

Biotechnology and Biosafety in ASEAN

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Work undertaken by the Association of South East Asian Nations (ASEAN) in the area of biotechnology and biosafety is reported, with special emphasis on the developments in the last three years. An increasing interest on the issues involved, including its bearing on public policy and the need to address them regionally, are manifested in the decision of the ASEAN Ministers for Agriculture and Food (AMAF) to adopt a set of harmonized guidelines in agriculture-related genetically modified organisms (GMOs). The methodology to build consensus among the ten member countries of ASEAN is also described. Programs lined up for implementation and future challenges that the region must address are also discussed.

Introduction

The ASEAN Secretariat welcomes the opportunity to participate in the SEAMEO SEARCA Regional Conference on Agricultural Biotechnology. SEAMEO's concerns have been very close to those of ASEAN. We serve the same member countries, and it is but fitting that the two regional organizations cooperate with each other in reaching similar goals for the region.

Not being sure that everyone in the Conference would know what ASEAN is. This presentation has been structured to begin with a brief introduction of the organization, starting with some general matters such as its history and its vision, and then proceed to focus on the topic of concern in this Conference, which is agricultural biotechnology. The presentation will end with a summary of steps being planned by ASEAN in this area, and a discussion of other related issues that the region must address in the near future.

Introducing ASEAN

Adopted in 1967 on the occasion of ASEAN's 30th anniversary, the ASEAN logo represents a stable, peaceful, united, and dynamic ASEAN. The colours of the logo – blue, red, white and yellow – represent the main colours of the crests of all the ASEAN countries.

The blue represents peace and stability. Red depicts courage and dynamism, white shows purity, and yellow symbolizes prosperity. The ten stalks of rice padi represent the dream of ASEAN's Founding Fathers for an ASEAN comprising all the ten countries in Southeast Asia bound together in friendship and solidarity, cooperating voluntarily for the common good, with peace, as well as economic, social and cultural development as its primary purposes.

This dream was enshrined in the ASEAN Declaration, signed in Bangkok in 1967 by 5 founding members, namely Indonesia, Malaysia, the Philippines, Singapore, and Thailand. The Declaration states that:

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“The Association represents the collective will of the nations of Southeast Asia to bind themselves together in friendship and cooperation, and through joint efforts and sacrifice, secure for their peoples and posterity the blessings of peace, freedom, and prosperity.”

Since then, ASEAN has grown into the full 10 member countries, with Brunei Darussalam joining in 1984, Viet Nam in 1995, and Lao PDR and Myanmar in 1997. Cambodia was the last to join, having been admitted to membership only in 1999. The five-year period 1995-1999 marked the fastest rate of expansion during which 4 countries were added to the membership.

The goals of peace, and economic, social and cultural development led to the pursuit of cooperation activities in these areas. These are the political security, economic, and functional areas. For example, in economic cooperation, ASEAN bodies have been established in the sectors of agriculture, trade, transport, energy, tourism, etc., to spearhead regional cooperation in their respective areas of concern. Social and cultural development activities are generally grouped together under the term “functional” cooperation. Science and technology is also included as a functional cooperation area.

ASEAN Vision 2020

In 1997, as it anticipated the dawning of the 21st century, ASEAN's leaders issued ASEAN Vision 2020, which encapsulates the three main long-term goals, succinctly stated as:

“... a concert of Southeast Asian nations, outward looking, living in peace, stability, and prosperity, bonded together in partnership in dynamic development, and in a community of caring societies.”

It is essentially a re-affirmation of the original goals in the Bangkok Declaration. The attainment of the goals of political and security cooperation is captured in the phrase “a concert of Southeast Asian nations”; the goals of economic development in the phrase “partnership in dynamic development” while the social and cultural concerns are captured in the term “a community of caring societies.”

Hanoi Plan of Action, 1999-2004

To realize the goals of ASEAN Vision 2020, a series of action plans will be adopted and implemented. The first of these is the Hanoi Plan of Action, covering the six-year time frame 1999-2004, which would identify 10 priority program areas. Of relevance to the theme of this conference are the programs in food, agriculture and forestry, in environment, and in science and technology.

By bearing in mind the factors of: 1) ASEAN's overall goals of economic, social and cultural development, 2) the general economic situation among the member countries, where agriculture still remains an important part of the development agenda, and 3) the sweep of globalization riding on liberalization efforts in trade, investment and capital market, and on the easier flow of information, it is easy to understand why

ASEAN would decide to pursue cooperation in biotechnology, especially its applications in agriculture and the environment. And in so doing, ASEAN also has to grapple with related issues on biosafety.

