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# INTERNATIONAL HARMONISATION OF BIOTECHNOLOGY REGULATORY POLICIES: ROLE OF USDA, APHIS[1]

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## ABSTRACT

**The United States Department of Agriculture (USDA) and Animal and Plant Health Inspection Service (APHIS) have played a pioneering role in establishing and promoting international harmonisation of biotechnology regulatory policies. USDA and APHIS have developed data sets for assessment of transgenic plants before commercial release, and standards of review for environmental risk assessment. APHIS, through the world wide web, is now providing instant information on field tests and biotechnology regulatory programmes.**

***Key Words*: Biosafety assessment, commericialisation, environment risk assessment, field tests, transgenic plants**

## RÉSUMÉ

**Le Département d'Agriculture des Etats-Unis d'Amérique (USDA) et le Service d'Inspection de Santé Végétale et Animale (APHIS) ont joué un rôle pionnier d'établir et de promouvoir l'harmonisation internationale des politiques réglémentaires de la biotechnologie . L'USDA et l'APHIS ont développé de jeux des données pour l'évaluation des plantes transgéniques avant la diffusion commerciale, et les standards de revue pour l'évaluation des risques d'environnement. L'APHIS, à travers le "world wide web" rend maintenant disponible l'information immédiate sur les essais aux champs et les programmes de réglement biotechnologique.**

***Mots Clés*: Evaluation de la biosécurité, commercialisation, évaluation de risque d'environnement, essais en champs, plantes transgéniques**

International harmonisation was a phrase first used in the biotechnology regulatory context, in 1988 by Terry L. Medley, the then director of the Biotechnology, Biologies, and Environmental Protection (BBEP) Programme of the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS). Under his leadership, APHIS has clearly led the world biotechnology community towards achieving such a goal by laying emphasis on the scientific principles on which biotechnology regulatory policies needed to be developed and adapted. APHIS has always been sensitive to recognising the sovereignty of each country in writing biosafety and environmental laws pertinent to the release of genetically engineered organisms

[1]*The contents of this article are meant for information purposes only, and should not be taken as an official policy document of USDA, APHIS.*

into the environment. APHIS, in collaboration with the European Union, Organisation for Economic Cooperation and Development (OECD), and by either sponsoring biosafety workshops, scientific meetings, lending the professional expertise of APHIS biotechnologists, or making available field tests database, has contributed immensely towards education, and promotion of international harmonisation of biotechnology policy activities.

International harmonisation is critically important for APHIS and other leading biotechnologically advanced countries as several products of agricultural biotechnology will be entering the market place through commercialisation. A key effort it has undertaken is to ensure that these products can enter the market place or export markets without the imposition of undue regulatory burdens. APHIS is working on several fronts to bring about international harmonisation of regulatory approaches for the products of agricultural biotechnology:

- APHIS has ongoing bilateral environmental consultations with the Commission of the European union, and they have established a permanent technical Working Group on Biotechnology and the Environment. The Group has drafted a letter of intent to develop mutually acceptable, specific data sets to be used in the assessment of transgenic plants prior to commercial release into the environment.
- Under the auspices of the OECD Environment and Agriculture Directorates, the United States has taken the lead in a project on the Commercialization of Agricultural Products Derived Through Modern Biotechnology. The aims of this project are to assist member countries in their efforts to ensure safety, to make oversight policies more transparent, and to facilitate trade. The project was initiated with a questionnaire, completed in 1994, which surveyed the regulatory approaches and data considered by participating countries in the evaluation of these products. A conference held in Washington, D.C. in June 1994, brought together regulatory officials involved in assuring environmental biosafety, food safety, and seed certification from member countries and others participating in OECD Schemes for seed certification; Information was exchanged on relevant considerations in reviews under each of the product review sectors. The project is continuing in several directions, which together are aimed at the goals of harmonisation and mutual acceptance of data and assessment, i.e., the development of "generic answers" for particular environmental biosafety related questions that may be useful to regulatory officials; Ongoing discussion of regulatory considerations and approaches for particular case study organisms (such as delayed softening tomato or herbicide tolerant canola) or classes of organisms (such as virus resistant crops); Discussions to ensure efficient coordination between product review sectors concerned with product safety and those concerned with seed certification and varietal registration.
- Informal meetings have been held with representatives of the Commission of European Union to discuss developments of the European policy relating to commercialisation of, and trade in, new agricultural commodities.
- Regular meetings continue to be held with Canada and Mexico to address safety issues relevant to biotechnology that are under regulatory review or already approved in one of the three nations, and to facilitate trade in these products.
- APHIS participated in the OECD project on Biotechnology for a clean Environment. A report was completed in 1994 highlighting technological developments involving the use of living organisms for the detection, prevention, and bioremediation of pollution problems. A follow up activity in which APHIS participated in December 1994 in Tokyo, Japan, addressed the technical aspects of bioremediation progress worldwide as well as broader efforts to use living organisms to address global environmental issues such as the build up of greenhouse gases.
- APHIS continues to be an active participant in discussions by the Conference of Parties to the Convention on Biological Diversity, working to ensure that appropriate policies are agreed upon to guarantee the safe international use and development of new products derived through biotechnology.

- APHIS has either organised or sponsored more than a dozen international crop specific biosafety consultations or workshops to develop science based guidelines or practices to field test genetically engineered organisms (crops specifically). The recommendations from these scientific consultations have been extremely valuable to scientists and biotechnology regulators alike all over the world, and have clearly set a standard for regulatory review.

APHIS firmly believes in developing a worldwide biotechnology regulatory policy that is based on scientifically based risk assessment of biotechnology products, and standards of review for environmental risk assessment that are mutually acceptable. To that end, APHIS has always made available its resources in terms of experience of overseeing more than four thousand field tests, and its database. Recently APHIS opened a home page on the worldwide web to make available on a daily basis, all the field test permitting and monitoring activity, and any other developments in its regulatory policies and regulations so that the entire world can get instant access to its biotechnology regulatory programmes. APHIS believes that biosafety assessment and environmental assessment are critical factors in product certification leading to safe technology transfer, and technology assessment leading to commercialisation.

It is important for all the countries of the world to participate in the international harmonisation of biotechnology regulatory polices that is solely based on scientifically well characterized risks, and conduct biosafety and environmental safety reviews with mutually acceptable standards and methodology for risk assessment and management. Such an approach would pave way for technology transfer, and expansion of the market potential in the present day world that is headed toward a global market in the post GATT era.