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The global pipeline of new GM crops

Implications of asynchronous approval for international trade

Alexander J. Stein and Emilio Rodríguez-Cerezo

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European Commission
Joint Research Centre
Institute for Prospective Technological Studies

Contact information
Address: Edificio Expo. c/ Inca Garcilaso, 3. E-41092 Seville (Spain)
E-mail: jrc-ipts-secretariat@ec.europa.eu
Tel.: +34 954488318
Fax: +34 954488300

http://ipts.jrc.ec.europa.eu
http://www.jrc.ec.europa.eu

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Preface

This report is the outcome of the **workshop on the "Global commercial pipeline of new GM crops"** organised by the Institute for Prospective Technological Studies (IPTS), one of the seven institutes of the Joint Research Centre (JRC) of the European Commission, on 12-13 November 2008. The workshop gathered international experts and practitioners involved in the development, regulation and commercialisation of GM crops worldwide. The main objective of the workshop was to compile a global pipeline of new GM crops that are to be commercialised in the short to medium term by private and public technology providers. Against this background, a discussion of the experts in the cultivation, trade and processing of the main GM crops took place, in particular pointing to the **implications of "asynchronous approval"** of these crops for international trade.

The compilation of a comprehensive database of currently marketed GM crops and GM crops in the pipeline, and the summary of the issues regarding asynchronous approval and trade presented by the participants was the responsibility of JRC-IPTS after the workshop. This task has been facilitated by numerous contacts and information provided by workshop participants (see List of participants in the Appendix). We here acknowledge their contribution to the work that has resulted in the publication of this report.

The database that was compiled by the JRC-IPTS gives information on the status of approval of different GM crops in different world countries that are relevant for trade of agricultural commodities. We believe this will be a useful tool for policy makers in the EU and elsewhere. Inevitably, the database presented in this report represents the information available until January 2009. To accommodate for updates of this database it is also available as an electronic version (Stein and Rodríguez-Cerezo 2009); future updates will be published on the Internet (http://agrilife.jrc.ec.europa.eu/pipeline.htm).

Executive summary

- The commercialisation of new genetically modified (GM) crops generally is a regulated activity worldwide. Different countries have different authorisation procedures, and, even if submitted at the same time, new GM crops do not get approval simultaneously in all countries. This issue, known as **"asynchronous approval" of GM crops**, is of growing concern for its potential economic impact on international trade. Because if the importing country operates a **"zero tolerance" policy**, imports may be rejected if containing traces of genetically modified organisms (GMOs) that are not yet authorised.

- A problem similar to asynchronous approval (AA) occurs when a developer of a new GM crop does not seek approval for commercialisation in all world regions. (This may be the case if the crop in question is designed only for local markets or foreign markets do not represent major target markets for exports.) In this case there can be **"isolated foreign approval"** (IFA) by a cultivating country and any traces of unauthorised GM material in imports may again lead to their rejection by other countries.

- Finally, imports can also be rejected due to "low-level presence" (LLP) of research events; this can happen if a country has authorised the cultivation of a GM crop in field trials only, but due to accidental admixture traces end up in the commercial crop supply.

- In the case of the European Union (EU), any such **low-level presence of new GM crops** in agricultural imports has **already caused trade disruption** and economic problems. In particular, as acknowledged in a report by the Directorate-General for Agriculture and Rural Development of the European Commission (EC 2007), the **EU feed and livestock production sectors are affected** by this issue.

- In order to predict the evolution of the impact of LLP of GM crops for the EU agri-food sector, it is **essential to produce a forecast of the upcoming GM crops**. It needs to be clarified which and how many GM crops will be developed in the next years, in which countries, and when these new crops will be authorised by the different trading partners of the EU.

- To build the basis for such a forecast, the Joint Research Centre (JRC), Institute for Prospective Technological Studies (IPTS), organised a **workshop on the "Global commercial pipeline of new GM crops"** on 12-13 November 2008 that gathered international experts and practitioners involved in the development, regulation and commercialisation of GM crops worldwide.

- This report presents an **overview of the current status** of approvals of GMOs in different countries with relevance for EU trade. It also presents a **database of GM crops that are already in the pipeline** and may be marketed worldwide in the short term (2-3 years) to medium term (7-8 years from 2008). The pipeline was compiled for the **seven crops** (soybeans, maize, rapeseed, cotton, sugar beet, potatoes and rice) for which GM varieties already exist or are likely to be marketed in the near future. The pipeline includes GM crops to be marketed by private and public technology providers in all world regions.

- GM crops were classified in **five categories** according to their proximity to market:
    - Commercial crop: commercialised GM events (those currently marketed in at least one country worldwide).
    - Commercial pipeline: GM events authorised for marketing in at least one country but not yet commercialised (commercialisation only depends on the developer).
    - Regulatory pipeline: GM events already in the regulatory process to be marketed in at least one country.
    - Advanced R&D pipeline: GM events not yet in the regulatory process but at late stages of development.
    - Other crops: GM events authorised in at least one country, but not commercialised or commercialised once but phased out commercially or legally afterwards.

- The summary of the findings of the workshop and subsequent desk research predicts a **significant global increase in the number of individual commercial GM events**. While currently there are around 30 commercial GM events that are cultivated worldwide, the forecast is that by 2015 there will be over 120: for soybeans, currently only 1 GM event is available, but this number is predicted to increase to 17 different events; maize events are expected to increase from 9 to 24, rapeseed events from 4 to 8 and cotton events from 12 to 27. In the case of rice where currently no commercial events are cultivated, the prediction is that by 2015 as many as 15 GM events could be grown; potatoes also are predicted to move from no current cultivation to 8 events, and other, minor crops are predicted to grow from 7 events currently marketed to 23 events by 2015. Therefore, as problems of LLP have already occurred in the current situation (with about 30 events marketed), these are only likely to increase when moving from 30 to 120 events in the market.

- Individual GM events can easily be combined by conventional crossings by plant breeders to generate new GMOs with multiple desirable traits. Such "stacking" of (authorised) events is already common in maize and cotton. It is evident that in countries where stacked GM crops are required to go through the regulatory system as a new GM crop, the **possibility of generating new GM crops by stacking individual events** will create an increasingly large number of new "approvable" GMOs. This will cause significant increase in the workload of regulatory systems and will likely contribute to the asynchrony of approvals.

- Most of the existing events in commercial GM crops were developed by (private) technology providers from the USA or Europe, and cultivated first in North and South America. These developers also tended to seek broad authorisation of their products in key export target markets (in particular the EU and Japan). However, by 2015 about half the events in commercial **GM crops are expected to come from national technology providers in Asia** (and Latin America), designed for domestic agricultural markets. It seems very improbable that all these new GM crops will be submitted for approval in the EU, i.e. there will be isolated foreign approval (IFA). Hence future **incidents due to LLP in imports of crops or**

processed foods from these countries are very likely. An added complication in such cases is the need for information on validated tests for the detection of some of these events in order to enforce current regulatory provisions in many countries worldwide.

- In addition to new GM crops like rice and potatoes, it is also foreseen that a limited number of new traits will be commercialised. Currently the large majority of **commercial traits confer insect resistance, herbicide tolerance** or a combination of both. For minor crops virus resistance is already available. The pipeline predicts that by 2015 insect resistance and herbicide tolerance traits will still be dominant but also **new commercial traits will be available covering crop composition and abiotic stress tolerance** (mainly optimised oil and starch content, improved nutrient profiles, and drought tolerance).

- Given the EU's dependency on soybean imports, special attention should be paid to this crop. Currently **there are five new soybean events in the commercial and regulatory pipeline that could result in potential situations of AA already in the next 2-3 years**. In the longer term further AA incidents could arise from nine new events that are currently in the advanced R&D pipeline. In addition, difficulties with LLP due to IFA cannot be discarded because of the GM soybeans that are currently in the regulatory system in China.

- **For maize there are four new individual events in the pipeline** that could pose potential AA problems in the short term, with more difficulties being likely due to the stacking of events. In the longer term, seven more events could enter the market and contribute to the AA situation. Moreover, three GM maize events that could become potential issues of IFA are in the regulatory pipeline in China.

- **For GM rapeseed there is only one event in the regulatory pipeline that may pose difficulties** due to LLP in the short term; in the longer run the problem of LLP in rapeseed in the EU will depend on the evolution of the five events in the advanced R&D pipeline. Also **for GM cotton** the LLP issue may be less relevant because the EU imports of cottonseed meal and cotton oil are very small. However, the EU depends on the import of cotton seeds for domestic cultivation. It is also worth noticing that out of the 12 individual GM events of cotton cultivated in the world, as many as **eight events are not currently cleared for import into the EU** and only one of these has been submitted for EU approval. This situation is not likely to change and therefore LLP incidents, in particular due to IFA, cannot be ruled out.

- **None of the five GM rice events in the commercial and regulatory pipelines worldwide are authorised in the EU** and four of them are not even submitted for approval. Hence potential problems of LLP in rice imports may occur, especially due to IFA once the events that are currently in the advanced R&D pipelines in various Asian countries reach the market.

- Three events of GM potatoes are already in the regulatory pipeline worldwide; one event is being assessed exclusively in the EU, while the other **two events in GM potatoes are being assessed in Argentina.** Imports of potatoes into the EU have traditionally been very small and highly regulated for plant health reasons; therefore LLP issues with potatoes are unlikely, at least in the short to medium term. Regarding "other commercial GM crops", only GM sugar beet is authorised in the EU for import and all the other **events of other GM crops are not even submitted for EU approval**. Hence in these cases future LLP issues, if any, may be due to IFA and occur in particular in processed food products.

- For professionals in the global food and feed chain the **economic risk of rejections of shipments at the EU border** is the major problem in the context of LLP. Part of this problem, the "destination risk", arises if the tests for the detection of unauthorised GM material in imports are only carried out at the port of destination – when a cancellation of the shipment is impossible and when its re-direction is costly. And while identity preservation of crops is possible in principle, given the **bulk handling of grains** in international trade, commodity traders also question the **possibility to comply with a zero tolerance policy** for LLP of unauthorised material. A possible consequence mentioned is that **exporters could sell their grain to "preferred buyers"**, i.e. to countries that have found concerns about LLP not justified and to importers that are known to create little problems. Moreover, the price of grain is determined through demand and supply in "bid and offer" systems of grain exchanges where prices are based on quality and quantity, with a strong **relationship between price, specifications and risk**. As risk is increased if there is uncertainty whether imported grains will be in compliance with LLP regulations, prices are likely to rise (unless the risk cannot be measured or managed, in which case there will be no trade at all). In this context more general issues are the lack of predictability and legal certainty. Apart from problems for commodity traders, future price increases and supply bottlenecks in the EU due to LLP also carry the **risk of relocations of EU businesses** that are dependent on cheap imports of agricultural commodities, like livestock farming.

- Workshop participants considered that in particular the following two issues should be addressed with a view to mitigating the risks of LLP. First, participants saw the **need to reconsider zero tolerance thresholds, possibly replacing them with low-level marketing thresholds**; these new thresholds need to be higher than the technical detection limit to be practical, to reduce the negative impact on costs and to prevent trade disruptions. Second, participants highlighted the need to address the "destination risk", e.g. by **official testing of shipments already at the port of loading**. Other solutions proposed were the streamlining of the regulatory systems, **mutual recognition of risk assessments** of new GM crops and the flexible implementation of Codex Alimentarius guidelines.

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Acronyms and abbreviations

AA	-	asynchronous approval of GM crops
ALS	-	acetolactate synthase
APHIS	-	Animal and Plant Health Inspection Service of the USDA
ASA	-	American Soybean Association
CAD	-	Canadian Dollar
CGF	-	corn gluten feed
CIAA	-	Confédération des industries agro-alimentaires de l'UE
COCERAL	-	Comité du commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures
COPA-COGECA	-	Comité des organisations professionnelles agricoles, Confédération générale de la cooperation agricole
DDGS	-	distillers dried grains with solubles
DG	-	Directorate General of the European Commission
DNA	-	deoxyribonucleic acid
EFSA	-	European Food Safety Agency
EPA	-	Environmental Protection Agency of the USA
ESA	-	European Seed Association
EU	-	European Union
FAO	-	Food and Agriculture Organization of the United Nations.
FDA	-	Food and Drug Administration of the USA
FEDIOL	-	EU Oil and Proteinmeal Industry
FEFAC	-	Fédération Européenne des Fabricants d'Aliments Composés pour Animaux
FERM	-	Federation of European Rice Millers
GAFTA	-	Grain and Feed Trade Association
GM	-	genetically modified
GMO	-	genetically modified organism
ha	-	hectare
HPPD	-	hydroxyphenylpyruvate dioxygenase
IFA	-	isolated foreign approval of GM crops
IGTC	-	International Grain Trade Coalition
IP	-	identity preserved
IPTS	-	Institute for Prospective Technological Studies of the JRC
IRRI	-	International Rice Research Institute
JRC	-	Joint Research Centre of the European Commission
LLP	-	low-level presence of unapproved GM material
NAEGA	-	North American Export Grain Association
PBO	-	Plant Biosafety Office of the Canadian Food Inspection Agency
RR2	-	Roundup Ready 2
USDA	-	US Department of Agriculture
USD	-	US Dollar

1 Introduction

Which GM crops are likely to be commercialised worldwide in the next years? The answer to this question is relevant for many fields, spanning from agriculture, sustainable development, research and innovation and global trade. The commercialisation of new GM crops generally is a regulated activity worldwide. Different countries have different authorisation procedures, and, even if submitted at the same time, new GM crops do not get approval simultaneously in all countries. This issue, known as **"asynchronous approval" of GM crops**, is of growing concern for its potential economic impact on international trade. In such a situation, traces of new GM crops can appear in agricultural commodities exported to countries where these new varieties are not yet authorised, and shipments can be rejected. This can lead to economic losses of the supply chain operators and to more general disruptions of trade and ultimately closing the access to specific markets.

