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Item 4.6 of the Provisional agenda*

UNEP/CBD/SBSTTA/4/Inf.3 Supplementary information to UNEP/CBD/SBSTTA/4/9/Rev. 1 Consequences of the Use of the New Technology for the Control of Plant Gene Expression for the Conservation and Sustainable Use of Biological Diversity

This Information Document comprises the following documents:

- Terms of Reference from the Secretariat of the Convention on Biological Diversity - "*Terms of Reference. Preparation of a 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 5,723,765 and WO 94/03619*"
- Statement from Monsanto - "*Gene Protection Technologies; a Monsanto Background Statement*";
- Statement from the U.S. Department of Agriculture - "*Why USDA's Technology Protection System (aka "Terminator") Benefits Agriculture*";
- Statement from the *Delta and Pine Land Company;*
- Letter from Zeneca Agrochemicals of 24 February 1999 to CAMBIA
- Figures illustrating the technology described in U.S. patent 5,723,765 [Appendix to expert paper: Annex 1 UNEP/CBD/SBSTTA/4/9/Rev. 1].

* UNEP/CBD/SBSTTA/4/1/Rev. 1

Terms of Reference from the Secretariat of the Convention on Biological Diversity - "Terms of Reference. Preparation of a 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 5,723,765 and WO 94/03619"

Terms of Reference[1]

Preparation of a 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 5,723,765, and WO 94/03619

1. Introduction

1.1. Following discussions at its fourth meeting, and reiterating the precautionary approach the Conference of the Parties (COP) to the Convention on Biological Diversity in its decision IV/6 *requested the Subsidiary Body for Scientific, Technical and Technological Advice (SBSTTA) to consider and assess, in light of contributions to be provided by Parties, Governments and organisations, whether there are any consequences for the conservation and sustainable use of biological diversity from the development and use of new technology for the control of plant gene expression, such as described in the US patent 5723765, and to elaborate scientifically based advice to the COP.*

1.2. In this regard, a selected team of consultants or co-authors having appropriate expertise on scientific and technical issues, including molecular biology, plant breeding, socio-economic and intellectual property and legal issues, will be recruited by the CBD Secretariat to conduct the work programme outlined below. The work will be carried out under the overall supervision of the Principal Officer for Scientific, Technical and Technological Matters (STTM), under the direct supervision of the Programme Officer for Agricultural Biological Diversity, and in consultation with the co-authors and the review team of experts. The author-in-chief will be responsible for the biotechnology issues and, on the basis of contributions from the co-authors for the intellectual property, agronomic/plant breeding and socio-economic issues, for the overall compilation of a scientifically sound and balanced technical paper on the above-referred assessment of the new technology entitled "Control of Plant Gene Expression", that sterilizes or reduces the agronomic value of second generation seed.

1.3. The technical paper on the assessment will be prepared on the basis of a review of all available documentation, including the relevant findings of other scientists and researchers, and taking into account the different positions and concerns of the different constituencies from countries in the north and the south. The author-in-chief will also be responsible for liaison with the co-authors and the review panel of experts, as appropriate, with a view to taking into account in the final paper the positions of the different constituencies and the comments and contributions of the review panel. The paper will be prepared in accordance with paragraph 11 of decision IV/6 of the Conference of the Parties, on the basis of the following time frame and division of work, and a detailed outline, agreed upon by the co-authors, and taking into account the following tentative scope and outline. The CBD Secretariat will make available any submissions from various sources.

2. Time Frame and Division of Responsibility

2.1. The author-in-chief, in consultation as appropriate with the co-authors, will prepare a working draft outline for the overall paper by 22 January 1999. On the basis of the collection, review and analysis of any available information regarding the concerned technology, and in consultation with the plant breeder, he/she will prepare a paper on the technology and its scientific and technical implications, covering the two first points of the proposed structure of the

[1] 14 January 1999, SCBD

paper: 1) Introduction and 2) Description of the technology (technical paper 1) and will provide it to the CBD Secretariat and the co-authors by 5 February 1999 (2 weeks work).

2.2. The consultant/co-author responsible for the intellectual property, economic and policy issues, on the basis of the collection, review and analysis of available information regarding the concerned technology, and in collaboration with the author-in-chief on technical and scientific aspects, will prepare a background paper regarding the intellectual property, legal and economic issues (technical paper 2). He/she will provide this technical paper to the author-in-chief, with copy to the CBD Secretariat, by 12 February 1999 and will provide further inputs and comments on the draft assessment paper to the author-in-chief, with copy to the CBD Secretariat, until end March 1999 (3 weeks work).

2.3. The consultants/co-authors responsible for agronomy/plant breeding issues will contribute to the preparation of the paper through considering all aspects described under point 2 "Description of the technology" with a particular focus on agronomic and plant breeding issues, and providing inputs concerning the possible consequences/impacts on the conservation and sustainable use of biological diversity and equitable benefit sharing, and food security. The plant breeders will provide a substantial contribution to the first three points of the assessment: 1) Introduction, 2) Description of the technology and 3) Potential benefits and technical threats and risks, in the form of (i) a background paper and (ii) inputs for a revised version of technical paper 1 and for incorporation of plant breeding/ agronomic issues in the draft assessment on the technology and its implications. The initial inputs will be provided to the author-in-chief, with copy to the CBD Secretariat, by 18 February, and a more complete background paper and further inputs for incorporation into the assessment by 12 March, as well as comments on the draft paper until end March 1999 (2-3 weeks work).

2.4. The author-in-chief will provide the background papers, with any additional comments, to the co-author/consultant for socio-economic issues. He/she will then prepare a first draft of the assessment paper, combining the technology and intellectual property issues. This will be made available together with relevant documentation, during February 1999, to the CBD Secretariat, and to all three co-authors who will work together for a full week with the author-in-chief for a joint brainstorming on the assessment (1 weeks work).

