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Challenges of Harmonization of Agricultural Biotechnology Regulatory Systems across APEC Economies

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Abstract

The Asia Pacific Economic Cooperation (APEC) consists of a mixed group of countries with a range of technical and technological capabilities vis à vis the regulation of Genetically Modified (GM) crops. Most have regulations or laws in place that enable the use of GM crops to some degree whether they cover only R&D activities or extend further to cover importation, field trials or release into the environment. Because experience with GM crops varies widely across the twenty-one economies, member countries are at different stages of development and implementation, have contrasting philosophies which are often reflected in national policies and have different regulatory capacities and resources. Such discord may be cause for concern particularly when many member countries face food security challenges. Delayed authorizations due to regulatory uncertainty and unpredictability can cause supply delivery problems, disrupt trade and create new market constraints that could increase the volatility of food prices. Unnecessary regulatory requirements can also result in additional costs making it difficult for any GM crop to make it market and into farmers' hands. Although the road towards alignment and harmonization of biosafety regulations across APEC economies is likely to be long, the current realities of a more fragile global food system and climate change may hasten this process.

Keywords: GM crops; Biosafety; APEC; LMOs; Cartagena Protocol on Biosafety (CPB); GM events; Low-Level Presence (LLP)

Introduction

The Asia Pacific Economic Cooperation (APEC) is a mixed group of countries with a range of technical and technological capabilities. Consisting of twenty-one member economies[1], APEC includes large traders of agricultural commodities that differ in their use of genetically modified (GM) crops. There are some with many years of experience producing and using GM crops, others whose experience has been limited to imports only and the rest with little to no experience with GM crops. APEC also includes some of the world's major food importers and food exporters; parties and non-parties to the Cartagena Protocol on Biosafety, the first legally binding international agreement governing the movement on Living Modified Organisms (LMOs) across national borders; and developed and developing countries with some of the richest in the world and with others at an early stage of economic development. Given such differences alone plus the prevailing politics and developmental goals of each country, the road towards alignment and harmonization is likely to be long. However, current food security challenges across the region may aid this process. At a time of increased food prices and a more fragile global food situation, the impact of any further increase in price and/or reduced agricultural production and trade due to regulatory issues would only exacerbate the problem.

The aim of this paper is to provide a review of the status of regulatory systems in APEC with respect to their treatment of biotechnology crop plantings and their importation for food, feed and processing, and an analysis of factors causing hindrances to the harmonization of regulatory systems which may promote trade in important biotechnology food products. Finally, the features of a functional biotechnology regulatory system are discussed with prospects for the future noted.

[1]The word 'economies' is used to describe APEC members because the APEC cooperative process is predominantly concerned with trade and economic issues, with members engaging with one another as economic entities. The 21 member economies include: Australia, Brunei Darussalam, Canada, Chile, China, Hong Kong, Indonesia, Japan, Republic of Korea, Malaysia, Mexico, New Zealand, Papua New Guinea, Peru, Philippines, Russian Federation, Singapore, Chinese Taipei, Thailand, USA and Vietnam.

APEC and food security

While APEC's member economies have been successful at reducing the region's undernourished population by 24 percent over the last two decades, more needs to be done with still about a quarter of the world's undernourished residing in the region [1]. APEC economies continue to be vulnerable to food security risks throughout the food chain. As evidenced recently in Japan, New Zealand, Australia, China and the Russian Federation, the region is frequently exposed to natural disasters such as earthquakes, typhoons, tsunamis, floods and droughts that disrupt food supply, damage the food production base, disrupt livelihoods, displace people and reduce access to food. Because trade plays a key role in food security, APEC, as the premier forum for facilitating economic growth, cooperation and trade, can make a major contribution to food security efforts. With its members accounting for half of world grain production and including major exporters and importers of agricultural products, APEC is well positioned to help improve regional and global food security [1]. The free flow of goods and services within APEC is extremely important for its member economies which absorb over 67 per cent of the bloc's exports and imports. They enjoy a higher share of intra-regional trade than even the European Union, growing from USD 1.7 trillion in 1989 to 7.7 trillion in 2009 [2].

