

Deregulation of GE Alfalfa: Mounting Challenges for Risk Assessors and Policy Makers

Muthukumar V. Bagavathiannan, Armin Spök, & Rene C. Van Acker

Abstract

Genetically engineered (GE) glyphosate-resistant (GR) alfalfa (*Medicago sativa*, L.) is currently under moratorium in the United States (US). While GR alfalfa can provide operational benefits to farmers, there exist unique challenges with alfalfa in terms of novel trait confinement. Alfalfa is the first perennial, highly outcrossing, insect-pollinated GE crop to receive deregulation. It is not certain whether the benefits of GR alfalfa can be exploited without jeopardizing other sectors. Detailed investigation of the US regulatory framework and the perception of stakeholders and the general public suggest that crucial factors were not considered in the deregulation process for GR alfalfa. Addressing these factors will be vital for a broader acceptance and market success of GE agriculture in general.

Keywords:

Alfalfa; genetic engineering; glyphosate resistance; adventitious presence; deregulation; regulatory framework

Introduction

Genetically engineered (GE) crops have been legally authorized for commercial production in many countries and commercially grown worldwide for over a decade. The incidences of outcrossing with non-GE crops and adventitious presence (AP) of GE traits in non-GE crops are cause for serious concern among various commercial stakeholders, public interest groups and the general public [1]. Our ability to contain novel traits within production fields is far from absolute and there exist numerous examples of novel trait escape and associated unintended effects [2]. Strategies for the segregation of GE and non-GE crops can be expensive and often inefficient [3]. A notable example is the Starlink® corn case

74 *Muthukumar V. Bagavathiannan, Armin Spök, & Rene C. Van Acker*

in the US, where GE corn deregulated only for use as animal feed was found throughout the human food supply chain [4]. Similarly experience 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, road sides and waste lands [5–6]. 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 [7–8]. Previous evidences suggest that the retraction of transgenes might be impossible once they escape into the environment [9]. The possibility of transgene escape and presence in unintended destinations raises concerns over the safety of transgenic crop production and has led to lawsuits over the deregulation of such products, including the recent lawsuit over the deregulation of GR alfalfa in the US.

The deregulation of GR alfalfa in the US in June 2005 raised concerns among stakeholders and farmer organizations (see Box 1 in the annex) and subsequently attracted a lawsuit in February 2006. In May 2007, a federal district court in the US ordered a permanent moratorium on the sale and cultivation of GR alfalfa in the US, pending the production of a detailed Environmental Impact Statement (EIS) [10]. The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) is currently working on the preparation of an EIS (see Box 2 in the annex). US regulators face mounting challenges in regard to this case because several factors are left unaddressed by the current US regulatory framework on GE crops. Broad stakeholder and public opinion suggest that addressing these factors is critical before there can be a broader market and public acceptance.

Factors not considered by the present regulatory framework in the US

Alfalfa was the first perennial, highly outcrossing, insect-pollinated GE crop in the world to be commercially approved (in the US designed as deregulation). The ecology and biology of alfalfa greatly favours gene

flow [11] and among the GE crops deregulated to date it is possibly the highest risk in terms of trait movement (see Table 1 in the annex). The recent moratorium on GR alfalfa in the US requires that regulators more fully investigate and consider the issues associated with GR alfalfa in this regard including AP, market risks, stewardship practices, co-existence protocols, enforceability, testing procedures, thresholds, labelling and liability. However, the current US regulatory framework does not allow most of these factors to be considered in the assessment process, nor is the approach to their consideration standardized.