2.5. The co-author/consultant responsible for socio-economic issues, on the basis of the collection, review and analysis of any available information regarding the concerned technology, as well as technical papers 1 and 2 and, once available, the first draft assessment paper, will prepare a background paper regarding the socio-economic issues (technical paper 3). He/she will liaise with the co-author to ensure that these elements are incorporated into the draft assessment paper and will send the technical paper by 26 February 1999 and further inputs and comments on the draft assessment paper to the author-in-chief, with copy to the CBD Secretariat, during March 1999 (3 weeks work).

2.6. The author-in-chief, on the basis of the technical, intellectual property, agronomic and socio-economic contributions, will prepare, in consultation with the co-authors, the final draft of the comprehensive and scientifically-sound assessment of the concerned technology, and will provide it together with any relevant documentation to the CBD Secretariat, with copy to the co-authors for any final comments/suggestions, by 12 March 1999 (2 weeks work).

2.7. The CBD Secretariat, following its clearance of the draft paper on the assessment of the technlogy, will immediately provide the draft paper, together with any relevant documentation, to

the review team of experts requesting their comments and contributions to be sent directly to the author-in-chief, with copy to the CBD Secretariat, as soon as possible, and by 26 March 1999.

2.8. The author-in-chief will revise the assessment paper taking into account the comments and contributions received from the review team of experts, following due consultation with the experts/co-authors and the CBD Secretariat, as appropriate, and will provide the final technical paper to the CBD Secretariat by 2 April 1999 (1 weeks work)

2.9. The CBD Secretariat will provide the final paper to the translators, for translation in the 6 languages, and will subsequently make available the translated paper to governments and organisations. This will consist of a Note by the Secretariat explaining the process adopted, containing the technical assessment provided by the experts, and suggesting how SBSTTA may wish to consider the findings. Any further comments and contributions received by the Secretariat will be compiled in a background information document for SBSTTA.

3. **Consultant Authors**

3.1. The team of consultants/co-authors is as follows:

- Author-in-chief/biotechnology specialist: Dr. Richard Jefferson, Director, CAMBIA, Australia (6 weeks) when actually employed basis (WAE) Period: 15 January - 2 April 1999;
- Co-author/intellectual property and international economics specialist: Dr. Carlos Correa, University of Buenos Aires, Argentina (3 weeks) Period: 22 January - 12 February 1999 and comments on draft paper until 31 March 1999 (WAE);
- Co-author/agronomy and plant breeding specialist: Dr. Don Byth, Australia, (6 days) Period 2-18 February 1999 (WEA) and Dr. Calvin Qualset, University of Davis, California (2 weeks) Period: 22 February to 12 March 1999 as well as comments on draft assessment paper until 31 March 1999 (WAE);
- Co-author/ rural sociology specialist: Dr. Gerardo Otero, Mexico (3 weeks) Period: 13 February- 5 March 1999 as well as comments on draft assessment paper until 31 March 1999 (WAE).

4. **Scope and content of the paper** (to be further developed by the author-in-chief):

4.1. Besides the precise technology outlined in a patent entitled "Control of plant gene expression" (US Patent Number 5,723,765), it is generally understood that there may be other modifications of the process with the same aim of genetically altering seed (grain) so that it will not germinate, or will otherwise perform differently if replanted. In this regard, the assessment paper will thus not be strictly limited to a single precise technology but will address other similar technologies that are being developed, or which could be developed by other companies, entities and industries with the same aim. It will address the potential costs, benefits, risks and implications of the development and application of this technology and such "like" technologies, see Annex 1.

4.2. In the development of this precise technology by the US Department of Agriculture together with Delta & Pine Land Co. (an American cotton seed company in Mississippi which has since been taken over by Monsanto, the world's second largest agro-chemical corporation based in Missouri), patent applications are pending in 87 countries. A similar technology has been developed by Zeneca (Patent WO 94/03619). Abstracts are available describing these known

patents. Other technologies may also be in the process of development and testing by other bodies.

4.3. In view of the nature and implications of the technology in regard, not only to the risks to biological diversity, but also concerning the rights of farmers to save and reuse seed, trends and implications concerning plant breeding and the seed sector, the relationship between agro-industry and food security, and so forth, it is understood that it would not be useful to conduct a scientific assessment without due consideration of the social, economic, political and ethical issues. In this regard the assessment should look at the whole package of implications, starting with a dispassionate analysis of the technology and its potential costs and benefits.

5. **Structure of the Paper** (to be further developed by the author-in-chief)

5.1. It is proposed that the paper could be generally structured as follows, though the consultant(s), with the advice of the peer group, will further develop this preliminary outline:

I. Introduction: overview of the technology, applications for patents on the technology and areas of concern regarding its possible impacts on the conservation and sustainable use of biological diversity and equitable benefit sharing, on farmers and food security;

II. Description of the technology: mechanisms, technical restrictions and requirements, crops concerned, targeted markets, aims and objectives, including reference to similar technologies under development.

III. Potential benefits and technical threats and risks: indicating who may benefit /suffer, which biological resources may be affected and what the precautionary approach may mean. Analogies to hybrid seeds industry.

IV. Social, economic and ethical issues: including cost- benefit analysis, access and benefit sharing issues including IPR and Farmers Rights

V. Political and legal considerations and strategies: power and aims of seed and agro-chemical industry and trade vis-à-vis long term environmental policies and decisions, public and private sector roles; etc. Analogies to the software industries: copy protection.

VI. Overall assessment, conclusions and recommendations, in accordance with the precautionary approach, including information on ongoing activities to assess the technology and suggestions for any follow up action before COP-V in May 2000.

