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ARTICLES

Commercialization of Perennial GE Crops: Looming Challenges for Regulatory Frameworks

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Abstract Overall, the deregulation of genetically engineered (GE) crops for commercial cultivation in North America has been a success story. In several cases, however, GE crops have sparked concerns and disagreements among the stakeholders and there are incidences of court lawsuits, including a recent one on glyphosate resistant (GR) alfalfa (*Medicago sativa*, L.). While GE crops can provide operational benefits to farmers, challenges are looming from commercialization of perennial GE crops. The unique ecology and biology of these crops and GE alfalfa in particular can facilitate adventitious presence (AP) of GE traits and it makes more visible that economic risks for conventional growers and food/feed producers have not been adequately addressed by the GE regulatory system in the United States (US). Asynchronous market approvals and the existence of a number of GE sensitive export markets create uncertainties among the exporters. Policy development in these fields may be helpful for ensuring a broader acceptance and market success of GE agriculture in general. The analysis is focusing on the US, although many diagnosed problems are also relevant to other jurisdictions—in particular if no co-existence policy is in place.

Keywords Genetic engineering · GE alfalfa · Adventitious presence · Co-existence · Regulatory framework

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Introduction

Genetically engineered (GE) crops have been legally authorized for commercial production in many countries and commercially grown worldwide for over a decade. The adoption of GE crops has been tremendous with only 1.7 million hectares in 1996 to 134 million hectares in 2009 (ISAAA 2009). Globally, current acreage of more than 77% of soybean, 49% of cotton, 26% of maize, and 21% of canola is grown with GE traits. In the United States (US) in particular, about 85% of maize and more than 90% of cotton grown are genetically engineered (ISAAA 2009). The widespread cultivation of GE crops is not without its own challenges. The incidences of outcrossing with non-GE crops and adventitious presence (AP) are cause for concerns among various stakeholders (Ellstrand 2001). Our ability to contain novel GE traits within production fields is often challenging and there exist numerous examples of novel trait escape and associated unintended effects (APHIS 2009a). Strategies for the segregation of GE and non-GE crops can be expensive and in times it can also be inefficient (Wilson and Dahl 2006). An economically notable example is the Starlink® corn case in the US, where GE corn deregulated only for use as animal feed was found throughout the human food supply chain (Bucchini and Goldman 2002). In September 2006, an unauthorized GE version of Chinese rice (Bt63) was discovered in the food products in the UK, France, and Germany (EC-JRC 2008a). Similar incidents of unauthorized releases of regulated GE crops into the food and feed supply were reported with Prodigene® corn, Syngenta® Bt10 corn, and Liberty Link® rice events 601 and 604 (USGAO 2008). Such escapes have shown serious impacts on international trade. For example, the European Union (EU) has devised emergency measures, which often warranted the withdrawal or refusal of products contaminated with unapproved GE traits upon entry. Our apparent inability to segregate GE plants dedicated to food and feed is a good example of issues to be later addressed for non-food and non-feed GE plants (EFSA 2009).

Evidences with herbicide-resistant canola in Canada shows that transgenes will escape cultivation and will eventually end up in unintended destinations such as non-GE fields, roadsides, and waste lands (Friesen et al. 2003; Knispel and McLachlan 2010). Likewise, for creeping bentgrass, the escape and establishment of GE traits outside production areas was confirmed during field testing of still regulated products, and this was despite strict confinement efforts (Watrud et al. 2004; Zapiola et al. 2008). It may be often difficult to totally confine novel traits within the production fields and previous evidences suggest that the retraction of transgenes will be unlikely once they escape into the environment (Marvier and Van Acker 2005). Novel trait confinement can be much more difficult for crops whose ecology and biology favor AP and perennials are some of the challenging ones in this regard. In certain cases, stakeholders filed law suits over the commercialization of such GE products.

