been discussed elsewhere, including in the Conference of Parties to the Convention on Biological Diversity (CBD). At the request of the Conference of the Parties, a study on GURTs was prepared, with inputs from FAO.[3] This was reviewed by the Convention's Subsidiary Body on Scientific, Technical and Technological Advice in 1999. At its Fifth Meeting, in 2000, in decision V/5, the Conference of the Parties recommended that, in the current absence of reliable data on GURTs, without which there was an inadequate basis on which to assess potential risks, "products incorporating such technologies should not be approved by Parties for field testing until appropriate scientific data can justify such testing, and for commercial use until appropriate, authorised and strictly controlled scientific assessments with regard to, *inter alia*, their ecological and socio-economic impacts and any adverse effects for biological diversity, food security and human health have been carried out in a transparent manner and the conditions for their safe and beneficial use validated". [4]

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1 CL 116/9 para. 44 to 53.

2 Report of the Panel of Eminent Experts on Ethics in Food and Agriculture, FAO, Rome, 2001.

3 Jefferson, R.A., Byth, D., Correa, C., Otero, G., & Qualset, C. *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 US Patent No 5,723,765* in UNEP/CBD/SBSTTA/4/9/Rev.1.

4 UNEP/CBD/COP/5/23 - Decision V/5, page 88, para. 20 to 21.para. 23, available on the CBD webpage at http://www.biodiv.org/decisions/

4. The Conference of the Parties, “being cognizant of the work being undertaken and the expertise available in different forums, in particular, the Food and Agriculture Organization of the United Nations and its Commission on Genetic Resources for Food and Agriculture, invites 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;” and “invites 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.”[5]

5. This document responds to this request. An outline was made available to the second meeting of the Convention’s Liaison Group on Agricultural Biodiversity, in January 2001, and comments made are reflected in the final outline. 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 to a wide range of stakeholders in May 2001. The document takes into account the comments received.[6]

6. GURTs technology has been most studied in the context of crops. This study therefore focuses on GURTs within cropping systems, with reference to aquatic ecosystems, trees and livestock where possible. It should be noted that, whereas qualitative predictions on impacts can sometimes be made, data for a more quantitative analysis are often lacking.

7. The document discusses various technical aspects of GURTs, the potential impacts of these technologies on agricultural biodiversity, biosecurity implications, impacts at farming system level (especially seed systems) as well as economic implications, and identifies policy issues, which governments may wish to consider.

2. TECHNICAL ASPECTS OF GURTs TECHNOLOGIES

8. 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.

9. Two types of GURTs can be distinguished: variety use restriction (V-GURTs), rendering the subsequent generation sterile (the so-called “terminator” technologies); and use restriction of a specific trait (T-GURTs), requiring the external application of inducers to activate the trait’s expression.

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[5] UNEP/CBD/COP/5/23 - Decision V/5, page 88, para. 20 to 21, available on the CBD webpage at http://www.biodiv.org/decisions/.

[6] FAO prepared this document based on a background study undertaken by Plant Research International, on a consultancy basis. 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, GFAR, GRAIN, IFAP, International Agri-Food Network, IATP, IPGRI, ITDG, NGO CGIAR Committee, NGO SAFS Caucus Quaker UN Office, RAFI, Solagral, SIDA, UPOV, WIPO), not all of whom commented.

10. The use restriction aspect of these technologies has some parallels in classical genetics. Similar to offspring from V-GURTs products, sterile triploid[7] fish, seedless triploid fruits such as water melon or parthenocarpic[8] 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.

11. 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, (particularly V-GURTs) are perceived as restricting access without themselves necessarily adding value, and as raising concerns through potential impacts on biodiversity, agricultural practices, seed security and rural economies.

Functional mechanism of GURTs

12. At least three V-GURT strategies can be distinguished. *Strategy 1* uses the induced activation of a disrupter gene[9] which, if expressed, results in a product that inhibits embryo formation.[10] 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,[11] leading to expression of the disrupter gene in the second-generation seed. Consequently, the second-generation seed is fit for consumption, but infertile.

13. *Strategy 2* differs in that the breeder applies a chemical in all generations, but ceases before selling the seed.[12] 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.

14. *Strategy 3* focuses on crops reproduced vegetatively, like roots and tubers and many ornamentals, to prevent growth during storage, and extend shelf life.[13] Here a gene blocking growth is expressed by default, which can be suppressed by application of a chemical that induces a second gene.

15. 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,[14] or by excision of the transgene using an enzyme.

16. 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

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7. Having three chromosome sets instead of the normal two.

8. Seedless fruits produced from unfertilized ovaries.

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

10 Delta & PineLand/USDA concept.

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

12 Zeneca concept.

13 Syngenta concept.

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

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

17. *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.

18. 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:[15] 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.

19. 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.

20. 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

21. Three distinct aspects of GURTs need to be considered: use restriction, environmental containment[16], and agricultural productivity contributions.

22. 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[17] seed, including of hybrids.

23. 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

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

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

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

containment of traits posing possible human health risk, such as transgenic crops for drug or vaccine production, or biodiversity-threatening traits.

24. 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.

3. POTENTIAL IMPACT OF GURT APPLICATIONS: AGRICULTURAL BIODIVERSITY AND BIOSECURITY[18] ASPECTS

Potential impact on agricultural biodiversity

25. 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.

26. 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. 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.

27. Incentives for farm-level breeding may be reduced if desirable traits in GURT varieties cannot be accessed. 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.

28. 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.

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18 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*).

Biosecurity implications

29. 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.[19] However, this mechanism may not work adequately. For open-pollinated species, potential outcrossing of V-GURT varieties could reduce yield in subsequent years 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.

30. 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 relatives. 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.

31. 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.

32. 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.

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

33. 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: 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.

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19 A number of stakeholders, however, were of the opinion that the use of GURTs was not justified, even for this purpose.

34. 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, 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.

35. 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-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 may have implications similar to the introduction of "green revolution" cultivars: 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. 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.

36. 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.

5. POTENTIAL ECONOMIC IMPACTS OF GURTS

37. 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

38. 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.

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

40. 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.

41. 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 increased segmentation of the genepools used by private and public sector breeders. 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.

42. 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.

43. 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

44. 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.

45. 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.

46. 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.

Agricultural input and output markets

47. 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.

48. 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. 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.

49. There is 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

50. 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. 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. Moreover, IPRs are time-limited, and subject to the principle of territoriality, which is not the case with GURTs.

51. 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. 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.

52. 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.

53. 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.

54. 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

55. 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.

56. 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.[20] 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.

57. Countries may wish to take into consideration these regulatory aspects in the further development of the Commission's *Code of Conduct on Biotechnology as it Affects Genetic Resources for Food and Agriculture*.

6. CONCLUSIONS AND ISSUES FOR THE CONSIDERATION OF THE WORKING GROUP

58. 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.

(i) *Targets of GURTs.* Three aspects of GURTs need to be considered: use restriction, environmental containment, and agricultural productivity contributions. The most likely targets for V-GURTs are species for which hybrid technology is not yet well developed, including inbreeding seed crops like wheat, soybean and cotton, and vegetatively multiplied horticultural crops and ornamentals. T-GURTs could be applied to all crops.

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20 A number of stakeholders consulted called for the outright banning of "terminator" technologies, on the basis of not producing a viable second generation.

(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, 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, 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 impacton 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 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.

59. 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.

60. The Working Group is invited to discuss the information provided in this document and, as appropriate, to make comments in preparation for submission of this document to the Ninth Regular Session of the Commission.