A problem similar to asynchronous approval (AA) occurs when a developer of a new GM crop does not seek approval for commercialisation in all world regions. (This may be the case if the crop in question is designed only for local markets or foreign markets do not represent major target markets for exports). In this case there can be **"isolated foreign approval"** by a cultivating country and any "low-level presence" of unauthorised GM material in imports may again lead to their rejections by other countries. Finally, imports can also be rejected due to LLP of research events;[1] this can happen if a country has authorised the cultivation of a GM crop in field trials only, but due to accidental admixture traces end up in the commercial crop supply

However, since agriculture is an open process, a **low-level presence of unauthorised GM material** cannot be excluded in traded commodities, even in countries where the crop is not authorised. If the importing country operates a **"zero tolerance" policy**, any imports of crops or food products will be rejected if containing traces of genetically modified organisms (GMOs) that are not authorised. In the case of the European Union (EU), the issue of low-level presence (LLP) of new GM crops in agricultural imports has already caused trade disruption and economic problems (summarised in Section 2.2). In particular, as acknowledged in a report by the Directorate-General for Agriculture and Rural Development of the European Commission (EC 2007), the EU feed and livestock production sectors are affected by this problem.

Chapter 2 of this report reviews briefly the current GM crops already in the market and the recent cases of trade disruptions associated with LLP of GM crops. In order to predict the evolution of the impact of LLP of GM crops for the EU agricultural and livestock sector, it is essential to produce a forecast of what GM crops will be developed in the next years, by which countries and when these new crops will be authorised by different trade partners of the EU. **Chapter 3** of this report develops this GM crop pipeline. The pipeline was compiled for the seven crops (soy-

[1] For a definition of this and other technical terms, please consult the references provided in the Glossary.

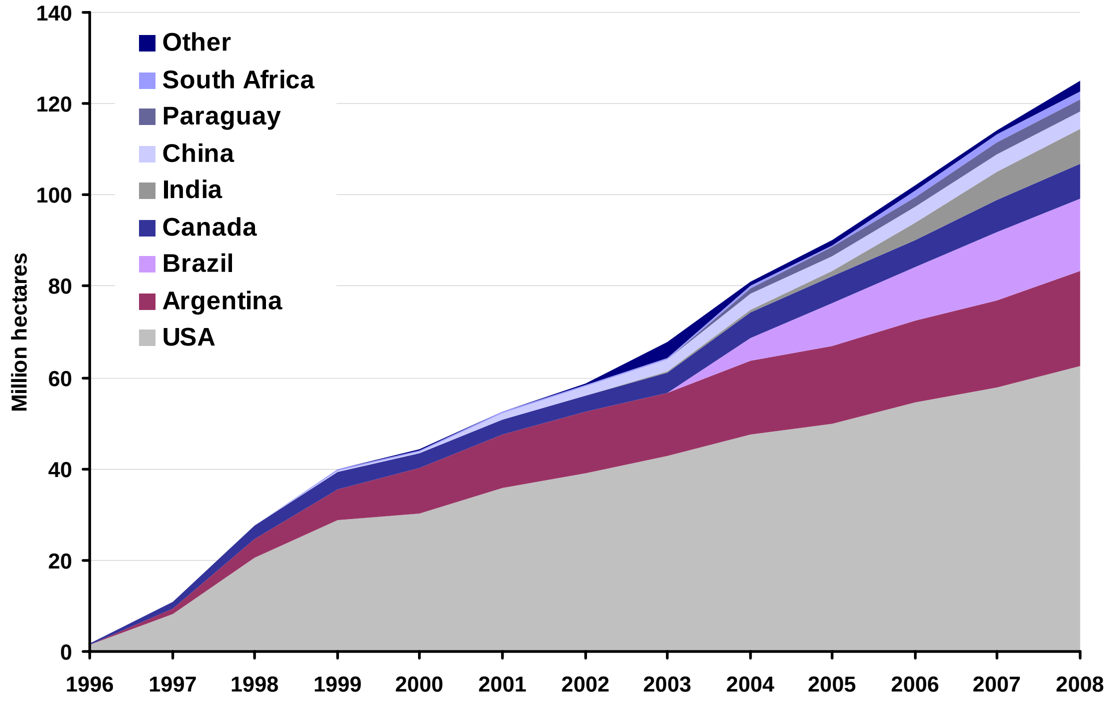
beans, maize, rapeseed, cotton, sugar beet, potatoes and rice) for which GM already varieties exist or are likely to be marketed in the near future. The pipeline focuses on GM events to be marketed in the short term (2-3 years) to medium term (7-8 years). We have deliberately not produced an analysis of early stages of R&D on GM crops that would generate a tentative long term pipeline for the years after 2015. In this context, the judgement about the potentials for commercialisation of events in the early R&D pipeline was considered too uncertain. This detailed global GM pipeline is summarised and critically discussed in **Chapter 4** with a focus on the possible evolution of LLP, including the particular issue of "stacked" GM crops (new GM crops produced usually by conventional crossing of existing GM crops). Finally, in **Chapter 5** we present a summary of the positions expressed by workshop participants regarding the impact of LLP in different commodity sectors and their proposed solutions to the problem.

2 Background

2.1 Overview of current GM crops cultivated worldwide

Large-scale cultivation of GM crops began in 1996 (Zika et al. 2007). Since then, the cultivation of GM crops has expanded continuously in both industrialised and developing countries – now reaching a global area of 125 million hectares in 25 countries (Figure 1). The area under GM crops in the EU itself amounts to only about 0.1 percent of the global area. The country with the largest area of GM crops (half of world's total acreage) is the USA, followed by Argentina, Brazil, Canada, India and China. Figure 1 shows that **developed countries still lead in terms of area devoted to GM crops**. However, the estimation is that **the majority of farmers cultivating GM crops are currently in developing countries** (Figure 2), indicating that the technology is increasingly being used by smaller farms, often in a subsistence setting (e.g. Qaim 2005, Qaim and Matuschke 2005).

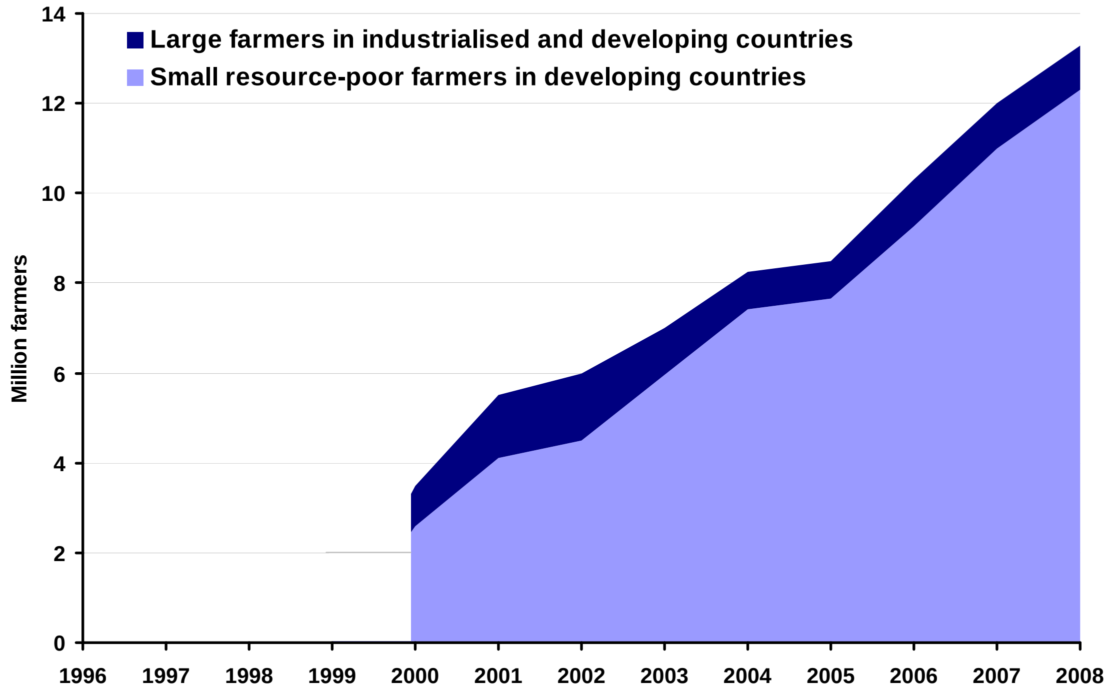
Figure 1: Country evolution of area cultivated with GM crops



Source: Based on data from James (2008 & previous years).

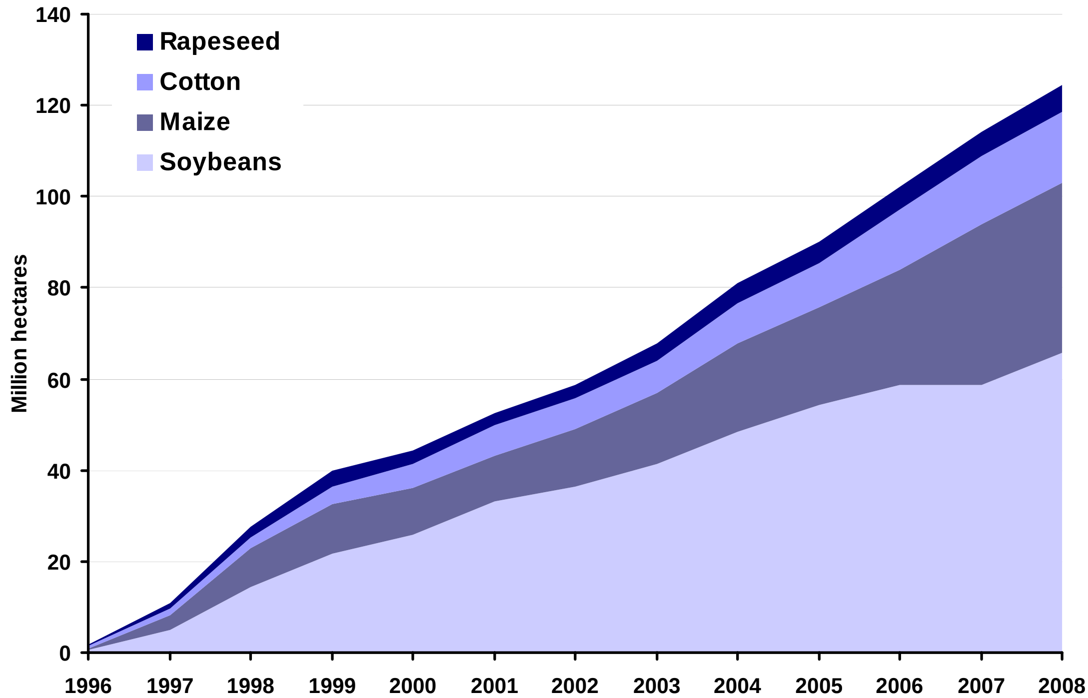
The four most important GM crops are soybeans, maize, cotton and rapeseed. Soybeans still account for about half the GM crop area (Figure 3). There are two dominant traits introduced into these GM crops: **herbicide tolerance** and **insect resistance**. While other traits do not play yet a significant role at the global level, the current two main **traits are being increasingly combined ("stacked")** into one crop to confer multiple benefits (Figure 4). For more information on the particularities posed by "stacked" GM crops regarding AA, see Section 4.2.

Figure 2: Estimated number of farmers cultivating GM crops worldwide



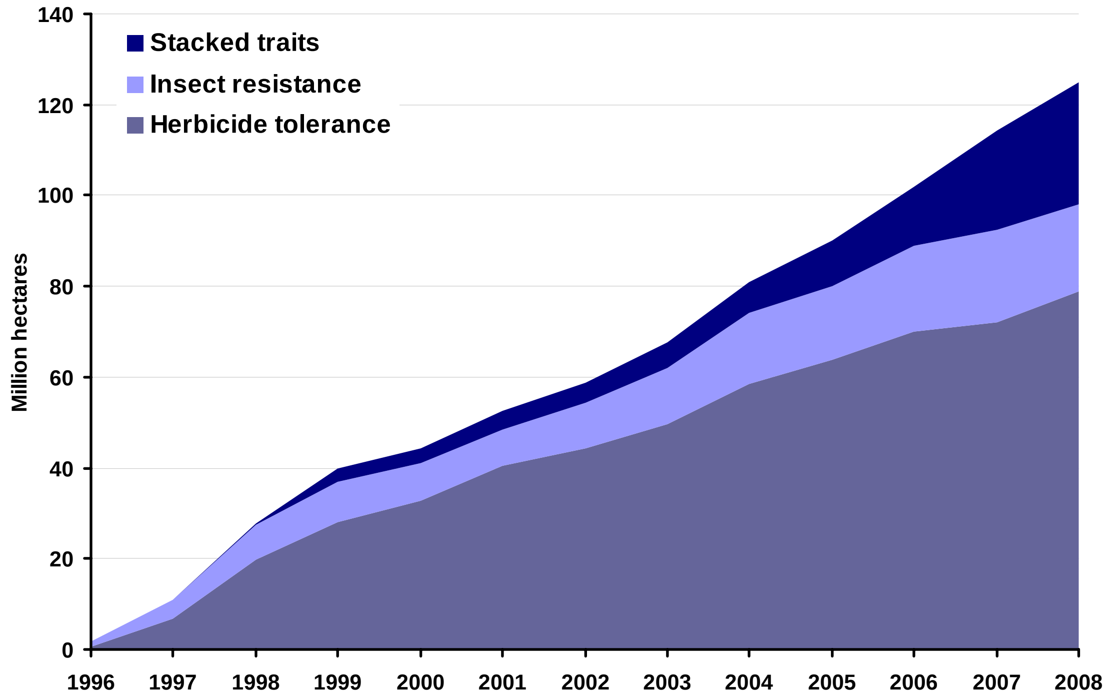
Source: Estimates taken from James (2008 & previous years); no estimates available before 2000.