For example, the deregulation of glyphosate resistant (GR) alfalfa in the US in June 2005 raised concerns among stakeholders and farmer organizations and subsequently attracted a law suit in February 2006 (see Table 1 for a description of plaintiff's arguments). In May 2007, a federal district court in the US ordered a moratorium on the sale and cultivation of GR alfalfa in the US, pending the

Table 1 Criticisms by various stakeholders of the regulatory decision on GE glyphosate resistant alfalfa

Alfalfa is a perennial, highly outcrossing, insect pollinated species and it is more likely that GE traits will escape cultivated alfalfa fields and contaminate nearby alfalfa populations. The strong ferality potential of alfalfa further aggravates this problem.
APHIS violated the National Environmental Policy Act (NEPA) by choosing not to prepare an EIS before the deregulation, despite the fact that the introduction of GE alfalfa might present several challenges for conventional and organic alfalfa hay, seed and honey growers.
The cumulative effects of the widespread cultivation of GR alfalfa, including potential increases in herbicide usage and related health and environmental risks were largely ignored.
APHIS failed to consider the increased need to use comparatively harmful herbicides including 2,4-D and Paraquat for stand termination and the control of volunteers and feral alfalfa populations.
Overall impacts from the introduction of yet another GR crop, including the effect of more GR crops in rotation on the crop and human environment, including the development of more herbicide resistant weeds were not adequately analyzed.
With regard to animal health, the impact of the mixture of GR alfalfa in rations that may already contain other GE products and its impacts on the intestinal fauna were not sufficiently explored.
APHIS only evaluates public health and environmental effects, as such there is no consideration of potential economic, socio-economic and other costs associated with the deregulation of GE crops.
Because three agencies [APHIS, Environmental Protection Agency (EPA) and Food and Drug Administration (FDA)] are involved in deregulation, responsibilities were not clearly portioned among agencies.
The1986 EPA guidelines on the reregistration of products containing glyphosate (EPA case no. 0178) identified solono grass, the valley elderberry longhorn beetle and the Houston toad as species under threat in relation to the use of this herbicide. The EPA's 1993 Re-registration Eligibility Decision for glyphosate identified even more species under threat and the list had not been updated since then. In addition, the surfactants used with glyphosate may cause adverse effects such as amphibian mortality. These effects were not considered by EPA.
The EPA did not adequately consult the US Fish and Wildlife Service with respect to setting tolerances for glyphosate in accordance with Section 7 (a) 2 of the Endangered Species Act.

Sources CFS (2006, 2007)

production of a detailed Environmental Impact Statement (EIS) (USDC 2007) (see Table 2 for a detailed note of regulatory developments on GR alfalfa). Similar well known examples of perennials subjected to lawsuit include GE papaya and GE creeping bentgrass. Stewardship and best management practices have been developed and made available to the commercial growers of GE crops (Monsanto Company 2008). Although the stewardship programs are found to be efficient in reducing gene flow, they are often not adequate to overcome market risks to GE sensitive sectors. This creates uncertainty among some of the stakeholders and it not clear whether it is possible to gain broader stakeholder acceptance and reap the operational benefits from these GE crops. The objective of this paper is to identify the strategies that can help facilitate broad acceptance, by investigating the gaps in the current GE regulatory frameworks. The analysis focuses on the US regulatory context, though frequent reference is made to the EU regulatory framework.

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) oversees the environmental impact assessment and deregulation of GE crops in the US. When GE crops are deregulated, they are allowed to exist anywhere in the environment and there are no US federal

Table 2 Regulatory developments regarding GE glyphosate resistant alfalfa in the US

