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New Biotechnologies for Pest and Disease Control

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

The new biotechnologies include 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 vectors insects are genetically modified to produce agents that prevent the disease from developing in the vector or from being transmitted.

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

There is an intercellular bacterium known as *Wolbachia* that also has significant potential to reduce crop pest and disease vector mosquitoes, such as those that transmit filariasis, and other pest insect populations when modified for that purpose. See the Wolbachia 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 the disease from mosquitoes to humans. Other new applications of biotechnology may soon be developed for similar biological control purposes.

A general characteristic of these new biotechnologies is their funding for development by either 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 large product-related profit incentives, which has driven the development of transgenic corn, soybeans, cotton, and other crops.

Uncertain and undefined regulatory pathways for approval before releases

An issue common to these new biotechnologies for crop pest and human disease control is uncertain and undefined regulatory pathways for approval before releases into the environment may be made. These technologies are so new or distinctive that most

country governments do not know how to regulate them and have not developed appropriate risk assessment abilities and guidelines for them.

This regulatory uncertainty has emerged from the regulatory history of transgenic crop plants commercially developed by multinational companies to which the precautionary principle has been applied in some countries. This is based to a degree on unknown risks, which may be difficult or impractical to quantitate or prove. Multinational companies 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 for other regulatory approvals.

Protocol Guidance Purpose and EIA Process

This Protocol proposes guidance for independent country regulation of these new crop pest and human disease control biotechnologies. The guidance is based on the use of environmental impact assessment (EIA) documentation, commonly used in North America, the European Union, and some 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. Scoping is used to identify the key issues of concern at an early stage in the planning process. Scoping should be carried out at an early stage in order to aid site selection and identify any possible alternatives. The scoping process for the EIA should involve all interested parties such as the proponent and planning or environmental agencies and members of the public. The results of scoping should help determine the scope, depth and terms of reference to be addressed within the environmental document.

Risk Assessment in the EIA

The EIA contains a risk assessment, which is case-by-case specific to the proposed biotechnology and its characteristics and includes assessment of potential human and nontarget organism effects, effects and persistence in the environment, societal impacts, and other possible environmental impacts or effects and is done before a decision is made to introduce a new biotechnology. Appropriate alternative technologies may also be considered along with their potential impacts, so that comparisons may be easily drawn. The EIS 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.

With genetically modified insects, risk assessment may include case-by-case discussion or analyses of stability of the gene over multiple generations, potential for horizontal 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 above IAEA/FAO transgenic insect risk assessment document concerning transgenic insect risk assessment.

Initiation of the EIA Process

The research agency or institution originating the new biotechnology should do the development of EIA documentation in collaboration with regulatory agencies within the proposed country of use because the originators would be 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 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 regulatory process and identification of information and data needs.

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, coordination is important to prevent redundancy and excessive time delays and costs.

In consideration of the considerable 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 institutional contributions, such as collaborative agreements for safety studies.

Form of the EIA Format

The specific form and content of the EIA should be planned to meet the needs of the country 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 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 for greater use of herbicides.

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 will be valuable to provide a working format for an EIA as a proposal to country regulatory agencies that can then be adapted to the specific need of agencies and the case-by-case risk assessment nature of each unique proposed biotechnology. Formats for the USA and EU environmental documentation are provided in the following two websites:
USA NEPA format:
http://www.nepa.gov/nepa/regs/ceq/toc_ceq.htm
EU format http://ec.europa.eu/environment/eia/home.htm

Participants in the development of this Protocol guidance are requested to review these and other environmental impact assessment formats and provide comments and recommendations for their modification and use to meet the regulatory needs for the new crop pest and human disease control biotechnologies.

Examples of 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, it 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 released into the environment.