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The African Centre for Biosafety (ACB) is a non-profit organisation, based in Johannesburg, South Africa. It provides authoritative, credible, relevant and current information, research and policy analysis on genetic engineering, biosafety, biopiracy, agrofuels and the Green Revolution push in Africa.

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Acronyms

ACB	African Centre for Biosafety
AGRA	Alliance for a Green Revolution in Africa
AHTEG	Ad-Hoc Technical Expert Group
APHIS	Animal and Plant Health Inspection Service (USA)
AU	African Union
BCH	Biosafety Clearing House
CBAN	Canadian Biotechnology Action Network
CBI	Confidential Business Information
CIMMYT	International Maize and Wheat Improvement Centre
CNBS	Conselho Nacional de Biosseguranca (Brazil)
CPB	Cartagena Protocol on Biosafety
CTNbio	Commissoa Tecnica Nacional de Biosseguranca (Brazil)
EFSA	European Food Standards Agency
EU	European Union
FAO	Food and Agricultural Organisation
FSC	Food Safety Commission (Japan)
FDA	Food and Drug Administration (USA)
FTA	Free Trade Agreement
FFDCA	Federal Food, Drug and Cosmetic Act (USA)
GEAC	Genetic Engineering Approval Committee (India)
GMO	Genetically Modified Organism
GE	Genetically Engineered
IAASTD	International Assessment of Agricultural Knowledge, Science and Technology for Development
IMF	International Monetary Fund
IPR	Intellectual Property Rights
ISAAA	International service for the Acquisition of Agri-biotech Applications
KFDA	Korea Food & Drug Administration
LMO	Living Modified Organism
MAFF	Ministry of Agriculture, Forestry and Fisheries (Japan)
MEXT	Ministry of Education, Culture, Sports, Science and Technology
MHLW	Ministry of Health, Labour and Welfare (Japan)
MOCIE	Ministry of Commerce, Industry, and Energy (South Korea)
MOP-5	Meeting of Parties number 5 [i]
MOE	Ministry of Environment (Japan)
NGO	Non-governmental Organisation
PAIA	Promotion of Access to Information Act
PBO	Plant Biosafety Office (Canada)
RDA	Rural Development Association (South Korea)
PIP	Plant Incorporated Protectants
rDNA	recombinant deoxyribonucleic acid
SAGPya	Secretaria de Agricultura, Ganadena, Pesca y alimentacion (Argentina)
SENASA	Servicio Nacional de Sanidad y Calidad Agroalimentaria (Argentina)
SPS	Sanitary and Phytosanitary Measures
TRIPS	Trade Related Intellectual Property Rights
TNC	Trans-national Corporation
UNEP	United Nations Environment Programme
RNA	Ribonucleic acid
USEPA	United States Environmental Protection Agency
USDA	United States Department of Agriculture
UN	United Nations
UPOV	Union Internationale pour la Protection des Obtentions Végétales
WTO	World Trade Organisation

i. This is scheduled to be the fifth meeting of parties to the Cartagena Protocol on Biosafety, to take place in Nagoya, Japan, in October 2010.

Structure of paper

In this paper we critically analyse the rationale underpinning the biotech industry's push for the adoption of 'stacked' GMOs. After a brief description of gene-stacking and the trends with regards to its adoption around the world, we highlight some of the significant biosafety concerns with gene stacking. This is followed by a discussion of the stacked GMO push and the power and control this will enable the biotech sector to exercise over the farming sector and its implications for farmers. Finally, the Byzantine network of national and multilateral regulatory systems that apply to the risk assessment and risk management of stacked GMOs is discussed, with particular attention being paid to the expeditious approvals granted to Smartstax, an 8 gene GM maize variety. The implications of the adoption of stacked GM crop plants for Africa are also briefly discussed.

Executive Summary

The regulatory approvals during 2009 for the environmental release in the USA and Canada, and the import into Japan and South Korea of a stacked GM maize variety, Smartstax, has paved the way for the mass release of the world's first eight-stacked GM food crop. Monsanto, who developed Smartstax in conjunction with chemical giant Dow AgroSciences, expects this to be the largest release of a GM maize product in history! This GM variety comprises of six Bt genes and two genes meant to confer tolerance to Monsanto's Round-up and Dow's Liberty Link herbicides.[1]

The authorisation of Smartstax will undoubtedly usher in the rapid proliferation of stacked GMOs worldwide. In 1997, stacked varieties accounted for less than 0.1% of the global GM crops planted.[2] However, by 2006 a staggering 25% of crops planted to GM were stacked varieties[3] and by 2008, nearly 30 million acres world-wide were planted with stacked GMOS.[4]

South Africa is a most fervent supporter of stacked GMOS. 19% of its GM maize area is currently being planted to stacked GM varieties, representing a four-fold increase since 2007.[5] Ninety percent of the 9,000 hectares of GM cotton planted in South Africa in 2007 comprised of stacked genes.[6] The South African authorities have granted a staggering 56 permits[ii] for stacked GM maize varieties during 2009 alone.[7]

Globally, by December 2007 just six companies accounted for almost 90% of approvals granted for GMOs containing more than one trait. Monsanto and Dow, needless to say, are amongst them.[8] This level of control gives Monsanto and Dow incredible leverage when setting prices for their seeds and chemical fertilisers. The push to roll out ever more stacked varieties is motivated by the fact that double and triple stacked GMOs deliver nearly twice the rate of profit as their single trait counterparts.[9] The American Antitrust Institute holds

ii. Permits granted include for trial release; import for planting and trial release; export for planting and contained use.

Monsanto primarily responsible for the 'impaired state of competition in transgenic seed', while the company has aggressively sought to protect this position of advantage through the courts.[10]

The 'technology fee' paid by farmers for triple stacked maize accounts for approximately 51% of the total cost of the seed, compared to a 25% fee for single trait GM maize. Double stacked GM cotton technology fees account for 67.8% of the total price, a 15% increase on its single trait counterpart.[11] In theory, the addition of more genes through stacking could lead to any number of potential new patents, including for complex physiological processes, which were previously unobtainable.[12]

It is a well known biosafety concern that inaccurate methods of gene transfer between species can result in gene instability and mutations. The insertion of multiple new transgenes into a genome increases this risk exponentially.[13]

The Austrian Federal Environmental Agency, often a solitary dissenting voice at the state level against the hasty acceptance of GMOs, has repeatedly called for a process based approach in the case of gene stacking.[14] This contrasts starkly with the approach adopted by those countries that have already approved Smartstax such as the US, Canada, Argentina, Brazil and South Korea that use a 'product' based risk assessment, rather than a 'process based' one. In other words, if the parent single-trait GM plants, which were cross-bred to produce a stacked GMO, have received prior regulatory approval, it is assumed that their progeny will also be safe.

Moves are afoot within the UN's multilateral system to develop guidelines for the risk assessment and risk management of GMOs with stacked genes or traits. This task is being undertaken by a sub-working group of the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety. The AHTEG will report on its work in Japan in October 2010 when Parties to the Cartagena Protocol on Biosafety (CPB) meet. The presence on the observers group of a Monsanto executive[15] unquestionably presents a gross conflict of interest, and is yet another worrying indication of the recent convergence of commercial interests, scientific research, and public policy formulation.[16] This has particular salience in the case of South Africa, which is seen as a GMO 'springboard' into the rest of the continent. The proliferation of stacked GMOs internationally, and the dramatic increase in permits granted for them in South Africa, hint at a potential future African deluge, all in the name of poverty alleviation and food security.[17]

Introduction

Between the 20th and the 31st of July 2009, the United States, Canada and Japan all granted regulatory approvals for Smartstax maize, the first ever eight-gene, stacked GMO variety. Smartstax has been developed by Monsanto and Dow AgroSciences. While the approvals are for commercial growing in both the US and Canada, the Japanese approval for import as food, feed and processing is significant because Japan was expected to import 20% of the world's maize exports of 16.26 million tons for the 2009 marketing year. In 2007/2008 the United States exported 15.24 million tons of maize to Japan. Its next biggest export market, Mexico, imported 9.53 million tons.[18] Announcing the Japanese regulatory approval, Monsanto also claimed that Smartstax could be imported into New Zealand and Australia.[19] [20] However, subsequent investigation by the ACB has found no mention of the latter approvals on either the Biosafety Clearing House website of the Cartagena Protocol on Biosafety, or the websites of Food Standards Australia New Zealand.[21] The BCH website's link to the office of the gene technology regulator,[22] designated as Australia's competent national authority for implementing the CPB, was not working at the time of writing. The BCH website did, however, reveal that South Korea had granted Smartstax approval for food and feed on the 2nd of November 2009.

Monsanto CEO Hugh Grant, expects the increased yield potential of Smartstax to be between 5 – 10%, and for the new product to be launched on 3 – 4 million acres in 2010,[23] which would make it the biggest maize release in history, with up to 1.6 million hectares (3,953,686 acres) expected to be planted in the US and Canada alone.[24] Smartstax is a combined trait maize product containing events MON 89034, MON 88017, DAS 59122-7 & TC 1507.[25] Of the 8 'stacked' transgenes that Smartstax contains, six of these genes generate different forms of insect killing Bt toxins: Cry1A.105, Cry2Ab2 (both under license from Monsanto), and Cry1F (Dow) for insects above ground; Cry3Bb1 (Monsanto), and Cry34Ab1, Cry35Ab1 (both Dow) for insects underground. The two remaining transgenes are resistant to certain herbicides: Glyphosate (traded as Roundup Ready by Monsanto) and Glufosinate (traded as LibertyLink by Dow AgroSciences, under licence from Bayer).[26]

Smartstax was conceived in September 2007, when Monsanto and DOW AgroSciences announced a collaborative agreement for the development of the 'first ever eight gene stack' GMO. The agreement includes a 10 year germplasm cross license, offering inbreds for use by the other party to create new hybrid combinations to be sold in their respective brands.[27]

The recent regulatory approvals have been met with howls of indignation from independent scientists and activists, NGOs, and national regulatory bodies. Debate on how stacked gene events should be assessed and regulated cut to the very heart of the biosafety discourse, as those opposing the 'substantial equivalence' principle and favour 'the precautionary principle' point to fundamental flaws within current regulatory regimes for stacked events.

The United Nations Environment Programme's (UNEP) Ad-Hoc Technical Expert Group (AHTEG) currently has a task force set up to deal with the issue. The outcome of this could have profound implications for the future direction of global agriculture as, in the words of one report issued by the European Commission on this subject, the potential for the proliferation of stacked events in the future could be 'exponential'.[28]

By 2008, South Africa joined the ranks of the world's top ten GMO growing countries. The industry-funded body,[iii] [29] the International service for the acquisition of agri-biotech applications (ISAAA) has hailed South Africa as one of 'five principle developing countries exerting leadership, and driving global adoption of biotech crops'.[30] Given the South African government's support for GM based agriculture, [31] [32] an application for Smartstax cannot be ruled out. Grain SA, representing commercial famers, holds an equally sanguine attitude towards stacked GMOs.[iv] [33] When contacted by the ACB, both Monsanto and Dow AgroSciences neither confirmed nor denied whether they intended to release Smartstax into the South African environment, or apply for permission to import.[34]

In 2004, 10 permits were granted in South Africa for applications made to the Executive Council involving stacked GMOs. The first 10 months of 2009 have seen 78 such permits granted, with maize accounting for 56 of these. Monsanto, Syngenta and Pioneer have received 92% of the permits granted for stacked maize events since 2004. Monsanto, Delta & Pine Lodge (who are owned by Monsanto) and Bayer account for 93% of permits for stacked cotton varieties. This is commensurate with the biotechnology and agricultural input markets in South Africa. For example, Monsanto had a 50% share in the entire South African maize market in 2009; while Bayer, Dow AgroSciences, Syngenta and BASF featured in the top 10 pesticide companies in 2007 by registered active ingredients.[35]

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iii. The ISAAA counts some of the world's largest biotech firms as its chief financiers, including AgrEvo, Monsanto, Novartis, and Pioneer Hi-Bred.

iv. 'Grain SA in principle supports all technological development that improves production efficiency and the competitiveness of our grain industries, on condition that such technological developments are not harmful to either human life, animals or the environment. The same viewpoint applies for stacked GMO's.'

What is stacking?

'Stacking' occurs where GM strains are mated together to produce both of their respective individual GE traits in their progeny/offspring.[36] The technology behind Smartstax is seen as a breakthrough by many in the biotechnology industry. Owing to the difficulty in transferring multiple genes between organisms, the majority of commercially available GMOs are based on single genes or traits (plants that are herbicide resistant or contain the Bt toxin being two such examples). Smartstax technology is based on the replication of chromosomes (termed 'mini-chromosomes') that can carry multiple genes. It is claimed that once they are inserted into the cell they will dramatically reduce side effects, as they will not disrupt the native genetic material of the engineered organisms. An additional development is the genetic engineering of cell organelles such as chloroplasts.[37]

According to the US Animal and Plant Health Inspection Service (APHIS), 'intentional' combinations (stacking) occur where genes or traits are inserted at the same time into the plant; new genes are inserted into a previously engineered plant; GE plants with different GE traits are intentionally crossed to combine traits in their progeny.[38]

The EU defines stacked events as 'those combined in the same plant by either conventional breeding or re-transformation of a plant containing one or more existing event(s)'.[39]

The global spread of stacked GMOs

Unsurprisingly the US leads the way in the adoption of stacked trait GMOs. The planting of stacked traits for insect resistance and herbicide tolerance in cotton and maize increased significantly from 1% of the area planted to GM in 1998, to 7% (2.9 million hectares) in 1999.[40] By 2007 as much as 37% of biotech area planted in the US contained 2 or 3 stacked traits,[41] and by 2008 78% of the US biotech maize crop contained more than one stacked variety.[42] Put another way, in the space of a decade, GM maize with stacked traits have expanded from a negligible part of the US GM crop area, to now occupying over 66% of the entire maize area planted in the United States.

