# Draft Draft Draft Draft Draft Draft Draft

## Daegu Protocol
### 11 December 2006

**New Biotechnologies for Pest and Disease Control**

Extraordinary new biotechnologies are being developed to improve crop pest, human disease vector, and agricultural crop and human disease control. These biotechnologies are at the forefront of biological science applied for the benefit of mankind for food production and public health protection.

The new biotechnologies include, but are not limited to, symbiotic control, also known as paratransgenesis, for Chagas' disease of humans and Pierce's disease of grapes in which symbiotic microorganisms living within the gut of disease vector insects are genetically modified to produce antagonistic antibodies or peptides that prevent the disease from developing in the vector or from being transmitted to the host plant or human.

Fruit flies, cotton pink bollworms, and the yellow-fever mosquito have been genetically modified to mass-produce these insects, which could be released mate with wild populations resulting in sexual sterility to reduce and eradicate pest populations in a manner similar to sterility caused by powerful gamma radiation. This is known as the Sterile Insect Technique and was used successfully to rid nearly all of N. America of the screwworm fly, which is a lethal parasite of living human and animal flesh.

There is an intercellular bacterium known as *Wolbachia* that also has significant potential to reduce disease vector mosquitoes, such as those that transmit human filariasis, and other insect pest and vector populations when modified for that purpose. See the *Wolbachia* information website at: http://www.wolbachia.sols.uq.edu.au/

New biotechnologies are being developed to genetically modify mosquito vectors of malaria to prevent the transmission of this prevalent and debilitating disease from mosquitoes to humans. Other new applications of biotechnology are likely to soon be developed for other biological control purposes.

A characteristic of these new biotechnologies is their funding for development by government agencies, international institutions, or philanthropic organizations such as The Grand Challenges in Global Health initiative funded by the Gates foundation. There is small commercial interest in these technologies due to the lack of product sales-related profit incentives, which has been the driving engine or factor for development of transgenic corn, soybeans, cotton, and other high cash value crops by multinational corporations.

**Uncertain and undefined regulatory pathways for approval before importation, distribution, contained research, and field implementation**

Most of these biotechnologies are so new or unique in their nature and science that they are unfamiliar to regulatory agencies, which must regulate their importation, distribution, contained research, and release or implementation in the environment. The unfamiliarity and inexperience leads to difficulty in devising risk assessment processes or procedures for each new biotechnology. Actual hazards must be identified and quantified and potential exposure to vulnerable nontarget organisms must also be quantified in order for credible risk assessments to be made. Conjecture in the risk assessment process leads to risk assessments that are precautionary in principle rather than based on identified risks. The precautionary principle is based to a degree on unsubstantiated hazards or theoretical exposure, which may be difficult or impractical to quantitate or prove, thus leading to a risk assessment process with elements of speculation.

An issue common to the new biotechnologies for crop pest and human disease control is uncertain and undefined regulatory pathways for approval before importation, distribution, contained research, and releases or utilization in the environment. These unique biotechnologies are so new or distinctive that most country governments have not established definitive processes, departments, or agencies to regulate them and have not developed appropriate case-by-case risk assessment guidelines for them.

This uncertainty has emerged from the regulatory history of transgenic crop plants commercially developed by multinational corporations, to which the precautionary principle has been applied in some countries. Multinational corporations are not as transparent to the public as government agencies, international institutions, or philanthropic organizations in revealing their safety risk assessment data because of confidential business information needs to protect against competition using their data to gain their own regulatory approvals.

## Protocol Guidance purpose and EIA process

The Environmental Impact Assessment (EIA) may also be known as a Strategic Environmental Assessment or Environmental Impact Statement, according to the country of use, but the purpose and content are generally similar. Environmental Assessments in the USA are usually a shortened version, but may also be comprehensive.