APEC and GM crops

During the 2010 Ministerial Meeting on Food Security, biotechnology which includes the use of GM crops, and other new

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technologies and innovations was recognized by all APEC economies as being an important set of tools to raise agricultural productivity to feed the world's growing population. Research and Development (R&D) activity in GM crops represented by field trials and laboratory or greenhouse experiments, extends across most of the APEC region, including its developing country members. In contrast, experience with commercializing and using GM crops has not been as far-reaching, not yet at least. By the end of 2011, only seven APEC economies (USA, Canada, China, Australia, the Philippines, Mexico and Chile) out of a total of twenty-nine countries planted GM crops but they accounted for 53 per cent of all GM crops planted globally in 2011 (84.9 million hectares out of 160 million hectares of GM crops) [3]. However, an additional nine APEC economies have GM crop approvals for import only.

Public acceptance of GM crops varies across member economies although various surveys have found two different patterns emerging from surveyed countries which can be related to their agricultural activities [4-6]. While respondents in food producing countries such as the US, China, the ASEAN 5 (Association of Southeast Asian Nations 5 are Indonesia, Malaysia, Philippines, Thailand and Vietnam) were more positive about the benefits which plant biotechnology can bring, consumers in food importing countries like the Republic of Korea and Japan were less favourable towards the technology and as a consequence seemed less likely to believe food biotechnology might bring benefits in the next five years.

Because of consumer misgivings towards GM crops particularly in high-income importing countries like Japan and Republic of Korea, many countries fear the perceived commercial risks of export losses [4] associated with the use of GM products. This is of course exacerbated by the fact that Europe, which imposes very stringent standards for GM products, is a major trading partner of many countries in the region. According to Gruère and Sengupta [7], this irrational fear of export losses represents a significant impediment to biosafety policymaking.

Biosafety Regulations in APEC Economies

In APEC, as elsewhere, biosafety regulations and their associated protocols seek to address the potential risks to human/animal health or to the environment associated with the introduction of one or more genes from completely unrelated organisms. They include the danger of unintentionally introducing allergens and other anti-nutrition factors in foods; the likelihood of introduced genes escaping from cultivated crops into wild relatives; the potential for pests to evolve resistance to the toxins produced by GM crops; and the risk of these toxins affecting non-target organisms.

Most APEC economies have regulations or laws in place that enable the use of GM crops to some degree whether they cover only R&D activities or extend further to cover importation, field trials or release into the environment. Because experience with GM crops varies widely across the twenty-one economies, member countries are at different stages of development and implementation and obviously have different regulatory capacities and resources. While most national regulatory systems are being developed in line with the Cartagena Protocol on Biosafety (CPB), each addresses issues differently and contains different components and characteristics.

Although not exhaustive, eight areas of divergence are identified and discussed in this section.

Parties vs. non-parties to the cartagena protocol on biosafety

The Cartagena Protocol on Biosafety, hereinafter referred to as the protocol, is the first legally binding international agreement governing the movement of LMOs across national borders. Those countries that ratified the protocol became Parties to the Protocol and are required to comply with and implement all of its provisions. Biosafety risk assessment procedures are now an established prerequisite for trans-boundary movements of LMOs intended for research, development, or release into the environment for all Parties to the protocol. In addition, the Protocol states that the trans-boundary movements of LMOs between Parties and non-Parties must be carried out in a manner that is consistent with the objective of the protocol. Therefore, even non-parties that export LMOs to parties are encouraged to comply with the protocol's provisions implemented in the importing country. The Protocol features a set of procedures including one for LMOs that are to be intentionally introduced into the environment such as seeds and microorganisms and one for LMOs that are intended to be used directly as food or feed or for processing (LMO-FFPs) which represent about 90 per cent of all trans-boundary movements of LMOs. Parties to the protocol must ensure that LMOs are handled, packaged and transported under conditions of safety. Furthermore, the shipment of LMOs subject to trans-boundary movement must be accompanied by appropriate documentation specifying, among other things, identity of LMOs and contact point for further information. The party of import makes its decisions in accordance with scientifically sound risk assessments. However, one element of the protocol is the ability of parties to reject a shipment in case of insufficient relevant scientific information and knowledge, the so-called precautionary approach. Parties may also take into account non-safety considerations such as socio-economic considerations in reaching decisions on import of LMOs.

APEC consists of both parties and non-parties to the protocol and of GM-producing and non-GM producing countries. Based on the provisions of the protocol described above and on current proposed stringent information requirements, one can see that there could be potential conflict between GM crop producing countries such as Australia, Canada or the USA that export a large amount of LMOs, but are not Parties to the Protocol, to fellow APEC economies that are Parties and that have to comply with all of the protocol's provisions. To assess the potential effects of the protocol's proposed stringent information requirements on LMO-FFPs on trade flows, Gruère and Rosegrant [8] grouped the APEC economies into four groups depending on their protocol membership and their adoption of GM crops.