6. **Format of the Submitted Technical Papers**

6.1. The technical contributions and the drafts of the paper will be made available in hard copy, through registered courier service, as well as in electronic form in Word 6 or 7, or Word Perfect 6.1. The final paper should not exceed 20-25 pages in length (e.g. font: Times 11 pt. single line spacing), though may include stand alone annexes and relevant documentation. Address for submission: E mail: <sally.bunning@biodiv.org>, copy <anaclara.schenberg@biodiv.org>. Mail: CBD Secretariat, 393 St. Jacques (suite 300), Montreal, H2Y1N9, Quebec, Canada Telephone 1 514 288 2220/ 287 7012 Fax : 1 514 288 6588

7. **Review Panel and Process**

7.1. The draft paper will be made available to the chair of the SBSTTA bureau and a panel/team of experts for review taking into account biotechnology, intellectual property, agronomic/plant breeding and socio-economic issues. The reviewers will be selected from the five main geographic regions and nominated by key international organisations and selected business/industry and civil society organisations, for example:

2/3 Experts from each Region

- **GRULAC**
- **WEOG**
- **Asia and the Pacific**
- **Africa**
- **C. and E. Europe**

Intergovernmental Organisations

- **FAO** - Food and Agriculture Organisation of the United Nations: FAO Working Group on Biodiversity for Food and Agriculture and the joint division with the International Atomic Energy Agency (IAEA);
- **CGIAR system**: Consultative Group on International Agricultural Research IPGRI - International Plant Genetic Resources Institute, in liaison with relevant bodies and centres of CG system, as appropriate, will collate the CG inputs in accordance with its coordinating role for the CGIAR system wide genetic resources programme;
- **WIPO** - World Intellectual Property Organisation;
- **UPOV** - International Union for the Protection of New Varieties of Plants
- **UNIDO** - United Nations Industrial Organisation;
- **ICGEB** - International Center for Genetic Engineering and Biotechnology, Trieste, Italy;

International Non Governmental Organisations and Civil Society Bodies

- **FIS/ASSINSEL** - International Seed Trade Federation/International Association of Plant Breeders;
- **ICC** - International Chamber of Commerce;
- **IFAP** - International federation of Agricultural Producers
- **GRAIN**- Genetic Resources Action International

Statement from Monsanto - "Gene Protection Technologies; a Monsanto Background Statement"

MONSANTO
Food • Health • Hope

Hugh Grant
Co-President

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May 14, 1999

Mr. Hamdallah Zedan
Acting Executive Secretary of the Secretariat
of the Convention on Biological Diversity
United Nations Environment Programme
World Trade Center
393 St. Jacques Street, Office 300
Montreal
Quebec
Canada H2Y 1N9

Via facsimile: (1-514) 288.65.88

Dear Mr. Hamdallah,

You have my permission to make the attached statement available as part of one of your documents for the Fourth Meeting of the Subsidiary Body on Scientific, Technical and Technical Advice, to be held from June 21 to 25 1999, in Montreal, Canada.

Sincerely,

Hugh Grant

Gene Protection Technologies:
A Monsanto Background Statement

In recent months, there has been considerable publicity in a number of countries about a potential new plant technology dubbed the "terminator." This technology is one of a class of so-called gene protection or gene control technologies, still in research and development, that may be used to control the germination of seeds produced by plants modified by biotechnology.

Monsanto has been the subject of much of that publicity because of its announced intention to purchase Delta and Pine Land Company (D&PL). D&PL, along with the U.S. Department of Agriculture, developed this particular gene protection technology.

The news stories and numerous interested parties have raised questions about the impact of such technologies on traditional farming methods and on the production of adequate food supplies to meet the anticipated increases in the world's population.

Many seed companies around the world, as well as government and independent research institutions, are in some stage of research and development on gene protection technologies. We know of none, however, that have moved beyond the research and development phase. The securing of a patent related to these technologies is one part of the research and development effort, and does not predict commercial viability or acceptability.

Companies are developing these technologies because they believe they may provide a number of benefits, the primary benefit being protection of the investment required to develop the seeds. Such protection encourages more research and investment in future agricultural improvements and thereby would expedite access to the benefits of biotech seeds by farmers who want them.

At the same time, however, the fact that there is so much concern being expressed about this type of technology indicates that there are many who have serious misgivings about them and their potential impact on food production.

We believe that the concerns about gene protection technologies should be heard and carefully considered before any decisions are made to commercialize them.

We have conferred in the last several months with a number of international scientific and agricultural leaders about this situation including Ismail Serageldin of the World Bank, Professor Swaminathan of India, Calestous Juma, former head of the Secretariat for the Convention on Biodiversity, Jose Sarukhan, Director of CONABIO, the National Biodiversity Council in Mexico, and Jim Moody, President and CEO of InterAction, an umbrella organization representing 160 development and humanitarian aid organizations.

These individuals have been generous in their counsel and have recommended that thorough, independent and comprehensive consideration be given to the concerns raised about the impact of new gene protection technologies. We agree, and we are calling for just such consideration and public discussion, covering the full range of questions and issues that relate to the impact of these technologies on farming practices around the world.

One important issue, especially in developing countries, is that of small holder farmers who rely on saved seed to provide growing stock for the next year. We also hope that serious study and consideration will be given to the potential environmental, economic and social impacts of gene protection systems; how they should be developed; under what conditions or circumstances they should be utilized; and who should own them.

There is time for all aspects of this situation to be considered carefully, and in an open, comprehensive and consultative fashion. Experts agree that these systems are not expected to be ready for potential commercial use for at least five years.

It is important that the interests and perspectives of the food security and development communities be fully considered throughout the study and consultative process. In this connection, we are pleased that InterAction has agreed to work with its members and other groups to help achieve this objective. It is our hope that the many organizations interested in food security and development will contribute their expertise and perspectives.

Until a thorough, independent examination of gene protection systems has been conducted and all points of view considered, we will not commercialize these technologies. Moreover, in considering whether to commercialize such technologies, we will respond publicly and fully to the conclusions, opinions and arguments that are raised.

We believe in biotechnology and its potential to help address the very real and serious food and environmental demands facing the world, but we know that the success of biotechnology depends on its acceptance by farmers and the broader public. Many parties, both private and public, have an important stake in the issues surrounding gene protection technologies. We hope they will participate in a careful examination of those issues.

