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BIOSAFETY PROTOCOL

IMPLEMENTATION MECHANISMS FOR INFORMATION SHARING UNDER A PROTOCOL ON BIOSAFETY UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY

Summary

The development of a Biosafety Protocol is likely to have a number of requirements for information transfer and sharing. Two main categories of information are identified, publicly available information; and information (related to AIA) for exchange among the Parties. The document reviews the international information sharing systems focusing on biosafety information with a view to identifying possible synergies and opportunity that could be of benefit in meeting the objectives of information sharing under a Protocol on Biosafety.

Background

1. The Convention on Biological Diversity identifies information sharing as an important element in its implementation. Information sharing has several aspects that differ according to which Article of the Convention is under consideration. Article 13, Public Education and Awareness, and Article 17, Exchange of Information specifically relate to information transfer, but in addition Article 18, Technical and Scientific Cooperation , and Article 19, Handling of Biotechnology and Distribution of its Benefits, also refer to the needs for information sharing. Article 18 calls upon Parties to establish a "clearing house mechanism" to promote and facilitate technical and scientific cooperation. This directly relates to the requirements under Article 17 for the exchange of information from all publicly available sources.

2. The development of a biosafety protocol under the Convention will result in specific requirements for information transfer and sharing that can impact

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on Parties. Parties have placed a high priority on the development of a Protocol both in time and in effectiveness. A mechanism to implement such a protocol, and to establish its effectiveness and compliance with the requirements, demands a highly efficient information transfer system. In addition, there is a need for information to be available to Parties and the public, on the science, status and activities that are undertaken with respect to biosafety under the Convention. There are therefore at least two elements to be considered in the development of an information sharing system under a Protocol, a) sharing of public information access to which can assist in building public awareness and in capacity building; and b) information sharing between Parties that will allow for effective implementation of the protocol, and that will also assist in capacity building in terms of national capacity to implement and to utilise the protocol.

3. At the Second Meeting of the Ad Hoc Working group many Parties identified Information sharing as an essential element in the development and implementation of an effective Protocol on Biosafety.

4. The Parties also recognized the differing character of information sharing as it related to public available information as related to the need for an information sharing system for the Advanced Informed Agreement (AIA) component of a Protocol on Biosafety. This would involve information sharing among Parties , with possible need for certain elements of confidentiality and the need for transparency between Parties in terms of decision making, results and actions undertaken with respect to LMO's under AIA.

5. Many delegates referred to the need to examine and consider the use of existing mechanisms for information transfer and determine if these mechanisms could be used either directly, or as a basis for any information transfer mechanism under a Protocol.

6. Requirements:

a) Public available information from:

i. Parties;
ii.Industry;
iii.NGO's;
iv.research institutes.

b) Interparty non-public available information:

i. releases;
ii.notifications;
iii.commercialization;
iv.regulatory actions;
v. risk assessments;
vi.risk management plans.

c) Confidential information;

d) Validation of information;

e) Compliance monitoring.

7. There is a clear need to separate the information that could be provided under the generic "clearing house scheme", that can usefully facilitate the development of public awareness and some aspects of capacity building, e.g. exchange of scientific information, from the information pertaining to Party to Party interactions relating to Advanced Informed Agreement. Decisions will need to be made on what information under AIA should be made available to the public and in what form. There is no possibility that information in the general "clearing house", other than that provided by national authorities, can be validated by either national or international bodies . However, there is a critical need for information with respect to AIA to come from national authorities since this information will have a significant impact on any future revisions to the protocol or implementation of the protocol.

8. Information is only useful under certain conditions, i) that it is Valid, ii) that it is comprehensible or in a context where it makes sense, iii) that it is comparable. Regarding biosafety, it is expected that there will be many sources of information on a wide range of topics, ranging from research results from academia, non-government sources, government and industry; analyses of decisions, legislative and regulatory text, information on contact points and competent authorities, information on releases and regulatory status of LMO's.

Existing Information Sharing Systems:

9. A review of existing information sharing systems must be placed in the context of optional forms of the final protocol, and must include an analysis of the ability of the existing system to handle the requirements of a final protocol.