Group 1: GM producers; non-parties to the CPB (Australia, Canada, Chile, USA)

Group 2: Non-GM producers; Parties to the CPB (Indonesia, Japan, Malaysia, New Zealand, Papua New

Guinea, Peru, Republic of Korea, Thailand and Vietnam)

Group 3: GM producers; Parties to the CPB (China, Mexico, Philippines)

Group 4: non-GM producers; non-parties to the CPB (Brunei Darussalam, Hong Kong, Russian Federation, Singapore, Chinese Taipei)

They found that the most affected countries in terms of trade flows are Group 3 countries that are both parties to the protocol and

GM producers. These countries would have to control and verify not only imports from all GM producing countries but also exports to other Parties, as well as exports to all non-Parties. Group 2 countries would only have to control imports on shipments coming from GM producing countries. Among non-Parties, only Group 1 countries that are also exporters will be affected, whereas Group 4 countries will not be affected.

Number of GM crops authorized

The number of GM crops authorized for use in different countries is very different across APEC economies (see Table 1). Based on information published by the International Service for the Acquisition of Agri-biotech Applications (ISAAA) in 2011 [3], there are currently 7 APEC economies that have approved GM crops for cultivation with another 9 having granted approvals for imports for food and feed use and for release into the environment (but not necessarily in commercial production at present). One can see that the number of GM events approved across APEC economies varies widely thus raising concern with delayed or asynchronous import authorizations which may result in temporary trade disruptions. Currently, Gruère estimates that over 90 per cent of traded soybeans are likely GM, at least 50 per cent of traded cotton and maize and a large portion of canola are also likely GM [9]. Lengthy import approval procedures of certain countries are a cause for concern in terms of supply delivery problems but they may also create new market constraints that increase the volatility of commodity prices and likely contribute to the overall inflation of food prices. At a time of increased food prices, the impact of any further increase in price and/or reduced production would only exacerbate the problem particularly for countries already suffering from food price inflation.

Member Economy	GM Crops Approved for Cultivation	Approved GM Events*
Australia	Bt/Bt-HT cotton, HT/F/HT-F canola **(0.7 million ha)**	126
Brunei Darussalam	n/a	n/a
Canada	HT canola, HT soybean, HT/Bt/HT-Bt maize, HT sugar beet **(10.4 million ha)**	101
Chile	HT canola, Bt/HT maize, HT soybean **(<50,000 ha)**	3
China	Bt cotton, FC petunia, Bt poplar, VR- papaya, DR, VR tomato, VR sweet pepper **(3.9 million hectares)**	37
Hong Kong	n/a	n/a
Indonesia	n/a	7
Japan	n/a	119
Republic of Korea	n/a	78
Malaysia	n/a	5
Mexico	Bt cotton, HT soybean **(0.2 million ha)**	81
New Zealand	n/a	54
Papua New Guinea	n/a	n/a
Peru	n/a	n/a
Philippines	Bt/HT/Bt-HT maize **(0.6 million ha)**	68
Russian Federation	n/a	18
Singapore	n/a	13
Chinese Taipei	n/a	46
Thailand	n/a	2
Vietnam	n/a	n/a
USA	HT/Bt/HT-Bt maize, Bt/HT/Bt-HT cotton, Bt/HT potato, HT soybean, VR squash, HT sugar beet, HT canola, VR papaya, HT alfalfa **(69 million ha)**	126

Bt – Insect resistance; HT – herbicide tolerance; VR – virus resistance; FC – flower colour; DR – delayed ripening; n/a – not applicable; *Approved for imports for food and feed use only or for release into the environment but not necessarily in commercial production at present or both
Source: James [3]

Table 1: GM crops approved by APEC governments, 2011.