Adventitious presence

When GE crops are deregulated they are allowed to exist anywhere in the environment and there are no US federal requirements that prohibit the adventitious presence (AP) of wholly owned deregulated GE products in or on another person's property. In the US, rules requiring farmers who cultivate GE crops to avoid the contamination of neighbouring fields or feral populations have never been considered. 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 dealt with neither by APHIS nor by any other US federal agencies [12]. Since economic losses and liabilities can be considered as damaging to the human environment [10], 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), standard and comprehensive segregation protocols and effective policies on the adventitious presence of GE traits, including protection of sectors that may realize economic harm from the adventitious presence of GE crops. Achieving the segregation of GE and non-GE crops is a challenge and practical experience suggests that this is generally true in current commodity supply chains even when acceptable AP levels are in the range of 1 to 5 %. There is broad uncertainty about the practicality and

76 *Muthukumar V. Bagavathiannan, Armin Spök, & Rene C. Van Acker*

affordability of managing IP for AP levels significantly below 1 % [13]. It is not certain who should cover costs associated with confining deregulated GE traits and the costs are currently borne by those who can achieve premiums for ensuring low AP levels. To date, no GE crops have commanded market premiums which could be used to offset segregation costs. More research is necessary to develop reliable segregation and IP protocols in order to better serve the markets with specific AP requirements.

Market risks

Risks to the conventional US hay export market

Asynchronous market authorizations of GE crops, food and feed in the various jurisdictions, particularly in the USA, Japan and the EU, have long been a threat of market harm and have sparked disputes. At the time the deregulation decision on GR alfalfa was taken in the US, market authorizations had not been granted by most of the key importing countries, including Japan, which is the destination for about 72 % of all US alfalfa hay exports (annual value of about 500 million US\$) [14]. Since that time approvals as food/feed have been secured in most of the hay export markets [15], but took a long time in some cases (see Table 2a in the annex). 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 granted approvals for food, feed and environmental release, while others granted approvals for food and/or feed use only.

Although approvals for GE alfalfa were granted in key hay export markets, market barriers still exist in some importing countries [15], including for example, extremely low tolerance levels for the presence 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 of segregating GE and non-GE hay lots and also to consumers scepticism (including Japanese dairies) [16]. Some reports indicate that between 10 and 20 % of Japanese hay customers demand

GE-free hay [16] even though the national threshold for AP of approved GE events is 5 %. Exporters fear that shipments could be rejected at their expense and these fears can cripple markets.

Risks to the conventional US alfalfa seed export market

Most of the approvals secured to date for genetically engineered GR alfalfa in the US are for alfalfa hay markets, 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 [17]. Notable seed importers are Saudi Arabia, Mexico, Argentina, Canada and UAE [17] (see Table 2b in the annex). Among the seed importing countries, only Canada and Japan have authorized environmental release of GR alfalfa [18], while about 43 countries, comprising 81 % of the US seed imports, 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 [17]. Markets in the EU remain sensitive to the AP of GE materials. As the EU has not yet set any tolerances for AP in seed, alfalfa seed exports to the EU remain threatened if GE is detected at any level [19].

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. Previous evidence suggests that total containment of novel traits in commercialized GE crops grown commonly across a broad agricultural region may be impossible [9] and the contamination of conventional seeds in these regions may be inevitable. This triggers concerns of customers in sensitive importing countries, including EU Member States. And accidental AP does in fact happen. For example, the USDA Foreign Agricultural Service has reported the discovery of a non-EU approved biotech event in conventional rapeseed sown on about 3500 acres in Germany, even though the seed used to plant this crop tested negative for GE materials [20]. 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

78 *Muthukumar V. Bagavathiannan, Armin Spök, & Rene C. Van Acker*

import requirements in GE sensitive markets [21], and this may be particularly true for seed producers.

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 [22]. In this 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 currently about 87,000 cows and a growth rate of 25 % per year [22]. National Organic Program (NOP) rules in the US prohibit planting of GE seeds and the presence (at any level) of GE materials in organic products [23–25]. Alfalfa is an important feed for organic livestock, especially for dairy cows. It is also an important legume crop in organic rotations. Threats to the availability of GE-free alfalfa seeds, due to AP and contamination of conventional seed production fields, would prohibit organic farmers from planting alfalfa and would create tremendous challenges and costs for organic producers in the US both in relation to cropping system agronomy and dairy cow nutrition challenges [26].

