

GM Crops and Biosafety in South-East Asia: Singapore as Case Study

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The aim of drawing a picture of regulation and legislation on transgenic crops and biosafety issues in South-East Asia is more complex than describing the situation in the United States or in Europe.

South-East Asia consists of 10 countries and although they are grouped in the Association of South-East Asian Nations (ASEAN), each country maintains its independence and has the right to develop national policies (on some topics, including agriculture) according to national needs, values and religion.

Cooperation in agriculture between the ASEAN members dates back to 1968 with cooperation in food production and supply. As early as 1977 ASEAN was clearly aware that local needs had increased and the scope of cooperation was thus broadened to include agriculture and forestry.

The main goal of ASEAN in the 21st century is to implement regional cooperation activities in order to boost the international competitiveness of ASEAN's food, agriculture and forestry products, together with a further strengthening of the food security arrangement in the region. To move in this direction, the implementation of agriculture and forestry projects has been boosted with the inclusion of a wide range of activities, from crop production to post-harvest tasks and handling, from research and development to training and exchange of information and to the field of trade promotion in the areas of crops, livestock, fisheries, and forestry.

Finally, ASEAN has been seeking to find its place in the global market and trade, with simultaneous measures to sustain local production at a competitive level in international trade. For this reason, it focused on harmonization of quality and standards, assurance of food safety, and standardization of trade certification, according to the main international regulation for commercialisation of food, agricultural and forestry products.

Overview

Food security is the key to maintaining stability and assuring prosperity for a region, which is particularly important for regions composed mainly of developing countries as is the case in South-East Asia. With this principle clearly in mind the ASEAN member states signed the Agreement on the ASEAN Food Security Reserve (AFSRB) in 1979.

Under the terms of this agreement, each ASEAN Member State had to establish an ASEAN Emergency Rice Reserve (AERR), a basic food stock (rice) that had to be maintained by each Member State within its national border.

In response to the food crisis causing a global increase in food prices and a growing concern about food security in the ASEAN region, the ASEAN Integrated Food Security (AIFS) Framework and the Strategic Plan of Action on ASEAN Food Security (SPA-FS) were endorsed at the 30th Meeting of Ministers of Agriculture and Forestry (2008). The main goals were ensuring long-term food security and improving the livelihoods of farmers in the ASEAN region.

Although a number of food, agriculture and forestry measures have been put into place, I will refer only to those concerning genetically modified crops and plants in the following.

In 1997, Singapore made a proposal for harmonizing the guidelines on agricultural biotechnology products in ASEAN. The idea was endorsed during the 17th meeting of the ASEAN Ministers of Agriculture and Forestry.

The *ASEAN Guidelines on Risk Assessment of Agriculture-Related Genetically Modified Organisms*, a direct result of the 17th meeting of the ASEAN Ministers of Agriculture and Forestry and endorsed in 1999 during the 21st meeting, is the most important document concerning agrobiotechnology (ASEAN 1999). It is based on the idea that having a common understanding on this issue and a global strategy can help ASEAN Ministers in making scientific evaluations on the applications for releasing genetically modified organisms into the environment or on the market. Biotechnology applied to agriculture is in fact considered to be a tool for bringing new stimulus to the field and boosting productivity.

Accordingly, the only strategy to be pursued in this area – especially given the strong role agriculture is playing in the lives of numerous people – seemed to be working together in order to manage agrobiotechnology and to obtain the best results it can achieve.

In the following year, the ASEAN Ministers of Agriculture and Forestry approved the proposal of collaboration with the International Life Sciences Institute (ILSI) to organize a training programme for regulators and decision-makers of ASEAN member countries on the use of the *ASEAN Guidelines on Risk Assessment of Agriculture related GMOs* with Singapore being responsible for the organization of the 1st workshop. This activity – carried out under the ASEAN Public Awareness Programme on GMOs – is part of an ILSI-ASEAN 2-year training programme and has been considered very important in promoting capacity building and public awareness in risk assessment of agriculture-related GMOs (ASEAN-ILSI 2001).