April, 1999

Statement from the U.S. Department of Agriculture - "Why USDA's Technology Protection System (aka "Terminator") Benefits Agriculture"

United States Department of Agriculture
Agricultural Research Service
Office of the Administrator
Washington, D.C. 20250

May 14, 1999

Mr. Hamdallah Zedan
Acting Executive Secretary
Secretariat on Biological Diversity
United Nations Environment Programme
World Trade Centre
383 Jacques Street, Office 300
Montreal, Quebec, Canada H2Y 1N8

Dear Mr. Zedan:

The Secretariat of the Convention on Biological Diversity requested on May 13, 1999, that a statement prepared by the U.S. Department of Agriculture, Agricultural Research Service, be made available for distribution. This document has been revised and is now available for your distribution to Parties and Organizations. The statement on the control of plant gene function is enclosed.

We appreciate having an opportunity to provide this paper for the Montreal meeting.

Sincerely,

Edward B. Knipling

EDWARD B. KNIPLING
Associate Administrator

Enclosure

The Control of Plant Gene Function

On March 3, 1998, U.S. patent 5,723,765 was awarded to the Agricultural Research Service of the U.S. Department of Agriculture (USDA-ARS) and to the Delta and Pine Land Co., a major cotton seed supplier in the U.S. This patent, entitled "Control of Plant Gene Expression," describes a new concept that would permit external control of when a gene functions. One application has been termed the technology protection system (TPS; sometimes called the "Terminator"), a genetic modification that allows a normal crop of an improved plant variety to be produced but prevents germination of its progeny seeds. Since then the patent has received a great deal of attention, both in terms of the possible benefits of the new technology and also whether there is significant potential for harm.

What is the potential benefit to U.S. agriculture?
The germination control technology has two main purposes. First, it protects specific plant varieties with genetically engineered desirable traits from unauthorized regeneration and ensures benefits sharing for those who accomplished the improvements. The ability to protect intellectual property under the legal framework in the U.S. and other countries allows patenting of new and useful inventions, such as genetically engineered plants. The TPS may enhance investment in the research to develop high-value crop varieties, because companies will have more prospects for a fair return on their investment. There is a strong parallel in the development of hybrid corn. Hybrids do not breed true, and thus the productive value of the hybrid is largely lost after the first year. This revolutionary development of 70 years ago also required that farmers buy new seeds each year. The result is that seed companies invested heavily in improving corn, which has become a dominant American crop. The cost of seed to farmers has been more than offset by the economic returns to them due to highly dependable germination, improved crop yield, quality, and profitability.

Second, TPS provides a way to prevent the spread of genes introduced into improved crops. Pollen from genetically engineered crop plants can sometimes find its way to other plants. There may be native plants that can hybridize with the crop plant, and this pollen transfer could introduce new and unwanted traits into the wild population. TPS solves this problem and eliminates a theoretical biosafety concern over widespread use of genetically engineered crops.

Other potential uses of this technology have also been proposed such as control of flowering of forage grasses and managing pest resistance mechanisms in the plant. These applications are currently being investigated by ARS laboratories.

What is the potential for direct harm to U.S. agriculture?
Research will be conducted to determine whether TPS pollen from one field could be transferred to a neighboring field of non-engineered plants of the same crop. If such an event occurred, this could prevent germination of some portion of the seeds. But, TPS is intended to be deployed only in self-pollinated crops, i.e., plants that pollinate themselves instead of using pollen from other plants. If TPS is used as originally intended, the risk from pollen transfer is extremely low. Self-pollinated crops include rice, cotton, soybeans, and many others of importance to the U.S.

What is the potential for indirect harm?
Some constituent groups are concerned that this technology will allow seed companies to overcharge farmers for seeds, because all seeds will be sterile and no alternative sources will exist. To introduce TPS into a variety is expensive and time-consuming. It is highly likely that companies would introduce it into only a few varieties in which they have a heavy investment, especially those that have been genetically engineered and cannot be protected in any other way. If the added value is not there to justify the cost of TPS-protected seed, the farmer will substitute less expensive seed.

What is the current status of the technology?
The patent was awarded based on a demonstration of its efficacy in a tobacco plant test system. Work is currently underway to introduce the system into cotton for further testing. We do not expect that TPS will be available for commercialization before 2005. Other applications of the gene control system will not be available until a later date.

Why was USDA-ARS involved in development of TPS?
The use of biotechnology to improve crop plants has tremendous potential to improve agricultural productivity, but there are many barriers to achieving that potential. Today, even though there are prominent examples of insect-resistant corn, cotton, and potatoes and herbicide-tolerant soybeans, biotechnology simply cannot be used for many crops. It is too expensive to be used when the planted acreage is small. As a result, many horticultural crops or other specialty crops are denied the benefits of modern plant genetic improvements. TPS may allow an extension of the benefits of biotechnology to crops that serve limited markets or unique production systems. This potential impact is extremely broad and will benefit many aspects of American agriculture. However, fundamental biological research was needed to provide a foundation for discovery of system to control plant gene expression. ARS research, and the patent, actually deal with a system of gene regulation that has numerous applications beyond germination regulation. In addition to TPS, ARS sees many examples of the new technology offering other opportunities to improve cropping systems and benefit agriculture and farmer profitability. This fundamental research is an appropriate role for ARS, which is the in-house research arm of the USDA.

Why did USDA-ARS partner with Delta and Pine Land Co. on the patent?
From the beginning, scientists of both organizations were jointly responsible for conceiving the project, and doing follow up work. This means that Delta and Pine and ARS would have been co-owners of any patented research products regardless of how the patent was submitted. In order to perfect this discovery, ARS and Delta and Pine negotiated a Cooperative Research and Development Agreement (CRADA), which offers the company the right of first refusal to an exclusive license for the patent. The U.S. Technology Transfer Act of 1986 requires that research agencies such as ARS offer this license for discoveries made under CRADA collaborations.

What are the USDA-ARS plans at this point?
USDA has no plans to introduce TPS into any germplasm in our collections or plant research programs. Our involvement has been to help develop the technology, not to assist companies to use it. ARS is also committed to making the technology as widely available as possible, so that its benefits will accrue to all segments of society. Negotiations with Delta and Pine on the licensing terms have focused on this need. ARS intends to do research on other applications of this unique gene control discovery, but which are unrelated to seed germination. When new applications are at the appropriate stage of development, this technology will also be transferred to the private sector for commercial application.