Stewardship practices, co-existence and enforceability

Various stewardship approaches have been proposed by academic researchers and industry stakeholders as means of achieving co-existence between GE and non-GE alfalfa [27–28]. Strict adherence to these approaches requires incentives, diligence and enforcement [13]. Stewardship approaches are more practicable if they are based on real management practices and not best management practices. Unfavourable weather conditions, human error and rare events make the confinement of novel traits very challenging. In most cases, total confinement of novel traits within production fields is highly unlikely even if the stewardship practices are strictly followed. There are numerous

examples of regulated materials escaping even confined field tests conducted under strict protocols and severe vigilance [2]. Therefore, co-existence programs aimed at achieving zero AP levels will most likely fail. The success of co-existence programs depends on the establishment of consensual, achievable and enforceable tolerance levels (above zero). In the US there is no governmental oversight of deregulated traits and co-existence is left to the market even when there is a known risk of market harm in the event of failure.

Testing procedures

Technologies for testing the presence of GE material are neither fully developed nor internationally standardized [29]. Most available testing procedures are not capable of precisely detecting the presence of GE materials, especially at low levels, due to the variability of sampling procedures [30]. Ongoing issues around testing for AP of GE mean that false negatives and positives remain a problem [31]. This uncertainty translates into marketplace issues. For example, after the deregulation of GR alfalfa, the US federal seed lab was no longer willing to provide a GE-free declaration for alfalfa seed exporters [21].

Common AP testing procedures are either protein based (lateral flow test strips [LFTS] and enzyme-linked immunosorbent assays [ELISA]) or DNA based. LFTS are simple to use and inexpensive but can vary in their outcome as they depend on the eyesight and judgment of the analyst. The accuracy of two LFTS developed for detecting the presence of the GE GR trait in alfalfa haystacks, hayfields and seeds was evaluated by researchers in Washington State [30], who concluded that LFTS were not reliable for confirming the presence of the GE GR trait at levels below 5 %. ELISA tests are more accurate than LFTS but are expensive and require higher levels of skill [29]. DNA based tests are more reliable than protein based tests [32] but are not available for many GE traits including the GE GR trait in alfalfa.

80 *Muthukumar V. Bagavathiannan, Armin Spök, & Rene C. Van Acker*

Thresholds and labelling

Currently there are no internationally accepted threshold levels or labelling standards for AP of GE materials authorized for market commercialization, although the expected threshold for regulated traits is zero [29]. Labelling 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 % [19]. This threshold level applies only to food or feed materials so that there is no threshold level for GE material in seeds, leading some to suggest this implies a zero threshold level [19]. If traces of EU approved GE material are found in conventional seed, then it must be labelled as containing GE material. If AP of unapproved GE material is detected, the crop must be destroyed [19]. In Japan and Australia, labelling thresholds for approved GE materials are 5 % and 1 %, respectively [29]. By contrast, some countries, including China, have not yet established any AP thresholds, nor any requirements for feed labelling. Against this global backdrop, US alfalfa hay and seed exporters are often concerned that particular shipments could be rejected because of AP of GE material [21]. What is certain is that exporters bear the market risk.

Liability

Liability is a key issue in relation to functional field and market co-existence. The liabilities for non-compliance with standards are often not addressed in regulatory frameworks. In the EU, 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 labelling, and deregulated GE crops are granted unconfined release. These conditions make it difficult for stakeholders affected by AP of GE material to mount any efforts for recourse if they experience market harm as a result. 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 [9]. Technology developers in the US 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 [28]. The Technology Use Agreements that farmers sign in the US in order to purchase GR alfalfa and other GE crops binds them to any liability associated with AP. Globally, there are no examples of legislation or regulations which hold technology developers or owners of GE crop traits liable for AP [33]. A clear assignment of responsibilities and liability would be required, including a consideration of who is responsible and who pays the expenses related to IP, testing and market loss [13].