May 2003, APHIS receives petition from Forage Genetics International (FGI) for deregulation of GR alfalfa events J101 and J163 (petition 03-127-01p). Petition was subsequently withdrawn after APHIS's request for additional information.
April 2004, FGI re-submits petition with additional information requesting the deregulation of GR alfalfa (petition 04-110-01p).
May 2005, APHIS issues Finding of No Significant Impact (FONSI) report. APHIS decides not to prepare an EIS.
June 2005, APHIS decides to deregulate GR alfalfa based on FONSI report under 1969 National Environment Policy Act (NEPA), as amended (42 USC 4321 *et seq.*; 40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 342) (APHIS 2005).
Following deregulation, in September 2005, GR alfalfa was grown on 5,485 farms with over 263,000 acres sown.
February 2006, lawsuit filed against deregulation decision on GR alfalfa, on the grounds of violation of NEPA, the Endangered Species Act (ESA) and the Plant Protection Act (PPA).
February 2007, Federal District Court judge in San Francisco concludes that APHIS violated NEPA by choosing not to prepare an EIS on GR alfalfa.
March 2007, court issues preliminary injunction order for the sale and cultivation of GR alfalfa in the US and consequently, GR alfalfa is returned to regulated status (APHIS 2007).
May 2007, permanent injunction order issued by the court, pending the production of a detailed EIS on GR alfalfa (USDC 2007).
July 2007, court issues an amended order detailing the confinement requirements including the storing of GR alfalfa, labeling containers and cleaning equipment associated with GR alfalfa fields that were already established.
December 2007, APHIS issues a supplementary administrative order that specifies practices that must be implemented by GR alfalfa growers.
January 2008, APHIS publishes a Notice of Intent (NOI) in the Federal Register to prepare an EIS on GR alfalfa.
September 2008, the ninth circuit court of appeals in San Francisco upholds the injunction.
November 2009, APHIS prepares a draft EIS (APHIS 2010)
December 2009, EPA published a notice in the federal register announcing the availability of APHIS's draft EIS
APHIS extended the commenting period on Draft EIS closing on March 3, 2010, and it is currently reviewing the comments for an appropriate regulatory decision

requirements that prohibit the adventitious presence (AP) of wholly owned deregulated GE products in or on another person's property. APHIS's assessment mandate does not include economic and market risks associated with such deregulation (USGAO 2008). However, the court order indicated that market risks should be considered a part of the human environment (USDC 2007) and as such market risks need to be adequately addressed in GE risk assessment programs. With this scope, the paper aims to bring forward some of the economic considerations that are not previously dealt with by GE regulatory frameworks. The issues include but are not limited to AP, asynchronous market approvals, stakeholder reluctance, absence of comprehensive polices on co-existence, testing procedures, thresholds, liability, and enforceability. Particular reference is made to GR alfalfa case when analyzing the market issues associated with the AP of GE traits but many of these issues are common to most GE crops, including annuals.

More Case Specific Considerations

Perennial GE plants can differ substantially from annual GE crops in terms of their ecology and biology. For example, perennial, highly outcrossing crops such as alfalfa, papaya, and creeping bentgrass pose unique challenges to novel trait confinement when compared to annual GE crops. Perennials have comparative advantage over annuals due to their ability to live longer and persist in the environment. The risks posed by perennials may become intense if such crops are able to establish feral populations in unmanaged habitats (Bagavathiannan and Van Acker 2008) and feral alfalfa is a well known example in this regard (Bagavathiannan et al. 2010). Unlike in self-pollinated crops, when outcrossing is facilitated by insects or wind, it may be very difficult to confine novel traits within the production fields (see Table 3 for a detailed comparison of the ecology and biology of some of the major GE crops developed to date). Similarly, plants that are used for human consumption (e.g., papaya) warrant strict regulations than those used for industrial purposes (e.g., cotton). Particular emphasis on the nature of the introduced trait is also vital since some traits may cause more substantial impacts than others. For example, herbicide/insect resistant traits can have considerable impacts on the on-farm biological diversity when compared to the traits that improve end product quality (e.g., high oil content) (Ammann 2005). GR alfalfa and GE papaya resistant to papaya ring spot virus (PRSV) are some of the good examples of deregulated GE crops that caused concerns among the stakeholders due to their unique biology and tendency for outcrossing, which led to lawsuits. The deregulation of perennial GE crops pose additional challenges to trait confinement and makes prominent some of the existing issues associated with the commercialization of GE crops. Another type of GE crops that will require specific regulations are non food/non-feed crops, i.e., GE crops that are cultivated for non-food/non-feed purposes and that themselves are sometimes non-food/non-feed crops (EFSA 2009).