ASEAN Bodies Concerned with Biotechnology and Biosafety

There are 3 ASEAN sectoral bodies that deal with biotechnology and biosafety issues, each one with its own mandate, structure and mechanisms to handle the technical and policy aspects of the matter. The first of these is the ASEAN Ministers for Agriculture and Food (AMAF) who tackle the issues from the twin perspectives of the promotion of trade in ASEAN food products and food safety. Implementation of cooperation programs in food, agriculture and forestry is handled by the Senior Officials Meeting on Food, Agriculture and Forestry (SOM-AMAF). The SOM-AMAF has organized, among its many technical working groups and subsidiary bodies, a Task Force on the Harmonization of Regulations for Agricultural Products Derived from Biotechnology.

The second ASEAN body with interest in biotechnology and biosafety is the ASEAN Committee on Science and Technology (COST), which approaches it from the perspective of research and technology development and its utilization. For the purpose of overseeing overall conceptualization, implementation, monitoring and evaluation of joint Research & Development and training programmes in biotechnology, it has established a Sub-Committee on Biotechnology.

The third is the ASEAN Senior Officials on Environment (ASOEN) who deal with it from the perspective of environmental protection. ASOEN has a Working Group on Nature Conservation and Biodiversity to look at the matter in the context of international conventions and protocols within their purview, such as the Convention of Biological Diversity, and the Cartagena Protocol on Biosafety.

A quick look at some of the major program areas of SOM-AMAF, COST and ASOEN could give a better sense of the mandates of these three ASEAN bodies, and why their work in the area of biotechnology and biosafety are complementary to each other. AMAF's domain are the food, agriculture and forestry sectors, and some of its major programs are in food security, facilitation of intra- and extra-ASEAN trade in agriculture, fishery and forest products, agricultural rural community human resources development, and strengthening of ASEAN common position and joint approaches in addressing relevant regional and international issues. For example, in crops, the emphasis on trade issues is evident in SOM-AMAF's work on harmonization of phytosanitary measures and harmonization of maximum residue limits of pesticides for vegetables. In livestock, they are developing ASEAN standards for animal vaccines. Insofar as it is concerned with improving agricultural productivity through R&D and technology transfer, then it has an interface with the activities of COST.

COST looks at the broader, overall development of science and technology capability within the region through joint R&D, human resource development, regional networking of Science & Technology infrastructure and programs, and promotion of technology transfer. However, these activities have to be implemented in specific, identified economically significant sectors and disciplines, such as food science and technology, marine science, non-conventional energy, and biotechnology among others.

In particular, for the Sub-Committee on Biotechnology, the priority areas for the period 2001-2004 are in food and horticultural crops, improvement of livestock production, value-addition to natural products, and bioinformatics. From this list, the interface with SOM-AMAF can be easily recognized.

On the other hand, ASOEN's concerns are in the introduction of policy measures and institutional development. These promote the integration of environmental factors into national and regional development planning, establishment of long-term goals on environmental quality and work towards harmonization of environmental quality standards, and joint actions to address common environmental problems in the region, such as haze. ASOEN's work on promoting cleaner production techniques through the introduction and adoption of technology, or promoting technology solutions to environmental problems has an interface with the work of COST.

Moving on to specific ASEAN programmes and actions in biotechnology and biosafety, COST was the pioneer, having started joint R&D and training in biotechnology back in the 1980's. Since 1983, when the Working Group on Biotechnology (later renamed as the Sub-Committee on Biotechnology in 1989) was established, joint projects with some of ASEAN's Dialogue Partners have been pursued. These partners include the European Union, Australia and Japan in the earlier days, and more recently, India, Korea and China. These activities have contributed to the development of the infrastructure in the ASEAN member countries as well as to the training of staff.

While COST has been steadfastly pursuing joint R&D and human resource development in biotechnology since the early 1980s, the involvement of SOM-AMF and ASOEN is quite recent. This is to be expected, in view of the nature of their mandates being more in the realm of trade promotion, policy development and crafting of joint positions and approaches in the context of international agreements. SOM-AMAF's and ASOEN's involvement in biotechnology and biosafety were initiated only in the late 1990s. SOM-AMAF's involvement began when it agreed to take up Singapore's initiative on the harmonization of regulations for agricultural products derived from biotechnology in 1997. In the same year, ASOEN also agreed to develop a common protocol on access to genetic resources and related intellectual property rights. This was because by this time, genetic modification technology had moved out of the research laboratories and into agribusiness which has started marketing products derived from genetically modified organisms. Likewise, the search for genetic resources that might have relevant desirable properties for horticultural crops, for example, had also intensified, so that the issues of access and ownership of intellectual property rights were being intensely debated over around the world.

