India's preliminary views in preparation for ICNP-1

(i) Modalities of Operation of the Access and Benefit Sharing Clearing House

The Biosafety Clearing House (BCH) presents a valuable precedent for the ABS Clearing House. In this regard, it would be important to take on board the various critiques and assessments of the BCH as has been documented since 2009. One of the criticisms of the BCH for instance has been its lack of a strong user interface. The BCH by its very nature demanded a higher degree of complex technical as well as confidential business information, and understanding this information has been one of the major criticisms. In contrast, the ABS Clearing House may be a simpler proposition to put in place, since the level of technical information required may be lesser. Any recommendations would also have to consider the ease with which Parties and others would be able to comply with such requirements as providers as well as users.

An important aspect in the ABS Clearing House is clear information on legislative, administrative and policy measures on access and benefit sharing. A few important aspects that need to be flagged are as follows:

- A user-friendly interface and a tool-kit that can have multiple search options, is material for any effective functioning of the clearing-house.
- It is not sufficient, therefore for texts of laws themselves to be submitted by parties. Instead parties should be asked to explain the various steps involved- such as the applicable rules, forms to be filled, authorities to be approached, timelines, etc.
- Measures for access both in respect of in-situ and ex-situ collections would need to be clearly identified.
- Language related requirements would also need to be addressed in order to ensure that accurate translations of all laws, regulations and administrative measures are available.
- It is also important to assess whether or not the ABS Clearing House can play a more active role than just being a repository of information. For instance, could the operational modalities envisage a role for the ABS-CH which entails that once a patent office in a CBD member receives an application involving a patent, the information could be immediately sent to the ABS-CH which can access the relevant regulatory information on the country from which the resource has been accessed. The important aspect to bear in view if this system is built into the ABS-CH, the role of the ABS-CH should be clearly specified as one only relevant for providing relevant information, and should

not in any way dilute the responsibility of the concerned patent office to make its more detailed assessment.

- Adequate budgeting and sources of funding would need to be worked on in order to ensure the robust functioning of the system.
- Other network information centres would need to be studied and investigated more thoroughly. The experience of the ITPGFRA, and Consultative Group on International Agricultural Research (CGIAR) is cited, for instance, as a framework that could be used as a valuable example. The CGIAR's role is envisaged to be wider- as an institute that actively engages in research and diffusion of results of the research. The CGIAR's functioning could however provide insights.
- Institutional factors would ultimately determine the effectiveness of the ABS-CH.

(ii) Measures to assist in the Capacity-Building, Capacity Development and Strengthening of Human Resources and Institutional Capacity in Developing Countries

(iii) Measures to raise awareness

(iv) Cooperative procedures and institutional mechanisms

As discussed under point (i) above, a strong institutional framework for the ABS-CH would be necessary for ensuring the nature of measures it could undertake in capacity building and institutional capacity building in developing countries.

If the ABS-CH were to be envisaged as performing the role as envisaged above, this would indicate that it is not merely a 'clearing house', but that it has a crucial role as a knowledge centre that can perform functions relating to human resource development, institutional capacity building etc. Such an objective can be said to be implicit in the idea of a clearing house under Article 18.3 of the CBD, which provides the basis for Article 14 of the Nagoya Protocol on the ABS-CH.

Also, in keeping with the purpose of ABS and PIC requirements, any capacity building and capacity development activity cannot also be confined to governmental actors, but should also address commercial entities which would be seeking access to genetic resources.

Some of the aspects which merit consideration include:

- Dedicated technical staff for ABS-CH
- To conduct capacity building, information sharing, and knowledge generation activities based on requests expressed by member countries.

- Facilitate exchange of best practices among countries on legislation and policies, data reporting.
- Specialized seminars, targeted training sessions aimed at both at Government actors as well as private sector.
- Electronic discussion forum to strengthen capacities and share perspectives.
- Periodic meetings for review exercises.

India's Experience relating to Biosafety Clearing House

Background

In accordance with Article 20 of Biosafety Protocol, all Parties are required to put in place a Biosafety Clearing-House Mechanism to comply with the information sharing obligations. The main objective of BCH is to facilitate the exchange of scientific, technical, environmental, experimental and legal information on LMOs and to assist Parties to implement the Protocol, BCH comprises a Central Portal and a distributed network of national components to assist Parties to fulfill obligation under the protocol. BCH is an important tool for verification as also to obtain relevant information and keep abreast with new developments. The Central Portal may be seen at http://bch.biodiv.org/

The following information may be sourced from the BCH :

- access to information regarding competent National Authorities, NFPs, domestic laws and regulations
- summaries of risk assessment conducted under the protocol and links to more details of those assessments
- access to information on decisions taken by the Parties regarding the use of LMOs for contained use/ FFP/Intentional release either through import or domestically produced.
- access to information on capacity building initiatives and opportunities for participation in such initiatives
- access to a search mechanism for experts on biosafety on a roster.