Product- vs. process-based regulations

A third area of divergence is a philosophical difference in the way countries view how GM foods should be assessed. Product-based regulations suggest that GM products should be evaluated on the basis of the unique characteristics and features that they exhibit and not their method of production. The national regulatory systems of the USA and Canada have adopted such an approach. Their systems reflect the OECD recommendation that there is no need for countries to develop new regulations for biotechnology as "there is no scientific basis for specific legislation to regulate the use of recombinant DNA organisms" [10]. In contrast, process-based regulations assumes that GM technology itself represents new sets of risks and that existing legislation is not sufficient to cover products and applications arising from the use of modern biotechnology. This is the approach adopted by the European Union. For many of the developed countries within APEC like Japan, Australia and New Zealand, their regulations share features of both the EU and US systems. For the others, the ratification of the Protocol effectively means the adoption of process-based regulations. Though the underlying philosophies of product- or process-based regulations are fundamentally different, the information requirements for risk assessment are similar and may differ only in the degree of detail, particularly in the requirements of molecular characterization [11]. Almost all adopted risk assessment strategies are based on a common set of principles and guidelines.

Labelling regulations and thresholds

Nowhere is there more heterogeneity than in the laws and regulations governing the tolerance or threshold levels for GM material in non-GM food and in the labelling of GM products. Labelling policies for GM food across economies differ widely in their nature, scope, coverage, exceptions, and their degree of enforcement [12]. The only common feature among them appears to be the mandatory requirement to label products derived from GM crops that are *not substantially equivalent* to their conventional counterparts, such as nutritionally enhanced GM crops (e.g. Golden Rice). In contrast, for products that are considered *substantially equivalent* to their conventional counterparts, there are large differences in labelling regulations across APEC economies. A summary of the national labelling systems in APEC economies is presented in Table 2.

A first major dichotomy is whether countries have either voluntary labelling (e.g. Canada or Hong Kong, or USA) or mandatory labelling requirements (e.g. Australia, Japan or China). For those that fall under the first category, voluntary labelling guidelines dictate the rules that define which foods are called GM or non-GM and allow companies to decide whether they want to use such labels on their products. For those countries with mandatory labelling, regulations differ widely according to the following: 1. coverage, whether they are just for a list of particular ingredients or all ingredients or include highly processed products derived from GM ingredients, even without quantifiable presence of GM material or animal feed or for meat and animal products fed with GM feed or for food sold at restaurants and for unpackaged food; 2. threshold level, whether it is applied to each ingredient or only to three or five major ingredients as in the case for Republic of Korea and Japan, respectively; and its level ranges from 0.9 per cent to 5 per cent

Member Economy	Labelling Type	Coverage	Major Exemptions	Threshold Level
Australia	Mandatory	All products based on content	Processed products; restaurants	1%
Brunei Darussalam	n/a	n/a	n/a	n/a
Canada	Voluntary	All products based on content		5%
Chile	Draft biosafety framework/Pending legislation			
China	Mandatory	List of food items; products derived from GM	Outside of list	None (0%)
Hong Kong	Voluntary	Packaged food items	n.d.	5%
Indonesia	Mandatory†	List of food items; packaged foods only	Outside of list	
Japan	Mandatory	List of food items	Processed products	5%
Republic of Korea	Mandatory	List of food items	Processed products	3%
Malaysia	Mandatory†	n.d	n.d	n.d
Mexico	Mandatory	Seeds for planting	n.d	n.d
New Zealand	Mandatory	All products based on content	Processed products; restaurants	1%
Papua New Guinea	n/a	n/a	n/a	n/a
Peru	Draft biosafety framework/Pending legislation			
Philippines	Voluntary	All products based on content		5%
Russian Federation	Mandatory	All products based on content	Feed	0.9%
Singapore	n/a	n/a	n/a	n/a
Chinese Taipei	Mandatory	List of food items	Outside of list	5%
Thailand	Mandatory	List of food items	Outside of list	5%
Vietnam	Mandatory†	Pending legislation		
USA	Voluntary	All products based on content		n/a

†Not yet implemented; n/d - not disclosed; n/a – not applicable
Source: Modified from Gruère and Rao [12]

Table 2: Characteristics of national labelling systems in APEC economies.

(with the exception of China); 3. labelling information given, whether the term "genetically modified" is written on the list of ingredients, or in the front of food packages; 4. Lastly, the degree of implementation also differs with several countries within APEC yet to implement their labelling laws or partially enforcing them.

Policies on low-level presence (LLP) of unapproved GM events

Another area of concern among national regulatory systems is the way in which a country addresses the adventitious or low level presence (LLP) of unapproved GM events. Differing policies on LLP across APEC economies could increase the risk of temporary trade disruption. The acceleration in the release of new GM crop varieties in major commodity exporters like the USA, Argentina, or Brazil is a cause for concern for importers with delayed import approvals and the lack of a policy on LLP or a zero per cent tolerance for unapproved events. A few recent incidents have shown their significant impact on trade.