Recent Initiatives

The initiatives launched in 1997 progressed during the following year, with consultations among various stakeholders conducted by way of an ASEAN Workshop on Regulations for Agricultural Products Derived from Biotechnology, hosted by Singapore. This Workshop became the venue where baseline data on the various national regulations being imposed by the ASEAN member countries were established, as well as where the views of the private sector and civil society groups were heard.

Information reported by the ASEAN member states during the Workshop as to the status of biosafety regulation in their respective countries revealed that although a few member countries (Indonesia, Malaysia, Philippines, Singapore and Thailand) have developed some guidelines of R&D and field releases of genetically modified organisms, none has a comprehensive legal framework to address commercial and consumers' concerns. The key weakness of the guidelines in these countries is that they do not have the force of law, and the standard S&T infrastructure for most operational procedures in risk assessment and risk management is weak. Much work remains to be done in ASEAN in the area of building up the institutional and legal framework, as well as developing the scientific and technical capacity to implement the framework.

The Workshop was followed at the official level by the creation of the Task Force on Harmonization of Regulations for Agricultural Products Derived from Biotechnology (ATFHRAPB) to attend to the drafting of harmonized guidelines.

In the same year, ASOEN also convened its first Workshop to draft a Framework Agreement on Access to Biological and Genetic Resources, held in Manila.

By 1999, SOM-AMAF started activities on public awareness of the GMO issue, with a seminar in Jakarta, again involving the participation of government, private sector, and national government organization (NGO) representatives. The drafted guidelines were also ready by this time, and the Task Force met to review the draft.

The SOM-AMAF laid down some principles to form the basis of the guidelines. These mainly defined the scope of the guidelines to cover the release of agriculture-related GMOs only, not their products. It also excluded questions of liability and compensation, labeling, and socio-economic issues. Furthermore, they also defined the framework within which the Guidelines will operate: as a statement of ASEAN's common understanding and approach to scientific evaluations of applications from various parties for the release of agriculture-related GMOs. They also agreed to go by the Food and Agriculture Organization (FAO) definition of substantial equivalence.

By October 1999, much of the work of the Task Force was completed, as the guidelines were ready for presentation to the ASEAN Ministers for Agriculture and Food, who subsequently adopted the Guidelines, now renamed as ASEAN Guidelines on Risk Assessment of Agriculture-Related GMOs, to better reflect its scope and framework. A significant condition stated in the adoption of the Guidelines is that they are legally non-binding and would not take precedence over national legislation. This condition has its roots in the very nature of ASEAN as an organization, which, in the words of the current Secretary-General of ASEAN, is "not meant to be a supranational entity acting independently of its members."²

Even more activities are being pursued this year, with SOM-AMAF continuing its work on creating public awareness on GMOs. ASOEN is also continuing with the refinement of its Draft Framework Agreement on Access to Genetic Resources.

² Rodolfo C. Severino, Jr., "What ASEAN Is and What It Stands For", Remarks at the Research Institute for Asia and the Pacific, University of Sydney, Australia, 22 October 1998, *ASEAN Rises to the Challenge, A Selection of Speeches*, The ASEAN Secretariat, Jakarta, November 1999, pp. 83-100.

The ASEAN Ministerial Meeting on Environment held this year in Bandar Seri Begawan, Brunei, with respect to the Convention on Biological Diversity (CBD), also agreed to share information and promote better understanding on the position of member countries on specific issues under the CBD, especially on GMOs. In support of this decision of the ASEAN Ministers for Environment, Malaysia organized a regional workshop on Biosafety of GMOs.

ASEAN participation in the global debate on GMOs further intensified with the private sector weighing in, when the ASEAN Chambers of Commerce and Industry (ASEAN-CCI), an ASEAN-affiliated NGO since 1981, called for labeling of GMO foods and the development of science-based standards for testing the safety of GM food products, during a meeting with the US Business Council.

In the meantime, the Sub-Committee on Biotechnology continues its work, and is now preparing to conduct a workshop with China on Transgenic Plants, to discuss possible joint R&D and training activities. With the increasing calls for science-based standards for risk assessment and risk management of GM food products, COST is well aware of the urgent need to develop in ASEAN the technical expertise and facilities to undertake the task, and its important role in implementing such S&T infrastructure development and training programs.