Three more workshops were then organized in the following years. In 2002, the *2nd ASEAN-ILSI Training Workshop on Safety and Risk Assessment of Agriculture-Related GMOs* was held in Malaysia. It provided participants with hands-on practice in safety and risk assessment of agriculture-related GMOs (ASEAN-ILSI 2002). The *3rd ASEAN-ILSI training workshop* was held in Thailand in 2003. It covered the new development in the field of genetic engineering and was also meant to further enhance the cooperation and solidarity among people in the ASEAN region (ASEAN-ILSI 2003).

Finally, the *4th ASEAN-ILSI training workshop* took place in Indonesia in 2004. Its aims were the following: (1) to provide training in the safety assessment of genetically modified (GM) foods, leading to greater consistency of GM food safety assessment throughout the ASEAN region and possible harmonization of standards regulating GM foods; (2) to provide the scientific background for the adoption of safety assessment methodology for GM foods into the technical infrastructure of the participating countries; and (3) to assist in capacity building within the ASEAN region to enhance food safety through continuous training and identification of potential trainers (ASEAN-ILSI 2004).

ASEAN Guidelines on Risk Assessment of Agriculture-Related Genetically Modified Organisms

The main goal of the above mentioned guidelines is 'to ensure a common ASEAN framework for assessment of risks associated with transboundary movements of agriculture-related GMOs', specifically for issues related to the safety of GMOs for human health and for the environment. Moreover, they should guarantee a scientific basis for addressing the issue in the South-East Asian countries.

According to these guidelines, every country should establish a National Authority on Genetic Modification (NAGM) responsible for all the issues and duties related to GMOs, in particular for scientific evaluation and review, for providing prompt and transparent information to the public, for ensuring the guidelines are harmonized with regional and international practices, for notifying the ASEAN Secretariat of all approvals in the registration of transgenic organisms in their country and for creating an efficient system for the exchange of information among all the ASEAN countries.

A specific procedure must be followed when introducing transgenic organisms (plant, crop or derived products) into the ASEAN region, and the so called Proponent (who is responsible for the introduction of the GMO) must comply with the existing national and international regulations. Specifically, the Proponent must verify the procedure for approval in the case of the specific product for which introduction is sought and submit a proposal according to the procedure.

The NAGM will appoint a panel of scientific experts to evaluate any possible risk connected with any stage of the requested release and their conclusion will be forwarded to the NAGM within 90 days. The evaluation process will be based on the concept of *substantial equivalence*.

The NAGM will then decide within 60 days on the basis of the recommendation from the scientific panel and also has the right to demand any further information that may be necessary for its decision. Any decision is taken on a case-by-case basis.

The NAGM may make the following decisions:

- (1) grant approval for the release of the agriculture-related GMOs,

- (2) grant approval for the release of the agriculture-related GMOs under specified conditions,
- (3) prohibit release of the agriculture-related GMOs with reasons for the prohibition given in writing, or
- (4) require the Proponent to submit additional information which the NAGM deems necessary to complete the assessment, followed by decision (1), (2) or (3), (ASEAN 1999).

Any GMOs will be registered by the ASEAN Secretariat.

Any new information obtained through post-release monitoring should be immediately reported to the NAGM, which has the right to suspend the release based on the new information available.

Food safety and biosafety in ASEAN countries

The main concept behind any consideration on safety and risk assessment is that very few of the foods we eat today have been subjected to any toxicological assessment, and they are generally recognized as safe. The same approach should then be followed for any 'novel' food; therefore foods produced through genetic engineering present the same risks as those produced from conventionally bred crops. For the above mentioned reasons, according to the UN Food and Agricultural Organization (FAO), the UN World Health Organization (WHO) and the Organization for Economic Co-operation and Development (OECD), the safety assessment principles and standards applied to conventional food should also be applied to GM crops and the food derived from them (ASEAN-ILSI 2001; FAO 2008).

The novel food is compared with its traditional counterpart to verify if the modification results in any new or altered hazard that could affect the health or nutritional status of the consumer: this approach is known as *Substantial Equivalence* and is the most widely used worldwide benchmark when addressing issues of food safety.

ASEAN countries have in any case different approaches towards agrobiotechnology, and therefore their own level of development concerning

biosafety and food safety policies related to agrobiotechnological products. They can, however, be divided into two groups in accordance with their level of development in the context of GM products and biosafety policies.