Lack of Adequate Investigations

Because the ecology and biology may differ considerably among the species, the risks posed by the introduction of novel traits might also vary. This suggests that the biology and ecology of the species as well as the changes in species fitness with respect to the introduced trait needs to be thoroughly investigated before any regulatory decision is taken (Bagavathiannan and Van Acker 2008). However, such knowledge is often lacking in the scientific literature and it becomes a cause for concern among the stakeholders when regulatory decisions are taken without adequate investigations. In the recent GR alfalfa case, for example, the US court directed that the APHIS should produce a detailed EIS before an appropriate regulatory decision is taken (USDC 2007). In such cases, detailed investigations could have assisted the development of more efficient trait confinement protocols. The practical challenge to this is that such investigations typically take a long time and may involve inter-disciplinary studies. Further, it may sometimes be difficult to

Table 3 Comparison of the ecology and biology of some of the major GE crops approved worldwide

Common name	Scientific name	Life cycle	Type of pollination	Mode of pollination	Level of self-incompatibility	Issue of volunteers	Ferality potential	Other remarks	Risk of gene flow
Alfalfa	*Medicago sativa*	Perennial	Predominantly outcrossing	Insect	High	Low–medium	High	May sometimes be weedy/invasive†	High
Canola	*Brassica napus*	Annual	Selfing/outcrossing	Insect, wind	Low	High	Medium–high	Seed shattering/huge seed bank	Medium–high
Cotton	*Gossypium hirsutum*	Annual/perennial	Predominantly selfing	Insect	Negligible	Low	Medium	Can be weedy/invasive†	Low–medium
Creeping bentgrass	*Agrostis stolonifera*	Perennial	Predominantly outcrossing	Wind	High	N/A	High	Both vegetative propagules/seeds	High
Flax	*Linum usitatissimum*	Annual	Predominantly selfing	Insect	Low	Medium	Medium	Hermaphroditic flowers	Low–medium
Lentil	*Lens culinaris*	Annual	Predominantly selfing	Insect	Low	Medium	Negligible	Pollination occurs before flower opens	Low
Maize	*Zea mays*	Annual	Selfing/outcrossing	Wind	Low	Low–medium	Low	Staminate and pistillate flowers	Medium
Papaya	*Carica papaya*	Perennial	Selfing/outcrossing	Insect, Wind	Low	Low	Low	Dioecious plants	High
Potato	*Solanum tuberosum*	Annual	Selfing/outcrossing	Insect	Low	Low–medium	Low	True seeds and tubers	Low
Rice	*Oryza sativa*	Annual	Predominantly selfing	Wind	Low	Medium	Low–medium	Can be weedy/invasive†	Medium
Soybean	*Glycine max*	Annual	Predominantly selfing	Insect	Negligible	Low	Negligible	Flowers attract few bees	Low
Sugar beet	*Beta vulgaris*	Biennial	Predominantly outcrossing	Wind, insect	High	Medium	High	High levels of self-sterility	High
Sunflower	*Helianthus annuus*	Annual	Predominantly outcrossing	Insect	Medium–high	Medium	Low–medium	Recent varieties are self compatible	Low–medium
Wheat	*Triticum aestivum*	Annual	Predominantly selfing	Wind	Low	Medium–high	Low–medium	Florets remain open only for short period	Medium

Souces Agbios (2008), CFIA (2008)

† *Source* SWSS (1998)

predict the long-term risks associated with GE traits through few short-term investigations.

Adventitious Presence

In the US, rules requiring farmers who cultivate GE crops to avoid the contamination of conventional fields or feral populations are not explicit. APHIS has no responsibility to consider the AP of deregulated materials outside of GE crop production fields and that includes AP in conventional and organic farms, even if such AP causes economic harm. Market losses and liabilities associated with the AP of deregulated traits are neither dealt with by APHIS nor by any other US federal agencies (USGAO 2008). Specifically, USDA, federal drug agency (FDA), and environmental protection agency (EPA) do not have a co-ordinated program for assessing the impact of the AP of GE traits on non-GE segments of agriculture (USGAO 2008). Because economic losses and liabilities can be considered damaging to the human environment (USDC 2007), broader policies may need to be established regarding AP. In addition, the differentiation of world markets into GE, non-GE, and organic sectors demands efficient identity preservation (IP) protocols (for deregulated products) and effective policies on the AP of deregulated GE traits. Practical experience suggests that achieving the segregation of GE and non-GE crops is a challenge in current commodity supply chains even when acceptable AP levels are in the range of 1–5% (Isaac et al. 2005). Some traders have put in place efficient IP protocols to avoid market risks. However, there is broad uncertainty about the practicality and affordability of managing IP for AP levels significantly below 1% (Van Acker et al. 2007).