Globally, stacked trait GMOs experienced modest growth between 1997 and 1998, rising from less than 0.1% of the total planted GMO area to 1% by 1998.[43] 2000 saw the introduction of the first GM crop plants stacked with herbicide tolerance and the Bt gene. The following year saw their introduction into Canada.[44] By 2003, 8% of the commercially grown GM crop area worldwide contained stacked traits. Of this, the vast majority of plantings were for crops containing genes conferring insect resistance and herbicide tolerance.[45]

By 2006, the globally planted biotech area containing stacked genes had reached 28%. This represented a 30% growth since 2005, compared to a 17% growth in areas planted to insect resistant crops and 10% to herbicide resistant crops over the same period. The increase in maize, at 37%, was even greater than the average increase. The first triple stacked construct in maize was introduced into the US in 2005 on half a million hectares (note that Monsanto expects Smartstax to be released on to three times this area, including in Canada). By 2006 this had increased to 2 million hectares with only the US, Canada, Australia, Mexico, South Africa and the Philippines having planted stacked trait GMOs (of these only the US, Canada and the Philippines grew stacked maize varieties – maize is not a food staple in any of these countries).[46]

From 2006 to 2007 the global area of stacked trait GMOs planted for cotton and maize grew by 66%, with maize alone increasing by over 100%, from 9 million to 19 million hectares. Stacked trait products saw the fastest growth between 2007 and 2008 at 23% compared with 9% for herbicide tolerance and -6% for insect resistance. A total of 26.9 million hectares of stacked biotech crops were planted globally in 2008 compared with 21.8 million hectares in 2007.

Ten countries planted biotech crops with stacked traits in 2008: the USA, Canada, Philippines, Australia, Mexico, South Africa, Honduras, Chile, Colombia, and Argentina.[47] The USA led the way with 41% of its total 62.5 million hectares of biotech crops stacked.[48] In South Africa itself, GM stacked traits accounted for 19% of the GM maize area (stacking Bt and herbicide tolerance traits) in 2008. This represented a four-fold increase over the course of the year.[49] Ninety percent of the 9,000 hectares of GM cotton planted in South Africa in 2007 were stacked.[50]

Double stacks with pest resistance and herbicide tolerance in maize were also the fastest growing component in the Philippines in 2008 doubling from 25% of biotech maize in 2007 to 57% in 2008.[51]

Monsanto introduced its first double stacked variety back in 1998, and its first triple stacked in 2005. Monsanto expected 79% of its maize seed sales in 2009 to be triple stacked varieties, while Syngenta plans to make triple stacked maize account for 85% of its portfolio by 2011.[52] In 2006 stacked GMOs accounted for 23.7% (approximately $1.4 billion) of a global GMO market worth $6.05 billion.[53]

Table 1: Permits granted for stacked GMOs in South Africa

Year	Maize	Cotton	Total
2009*	56	22	78
2008	39	14	53
2007	22	9	31
2006	8	20	28
2005	2	5	7
2004	2	8	10
Total	**129**	**78**	**207**

(Source: Department of Agriculture, Fisheries and Food, 2009)
*To end of October

Table 2: Permits granted for stacked GM maize in South Africa, by company

Year	Company						
	Monsanto	Syngenta	Pioneer	Pannar	Bayer	Cargill	Total
2009*	41	3	11	0	1	0	56
2008	19	4	12	1	0	3	39
2007	7	1	10	4	0	0	22
2006	6	2	0	0	0	0	8
2005	2	0	0	0	0	0	2
2004	1	0	0	1	0	0	2
Total	**76**	**10**	**33**	**6**	**1**	**3**	**129**

(Source: Department of Agriculture, Fisheries and Food, 2009)

Table 3: permits granted for stacked GM cotton in South Africa, by company

Year	Company					
	Monsanto	Bayer	Delta & Pineland*	Syngenta	Other	Total
2009*	7	15	0	0	0	22
2008	6	8	0	0	0	14
2007	3	1	5	0	0	9
2006	4	0	12	4	0	20
2005	1	0	2	1	0	4
2004	2	0	3	0	3	8
Total	**23**	**24**	**22**	**5**	**3**	**77**

(Source: Department of Agriculture, Fisheries and Food, 2009)
*Owned by Monsanto

By 2007, of the 615 GMO approvals granted globally for environmental release, planting, or imports as food and feed, 227 were for events containing more than one trait, and 131 of these were for maize.[54] These figures indicate the significance of maize as a crop in the research and adoption of stacked trait GMOs. A recent EU Joint Research Council report predicts that the potential number of events just for maize utilising gene stacking could rise 'exponentially' within the next few years.[55]

On the 7th of October 2009, Monsanto announced that it would increase seed prices by 10%. Monsanto's chief financial officer Carl Casale 'said the company did not correlate its seed pricing strategies with crop prices but rather with *how much value the company thought it was providing the farmer*' (emphasis added).[56] By stacking more genes into a single crop Monsanto (and the other behemoths of the agri-biotech landscape) increase their profitability. Compared to the original single trait GMOs, double and triple stacked varieties are nearly twice as profitable.[57] The 'technology fee' paid by farmers for triple stacked maize accounts for approximately 51% of the total cost of the seed, compared to a 25% fee for single trait GM maize. Double stacked GM cotton technology fees account for 67.8% of the total price, a 15% increase on its single trait counterpart.[58]

In the words of one US farmer 'I like to buy what I want. When they start stacking for things I don't need, it just makes the price of the seed go up.'[59] Monsanto has a new 'violator exclusion policy' denies farmers who break the terms of its licenses access to all of its technology forever,[60] leaving many farmers trapped between spiralling costs on one hand, and a threat to their future livelihoods on the other. One US farmer, Homan McFarling, was fined US$1.7 million and sentenced to eight months imprisonment for various offences that began with a Monsanto lawsuit.[61]

Scientific concerns over stacking

Ricarda Steinbrecher, of the federation of German scientists and the Ad-Hoc Technical Expert Group (AHTEG) on stacked LMOs, has commented that gene stability is already a serious concern in single event GMOs, and that its pertinence will increase in the case of stacked events. In a stacked event the inserted genes will be distributed at different places within the genome, potentially giving rise to different positional effects. The potential for mutations will also be different and potentially more varied than in a single GMO.[62] Additionally, warnings have been raised that the combined presence of transgenes in stacked events may lead to gene silencing, where certain agronomic traits are inadvertently rendered inactive.[63] Studies have shown that the infection of susceptible plants with the Cauliflower Mosaic Virus (the source of the 35S promoter, which is widely used by the biotech industry) can lead to the silencing of herbicide tolerance in plants that use the same promoter.[64]

Genetic contamination

Transgene escape from GM crops has been well documented, from Mexico[65] to China.[66] Industry claims that through the process of 'maternal inheritance' (where identical copies of organelles are transferred from the mother to her offspring/seeds) the stability of GM traits will be secured from one generation to the next. Additionally, as pollen grains and semen cells do not carry organelles, this will prevent potential genetic contamination. Claims that genetic contamination will be prevented are disputed by the NGO GRAIN, who argues that transfer would still be possible through bacteria, citing the example of the pathogen Agrobacterium tumefaciens (Bt). Bt is already widely used in genetic engineering to confer resistance to certain pests by transferring the pathogen from the Bt gene in the GM plant to the plant pest. The artificial mini-chromosomes used in gene-stacking have the potential to create new forms of contamination between species and even kingdoms.[67] Prior studies have already revealed incidences where transgene escape has resulted in stacked multiple resistances to herbicides in both wild canola and rice populations.[68]

Refuge and pest resistance

One of the key advantages being marketed by Monsanto and Dow with regard to Smartstax is reduced refuge requirements.[69] A refuge is an area planted with a non-GM variety of crop alongside the GM crop that allows pests to breed naturally, thus ensuring that these pests will breed with those in the GM fields countering any resistance to the GM traits that may have developed. Although South Africa requires farmers to plant refugia, research carried out by Biowatch with regard to a Bt cotton project run by Monsanto, Delta Pine and the Department of Agriculture in the Makhathini Flats revealed that only 5 of the 12 farmers inteviewed understood the need to plant refuges (of the 5 only 3 were actually doing so).[70]

Similar concerns over the implementation and monitoring of refuge requirements were raised during a UN Food and Agricultural Organisation (FAO) online conference into stacked genes as long ago as 2003.[71] Even in the United States, farmer compliance with refuge requirements for Bt maize fell from above 90% in 2003, to 75% in 2008. Owing to increases in overall plantings of Bt maize over the same period, the total maize acreage in non-compliance with refugia requirements rose from 2.29 million acres (3% of the biotech and conventional corn area), to 13.23 million acres (almost 15%).[72]

The prudence of the decision to reduce the refuge requirements as part of Smartstax's regulatory approval in Canada has been questioned by two world renowned experts. Bruce Tabishnik, head of entomology at the University of Arizona, is of the view that "resistance is expected no matter what toxin or combination of toxins is used to control insects", and has raised concerns that the decision to reduce the required refuge area was not backed up by adequate research. David Andow, professor of insect ecology at the University of Minnesota and internationally recognized biosafety expert and advisor to organizations like the UNFAO, World Bank, and WTO went as far as to say that the decision to reduce refuge requirements is not a science-based decision.[73]

Furthermore, a recent study published by Tabishnik in the Proceedings of the National Academy of Sciences has revealed that under lab conditions species of Pink Bollworm (*Pectinophora gossypiella*) demonstrated cross resistance to two different Bt toxins produced in transgenic cotton, Cry1Ac and Cry2Ab.[74] Previous studies have also shown that increased resistance was observed in pest populations exposed to the concurrent use of pyramid plants (where two dissimilar Bt toxins are inserted to reduce the risk of resistance development) and single Bt events, as 'exposed populations were given a "stepping stone" to develop resistance to both toxins'.[75]

According to Tabashnik, a Dow AgroSciences employee once threatened him with legal action if he published information he received from the EPA concerning an insect-resistant variety of maize known as TC1507 (which is one of the components of Smartstax), made by Dow and Pioneer. The companies suspended sales of TC1507 in Puerto Rico after discovering in 2006 that an armyworm (*Spodoptera frugiperda*) had developed resistance to it.[76]

Potential increases in herbicide use and weed resistance

Owing to the increasingly reported incidences of herbicide resistant weeds, the biotech industry has developed three main strategies to counter this: subsidies for farmers to use non-glyphosate-based herbicides, the development of crops with resistance to increased dosages of glyphosate, and the development of GM stacked varieties resistant to multiple herbicides. With a small variety of herbicides currently on the markets, companies will be forced to engineer crops with resistance to older and often riskier herbicides. While publicly denying or down-playing the reports of herbicide resistance developing in weeds, behind the scenes, the biotech industry is investing heavily in the development of crops with multiple-resistance to herbicides. Du-Pont and BASF have both developed GM maize that combines resistance to glyphosate with resistance to herbicides that inhibit the *acetolactate synthase* (ALS), the latter in collaboration with Monsanto. In another partnership between the two industry giants, Monsanto has developed soya beans that are resistant to the *chlorophenoxy herbicide dicamba* (BASF is the world's largest producer of this). Dow AgroSciences recently petitioned the USDA for commercial approval of a GM-corn variety resistant to a second chlorophenoxy herbicide known as 2,4-D, a component of the defoliant Agent Orange used in the Vietnam War.[77]

Currently the industry's largest corporations have discovered or developed at least 12 genes conferring resistance to herbicides. The current practice of stacking two herbicide tolerant genes, such as in Smartstax, is set to be superseded in the very near future. Dow Agro sciences and Du-Pont Pioneer recently announced they have entered into a commercial cross licensing agreement for the development of soyabeans stacked for resistance to 3 varieties of herbicide,[78] while a 2009 patent granted to Du-Pont describes a single plant that is tolerant to two, three, four, five, six, or seven or more different herbicide families of chemistry, encompassing dozens to hundreds of individual herbicide products.[79] It is extremely difficult to reconcile the above trends with biotech industry claims that GMOs will lead to reductions in the use of chemical inputs in agriculture.

