June 10, 2003

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Dear Ms. Stancic,

In response to your requests for comments regarding an analysis of the implications, including advantages and disadvantages, of possible legally binding options, Biotechnology Industry Organization appreciates the opportunity to offer the following thoughts. The Biotechnology Industry Organization (BIO) represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

Ascertaining the Need for Action

As a number of countries with experience in the field of biosafety, decision making and public participation indicated at the April 9-11 meeting of the Working Group (WG-1) before considering in detail which solution might be most appropriate (amending the Convention, negotiating a separate Protocol on public participation for GMO decision making, etc.), *one must identify the problem for which a solution is sought*.

In preliminary discussions at WG-1 to identify the "needs" of countries for a legally binding international approach to public participation in decision making on GMOs, only a handful of NIS countries identified any "need" at all. As was pointed out by France and others, the "need" they were describing was for the development of national biosafety regulatory systems. Without a regulatory system in place (even if it is nothing more than simple implementing legislation that allows the country to utilize the procedures set forth in the Cartagena Protocol), informed decision making cannot take place. Obviously

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public information and awareness and especially public participation of any kind is dependent upon the existence of a regulatory system.

The NIS countries that identified a need for action under Aarhus appeared to be in search of an international legal mandate that would force action at home. If these and other countries have or intend to ratify the Aarhus Convention or the Cartagena Protocol, however, they already have what they need:

1) Article 6(11) of the Aarhus Convention already mandates that "Each Party shall … apply, to the extent feasible and appropriate, provisions of this article to decisions on whether to permit the deliberate release of genetically modified organisms into the environment." The legal compulsion is already there: it is merely left up to the discretion of countries as to how they wish to implement this obligation.

2) Article 23 of the Cartagena Protocol also states very clearly that Parties shall:

- "Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health." see Art. 23.1(a); and
- "In accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information …" see Art. 23.2.

Given these legal instruments and mandates, the private sector believes that the "solution" lies in capacity building. Having yet more international instruments and obligations will only add to the enormous burden already faced by countries that have no biosafety regulatory systems in place (and yet are ratifying these legal instruments even though unable to implement them at the present time) and will certainly not solve their identified "problem." Indeed, countries should be aware of the legal obligations entailed in signing and ratifying any international instrument: they must not only intend to implement the obligations but must in fact do so or they will find themselves in violation of their international obligations and with a bigger problem on their hands.

Ongoing Capacity Building Initiatives

We offer the following information in the hopes that those countries that lack biosafety regulatory systems will be able to take full advantage of ongoing capacity building programs and initiatives.

Building capacity in biosafety at the national and regional level is considered a critical element in the implementation of the Cartagena Protocol on Biosafety (BSP). Article 22

provides that the Parties will assist developing countries to build the human resources and institutional capacity needed to implement BSP requirements.

In order to move ahead on implementation, and in compliance with Article 22, the Intergovernmental Committee on the Cartagena Protocol (ICCP) endorsed an Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biodiversity. At its third meeting, the ICCP recommended a coordinating mechanism for implementation of the capacity-building action plan that consists of the following elements[1]:

1. *A regionally-balanced liaison group on capacity building for biosafety:* This shall be established by the Executive Secretary to provide expert advice to the Secretariat and the intergovernmental Committee for the Cartagena Protocol on Biosafety/Conference of the Parties serving as the meeting of the Parties on ways and means to enhance the coordination and effective implementation of the Action Plan.

2. *The biosafety capacity-building projects database:* The projects database currently maintained by the Secretariat on the Biosafety Clearing-House shall be strengthened and kept up-to-date to facilitate coordination and exchange of information, and also to serve as a tool for identifying the coverage, overlaps and gaps in the capacity-building activities and funding by different organizations.

3. *An information sharing and networking mechanism:* An information sharing mechanism (including, an e-mail list-server) shall be established to facilitate regular and timely exchange of information and lessons learned between individuals in different countries, relevant organizations and donor agencies involved in promoting biosafety capacity-building. In addition, the Secretariat shall collaborate with the ad-hoc Inter-Agency Network for Safety in Biotechnology (IANB), coordinated by the Organisation for Economic Co-operation and Development, in promoting regular interaction and networking.

4. *Coordination meetings and workshops:* Periodic coordination meetings, workshops or roundtables for government representatives, relevant organizations and donors agencies shall be organized on a regular basis, to promote dialogue, identify and promote synergies, encourage partnerships,

[1] from Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety, Annex 1:Coordinating Mechanism for the Implementation of the Action Plan on Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety

address emerging common issues, promote greater understanding of evolving capacity needs of countries and encourage mutually supportive strategies across organizations involved in capacity-building for biosafety.

5. *Reporting mechanism:* A central reporting mechanism, using existing databases, for major capacity-building projects and other initiatives using a uniform format, for example, a central portal or database linked to relevant national, regional or institutional nodes/databases, shall be established to facilitate the identification of the coverage, progress and impact made, and major gaps, on the basis of the information received. The projects database maintained under the Biosafety Clearing-House shall be expanded and resourced to play this role.

In line with the ICCP Action Plan, a number of major capacity building projects are now well underway. These include, most notably, the UNEP-GEF Project on Development of National Biosafety Frameworks and the GEF pilot Implementation Projects. Extensive initiatives by the European Union and its Member States as well as other donor countries with experience in biosafety also are operating and may help to meet the needs of countries in the NIS and other regions.

The users and developers of biotechnology fully support biosafety capacity building and through various partnerships has been and will continue to be active in these and other capacity building activities. We also are supportive of the aims expressed in Rio Principle 10 and look forward to participating more actively in the Aarhus Convention's Working Group on Genetically Modified Organisms in the coming months.

Sincerely,

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Vice President
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Biotechnology Industry Organization