AP does in fact happen; for example, the USDA-Foreign Agricultural Service has reported the discovery of an EU-unapproved biotech event in conventional rapeseed sown on about 1458 ha in Germany, even though the seed used to plant this crop tested negative for GE materials (GAIN 2007). Reports also indicate the discovery of approved GE materials around the ports even when the GE crop in question was not commercially cultivated (e.g., Saji et al. 2005). Incidents like this point to a need for the development and implementation of special considerations and confinement protocols for producers (and perhaps regions) that wish to meet import requirements in GE sensitive markets (NAFA 2008b). It is also not certain who should cover the costs associated with confining deregulated GE traits and to-date the costs have been borne by those who can achieve premiums for ensuring low AP levels. To date, no GE crop has commanded market premium which could be used to offset segregation costs.

Market Risks

In this section, particular reference is made to GR alfalfa due to the need for specific market data for a detailed analysis of market risks. The analysis will provide a general understanding of the nature of market risks associated with the deregulation of GE crops in general.

Risks to the Conventional Alfalfa Hay Export Market

Asynchronous market authorizations of GE crops, food, and feed in various jurisdictions, particularly in the US, Japan, and EU, have long been a threat of market harm (JRC-IPTS 2009). Asynchronous authorization is a growing concern due to its potential economic impact on international trade in case of AP of GE traits in conventional food/feed products. Even if the request for approvals is submitted at the same time, the approvals are not usually granted simultaneously in all countries (JRC-IPTS 2009). For example, at the time the deregulation decision was taken on GR alfalfa in the US, market authorizations were not granted by most of the key US hay importing countries, including Japan, which is the destination for about 72% of all US alfalfa hay exports (annual value of about 500 million US$) (USDA 2005). Since that time approvals as food/feed have been secured in most of the hay export markets (McCaslin 2008) but the approvals took a long time (Table 4). Some delays may have been due to the fact that many approvals were sought only after deregulation in the US. Furthermore, the approvals varied among countries in terms of the type of usage. Some countries (e.g., US, Canada, Japan) granted approvals for food, feed, and environmental release, while others (e.g., Philippines, South Korea, Mexico) only granted approvals for food and/or feed use.

Even when approvals for GE alfalfa were granted in key hay export markets, market barriers still exist in some importing countries (McCaslin 2008), including, for example, low tolerance levels for AP of GE traits in conventional hay shipments (as low as 0.1%). Importers in Japan have generally expressed preferences for non-GE alfalfa due in part to the difficulty in segregating GE and non-GE hay lots and to the reluctance of consumers to adopt GE products (including Japanese dairies) (NAFA 2008a). Reports indicate that between 10 and 20% of Japanese customers

Table 4 Regulatory status of GR alfalfa in important US hay importing countries

Export destination	Exports (tones)*	% of total export	Status/year approved			Reference
			Food	Feed	Environment	
Japan	680,769	71.6	2005	2006	2006	JBCH (2006)
South Korea	128,331	13.5	2007	2008	Not approved	KBCH (2008)
Taiwan	68,662	7.2	Approval not required†			–
Canada	39,447	4.2	2005	2005	2005	CFIA 2005
UAE	19,864	2.1	No regulatory process in place†			–
Mexico	8987	1	2005	2005	Not approved	COFEPRIS (2005)
Hong Kong	1,087	0.1	Approval not required†			–
China (PRC)	420	0.04	Approval not required†			–
UK	407	0.04	No information available			–
Australia/ New Zealand	–	–	2006	2006	Not approved	FSANZ (2006)
Philippines	–	–	2006	2006	Not approved	NBCP (2006)

* Export of alfalfa hay, cubes and meal—2006 statistics (*Source* NASS 2008)

† *Source* NAFA (2008a)

demand GE-free alfalfa hay (NAFA 2008a) even though a relatively high threshold level of 5% has been established for AP of approved GE events in conventional products. Exporters fear that shipments could be rejected at a cost to them and these fears can cripple markets.