Implications for other GE crops

The case of GR alfalfa reveals some more fundamental challenges to the US regulatory system from GE crops. The lack of a comprehensive regulatory framework creates concerns among farmers, agricultural stakeholders and the public, and it creates uncertainty for exporters to GE sensitive markets. Stakeholders demand a regulatory approach that can deal with the regulation of GE crops in a comprehensive and coordinated fashion. In the US, federal agencies have limited assessment mandates and there is no supreme body that ensures overall assessments are inclusive. The lack of clear policies also hinders the regulatory process. Therefore, appropriate policies on AP, market risks, stewardship practices, co-existence protocols, enforceability, testing procedures, thresholds, labelling and liability need to be established and included in the existing US regulatory frameworks on GE crops. GE crops should also be assessed on these factors before regulatory decisions are taken. Governments must consider enacting appropriate laws and establishing or empowering institutions to ensure that these regulations are adequately enforced. Furthermore, co-operative international initiatives are required to establish internationally accepted standards with regard to IP, testing, thresholds and labelling of regulated and deregulated GE materials. Additionally, more research is required into the development and standardization of trait confinement protocols that are reliable and practicable under different circumstances.

82 *Muthukumar V. Bagavathiannan, Armin Spök, & Rene C. Van Acker*

So long as the GE crops jeopardize the interests of non-adopting farmers, stakeholders and the public within and outside the US, it is unlikely that the full benefits of this technology can be harnessed. In this context, a revision of the US regulatory framework on GE crops is required, and there needs to be an acceleration of international co-operation and agreement on standards regarding AP and labelling.

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References

- [1] Ellstrand, N. C. (2001), 'When transgenes wander, should we worry?', *Plant Physiol.* 125: 1543–1545.
- [2] APHIS. (2009), 'Non-compliance history', Animal and Plant Health Inspection Service, (http://www.aphis.usda.gov/biotechnology/compliance_history.shtml).
- [3] Wilson, W. W. and Dahl, B. (2006), 'Costs and risks of segregating GM wheat in Canada', *Can. J. Agrl. Econ.* 54: 341–359.
- [4] Buccini, L. and Goldman, R. (2002), 'Starlink corn: A risk analysis', *Environ. Health Pers.* 110: 5–13.
- [5] Friesen, L. F. et al. (2003), 'Evidence of contamination of pedigreed canola (*Brassica napus*) seedlots in western Canada with genetically engineered herbicide resistance traits', *Agron. J.* 95: 1342–1347.
- [6] Legere, A. (2004), 'Risks and consequences of gene flow from herbicide-resistant crops: Canola (*Brassica napus* L) as a case study', *Pest Mgt. Sci.* 61: 292–300.
- [7] Watrud, L. S. et al. (2004), 'Evidence for landscape-level, pollen-mediated gene flow from genetically modified creeping bentgrass with *CP4 EPSPS* as a marker', *Proc. Natl. Acad. Sci.* 101: 14533–14538.

- [8] Zapiola, M. L. et al. (2008), 'Escape and establishment of transgenic glyphosate-resistant creeping bentgrass *Agrostis stolonifera* in Oregon, USA: a 4-year study', *J. Appl. Ecol.* 45: 486–494.
- [9] Marvier, M. and Van Acker, R. C. (2005), 'Can crop transgenes be kept on a leash?', *Front. Ecol. Environ.* 3: 93–100.
- [10] USDC (2007), Memorandum and order re: permanent injunction report from the *United States District Court for the Northern District of California*, order No. C06-01075 CRB.
- [11] Bagavathiannan, M. V. and Van Acker, R. C. (2009), 'The biology and ecology of feral alfalfa (*Medicago sativa* L.) and its implications for novel trait confinement in North America', *Cri. Rev. Pl. Sci.* 28: 69–87.
- [12] USGAO (2008), 'GAO Report to the committee on agriculture, nutrition, and forestry, U.S. senate genetically engineered crops: Agencies are proposing changes to improve oversight, but could take additional steps to enhance coordination and monitoring', *United States Government Accountability Office*, November 2008, GAO-09–60 Pp 103.
- [13] Van Acker R. C. et al. (2007), 'Development of quality assurance protocols to prevent GM-contamination of organic crops', in Cooper, J. et al. (Eds.), *Handbook of Organic Food Safety and Quality*, Boca Raton, USA: CRC Press, 466–489.
- [14] USDA (2005), 'USDA/APHIS environmental assessment and finding of no significant impact', *United States Department of Agriculture* (http://www.aphis.usda.gov/brs/aphisdocs2/04_11001p_com.pdf).
- [15] McCaslin, M. (2008), 'An update on Roundup Ready alfalfa', in *Proceedings of the Washington State Hay Growers Association Annual Conference* (<http://www.wahay.org/Proceedings/08%20Proceedings/Update%20on%20RR%20Alfalfa%20%20McCaslin.pdf>).
- [16] NAFA (2008a), 'Coexistence for alfalfa hay export markets', *National Alfalfa and Forage Alliance* (<http://alfalfa.ucdavis.edu/+producing/files/biotech/CSExportHay.pdf>).
- [17] USDA-FAS (2009), 'Market and trade data', *United States Department of Agriculture-Foreign Agricultural Service* (<http://www.fas.usda.gov/seeds/seedstats.html>).
- [18] CFIA (2005), 'Decision document – DD 2005-53: Determination of the safety of Monsanto Canada Inc.'s Roundup Ready alfalfa events J101 and J163', *Canadian Food Inspection Agency* (<http://www.inspection.gc.ca/English/blaveg/bio/dd/dd0553e.shtml>).
- [19] GAIN (2006), 'Germany biotechnology annual 2006', Report no. GM6021, *Global Agricultural Information Network* (www.fas.usda.gov/gainfiles/200606/146198089.doc).