In 2006, the approval of new GM maize (Herculex) in the USA disrupted trade in maize products between the USA and the EU where Herculex maize was not yet authorized for use as food and feed. A study reported that this incident may have imposed additional costs to the EU livestock sector of about Euros 1.6 billion in 2007-2008 since the EU had to source their maize from alternative sources which were more expensive [13]. Similarly, the accidental introduction of LL601 (Liberty Link) rice under a confined field trial into the rice supply chain in the USA forced Europe and others to ban US rice. While in 2005, the EU imported 32 per cent of its rice from the USA, in 2007 it was only 2.5 per cent. The incident cost the EU rice sector up to Euros 111 million between 2006 and 2008 [14]. Among the APEC economies, China, Japan and Republic of Korea have a zero tolerance for unapproved events whilst the majority of the economies have no articulated or dedicated LLP policy in place which may mean a default to zero tolerance. Only the Philippines have adopted an LLP policy and is in the process of finalizing the guidelines for implementation.

A study by Gruère in 2009 [9] found that APEC economies would benefit from adopting LLP policies, especially given the fact that a significant proportion of corn and soybeans imported are from GM producing countries. Table 3 and Table 4 show the major corn and

Importing Country	Volume (million MT)	Source (% share of imports)
Japan	16.2	**USA (89%), Argentina (5.5%), Brazil (4%), China (0.15%),**
Republic of Korea	8.5	**USA (86%), Brazil (3.3%), Argentina (2.9%)**
Mexico	7.8	**USA (99%)**
Chinese Taipei	4.6	**USA (63%), Brazil (24%), Argentina (11.1%)**
Malaysia	3.1	**Argentina (48%), Brazil (29%), India (15%), Thailand (3.3%)**
Peru	1.9	**Argentina (56%), USA (33%), Brazil (3.2%)**
Canada	1.6	**USA (>99%)**
China	1.6	**USA (96%)**
Vietnam	1.5	**India (35%), Thailand (31%), Brazil (12%), Argentina (10%), USA (4%)**
Indonesia	1.5	**Argentina (55%), Brazil (22%), USA (11%), India (9%)**

(countries in bold produce GM maize)
Source: United Nations Commodity Trade Statistics Database [15]

Table 3: Major corn-importing countries in APEC, 2010.

Importing Country	Volume (million MT)	Source (% share of imports)
China	54.8	**USA (43%), Brazil (34%), Argentina (20%)**
Japan	3.5	**USA (72%), Brazil (16%)**
Mexico	3.8	**USA (95%), Brazil (1%)**
Chinese Taipei	2.2	**USA (65%), Brazil (29%), Argentina (5%)**
Indonesia	1.7	**USA (91%), Argentina (5%)**
Republic of Korea	1.2	**USA (60%), Brazil (36%)**
Thailand	1.8	**Brazil (71%), USA (13%), Argentina (11%)**
Russian Federation	1.1	**USA (4%), Brazil (39%), Paraguay (46%)**
Malaysia	0.6	**USA (55%), Argentina (17%)**
Vietnam	0.1	**USA (86%), Argentina (2%)**

(countries in bold produce GM soybean)
Source: United Nations Commodity Trade Statistics Database [15]

Table 4: Major soybean-importing countries in APEC, 2010.

soybean importing countries in APEC, respectively. For maize, Japan, Mexico, Chinese Taipei, Republic of Korea and Canada could be the most potential affected since majority of their maize originates from the USA. Canada may not face the same problem as the others since new GM crops tend to be approved simultaneously in Canada and the USA, therefore avoiding the issue of asynchronous approval. For soybeans, the countries potentially most affected by LLP disruption are China, Japan, Mexico, Chinese Taipei and Indonesia as the majority of their soybean comes from the USA and Latin America.

Treatment of stacked events

With the increasing adoption of GM crops globally, a noticeable trend is the tendency to generate new products by combining previously approved GM events[2] in one plant by conventional breeding, hereafter referred as a stacked event. The resulting plant may have a different regulatory status in different countries. Currently, there is no global consensus for the regulation of such a kind of stacked events. Some countries require the stacked event to go through the regulatory system as a new GM crop, irrespective of whether the parental GM events were already authorised or not. Within APEC, there are the likes of Australia, New Zealand, Canada and the USA that do not require additional data requirements or separate approval if traits being combined have already been approved individually unless there is potential for the traits to interact in a manner affecting safety [16]. In contrast, countries like Japan treat stacked events as a single or new event and require separate environmental approvals. There are also those countries, like the Philippines and Republic of Korea that fall in between the two extremes and that have devised their own requirements and data packages which may range from minimal to extensive. Lastly, there are those (e.g. Malaysia) that have yet to articulate a policy for risk assessment for stacked events.