The important stakeholders include Members of National Biosafety Committees, Civil Society Organizations (CSOs), Customs Officers, Emergency Points of contact under Article17, Members of Farmers Associations, Industry representatives, Media representatives, Members of expert NBCs, National Focal Points for the CPB, National Focal Points for the BCH, National Authorized Users from Competent National Authorities, Parliamentarians and their researches, Participants in previous BCH workshops, Phytosanitary officers, Regional advisors, Representatives of relevant UN agencies and bodies, Scientists, Members of Seed associations, University students and University professors.

a. Administrative Compliance: Setting up National BCH

In accordance with the requirement under Article 20 of CPB, a National BCH Portal was set up as part of the Phase-I Capacity Building Project on Biosafety. At the time of setting up the National BCH, four options namely, (1) Register data in the central portal using the Management Centre, (2) Register data locally using database templates and send data to the Central portal, (3) Make data available through a local website and allow the central portal to crawl to retrieve metadata, (4) Store data on national BCH databases, and actively make those data available through the central portal using BCH interoperability protocols. India had opted for option No.3 wherein the relevant information could be posted on the National BCH and periodically the Central Portal would retrieve the met data. However, due to security reasons an open-ended access from the NIC website was not available and therefore inter-operatability between the National BCH and CBD Central portal was not functional.

This constraint was not initially envisaged during the pilot phase of the BCH. Subsequently, many Parties have expressed difficulties in making their data base inter-operable with the BCH. Several countries had also complained that the BCH was not user-friendly and had recommended data-base re-organisation through refined search options and option for grouping of information.

Subsequently, to meet the specific needs of the Parties and make it user-friendly, the Central BCH Portal has been revamped to include two applications, namely, Hermes and the BCH Ajax plug-in. Recently, while revamping the National GEAC website, it has been decided to dispense with the National BCH and opt for direct online submission of information through the central portal using Hermes.

Therefore lack of compliance can be attributed to initial start-up problem which was not envisaged during the pilot phase.

b. Technical Compliance : Sharing of relevant information

While India has complied with the requirement for notification of competent authorities, National Focal Points, Biosafety Laws, Regulations, Guidelines, Risk assessment and Country decision for commercialization of Bt Cotton and Capacity building. However, compliance with respect to notification of Risk Assessment Summaries related to GM crops approved for field trials, rooster of experts Unique Identifier Code and updation of capacity building needs is not satisfactory.

The main constraints identified in complying with the above requirement include:

- Lack of clarity on whether GM crops under confined field trials with appropriate isolation distance, etc. are considered as environmental release. It has only recently been clarified that confined field trials are equated with environmental release even if they are grown in confined conditions and therefore summaries of risk assessment in such cases is mandatory. This has created an extensive backlog.
- Lack of clarity in implementation of several Articles of the CPB (Article 18 2(a)).
- Lack of dedicated manpower for collection and compilation of the highly technical information by interacting with all the relevant national agencies/ institutions for updating the contents of the BCH.
- Modalities for verification of information is absent in most of the countries.
- Lack of guidance for designation of Unique Identifier Code for transgenic plants.
- Notification of Rooster of Experts: Luke warm response from institutions / experts in submitting information as the proforma for Rooster of Experts is extremely cumbersome.

c. Constraints in optimizing the effective use of BCH

While the BCH Central Portal is user friendly for Scientists and Regulators, several target groups find it difficult to use without training. Some of the main constraints identified in the effective use of BCH by various stakeholders is listed below**:**

- Lack of awareness among stakeholders.
- Staff attrition and turnover rate of Government officials especially customs, plant quarantine, etc. which leads of loss of institutional memory.

- Lack of effective monitoring of implementing of CPB obligations.
- Use of BCH is a low national priority for regulatory purpose in view of the country specific data requirements, prescribed under the domestic law.
- Biosafety is a low national priority
- Lack of quality and accuracy of the information, e.g. The Republic of South Korea website indicated that they have been importing GM Maize from India. It was only during a participation in the BCH workshop this discrepancy was noted while the representative of Korea made the presentation.

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