How will TPS affect agriculture in the developing world?
The primary use of TPS will be in the markets of developed nations, where farmers have the technology and infrastructure to take maximum advantage of high-value crop varieties. If subsistence farmers can support and develop a seed industry that is able to supply locally adapted, high-tech varieties, the use of TPS-containing seeds in the developing world is possible.

Will TPS force subsistence farmers to give up saving seeds?
No, it will not. The germplasm used by subsistence farmers is not the target of this technology. In fact, like ARS, the international research institutes that make up the Consultative Group on International Agricultural Research (CGIAR), such as the International Rice Research Institute in the Philippines, have announced that they will continue to produce varieties without TPS. These decisions reinforce that new germplasm will continue to be made available for use by all, without restrictions imposed by TPS.

Will farmers in the developing world be denied access to genetically engineered seeds because of TPS?
Seed companies have been reluctant to distribute high-value genetically engineered seeds in countries that do not have a creditable system of patent protection. As a result, most farmers in the developing world are currently denied access to genetically engineered seeds. TPS may in fact allow companies to begin distributing improved crops to those who want them. Protecting unauthorized use of plant intellectual property would assure the seed companies of continued demand in these markets, and therefore stimulating research for improved varieties in the future. Although the farmers would have to purchase seed each year, their crops would have improved productivity, health and quality that will repay the investment cost many fold.

Has development of TPS departed significantly from research to improve crops?
To the contrary, TPS represents a single step forward in a long and elegant history of plant improvement for human use. Successes in plant breeding, which allow Earth to carry its current population of more than six billion people, have come through a series of individual advances, most of which introduced a higher level of technology to agriculture than before. Control of plant gene expression should be viewed as a tool that will continue this longstanding trend toward technology by facilitating the wider introduction of beneficial improvements into crops. In that sense, it is part of a continuing evolution of modern improved crops, rather than a revolution in

technology. There should be a public discussion of TPS and the potential benefits and detriments. At the end, there must be public guidance, not on whether to shun technological advances in crops, but how to manage them to the advantage of humankind.

For additional information contact:
Richard M. Parry, Assistant Administrator
Agricultural Research Service, USDA
Washington, D.C. 20250-0302

Statement from the Delta and Pine Land Company

D&PL DELTA AND PINE LAND COMPANY

P.O. Box 217 • One Cotton Row • Scott, Mississippi 38772 • (601) 742-4500

May 14, 1999

Mr. Hamdallah Zedan, Acting Executive Secretary
Secretariat of the Convention on Biological Diversity
World Trade Centre
393 St. Jacques Street, Office 300
Montreal, Quebec
Canada H2Y 1N9

Dear Mr. Zedan:

By this letter, we wish to grant permission to the Convention on Biological Diversity to make the attached statement available in your document packet as you see fit. I understand that it would be appropriate for our statement to be included as one of the documents presented at the Fourth Meeting of the Subsidiary Body on Scientific, Technical and Technological Advice, to be held in June in Montreal.

You are welcome to use our statement, and we are happy to provide more information as needed. Please don't hesitate to contact me, or Dr. Harry Collins, our Vice President of Technology Transfer, should you require our assistance in any way.

With best regards,

Sincerely yours,

Ann Jennings Shackelford
Vice President, Corporate Services

Attachment
cc: Dr. Harry Collins

Delta and Pine Land Company welcomes the opportunity to provide information on the Technology Protection System for the review of participants in the United Nations Convention on Biological Diversity. Since the shared patent was announced, there has been a significant amount of misinformation distributed to the general public. We appreciate the opportunity to discuss the research, as we are actively involved in its development with the United States Department of Agriculture's Agricultural Research Service (USDA-ARS).

UNDERSTANDING THE SYSTEM

TPS is a transgenic system comprised of a complex array of genes and gene promoters which, in the normal state, are inactive. This means the plant is normal and produces normal seeds which will germinate when planted. Seeds carrying TPS produced for sale to the farmer will simply have a treatment applied prior to the sale of the seed which, at time of germination, will trigger an irreversible series of events rendering the seed produced on farmers' plants non-viable for replanting. It's important to note that TPS, like hybridization, will have no effect on the seed product whether for feed, oil, fiber or other uses.

WHY TPS?

The Technology Protection System (TPS) will insure farmers a more level playing field worldwide. Farmers in some of the more developed countries have been purchasing advanced seed technologies for the past several years based upon the value of proven enhancements. TPS will stimulate breeding and marketing efforts in countries which, due to lack of protection of intellectual property, have not benefited from advances currently available in the developed world.

Critics of TPS say the technology will limit choices these farmers have. On the contrary, it will actually result in growers, particularly in less developed countries, having more options available to them, including high-yielding, disease-resistant and even transgenic varieties. We expect this new opportunity to present farmers in developing countries with the option of moving into production agriculture rather than their current subsistence farming.

BIOSAFETY REALIZED THROUGH TPS

Biosafety produced by TPS prevents the remote possibility of transgene movement. There has been some concern that biotech-derived genes might cross to wild relatives. This slight possibility should be prevented by TPS activated plants, as even the pollen, if it happens to pollinate flowers of a wild, related species, will render the seed produced non-viable. In addition, the non-viable seed produced on TPS plants will prevent the possibility of volunteer plants, a major pest problem where rotation is practiced.

OTHER GERMPLASM PROTECTION

While TPS is a first in biotechnology-based germplasm protection systems, there are other means of protecting genetic breakthroughs. The most common type of protection system is hybrid seed production. Although primarily utilized for increased yield via hybrid vigor, it is also a protection system. Hybrids are seen in many cross-pollinated crops such as corn, sorghum, sunflower and canola. Reduction in performance and changes from the parent seed leads to little saving of hybrid seed. Farmers, recognizing the value added from increased yields, are willing to buy new hybrid seed each year instead of saving and replanting seed from their previous crop. Their purchase of new seed each year insures quality and funds new research that leads to new and improved products.