Figure 3: Global area cultivated with the 4 main GM crops



Source: Based on data from James (2008 & previous years).

Figure 4: Global area cultivated with the main GM traits



Source: Based on data from James (2008 & previous years).

2.2 Impact of low-level presence of unapproved GMOs on trade

The potential impact of AA of GM crops on trade became for instance evident in 2006, when the approval of a new GM maize (Herculex) in the USA disrupted trade in maize products between the USA and the EU. Of course, the dimensions of future problems will depend on the relevance of the crop for EU imports (see Figure 11 to Figure 18 in the Appendix) and on the rate at which new GM crops are authorised by potential trading partners. But as soon as a GMO is cultivated in a country that is exporting to the EU, even on a small scale, the repercussions can be big: for instance in the case of Herculex, the corresponding GM maize was grown on only one percent of the total maize acreage in the USA, but in approximately two thirds of all samples tested subsequently, traces of Herculex maize were found (Toepfer 2008). As a consequence, the EU imports of US maize products for feed (like distillers dried grains with solubles (DDGS) or corn gluten feed (CGF)) dropped after the incident and had to be replaced by more expensive Brazilian maize and other products (c.f. Figure 11 in the Appendix).[2]

In 2006, another case with economic consequences occurred with Bayer's LibertyLink rice 601 (LLRICE601). In this case the problem was the LLP of a research event, because at that time LLRICE601 was authorised neither in the exporting country (the USA) nor in the EU (see Box 1). The subsequent collapse in the rice trade between the USA and the EU is illustrated in Figure 5. While in 2005 the EU imported 32% of its rice from the USA, in 2007 it was only 2.5%. The re-

[2] Further details on the recent trade evolution of main commodities affected by asynchronous approval can be found in Ceddia and Rodríguez-Cerezo (2008).

duction in rice imports from the USA has been compensated by higher imports from other suppliers, mainly Thailand, Uruguay and Pakistan; in fact, since 2005 overall EU rice imports have risen constantly.

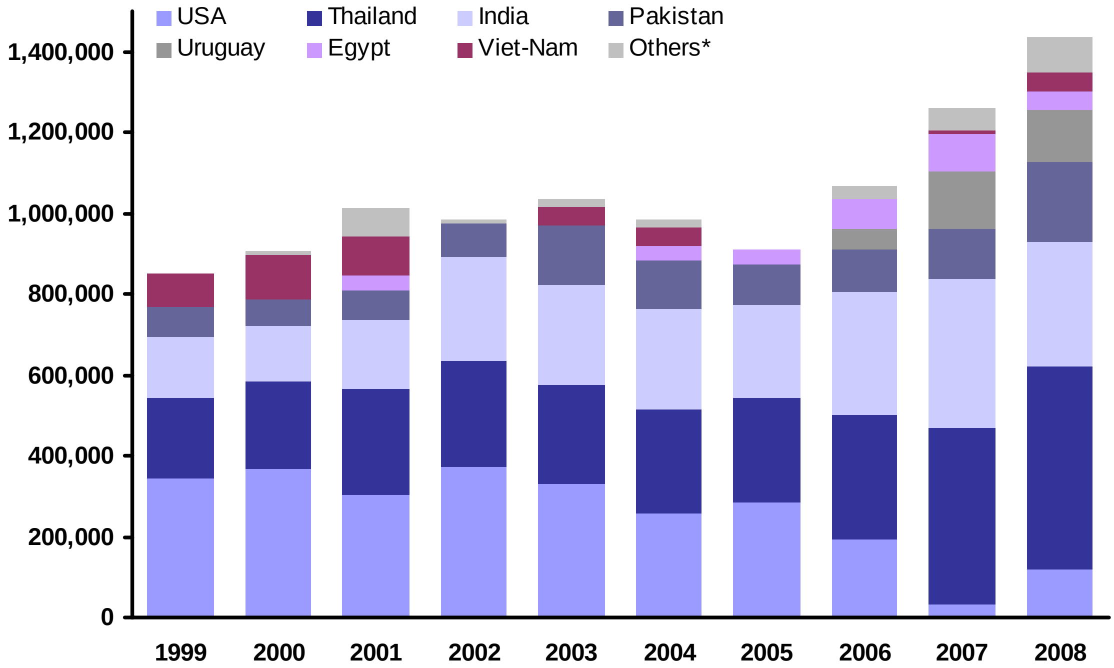
Box 1: The LibertyLink rice 601 case

In August 2006 trace amounts of herbicide tolerant GM rice (Bayer CropScience's LLRICE601) had been discovered in commercial rice samples in the USA – although LLRICE601 was only a research event that had not been approved for commercial cultivation. The discovery lead to an immediate closure of the EU markets for rice imports from the USA. The LLRICE601 incident thus disrupted rice trade between the USA and the EU and resulted in large economic losses to US rice growers and exporters as well as to EU rice importers – despite the minuscule amount of LLRICE601 in the overall US supply.

In October 2006 the EU required that all imports of US long-grain rice be certified as free of LLRICE601 before they were exported – and then they were again counter-tested for unauthorized transgenes by EU member states at their borders. According to the Commission, with the official involvement of the US authorities in the sampling and testing of shipments, the systematic counter-testing by EU inspectors was no longer necessary. For US rice exporters the implication of this decision is considerable: There is no longer the risk of shipments being rejected only after they reached the other side of the Atlantic. US authorities could not determine how exactly the traces of LLRICE601 had entered the commercial rice supply, but irrespective of the original source, the US rice industry has taken various measures to ensure that the future supply of US rice is free of LLRICE601. Accordingly, in 2008 the EU's Standing Committee on the Food Chain and Animal Health approved a Commission proposal to stop systematic testing of shipments of US rice imports for LLRICE601 (Commission Decision of 26 February).

Little quantitative information on the impact of the LLRICE601 incident is available. The US Rice Producers Association mentions a 6% loss of market volume and USA Rice states that the industry has been hit hard by the loss of foreign markets and the new burden of testing. FERM highlights that the incident created significant costs for EU importers because of the need to recall products from the supply chain, the higher costs due to additional testing, the disruption to the rice supply and the damage to their brands. A study commissioned by FERM has estimated that until early 2008 the LLRICE601 incident costed the European rice industry EUR 50m-110m, with US rice imports having dropped to less than 10% of normal trade. At the level of individual rice millers, the average cost of dealing with LLRICE601 has been estimated to fall into a range of EUR 4m-7m. According to this study, the cost to the European rice industry are equivalent to 6-13% of the total value of the EU long grain rice market and to 27-57% of the total market's gross margin.

Figure 5: Net imports of rice into EU-25 from rest of the world, 1999-2008 (tonnes)



Note: * Others also include listed countries if their share is below 3%.
Source: Based on data from Eurostat (2009).

For the EU, the potential economic impact would be highest in the case of soybean trade being affected by LLP, due to the high dependence of the EU animal feed sector on imported soybeans (see Figure 18 in the Appendix). A 2007 report by the Directorate-General for Agriculture and Rural Development of the European Commission (EC 2007) focused on the short-term issue of the imminent commercialisation of Monsanto's "Roundup Ready 2" soybeans (MON 89788) in the USA, which at that time was still unapproved in the EU. For this new GM soybean the consequences of AA didn't materialise since the EU approved its use for import in 2008 before large-scale commercial plantings had begun in the USA. However, given the expanding development of new GM crops worldwide (see next Chapter), the issue of AA in soybean trade may very well reappear and become more obvious.

Although some of the major exporters of agricultural commodities to the EU, like Argentina and Brazil, so far seem to consider trade implications in their final decision on authorising cultivation of new GM events, it is by no means guaranteed that this situation will last. Other countries could emerge as potential trading partners (China is an example) or the advantages of cultivating certain new GM crops in exporting countries could simply outweigh the potential loss of the EU market. Moreover, with more GM crops becoming available, other alternative suppliers of the EU could also turn to GM crops.

The problem of LLP does not affect only the EU. It is also becoming an issue for stakeholders in the USA (Pew 2006, USDA 2008), especially when considering the multiplicity of new GM crops that may be developed outside the USA (see next Chapter). If the developers of these new GM crops do not even intend to seek approval in potential importing countries, LLP of these crops in imports could become a more general problem, at least for importing countries where there is a very low or even zero tolerance for unapproved GM material.

3 The global commercial pipeline of new GM crops

To predict the evolution of the impact of LLP of GM crops for the EU agricultural and livestock sector, it is essential to produce **a forecast of what GM crops will be developed in the next years, by which countries and when** these new crops will likely be authorised by different trade partners of the EU. This chapter describes this GM crop pipeline. The pipeline was compiled for the seven crops (soybeans, maize, rapeseed, cotton, sugar beet, potatoes and rice) for which GM already varieties exist or are likely to be marketed in the near future. The pipeline focuses on GM events to be marketed in the short term (2-3 years) to medium term (7-8 years).

The November 2008 workshop on "The global commercial pipeline of new GM crops" organised by the JRC-IPTS was the main source of information to compile the global pipeline of GM crops that is presented here; this workshop gathered scientists from private and public institutions developing GM crops, regulators and other experts involved in the development, authorisation and commercialisation of GM crops worldwide. Additional information was taken from the websites of government authorities, as well as from databases of the OECD, AGBIOS, BIO and the Biosafety Clearing-House. In this chapter we present an overview of this pipeline.[3] To classify the information, five categories are used, expressing the proximity of the respective GM "event" to market

- **Commercial crop**: commercialised GM events (those currently marketed in at least one country worldwide).
- **Commercial pipeline**: GM events authorised in at least one country but not yet commercialised (commercialisation only depends on the decision by the developer).
- **Regulatory pipeline**: GM events already in the regulatory process to be marketed in at least one country.
- **Advanced R&D pipeline**: GM events not yet in the regulatory process but at late stages of development (large-scale multi-location field trials, generation of data for the authorisation dossier).
- **Other crops**: GM events authorised in at least one country, but not commercialised or commercialised once but "phased out" commercially or legally afterwards.

Figure 6: Categorisation of GM crops depending on their proximity to market

[3] In the Appendix to this report, the full database (status January 2009) is reproduced in overview tables by crop and by country. Parallel to this report this information is also published in the form of an Excel database where last-minute updates were incorporated (Stein and Rodríguez-Cerezo 2009). Furthermore it is planned to update this information regularly on http://agrilife.jrc.ec.europa.eu/pipeline.htm

3.1 Soybeans

Commercial GM soybeans

In early 2009, worldwide **all GM soybean varieties contained only one GM event**, namely Monsanto's event 40-3-2, which confers tolerance to the herbicide glyphosate (Table 1). These soybeans are commonly known as Roundup Ready soybeans (MON-Ø4Ø32-6). In the EU, this event is authorised since 1996 for import (food and feed) and the renewal of the authorisation of the use of 40-3-2 soybeans for food and feed is currently ongoing; the application for authorisation of these soybeans for cultivation is under assessment by the European Food Safety Agency (EFSA).

GM soybeans in the commercial pipeline

In addition to event 40-3-2, until January 2009 **four more GM soybean events are authorised** in at least one country worldwide (see Overview 1 on p. 73). However, these soybeans are not yet commercialised anywhere, although two of them are expected to become commercially available later in 2009. These two soybeans are Monsanto's RR2 soybeans (MON89788) and Bayer CropScience's LibertyLink soybeans (A2704-12); both are herbicide tolerant (the former to glyphosate, the latter to glufosinate). The other two soybeans are Pioneer Hi-Bred's Optimum GAT soybeans (DP356Ø43-5), which are herbicide tolerant to glyphosate and ALS inhibitors, and Bayer's other glufonsinate-resistant LibertyLink soybean (ACS-GMØØ6-4) (Table 1).

GM soybeans in the regulatory pipeline

Until January 2009, **three additional GM soybean events were in the regulatory pipeline of at least one country** (Table 1). These soybeans are Pioneer Hi-Bred's high oleic soybeans (DP-3Ø5423-1), BASF's imidazolinone tolerant soybeans (BPS-CV127-9) and insect-resistant GM soybeans that are currently being assessed in China.

GM soybeans in the advanced R&D pipeline

When it comes to GM soybeans that have not yet entered the regulatory pipeline but are in advanced stages of R&D (large-scale multi-location field trials, generation of data for the regulatory process), there is a considerable increase in numbers of upcoming GM soybeans compared to what is currently on the market: not less than **nine new GM soybean events** could be ready for commercialisation within the next years (Table 2).

Table 1: Commercial GM soybeans and GM soybeans in the commercial and regulatory pipeline worldwide

Developer	Product name	Event name / genes	Trait	Unique identifier
Commercialised soybean events				
Monsanto	Roundup Ready	MON 40-3-2	Herbicide tolerance (to glyphosate)	MON-Ø4Ø32-6
Soybean events authorised in at least one country but not yet commercialised anywhere				
Monsanto	Roundup Ready 2	MON89788	Herbicide tolerance (to glyphosate)	MON-89788-1
Bayer CropScience	LibertyLink	A2704-12	Herbicide tolerance (to glufosinate)	ACS-GMØØ5-3
Bayer CropScience	LibertyLink	A5547-127 *	Herbicide tolerance (to glufosinate)	ACS-GMØØ6-4
Pioneer Hi-Bred	Optimum GAT	356043 *	Herbicide tolerance (to ALS inhibitors and glyphosate)	DP356Ø43-5
Soybean events in the regulatory pipeline in at least one country				
Pioneer Hi-Bred	High oleic	305423 *	Crop composition (high oleic content)	DP-3Ø5423-1
BASF Plant Science and Embrapa	Imi	CV127 *	Herbicide tolerance (to imidazolinone)	BPS-CV127-9
n/a (China)	n/a	Gna * #	Insect resistance	n/a

Notes: Until early 2009, events marked with an asterisk (*) were not yet authorised in the EU for any use and events marked with a hash (#) even not even submitted for authorisation in the EU. For more details, in particular on the situation in selected countries, please see Overview 1 on p. 73.