Substantial oversight

The concept of 'substantial equivalence' (introduced by the OECD in 1993) in the risk assessment of GMOs dictates that a GMO that is deemed to be equivalent in terms of its genetic traits to a conventional variety does not need rigorous biosafety assessment.[80] In the case of stacked GMOs this rationale has been extended to dictate that information gathered about a stacked GMO's parent lines will provide adequate safety information for their progeny. Nevertheless, a recent study notes that 'activities (stacking) between various compounds in the plants during their cultivation might produce results which can hardly be predicted from analyses of their single components.'[81] These views are echoed by senior scientists on the Biosafety Clearing House (BCH) website.[82] Further, within the suggested reading on the website's online stacked gene conference comes another stark warning:

> 'However, hardly any, if none, scientific evidence proving that (trans)genes are inherited in an intact way during breeding is publicly available. In particular, information on the occurrence of point mutations, deletions and/or rearrangements during breeding is lacking. … The true impact of 'small' insertional changes on the intrinsic characteristics of the crop will, however, not completely resolved through sequence analysis followed by bio-informatic analysis… Transgene expression may change when a transgene is placed in a different genetic back-ground through breeding. … in the case of stacked genes, the combined presence of transgenes may influence expression.' (for example, gene silencing).[83]

Prevalence of consolidation in gene stacking

The NGO GRAIN has noted that the development path of stacked GMOs has broadly followed that of earlier biotechnology developments, 'from publicly funded basic research to fully private application and use, with growing concentration in the hands of a few corporations.'[84] Monsanto has arguably been the most active of the large TNCs in the field of gene stacking, having signed agreements or obtained licenses from Chromatin, Evogen, Asgrow and BASF.[85] By December 2007, almost 90% of the global approvals given for GMOs with more than one trait were granted to 6 companies: Monsanto, Syngenta, Dow Agroscience, Pioneer Hi-Bred, DuPont, and Bayer.[86] Of these Monsanto, DuPont and Syngenta account for 47% of the global proprietary seed market; Bayer, Syngenta, Dow, Monsanto and DuPont for 63% of the global agrochemicals market; and Dow Chemical and DuPont are among the world's top 10 chemical companies.[87]

In 2008, the investment bank Goldman Sachs predicted that Monsanto's net income would triple from $984 million to $2.96 billion between 2007 and 2010.[88] Despite the onset of the global financial crisis Monsanto's Chairman, Hugh Grant, remains bullish about the company's prospects, revealing that the launch of Smartstax and Roundup Ready 2 Yield® soybean products, with accelerated trait penetration in Latin America, will enable the company to double its 2007 gross profits by 2012.[89] Preceding the regulatory approvals of Smartstax, Monsanto announced that it plans to increase prices of its new GM seeds by 43%

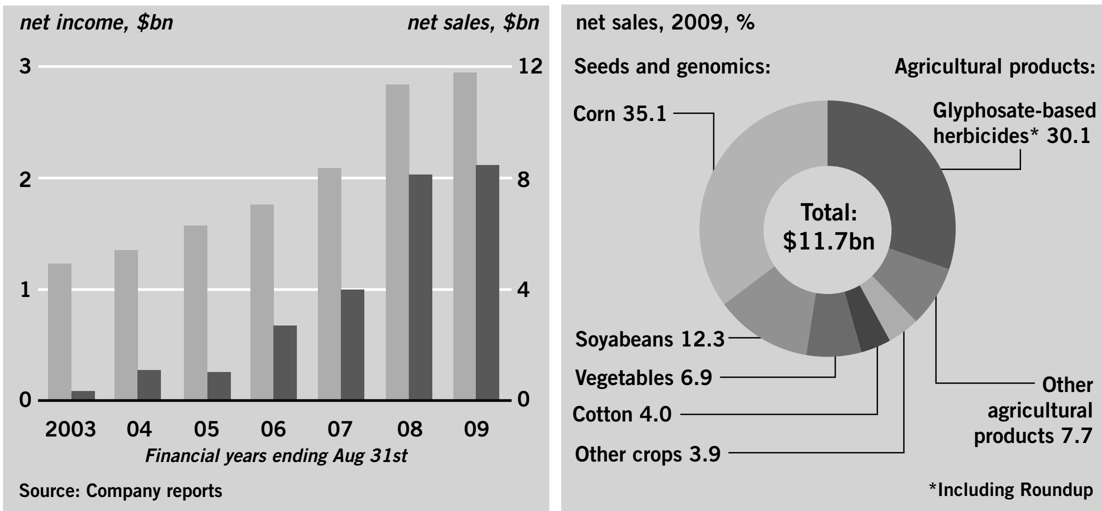
over older varieties. Smartstax is set to cost $130 an acre, 17% more than the YieldGuard triple stacked seeds they will replace. According to one analyst at Morgan Stanley, "SmartStax pricing is higher than initially expected."[90]

Responding to Monsanto's announcement in July 2008 that the costs of its triple stacked variety maize would increase by 35%, Fred Stokes of the US-based Organisation for Competitive Markets estimated that this translated into farmer spending of an extra $40,000 a year for farmers planting on 1,000 acres. Stokes notes that there is no scientific basis to justify this price hike.[91] The American Antitrust Institute, an independent competition watchdog, published a paper in October 2009 noting the 'impaired state of competition in transgenic seed', and which held Monsanto primarily responsible for this. During 2008, Monsanto's global market share for GM maize and soyabean was 65%, while cotton was 45%.[92]

The average soyabean price in the US rose by more than 50% between 2006 and 2008, while Round-up Ready 2, Monsanto's latest triple-stack soybean, cost 50% more than its original RR soyabeans. A report by Friends of the Earth calculated that the increased cost to soybean farmers from replacing just 50% of original RR with RR2Y soybeans would amount to a substantial $788 million. Maize and cotton seeds saw similar increases over the same period, with Monsanto's triple stack maize increasing by up to $100 a bag in 2009. The company has raised its trait prices for its less expensive single- and double-stack maize seed more sharply than for triple-stack maize in order to "move as many customers to triple-stacks as possible…" and to "create a captive customer base for the 2010 launch of its SmartStax octo-stack product."[93]

Between December 2006 and June 2008 the price of Monsanto's glyphosate based Round-up herbicide increased by 134%. Like the proprietary seed market, Monsanto has a huge share of the $3.8 billion market for glyphosate – estimated at 60% in 2006 by Goldman Sachs. Friends of the Earth have pointed to the linkages between Monsanto's push for increased trait penetration and sales of Round-up herbicide. For example, world acreage planted to Monsanto GM maize seed that does NOT incorporate the RR trait peaked at 29.6 million acres in 2004, and has since fallen by half (15 million acres in 2008). In the US, the trendsetter for GM crops worldwide, the fall is even more precipitous: from 25.3 million acres in 2004 to just 4.9 million acres in 2008. Over the same period, Monsanto dramatically increased worldwide sales of GM maize varieties with the RR trait, from 17.4 million acres (2004) to 72.6 million acres (2008).[94] These trends would seem to corroborate the findings of a recent report from the Organic Centre which found that contrary to the widely peddled myth from the biotech industry that GMOs lead to reductions in the use of chemical inputs, the USA saw an additional 318.4 million pounds (144,424 metric tons) of chemical inputs applied between 1996 and 2009 as a result of GM crops.[95]

Gene giant
Monsanto's:



Source: The Economist, 2009

Stacking up the patent regime

In theory, the addition of more genes through stacking could lead to any number of potential new patents, including for complex physiological processes, which were previously unobtainable.[96] According to WIPO patent 2007/030510, it may be possible to obtain "resistance or tolerance to drought, heat, chilling, freezing, excessive moisture, salt stress, mechanical stress, extreme acidity, alkalinity, toxins, UV light, ionising radiation or oxidative stress; increased yields, whether in quantity or quality; enhanced or altered nutrient acquisition and enhanced or altered metabolic efficiency; enhanced or altered nutritional content and makeup of plant tissues used for food, feed, fibre or processing; physical appearance; male sterility; drydown; standability; prolificacy; starch quantity and quality; oil quantity and quality; protein quality and quantity; amino acid composition; modified chemical production; altered pharmaceutical or nutraceutical properties; altered bioremediation properties; increased biomass; altered growth rate; altered fitness; altered biodegradability; altered CO2 fixation; presence of bioindicator activity; altered digestibility by humans or animals; altered allergenicity; altered mating characteristics; altered pollen dispersal; improved environmental impact; altered nitrogen fixation capability".[97]

In the US, between 1982 and 2001, over half of all private sector held agricultural biotech patents granted are owned by Monsanto, DuPont, Syngenta, Bayer and Dow.[98] The same 5 'gene-giants' had, by the middle of 2008, filed 532 patent documents on 'climate ready' genes at patent offices around the world.[99] Many of these patent claims extend beyond abiotic stress tolerance in single plant species to 'substantially similar' genetic sequences in virtually all transformed plants. For example, Du Pont's November 2007 patent entitled 'transcriptional advocators involved in abiotic stress tolerance' claims ownership of a genetic sequence that improves its cold and/or drought tolerance. However, the claims also apply to the use of technology in transgenic monocots (maize, barley, wheat, rye, sorghum or rice, to name but a few), and dicots (e.g. soybean, alfalfa, safflower, tobacco, sunflower, cotton or canola). In short, the patent would cover the majority of the world's plant food sources. BASF holds a similarly all encompassing patent on a polynucleotide sequence associated with increased tolerance to environmental stress. In addition to the crops already mentioned, pepper, potato, eggplant, tomato, coffee, tea and oil palm also fall under its gamut.[100] In its patent application WO2004053055, Monsanto went so far as to lay claim to unintended effects in genetically engineered plants.[101]

Law Professor James Boyle has labelled the construction of the global Intellectual Property Regime, through mechanisms such as the UPOV convention and TRIPS, as a new round of 'enclosures in what were once the global commons', of genetic information encoded in the genes of people, plants, animals and micro-organisms.[102] This latter day 'enclosures movement' is supported by a myriad of free trade agreements (FTA) often, as in the case of the US South Korea agreement, negotiated outside of the public realm. Where certain actors cannot gain concessions in one forum, they will partake in what is known in the trade as 'forum shopping', until they can find or construct a forum that will preserve their own specific interests. Consequently, and in spite of much free trade rhetoric, the number of bilateral FTAs increased from 60 in 1996, to nearly 200 ten years later.

In many of these, including the United States-Sub Saharan Africa agreement of 2000, and EU Contonou agreement (with African, Caribbean and Pacific nations), trade benefits are conditional upon the level of IPR they are willing to impose.[103] The fact that around the world an estimated 1 billion people save seed[104] (predominantly in countries of the global south) does not lend itself to the simple integration of this group into the globalised (and patented) agricultural economy. This, together with the emergence of mass consumer resistance to GMOs (particularly in Europe), has forced the Biotech industry to change track. Food insecurity and climate change, the illegitimate offspring of the neo-liberal agricultural model, are both currently under siege from the most eloquent hyperbole that the PR industry can churn out. If the romantic in us cannot be persuaded, then an appeal to our 'rational' natures will surely suffice. The fact that it is no longer Margaret Thatcher proselytizing at us that 'there is no alternative' hardly matters, as the biotech industry has a host of figureheads ready to take up the baton. Africa in particular faces a potential deluge of 'climate ready', fully patented GMOs under the charitable guise of what the International Maize and Wheat Improvement Centre (CIMMYT) has termed 'a user-led philanthropic-private-public partnership paradigm'.[105] The scramble for resources and markets in Africa through the introduction of ever more complex, 'climate ready' GMOs is likely to be mirrored in the patent offices of the north.

Regulatory approaches to stacked genes

Below is a synopsis of the regulatory regimes of those countries that have approved stacked GM varieties.

South Africa

South Africa became a Party to the Cartagena Protocol on Biosafety on the 11th of November, 2003.[106] In a 2006 report, the ISAAA argued that 'the approval of the stacked traits is an important policy decision that would allow South Africa to retain its leadership role in biotech crops.' In October 2005, Monsanto received approval to launch stacked-gene cotton in South Africa. The seed combines an insecticide with a built-in resistance to weed-killer.[107]

The ACB has, submitted objections to separate applications made for field trials,[108] and commodity import[109] by Syngenta for stacked maize events. In both cases, objections were specifically made to Syngenta's reliance on the biosafety assessment of the parent GM lines as proof of the safety of the new transgenic lines. Monsanto took a similar approach in its permit application for GM food and feed and nutritional assessment of GM maize MON88017 x MON810 [110] (both component traits of Smartstax).

Through a submission under the Promotion of Access to Information Act (PAIA), the ACB has been able to obtain the non-Confidential Business Information (CBI) records of Monsanto's applications to the Executive Council (the decision-making body for GM applications) for the above events. In both studies the toxicology, nutritional, and allergenicity reports make liberal use of the terms 'substantial equivalence' and 'compositional equivalence', as well as drawing on prior approvals granted to GM traits in singular form. For example, when discussing previous approvals granted in the case of MON89034: 'The significant amino acid sequence homology and structural, biochemical and functional similarity of Cry1A.105 (present in MON89034) to other (previously approved) cry1A proteins indicate that Cry1A. 105 should be as safe as Cry1A proteins currently on market.'[111] Further, both applications' digestive studies were undertaken using 'simulated digestive fluids'.[v] [112] Unfortunately, a large part of the relevant documentation was omitted as 'confidential business information', making comprehensive review of the documents impossible.

Argentina

Argentina approved its first stacked gene, Monsanto's NK603 x MON810, on the 31st of August, 2007. In February of the same year the government of Argentina had already simplified the process by which stacked genes are regulated, allowing applications for a transgenic crop combining two already approved events without a full analysis of the new crop.[113]

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v. US EPA approval of a stacked maize variety 'YieldGuard plus' has been similarly criticised on the basis that the mammalian and environmental safety testing of the Cry gene toxins accepted by EPA was done with toxin proteins that were produced in bacteria, and the toxin proteins tested were clearly different from the protein toxin produced in the commercial maize crop.