On the other hand, few germplasm protection systems have been successfully implemented for self-pollinated species, such as cotton, soybeans, wheat and rice. The difficulty in producing hybrids, combined with costly implementation and poor product performance has kept companies from investing heavily in some of these crops.

FARMERS TO RECEIVE CHOICE AND BENEFITS

Farmers all over the world will continue to have the choice to buy varieties enhanced with the latest in breeding and biotechnology or to save seed which do not include TPS or patented enhancements. Farmers will continue to select those varieties which offer the highest returns and most benefits. It is the expectation of both D&PL and the USDA-ARS that the benefits realized by planting TPS varieties, carrying advanced technology traits, will be significant. Many farmers will be likely to choose TPS varieties when given the opportunity.

TPS LIKELY TO INCREASE RESEARCH

TPS will be broadly available to both large and small seed firms. Because of this, it is anticipated that TPS will encourage increased breeding research in many crop species and geographic areas. Consequently, there should be sizable improvements in technology. Delta and Pine Land Company and the USDA-ARS believe that this is a distinct advantage to farmers because they will have better varieties and transgenics more widely available to them.

Genetic diversity in many important crops is a real concern of both private and public breeders today. There is no correlation between TPS and lack of genetic diversity. In fact, with the increased incentive for many private seed companies as well as universities to breed crops which have not received sufficient attention in the past, it is entirely possible that diversity will increase as breeders focus on providing unique and improved versions of germplasm to farmers.

TIMETABLE FOR DEVELOPMENT

Several years ago, a D&PL cotton breeder and researchers from the USDA-ARS generated the idea for a technology protection system during a casual meeting. Research began in 1993 and progressed over the next few years to move the concept to reality. In the spring of 1998, D&PL and the USDA were awarded a patent by the US Patent and Trademark Office . The system is being developed further and we expect that it will be a few years before TPS transgenic varieties are commercialized. Though research is progressing well, there are no TPS plants, nor have there been any TPS plants of any species, growing in a field, anywhere in the world.

MEASURING SUCCESS

In the end, it is the farmers who will decide if the TPS and other new agricultural technologies have tangible benefits. Seed companies and technology providers, of necessity, are committed to helping farmers be more successful. The success of these companies depends on the farmers' success. If a technology does not bring benefits and increased prosperity to our customers, then they will not purchase the technology. It is in everyone's interest that more choices be available to all of the world's farmers, and the TPS is a means of achieving this goal.

FOR ADDITIONAL INFORMATION

Dr. Harry B. Collins, Vice President of Technology Transfer, leads the TPS effort for D&PL and is glad to discuss the TPS with interested media, seed and technology companies, as well as individuals. He can be reached at D&PL's headquarters in Scott, Mississippi by calling 601-742-4533 (8 a.m. to 5 p.m. CST), faxing 601-742-3795 or e-mailing harry%202-2946@mcimail.com.

Statement from Zeneca Agrochemicals of 24 February 1999 to CAMBIA

ZENECA

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Fax Cover Sheet

To	**Ana Clara Schenberg**		
Company Name	**Principal Officer, STTM**		
Fax No.	**001 514 288 6588**	**Ref**	
From	**Dr David A Evans**	**Direct Tel No**	**01428 655269**
Date	**14/05/99**		
No. of pages following cover note	**0**		
Copies:			

Zeneca Agrochemicals Statement

With regard to the above, I am providing permission to make the statement available as indicated in your fax of 13 May, 1999, provided that the statement is always made available in full.

David A Evans

In the event of poor transmission
please ring 01428 655269

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Prof. A Jefferson
Executive Director
Cambia
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Australia

24 February 99

Dear Professor Jefferson

Thank you for providing me the opportunity to comment on "Terminator" technology from a ZENECA perspective. Firstly let me state categorically that ZENECA is not developing any system that would stop farmers growing second-generation seed, nor do we have any intention of doing so. Our belief is that the application of biotechnology in agriculture has the potential to bring great benefits to mankind, by raising the quantity and quality of food, and encouraging sustainable farming practices. We believe these benefits need not be restricted to developed agriculture, and that they can help retain the diversity of our biological resources.

We would not regard products that stopped farmers growing second-generation seed as fundamentally immoral or unethical, *provided* that they brought benefits to the farmer and consumer, and there was freedom of choice. Growers have in the past moved voluntarily to hybrids in a variety of crops in a range of countries. For example, in the USA anyone is free to set up to sell open-pollinated lines, if they believed they could compete successfully for sales opposite hybrids. On the other hand, we would not support any use of "Terminator" which reduced biodiversity, increased third world poverty, or limited free and fair competition in agriculture or lead to monopoly.

The principle ZENECA has consistently followed has been to give our customers – from farmers to consumers – enough information to allow them to make their own choices on issues such as genetically modified food, and we will continue to do so. In this context, we are interested in investigating the benefits of controllable gene expression systems which do not involve stopping farmers growing second-generation seed, for example to:

- control the timing of plant developmental changes, such as flowering, for example to avoid frost or to synchronise pollination in hybrids
- provide limited windows when insect or fungal control genes are active, as a more effective resistance management strategy than *refugia*, especially when combined with a limited regime of chemical treatments, additionally reducing the levels of the gene product from the final harvested crop

ZENECA

- limit the impact of gene transfer to wild relatives or volunteer crop species, through the loss of traits through successive generations, in the cases where there is a significant risk of such problems arising
- provide cheaper and more robust methods for producing existing hybrid seeds which provide increased yields compared to their inbred parents, in crops such as maize
- control post-harvest losses, e.g. providing a more effective alternative to sprout suppressants in potato

All of this work is at an early research stage, and any decision to develop it requires not only technical success, but also a full science-based risk assessment, including the environmental impact. If and when we were to decide to develop such a system, we would be happy to justify its benefits to our potential customers and regulatory authorities. Reaching the balance between the benefits offered and the control of abuses requires open discussion from positions of knowledge, rather than closed decisions and prejudice driven by fear and ignorance. We are not ashamed of our work, and have therefore published our progress in the open scientific literature. I enclose a set of reprints or articles from peer-reviewed journals.