GM soybeans with stacked events

If several authorised GM events are "stacked" by conventional crossing (a very common practice by seed breeders to produce new crop varieties), the resulting new variety may have different regulatory status in different world regions. The EU and other countries require the stacked GM crop to go through the regulatory system as a new GM crop, irrespective of whether the parental GM events were already authorised or not (see Section 4.2).

No stacked variety of GM soybean has yet been commercialised. However, based on the tables presented above, by 2015 there could be up to 17 individual GM soybean events marketed and therefore available for combination into new stacked varieties. Considering only double-stacking of events (and not triple or quadruple), this means that theoretically there would be 136 different possible combinations of (although obviously not all combinations would make sense in agronomic or commercial terms).

Table 2: GM soybeans in the advanced R&D pipeline worldwide

Developer	Product name	Event name / genes	Trait	Possible commer-cialisation
Syngenta	n/a	n/a	Nematode resistance	*2011*
Monsanto	Omega-3	MON87769	Crop composition (stearidonic acid content)	*2012*
Monsanto	n/a	n/a	Herbicide tolerance (to dicamba)	*2012*
Monsanto	n/a	n/a	Insect resistance and herbicide tolerance (to glyphosate)	*2013*
Dow AgroSciences	DHT	n/a	Herbicide tolerance	2013
Monsanto	Vistive III	MON87754	Crop composition (high oleic content)	*2014*
Syngenta	n/a	n/a	Herbicide tolerance (to HPPD inhibitors)	*2014*
Bayer CropScience	n/a	n/a	Herbicide tolerance (to HPPD and glyphosate)	2015
Bayer CropScience	n/a	n/a	Herbicide tolerance (to HPPD and glufosinate)	2015

Notes: The possible commercialisation dates marked *in italics* are estimates by the authors only. For more details, in particular on the situation in selected countries, please see Overview 2 on p. 74.

Other GM soybean events

For completeness, in the Appendix (Overview 3) also "other" events for GM soybeans are listed. These were authorised in at least one country but are not and (probably) will not become commercially available; this covers mainly research events that were authorised to avoid potential problems due to LLP in commercial crops or GM crops that were phased out and are not commercialised any more.

Potential low-level presence issues with GM soybeans

Based on Table 1, for the EU the conclusion is that two of the GM soybean events in the commercial pipeline (A5547-127 and 356043) as well as the three events in the regulatory pipeline may pose **potential problems of asynchronous approval already in the short term**. In addition, Table 1 points to an insect-resistant soybean already in the regulatory pipeline in China. It is not known if the developer of this event will seek regulatory clearance in the EU, i.e. this event could become a potential IFA issue. In the longer term (by 2011-2012) problems due to AA depend on the evolution of the 9 GM soybean events that are in the advanced R&D pipeline and on the evolution of the stacking of GM varieties.

3.2 Maize

Commercial GM maize

In early 2009 there were **nine different events of GM maize** in the varieties cultivated globally; until January 2009 two of these events (MON88017 and MIR604) were not yet authorised in the EU (Table 3).

Table 3: Commercial GM maize and GM maize in the commercial pipeline worldwide

Developer	Product name	Event name / genes	Trait	Unique identifier
Commercialised maize events				
Monsanto	YieldGard Corn Borer	MON810	Insect resistance (to lepidopterans)	MON-ØØ81Ø-6
Monsanto	Roundup Ready Corn 2	NK603	Herbicide tolerance (to glyphosate)	MON-ØØ6Ø3-6
Monsanto	YieldGard Rootworm	MON863	Insect resistance (to coleopterans)	MON-ØØ863-5
Monsanto	YieldGard VT	MON88017 *	Insect resistance (to coleopterans)	MON-88Ø17-3
Dow AgroSciences and Pioneer Hi-Bred	Herculex I	1507	Insect resistance (to lepidopterans)	DAS-Ø15Ø7-1
Dow AgroSciences and Pioneer Hi-Bred	Herculex RW	59122	Insect resistance (to coleopterans)	DAS-59122-7
Syngenta	Agrisure CB	Bt11	Insect resistance (to lepidopterans)	SYN-BTØ11-1
Syngenta	Agrisure GT	GA21	Herbicide tolerance (to glyphosate)	MON-ØØØ21-9
Syngenta	Agrisure RW	MIR604 *	Insect resistance (to coleopterans)	SYN-IR6Ø4-5
Maize events authorised in at least one country but not yet commercialised anywhere				
Monsanto	YieldGard VT PRO	MON89034 *	Insect resistance (to lepidopterans)	MON-89Ø34-3
Monsanto	High lysine	LY038 *	Crop composition (high lysine content)	REN-ØØØ38-3
Syngenta	n/a	3272 *	Crop composition (amylase content)	SYN-E3272-5

Notes: Until early 2009, events marked with an asterisk (*) are not yet authorised in the EU for any use. For more details, in particular on the situation in selected countries, please see Overview 4 on p. 76.

GM maize in the commercial pipeline

Until January 2009, **three additional GM maize events were already authorised in at least one country** worldwide, but not yet commercialised anywhere. These are Monsanto's event MON89034 that confers insect resistance and will be marketed as YieldGard VT PRO, Monsanto's event LY038 that results in changes in the composition of the crop (high lysine content) and Syngenta's event 3272 that also changes crop composition (amylase content) (Table 3).

GM maize in the regulatory pipeline

In addition, there are **five more GM maize events that have entered the regulatory system in at least one country** but that are not yet authorised anywhere in the world, namely Syngenta's new lepidopteran-resistant maize, Pioneer's Optimum GAT maize and three GM maize events from China (Table 4).

Table 4: GM maize in the regulatory pipeline worldwide

Developer	Product name	Event name / genes	Trait	Unique identifier
Syngenta	Agrisure Viptera	MIR162 * #	Insect resistance (to lepidopterans)	SYN-IR162-4
Pioneer Hi-Bred	Optimum GAT	98140 *	Herbicide tolerance (to ALS inhibitors and glyphosate)	DP-Ø9814Ø-6
n/a (China)	n/a	Cry1A * #	Insect resistance	n/a
n/a (China)	n/a	n/a * #	Crop composition (high lysine content)	n/a
n/a (China)	n/a	n/a * #	Crop composition (phytase enzyme)	n/a

Notes: Until early 2009, events marked with an asterisk (*) are not yet authorised in the EU for any use and events marked with a hash (#) are not even submitted for authorisation in the EU. For more details, in particular on the situation in selected countries, please see Overview 4 on p. 76.

GM maize in the advanced R&D pipeline

For GM maize we identified seven new events at advanced stages of R&D and could be commercialised by 2015 (Table 5). The main new traits for GM maize are crop composition and drought tolerance.

GM maize with stacked events

Contrary to the case of soybeans, commercial "stacked" GM maize is already a reality and includes both double and triple stacking of individual GM events. Currently **four maize types of maize with stacked GM traits are authorised in the EU** (for import and use in food and feed), while another **13 maize stacks are in the EU's regulatory pipeline** – including stacking of up to four different GM events (Table 6).

Table 5: GM maize in the advanced R&D pipeline worldwide

Developer	Product name	Event name / genes	Trait	Possible commer-cialisation
Monsanto	n/a	MON87754	Crop composition (high oleic content)	*2010*
Pioneer Hi-Bred	Optimum AcreMax 1	n/a	Insect resistance (to coleopterans)	2010
Monsanto and BASF	n/a	MON87460	Abiotic stress tolerance (to drought)	2012
Dow AgroSciences	DHT	n/a	Herbicide tolerance	2012
n/a (India)	n/a	cry1Ac + cp4epsp4	Insect resistance	*2014*
Syngenta	n/a	n/a	Abiotic stress tolerance (to drought)	*2015*
BASF Plant Science	NutriDense	n/a	Crop composition (protein, amino acid and phytase content)	*2015*

Notes: The possible commercialisation dates marked *in italics* are estimates by the authors only. For more details, in particular on the situation in selected countries, please see Overview 6 on p. 82.

Based on the tables presented above for maize, by 2015 there could be up to 24 individual GM maize events authorised for marketing and therefore available for combination into new stacked varieties. Considering only double-stacking of events (and not triple or quadruple), this means that theoretically there would be 276 different possible combinations for double stacking and 2,024 combinations for triple stacking. Although obviously not all combinations would make sense in agronomic or commercial terms, the figure gives an idea of the possibility to quickly generate new GM maize varieties and the potential associated regulatory and trade issues.

Table 6: GM maize stacks and their regulatory situation in the EU

Stacking	Number of stacks worldwide*	EU situation		
		Authorised	Pending	Under assessment
Double	13	4	1	8
Triple	3	0	1	2
Quadruple	1	0	0	1

Notes: * Total number of the commercial GM maize stacks and the GM maize stacks in the commercial and regulatory pipeline. Due to differences in the regulation of stacked events (see next Section), on a global scale there may be more (implicitly) authorised GM maize stacks available. *Source*: Please see Overview 5 on p. 79.

Other GM maize events

For completeness, in the Appendix also "other" events for GM maize are listed (see Overview 7 on p. 83). These were authorised in at least one country but are not and (probably) will not become commercially available; this covers mainly research events that were authorised to avoid potential problems due to LLP in commercial crops or GM crops that were phased out and are not commercialised any more.

Potential low-level presence issues with GM maize

Based on Table 3, for the EU the conclusion is that there are two individual GM maize events in the commercial pipeline (MON88017 and MIR604) plus another two in the regulatory pipeline (MIR162 and 98140) that pose **potential problems of asynchronous approval in the short term**. Especially for maize increased use of stacking will also be a source of AA issues. In addition, Table 3 also points to three GM maize events already in regulatory pipeline in China. It is not known if the developers of these events will seek regulatory clearance in the EU, i.e. these events could become potential IFA issues.

In the longer term (by 2011-2012) AA in maize will focus on the evolution of the seven new GM events that are in the advanced R&D pipeline (mostly in the USA with one exception from India) and on the evolution of the stacking of GM varieties.

3.3 Rapeseed (canola)

Commercial GM rapeseed

In the case of rapeseed only **four GM events are currently commercialised**.[4] These are Monsanto's event GT73 (in Roundup Ready canola) and Bayer CropScience's events MS8xRF3 (stacked in InVigor canola) and T45 (in LibertyLink canola). All events confer herbicide resistance, the former to glyhposate and the latter three to glufosinate (Table 7). However, T45 is currently being phased out.

GM rapeseed in the commercial pipeline

In the case of GM canola there are **no new events in the commercial pipeline**.

GM rapeseed in the regulatory pipeline

Apart from one event in GM rapeseed that is apparently in **pre-production trials in China, elsewhere no new events are in the regulatory pipeline**.

GM rapeseed in the advanced R&D pipeline

For **GM canola** five new events are at advanced stages of R&D (Table 7); next to herbicide tolerance the main new trait in these crops is enhanced oil content.

[4] Canola is a type of rapeseed whose oil contains less than two percent of erucic acid (http://www.canola-council.org/canola_the_official_definition.aspx, 19 January 2009).

Table 7: Commercialised GM rapeseed and GM rapeseed in the regulatory and advanced R&D pipeline worldwide

Developer	Product name	Event name / genes	Trait	Unique identifier
Commercialised rapeseed events				
Monsanto	Roundup Ready	GT73	Herbicide tolerance (to glyphosate)	MON-ØØØ73-7
Bayer CropScience	LibertyLink	T45	Herbicide tolerance (to glufosinate)	ACS-BNØØ8-2
Bayer CropScience	InVigor	MS8 x RF3 (stacked)	Herbicide tolerance (to glufosinate) and male fertility (for plant vigor)	ACS-BNØØ5-8 x ACS-BNØØ3-6
Rapeseed events in the regulatory pipeline in at least one country				
n/a (China)	n/a	n/a * #	n/a	n/a
Rapeseed events at advanced stages of R&D				**Possible commercialisation**
Bayer CropScience	n/a	n/a	Herbicide tolerance	2011-2013
Bayer CropScience	n/a	n/a	Disease resistance	2011-2013
Bayer CropScience	n/a	n/a	Crop composition (oil content)	*2014*
BASF Plant Science	n/a	n/a	Crop composition (fatty acid content)	*2013*
BASF Plant Science	n/a	n/a	Crop composition (oil content)	*2015*

Notes: Until early 2009, events marked with an asterisk (*) are not yet authorised in the EU for any use and events marked with a hash (#) are not even submitted for authorisation in the EU. The possible commercialisation dates marked *in italics* are estimates by the authors only. For more details, in particular on the situation in selected countries, please see Overview 8 on p. 86.

GM rapeseed with stacked events

The events in Bayer CropScience's InVigor canola (MS8 x RF3) are only available as stacked events.

Other GM rapeseed events

For completeness, in the Appendix also "other" events for GM rapeseed are listed (see Overview 9 on p. 87). These were authorised in at least one country but are not and (probably) will not become commercially available; this covers mainly research events that were authorised to avoid potential problems due to LLP in commercial crops or GM crops that were phased out and are not commercialised any more.

Potential low-level presence issues with GM rapeseed

For GM rapeseed there is only one event in the regulatory pipeline (from China) that may pose problems of IFA in the short term. As the EU may eventually become a net importer of rapeseed to supply a rising demand for biofuel (Fellmann 2009, EC 2009), for the longer term issues of LLP in the EU will depend on the evolution of the five events in the advanced R&D pipeline.

3.4 Cotton

Commercial GM cotton

In early 2009, **twelve different events of GM cotton were authorised for cultivation globally**. Until January 2009, eight of these events (MON88913, 281-24-236 x 3006-210-23 and the events from China and India) were not yet authorised in the EU. The two events from Dow AgroSciences events are only available as stacked GM cotton (Table 8).