Further approvals for stacked events were granted in 2008, when Pioneer received approval from the Argentinean Secretariat for Agriculture for its triple-stacked maize trait, containing insect protection trait (Herculex I technology), resistance to Ammonium Glufosinate (Liberty Link technology) and to Glyphosate (Round Up Ready Technology). This marked the first approval of a triple stacked variety in Argentina. In 2007/2008 74% of the total area planted to maize in Argentina was GM. Stacked traits represented 2% of the total area (82,000 hectares).[114] By the 2008/09 cropping season this had jumped to 25%. Only one new GM event was approved in 2009: GM cotton event MON 1445 x MON 531. This was the first stacked cotton variety to be approved in Argentina.[115]

The Argentinean biosafety system is based on the evaluation of the product, rather than the process. When individual events present in a 'new' stack have previously been approved, the applicant is required to only submit experimental proof, or otherwise sound scientific evidence, that there are not interactions between genes in the stack, that locations are different, and that metabolic pathways are unrelated.[116] The only incidence where the process is taken into consideration is where the environment, the agricultural process or the health of humans or animals is at risk. The National Advisory Committee on Agricultural Biotechnology is responsible for evaluating impacts on the agricultural ecosystem, and also for stacked genes. The applicant must submit a letter simultaneously to SAGPyA (Office of Biotechnology) and to SENASA (National Service of Agricultural and Food Health and Quality) requesting authorization for commercialisation of the specific stacked event.[117]

Brazil

Brazil is a large producer of GM crops, with a planted area in 2008 of 15.8 million hectares.[118] In 2008 Brazil planted Bt maize for the first time[119] and is expected to become the world's second largest producer of GM food crops in the 2009-2010 crop year.[120] On the 17th of September 2009, CTNbio approved two stacked gene maize events from Monsanto and Syngenta, both of which have been engineered for resistance to pests and glyphosate-based herbicide.[121] According to one commentator, this would signal 'that the floodgates have been opened for GM maize varieties in Brazil'.[122]

There are two main governing bodies for regulating biotechnology in Brazil: The National Biosafety Council (CNBS in Portuguese), and the National technical commission of Biosafety (CTNbio). CNBS is responsible for the broader formulation and implementation of the national biosafety policy in Brazil. It evaluates socio-economic implications of biotechnology, not technical safety aspects. The CTNbio, initially established in 1995 under Brazil's first biosafety law (#8,974), is responsible for all technical related issues including imports of any agricultural commodity for animal feed or for further processing, or any ready-to-consume food products, and pet food containing biotech events.

This clear separation of duties was consolidated in June 2008, when CNBS decided that it would consider all technical approvals of CTNbio as conclusive. This followed Law #11,460 of March 21st 2007, establishing that a simple majority of votes of the CTNbio 27 member board would be needed to approve new biotechnology products. These two decisions, in the words of the USDA, 'eliminates a major barrier for approval of biotech events in Brazil'.[123]

The above claim would seem to be substantiated by CTNbio resolution No.5, March 12th 2008, chapter 1, article 4: 'At the CTNbio's discretion, subject to consultation, the assessment and issuance of a new technical opinion may be dismissed for GMOs that comprise more than one event, combined by means of classic genetic breeding and which have already been previously approved for commercial release by CTNbio'.[124]

Canada

In approving Smartstax, Health Canada did not in fact submit the application for safety assessment, as the traits present in it had already been approved in previous single or stacked traits. Rather than regulate GMOs as such, Health Canada regulates them as 'novel foods', identified by 'novel traits'. Several commentators, including Lucy Sharrot of the Canadian Biotechnology Action Network (CBAN), have noted that this classification methodology is unique to Canada.[125] [126] Proponents of plants containing stacked traits are asked to advise the Plant Biosafety office (PBO) of the food inspection agency at least 60 days prior to the anticipated environmental release of these plants if they are the result of either intentional intra or inter-specific crosses between plants with a novel trait already authorised for unconfined environmental release. The PBO may issue a letter, within 60 days of the notification, informing the proponent of any concerns. An environmental safety assessment may be requested if the PBO is not satisfied with data provided to support a new event's introduction into the environment. Alternatively, if the PBO has no concerns it may not respond, and after 60 days the stacked product can be released into the environment.[127]

European Union (EU)

Contrary to popular perceptions that the EU is a hotbed of rabid anti-GMO scepticism, as a single economic bloc it is one of the world's largest importers of GMOs.[128] Since 2004 the EU has approved a series of GM products, mostly maize, and already authorised several stacked events for imports, including NK603 x MON810 and MON863 x MON810.[129] Where ministers cannot agree EU law allows default approval by the 27-country bloc's Executive Commission.[130]

According to Directive 2001/18, the Food Standards Agency (EFSA) is bound by law to examine and undertake monitoring of interactions between plants and cumulative effects when dealing with genetically engineered plants. Annex ii of the 2001 directive also mentions interactions between GE plants and cumulative effects.[131] [132] Both of these have implications for the assessment of gene stacking. Despite this, a recent paper published on risk analysis of biotechnology in the European Union concluded that the EFSA is 'in the main, following the (biotech) industry's guidelines' (that is, of accepting previous assessment of single GM traits as adequate in the case of new stacked events).[133]

At the national level a wide divergence in approaches can be observed within the EU. In considering applications for other multi-gene events, the Dutch and British regulatory bodies responsible have both taken the line of their counterparts in Canada and the US. That is, since the traits being used in the new stacked gene sequences have already been subjected to regulatory scrutiny individually, there is no need for further investigation. In stark contrast to this is a statement by the Austrian Federal Department for Health:

> "A stacked organism has to be regarded as a new event, even if no new modifications have been introduced. The gene-cassette combination is new and only minor conclusions could be drawn from the assessment of the parental lines, since unexpected effects (e.g. synergistic effects of the newly introduced proteins) cannot automatically be excluded."[134]

During a recent discussion of stacked GM event 59122 x NK603, the Austrian delegation raised several points of concern explicitly purporting to stacked genes:

> "As long as no official (guidance) document on the interpretation of detection results of the described methods for stacked events are available, no approval for placing on the market of this product should be given."[135]

Several applications for Smartstax are at varying stages within the EU, including field trials in Spain, Slovakia and Romania.[vi]

India

The Genetic Engineering Approval Committee (GEAC) is responsible for granting permission for the release of GMOs in India. Plants with stacked genes produced in any of the following ways are regulated in the same manner: 1) traditional breeding of and selection of two plant varieties, each containing one or more previously inserted transgenes; 2) the insertion of an additional transgene by transformation of a plant already improved by biotechnology; and 3) the insertion of multiple genes and traits into a non-transgenic plant via a single transformation event. Except where 'there is a reasonable mechanism for the combined traits to interact or target the same metabolic pathway', previous assessment of single traits that are present in the new stack are deemed to be sufficient. In the case of the former, additional safety information will be required.[136]

Contrary to the above report, the USDA's India Biotechnology annual from 2008 claims that a 'stacked event, even if consisting of already approved events, is treated as a new event for approval purposes.' On 24 August 2006, the Indian government enacted the integrated food law, namely the "Food Safety and Standards Act, 2006", to bring all existing laws under one unitary body. The aim is to 'align Indian food standards with international standards', using science-based standards.[137]

Research into stacked GM rice in India combining Bt toxins and herbicide (glufosonate) tolerance has taken place,[138] while in May 2006, the GEAC approved 'Bollgard II'[139] for commercial release, which contains stacked events Cry1Ac & Cry2Ab (Mon 15985).[140]

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vi. Agent Green, a Romanian NGO, has just submitted legal proceedings at the Bucharest court of appeal against the Romanian ministry of agriculture and the national agency for environmental protection because they both refused to disclose the location of where cultivation of MON 810 is taking place. Further details: http://db.zs-intern.de/uploads/1253689203-20090923_pr_gmo_court_case.pdf

Japan

Japan is the world's largest per capita importer of foods and feeds, importing approximately two thirds of the 16 million metric tons of maize derived from GMOs. Japan is also the largest export market for US maize. In spite of this, the Japanese regulatory regime, owing to widespread public concerns, 'extensively test and use other enforcement tools, even when there is no apparent health or environmental concern'.[141] Commercialisation of biotech plants in Japan requires approval from four different ministries: the Ministry of Agriculture, Forestry and Fisheries (MAFF); the Ministry of Health, Labour and Welfare (MHLW); Ministry of Environment (MOE); and the Ministry of Education, Culture, Sports, Science and Technology (MEXT). The Food Safety Commission (FSC), an independent risk assessment body established in 2003, performs food and feed safety risk assessment for MHLW and MAFF. Japan ratified the biosafety protocol in 2003, adopting the 'Law concerning the conservation and sustainable use of biological diversity through regulations on the use of living modified organisms' also called the "Cartagena Law" in 2004 as way of implementing the Protocol.[142]

For stacked trait GMOs, Japan requires separate environmental approvals for each trait.[vii] [143] Both MAFF and MOE allow for the use of data on existing parent lines as far as stacked events are concerned. For food safety approvals, a 2004 FSC opinion paper categorised biotech events into three groups: 1) introduced genes which do not influence host metabolism and mainly endow the hosts with insect resistance, herbicide tolerance or virus resistance; 2) introduced genes which alter host metabolism and endow the hosts with enhanced nutritional component or suppression of cell wall degradation by promoting or inhibiting specific metabolic pathways; and 3) introduced genes which synthesize new metabolites not common to the original host plant.

The FSC requires safety approval on the stacked event if the crossing occurs:
1. above the subspecies level between a biotech event and a non-biotech event,
2. between biotech events in category 1,
3. between those in category 1 if the amount consumed by humans, the edible part or processing method is different from that of the parents,
4. between biotech events in 1 and 2, 1 and 3, 2 and 2, 3 and 3, and 2 and 3.

Most stacked events that result from traditional crossbreeding do not require a safety review.

For feed safety of stacked events, MAFF requires approvals from the Expert Panel on Recombinant DNA Organisms of the Agricultural Material Committee (AMC). Unlike the feed safety full approvals, the approvals by the Expert Panel are neither subject to MAFF Minister notification, nor to public comments.[144]

vii. Interestingly, the USDA Japan biotech report notes 'this is perhaps an unwanted regulatory burden', p.12

South Korea

Although South Korea is not one of the world's major producers of GMOs, in 2008 the ISAAA placed South Korea as the fifth most prolific approver of them. In the same year, along with Japan, it imported GM maize for food for the first time.[145] At the time of writing South Korea is the latest country to grant approval for Smartstax. According to the Biosafety Clearing House, South Korea granted regulatory approval for the import for domestic use of Smartstax in food and processing on the 2nd of November 2009.[146] At the time of writing, the ACB could not find any record of this on either the Ministry of Knowledge Economy's[147] (the competent national authority presented on the BCH website) or the South Korean BCH's websites.[148]

South Korea ratified the Cartagena Protocol on the 3rd of October 2007, with its entry into force on the 1st of January 2008.[149] Despite a groundswell of anti-GMO opinion, South Korea aspires to be the world's seventh largest biotech country by 2016.[150] The Ministry of Agriculture & Forestry (MAF) regulates labelling of unprocessed biotech products and conducts environmental risk assessments of biotech crops. The Korea Food & Drug Administration (KFDA) regulates food safety approval of biotech crops and labelling of processed food products containing biotech components. The Ministry of Knowledge Economy took over as the national competent authority for the CPB from the ministry of Commerce, Industry, and Energy (MOCIE) at its inception in February 2008.

In terms of stacked events, KFDA does not require additional approvals if they meet the following criteria: 1) traits that are being combined were already approved individually; 2) there is no difference in the given traits, intake amount, edible part and processing method in the stacked event and the conventional non-biotech counterpart; and 3) there is no crossbreeding among subspecies. In June 2007 provisional guidelines were drafted regarding environmental assessment of stacked GMOs, requiring the following to be made available to the Rural Development Association (RDA – a branch of MAF): Information to verify whether there is interaction of traits in nucleic acid inserted in parental line; available information pertinent to characteristics of stacked events; evaluation of both; confirmation from the developer who received approval for the parental event used in stacked events and agreement for review of already submitted information for the parental event. Upon review of this information the RDA will decide whether to recommend an environmental assessment. Otherwise no further assessment will be required.[151]

A year after this announcement the NGO GRAIN reported on the events leading up to South Korea's policy decision regarding GMOs. In March 2007 South Korea and the United States were engaged in the last round of negotiations over a free trade agreement (FTA). Concurrently, and out of the public domain, the two countries were also concluding a bilateral deal on GMOs. Part of South Korea's obligations under the deal included a prohibition against testing stacked GMOs in a GM shipment where the individual traits have previously received regulatory approval in the US.[152]

USA

Regulatory responsibility of 'combined-trait GE plants' is coordinated by three primary agencies: APHIS (a branch of the USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

APHIS regulates GMOs if it deems them to be genetically modified, and to pose a potential plant pest. A person may submit a petition to request that APHIS no longer regulate a GMO. APHIS will grant this if, after it conducts a scientific review, it determines that the GMO is unlikely to be a plant pest. In all petitions to date APHIS has granted non-regulatory status *that includes any offspring that would be derived from traditional breeding* (emphasis added).[153]

Under the Federal Food, Drug and Cosmetic Act (FFDCA), the FDA approach is that all foods, regardless of the method used to develop the crop, are held to the same safety standards. The FDA does not consider the conventional crossing of GM crops to pose any greater risks than the crossing of conventional varieties. It is the responsibility of the developer of the food to consult with the FDA if it envisages any safety or nutritional issues arising from the above process.[154]

Among the EPA's responsibilities is the safe use of pesticides in US agriculture, including plant-incorporated protectants (PIPs). These consist of the pesticidal compound and the genetic material responsible for the production of that compound in the GM plant. The EPA considers a plant to be 'stacked' where it contains two or more traits for different purposes (e.g. different Bt toxins aimed at different pests). The EPA registers any product containing one or more traits that produce pesticides. A stacked product will have to be registered as new, regardless of whether the traits it contains have previously registered. In the case of a stacked event containing a Bt trait and herbicide tolerance, if the herbicide tolerant trait is added to a registered Bt trait through conventional breeding, the final stacked product would not require registration.[155]

International Regulation

The multilateral bodies most active in the field of GMOs (and consequently gene stacking) are the Codex Alimentarius, a joint body of the UN Food and Agricultural Organisation (FAO) and the World Health Organisation (WHO), and the UN Environment Programme (UNEP). The development and implementation of standards and practices within these bodies is complicated enough, given the divergence of opinion from their constituent bodies of experts. However, trying to reconcile their emphasis on environmental and health issues with the free trade agenda of the World Trade Organisation (WTO) is proving eminently more difficult.[156] Although the WTO agreement on the application of Sanitary and Phytosanitary measures (SPS) recognizes Codex, the WTO is the only international organization with an enforceable dispute settlement system. The SPS agreement is an elaboration on article XX (b) of the General Agreement on Tariffs and Trade (GATT 1994), which provides some provision for temporary trade-restricting measures where 'necessary to protect human, animal or plant health'. However, article XX also states that measures cannot be 'arbitrary or unjustified discrimination between countries where the same conditions prevail or a disguised restriction on international trade'. Temporary bans are also allowed under article 5.7 of the SPS agreement 'in cases where relevant scientific evidence is insufficient'.[157]

The relationship between the WTO and the Cartagena protocol on Biosafety remains ambiguous. Under international law the Vienna Convention on the law of treaties stipulates that a later agreement supersedes an earlier one, and an agreement on a specific subject prevails over a general one. By both measures the Biosafety Protocol *should* supersede any conflicting laws that appear under the WTO. In practice, due to compromises made during the negotiations stage, the Protocol simultaneously states it shall not undermine the rights of a party under existing international treaties, nor subordinate the Protocol to other international agreements. The outcome of any dispute will be heavily influenced by where the dispute is arbitrated. In the case of the United States, where arbitration must happen at the WTO, the effectiveness and reach of the Protocol could be called into question.[158] The example of South Korea highlights instances where multi-lateral agreements can be undermined by the narrow interests of bilateral trade deals.

