UNITED STATES OF AMERICA [25 SEPTEMBER 2003]
[SUBMISSION: ENGLISH]

Views of the United States on information sharing

The United States wishes to emphasize its continued commitment to making United States biosafety information available to the Biosafety Clearing-House to support the needs of Governments. The United States intends to make information available to the Biosafety to share our experience in regulating LMOs, to facilitate transboundary movement of LMOs, and to support science-based decision-making.

We have previously shared with the Secretariat our experiences in establishing our national biosafety database, first at the Montreal meeting of the Liaison Group of Technical Experts on the Biosafety Clearing-House (10 and 11 April 2003) and then more recently at the technical meeting held in Geneva on 29 and 30 September on implementation of the Biosafety Clearing-House in industrialized countries.

We look forward to continuing to make United States information available through the Biosafety Clearing-House and will work closely with the Secretariat to establish interoperability between the United States website and the international Biosafety Clearing-House.

The United States website unifies the data from the three Federal agencies (United States Department of Agriculture, United States Environmental Protection Agency and United States Food and Drug Administration) responsible for regulating LMOs in the United States. The United States Government developed a number of fundamental components in setting up its own Biotechnology Regulatory Website that we firmly believe would optimize the opportunities for information sharing with the international Biosafety Clearing-House. They include:

- Distributed networks of interoperable databases where owners of the data remain the custodians and are responsible for its upkeep.
- Common formats that are consistent with the types of data fields used by experienced regulators, and that are flexible enough to reflect accurately the various types of regulatory structures used by different countries.
- Searchable databases that take into account the needs of intended users.
- Unique identifiers for transgenic plant lines based on OECD guidelines to allow access to the regulatory information about that specific plant line.

The United States commends the Secretariat for its successful development of the Pilot Phase of the Biosafety Clearing-House, which we regard as a critical element for the successful implementation of the Protocol. We have continued to support cooperation with the OECD Product Database during the Pilot Phase. To create a fully functional Biosafety Clearing-House, the United States believes that particular attention should be paid to the feedback from government users of the Biosafety Clearing-House, with priority placed on the categories of information that regulatory bodies provide.

Finally, if the Biosafety Clearing-House is to be wholly successful, then the roles and responsibilities of the National Focal Point (NFP) for the Biosafety Clearing-House need to be carefully defined. We seek to ensure that this does not become a burdensome requirement for any Government. To that end, the United States intends to supply certain data through direct, secure electronic arrangements. This information should not need verification by the NFP once the authenticity of the source has been established.