Table 8: Commercial GM cotton worldwide

Developer	Product name	Event name / genes	Trait	Unique identifier
Monsanto	Bollgard	MON531	Insect resistance (to lepidopterans)	MON-ØØ531-6
Monsanto	Roundup Ready	MON1445	Herbicide tolerance (to glyphosate)	MON-Ø1445-2
Monsanto	Bollgard II	MON15985	Insect resistance (to lepidopterans)	MON-15985-7
Monsanto	Roundup Ready Flex	MON88913 *	Herbicide tolerance (to glyphosate)	MON-88913-8
Bayer CropScience	LibertyLink	LLCotton25	Herbicide tolerance (to glufosinate)	ACS-GHØØ1-3
Dow AgroSciences	WideStrike	281-24-236 * 3006-210-23 *	Insect resistance (to lepidopterans)	DAS-24236-5 DAS-21Ø23-5
CAAS (China)	SGK321	Cry1A + CpTI * #	Insect resistance (to lepidopterans)	n/a
CAAS (China)	GK19	Cry1Ab - Cry1Ac * #	Insect resistance (to lepidopterans)	n/a
Nath Seeds (India)	GFM	Cry1A * #	Insect resistance (to lepidopterans)	n/a
JK Agri Genetics Seeds (India)	JK-1	Event 1 * #	Insect resistance (to lepidopterans)	n/a
CICR (India)	n/a	Cry1Ac * #	Insect resistance (to lepidopterans)	n/a

Notes: Until early 2009, events marked with an asterisk (*) are not yet authorised in the EU for any use and events marked with a hash (#) are not even submitted for authorisation in the EU. For more details, in particular on the situation in selected countries, please see Overview 10 on p. 89.

GM cotton in the commercial pipeline

For GM cotton there is only **one new event in the commercial pipeline**, namely Syngenta's COT102 insect-resistant cotton (Table 9). This event is only authorised for use in food & feed in Australia, but the authorisation for cultivation is pending in the USA (see Overview 11 on p. 91).

Table 9: GM cotton in the commercial and regulatory pipeline worldwide

Developer	Product name	Event name / genes	Trait	Unique identifier
Cotton events authorised in at least one country but not yet commercialised anywhere				
Syngenta	n/a	COT102 * #	Insect resistance (to lepidopterans)	SYN-IR1Ø2-7
Cotton events in the regulatory pipeline in at least one country				
Syngenta	n/a	COT67B * #	Insect resistance (to lepidopterans)	SYN-IR67B-1
Bayer CropScience	GlyTol	GHB614 *	Herbicide tolerance (to glyphosate)	BCS-GHØØ2-5
Metahelix (India)	n/a	Event 9124 * #	Insect resistance (to lepidopterans)	n/a
JK Agri Genetics Seeds (India)	n/a	Event 24 * #	Insect resistance (to lepidopterans)	n/a

Notes: Until early 2009, events marked with an asterisk (*) are not yet authorised in the EU for any use and events marked with a hash (#) are not even submitted for authorisation in the EU. For more details, in particular on the situation in selected countries, please see the see Overview 11 on p. 91.

GM cotton in the regulatory pipeline

Until January 2009 **four new events of GM cotton were in the regulatory pipeline** worldwide (Table 9). These are Syngenta's insect-resistant COT67B cotton, Bayer CropScience's glyphosate-tolerant GlyTol cotton (event GHB614) and two new GM cotton events that are under assessment in India (Metahelix' Event 9124, which confers resistance to lepidopteran pests, and JK Agrigenetics' Event 24, which also confers resistance to lepidopteran pests and which will be marketed with the company's already authorised Event 1 as "JK Stack"). Of these four crops only Bayer's GlyTol cotton is also under assessment in the EU (see Overview 11 p. 91).

GM cotton in the advanced R&D pipeline

Two events are in an advanced R&D phase by Western companies and no less than eight different GM cotton events are currently in advanced stages of R&D in India (Table 10). Most of these new events are engineered to confer insect resistance upon cotton.

GM cotton with stacked events

Stacking GM events to produce new GM cotton is very common and is widely used in GM cotton cultivation. The technique is used to confer resistance to different insect pests (a gene pyramiding strategy similar to the one used in conventional breeding) or to combine insect resistance and herbicide tolerance. Currently two GM cotton with stacked events are authorised in the EU (for import and use in food and feed), while another three are in the EU's regulatory pipeline. Three additional individual events and **three more stacks are authorised or under assessment in other countries** (see Overview 12 on p. 92).

Table 10: GM cotton in the advanced R&D pipeline worldwide

Developer	Product name	Event name / genes	Trait	Possible commer-cialisation
Bayer CropScience	TwinLink	n/a	Insect resistance (to lepidopterans) and herbicide tolerance (to glufosinate)	2012
Dow AgroSciences	DHT	n/a	Herbicide tolerance	2013
n/a (India)	n/a	cry1Ac	Insect resistance	2013
n/a (India)	n/a	cry2Ab	Insect resistance	2013
n/a (India)	n/a	cry2Ax1	Insect resistance	2013
n/a (India)	n/a	cry1Ia5	Insect resistance	2013
n/a (India)	n/a	vip	Insect resistance	2013
n/a (India)	n/a	cry1Aa3	Insect resistance	2013
n/a (India)	n/a	cry1F	Insect resistance	2013
n/a (India)	n/a	asal	Insect resistance	2013

Note: For more details, in particular on the situation in selected countries, see Overview 13 on p. 93.

GM cotton has a busy pipeline as summarised in Table 9 and Table 10. By 2015 we forecast around 25 individual GM cotton events authorised for marketing. If used for double-stacking only, this means that theoretically **hundreds of possible combinations can be produced through breeding** (although obviously not all combinations would make sense in agronomic or commercial terms).

Other GM cotton events

For completeness, in the Appendix also "other" events for GM cotton are listed (see Overview 14 on p. 94). These were authorised in at least one country but are not and (probably) will not become commercially available; this covers mainly research events that were authorised to avoid potential problems due to LLP in commercial crops or GM crops that were phased out and are not commercialised any more.

Potential low-level presence issues with GM cotton

The EU imports of cottonseed meal (for feed use) or of cotton oil (for cooking) are extremely small when compared with imports of other oilseed meals such as soybean. And of cottonseed meal only 18 to 32,000 tonnes were imported annually during 2000-2005 (Ceddia and Rodríguez-Cerezo 2008); main suppliers were Benin and Brazil. From this point of view, possible impacts of AA or IFA in cotton will have far less economic impacts than similar problems in soybean or maize. However, the EU depends on the import of cotton seeds for domestic cultivation so LLP may affect the EU's supply of seeds.

It is also worth noticing that out of the 12 individual GM events of cotton cultivated in the world, as many as eight are not currently cleared for import into the EU. Among those in the commercial and regulatory pipeline none is authorised in the EU and only one has been submitted for EU approval in the first place. Given that most of the GM cotton events in the advanced R&D pipeline are developed in India (and although no information is available for China, it can be assumed that also there new events are being developed), and given that so far no GM cotton events that were commercialised by Asian developers were submitted for approval in the EU, it can be assumed that developers of new events from these countries will follow the same scheme of seeking only local approvals.

3.5 Rice

Commercial GM rice

Table 11: GM rice in the commercial and regulatory pipeline worldwide

Developer	Product name	Event name / genes	Trait	Unique identifier
Rice events authorised in at least one country but not yet commercialised anywhere				
Bayer CropScience	LibertyLink	LLRICE62 *	Herbicide tolerance (to glufosinate)	ACS-OSØØ2-5
Rice events in the regulatory pipeline in at least one country				
n/a (China)	n/a	Bt63 * #	Insect resistance	n/a
n/a (China)	n/a	KMD1 * #	Insect resistance	n/a
n/a (China)	n/a	Xa21 * #	Disease resistance (against leaf blight)	n/a
n/a (Iran)	n/a	B827 * #	Insect resistance	n/a

Notes: Until early 2009, events marked with an asterisk (*) are not yet authorised in the EU for any use and events marked with a hash (#) are not even submitted for authorisation in the EU. For more details, in particular on the situation in selected countries, please see Overview 15 on p. 95.

GM rice has been cultivated on a commercial basis so far only in Iran. However, due to an inter-Ministerial lack of consultation the authorisation was suspended. Currently the final pan-Ministerial approval for the re-authorisation of the rice is pending (see Section below on "GM rice in the regulatory pipeline"). A GM rice event being tested in the USA showed up in commercial rice samples (LibertyLink rice 601, see Box 1 on p. 6). After this, GM event LLRICE601 was authorised in the USA, but subsequently it has not been commercialised (see "other GM rice" in Overview 15 on p. 95).

GM rice in the commercial pipeline

Until January 2009, one GM rice event is already authorised in at least one country worldwide, but the corresponding rice is not yet commercialised anywhere. This event is Bayer CropScience's LLRICE62 that confers tolerance to the herbicide glufosinate (Table 11).

GM rice in the regulatory pipeline

Apart from the event LLRICE62, four more GM rice events are already under regulatory assessment in China and therefore could be commercialised in the short term (Table 11).

Table 12: GM rice in the advanced R&D pipeline worldwide

Developer	Product name	Event name / genes	Trait	Possible commercialisation
IRRI (Philippines)	Golden Rice 1	n/a	Crop composition (beta-carotene cont.)	2011
Bayer CropScience	n/a	n/a	Herbicide tolerance	2011-13
Bayer CropScience	n/a	n/a	Insect resistance	2011-13
n/a (China)	n/a	Bar68-1	Herbicide tolerance (to glufosinate)	*2012*
IRRI (Philippines)	Golden Rice 2	n/a	Crop composition (beta-carotene cont.)	2012
n/a (India)	n/a	CP iORF-IV	Virus resistance	2012
n/a (India)	n/a	RTBV-ODs2	Virus resistance (to tungro bacilliform)	2012
n/a (India)	n/a	chi11 tlp	Disease resistance	2013
n/a (India)	n/a	cry1Ac	Insect resistance	2013-15
n/a (India)	n/a	cry1Ab, cry1C & bar	Insect resistance	2013-15
n/a (India)	n/a	Glyoxalase I and II	Abiotic stress tolerance (to salinity)	*2015+*
n/a (India)	n/a	Osmotin	Abiotic stress tolerance (to drought)	*2015+*
n/a (Indonesia)	n/a	Bacillus thuringiensis *	Insect resistance	*2015+*
n/a (Pakistan)	n/a	Bacillus thuringiensis *	Insect resistance	*2015+*

Notes: In Indonesia and Pakistan (*) more than one event are currently under development. The possible commercialisation dates marked *in italics* are estimates by the authors only; events that could only be commercialised the earliest in 2015 are not considered in the further analysis. For more details, in particular on the situation in selected countries, please see Overview 16 on p. 96.

GM rice in the advanced R&D pipeline

At least ten new GM rice events are at advanced stages of R&D all over the world (Table 12). These new events introduce a number of new traits into rice – in addition to herbicide tolerance, insect resistance and disease resistance that are already in the commercial and regulatory pipeline. These new traits are crop composition (beta-carotene), virus resistance, and abiotic stress tolerance to drought and salinity. It is very worth noticing that this pipeline of new GM products is dominated by technology providers in Asia. However, especially in this case – rice being a dominant staple food in of these countries – the possible commercialisation of the new events probably depends as much on political factors as on the timely and successful completion of the development of the events; the commercialisation years given in Table 12 are therefore indicative.

GM rice with stacked events

No commercial GM rice is yet grown, therefore no stacked GM events are marketed anywhere. However, Table 11 and Table 12 suggest that by 2015 there could be 15 individual commercialised GM rice events. Again, if only used for double-stacking, this allows hundreds of possible combinations (although obviously not all combinations would make sense commercially).

Other GM rice events

For completeness, in the Appendix also "other" GM rice events are listed (see Overview 15 on p. 95). These – including the above mentioned event LLRICE601 – were authorised in at least one country but are not and (probably) will not become commercially available; this covers mainly research events that were authorised to avoid potential problems due to LLP in commercial crops or GM crops that were phased out and are not commercialised any more.

GM crops that are used to produce plant-made pharmaceuticals or plant-made industrials, like the recombinant lactoferrin and lysozyme produced by Ventria Bioscience in rice, are not covered by this report; the issues surrounding so-called "plant molecular farming" are discussed in another recent report by the IPTS (Spök and Karner 2008).

Potential low-level presence issues with GM rice

None of the five GM rice events in the commercial and regulatory pipelines worldwide (Table 11) are authorised in the EU and, hence, all of them pose potential problems of AA already in the short term. Four of these events – those developed in China – are not even submitted for EU approval.

In the longer term (Table 12), it is noticeable that most of the GM rice events in the advanced R&D pipeline are developed in India and other Asian countries and it is not known whether their developers will submit these events for approval in the EU (i.e. there are potential IFA issues).

3.6 Potatoes

Commercial GM potatoes

GM potatoes (Bt potatoes resistant to Colorado beetle pests) where grown commercially in the USA between 1996 and 2000. The technology was withdrawn by the provider for commercial reasons; among others because of difficulties of marketing the crop given that some food processors did not accept it. Currently **no GM potatoes are cultivated** anywhere on a commercial basis.

GM potatoes in the commercial pipeline

Currently there are **no GM potato events in the global commercial pipeline**. (Although numerous events in GM potatoes were authorised in the USA, Canada and Mexico, they were never commercialised – see the section below on "Other GM potato events" or Overview 18 on p. 99.)