The first group includes countries that have yet to develop a policy on GMOs: Cambodia, Lao PDR, Myanmar and Brunei Darussalam. The second group (Indonesia, Malaysia, Philippines, Thailand, Singapore and Vietnam) comprises countries that exercise regulation over GMOs, either through their existing systems or new regulations. In many cases, as described below, new decrees or regulations entered into force only recently, changing the regulatory landscape in some of those countries.

Although all the ASEAN countries have ratified the Convention on Biological Diversity, many of them still do not have the capacity to develop biosafety clearing house mechanisms. Moreover, the policy on the national biosafety legal framework is vitally important and should be set as the first priority and then be followed by a clear-cut plan of implementation for all the countries in the region.

Singapore is the only country to step out when describing the situation of agrobiotechnology in South-East Asia. It is an exception: although demonstrating a huge interest in biotechnology, due to its size and limited territory available for cultivation and also due to economic interests, it invests mainly in research and development in the fields of biomedical science and industrial or pharmaceutical biotechnology.

However, Singapore pays great attention to the outcomes of agrobiotechnology both worldwide and in the area and closely follows the specific policies developed to regulate the import/export of GM products as well as research. The following section focuses on these topics.

Singapore

Singapore is the only country in the area that is not a developing country. For this reason and also due to its small territory, its approach to the development of agriculture and agrobiotechnology is very different to that of the other countries of the region. It is involved with its neighbours in creating a common strategy to face all the issues related to agricultural supply, food safety and agrobiotechnology.

Agriculture, including fishery, accounts for just 0.2 % of the gross domestic product (GDP) in Singapore. It is therefore evident that it does not represent an important part of Singapore's economy. Around the end of the 1980s, urbanization caused a progressive reduction of the land devoted to agriculture, to less than 3%. Nevertheless, some incentives were planned to support agro-industries as well as research and development of commercial and high-technology farming.

In the late 1990s, Singapore opened up to biotechnology in agriculture and genetically modified products, with an approach limited by its small territory and by the very limited areas available for field experiments (Leitch Lepoer 1989).

So far, Singapore does not have umbrella legislation specifically for transgenic organisms and derived products; however, it has developed two sets of guidelines covering the commercial release of agriculture-related GMOs and research on genetically engineered products: specifically, the *Singapore Guidelines on the Release of Agriculture-Related Genetically Modified Organisms* (GMOs) and the *Singapore Biosafety Guidelines for Research on Genetically Modified Organisms* (GMOs).

The main authority on the topic is the Agri-Food and Veterinary Authority of Singapore (AVA) which is responsible for food, animals and pets as well as the agricultural and fisheries sectors.

AVA regulates the import of plants, plant products, fertilizers of plant origin, insects or microorganisms of agricultural importance and cut flowers, in order to safeguard plant health and to prevent any introduction of exotic pests and diseases into the country. The main regulation for cultivation, import and export of plants and plant-derived products is the *Control of Plants Act* (1994).

This Act covers the import and transshipment of fresh fruit and vegetable, control of plant cultivation (licences and use of pesticides), any issue related to prohibited plants, pest controls, licences and permits.

It does not cover genetically modified plants, for any importer needs to obtain a recommendation from the Genetic Modification Advisory Committee of Singapore (GMAC) before importation.

Advances in the development of recombinant DNA technology have resulted in a huge increase in application of these technologies to plants

even in Singapore, despite the limited land available for field trials. To cover other possible applications, GMAC has developed two sets of bio-safety guidelines on GMOs: one specifically for the commercial release of GMOs and derived products, and one for research on GMOs. These guidelines have been developed together with the Ministry of Health (MOH), the AVA, the National Environment Agency (NEA) and the Ministry of the Environment and Water Resources (MEWR).

Research using GMOs or derived products requires the involvement of another authority, the Institutional Biosafety Committee (IBC). This Committee was appointed under the Biological Agents and Toxic Act (BATA). Its duties include conducting risk assessments on the activity proposed by the applicant, evaluating the correlated risk management, advising the applicant on the best practice and code of conduct to carry out the proposed activity safely (including personnel training) and finally reviewing and controlling the proposed activity every two years to make sure it is properly conducted.