Inclusion of non-safety considerations

It is universal among national regulatory systems that a GM crop should not be approved for environmental release or allowed for food use if there is no scientific determination that the GM product is safe based on an individual risk assessment with product-specific data. However, whether a country's biosafety decision making process includes non-safety concerns such as socio-economic considerations is not consistent among countries. While the Protocol focuses on the potential effects of GM crops on the environment, it also allows the possibility of including other non-safety considerations such as socio-economic ones in the decision-making process. Differing opinions about the desirability of this have polarized the debate. Some countries in APEC such as the Philippines and Mexico factor such issues and concerns into their safety approval process while others like the USA and Canada leave it to the marketplace and the court system to resolve such issues. While both sides of the debate have very convincing arguments for or against the inclusion of socio-economic considerations, this is an area of potential concern. The inclusion of non-safety considerations especially in national systems where there is very little clarity in terms of methods, guidelines and decision-making rules, can increase regulatory lags due to delays and could increase the cost of conducting such assessments.

Role of public participation

Public participation, which includes the opportunity for the public to provide information and comment on regulations, guidance and product applications, is essential for consumer trust in that process. Government agencies should make a special effort to solicit feedback from stakeholders to ensure all points of view are heard before regulatory decisions are made and should also respond to comments to assure that public concerns are taken seriously. Most regulatory systems in APEC include the ability for the public to comment before a decision is made on an application. Where there is divergence is in the length of time for public comment, the degree and manner of participation and the stage of the decision-making process the public is brought in for comment. For example, in the Philippine regulatory system, public participation applies to all stages of the biosafety decision-making process from the time the application is received. As is the case for the inclusion of non-safety considerations, there must be clear methods, guidelines and decision-making rules vis-à-vis public participation as this could also increase the potential of regulatory lags due to delays and would certainly add to the cost of regulatory compliance.

Characteristics of a Functional and Protective Biosafety System

Although there are many differences across APEC biotechnology regulatory systems, all of them have the same goal – to ensure that only safe GM products are released into the environment or are approved for food use. While there should be mutual respect and recognition among countries for each country's right to make their own decisions regarding the safety of GM crops, decisions need to be informed and based on the experiences of others that have already had some history regulating GM crops. Without actual 'hands-on' experience of actually testing a GM crop through a regulatory process, it will be difficult for a country to judge whether what they have established is workable, efficient, practical and at the same time protective.

Jaffe [17] identifies some characteristics and components that are generally important for a functional and protective biosafety regulatory system. They must be comprehensive, transparent, participatory, efficient, workable, fair and flexible enough to adapt to gains in knowledge and experience. They must also have an adequate legal authority, a clear safety standard, a proportionate risk-based review, and post-approval oversight. Not having a fully functional individual component does not necessarily mean that the entire system is non-functional. These components can be used to evaluate how functional a particular system is as a whole. However, should there be a breakdown or disruption in any of the components, several consequences may arise which could have significant impacts further down the road.

First, delayed authorizations due to unnecessary regulatory requirements can cause supply delivery problems, disrupt trade and create new market constraints that could increase the volatility of commodity prices. It is noteworthy that the four major GM crops – soybeans, maize, cotton and canola –are also the most heavily traded internationally, providing significant export revenues for many countries but also more importantly, providing a critical supply of cheap food, feed and fibre for many importing countries.

Second, unnecessary regulatory requirements can also result in additional costs. The high cost of regulatory compliance has been quoted as one of the reasons why the public sector in developing countries has been slow to release GM crops [18]. Costs associated with implementing a regulatory process for a specific GM product can be a significant portion of the total costs of bringing the product to market. Studies have shown that compliance costs differ by country, crop, and trait. For instance, the estimated cost of regulatory compliance for Bt

[2]A GM event refers to the unique DNA recombination event that took place in one plant cell, which was then used to generate an entire GM plant.

cotton developed by the public sector in India was between US$0.5 to US$1 million; for herbicide-tolerant soybeans in Brazil, the cost was estimated to be US$4 million; for Bt maize in the Philippines, the estimated cost was US$1.7 million. The high costs and onerous compliance procedures not only can add to the price of GM seed that a farmer has to pay but can also delay the availability of improved products to farmers and consumers.