Table 13: GM potatoes in the regulatory and advanced R&D pipeline worldwide

Developer	Product name	Event name / genes	Trait	Unique identifier
Potato events in the regulatory pipeline in at least one country				
BASF Plant Science	Amflora	EH92-527-1 *	Crop composition (amylopectin content)	BPS-25271-9
Tecnoplant (Argentina)	n/a	SY230 * #	Virus resistance (to potato virus Y)	n/a
Tecnoplant (Argentina)	n/a	SY233 * #	Virus resistance (to potato virus Y)	n/a
Potato events at advanced stages of R&D				**Possible commercialisation**
n/a (India)	n/a	RB	Disease resistance (to late blight)	2011
n/a (India)	n/a	Nt-Inhh, iIR-INV	Reduction in cold-induced sweetening	2012
n/a (India)	n/a	A20 oxidase	Dwarfness	2012
n/a (China)	n/a	n/a	n/a	*2014*
AVEBE (Belgium)	Cisgenic	n/a	Crop composition (starch content)	*2014*

Notes: Until early 2009, events marked with an asterisk (*) are not yet authorised in the EU for any use and events marked with a hash (#) are not even submitted for authorisation in the EU. The possible commercialisation dates marked *in italics* are estimates by the authors only. For more details, in particular on the situation in selected countries, please see Overview 17on p. 98.

GM potatoes in the regulatory pipeline

Until January 2009 **there are three GM potato events in the regulatory pipeline** in at least one country worldwide (Table 13). In the EU, a GM potato for starch production (BASF Plant Science's Amflora potato) is in the late stages of regulatory process. Even though the potatoes are intended to be used for industrial purposes rather than as food, approval is sought both for cultivation and use as food and feed (to avoid problems of LLP). In Argentina two events conferring virus-resistance to potatoes have just been submitted to regulatory assessment (see Overview 17 on p. 98).

GM potatoes in the advanced R&D pipeline

In the case of GM potatoes, **five new GM potato events are at advanced stages of R&D** at a global level (Table 13). The traits introduced into these potatoes are various and the activity takes place in India, China and the EU.

GM potatoes with stacked events

GM "stacked" potatoes have been produced to combine resistant to pests with resistant to viral diseases. Stacking therefore is regarded as interesting by potato breeders. Currently there is no commercial cultivation of GM potatoes.

Other GM potato events

For completeness, in the Appendix also "other" events are listed for GM potatoes (see Overview 18 on p. 99). These were authorised in at least one country but are not and (probably) will not become commercially available; this covers mainly research events that were authorised to avoid potential problems due to LLP in commercial crops or GM crops that were phased out and are not commercialised any more. This group also includes Monsanto's insect-resistant and virus-resistant Newleaf potatoes that were authorised in the USA, Canada and Mexico but that were never commercialised.

Potential low-level presence issues with GM potatoes

Imports of potatoes into the EU have traditionally been very small and highly regulated for reasons of plant health and plant diseases. The only countries exporting to the EU are basically from the Mediterranean basin, and the quantities imported are extremely small compared with domestic EU production.

In the case of GM potatoes there are three events in the regulatory pipeline. One GM event (Amflora) is only being assessed in the EU. The other two events being developed in Argentina are not submitted for EU approval. However potato trade with Argentina is basically zero. For the longer term, most of the events in the advanced R&D pipeline are being developed in Asia – for local production and use, and likely will not be submitted for EU approval.

3.7 Other crops (sugar beet, papaya, alfalfa, etc.)

Other commercial GM crops

Apart from the crops described so far, until January 2009 **there are seven more events in different GM crops** that are commercialised in at least one country worldwide (Table 14). Since 1998, papayas resistant to the ringspot virus (event 55-1) are cultivated in Hawaii; these **GM papayas** were developed in partnership between Cornell University, the USDA and the University of Hawaii, and seeds were distributed free to growers (Gonsalves 2004). Since 2007 also **GM sugar beet** (event CZW-3) resistant to the herbicide glyphosate is commercialised in the USA.[5] According to a company website,[6] in the USA also virus-resistant **GM squash** is marketed. And also **in China more GM crops are approved**, namely tomatoes with longer shelf-life, virus-resistant tomatoes, virus-resistant sweet peppers and virus-resistant papayas (Yang et al. 2006, James 2008), even if their actual commercial status is unclear.

Table 14: Other commercial GM crops

Developer	Crop	Event name / genes	Trait	Unique identifier
Commercialised events				
Cornell University (USA)	Papaya	55-1 * #	Virus resistance (to ringspot virus)	CUH-CP551-8
n/a (China)	Papaya	n/a * #	Virus resistance	n/a
Monsanto	Squash	CZW-3 * #	Virus resistance (to mosaic virus)	SEM-ØCZW3-2
KWS (Germany) and Monsanto	Sugar beet §	H7-1	Herbicide tolerance (to glyphosate)	KM-ØØØH71-4
n/a (China)	Sweet pepper	n/a * #	Virus resistance	n/a
n/a (China)	Tomato	n/a * #	Virus resistance	n/a
n/a (China)	Tomato	n/a * #	Crop handling (longer shelf life)	n/a

Note: Until early 2009, events marked with an asterisk (*) are not yet authorised in the EU for any use and events marked with a hash (#) are not even submitted for authorisation in the EU. For more details on sugar beet (§), please see Overview 19 on p. 101.

[5] http://www.kws.de/aw/KWS/company_info/breeding_r_d/Methods/~cjxj/genetic_engineering/ (28 January 2009).

[6] "Seminis developed the first virus-resistant squash developed through biotechnology. [...] It's available only in the United States" (http://www.seminis.com/research/history_innovations.asp, 19 January 2009).

Other GM crops in the commercial pipeline

Currently there are only virus-resistant plums in the commercial pipeline in the USA (Table 15).

Other GM crops in the regulatory pipeline

Until January 2009, only two events are in the regulatory pipeline anywhere in the world (Table 15).In the USA the commercialisation of two events for **GM alfalfa** (Monsanto's J101 and J163) is pending an environmental impact statement by the USDA – which is expected for late 2009.[7] These crops had already been commercialised in the USA from 2005 to 2007 (as glyphosate-resistant Roundup Ready alfalfa) but since then the further sale and planting of the corresponding seeds had been stopped to await the environmental impact statement.

Table 15: Other GM crops in the commercial and regulatory pipeline worldwide

Developer	Crop	Event name / genes	Trait	Unique identifier
Other GM crops authorised in at least one country but not yet commercialised anywhere				
USDA-ARS (USA)	Plum	C5 * #	Virus resistance (to plum pox virus)	ARS-PLMC5-6
Events in the regulatory pipeline in at least one country				
Monsanto	Alfalfa	J101 * #	Herbicide tolerance (to glyphosate)	MON-Ø1Ø1-8
Monsanto	Alfalfa	J163 * #	Herbicide tolerance (to glyphosate)	MON-ØØ163-7

Note: Until early 2009, events marked with an asterisk (*) are not yet authorised in the EU for any use and events marked with a hash (#) are not even submitted for authorisation in the EU.

Other GM crops in the advanced R&D pipeline

Mainly in India and China **14 more new transgenic events in different crops** are in the advanced R&D pipeline (Table 16). These are mostly **horticultural crops**, but in China also **GM wheat** is already in pre-production trials. (And while the eventual commercialisation of GM wheat in other countries does not seem likely before 2015, it is strongly supported by the Canadian, American and Australian Wheat organisations. It is also noteworthy that these organisations call for an introduction of GM wheat varieties "in a coordinated fashion to minimize market disruptions" (Wheat 2009).)

[7] See http://www.roundupreadyalfalfa.com/home.aspx?page=legal and http://hayandforage.com/hay/alfalfa/roundup-ready-alfalfa-2009-return/ (19 January 2009).

Table 16: Other GM crops in the advanced R&D pipeline worldwide

Developer	Crop	Event name / genes	Trait	Possible commercialisation
Embrapa (Brazil)	Bean	RNAi	Virus resistance (to geminivirus)	2012
n/a (India)	Eggplant	cry1Ac	Insect resistance	2009
n/a (India)	Eggplant	Mannitol-1-phosphate dehydrogenase	Abiotic stress tolerance	2014
n/a (India)	Eggplant	Chitinase	Fungus resistance	2014
n/a (India)	Tomato	Mannitol-1-phosphate dehydrogenase	Abiotic stress tolerance	2014
n/a (India)	Tomato	Arginine decarboxylase	Extended shelf life	2014
n/a (India)	Cabbage	cry1Ac	Insect resistance	Biosafety research level I, *2015*
n/a (India)	Cauliflower	cry1Ac	Insect resistance	
n/a (India)	Okra	cry1Ac	Insect resistance	
n/a (India)	Mustard	barnase/barstar	Male sterility (for plant vigour)	
n/a (China)	Wheat	n/a	n/a	Pre-production trials, *2012-14*
n/a (China)	Chilli	n/a	n/a	
n/a (China)	Peanuts	n/a	n/a	Environmental release, *2015*
n/a (China)	Cabbage	n/a	n/a	

Note: The possible commercialisation dates marked *in italics* are estimates by the authors only.

Potential low-level presence issues with other GM crops

From the "other commercial GM crops" described in Table 14, only GM sugar beet is authorised in the EU for import (as food and feed); all the other events are not even submitted for EU approval. And also with regard to future developments, it seems rather unlikely that the developers of these GM crops (mainly in India and China) will seek EU approval for import of these products.

4 Implications of the GM pipeline and prospective developments

4.1 Overview of the GM events that are expected to reach the market by 2015

As reported in the previous chapter, **the number of events, GM crops and countries where they are cultivated is bound to increase considerably over the next years**. While in 2008 one GM soybean was on the market worldwide, globally two more will be commercialised this year and three more are in the regulatory pipeline in some country or another – and eleven more are at an advanced stage of development and could be commercialised until 2015. This development is similar for the other crops, too, with a particularly pronounced potential increase in the number of GM events in rice and, to some extent, also in potatoes (Table 17, Figure 7). When looking at the traits introduced into the new GM crops, it is clear that the currently dominant traits (herbicide tolerance and insect resistance) continue to play a major role also in the upcoming GM crops. However, crop composition (mostly type and proportion of oil and starch content in the crop) becomes an important feature in new GM crops, and crops that are tolerant to abiotic stress (mostly drought) also will become available (Table 18, Figure 8).[8]

Table 17: Events in commercial GM crops and in pipelines worldwide, by crop

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

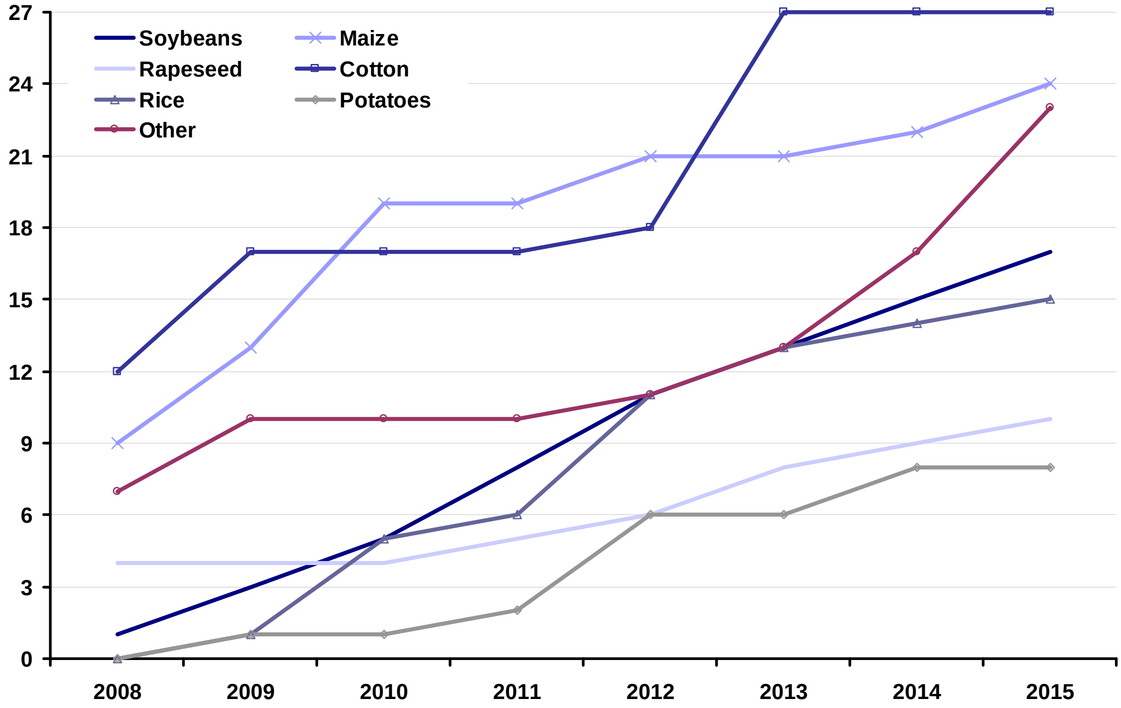
Notes: * The total number of GM crops by 2015 represents an upper limit, given that by then some of the current GM crops may have been phased out commercially or legally. However, traces of the events could still be found in commercial samples – and therefore represent a problem of LLP if they are not authorised. *Source*: Based on the overview tables in the Appendix.

The FAO's database on biotechnologies in developing countries (FAO 2009) shows that new crops for which GM varieties have not yet been grown (in particular vegetables, pulses and fruits) could enter the market in developing countries with more and different new traits (in particular resistance to pests and diseases and tolerance to abiotic stress factors). The R&D on these crops and traits could be an indication that the GM crops that are currently developed and

[8] For a separate outlook on the commercialisation of new GM crops based on GMO field trial data applications in the USA, see Stein and Rodríguez-Cerezo (*forthcoming*).