Harmonized Guidelines on Risk Assessment of Agriculture-related GMOs

In summary, what is clearly a solid accomplishment out of the activities in the last three years is the adoption of harmonized Guidelines on Risk Assessment of Agriculture-Related GMOs. The guidelines are posted on the website of the ASEAN Secretariat at <http://www.aseansec.org> under the area of cooperation in food, agriculture, and forestry. They provide a common understanding of, and approach to, science-based evaluation of applications for the release of agriculture-related GMOs. The Guidelines also describe procedures for notification, assessment, approval, and registration of release of agriculture-related GMOs. A risk assessment questionnaire forms part of the Guidelines, to facilitate provision of required information by the parties proposing to introduce agriculture-related GMOs into the region. The questionnaire was developed by drawing upon the experience of ASEAN's dialogue partners Australia, Canada, and USA in the development of risk assessment tools.

Administratively, the guidelines call for the establishment of a National Authority on Genetic Modification in each member country, to oversee the implementation of the guidelines. Obviously, the implementation of the guidelines would have a bearing on the activities of researchers in GMOs, insofar as following the prescribed procedures for notification, assessment, and approval of the release of GMOs are concerned.

How has harmonization been arrived at? ASEAN followed its usual process of consensus building, essentially taking the following steps:

- Experts from the Ministries of Agriculture and the national biotechnology regulatory agencies in the member countries were mobilized to collect and jointly review baseline information on pertinent national regulations and guidelines and discuss the relevant technical issues;

- Consultations with other stakeholders, such as NGOs and business groups were conducted, to obtain their views on the technical and policy issues;
- A lead country, in this case, Singapore, was requested to draft the guidelines;
- The draft guidelines were presented to the member countries for review by an appropriately mandated body, in this case the ATFHRAPB;
- Further review and consensus building was conducted at the level of Senior Officials; and finally
- Adoption by the relevant sectoral ASEAN Ministers (AMAF).

This is a procedure that works well for ASEAN and ensures that the views of all stakeholders are duly sought.

After the adoption of the harmonized Guidelines, SOM-AMAF will proceed with the public awareness programme on GMOs. The public awareness program is designed to meet the following needs:

- To raise awareness among the ASEAN public comprising different age groups and educational and social backgrounds, including members of the press, on the utilization of GMOs and its implications;
- To provide clear and simple information to the public so as not to frighten them with too many technicalities;
- To clear the misconceptions and negative images such as references to “Frankenfood”, surrounding GMOs as initiated and disseminated by certain interest groups;
- To generate resources to develop publicity and educational tools in various media formats to launch the program.

The relevant national bodies have embarked on the publication of brochures in the format of FAQs on GMOs, to help clarify the issues to the general public in a simple and layman-friendly manner. The Environment Ministers are expected to sign the Framework Agreement on Access to Genetic Resources when the document is finalized, and COST will continue with its R&D and human resource development activities to strengthen capability in the member countries to deal with GMOs.

The Next Step

Beyond these short-term activities, ASEAN would have to look at other issues and prepare to take action on them. Among these, clearly, are those that were excluded from the scope of the harmonized Guidelines, such as labeling of GMO foods. This is already the subject of a raging global debate to which the South East Asian scientific community must strengthen and contribute its expertise to the clarification of the technical issues, as well as to the design and implementation of the science-based assessments that will facilitate sound decision-making. As the subject has become more and more politically-charged, it is also important that the national decision-makers engage civil society in dialogue to ensure that the latter’s views are taken into account in policy formulation. This approach helps build public trust in government regulatory mechanisms.

Specifically for COST, as the driver of ASEAN regional cooperation in science and technology, it must accelerate the pace of capacity building in biotechnology, with special attention to the newer member countries that are at a much lower level of development in the area of high technologies. In particular, it should work with SOM-AMAF in building up technical expertise at the national level on science-based risk assessment and risk management of GMOs.

In the case of ASOEN, it is posed to develop regional institutional mechanisms to address biodiversity concerns, including the upgrading of regulatory agencies' capacity to regulate biosafety, and establish biosafety clearing house mechanisms.

Conclusion

The adoption of the ASEAN harmonized guidelines on risk assessment of agriculture-related GMOs is but a first step in the region's efforts to keep at par with global developments in agricultural biotechnology. Because of the implications of biotechnology and its applications on trade, environment, human health, as well as on legal, religious and ethical matters, it is imperative that ASEAN prepare itself to address these issues. Aside from strengthening the legal and institutional framework to address biosafety concerns, capacity building in risk assessment and risk management, enhancing information sharing and networking, and building public awareness of biotechnology and its products are concerns that have to be addressed in an integrated and coordinated way, and on a sustained basis. ASEAN welcomes cooperation with other entities and organizations to get going in some of these activities.