According to Falck-Zepeda et al. [19], the time value of money lost from regulatory delays tend to be larger than the cost of compliance itself. The higher the cost of compliance, the more likely it becomes a barrier to entry, the less likely developers enter the market, and thus less technologies may make it to market. Regulatory uncertainty and unpredictability due to the above factors make it difficult for any player whether large or small to invest in the development of GM crops as large investments in R&D may generate a pipeline which becomes "constipated" because no product can be commercialized or released beyond the R&D phase [20].

Future Outlook

The global adoption of GM crops has been continuously expanding since they were first grown in 1996 in both developed and developing countries. In 2011, GM crops were grown on approximately 160 million hectares by 29 countries and by over 16 million farmers worldwide. This is a record 94-fold increase in area between 1996 and 2011 making GM crops the fastest adopted crop technology in the history of modern agriculture [3]. Currently, there are about 30 commercial GM events that are cultivated worldwide with the four most important GM crops being soybean, maize, cotton and canola and the two most dominant traits being herbicide tolerance and insect resistance. However, the forecast is that by 2015 there will be more than 120 GM events in commercialized GM crops worldwide with a particularly pronounced potential increase in the number of events in rice (Table 5) [21]. The current dominant traits in GM crops will continue to be the most common traits in 2015 although optimized crop composition (mostly type and proportion of oil or starch content) is expected to gain increasing importance and crops that are tolerant to abiotic stresses such as drought will also become available by 2015. In addition to the increasing number of individual GM events, eventually hundreds of combinations of these events can be quickly developed by stacking, therefore resulting in a dramatic increase in the number of GM crops that could be submitted for regulatory approval.

Another development in the R&D of new GM crops is the emergence of more players. While at present, private companies from the USA and Europe dominate the industry, over the next few years more GM crops will be supplied by private and public institutions in Asia, in particular from China and India. By 2015, it is estimated that 44 per cent of commercial GM events will come from Asia. This may present new challenges with regards to LLP issues. Because GM crops in Asia are usually developed for domestic consumption, the expected GM events are less likely to be submitted for regulatory approval in the USA, Europe or elsewhere for that matter. These isolated foreign approvals could lead to traces of the new events being found in imports of processed specialty foods entering these countries [21].

Crop	Commercial in 2008	Commercial pipeline	Regulatory pipeline	Advanced development	Total by 2015
Soybeans	1	2	4	10	17
Maize	9	3	5	7	24
Rapeseed	4	0	1	5	10
Cotton	12	1	5	9	27
Rice	0	1	4	10	15
Potatoes	0	0	3	5	8
Other crops	7	0	2	14	23
All crops	33	7	24	61	124

Rapeseed- canola
Source: Stein and Rodriguez-Cerezo [21]

Table 5: Events in commercial GM crops and in pipelines worldwide, by crop.

Will current biotechnology regulatory systems in APEC cope with the future pipeline of GM crops being developed without causing any problems? It is difficult to say given all that has been discussed above and the heterogeneity of current national regulatory systems. Incidents with asynchronous approvals and LLP (with significant economic consequences) have already occurred with the current 30 commercial events. These issues are only likely to intensify with more events becoming available in more countries worldwide.

Conclusion

With over 90 per cent of traded soybeans, 50 per cent of traded cotton and maize, and a large portion of traded canola likely to be GM, plus 29 countries and over 16 million farmers growing GM crops globally, there is no turning back. It is therefore incumbent on regulatory systems not only in APEC but worldwide to deal with current and future GM crops appropriately and responsibly. Calls have been made by various members of the international community for simpler, workable and fair regulatory processes; mutual recognition of other country's decisions; regional harmonisation; practical policies on LLP and so on.

With the accumulated knowledge and experience of the last sixteen years regulating GM crops, it should now be possible to design appropriate regulatory systems that are responsible, rigorous, functional and yet not stifling and that only require modest resources that are within the reach of most countries. At a time of increased food prices and a more fragile global food situation, the impact of any further increase in price and/or reduced agricultural production due to regulatory issues would only exacerbate the problem particularly for countries already suffering from food price inflation.

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