The Codex Alimentarius Commission has 175 member governments and was established in 1963 to protect the health of consumers, to ensure fair trade practices in the food trade, and to promote co-ordination of all food standards work undertaken by international governmental and non-governmental organizations. In 1999 the Ad-Hoc Intergovernmental task force was established to elaborate standards, guidelines and other principles for food derived from biotechnology. It presented its findings in 2003.[159] Despite this, debates within Codex are ongoing. The Codex Ad Hoc intergovernmental task force on foods derived from biotechnology, held in Japan in September 2005, re-iterated the divergence of opinion on stacked GMOs. Brazil, Canada and Japan felt this should be a priority area for a new task force, while the USA and Australia had this as a lower priority. "The United States is not aware of substantial safety issues associated with foods derived from 'stacked' varieties of rDNA plants that are not covered by the existing recombinant-DNA plant guideline."[160]

An Ad Hoc Technical Expert Group (AHTEG) on risk assessment and risk management under the Cartagena Protocol on Biosafety have prioritised[viii] the need for the development of risk assessment and risk management of LMOs containing stacked genes or traits. The working group is expected to present its findings at the Meeting of Parties 5 (MOP-5) in Nagoya, Japan in October 2010.[161] While the core group consists of members of academia, members of the observers group include: Phil MacDonald of the Canadian Food Inspection Agency (plant biosafety office), David Heron of the USDA APHIS (both bodies of which have already approved Smartstax), and Thomas Nickson of Monsanto.[162]

Ricarda Steinbrecher, who is a member of the observers group of the AHTEG working group on stacked genes, has pointed out that the Codex Alimentarius 'Guideline for the conduct of food and safety assessment of foods derived from recombinant-DNA plants' (2003) provides ample scope for the regulation and assessment of stacked genes. Paragraph 14

viii.Of the 14 items on the agenda, LMOs containing stacked genes or traits were placed at number 3.

states: "Unintended effects in recombinant-DNA plants may also arise through the insertion of DNA sequences and/or they may arise through the subsequent conventional breeding of the recombinant-DNA plant. Safety assessment should include data and information to reduce the possibility that a food derived from a rDNA plant would have an unexpected, adverse effect on human health."[163]

Steinbrecher concludes that "it is evident that the Codex Plant Guideline does clearly apply to stacked genes and it lays out clearly that these should indeed go through a safety assessment, as para 14 clearly says that subsequent conventional breeding of a GM plant – which is exactly what is used to produce stacked genes/traits as we are dealing with in this guidance material – could produce unintended effects, while para 17 clearly says GM plants should be screened by breeders for unintended effects and any plant that survives such screening should subsequently go through a full safety assessment".[164]

Implications for Africa

The marginalisation of agriculture to the sidelines of policy discussion since the onset of the Washington consensus in the early 1980s was bought into sharp focus during the 2007/08 global food price increases. At a UN summit convened to discuss the crisis in June 2008 a new task force consisting of UN agencies, the World Bank and the International Monetary Fund (IMF) was established. From its inception the task force proved very amenable to biotechnology, with US agriculture secretary Ed Schafer stating that, *"biotechnology is one of the most promising tools for improving the productivity of agriculture and the incomes of the rural poor"*.[165] The Alliance for a Green Revolution in Africa (AGRA), launched in 2006 as a partnership between the Bill and Melinda Gates Foundation and the Rockerfeller Foundation, with Kofi Annan as its chairperson, is the very public face of the push to integrate Africa into the global industrial food system. While AGRA's stance towards biotechnology so far has been a diffident one, the Gates Foundation has been far less apprehensive in its support.[166]

The biotech industry has lauded South Africa's adoption of stacked traits as 'an important policy decision that would allow South Africa to retain its leadership role in biotech crops.'[167] This statement takes on added significance in the light that South Africa is also coveted as a potential 'springboard' into the rest of the African continent.[168] The African Union (AU), recognising the importance of a rigorous biosafety regime, has been pushing for the continental harmonisation of biosafety through the existing regional economic communities in Africa. The ACB has recently expressed grave misgivings over this approach, pointing out that undue influence by pro-GMO elements has already significantly undermined the strength of legislation at national level in Uganda, and that wider harmonisation could ultimately 'open up opportunities for actors with strong interests in GMOs to create regional markets for GM products with lax and uniform regulatory processes.'[169] The proliferation of stacked GMOs internationally, and the dramatic increase in permits granted for them in South Africa, hint at a potential future African deluge, all in the name of poverty alleviation and food security. Monsanto CEO Hugh Grant, when discussing the current global market for GMOs, recently noted 'we are where transistors were in the 1970s'.[170]

Conclusion

Recent regulatory approvals granted to Smartstax, the world's first eight-stacked GMO, appear to have laid the foundations for the largest release of a GM maize product in the history of genetic engineering. Despite evidence of genetic instability, increased incidences of pest and weed resistance, and a huge increase in the application of chemical herbicides associated with stacked GMOs, their rate of adoption has risen markedly in the last five years. The development and release of stacked GMOs has remained concentrated within the largest biotech companies as the earlier single traits events were, if not more so. Farmers in the USA and Canada have already experienced the length that these companies will go to in order to safeguard their market ascendancy, while the public at large has been kept in the dark.

The representation of the biotech industry at the policy making level, even within the Biosafety Protocol process has the potential to significantly prejudice the current discourse on the risk assessment and regulatory approach towards gene stacking This process is already heavily weighted in their favour in the world's largest GMO producing nations and corporations.

The ACB has previously expressed concern that attempts at the harmonisation of Biosafety law in Africa could potentially leave loop-holes for further entrenchment of these imprudent regulatory approaches. While the influence of the biotech lobby in North America and Europe is considerable, farmers' groups and civil society is at least able to mobilise to bring these issues into the public realm.

With scant information on the potential release of Smartstax in South Africa coming from the developers, Monsanto or Dow AgroSciences, the ACB will continue to monitor the situation in South Africa with vigilance. As the 'springboard' into the rest of Africa, what happens in South Africa is likely to profoundly influence the adoption of Smartstax on the continent. The current trends indicate that stacked GMO penetration will increase in South Africa. This makes it imperative that civil society in South Africa continues to illustrate the very significant scientific concerns that have been raised, on behalf of those here, and elsewhere on the continent whose voices are rarely heard.

Annexure 1 : Stacked GMO permits granted in South Africa, 2009

Date	Applicant	Organism	Trait	Foreign supplier/ receiver	Volume / Quantity	Purpose	Status
Jan	Pioneer 386	Maize MON810 x NK603	Insect ^{R} Herb^T	Austria	1 005 Kg	Export for contained use	Export
	Bayer 015	Cotton BGII x RR Flex	Insect ^{R} Herb^T	USA	1 152 g	Export for planting	Export
Feb	Pioneer 390	Maize MON810 x NK603	Insect ^{R} Herb^T	USA	50 Kg	Import for planting	Import
	Monsanto 563	Maize MON810 x NK603	Insect ^{R} Herb^T	Philippines	2 500 MT	Export for planting	Export
	Monsanto 564	Maize MON810 x NK603	Insect ^{R} Herb^T	Philippines	900 MT	Export for planting	Export
	Monsanto 565	Maize MON810 x NK603	Insect ^{R} Herb^T	Philippines	500 MT	Export for planting	Export
	Bayer 011	Cotton Bollgard II x GlyTol x LLCotton25	Insect ^{R} Herb^T	USA	10 Kg	Import for trial release	Import
	Bayer 011	Cotton Bollgard II x GlyTol x LLCotton25	Insect ^{R} Herb^T	USA	10 Kg	Trial release	Trial release
Feb	Bayer 009	Cotton Twinlink x GlyTol	Insect ^{R} Herb^T	USA	10 Kg	Import for trial release	Import
	Bayer 009	Cotton Twinlink x GlyTol	Insect ^{R} Herb^T	USA	10 Kg	Trial release	Trial release
	Pioneer 391	Maize MON810 x NK603	Insect ^{R} Herb^T	USA	1 005 Kg	Export for contained use	Export
	Monsanto 567	Maize MON810 x NK603	Insect ^{R} Herb^T	France	10.7 Kg	Export for contained use	Export
	Bayer 017	Cotton GlyTol x LLCotton25	Herb^T	USA	432 Kg	Export for planting	Export
	Bayer 018	Cotton Bollgard II x LLCotton25	Insect ^{R} Herb^T	USA	504 Kg	Export for planting	Export

Date	Applicant	Organism	Trait	Foreign supplier/ receiver	Volume / Quantity	Purpose	Status
Mar	Monsanto 569	Maize MON810 x NK603	Insect R HerbT	France	10.71 Kg	Export for contained use	Export
	Monsanto 572	Maize MON810 x NK603	Insect R HerbT	USA	44.685 Kg	Export for contained use	Export
	Monsanto 576	Maize MON810 x NK603	Insect R HerbT	France	13.150 Kg	Export for contained use	Export
Mar	Monsanto 579	Maize MON810 x NK603	Insect R HerbT	France	12 250 Kg	Export for contained use	Export
	Monsanto 587	Maize MON810 x NK603	Insect R HerbT	France	1.75 Kg	Export for contained use	Export
April	Monsanto 595	Maize MON810 x NK603	Insect R HerbT	France	4.75 Kg	Export for contained use	Export
	Pioneer 411	Maize MON810 x NK603	Insect R HerbT	Austria	1005 Kg	Export for contained use	Export
	Monsanto 603	Maize MON810 x NK603	Insect R HerbT	Philippines	6 Kg	Export for planting	Export
May	Monsanto 608	Maize MON810 x NK603	Insect R HerbT	France	1 Kg	Export for contained use	Export
	Monsanto 614	Maize MON810 x NK603	Insect R HerbT	France	6.75 Kg	Export for contained use	Export
	Monsanto 617	Maize MON810 x NK603	Insect R HerbT	Philippines	50 Mt	Export for planting	Export
	Monsanto 620	Maize MON810 x NK603	Insect R HerbT	France	3.0 Kg	Export for contained use	Export
May	Monsanto 622	Maize MON810 x NK603	Insect R HerbT	USA	7.5 Kg	Export for contained use	Export
	Monsanto 626	Cotton BG x RR	Insect R HerbT	Colombia	75 000 Kg	Export for planting	Export
	Monsanto 631	Maize MON810 x NK603	Insect R HerbT	France	3 Kg	Export for contained use	Export
	Pioneer 419	Maize MON810 x NK603	Insect R HerbT	USA	1005 kg	Export for contained use	Export

Date	Applicant	Organism	Trait	Foreign supplier/ receiver	Volume / Quantity	Purpose	Status
June	Monsanto 635	Maize MON810 x NK603	Insect ^{R} Herb^T	France	2.25 Kg	Export for contained use	Export
	Monsanto 636	Maize MON810 x NK603	Insect ^{R} Herb^T	Philippines	1550 MT	Export for planting	Export
	Pioneer 422	Maize MON810 x NK603	Insect ^{R} Herb^T	USA	20000 Kg	Import for planting	Import
	Monsanto 643	Maize MON810 x NK603	Insect ^{R} Herb^T	France	1.5 Kg	Export for contained use	Export
	Bayer 020	Cotton BGII x RR Flex	Insect ^{R} Herb^T	USA	50 Kg	Import for planting	Import
June	Monsanto 646	Maize MON810 x NK603	Insect ^{R} Herb^T	France	2.5 Kg	Export for contained use	Export
	Monsanto 652	Maize MON810 x NK603	Insect ^{R} Herb^T	USA	38 g	Export for contained use	Export
July	Monsanto 656	Maize MON810 x NK603	Insect ^{R} HerbT	France	2.5 Kg	Export for contained use	Export
	Pioneer 428	Maize MON810 x NK603	Insect ^{R} Herb^T	USA	5000 MT	Import for planting	Import
	Monsanto 664	Maize MON810 x NK603	Insect ^{R} Herb^T	France	3.25 Kg	Export for contained use	Export
	Monsanto 671	Maize MON810 x NK603	Insect ^{R} Herb^T	France	5 Kg	Import for planting	Import
	Monsanto 677	Maize MON810 x NK603	Insect ^{R} Herb^T	France	11.25 Kg	Export for contained use	Export
Aug	Bayer 018	Cotton Bollgard II x LLCotton25	Insect ^{R} Herb^T	USA	5 Kg	Import for trial release	Import
	Bayer 018	Cotton Bollgard II x LLCotton25	Insect ^{R} Herb^T	USA	5 Kg	Trial release	Trial release
Aug	Bayer 019	Cotton GlyTol x LLCotton25	Herb^T	USA	5 Kg	Import for trial release	Import