Risks to the Conventional Alfalfa Seed Export Market

Most of the approvals secured to-date for GR alfalfa in the importing countries are for hay markets and not seed markets. The US alfalfa seed export market is valued at about 43 million US$ annually with about 14 million kg of seeds exported to 63 countries (USDA-FAS 2009). Notable seed importers include Saudi Arabia, Mexico, Argentina, Canada, and United Arab Emirates (UAE) (USDA-FAS 2009) (Table 5). Among the seed importing countries, only Canada and Japan have authorized environmental release of GR alfalfa (CFIA 2005), while about 43 countries comprising 81% of the US seed exports have either not yet authorized GR alfalfa for environmental release or not put a regulatory system in place. US exports of alfalfa seed to the European Union (EU) were valued at 1.8 million US$ in 2005, accounting for about 5% of total US alfalfa seed export revenues (USDA-FAS 2009). Markets in the EU remain particularly sensitive to the AP of GE materials. In the absence of a marketing approval, a zero tolerance policy is effective, threatening US alfalfa seed exports to the EU (GAIN 2006). As of yet no application has been filed under EU law for approving GE alfalfa for food/feed/environmental release, hence this situation is likely to continue.

Table 5 Regulatory status of GR alfalfa in important US seed importing countries

Importing country	Approval for Environmental release	Alfalfa seed export value ('000 dollars)			% of total alfalfa seed export value
		Certified	Uncertified	Total	
Saudi Arabia	No	10165	139	10304	23.77
Mexico	No	3173	5249	8422	19.43
Argentina	No	6225	1144	7369	17.00
Canada	Yes	7362	–	7372	16.99
UAE	No†	1937	19	1956	4.51
Italy	No	1170	158	1328	3.06
Peru	No	441	557	998	2.30
Chile	No	426	319	745	1.72
Japan	Yes	236	509	745	1.72
Libya	No	326	400	726	1.68
South Africa	No	363	123	486	1.12
Other countries (35)	No	2192	708	2900	6.70
Total seed export value ('000 dollars)				43,351	

** Alfalfa seeds exported for planting purposes in 2005 (*Source* USDA-FAS 2009)

† No regulatory process in place (Source: NAFA 2008a)

Exporters of conventional alfalfa seed to sensitive markets may be required to declare and/or prove that their seed lots are free from GE material. Evidences suggest that total confinement of GE crops grown commonly across a broad agricultural region may be highly unlikely (Marvier and Van Acker 2005) and that the contamination of conventional seeds in these regions is possible. This triggers concerns of customers in sensitive importing countries, including EU Member States.

Risks to Organic Markets

Organic crop and livestock production is one of the fastest growing agricultural sectors in the US with about 4.1 million hectares of land dedicated to organic production and about 196,000 organic livestock animals in 2005 (USDA-ERS 2005). In the same year, certified organic alfalfa hay was produced on over 200,000 acres in the US. Organic milk production is also a significant industry in the US with about 87,000 cows currently and a growth rate of 25% per year (USDA-ERS 2005). National organic program (NOP) rules in the US prohibit planting of GE seeds and the presence of GE materials in organic products (Furtan et al. 2007; Demont and Devos 2008; USDA-AMS 2009) and this includes feeding animals grown for organic milk and meat production. Alfalfa is an important feed for organic livestock especially dairy cows. It is also an important legume crop in organic rotations. Threats to the availability of GE-free alfalfa seeds, due to the AP and contamination of conventional seed production fields, may prohibit organic farmers from planting alfalfa and would create tremendous challenges and costs for organic producers both in relation to cropping system agronomy and dairy cow nutrition challenges (SOD 2006).

Other Challenges Related to Market Co-existence

There exist several confounding factors that often hinder the successful market acceptance and co-existence of GE crops. Such factors are not specific to perennials but are common to most of the commercialized GE crops. They include stewardship practices, co-existence and enforceability, testing procedures, thresholds and labeling, and liability.

