

THE QUEST FOR HARMONISATION OF REGULATORY OVERSIGHT FOR BIOTECHNOLOGY: THE ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD) EXPERIENCE

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ABSTRACT

In the 1980s, the guidelines, rules and regulations on biosafety in the Organisation for Economic Cooperation and Development (OECD) countries were based on the best available scientific knowledge, but were allowed sufficient flexibility to adapt to new knowledge. At present, when products of modern biotechnology are reaching commercialisation, additional emphasis has been placed on harmonisation and trade issues. Thus the project on the "Commercialisation of Agricultural Products Derived Through Modern Biotechnology" was initiated to make oversight policies that are transparent and efficient in the facilitation of trade of modern biotechnology products. In this paper, the present and future activities of the project are briefly discussed.

Key Words: Biosafety, biotechnology, commercialisation, trade

RÉSUMÉ

Pendant les années 1980, les directives, les règles et les règlements sur la biosécurité dans les pays de l'OECD étaient basés sur les meilleures connaissances disponibles, mais ils étaient assez souples pour s'adapter à une nouvelle connaissance. Actuellement, comme les produits de la biotechnologie moderne atteignent la commercialisation, un accent supplémentaire est mis sur l'harmonisation et les sujets de commerce. Ainsi le projet sur la "Commercialisation des Produits Agricoles dérivés de la Biotechnologie Moderne" a été lancé en vue de formuler, du jour au lendemain, des politiques transparentes et efficaces quant à la facilitation du commerce des produits de la biotechnologie moderne. Dans ce papier, les activités actuelles et futures du projet sont brièvement discutées.

Mots Clés: Biosécurité, biotechnologie, commercialisation, commerce

INTRODUCTION

Biotechnological innovation is playing a significant and growing role in addressing health, environmental and agricultural issues in the 1990s. Many products of biotechnology will be commercially viable in this decade. In a recent Organisation for Economic Cooperation and

Development (OECD) survey on agricultural products derived through modern biotechnology, authorisations for field testing for more than 36 types of genetically-modified crop plants have been given (OECD, 1995a).

In order to ensure the safe use of modern biotechnology and to address public concerns with respect to environmental health and safety,

countries have developed, or are in the course of developing, regulatory oversight systems for the application of this technology. These regulatory oversight systems allow for the production of data to adequately assess the safety of the products. The institution of different types of regulatory systems in the various member countries presents issues in international trade.

In light of its experience with addressing similar harmonisation of regulatory oversight systems for industrial chemicals and pesticides, the OECD can play an important role in the harmonisation in biotechnology, in order to contribute to its safe applications and to avoid future trade barriers. Such an effort would aid in further development and public acceptance of this technology. In addition, harmonised structures would help to avoid duplicative work for industry and governments in the preparation and assessment of products.

ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT

The OECD is an intergovernmental organisation of 25 democratic member countries¹ with advanced market economies. The OECD was established in 1960. Its aims and responsibilities are: achieving the highest sustainable economic growth and employment; promoting economic and social welfare throughout the OECD region by coordinating policies of its member countries; stimulating and harmonising the efforts of member countries in favour of developing countries; and contributing to the expansion of world trade on a multilateral, non-discriminatory basis.

In the OECD, government representatives meet to compare and co-ordinate both domestic and international policies. This provides member countries with the opportunity to discuss critical issues and policy options and to exchange information with the aim of ultimately reaching agreements on coordinated or harmonised policy approaches.

Principal aspects of OECD work include diagnosing current situations and monitoring trends; facilitating discussions among countries and searching for common solutions; collecting and analysing comparative data; and coordinating and harmonising national policies.

The Council is the highest authority of the OECD, consisting of representatives from all member countries. Using a consensus approach, the Council representatives reach various types of agreements. Two most notable are council decisions, which are legally binding, and council recommendations, which are expressions of political will.

The OECD has over 200 specialised committees and subsidiary groups, composed of representatives designated by the governments of member countries. These committees are staffed by the OECD Secretariat which is organised into directorates and divisions.

BIOTECHNOLOGY ACTIVITIES AT OECD

In the area of biotechnology, the Directorate for Science, Technology and Industry was the pioneer in bringing this subject into the international fora. Many of the activities in the 1980s primarily focused on biosafety. One of the first principles defined in this area was that guidelines, rules and regulations are based on the best available scientific knowledge, and they have to be sufficiently flexible to adapt to new knowledge.

From this principle, the group of National Experts on Safety and Regulations in Biotechnology drafted several reports, beginning with the recombinant DNA (rDNA) Safety Considerations (OECD, 1992) which provide general guidelines for the evaluation of rDNA organisms. Several revisions have occurred and the updated version is entitled "Safety Considerations for Biotechnology" (OECD, 1992). Many countries have adopted the general OECD safety principles in concept (OECD, 1993e).