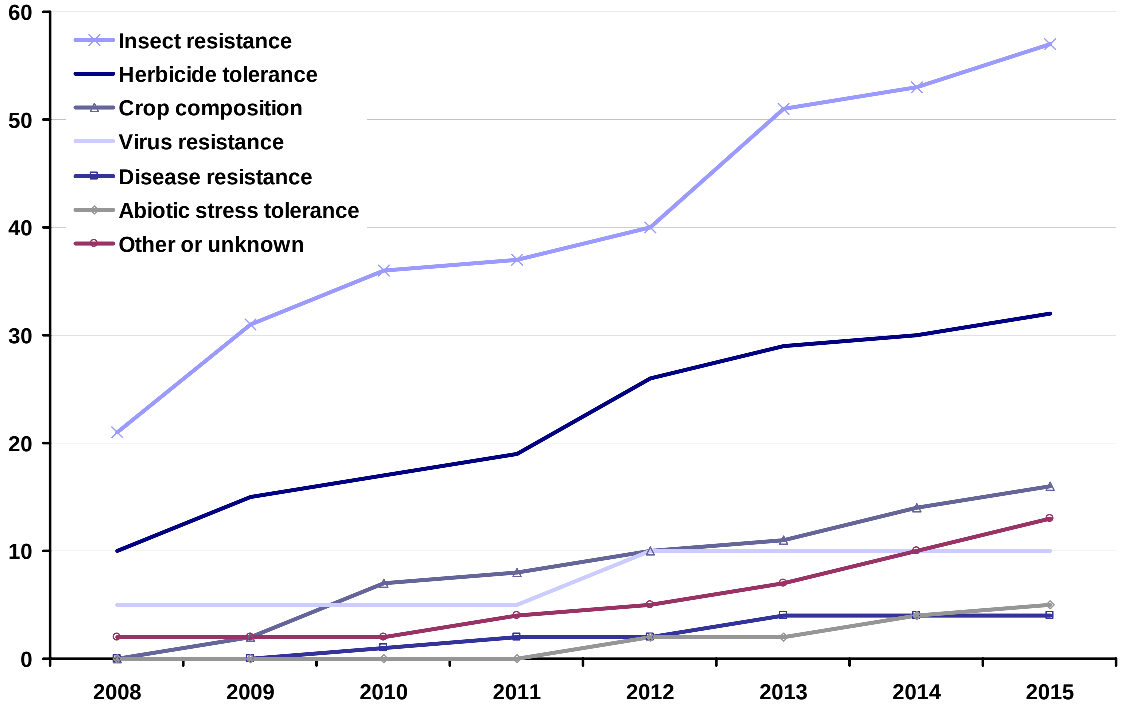
marketed only fulfil part of the needs of farmers in developing countries – and that the cultivation of GM crops in general could greatly increase if these needs can be met one day.

Figure 7: Projected number of events in GM crops worldwide, by crop



Source: Based on the overview tables in the Appendix.

Figure 8: Projected number of events in GM crops worldwide, by trait



Source: Based on the overview tables in the Appendix.

Table 18: Events in commercial GM crops and in pipelines worldwide, by trait

Trait category	Commercial in 2008	Commercial pipeline	Regulatory pipeline	Advanced development	Total by 2015 *
Insect resistance	21	3	11	22	57
Herbicide tolerance	10	4	5	13	32
Crop composition	0	1	5	10	16
Virus resistance	5	0	2	3	10
Abiotic stress tolerance [#]	0	0	0	5	5
Disease resistance	0	0	1	3	4
Nematode resistance	0	0	0	1	1
Fungus resistance	0	0	0	1	1
Other	2	0	0	11	13

Note: * The number of traits can be bigger than the number of GM crops in Table 17 due to stacking of traits. [#] Abiotic stress tolerance includes drought tolerance. *Source*: Based on the overview tables in the Appendix.

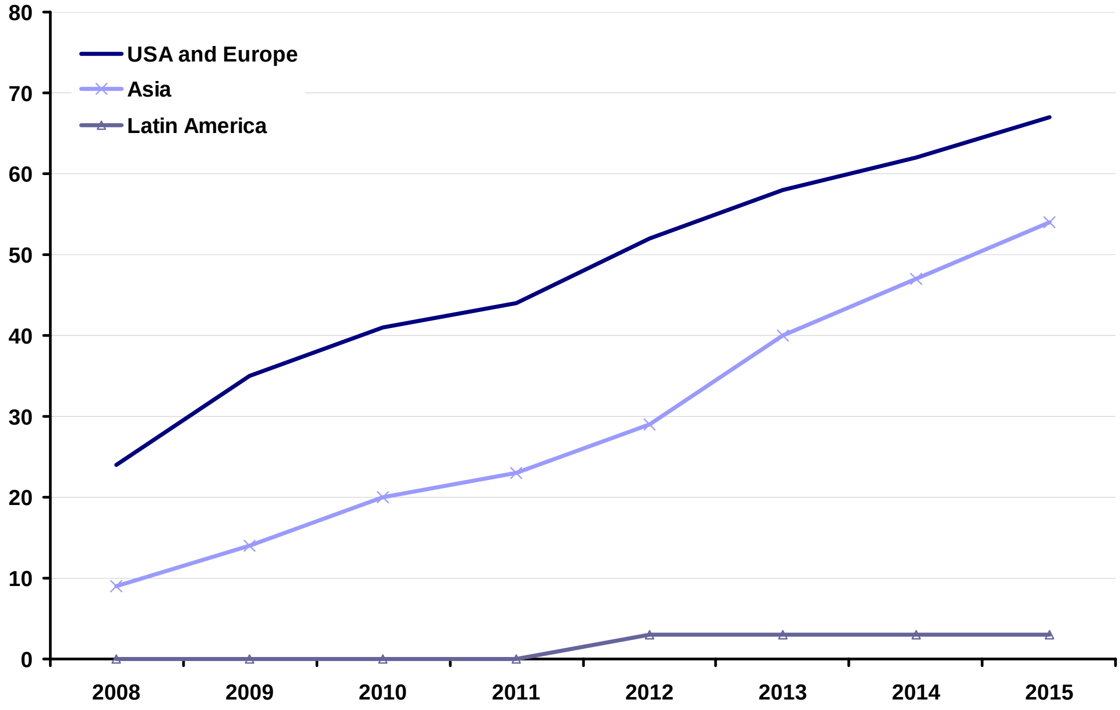
Another development in the R&D of GM crops is the emergence of more players. While currently it is private companies from the USA or Europe that develop most of the GM events and crops (which are generally first authorised and cultivated in North America), over the next years more GM crops will be supplied by private and public entities from Asia (Table 19, Figure 9), in particular from China and India. And in the longer-term even more developing countries may commercialise GM crops (FAO 2009). Hence, while in the past GM crop adoption spread from the USA and Canada to other parts of the world (with asynchrony of approvals following the same path), in future the adoption pattern may change fundamentally, with more new GM crops being adopted first in Asia (and then potentially spreading from there).

Table 19: Events in commercial GM crops and in pipelines worldwide, by region of origin

Developer country *	Commercial in 2008	Commercial pipeline	Regulatory pipeline	Advanced development	Total by 2015
USA & Europe	24	7	10	26	67
Asia	9	0	11	34	54
Latin America	0	0	2	1	3

Note: * While also in other parts of the world R&D on GM crops is under way, it is not expected that these crops will be cultivated before 2015. *Source*: Based on the overview tables in the Appendix.

Figure 9: Projected number of events in GM crops worldwide, by region of origin



Source: Based on the overview tables in the Appendix.

Table 20: Asynchronous and isolated foreign approvals as potential sources of LLP

Crop	Asynchronous approvals *	Foreign domestic approvals #	Total sources for LLP
Soybeans	2	1	3
Maize	6	5	11
Rapeseed	0	1	1
Cotton	3	9	12
Rice	1	4	5
Potatoes	0	2	2
Other crops	0	8	8
All crops	12	30	42

Notes: * Number of individual events authorised for commercial use in at least one country worldwide, and submitted but not yet authorised in the EU. # Number of events *not* submitted for authorisation in the EU but already in the regulatory pipeline in at least one country worldwide. *Source*: Based on the overview tables in the Appendix.

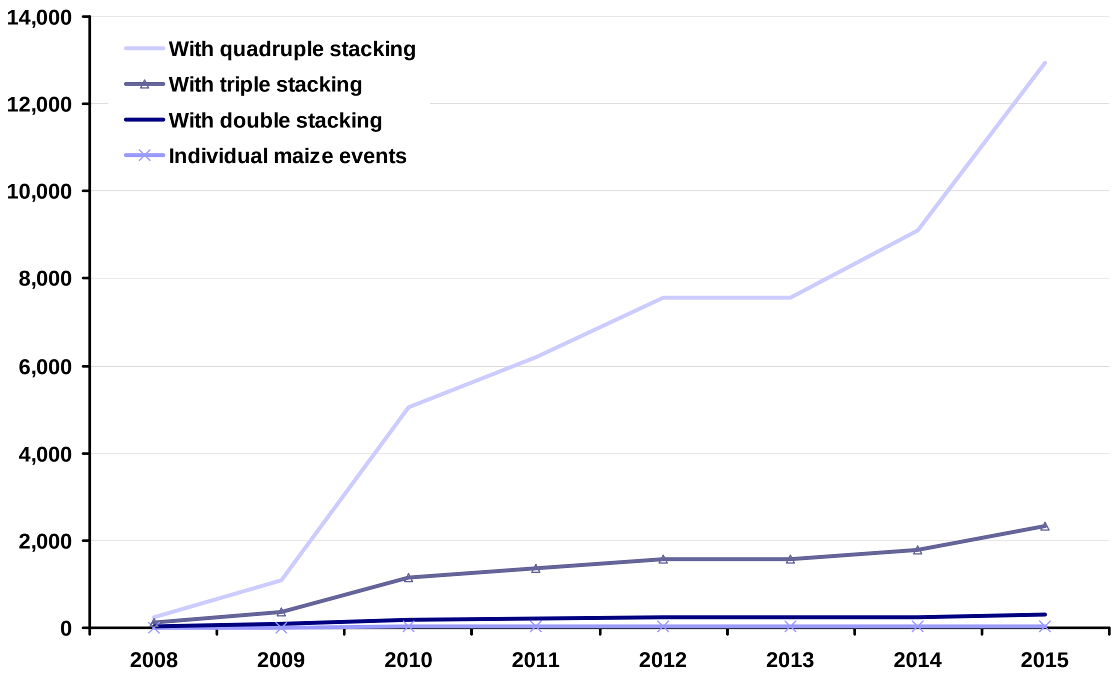
This changing pattern, with more new GM crops coming from Asia, has consequences for the issue LLP. In Asia GM crops are usually developed for domestic consumption and not for export (as opposed to those developed by large exporting countries of North and South America), and therefore the respective events are less likely to be submitted for approval in the EU – or the Americas for that matter. The approvals of these crops only in the developer countries would represent clear cases of IFA (Table 20). However, traces of such events can eventually be found in imports of processed speciality foods (as exemplified by the case of Chinese rice Bt63 that was not even approved yet but only a research event). In the case of IFA the LLP problem cannot be solved by streamlining the approval process in importing countries since no dossier for authorisation is submitted.

In summary, we show that taken together, until early 2009, there are already over 40 individual GM events that may become potential sources of LLP due to AA or IFA (Table 20).

4.2 The special case of "stacked" GM crops

A trend that can be observed for all crops presented so far is the increasing tendency to generate new products by combining several GM traits in one plant, for instance through the stacking of already approved GM events. When individual authorised GM events are "stacked" by conventional crossing, the resulting new plant may have different regulatory status in different countries (see next Section). The EU and other countries require the stacked GM crop to go through the regulatory system as a new GM crop, irrespective of whether the parental GM events were already authorised or not. Given the increase of individual GM events that are to come to market in the next years, as discussed in previous chapters, eventually hundreds of combinations of these events can be quickly developed by stacking – meaning that the number of GM crops that could be submitted for approval could increase dramatically.

Figure 10: Theoretical combinations to produce new GM maize by stacking



Source: Based on the overview tables in the Appendix. *Note*: Obviously not all trait combinations would make sense, but this graph illustrates how the number of possible stacked crops increases disproportionately with the number of new events and the number of stacked events that can be put into one plant. For n = number of events in a given year, and k = number of stacked events, the number of possible stacks is derived from the binomial coefficient $\binom{n}{k}$.

As an example, currently there is already a quadruple maize stack in the EU's regulatory pipeline (namely MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7; also see Overview 5 on p. 79). By 2015 we forecasted 24 different individual GM events to be available in maize (see Section 3.2). This gives a theoretical number of 10,626 possible quadruple maize stacks, 2,024 possible triple maize stacks and 276 possible double maize stacks – altogether 12,926 possible maize stacks (Figure 10). And even if obviously it doesn't make sense to combine all available events indiscriminately, the message is that the number of "approvable" GMOs is bound to increase exponentially.

4.3 The regulatory situation of stacked GM crops in selected countries

In this section we present a quick review of the way different regulatory systems approach the issue of stacked GM crops, based mostly in the contributions of participants in the workshop.

European Union[9]

Stacked events are defined as those combined in the same plant by either conventional breeding or re-transformation of a plant containing one or more existing event(s).

In the EU, these stacked events require a specific authorisation even if the single events are already authorised. Therefore, the risk assessment of stacked events obtained by re-transformation or conventional crossing should follow the requirements set out in the EU regulation. However and on a case-by-case basis, not all these requirements may be relevant for the risk assessment of stacked events combined by conventional crossing and conversely, additional information may be required. Where all single events have been previously assessed, the risk assessment of stacked events combined by conventional crossing should mainly focus on issues related to stability, expression of the events and potential synergistic or antagonistic effects resulting from the combination of the events.

A single assessment for the highest number of stacked events may cover all combinations with fewer of these events. In order to apply this approach, it should be demonstrated that the events are behaving in the same way as singles or stacked with respect to stability, expression of the events and potential synergistic or antagonistic effects resulting from the combination of the events.

[9] Information supplied the European Commission's DG Health and Consumers, 23 April 2009.