Let me turn to the specific patent on the mammalian uncoupler protein, and fit it into this picture. This patent came from some of the earliest work looking at new ways of controlling male fertility in maize. Hybrid maize seed production in the USA involves either physical detasseling by man or machine, or the use of complex breeding systems involving natural cytoplasmic male sterility. Both are expensive, and the most robust cytoplasmic sterility system also confers susceptibility to the toxin from one of the major maize leaf blights. Pollen formation is energy intensive, and the protein in the patent is involved in uncoupling the "burning" of sugars in the plant mitochondrion from useful energy production. It was therefore a model to ask the question whether this approach could ever provide an effective system to control male fertility, though there were a number of alternatives. Given some initial success, we filed a patent application, as is normal practice in a highly competitive research environment, to protect the invention. Again, as is normal practice, we also claimed a range of similar applications and because the idea of controlling germination was around in academia and industry at the time, we claimed that as well. Whilst we needed to do a certain amount of work to reduce these ideas to practice, we rapidly came to the conclusion that this was one piece of technology we **did not want to take forward**, and the project was stopped in 1992.

In fact the patent leaves us with a dilemma. We do not intend to take any of the claims forward, and we certainly do not want to be constantly put in the position where we are asked to justify applications others have advocated, where this patent could theoretically be used. The world is full of such patents which remain in force, but where the inventions described in them have not, for many reasons, ever been commercialised. In the normal course of events, we would choose to abandon such patents when they require payment of renewal fees and the chance of a competitor taking up the invention has faded. Our concern in this case is that given all the publicity, and the stated intention of others to develop the technology, there is a genuine possibility it might be taken up by a competitor. We would rather be castigated unjustly for holding the patent, than for effectively handing it over to someone who turned the fears to reality.

ZENECA

I hope this response helps you stimulate an informed, science-based discussion in the context of biodiversity. Let me just restate ZENECA's position for the sake of clarity. ZENECA is not developing any system that would stop farmers growing second-generation seed, nor do we have any intention of doing so.

Yours sincerely,

Dr D A Evans,

Research & Development Director

Ref: Feb.38

Enclosed reprints from articles:

Holt DC, Lay VJ, Clarke ED, Dinsmore A, Jepson I, Bright SWJ & Greenland AJ (1994) *Planta* **196** 295-302. Characterisation of the safener-induced glutathione S-transferase isoform II from maize.

Jepson I, Lay VJ, Holt DC, Bright SWJ & Greenland AJ (1994) *Plant Molecular Biology* **26** 1855-1866. Cloning and characterization of maize herbicide safener-induced cDNA's encoding subunits of glutathione S-transferase isoforms I, II and IV.

Greenland A, Bell P, Hart C, Jepson I, Nevshemal T, Register III J & Wright S (1997) *Journal of the Society for Experimental Biology* **1044** 141-147. Reversible male sterility: a novel system for the production of hybrid corn.

Caddick MX, Greenland AJ, Jepson I, Krause K-P, Qu N, Riddell KV, Salter MG, Schuch W, Sonnewald U & Tomsett B (1998) *Nature Biotechnology* **16** 177. An ethanol inducible gene switch for plants used to manipulate carbon metabolism.

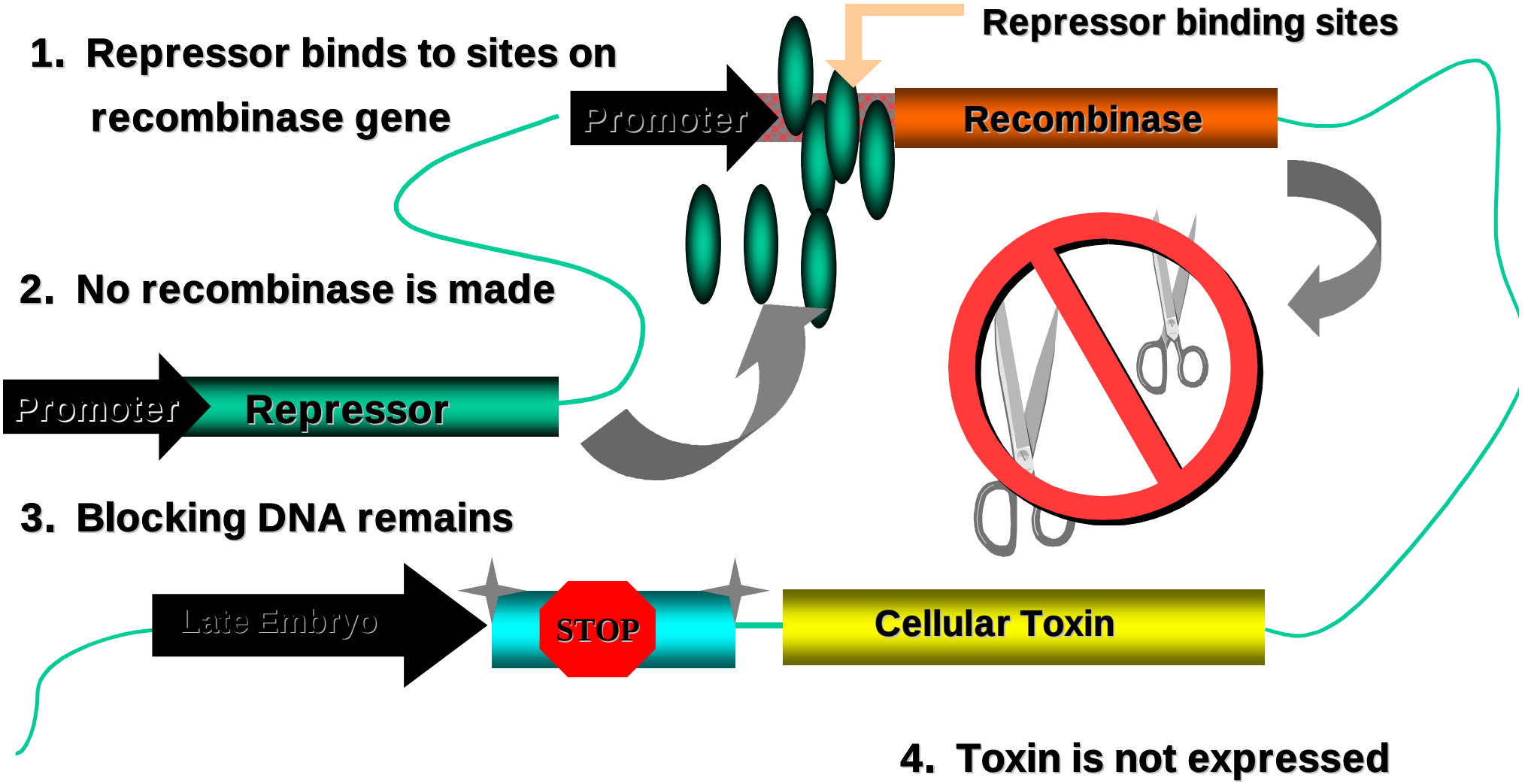
Jepson I, Martinez A & Sweetman JP (1998) *Pesticide Science* **54** 360-367. Chemical-inducible gene expression systems for plants – a review.