This Protocol proposes guidance for independent country regulation of new crop pest and human disease control biotechnologies. The guidance is based on the use of EIA documentation and analysis, commonly used in North America, the European Union, Canada, Australia, and other countries as a format to provide for public transparency of the process and to meet country government regulatory agency requirements. The EIA is a document that is developed openly to the public with all available scientific, societal, and stakeholder input, so the public is provided the opportunity to be informed and comment on decisions to release new forms biotechnology into the environment before releases occur. The EIA procedure ensures that environmental consequences of projects are identified and assessed before authorization is given. The public can give its opinion and all results are taken into account in the authorization procedure of the project. The public is informed of the decision afterwards.

The EIA process is an internationally accepted regulatory mechanism that is proposed in this Protocol Guidance as the most practical regulatory means to implement and achieve utilization of innovative new biotechnologies in most countries.

It is possible in the EIA investigative process that a decision can be scientifically justified that an EIA is unnecessary due to factors such as indigenous presence, commonality of the biotechnology to the environment, or substantial similarity to an existing biotechnology, to the extent that no environmental impacts are expected or likely to occur.

### Scoping or preliminary investigations

Scoping is used to identify the key issues of concern at an early stage in the EIA planning process. Scoping should be carried out at an early stage in order to aid site selection and identify possibly alternatives. The scoping process for the EIA should involve all interested parties such as the proponent(s) of the biotechnology and planning or environmental agencies and appropriate members of the public, such as university or medical community professionals. The results of scoping should help determine the scope, depth, and terms of reference to be addressed within the EIA document. In some countries, scooping may involve public meetings, which are advertised in advance of their occurrence.

### Risk assessment in the EIA

The EIA contains a risk assessment, which should be case-by-case specific for the proposed biotechnology and its characteristics, unless there are close analogies that may be applicable on a scientific basis. It includes assessment of potential human and nontarget organism effects, effects and persistence in the environment, societal and health impacts, and other possible environmental impacts or effects. It is done before a decision is made to introduce a new biotechnology. Appropriate alternative technologies may also be considered along with their potential environmental and societal impacts, so that comparisons may be easily drawn. The EIA is written in the most common language of the county for mass-communication and publicized to provide opportunity for comments. Comments with no scientific basis or rationale are usually dismissed due to lack of credibility. However, public sentiment may play a significant role in the decision making process for political, ethical, or religious reasons.

With genetically modified insects, risk assessment may include case-by-case discussion or analyses of stability of the gene over multiple generations, potential for gene transfer to other species, biological fitness assessments, efficacy or performance of intended use, dispersion or range of movement and other physiological, behavioral, or ecological aspects in comparison to the same or similar native, endemic, or sylvan species. See below IAEA/FAO transgenic insect risk assessment document website link concerning transgenic insect risk assessment.

### Initiation of the EIA Process

The research agency or institution originating the new biotechnology should develop the EIA documentation in collaboration with regulatory agencies within the proposed country

of use because the originators are most familiar with the technology and its potential effects and risks. Often, more than one agency may have regulatory authority and responsibilities for new biotechnologies and they may include federal, state, provincial, tribal, or country departments of environment, agriculture, public health, forestry, natural resources, and other departments or agencies that may claim some degree of regulatory authority.

After identification of the country regulatory agencies, which may be involved in the regulatory process, meetings and discussions should focus on coordination of the EIA process and identification of risk assessment information and data needs that are scientifically relevant and can be obtained within reasonable cost and time.

It is a great advantage, in respect to coordination of the regulatory process, if there is a lead agency with clear regulatory authority and responsibility that is willing to coordinate with other agencies or departments that have less clearly defined regulatory responsibility. Due to the newness of the biotechnology pest or disease control agent and lack of familiarity by agencies that may become involved, good coordination is critical to prevent redundancy, confusion, and excessive time delays and costs.

In consideration of the costs that may arise in the development of risk assessment information and data, regulatory agencies must be encouraged to define scientifically achievable requirements and participate in the studies in the form of grants or other agency or institutional contributions, such as collaborative agreements for safety studies.