Date	Applicant	Organism	Trait	Foreign supplier/ receiver	Volume / Quantity	Purpose	Status
	Bayer 019	Cotton GlyTol x LLCotton25	Herb^{T}	USA	5 Kg	Trial release	Trial release
	Syngenta 104	Maize BT II	Insect ^{R}	USA	50 Kg	Import for planting	Import
	Monsanto 470a	Maize MON89034 x NK603	Insect ^{R} Herb^{T}	USA	18 Kg	Import for trial release	Import
	Monsanto 470a	Maize MON89034 x NK603	Insect ^{R} Herb^{T}	USA	18 Kg	Trial release	Trial release
	Monsanto 679	Maize MON810 x NK603	Insect ^{R} Herb^{T}	France	5 Kg	Export for contained use	Export
	Pannar 065	Maize BT II	Insect ^{R}	USA	5.1 Kg	Import for planting	Import
Aug	Pioneer 436	Maize MON810 x NK603	Insect ^{R} Herb^{T}	USA	1 865 Kg	Export for contained use	Export
	Monsanto 686	Maize MON810 x NK603	Insect ^{R} Herb^{T}	France	4.5 Kg	Export for contained use	Export
	Pannar 066	Maize BT II	Insect ^{R}	USA	120 Kg	Import for planting	Import
	Bayer 021	Cotton Twinlink x GlyTol	Insect ^{R} Herb^{T}	USA	20 Kg	Import for trial release	Import
	Monsanto 695	Maize MON810 x NK603	Insect ^{R} Herb^{T}	France	4.25 Kg	Export for contained use	Export
	Monsanto 696	Cotton BG x RR	Insect ^{R} Herb^{T}	Argentina	112 500 Kg	Export for planting	Export
Sept	Monsanto 688	Cotton BGII x RR Flex	Insect ^{R} Herb^{T}	Australia	3 040 Kg	Import for planting	Import
	Monsanto 689	Cotton BG x RR	Insect ^{R} Herb^{T}	Australia	40 Kg	Import for planting	Import
	Pioneer 441	Maize MON810 x NK603	Insect ^{R} Herb^{T}	Argentina	10 Kg	Import for planting	Import
	Pioneer 444	Maize MON810 x NK603	Insect ^{R} Herb^{T}	Brazil	4 Kg	Import for planting	Import
Sept	Pioneer 447	Maize MON810 x NK603	Insect ^{R} Herb^{T}	USA	33 Kg	Import for planting	Import
	Monsanto 698	Maize MON810 x NK603	Insect ^{R} Herb^{T}	Philippines	250 MT	Export for planting	Export

Date	Applicant	Organism	Trait	Foreign supplier/ receiver	Volume / Quantity	Purpose	Status
	Monsanto 699	Maize MON810 x NK603	Insect R Herb T	France	8.5 Kg	Export for contained use	Export
	Syngenta 103	Maize BT11 x GA21	Insect R Herb T	USA	50 Kg	Import for trial release	Import
	Syngenta 103	Maize BT11 x GA21	Insect R Herb T	USA	50 Kg	Trial release	Trial release
	Monsanto 702	Maize MON810 x NK603	Insect R Herb T	France	11.75 Kg	Export for contained use	Export
	Monsanto 708	Cotton BGII x RR Flex	Insect R Herb T	USA	29.8 Kg	Import for planting	Import
	Monsanto 713	Maize MON810 x NK603	Insect R Herb T	Philippines	2 300 120 Kg	Export for planting	Export
Oct	Monsanto 716	Maize MON810 x NK603	Insect R Herb T	France	150 Kg	Import for planting	Import
	Monsanto 720	Maize MON810 x NK603	Insect R Herb T	France	7.75 Kg	Export for contained use	Export
	Monsanto 722	Cotton BG x RR	Insect R Herb T	Argentina	187 500 Kg	Export for planting	Export
	Pannar 073	Maize BT II	Insect R	France	14 Kg	Import for planting	Import
	Klein Karoo 002	Maize BT II	Insect R	USA	10 Kg	Import for planting	Import
	Monsanto 725	Maize MON810 x NK603	Insect R Herb T	France	1.25 Kg	Export for contained use	Export
	Monsanto 726	Maize MON810 x NK603	Insect R Herb T	USA	5 Kg	Import for planting	Import
	Pannar 075	Maize BT II	Insect R	USA	2.31 Kg	Import for planting	Import

(Source: South African Department of Agriculture, Forestry and Fisheries, 2009. Accessed 27/11/2009)

Annexure 2: Correspondence between the ACB and Dow AgroSciences/Monsanto

19-10-2009
Dear Gareth,

Thank you for your interest in Dow AgroSciences. Presently we are evaluating our seed strategy for RSA and consequently have no defined actions¬†relating to the maize seed market in South Africa.

Best Regards,

Patrick Dieterich

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From: Gareth Jones [mailto:garethj82@gmail.com]
Sent: Thursday, October 15, 2009 9:04 AM
To: Cullen, William (A)
Cc: Mariam Mayet
Subject: smartstax
Dear Bill,

My name is Gareth Jones, I was given your details by your public relations department. I am contacting you on behalf of the ACB. We are a Johannesburg based NGO who seek a robust and transparent biosafety regime in South Africa, and the rest of the continent. We have been following with interest the development of Smartstax between yourselves and Monsanto, and were hoping you would be able to answer some questions we have on the subject.

a) Does Dow intend to release Smartstax into the South African environment in 2009 or any other date thereafter? If so when exactly and in which areas in SA?

b) Does Dow intend to apply for a commodity clearance import for the said Smartstax GMO during 2009 or 2010?

c) In its application will Dow be seeking a reduction in refuge area requirements, as has happened in the United States and Canada?

d) Does Dow envision the need to apply for clearance for the events contained in Smartstax, bearing in mind they have all (separately) already been put before the executive council in terms of the GMO act previously?

e) What would be Dow's target market in South Africa for Smartstax be if it does intend to release it for planting or import it as food, feed or processing?

f) Does Dow plan to release the product in conjunction with any partner organizations in South Africa (whether public, private or civil society organizations)?

g) Does Dow have any plans to grow Smartstax (or future stacked gene products) in South Africa with the intention to export?

h) Does Dow expect the de facto moratorium placed on all imports of commodity GMOs in 2005 to be lifted soon? Will this have any influence on Dow's strategy regarding Smartstax in South Africa?

Regards,
Gareth

14-10-2009
Dear Gareth

Thank you for your mail.

As you would appreciate, any type of information about Monsanto's strategy and products is confidential. We are therefore not in a position to answer to your questions.

Kind regards
Michelle

Michelle Vosges
Regulatory Affairs Specialist
Monsanto South Africa

References

1. GMWatch. 4 August 2009. **Smartstax breakdown/Smartstax sows doubts** http://www.gmwatch.org/index.php?option=com_content&view=article&id=11355:smarts%20tax-breakdown-smartstax-sows-doubts (accessed 24/11/2009)
2. James, C. 1998. **Global Review of Commercialized Transgenic Crops: 1998**. ISAAA Briefs No.8. Ithaca, NY: ISAAA.
3. James, C. 2006. **Global Status of Commercialized Biotech/GM Crops: 2006**. ISAAA Brief No. 35. Ithaca, NY: ISAAA.
4. James, C. 2008. **Executive summary- Global status of Commercialised Biotech crops: 2008**. ISAAA Brief No.39. Ithaca, NY: ISAAA.
5. Karembu, M., Nguthi, F and Ismail, H. 2009. **Biotech Crops in Africa: The Final Frontier**. Nairobi, Kenya: ISAAA AfriCenter.
6. James, C. 2008. **Executive summary- Global status of Commercialised Biotech crops: 2008**. ISAAA Brief No.39. Ithaca, NY: ISAAA.
7. Department of Agriculture, Forestry and Fisheries. 2009. **GMO permits 2009**. http://www.nda.agric.za/doaDev/sideMenu/biosafety/doc/GMO_permits_2009.doc (accessed 24/11/2009)
8. James, C. 2007. Ithaca, NY: ISAAA. **Global Status of Commercialised Biotech/GM crops 2007**. ISAAA Brief No. 37. ISAAA: Ithaca, N.Y.
9. ETC Group. 2008. **Who owns nature? Corporate power and the final frontier in the commodification of life**. ETC group communiqué, issue #100, November 2008.
10. The Economist. 21 November 2009. **The parable of the sower**. http://www.economist.com/opinion/displaystory.cfm?story_id=14904184 (accessed 23/11/2009)
11. African Centre for Biosafety. 2009. **Biotechnology, seed and agrochemicals: Global and South African Industry structure and trends**. Biosafety, biopiracy and biopolitics series. Booklet 11. Johannesburg.
12. GRAIN. 2009. **The new weapons of genetic engineering**. Seedling, January 2009. http://www.grain.org/seedling/?id=576 (accessed 30/09/2009)
13. Steinbrecher, R. 2009. Biosafety Clearing House online discussion groups. **RA&RM of LMOs with Stacked Genes or Traits**. http://bch.cbd.int/onlineconferences/stacked2_ra.shtml?threadid=1225 (accessed 20/10/2009)
14. Austrian Federal Ministry of Health. 2008. **GM foof/feed application Risk assessment: Maize MON 89034 x MON 88017 x 59122** http://www.bmgfj.gv.at/cms/site/attachments/9/7/5/CH0808/CMS1228994124985/ages_stn__-_mais_mon89034x1507xmon88017x59122_public_version.pdf (accessed 13/11/2009)
15. UNEP Convention on Biodiversity. 2009. **Report of the first technical meeting of the Ad Hoc Technical Expert Group On Risk Assessment and risk management under The Cartagena Protocol On Biosafety. Montreal, 20th – 24th April**. http://www.cbd.int/doc/meetings/bs/bsrarm-01/official/bsrarm-01-03-en.pdf (accessed on 22/10/2009)
    Then, C. & Potthof, C. 2009. Risk Reloaded: **Risk analysis of genetically engineered plants within the European Union**. Testbiotech e.V. Institute for independent impact assessment in biotechnology. Munich
16. Langley, C. & Parkinson, S. **Science and the corporate agenda: The detrimental effects of commercial influence on science and technology**. Scientists for Global Responsibility. Folkestone. http://www.sgr.org.uk/SciencePolicy/CorporateInfluence.html (accessed 06/11/2009)
17. African Centre for Biosafety. 2009. **Biotechnology, seed and agrochemicals: Global and South African Industry structure and trends**. Biosafety, biopiracy and biopolitics series. Booklet 11. Johannesburg
18. Korves, R. 30 January 2009. **U.S Corn exports**. Truth about Trade and Technology. http://www.truthabouttrade.org/news/editorials/trade-policy-analysis/13254-us-corn-exports (accessed 25/11/2009)
19. Reuters. 31 July 2009. **Smartstax corn receives Japanese Import Approval**. http://www.reuters.com/article/pressRelease/idUS137266+31-Jul-2009+PRN20090731 (accessed 02/10/2009)
20. Monsanto. 31 July 2009. **Smartstax corn receives Japanese Import Approval**. http://monsanto.mediaroom.com/index.php?s=43&item=731 (accessed 02/10/2009)
21. http://www.foodstandards.gov.au/
22. www.health.gov.au/ogtr/index.htm
23. SeedQuest. 2009. **Monsanto reconfirms 2010 guidance and 2012 financial commitments on strength of larger expected launches for blockbuster products**. http://www.seedquest.com/news.php?type=news&id_article=11530&id_region=&id_category=&id_crop= (accessed 11/11/2009)
24. Leahy, S. 31 July 2009. **Monsanto, Dow stack up genes**. Asia Times online. http://www.atimes.com/atimes/Global_Economy/KG31Dj04.html (accessed 02/10/2009)
25. Canadian Food Inspection Agency. (n.d.) **CFIA authorisation of Smartstax corn**. http://www.inspection.gc.ca/english/plaveg/bio/bt/smartstaxe.shtml (accessed 01/10/2009)
26. GMWatch. 4 August 2009. **Smartstax breakdown/Smartstax sows doubts** http://www.gmwatch.org/index.php?option=com_content&view=article&id=11355:smarts%20tax-breakdown-smartstax-sows-doubts (accessed 01/10/2009)
27. Monsanto. 14 September 2007. **Monsanto – Dow AgroSciences collaborative agreement: Smartstax – New industry standard stacked-trait platform**. http://www.monsanto.com/pdf/investors/2007/09-14-07.pdf (accessed 02/10/2009)