10. Three such international information sharing systems have been developed, the biotechnology tracking system (BioTrack) developed and managed by the OECD; the Biotechnology Information Network and (BINAS) developed by UNIDO and the International Registry on Biosafety (IRB) developed by UNEP. Under a collaborative agreement Unido and OECD are working together towards a common information resource. A joint page "BIOBIN" helps navigating between OECD's "BIOTRACKon Line" and UNIDO's BINAS. It should be noted that, although the systems are linked, they are not directly compatible in that each system is maintained through the host organization, and each has different modalities, and procedures.

BioTrack (http://www.oecd.org/ehs/service.htm):

11. The BioTrack system is an OECD on-line world wide web site on the internet which also includes databases. It provides information on the regulation of biotechnology in the 29 OECD Member countries and on the work of the OECD in biotechnology. The system is based on voluntary provision of information by countries through a national coordinator identified by each Member country. The majority of the information on the site is publicly available.

12. The information provided by member countries is in three parts the first provides details of major regulatory developments including laws, regulations/guidance instruments, regulatory authorities. The second data set is information on commercialized products, and the third dataset is the database on field trials of transgenic organisms. The information is organized by country with access to the information through a country flag icon.

13. A critical element in the BioTrack system is the validation of information placed on the site by the OECD, through an expert group of delegates from Member countries. This is best exemplified by the consensus documents on modified plants and micro-organisms. These documents are generated by Member countries and are reviewed by the expert group prior to derestriction and addition to the web site.

14. The information is provided to the OECD through a group of national coordinators, most of whom are government officials from national regulatory ministries/agencies. A recent development is the inclusion on BioTrack of a

"password protected area" which contains information restricted to individuals nominated by governments.

BINAS (http://binas.unido.org/binas/):

15. The Biosafety Information Network and Advisory Service (BINAS) has been developed by the United Nations Industrial Development Organization (UNIDO). BINAS contains information on regulatory developments in countries which includes, in many cases, full texts of national laws and regulations related to biotechnology. BINAS covers a broader scope of countries than the OECD. The data base also provides details on a number of BINAS projects, a list of national contacts and an on-line biotechnology library. The BINAS system is also a voluntary initiative that provides a venue for governments to make available information germane to national approaches. Information on the BINAS system is also provided through national focal points, but much of the work of placing the information on the site is performed by UNIDO staff. The voluntary nature of data submission by the assigned national contacts is a limiting factor with regard to the administration of the system

16. Biosafety information is only part of the information available at the BINAS site, more extensive economic and industrial information is available.

Information sharing and information transfer:

17. The specific requirements for information transfer and sharing under both the Convention and the Biosafety protocol are still in the formative stages, and will more precisely defined as the development of the protocol proceeds. There are however some clear options that can be considered. Information sharing can be considered in three parts,

Voluntary:

18. This type of sharing fulfills the requirement under a "clearing house" mechanism according to Articles 17 and 18 (3) of the Convention. All information of this type is publicly available and will assist in promoting international technical and scientific cooperation, improving public awareness, building capacity in countries through making available information on both national and international initiatives in biotechnology. Three sources of information are generally available i) government sources of such information as laws and regulations, policies and activities; ii) information from non-government sources such as the industry, academia and public interest groups; and iii) scientific information on research.

19. Both BioTrack and BINAS operate on this level, where the information is provided to the organization from specified government sources. With the exception of OECD documents such as the consensus documents on modified organisms, the information provided is not subject to review within the organization and the OECD only provide an electronic pointer to the site.

Publicly Available Information:

20. The volume of publicly available information on biosafety and related topics is extremely large and is growing at a fast rate. The most useful mechanism to make this information generally available is to use the electronic media, or the Internet. All three existing international systems could facilitate the exchange of publicly available information, and currently do so to a greater or lesser extent. A common feature of these systems is the use of two tracks of information. Track 1 is the information placed onto

national web sites by the competent authority(s) of each Member country, over which the "system manager" (i.e. OECD, UNIDO or UNEP) has no control. Track 2 is the information to go onto the site controlled by the system manager, an example of this is the "field trials" data base on the OECD BioTrack system this information is provided to the system manager by a national coordinator for each member state. Another common feature of these systems is that they are all voluntary, the only information available is what member states provide to either their national site, or to the system.