## EIA Format

The specific form and content of the EIA should be planned to meet the needs of the country regulatory agencies involved and existing international agreements including the Cartegena Protocol, http://www.biodiv.org/biosafety/default.aspx, International Plant Pest Convention, https://www.ippc.int/IPP/En/default.jsp, World Health Organization, International Atomic Energy Agency, and other such international bodies that have published guidance, standards, or are biotechnology evaluation stakeholders. The following IAEA/FAO publication specifically addresses risk assessment for transgenic insects:
http://www-pub.iaea.org/MTCD/publications/ResultsPage.asp#name1
However, international organizations may also have little applied risk assessment experience with the newest insect and disease control biotechnologies, other than commercially transgenic crop plants that express various *Bacillus thuringinsis* (Bt) toxins for insect control and herbicide tolerance.

An example of the data requirements for USA EPA registration of biochemical and microbial pesticides may be viewed at the following location:
http://www.epa.gov/pesticides/biopesticides/regtools/guidelines/index.htm

It is essential to provide a working format for an EIA as a proposal to country regulatory agencies that can be adapted to the specific needs of agencies and case-by-case risk assessment of each unique proposed biotechnology. The objective is that it should be

acceptable by all responsible parties. Formats for environmental documentation are provided in the following websites:
USA NEPA format:
http://www.nepa.gov/nepa/regs/ceq/toc_ceq.htm
Canadian Environmental Assessment agency
http://www.acee-ceaa.gc.ca/
EU format http://ec.europa.eu/environment/eia/home.htm
Specifically regarding biotechnology in the EU:
http://ec.europa.eu/environment/biotechnology/index_en.htm

For the qualities of an EIA see the European Commission's guidance document (http://www.europa.eu.int/comm/environment/eia/eia-guidelines/g-review-full-text.pdf)
Australian Government Department of Environment and Heritage
http://www.deh.gov.au/index.html
Flowchart of the referral, assessment and approval process
http://www.deh.gov.au/epbc/assessmentsapprovals/flowchart.html
and
Convention on Environmental Impact Assessment in a Transboundary Context (Espoo, 1991) - the 'Espoo (EIA) Convention'
http://www.unece.org/env/eia/

Participants in the development and refinement of this Protocol Guidance are requested to review these and other EIA-type formats and provide comments and recommendations for their modification and use to meet the regulatory needs for new crop pest and human disease control biotechnologies.

Examples of previous Environmental Assessments for transgenic cotton pest pink bollworms may be found at: http://www.aphis.usda.gov/brs/arthropod_assess.html

Following consensus on an EIA general content format, the format will be proposed for adoption by regulatory agencies as a regulatory process tool in countries in which new crop insect pest and humans disease biotechnologies, of the type mentioned above, may be imported, tested in contained conditions, or released or utilized in the environment.

**Example**
Recommended format of an Environmental Impact Statement under the USA National Environmental Policy Act consist of the following:
(http://www.nepa.gov/nepa/regs/ceq/toc_ceq.htm)
(a) Cover sheet.
(b) Summary.
(c) Table of contents.
(d) Purpose of and need for action.
(e) Alternatives including proposed action
(f) Affected environment.
(g) Environmental consequences

(h) List of preparers.
(i) List of Agencies, Organizations, and persons to whom copies of the statement are sent.
(j) Index.
(k) Appendices

The body of the EIA should be written common language, while the appendices may address technical considerations in scientific terms.

However, the format of the EIA will most likely be modified to meet the requirements of the country into which the new biotechnology may be introduced and the case-by-case risk assessment nature of the specific biotechnology.

## Further Needs for this Protocol Guidance

Further refinement and development by an interdisciplinary group or body.
Consensus agreement by signature of participating scientists from several countries.
Draft or proposed EIA general format to be available for modification and development to meet regulatory requirements of each country of unique biotechnology use and case-by-case risk assessment nature of each biotechnology.