28. Stein, A.J. & Rodriguez-Cerezo, E. 2009. **The global pipeline of new GM crops: Implications of asynchronous approval for international trade**. Seville: Institute for prospective technological studies of the European Commission.
29. Mathews, J. 2009. **False Reports and the smears of men**. http://www.gmwatch.org/latest-listing/1-news-items/11608-scientist-who-chaired-royal-society-report (accessed 21/10/2009)
30. James, C. 2008. **Executive summary- Global status of Commercialised Biotech crops: 2008**. ISAAA Brief No.39. Ithaca, NY: ISAAA.
31. Swanby, H. 2008. **GMOs in South Africa 2008 overview**. Johannesburg: African Centre for Biosafety. Biosafety, biopircacy and biopolitics series. Booklet 8. http://www.biosafetyafrica.org.za/index.php/20090128189/GMOs-in-South-Africa-2008-Overviews/menu-id-100026.html (accessed 03/12/2009)
32. African Centre for Biosafety. 2007. **Objections to the application made by Syngenta Seedco for field trials in respect of GM maize events GA21 and Bt11xGA21**. http://biosafetyafrica.org.za/index.php/20070903132/Objections-on-Syngenta-GM-Maize-GA21-and-Bt11-x-GA21/menu-id-100023.html (accessed 22/10/2009)
33. Corné Louw. Senior economist – inputs, Grain SA. 25 November 2009. Personal correspondence.
34. Please see annex for email correspondence between the ACB and Monsanto, Dow AgroSciences
35. African Centre for Biosafety. 2009. **Biotechnology, seed and agrochemicals: Global and South African Industry structure and trends**. Biosafety, biopiracy and biopolitics series. Booklet 11. Johannesburg
36. Cummins, J. 2004. **Gene stacking is a bad idea**. http://www.ibiblio.org/ecolandtech/SoilWiki/message-archives/JoeCummins/msg00166.html (accessed 21/10/2009)
37. GRAIN. 2009. **The new weapons of genetic engineering**. Seedling, January 2009. http://www.grain.org/seedling/?id=576 (accessed 30/09/2009)
38. Stein, A.J. & Rodriguez-Cerezo, E. 2009. **The global pipeline of new GM crops: Implications of asynchronous approval for international trade**. Seville: Institute for prospective technological studies of the European Commission.
39. Ibid.
40. James, C. 1999. **Global Status of Commercialized Transgenic Crops: 1999**. ISAAA Briefs No.12: Preview. Ithaca, NY: ISAAA.
41. ETC Group. 2008. **Who owns nature? Corporate power and the final frontier in the commodification of life**. ETC group communiqué, issue #100, November 2008.
42. James, C. 2008. **Executive summary- Global status of Commercialised Biotech crops: 2008**. ISAAA Brief No.39. Ithaca, NY: ISAAA.
43. James, C. 1998. **Global Review of Commercialized Transgenic Crops: 1998**. ISAAA Briefs No.8. Ithaca, NY: ISAAA.
44. James, C. 2001. **Global status of commercialised transgene crops: 2001**. ISAAA briefs No. 24: Preview. Ithaca, NY: ISAAA.
45. Halpin, C. 2005. **Gene stacking in transgenic plants – the challenge for the 21st century**. Plant Biotechnology Journal, 3, pp. 141–155
46. James, C. 2006. **Global Status of Commercialized Biotech/GM Crops: 2006**. ISAAA Brief No. 35. Ithaca, NY: ISAAA.
47. James, C. 2008. **Executive summary- Global status of Commercialised Biotech crops: 2008**. ISAAA Brief No.39. Ithaca, NY: ISAAA.
48. Ibid.
49. Karembu, M., Nguthi, F and Ismail, H. 2009. **Biotech Crops in Africa: The Final Frontier**. Nairobi, Kenya: ISAAA AfriCenter.
50. James, C. 2008. **Executive summary- Global status of Commercialised Biotech crops: 2008**. ISAAA Brief No.39. Ithaca, NY: ISAAA.
51. Ibid
52. ETC Group. 2008. **Who owns nature? Corporate power and the final frontier in the commodification of life**. ETC group communiqué, issue #100, November 2008.
53. McDougall, P. 2007. Global Market Performance. CropLife International. http://www.croplifeasia.org/ref_library/others/Global%20market%20performance_13Sep07.pdf (accessed 02/11/2009)
54. James, C. 2007. Ithaca, NY: ISAAA. **Global Status of Commercialised Biotech/GM crops 2007**. ISAAA Brief No. 37. ISAAA: Ithaca, N.Y.
55. Stein, A.J. & Rodriguez-Cerezo, E. 2009. **The global pipeline of new GM crops: Implications of asynchronous approval for international trade**. Seville: Institute for prospective technological studies of the European Commission.
56. Gillam, C. 7 October 2009. **Update 1: Monsanto setting duel price plan for 2010**. Reuters. http://www.reuters.com/article/rbssChemicalsAgricultural/idUSN0747662920091007 (accessed 21/10/2009)
57. ETC Group. 2008. **Who owns nature? Corporate power and the final frontier in the commodification of life**. ETC group communiqué, issue #100, November 2008.
58. African Centre for Biosafety. 2009. **Biotechnology, seed and agrochemicals: Global and South African Industry structure and trends**. Biosafety, biopiracy and biopolitics series. Booklet 11. Johannesburg.

59. Friends of the Earth. 2009. **Who benefits from GM crops? Feeding the biotech giants, not the world's poor**. Food sovereignty, February 2009. Issue 116 http://www.foei.org/en/publications/pdfs/gmcrops2009full.pdf (accessed 26/11/2009))
60. The Economist. 21 November 2009. **The parable of the sower**. http://www.economist.com/opinion/displaystory.cfm?story_id=14904184 (accessed 23/11/2009)
61. African Centre for Biosafety. 2009. **Biotechnology, seed and agrochemicals: Global and South African Industry structure and trends**. Biosafety, biopiracy and biopolitics series. Booklet 11. Johannesburg.
62. Steinbrecher, R. 2009. Biosafety Clearing House online discussion groups. **RA&RM of LMOs with Stacked Genes or Traits**. http://bch.cbd.int/onlineconferences/stacked2_ra.shtml?threadid=1225 (accessed 20/10/2009)
63. De Schrijver, A. et al. 2006. **Risk assessment of GM stacked events obtained from crosses between GM events**. Trends in Food Science & Technology, doi:10.1016/j.tifs.2006.09.002 http://binas.unido.org/wiki/images/Stacked_Events.pdf (accessed 20/10/ 2009)
64. Heinemann, J (2007). **A typology of the effects of (trans)gene flow on the conservation and sustainable use of genetic resources**. FAO commission on genetic resources for food and agriculture. Background study paper no.35.
65. Mantell, K. 19 April 2002. **Mexico confirms GM maize contamination**. Science and Development network. http://www.scidev.net/en/news/mexico-confirms-gm-maize-contamination.html (accessed 30/11/2009)
66. Lu, B. 2008. **Transgene escape from GM crops and potential biosafety consequences: An environmental perspective**. Collection of Biosafety reviews Vol.4: 66 -141. Trieste: International centre for genetic engineering and biotechnology (ICGEB). http://www.icgeb.org/~bsafesrv/pdffiles/Bao-Rong.pdf (accessed 26/11/2009)
67. GRAIN. 2008. **Food safety: Rigging the game**. Seedling, July. http://www.grain.org/seedling_files/seed-08-07-6.pdf (accessed 26/11/2009)
68. Lu, B. 2008. **Transgene escape from GM crops and potential biosafety consequences: An environmental perspective**. Collection of Biosafety reviews Vol.4: 66 -141. Trieste: International centre for genetic engineering and biotechnology (ICGEB). http://www.icgeb.org/~bsafesrv/pdffiles/Bao-Rong.pdf (accessed 26/11/2009)
69. Monsanto. 20 July 2009. **Monsanto, Dow AgroSciences complete U.S. and Canadian regulatory authorizations for Smartstax corn; Plans to launch on seed platform on 3-4 million-plus acres**. http://www.monsanto.co.uk/news/ukshowlib.phtml?uid=13995 (accessed 02/10/2009)
70. Pschorn-Strauss. 2004. **Bt Cotton and Small-scale Farmers in Makhathini – A Story of Debt, Dependency, and Dicey Economics**. GRAIN. http://www.grain.org/btcotton/?id=100 (accessed 10/10/2009)
71. FAO Electronic Forum on biotechnology in food and agriculture. 2003. **Regulating GMOs in developing and transition economies**. 28th April – 1st June. http://www.fao.org/BIOTECH/C9doc.htm (accessed 02/10/.2009)
72. Jaffe, G. 2009. **Complacency on the farm: Significant non-compliance with EPA's refuge requirements threatens the future effectiveness of genetically engineered pest protected corn**. Washington: Centre for science in the public interest.
73. Little, M. 12 August 2009. **Agency's decision lacks scientific support, allege researchers**. Epoch times. http://www.theepochtimes.com/n2/content/view/20932/ (accessed 10/10/2009)
74. Tabashnika et al. 2009. **Asymmetrical cross-resistance between Bacillus thuringiensis toxins Cry1Ac and Cry2Ab in pink bollworm**. PNAS 106:11889-11894
75. Zhao et al. 2005. **Concurrent use of transgenic plants expressing a single and two Bacillus thuringiensis genes speeds insect adaptation to pyramided plants**. Proceedings of the National Academy of Sciences. 102:8426-8430
76. Waltz, E. 2009. **Under wraps**. Nature biotechnology. Volume 27, number 10. October 2009. http://www.emilywaltz.com/Biotech_crop_research_restrictions_Oct_2009.pdf (accessed 19/10/2009)
77. Benbrook, C. 2009. **Impacts of genetically engineered crops on pesticide use: The first 13 years**. The Organic Centre. http://www.organic-center.org/science.pest.php?action=view&report_id=159 (accessed 24/11/2009)
78. Dow AgroSciences. 12th November 2009. **Dow AgroSciences, Du-Pont agree to cross license next generation soybean herbicide tolerant traits** http://www.dowagro.com/newsroom/corporatenews/2009/20091112a.htm (accessed 20/11/2009)
79. Benbrook, C. 2009. **Impacts of genetically engineered crops on pesticide use: The first 13 years**. The Organic Centre. http://www.organic-center.org/science.pest.php?action=view&report_id=159 (accessed 24/11/2009)
80. Myhr, A.I. 2007. **The precautionary principle in GMO regulations**. In T. Traavik & L.L. Ching (Eds.) Biosafety first – Holistic approaches to risk and uncertainty in genetic engineering and genetically modified organisms. Tromso: Norsk institutt for genokologi & Trondheim: Tapir academic press.
81. Then, C. & Potthof, C. 2009. **Risk Reloaded: Risk analysis of genetically engineered plants within the European Union**. Testbiotech e.V. Institute for independent impact assessment in biotechnology. Munich
82. Biosafety Clearing House online discussion groups. **RA&RM of LMOs with Stacked Genes or Traits** http://bch.cbd.int/onlineconferences/stacked2_ra.shtml?threadid=1225 (accessed 20/10/2009)
83. De Schrijver, A. et al. 2006. **Risk assessment of GM stacked events obtained from crosses between GM events**. Trends in Food Science & Technology, doi:10.1016/j.tifs.2006.09.002 http://binas.unido.org/wiki/images/Stacked_Events.pdf (accessed 20/10/ 2009)
84. GRAIN. 2009. **The new weapons of genetic engineering**. Seedling, January 2009. http://www.grain.org/seedling/?id=576 (accessed 30/09/2009)
85. Ibid.
86. James, C. 2007. Ithaca, NY: ISAAA. **Global Status of Commercialised Biotech/GM crops 2007**. ISAAA Brief No. 37. ISAAA: Ithaca, N.Y.
87. ETC Group. 2008. **Who owns nature? Corporate power and the final frontier in the commodification of life**. ETC group communiqué, issue #100, November 2008.