84 *Muthukumar V. Bagavathiannan, Armin Spök, & Rene C. Van Acker*

- [20] GAIN (2007), 'Biotech traces in German rapeseed seeds', Report number GM7042, *Global Agriculture Information Network* (www.fas.usda.gov/gainfiles/200709/146292339.doc).
- [21] NAFA (2008b), 'Coexistence for alfalfa seed export markets', *National Alfalfa and Forage Alliance* (<http://alfalfa.ucdavis.edu/+producing/files/biotech/CSExportSeed.pdf>).
- [22] USDA-ERS (2005), 'Organic production', *United States Department of Agriculture-Economic Research Service* (<http://www.ers.usda.gov/Data/Organic/index.htm#tables>).
- [23] USDA-AMS (2009), 'National organic program', *United States Department of Agriculture-Agricultural Marketing Service* (<http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateA&navID=NationalOrganicProgram&leftNav=NationalOrganicProgram&page=NOPNationalOrganicProgramHome&acct=nop>).
- [24] Furtan, W. H. et al. (2007), 'Landscape clubs: Co-existence of genetically modified and organic crops', *Can. J. Agrl. Econ.* 55: 185–195.
- [25] Demont, M. and Devos, Y. (2008), 'Regulating coexistence of GM and non-GM crops without jeopardizing economic incentives', *Trends Biotechnol.* 26: 353–358.
- [26] SOD (2006), 'Position paper on the introduction of genetically modified alfalfa', *Saskatchewan Organic Directorate* (http://www.saskorganic.com/oapf/pdf/SOD_GMO_Alfalfa_Position_Paper.pdf).
- [27] Putnam, D. (2006), *Methods to Enable Coexistence of Diverse Production Systems Involving Genetically Engineered Alfalfa*, Agricultural Biotechnology in California Series, Publication 8193.
- [28] Monsanto Company (2008), 'Roundup Ready alfalfa: Farmers benefits, environmental safety and stewardship', (http://www.monsanto.com/pdf/products/alfalfa_benefits.pdf).
- [29] Viljoen, J. et al. (2004), 'Segregating GM and non-GM grain in the Australian grain storage system', (http://www.daff.gov.au/__data/assets/pdf_file/0003/182829/Final_GM_Report_July_04.pdf).
- [30] Woodward, W. T. W. (2006), 'Roundup Ready alfalfa test kits and influence on the market place', in *Proceedings of the Washington State Hay Growers Association Annual Conference* (<http://www.wa-hay.org/Proceedings/06%20Proceedings/Roundup%20Ready%20Alfalfa%20Test%20Kits%20and%20Influence%20%20Woodward.pdf>).
- [31] Remund, K. M. et al. (2001), 'Statistical considerations in seed purity testing for transgenic traits', *Seed Sci. Res.* 11: 101–119.