Stewardship Practices, Co-Existence, and Enforceability

Various stewardship approaches have been proposed by academic researchers and industry as means of achieving co-existence between GE and non-GE alfalfa (Putnam 2006; Monsanto Company 2008). APHIS has developed a Biotechnology Quality Management System (BQMS) to assist the development of sound management practices to enhance compliance with regulatory requirements when dealing with regulated GE organisms (APHIS 2009b). However, there is no governmental oversight of deregulated traits in the US and co-existence is left to the market even when there is known risk of market harm from AP. In the EU, guidelines on best management practices have been developed to ensure the co-existence of GE crops with conventional and organic segments (CEC 2003). In addition, specialized programs such as SIGMEA (www.inra.fr/sigmea), Co-Extra (www.coextra.eu) and Transcontainer (www.transcontainer.org) have been designed to identify the strategies that can enhance the success of co-existence programs. Nevertheless, strict adherence to stewardship approaches requires incentives, diligence, and enforcement (Van Acker et al. 2007).

Stewardship protocols are more practicable if they are based on real management practices rather than best management practices. Unfavorable weather conditions, human error, and rare events can make the confinement of GE traits very challenging. There are numerous examples of regulated materials escaping even from confined field tests conducted under strict protocols and severe vigilance (APHIS 2009a). Even very sophisticated stewardship protocols are likely to fail in case of zero tolerance for GE traits or reluctance of importers to accept commodity shipments that might have to be labeled as GE. Establishment of consensual, achievable, and enforceable tolerance threshold levels (above zero) for GE traits in conventional export markets is therefore vital. Further, there is no clear guideline or legislation as to who is responsible for enforcing the stewardship practices. In the US, the federal agencies such as USDA and EPA have the authority to inspect the fields but to date, most of the violations were detected by the developers of GE crops (USGAO 2008) and this perhaps points to a need for appropriate regulations for enforcing compliance with stewardship programs.

Testing Procedures

The existing seed testing procedures including that of International Organization for Standardization (ISO), International Seed Testing Association (ISTA), and Association of Seed Certifying Agencies (AOSCA) have general guidelines and requirements on seed sampling and testing standards that may apply to GE commodities. Further, there are specific standards from ISO and the European Committee for Standardization (CEN) for sampling and testing GE commodities. Several aspects of GMO testing were exemplified in the course of the first Global Conference on GMO Analysis (EC-JRC 2008b). Nevertheless, technologies for testing the presence of specific GE traits are neither fully developed nor internationally standardized (Viljoen et al. 2004). Most available testing procedures are not capable of precisely detecting the presence of GE materials, especially at low levels, due to variability of sampling methods used (Woodward 2006). Still, a topical issue around testing for the AP of GE is the problem of false negatives and false positives (Remund et al. 2001). This uncertainty translates into marketplace issues. For example, after the deregulation of GR alfalfa, the US Federal Seed Laboratory was no longer willing to provide a GE-free declaration for alfalfa seed exporters (NAFA 2008a). This is a common issue with many GE traits.

Common AP testing procedures are either protein based (lateral flow test strips [LFTS] and enzyme-linked immunosorbent assay [ELISA]) or DNA based. LFTS are simple to use and inexpensive but can vary in their outcome as they dependent on eyesight and judgment of the analyst. For example, the accuracy of two LFTS developed for detecting the presence of the GE GR trait in alfalfa haystacks, hayfields, and seeds were evaluated by researchers in Washington State (Woodward 2006) who concluded that LFTS were not reliable for confirming the presence of the GE GR trait at levels of less than 5%. Nevertheless, strip tests are generally useful for assessing labeling thresholds and therefore the limit of detection is not per se a limit of use. ELISA tests are more accurate than LFTS but are expensive and require higher levels of skill (Viljoen et al. 2004). DNA based tests are more reliable than protein based tests (Griffiths et al. 2002) and the tests are currently being developed for most of the GE traits. The currently validated collaborative trials on GE testing are available in the official website of the European Community Reference Laboratory for GM Food and Feed (http://gmo-crl.jrc.ec.europa.eu). The issues around testing can be expected to prevail until official detection methods are fully standardized and internationally accepted.