88. Friends of the Earth. 2009. **Who benefits from GM crops? Feeding the biotech giants, not the world's poor**. Food sovereignty, February 2009. Issue 116 http://www.foei.org/en/publications/pdfs/gmcrops2009full.pdf (accessed 26/11/2009)
89. 10 November 2009. **Monsanto reconfirms 2010 guidance and 2012 financial commitments on strength of larger expected launches for blockbuster product**. Seedquest. http://www.seedquest.com/news.php?type=news&id_article=11530&id_region=&id_category=&id_crop= (accessed 11/11/2009)
90. Kaskey, J. 13 August 2009. **Monsanto to charge as much as 42% for new seeds**. Greenpeace Canada Blogues. http://blogues.greenpeace.ca/?p=1449 (accessed 16/11/2009)
91. Ibid.
92. The Economist. 21 November 2009. **The parable of the sower**. http://www.economist.com/opinion/displaystory.cfm?story_id=14904184 (accessed 23/11/2009)
93. Friends of the Earth. 2009. **Who benefits from GM crops? Feeding the biotech giants, not the world's poor**. Food sovereignty, February 2009. Issue 116 http://www.foei.org/en/publications/pdfs/gmcrops2009full.pdf (accessed 26/11/2009)
94. Ibid.
95. Benbrook, C. 2009. **Impacts of genetically engineered crops on pesticide use: The first 13 years**. The Organic Centre. http://www.organic-center.org/science.pest.php?action=view&report_id=159 (accessed 24/11/2009)
96. GRAIN. 2009. **The new weapons of genetic engineering**. Seedling, January 2009. http://www.grain.org/seedling/?id=576 (accessed 30/09/2009)
97. **WIPO patent No.2007/030510**. http://tinyurl.com/a9crbb (accessed 30/09/2009)
98. Tansey, G & Rajotte, T (eds). 2008. **The future control of food: A guide to international negotiations and rules on intellectual property, biodiversity and food security**. The Quaker International Affairs Programme. Earthscan. London
99. ETC Group. 2008. **Patenting the 'Climate Genes'…And capturing the climate agenda**. ETC group communiqué, issue#99. May/June 2008.
100. Ibid.
101. Then, C. & Potthof, C. 2009. **Risk Reloaded: Risk analysis of genetically engineered plants within the European Union**. Testbiotech e.V. Institute for independent impact assessment in biotechnology. Munich
102. Tansey, G & Rajotte, T (eds). 2008. **The future control of food: A guide to international negotiations and rules on intellectual property, biodiversity and food security**. The Quaker International Affairs Programme. Earthscan. London
103. Ibid.
104. ETC Group. 2008. **Patenting the 'Climate Genes'…And capturing the climate agenda**. ETC group communiqué, issue#99. May/June 2008
105. Ibid.
106. http://www.cbd.int/biosafety/signinglist.shtml (accessed 06/11/2009)
107. Bickford. 2006. **Republic of South Africa Biotechnology: Pretoria's Biotechnology annual with minor corrections**. USDA Foreign Agricultural Service GAIN report.
108. Stafford, W. 2009. **ACB's objection to Syngenta's application for field trials of GM maize (GA21 and Bt 11 x GA21)**. African Centre for Biosafety. http://www.biosafetyafrica.net/index.html/images/stories/dmdocuments/ACB-objection-syngenta-20090914.pdf (accessed 05/11/2009)
109. Stafford, W. 2009. **ACB's objections to Syngenta's application for commodity import of triple stacked maize (Bt11xMIR162xGA21)**. African Centre for Biosafety. http://www.biosafetyafrica.net/index.html/images/stories/dmdocuments/Bt11xGA21XMIR162_Triple_Stacked_Maize_Syngenta.docfinal.pdf (accessed 05/11/2009)
110. Bogdanova, N. 2007. **Food and feed safety and nutritional assessment of MON88017 x MON810 Corn – Non confidential business information dossier**. Department of Agriculture, Forestry and Fisheries. Office of the director general. Pretoria
111. Monsanto South Africa. 2008. **MON 89034 Extended permit application – Non confidential business information version**. Department of Agriculture, Forestry and Fisheries. Office of the director general.Pretoria
112. Ibid.
113. Yankelevich. 2008, **Argentina Biotechnology report**. USDA Foreign Agricultural Service GAIN report. Buenos Aires. http://www.grupobiotecnologia.com.ar/PDF2009/USDA_2008_BIOTECHNOLOGY_ARG_ANNUAL_REPORTT.pdf (accessed 22/10/2009)
114. Ibid
115. Yankelevich. 2009. **Argentina Agricultural Biotechnology Annual**. USDA Foreign Agricultural Service GAIN report. http://gain.fas.usda.gov/Recent%20GAIN%20Publications/AGRICULTURAL%20BIOTECHNOLOGY%20ANNUAL_Buenos%20Aires_Argentina_10-27-2009.pdf (accessed 04/12/2009)
116. Stein, A.J. & Rodriguez-Cerezo, E. 2009. **The global pipeline of new GM crops: Implications of asynchronous approval for international trade**. Seville: Institute for prospective technological studies of the European Commission.
117. Yankelevich. 2008, **Argentina Biotechnology report**. USDA Foreign Agricultural Service GAIN report. Buenos Aires. http://www.grupobiotecnologia.com.ar/PDF2009/USDA_2008_BIOTECHNOLOGY_ARG_ANNUAL_REPORTT.pdf (accessed 22/10/2009)

118. James, C. 2008. **Executive summary- Global status of Commercialised Biotech crops: 2008**. ISAAA Brief No.39. Ithaca, NY: ISAAA.
119. Ibid.
120. Silva, J.F. 2008. **Brazil annual biotechnology report 2008**. USDA Foreign Agricultural Service GAIN report. Brasilia. www.fas.usda.gov/gainfiles/200807/146295139.pdf (accessed 25/10/2009)
121. Reuters. 17 September 2009. **Brazil approves new varieties of GMO corn**. http://www.reuters.com/article/rbssHealthcareNews/idUSN1720270520090917 (accessed 27/10/2009)
122. Gartland, K. 22 September 2009. **Brazil approves more GM corn varieties**. The Progressive Farmer. http://www.dtnprogressivefarmer.com/dtnag/common/link.do?symbolicName=/ag/blogs/template1&blogHandle=southamerica&blogEntryId=8a82c0bc239b24620123e3f2dcec0397 (accessed 27/10/2009)
123. Silva, J.F. 2009. **Brazil agricultural biotechnology annual: Agricultural technologies report**. Brasilia: USDA Foreign Agricultural Service. www.fas.usda.gov/gainfiles/200807/146295139.pdf (accessed 25/10/2009)
124. Stein, A.J. & Rodriguez-Cerezo, E. 2009. **The global pipeline of new GM crops: Implications of asynchronous approval for international trade**. Seville: Institute for prospective technological studies of the European Commission.
125. Sharratt, L. 10 September 2009. **Why did Monsanto's latest GE foods get a free pass into Canada?** Rabble. http://rabble.ca/news/2009/09/why-did-monsantos-latest-ge-foods-get-free-pass-canada (accessed 06/11/2009)
126. Paoletti et al. 2008. **GMO risk assessment around the world: Some samples**. Trends in Food and Science Technology. 19. S70-S78
127. Canada Food Inspection Agency. Directive 94-08 (Dir94-08) **Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits**. http://www.inspection.gc.ca/english/plaveg/bio/dir/dir9408e.shtml (accessed 30/10/2009)
128. 7 February 2006. **Europe's rules on GMOs and the WTO**. http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/06/61&format=HTML&aged=0&language=EN&guiLanguage=en (accessed 25/10/2009)
129. Then, C. & Potthof, C. 2009. **Risk Reloaded: Risk analysis of genetically engineered plants within the European Union**. Testbiotech e.V. Institute for independent impact assessment in biotechnology. Munich
130. Pethokoukis, J. 19th October 2008. **EU Exec to approve GM maize if ministers fail to agree**. Reuters. http://www.reuters.com/article/governmentFilingsNews/idUSLJ71756020091019 (accessed 26/10/2009)
131. Then, C. & Potthof, C. 2009. **Risk Reloaded: Risk analysis of genetically engineered plants within the European Union**. Testbiotech e.V. Institute for independent impact assessment in biotechnology. Munich
132. European Commission, Health and consumers directorate general. (2009) **Summary record of the standing committee on the food chain and animal health**. Brussels
133. Then, C. & Potthof, C. 2009. **Risk Reloaded: Risk analysis of genetically engineered plants within the European Union**. Testbiotech e.V. Institute for independent impact assessment in biotechnology. Munich
134. GMWatch. 4 August 2009. **Smartstax in Europe**. http://www.gmwatch.org/latest-listing/1-news-items/11359-smartstax-in-europe (accessed 11/10/2009)
135. European Commission, Health and consumers directorate general. 2009. **Summary record of the standing committee on the food chain and animal health**. Brussels
136. Stein, A.J. & Rodriguez-Cerezo, E. 2009. **The global pipeline of new GM crops: Implications of asynchronous approval for international trade**. Seville: Institute for prospective technological studies of the European Commission.
137. Singh, S.K. **India Biotechnology Annual 2008**. USDA Foreign Agricultural Service GAIN report. New Delhi. http://www.fas.usda.gov/gainfiles/200808/146295379.doc (accessed 23/10/2009)
138. Cummins, J. 2004. **GM rice in India**. Institute for Science in Society (ISIS). http://www.i-sis.org.uk/GMRII.php (accessed on 29-10-2009)
139. Kameswara Rao, C. 9 March 2007. **Gene stacked Bollgard II Cotton in India**. GMO Africa. http://www.gmoafrica.org/2007/03/gene-stacked-bollgard-ii-cotton-in.html (accessed 29/10/2009)
140. Singh, S.K. **India Biotechnology Annual 2008**. USDA Foreign Agricultural Service GAIN report. New Delhi. http://www.fas.usda.gov/gainfiles/200808/146295379.doc (accessed 23/10/2009)
141. Sato, S. 2008. **USDA Foreign Agricultural Service Japan Biotechnology annual report**. www.fas.usda.gov/gainfiles/200807/146295225.pdf (accessed 28/10/2009)
142. Ibid.
143. Ibid.
144. Ibid.
145. James, C. 2008. **Executive summary- Global status of Commercialised Biotech crops: 2008**. ISAAA Brief No.39. Ithaca, NY: ISAAA.
146. Biosafety Clearing House. **Decisions on LMOs**. http://bch.cbd.int/database/decisions.shtml?documentid=100361&tab=2 (accessed 01/12/2009)
147. Ministry of the Knowledge Economy of South Korea. http://www.mke.go.kr/language/eng/ (accessed 01/12/2009)
148. South Korea Biosafety Clearing House. http://kabic.niab.go.kr/bio/english/news/news_list.jsp (accessed 01/12/2009)

149. Biosafety Clearing House. **Parties to Cartagena Protocol on Biosafety. Country profile: Republic of Korea**. http://bch.cbd.int/about/countryprofile.shtml?country=kr (accessed 01/12/2009)
150. Chung, S. & Phillips, S. 2007. **Korea, Republic of Agricultural Biotechnology report**. USDA Foreign Agricultural Service GAIN report. Seoul www.fas.usda.gov/gainfiles/200707/146291775.pdf (accessed 24/11/2009)
151. Ibid.
152. GRAIN. 2008. **Food safety: Rigging the game**. Seedling, July. http://www.grain.org/seedling_files/seed-08-07-6.pdf (accessed 26/11/2009)
153. Stein, A.J. & Rodriguez-Cerezo, E. 2009. **The global pipeline of new GM crops: Implications of asynchronous approval for international trade**. Seville: Institute for prospective technological studies of the European Commission.
154. Ibid.
155. Ibid.
156. Bereano, P. & Peacock, E. 2005. **Harmony or Havoc: Can the WTO, Biosafety Protocol and Codex Alimentarius work together?** http://www.scidev.net/en/latin-america-and-caribbean/policy-briefs/harmony-or-havoc-can-the-wto-biosafety-protocol-an.html (accessed 19/11/2009)
157. Ling, Y.L. & Ching, L. 2007. **The WTO Agreements: An introduction to the obligations and opportunities for biosafety**. In T. Traavik & L.L. Ching (Eds) Biosafety first – Holistic approaches to risk and uncertainty in genetic engineering and genetically modified organisms. Tromso: Norsk institutt for genokologi & Trondheim: Tapir academic press.
158. Ibid.
159. Ching, L. 2007. **International standard setting on Biosafety: An introduction to some other international agreement forums**. In T. Traavik & L.L. Ching (Eds) *Biosafety first – Holistic approaches to risk and uncertainty in genetic engineering and genetically modified organisms*. Tromso: Norsk institutt for genokologi & Trondheim: Tapir academic press.
160. Codex Ad Hoc Intergovernmental Task Force On Foods Derived From Biotechnology, Fifth Session, Chiba, Japan, 19-23 September 2005 ftp://ftp.fao.org/codex/ccfbt5/bt05_04e.pdf (accessed 16/10/2009)
161. Professor Kazuo Watanabe. Member of core group, sub-working Group on risk assessment and risk management of living modified organisms with stacked genes or traits, AHTEG. 11 November 2009. Personal correspondence.
162. UNEP Convention on Biodiversity. 2009. **Report of the first technical meeting of the Ad Hoc Technical Expert Group On Risk Assessment and risk management under The Cartagena Protocol On Biosafety. Montreal, 20th – 24th April**. http://www.cbd.int/doc/meetings/bs/bsrarm-01/official/bsrarm-01-03-en.pdf (accessed on 22/10/2009)
Then, C. & Potthof, C. 2009. Risk Reloaded: Risk analysis of genetically engineered plants within the European Union. Testbiotech e.V. Institute for independent impact assessment in biotechnology. Munich
163. Steinbrecher, R. 2009. **RA&RM of LMOs with Stacked Genes or Traits**. Biosafety Clearing House online discussion groups. http://bch.cbd.int/onlineconferences/stacked2_ra.shtml?threadid=1225 (accessed 20/10/2009)
164. Ibid.
165. Swanby, H. 2008. **GMOs in South Africa 2008 overview**. Johannesburg: African Centre for Biosafety. Biosafety, biopircacy and biopolitics series. Booklet 8. http://www.biosafetyafrica.org.za/index.php/20090128189/GMOs-in-South-Africa-2008-Overviews/menu-id-100026.html (accessed 03/12/2009)
166. Ibid.
167. James, C. 2008. **Executive summary- Global status of Commercialised Biotech crops: 2008**. ISAAA Brief No.39. Ithaca, NY: ISAAA.
168. African Centre for Biosafety. 2009. **Biotechnology, seed and agrochemicals: Global and South African Industry structure and trends**. Biosafety, biopiracy and biopolitics series. Booklet 11. Johannesburg
169. Swanby, H. 2009. **On-going concerns about harmonisation of Biosafety regulations in Africa**. Johannesburg: African Centre for Biosafety. Briefing paper No. 11 http://www.biosafetyafrica.net/index.html/images/stories/dmdocuments/ACB_Response%20to%20AU%20 Biosafety%20Unit_Nov%202009.pdf (accessed 03/12/2009)
170. The Economist. 21 November 2009. **The parable of the sower**. http://www.economist.com/opinion/displaystory.cfm?story_id=14904184 (accessed 23/11/2009)