- [32] Griffiths, K. et al. (2002), *Review of Technologies for Detecting Genetically Modified Materials in Commodities and Food*, Department of Agriculture, Fisheries and Forestry – Australia, 128 pp.
- [33] WORC (2006), 'Understanding Monsanto's technology agreement', *Western Organization for Resource Councils* (<http://www.worc.org/pdfs/Understanding%20Monsanto%27s%20Technology%20Use%20Agreement%202-06.pdf>).
- [34] Agbios (2008), 'Global status of approved genetically modified plants' (<http://www.agbios.com/dbase.php?action=Synopsis>).
- [35] CFIA (2008), 'Biology documents: Companion documents for directive 94–08', *Canadian Food Inspection Agency* (<http://www.inspection.gc.ca/english/plaveg/bio/dir/biodoce.shtml>).
- [36] SWSS (1998), *Weeds of the United States and Canada*, Southern Weed Science Society Publications, Champaign, Illinois.
- [37] JBCH (2006), 'Approved LMOs', *Japan Biosafety Clearing House* (http://www.bch.biodic.go.jp/english/lmo_2006.html).
- [38] KBCH (2008), 'Korean decisions', *Korean Biosafety Clearing House* (<http://www.biosafety.or.kr/english/index.asp>).
- [39] COFEPRIS (2005), 'GMO liberacion, Mexico', *Comision Federal Para La Protection Contra Riesgos Sanitarios* (<http://www.cofepris.gob.mx/pyp/biotech/OMG.pdf>).
- [40] FSANZ (2006), 'Final assessment report – food derived from glyphosate-tolerant lucerne J101 and J163', *Food Standards Australia New Zealand* (http://www.foodstandards.gov.au/_srcfiles/FAR_A575_Glyphosate_tolerant_Lucerne.pdf).
- [41] NBCP (2006), 'Determination of the safety of Monsanto's alfalfa (Herbicide Tolerant Alfalfa) for direct use as food, feed and for processing', *National Biosafety Committee of the Philippines* (<http://www.biotech.da.gov.ph/document%20for%20the%20web/Decision%20Documents/Alfalfa.pdf>).
- [42] NASS (2008), 'Data and statistics', *National Agricultural Statistical Service* (http://www.nass.usda.gov/Data_and_Statistics/index.asp).
- [43] CFS (2006), First amended complaint for declaratory and injunctive relief (FRCP-15a), *Center for Food Safety*, Case no.Co6-1075 CRB, 48 pp.
- [44] CFS (2007), 'Initial lawsuit filed against the deregulation of Roundup Ready alfalfa'. The United States District Court for the Northern District of California San Francisco Division, *Center for Food Safety*, Case no.C06-1075 CRB.
- [45] APHIS (2005), 'Monsanto Co. and Forage Genetics International; availability determination of nonregulated status for alfalfa genetically engineered for tolerance

86 *Muthukumar V. Bagavathiannan, Armin Spök, & Rene C. Van Acker*

to the herbicide glyphosate', *Animal and Plant Health Inspection Service*, [Docket No. 04-085-3], Federal Register, 70 (122): 36917–36918.

- [46] APHIS (2007), 'Return to regulated status of alfalfa genetically engineered for tolerance to the herbicide glyphosate', *Animal and Plant Health Inspection Service*, [Docket No. 04-085-4], Federal Register, 72 (56): 13735–13736.