¹The OECD Member countries are: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, United Kingdom and United States of America. The Commission of the European Communities also participates in the work of the organisation.

Work on biosafety has continued with several reports published (OCED, 1993a-d): Safety Considerations for Biotechnology - Scale-up of Crop Plants; Traditional Crop Breeding Practices: A Historical Review; and Field Release of Transgenic Plants, 1986-92. In addition, reports have been developed on food safety and aquaculture.

At present, several OECD Directorates are involved in work on biotechnology issues. This is primarily because of the movement of biotechnology from the research and development stage to the development of a product. The products of biotechnology are so diversified that a sectoral approach was instituted for OECD activities. Currently the Environment Directorate and the Directorate for Food, Agriculture and Fisheries are the most notable participants.

HARMONISATION OF REGULATORY OVERSIGHT

In the 1990s, with many of the products of modern biotechnology reaching commercialisation, much of the focus will be on harmonisation and trade issues, although biosafety will always be a component of any activity. One project that is gaining attention is the "Commercialisation of Agricultural Products Derived Through Modern Biotechnology" (OECD, 1995a, b). This project is under the joint auspices of the Environmental Policy Committee and the Committee on Agriculture.

The focus of this project is on the review of national policies of participating countries with respect to oversight regulation, which will affect the movement of these products into the market place. The goal of the project is to assist member countries in their oversight of agricultural products derived through modern biotechnology, specifically in their efforts to ensure safety, to make oversight policies more transparent and efficient, and to facilitate trade.

The overall objective of this project is to provide a forum for participating countries to improve awareness and understanding of the various oversight/regulatory systems developed for agricultural products of biotechnology; identify similarities and differences in the various approaches; and identify the most appropriate role for OECD in further work towards harmonisation, while avoiding duplication of work done by other fora. Mechanisms for data sharing among participating countries and the development of guidance for the identification and evaluation of appropriate data will be reviewed.

The first phase of the "Commercialisation" project was to distribute a survey to OECD member countries and 16 additional countries² that participate in the OECD Scheme for Varietal Certification of Seeds. It was designed to collect information on countries' current biotechnology oversight/regulatory systems for crop plants. Data requirements for products produced through modern biotechnology and mechanisms for data assessment were also surveyed.

Sixteen OECD member countries and seven countries participating in the OECD Seed Schemes programme responded to the survey³. In the document produced to relay the survey results, information is divided into the major areas of national review: Overview of the Oversight/Regulatory Systems; Environmental Biosafety; Food Safety; and Varietal Registration and Seed Certification. Additional information on the responsible ministries/agencies, list of laws/regulations, field trial authorisations, diagrams of national oversight/regulatory processes and a numerical tally of responses is also included.

Overall, the survey responses provided a picture of the scope of legal frameworks and approaches adopted by the responding countries for the regulation of the products of agricultural biotechnology. The amount of experience in different countries with new agricultural

²The sixteen participating countries are: Argentina, Bulgaria, Chile, Cyprus, Hungary, Israel, Kenya, Morocco, Poland, Czech Republic, Romania, Slovak Republic, South Africa, Tunisia, Uruguay and Zimbabwe.

³Responding countries to the survey include: Australia, Austria, Belgium, Canada, Denmark, France, Germany, Italy, Japan, the Netherlands, New Zealand, Norway, Sweden, Switzerland, United Kingdom, United States, Argentina, Chile, Czech Republic, Hungary, Morocco, Slovak Republic and South Africa.

biotechnology products under development varied widely. Nonetheless, the survey indicated a relatively high degree of similarity in elucidation of relevant data elements considered in national oversight/regulatory systems.

Future work on this project will be divided into three separate areas: environmental biosafety, food safety, and varietal seed certification. Each area will be administered under the appropriate OECD Committee.

The work in the area of environmental biosafety will be oriented toward harmonisation. The identified activities leading to harmonisation include identification of data elements, mutual acceptance of data (including the exchange of assessment reports), and mutual acceptance of assessments

In the area of food safety, harmonisation was also identified as the avenue for future OECD work, recognising the importance of coordinating work with other international organisations, in particular World Health Organisation and, Food and Agriculture Organisation of the United Nations (WHO/FAO), to avoid duplication of effort.

As to varietal seed certification, the development of a "notification" for genetically modified seed was proposed at the annual meeting of the National Designated Authorities for the Implementation of the OECD Seed Certification Schemes (which was held 6-7 June 1994). Further development of this activity will be by the national authorities.

CONCLUSION

As the time when commercialisation of products derived through biotechnology nears, it is essential for national governments to harmonise their approaches to regulatory oversight. This allows for the safe use of the technology and the advancement of trade. These factors ultimately will lead to a realisation of the benefits that this technology has to offer in sustainable agriculture, environmental applications and health care.

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