21. A significant characteristic of each site is the architecture or structure of the site. As the volume of available information increases the ability of the general public, or Parties, to access relevant information for their needs will be dependent on the architecture of the site. Clearly it would be beneficial if all sites were designed with a similar architectural features, as well as compatible formats. This will permit ease of access and rapid searches of the databases.

22. The OECD and UNIDO have collaborated for some years on developing a common format and structure (the BIOBIN) and it is recommended that this initiative be further pursued.

23. Use of this system, or a similar system does have specific requirements beginning with dedicated focal points and national coordinators responsible for information flow into the biosafety page on the national site, and for information flow to the system manager.

Party to Party and Confidential Information:

24. Depending on the outcome of the negotiations, there will be a need for information sharing between parties that would not be publicly available. These requirements are outside of the "clearing house mechanism" , but would form a sub-category of information transfer that should utilize the same mechanism as clearing house to prevent duplication and to ensure coordination among Parties. Several options are available, but the critical element is the need to make available to Parties decisions, and the rational for each decision, under the AIA procedures. This will fulfill two requirements under a protocol; a) compliance with, and monitoring of, the operation of the protocol, and, b) permit rapid evaluation of the effectiveness of the protocol and provide the basis for review and modifications of requirements under the protocol where warranted.

Regional web sites

25. A difficulty that has emerged in consultation with member countries both as providers of information to the available international systems (Biotrack and BINAS) and as users (access) to the information is access to the internet, and the ability to ensure input of validated data by designated national authorities. Data validation and input is the rate limiting step and internet accessibility is the rate limiting component of the technology. Parties may wish to consider the feasibility of establishing regional centres where access to the internet and data input is provided on a regional or sub-regional basis. There is no technological reason to limit the information sharing system to a national, regional or global design. Centralized repositories can reduce administrative problems and costs provided the system

is designed to accommodate individual national sites within the same server system.

Recommendations:

26. The mechanism for sharing of publicly available information under the biosafety protocol should be designed to build on and best utilize the already available systems, such as BioTrack and BINAS.

27. Publicly available information should be placed on a world wide web site established by and managed by the national authority.

28. Parties should identify a national coordinator for information sharing under the biosafety protocol that is separate and independent of the focal point for the Convention. The national coordinator would be best sited within the competent authority for biosafety.

29. Similar to the structure for both BioTrack and BINAS, the national coordinator will have ultimate responsibility for the information that is placed on the site.

30. A common format and architecture for national web sites for biosafety should be designed and implemented. This architecture should clearly separate elements that are government generated, public generated, legislation and policies, and data bases.

31. Under this proposal, biosafety information will be accessed through the CBD Biosafety web site through a linked system to national sites managed and controlled by national coordinators. Currently there are national coordinators identified for both OECD and UNIDO systems. The coordinates for National Coordinators are available on the Web Site for each organisation.

32. Information will be placed on national sites by the national coordinator. This will require that Parties provide for the following:

a) A server system with access to the internet;

b) Training for a national coordinator in data control, and internet management.

Both of these activities could be initiated through the enabling provisions of the GEF at both the national or regional level.

33. Each of the organizations with activities on information sharing on biosafety has established a list of national coordinators for the sites they manage. The Convention Secretariat would be the fourth such international organization. Analysis of the national coordinators for the member countries of each organization indicates that there is no overlap, and that between OECD (BioTrack), UNIDO (BINAS) and UNEP (IRB) some 120 of the 168 countries that have ratified the Convention have identified national coordinators.

34. Clearly it would benefit efficiency and coordination and the national systems if the same coordinator could be identified for all activities on information sharing under biosafety. It is recommended that member countries consult and identify, for the purposes of information sharing under all systems, a single coordinator

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