Thresholds and Labeling

Currently there are no internationally accepted threshold levels or labeling standards for the AP of GE materials authorized for market commercialization, although the expected threshold for regulated traits is zero (Viljoen et al. 2004). Labeling is not mandatory in most countries. The EU requires a label if approved GE materials are present in non-GE crop, food, and feed items above a threshold level of 0.9% (GAIN 2006). This threshold level applies only to food or feed materials and as such there is no threshold level for GE material in planting seeds (GAIN 2006), leading some to suggest this implies a zero threshold level in seeds for labeling purposes. If traces of EU approved GE material is found in conventional seed, then it has to be labeled as containing GE material. If AP of unapproved GE material is detected, the material must be destroyed or should be withdrawn from the market (GAIN 2006). In Japan and Australia, labeling thresholds for approved GE materials are 5 and 1%, respectively (Viljoen et al. 2004).

Conversely, some countries, including China, have neither established any AP thresholds nor any requirements for labeling. In this sort of global context, exporters, particularly seed exporters, are often concerned that particular shipments could be rejected because of the AP of GE material (NAFA 2008a). What is certain is that exporters bear the market risk, which has forced the export companies to require a practical threshold, which often lie between 1/3rd and 1/10th of the export destination's actual labeling thresholds. For countries in the EU, for example, the stakeholders are using a practical threshold generally at 0.1%, meaning that co-existence protocols would require large isolation distances or dedicated production areas (Co-Extra 2009). All EU member states are using the 0.1% threshold for defining GMO-free status of the products. Globally, non-uniformity in threshold and labeling standards cause uncertainties among the stakeholders.

Liability

Liability is a key issue in relation to functional field and market co-existence. The liabilities for non-compliance with standards are not adequately addressed in most regulatory frameworks. In the EU, Directorate-General for Agriculture and Rural Development (DG AGRI) has prepared a report on the liability and compensation schemes for damage resulting from the presence of GE materials in non-GE crops (ARD 2007). Farmers growing GE crops are typically held liable for AP, depending on the co-existence legislation of the individual EU Member State. In the US, there is no co-existence legislation and no mandatory labeling, and deregulated GE crops are granted unconfined release. These conditions make it difficult for growers or food producers affected by the AP of GE material to mount any efforts for recourse if they experience economic losses as a result of the AP of GE. This is not necessarily true for regulated GE material, however, and the Starlink® case in the US did result in payment of damages to a range of affected stakeholders (Marvier and Van Acker 2005).

Some suggest that farmers who serve markets that have standards beyond what is available in typical commercial streams hold the responsibility and liability to meet those standards. The Technology Use Agreements in the US bind the farmers to any liability associated with AP. Globally, there seems to be no standard guideline on the liabilities associated with the AP of GE traits. A clear assignment of responsibilities and liability would be required, including a consideration of who is responsible and who pays for expenses related to IP, testing, and market loss (Van Acker et al. 2007).

Conclusion

Our analysis makes visible some of the fundamental challenges to the US GE regulatory systems and identifies opportunities for further improvement. The lack of a comprehensive regulatory framework in the US—in particular the so-far absence of a policy considering economic risks for conventional seed, food, and feed markets—creates concerns among the stakeholders and uncertainty for exporters to GE sensitive markets. However, in light of the US court guidelines on GR alfalfa, APHIS has now included the socio-economic aspects as part of its environmental risk assessment mandate in the recently prepared draft EIS on GR alfalfa (APHIS 2010). This implies the first step in the direction highlighted in this paper. Similar consideration on other aspects including co-existence protocols, thresholds, labeling, and liability by concerned authorities will greatly facilitate the adoption of GE crops. Governments must consider enacting laws and establishing or empowering institutions to ensure that these regulations are adequately enforced. Furthermore, co-operative international initiatives are necessary in order to establish internationally accepted standards with regard to IP, testing, thresholds, and labeling of regulated and deregulated GE materials. Additionally, more research is required into the development and standardization of trait confinement protocols, IP and testing standards that are reliable and practicable under different circumstances. While this analysis has mainly focused on GR alfalfa and the US regulatory framework, the diagnosed problems and conclusions are also true for many other jurisdictions and crops—in particular if there is no co-existence policy in place.

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