Deregulation of GE Alfalfa: Mounting Challenges for Risk Assessors and Policy Makers

87

Annex

88 *Muthukumar V. Bagavathiannan, Armin Spök, & Rene C. Van Acker***Table 1. 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
Alfalfa	<i>Medicago sativa</i>	Perennial	Predominantly outcrossing	Insect
Canola	<i>Brassica napus</i>	Annual	Selfing / outcrossing	Insect, wind
Cotton	<i>Gossypium hirsutum</i>	Annual / perennial	Predominantly selfing	Insect
Creeping bentgrass	<i>Agrostis stolonifera</i>	Perennial	Predominantly outcrossing	Wind
Flax	<i>Linum usitatissimum</i>	Annual	Predominantly selfing	Insect
Lentil	<i>Lens culinaris</i>	Annual	Predominantly selfing	Insect
Maize	<i>Zea mays</i>	Annual	Selfing / outcrossing	Wind
Potato	<i>Solanum tuberosum</i>	Annual	Selfing / outcrossing	Insect
Rice	<i>Oryza sativa</i>	Annual	Predominantly selfing	Wind
Soybean	<i>Glycine max</i>	Annual	Predominantly selfing	Insect
Sugar beet	<i>Beta vulgaris</i>	Biennial	Predominantly outcrossing	Wind, insect
Sunflower	<i>Helianthus annuus</i>	Annual	Predominantly outcrossing	Insect
Wheat	<i>Triticum aestivum</i>	Annual	Predominantly selfing	Wind

{34–35}; †{36}

Level of self-incompatibility	Issue of volunteers	Fertility potential	Other remarks	Risk of gene flow
High	Low – medium	High	Can be weedy / invasive [†]	High
Low	High	Medium – high	Seed shattering / huge seed bank	Medium – high
Negligible	Low	Medium	Can be weedy / invasive [†]	Low – medium
High	N / A	High	Both vegetative propagules / seeds	High
Low	Medium	Medium	Hermaphroditic flowers	Low – medium
Low	Medium	Negligible	Pollination occurs before flower opens	Low
Low	Low – medium	Low	Staminate and pistillate flowers	Medium
Low	Low – medium	Low	True seeds and tubers	Low
Low	Medium	Low – medium	Can be weedy / invasive [†]	Medium
Negligible	Low	Negligible	Flowers attract few bees	Low
High	Medium	High	High levels of self-sterility	High
Medium – high	Medium	Low – medium	Recent varieties are self compatible	Low – medium
Low	Medium – high	Low – medium	Florets remain open only for short period	Medium

90 *Muthukumar V. Bagavathiannan, Armin Spök, & Rene C. Van Acker***Table 2a. Regulatory status of GR alfalfa in important US hay importing countries**

Export destination	Exports (tonnes)*	% of total export	Status / Year approved			Reference
			Food	Feed	Environment	
Japan	680,769	71.6 %	2005	2006	2006	{37}
South Korea	128,331	13.5 %	2007	2008	Not approved	{38}
Taiwan	68,662	7.2 %	Approval not required [†]			–
Canada	39,447	4.2 %	2005	2005	2005	{18}
UAE	19,864	2.1 %	No regulatory process in place [†]			–
Mexico	8,987	1 %	2005	2005	Not approved	{39}
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	{40}
Philippines	–	–	2006	2006	Not approved	{41}

* *Export of alfalfa hay, cubes and meal – 2006 statistics {42};*[†] {16}

Table 2b. Regulatory status of GR alfalfa in important US seed importing countries**

Export destination	Approval for environmental release	Alfalfa seed export value ('000 dollars)			% of total alfalfa seed export value
		Certified	Un-certified	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 {17}

† No regulatory process in place {16}

Box 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 [PHIS, Environmental Protection Agency (EPA) and Food and Drug Administration (FDA)] are involved in deregulation, responsibilities were not clearly portioned among agencies.

- The 1986 EPA guidelines on the re-registration 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.

{43–44}

Box 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' 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 NEPA, as amended (42 USC 4321 et seq.; 40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 342) [45].
- 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 the National Environmental Policy Act (NEPA), Endangered Species Act (ESA) and 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 [46].
- May 2007, permanent injunction order issued by the court, pending the production of a detailed EIS on GR alfalfa [10].
- July 2007, court issues an amended order detailing the confinement requirements including the storing of GR alfalfa, labelling containers and cleaning equipment associated with GR alfalfa fields already established.
- December 2007, APHIS issues a supplementary administrative order specifying 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.
- APHIS is currently working on the preparation of a draft EIS.