Salter MG, Paine AJ, Riddell KV, Jepson I, Greenland AJ, Caddick MX & Tomsett AB (1998) **16** 127-132. Characterisation of the ethanol-inducible *alc* gene expression system for transgenic plants.

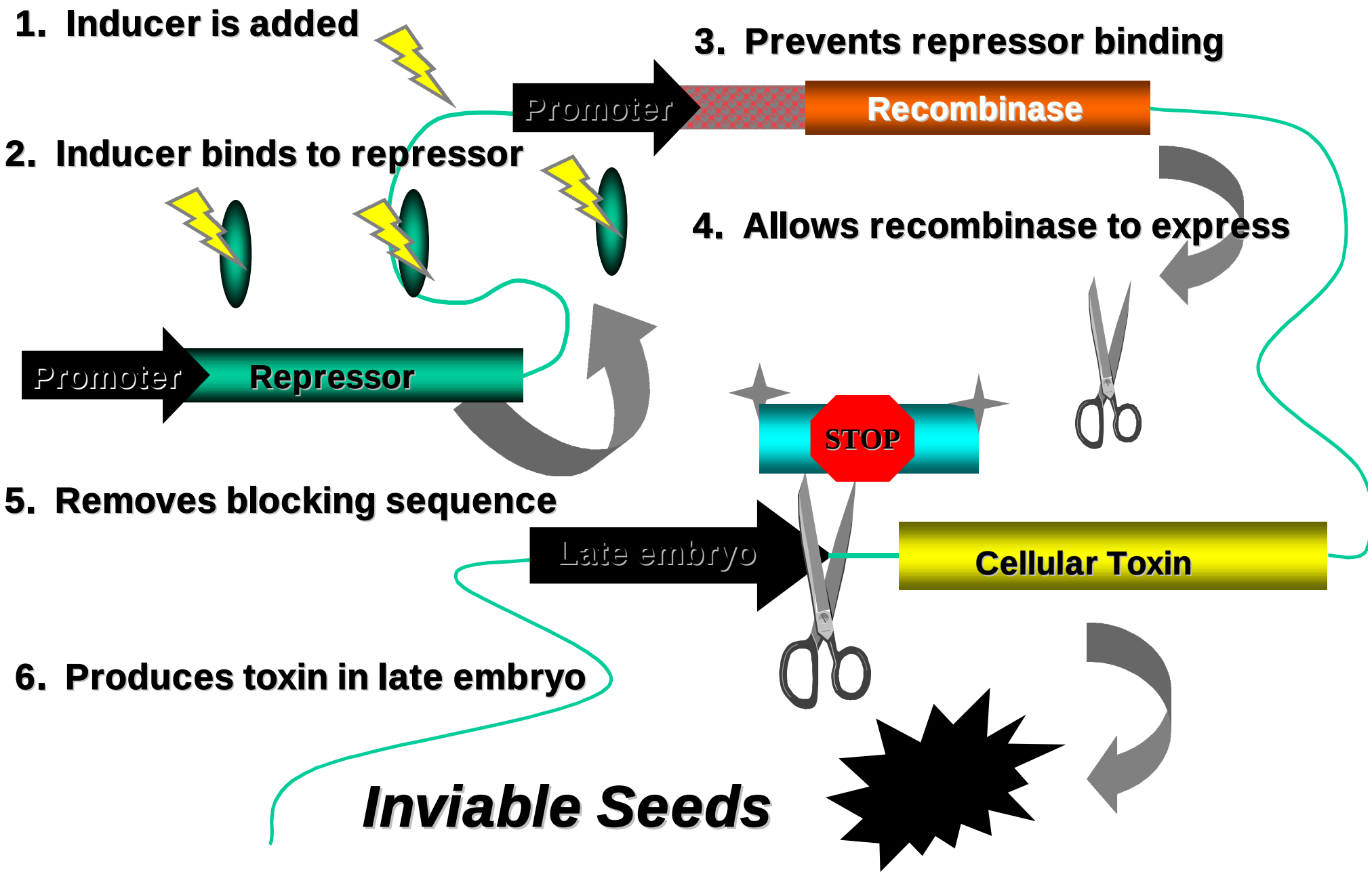
Figures 1&2: Appendix to the expert paper, Annex/UNEP/CBD/SBSTTA/4/9/Rev. 1 to illustrate the technology described in U.S. patent No. 5,723,765

Figure 1: Viable Embryos and Seed

Figure 2: Inviable Seeds



Viable Embryos and Seed


1. Inducer is added
2. Inducer binds to repressor
3. Prevents repressor binding
4. Allows recombinase to express
5. Removes blocking sequence
6. Produces toxin in late embryo
Promoter
Recombinase
Promoter
Repressor
STOP
Late embryo
Cellular Toxin
Inviable Seeds