In the specific context of activities involving genetically modified organisms, the Committee is responsible for conducting inspections, monitoring the facilities and assessing the level of competence of the personnel involved in the work.

Singapore Guidelines on the Release of Agriculture-Related GMOs (1999)

These guidelines were developed to ensure safe import, release and use in Singapore of agriculture-related organisms obtained through genetic engineering. They cover two main issues: the assessment of risk to the environment and human health and the mechanism for approval of agriculture-related GM organisms in Singapore. The term *agriculture-related organism* is used to indicate plants, animals, microorganisms and vaccines used in cultivation, farming, horticulture, husbandry and agronomy.

Anyone who intends to import agriculture-related GM organisms into Singapore is required to submit an application to GMAC, which forwards it to the *Subcommittee on the Release of Agriculture-Related GMOs*. Each application is evaluated on a case-by-case basis, and can either be fully approved or endorsed under specified conditions.

Singapore Biosafety Guidelines for Research on GMOs (2006)

In 2006, after consultation with researchers, regulatory authorities and biosafety experts, the Singapore Genetic Modification Advisory Committee released the *Singapore Biosafety Guidelines for Research on Genetically Modified Organisms (GMOs)*. The guidelines take into account international regulations and recommendations (mainly from Australia, USA, Europe, World Health Organization and United Nations Environment Programme) and are not legally binding.

These guidelines were designed to grant a safe containment, handling and transport of GMOs intended for research purposes and moreover to keep track of the status of research on GMOs. If the GMOs are derived from biological agents and toxins known for their danger to human health, the research work must comply with the Biological Agents and Toxins Act (2005).

The scope of the guidelines...

...covers experiments that involve the construction and/or propagation of all biological entities (cells, organisms, prions, viroids or viruses) which have been made by genetic manipulation and are of a novel genotype and which are unlikely to occur naturally or which could cause public health or environmental hazards (GMAC 2006).

The GMAC research guidelines differentiate experiments involving GMOs or derived products into three categories according to the level of risk, giving clear indications on how to manage each situation, which is the responsible authority and how to apply them in order to adhere to the requirements.

Conclusions

In the past 25 years, many ASEAN countries have decided to invest in agricultural biotechnology research and development, partly as an answer to the pressing issues of the increase in their populations – a huge challenge for developing countries around the world – but also foreseeing a possibility

to boost their economy through this new technology. Another reason is the chance to take advantage of the worldwide economic investments in the biotech field and at the same time making their own contribution to this market.

Joining the big players, however, requires an adaptation of the international requirements, especially in a field as delicate as agricultural biotechnology, quite often in the middle of huge debates and legal controversies among the main producers and importers of transgenic products.

ASEAN countries recognized the importance of adapting their regulation to the international treaties, and have therefore been working actively to develop legal frameworks complying with the requirements of the main international benchmark regulations.

With the sole exceptions of Singapore and Brunei, they have ratified the Convention on Biological Diversity and even the Cartagena Protocol on Biodiversity.

Hence, many meetings at the ministerial level have taken place with the aim of harmonizing the regulation of agricultural biotechnology in South-East Asia.

The adoption of the ASEAN Guidelines on Risk Assessment of Agriculture-related Genetically Modified Organisms in 1999 is the first cooperative action undertaken by the whole region to face the main issues related to such a delicate topic as agrobiotechnology. These sets of guidelines, however, are not legally binding and do not overcome the national regulations, but provide a good framework for science-based risk assessment. The idea behind these guidelines is to create a common understanding and scientific approach towards agrobiotechnology products and toward the need of a proper scientific risk assessment before their release into the environment.

Some other areas, however, are not harmonized throughout the region yet, including specific data management and information sharing databases or common frameworks for industrial production of GMOs or bio-fuels. In order to become fully competitive at the international level the South-East Asian countries should find a means of being recognized as a unit, which is composed of single independent countries joining forces to succeed in the big game of agrobiotechnology.

Enhanced coordination between the governments on biosafety, data management and information sharing and the establishment of a research network system could help the region to take the final step forward into the international league.

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