USA[10]

The term "stacked genes" refers to multiple biotech traits/genes incorporated or combined into the same plant. Plants with stacked genes may arise either intentionally or unintentionally; intentional combinations of two or more genetically engineered (GE) traits in plants are:

- Inserting the genes or traits together, at the same time, into the plant.
- Inserting new genes into a previously engineered plant.
- Combining traits by deliberately crossing individual GE plants with different GE traits (breeding stack).

Unintentional combinations of two or more GE traits in plants (field-stacked traits) happen without human-directed actions when one GE plant pollinates a different GE plant. For example this can occur when different GE crops of the same species are grown by farmers, resulting in field stacking of traits in the resultant seed or grain. A low level of unintentional stacking can occur during seed production as well pollen is coming from unanticipated sources (leading to the production of off-types, the allowable percentage of which is set by seed regulations).

The federal regulatory responsibility of so-called "combined-trait GE plants" is coordinated among three primary agencies, the Animal and Plant Health Inspection Service (APHIS) of the US Department of Agriculture (USDA), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA).

USDA regulation of GE plants with stacked traits

APHIS regulates GE organisms, including plants, if they meet the definition of a regulated article (essentially they are genetically engineered and pose a plant pest risk). A person may also request that APHIS no longer regulate a GE organism by submitting a petition for nonregulated status. APHIS grants nonregulated status if it determines after a scientific review that the GE organism is unlikely to be a plant pest. Once the GE organism has nonregulated status, it is no longer subject to the APHIS biotechnology regulations.

In all petitions to date, APHIS has granted nonregulated status to the GE plant identified in the petition and any offspring that would be derived from traditional breeding. As part of its thorough scientific review when determining nonregulated status, APHIS considers all the ways that these plants would be used, including being used as part of breeding programmes with other plants, including GE plants that have been granted nonregulated status by APHIS.

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[10] Based on a personal communication by Beverly Simmons, Associate Deputy Administrator for Emerging and International Programs, Biotechnology Regulatory Services, APHIS, USDA, 24 December 2008.

FDA's approach to "stacked" traits

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), all foods are held to the same safety standards, irrespective of the method by which the crop has been developed. FDA has an established consultation process which is described on its website, where it also posts the results of the consultations.[11]

Under most circumstances, FDA would not see a reason for a developer to consult with the agency regarding food from a plant line that was developed through conventional breeding of two or more bioengineered plant lines that (i) had individually successfully completed a consultation, or (ii) were derived from lines that had successfully completed a consultation. FDA would not anticipate that such conventional crosses of bioengineered crops would be any more likely to result in unintended changes to the food than would occur from conventional crosses of non-bioengineered crops. However, if a developer had reason to believe that the combination of traits, whether introduced through bioengineering or otherwise, might affect the safety, nutritional status, or other regulatory status of the resulting food, FDA would encourage the developer to consult with FDA about such food. As is the case with any plant food, it is the responsibility of the developer or marketer of a food to ensure that it complies with the requirements of the FFDCA.

EPA regulations of stacked traits and plant-incorporated protectants

EPA regulates the safe use of pesticides and registers their use under provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under regulations pursuant to FIFRA, EPA registers plant-incorporated protectants (PIPs) that are produced in GE plants. The PIP consists of the pesticidal compound and the genetic material necessary for production of that compound in the GE plant.

For EPA, a stacked product has two or more introduced traits in one plant when those traits are for different purposes such as one Bt trait to control European corn borer and another Bt trait to control corn rootworm. A pyramid product contains two or more introduced traits for the same target pest. EPA registers products that contain one or more traits which produce pesticides. Even if both traits are registered separately, the combination product must be registered. This is true whether the combination has been made through genetic engineering or through conventional breeding.

EPA also accepts that a stacked product might have a Bt trait and a herbicide tolerance trait in the same plant. EPA regulates the Bt trait and may have some regulatory authority over the herbicide tolerance trait as an inert, but this is not true in all cases: herbicide-tolerant traits are handled differently, because in this case EPA regulates the herbicide as an active ingredient,

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[11] See http://www.cfsan.fda.gov/~lrd/consulpr.html and http://www.cfsan.fda.gov/~lrd/biocon.html

but often the herbicide tolerant trait is an inert ingredient (marker gene). Where there is a pesticidal trait combined with a herbicide-tolerant trait that is used as a marker in the production of the product, the stacked product must be registered. But if the herbicide-tolerant trait is "added" to a registered Bt trait through conventional breeding, that stack product would not require registration.

Argentina[12]

For GM crops with stacked events the information of the individual events is only reviewed again if the events may differ from the original (individual) dossiers. If unchanged, the information is directly used in the process of reviewing the stacked GM crop (i.e. if the event has already been approved, the information is not reviewed again). Hence, even though a stacked GM crop is considered to be "new", existing information is taken into consideration when it is regulated. When the individual events are approved already, the authorisation dossiers for stacked GM crops are much simpler: applicants must only submit experimental proof or otherwise sound scientific evidence that there are not interactions between the genes in the stack, that locations at different, and that metabolic pathways are unrelated. Other criteria are the composition of the product and the level of expression of individual genes; also silencing is considered.

However, if dossiers are submitted for GM crops that contain stacked events that were not previously reviewed individually (because the applicant chose to directly submit the stacked crop), the crop is considered a completely new product and all the information concerning each individual event as well as the stack is to be reviewed completely.

Brazil[13]

In the Brazilian regulation of GM crops, stacked events are considered case by case; the corresponding normative resolution by the National Technical Biosafety Committee (CTNBio, Resolution No. 5 of 12 March 2008, Chapter I, Article 4) details: "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."

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[12] Based on a personal communication by Moisés Burachik, Coordinador General, Oficina de Biotecnología, Secretaría de Agricultura, Ganadería, Pesca y Alimentos, 5 December 2008.

[13] Based on a personal communication by Marcus Vinícius Segurado Coelho, Coordenação de Biossegurança de OGM, Secretaria de Defesa Agropecuária, Ministério da Agricultura, Pecuária e Abastecimento, 6 December 2008.

Canada[14]

In Canada, proponents of plants having stacked traits are asked to advise the Plant Biosafety Office (PBO) of the Canadian Food Inspection Agency at least 60 days prior to the anticipated environmental release of these plants if they result from either intentional intra-specific or inter-specific crosses between plants with a novel trait already authorised for unconfined environmental release. Following notification, the PBO may issue a letter (within 60 days of notification) informing the proponent of any concerns it may have regarding the unconfined environmental release. The PBO may request and review data to support the safe use of the modified plant in the environment. Stacking of traits with potential incompatible management requirements (e.g. insect resistance management plans, herbicide tolerance stewardship plans, etc.), possible negative synergistic effects, or where production of the plant may be extended to a new area of the country, may elicit an environmental safety assessment. Until all environmental safety concerns have been resolved, the modified plant is not permitted to be released in the environment. If there are no concerns about the active combining of traits, the PBO may not respond to that effect, i.e. after 60 days the stacked event can be released into the environment.

India[15]

The regulatory process for plants produced by any of the following three approaches is similar: plants with stacked genes produced through (i) traditional breeding and selection of two plant varieties, each of which contains one or more previously inserted transgenes, (ii) the insertion of an additional transgene by transformation of a plant already improved by plant biotechnology, and (iii) the insertion of multiple genes and traits into a nontransgenic plant via a single transformation event. Regardless of the method used, plants with transgenic traits can be crossed with either non-transgenic or other transgenic plants using methods that are the basis for traditional plant breeding.

Based on scientific principles and the experience with traditionally bred crops, from a food, feed and environmental safety perspective the conclusions of the assessments conducted on each of the independent, single gene products should also apply to the combined stacked gene products, except where there is a reasonable mechanism for the combined traits to interact or target the same metabolic pathway. Where the combination of two traits might be expected to have an interactive effect, then additional safety information on the specific stacked gene product would be warranted. Under these circumstances, the developer would need to perform detailed characterisation of the stacked gene product to assure that the desired effect was achieved and that no unpredicted effects resulted. Since unintentional as well as intentional food, feed and/or envi-

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[14] Based on a personal communication by Stephen Yarrow, Director of the Field Crops Division, Plant Health and Biosecurity Directorate, Canadian Food Inspection Agency, 11 December 2008.

[15] Adapted from Tripathi (2007), Adviser, Department of Biotechnology.

ronmental effects are evaluated for each trait independently during the safety assessment and regulatory approval processes, only combinations of traits that produce an unexpected interactive or synergistic effect warrant additional safety assessment of the stacked gene product. Based on scientific principles and significant experience with plant biotechnology products, there seems no justification for requiring products resulting from the combination of two unrelated or non-interacting traits that have been individually approved by the regulatory authority to undergo the full food, feed and environmental reviews required of the initial products.

The Indian regulatory system has issued guidelines for the biosafety evaluation of transgenic plants with single as well as stacked genes. When a transgenic variety is developed and released based on a cassette comprising given promoter(s) and gene(s) following all the necessary biosafety and agronomic trials, the further derivatives of this variety or its immediate transgenic parent can be released upon evaluation of agronomic performance trials by the applicant under the All India Coordinated Crop Improvement Project (AICCIP) system. The necessary permission for release is granted by the Genetic Engineering Approval Committee (GEAC) upon examination of the relevant data submitted to it by the applicant and the AICCIP.

5 The impact of LLP incidents on the agri-food supply chain

While in previous chapters if this report we have presented the outcome of discussions and own research in order to compile a global GM crop pipeline, here we deal with the economic and trade consequences of LLP of unapproved GMOs. In section 5.15.2 we summarise the appraisal of the economic impacts and possible solutions made by participants that are affected by this issue, based on their presentations and discussion at the workshop. In section 5.2 we briefly summarise the research papers and studies published recently evaluating the economic impact of AA on the EU.

5.1 Discussion of supply-chain actors

At the workshop several presentations were given by actors in the global food and feed chain (see List of participants), which are summarised here.

According to the joint presentation of the practitioners in **the EU food and feed chain**,[16] one of the main issues is the economic risk that comes with potential LLP incidents due to new GM crops (and with a zero tolerance policy towards traces of these events). In the current trading system risk and responsibilities are passed on along the supply chain from one actor to the next. This is problematic because tests to detected LLP can deliver different results at the origin of the shipment and at the port of destination. Moreover, most of the agricultural crops are traded as bulk, i.e. their collection, trade, transport and processing is characterised by the aggregation of many small consignments into large, uniform bulk shipments. Hence, crops are mixed at all levels of the supply chain and, while compliance with certain quality parameters is important, the identity and origin of the crops is less so; what matters is the realisation of economies of scale.

To allow trading in commodities of specific qualities, identity preserved (IP) systems have been developed to comply with tighter tolerance levels than those applied in normal crop shipments (by segregating the IP crops throughout the supply chain from the farm to the final processor). Obviously, for such IP crops market premiums are demanded. However, also in this case it is impossible to guarantee compliance with a zero tolerance approach.

In the case of "non-GM" soybean meal (i.e. meal with a GMO content below 0.9 percent), the premiums that had to be paid until 2004 lay under 5 USD/t, from 2005 until the third quarter of 2007 they were about 10 USD/t and in the fourth quarter of 2007 a supply shortfall lead to an increase of the premiums to 60-80 USD/t; with the Brazilian harvest in 2008 premiums fell again to around 50 USD/t. Expectations are that premiums increase again in 2009. At the same time, EU imports of soybeans account for about 20 percent of world trade in that crop and the EU can only meet two percent of its soybean meal consumption from domestically produced soybeans.

[16] COCERAL, FEDIOL, GAFTA, FEFAC, European Flour Millers, Euromaisiers, FERM and CIAA.

(In a scenario describing the loss of 2.4 million tons of US soybean imports over three months due to delayed approval of a new GM soybean in the EU, the experts calculated a related total cost of EUR 1.7 billion.[17])

The example of maize imports into the EU also shows the price impact of a zero tolerance policy: Since 1997 there are no maize grain imports from the USA into the EU and in 2007/08 the presence of the event GA21 also restricted maize imports from Argentina; in addition in 2007 also maize exports from Ukraine to the EU were stopped. This only left Brazil as remaining supplier of large quantities of maize – at an additional cost of 50-70 EUR/t compared to US maize. Similarly, with the introduction of Herculex maize in the USA, the EU import of corn gluten feed and distillers dried grains collapsed from 3.0 million tons in 2006 to 0.3 million tons in 2008.

Soybean and maize as well as their co-products constitute an important share in feed material. Feed costs, in turn, are the most important input costs for livestock farmers, ranging from 50 to 80 percent of total production costs. Due to high raw material prices the cost of compound feed in the EU increased considerably over the last years. The experts attributed 17 percent of the overall increase in feed costs to the EU's zero tolerance to traces of unapproved GM crops (which would e.g. translate into a loss of 3.5 EUR/100 kg per carcass for EU pig farmers). The experts highlighted that the economic impact of the present EU policy on GM crops on the EU livestock sector would be significant and that it would be the single most distorting EU policy that would lead to the delocalisation of the EU livestock sector – and they predicted further supply problems for major food and feed products that would threaten EU food security.

In addition to the use of soybeans and maize in feed, the supply-chain actors also pointed out that many food ingredients are derived from commodities such as maize, soybeans, rapeseed or rice – and that, following the highly complex and interrelated food chain, LLP therefore has an impact on a wide range of products. They also underlined that the economic fallout from any LLP would be reinforced because food products have a high added value. In particular, the consequences of LLP at various links in the food and feed supply chain were presented as:

- In the port: Boats that are impounded or stuck in a harbour with an illegal shipment will cause daily costs for the vessels.
- At the stage of first processing: Silos that are full of products with LLP leave no space for new supply, there is a need to clean the silos and the processing equipment, the level of testing needs to be increased, there will be delays in the deliveries to customers and illegal products will be returned from customers.
- At the second processing stage: There have to be recalls of illegal products, there can be shortages of supplies, illegal products will be returned or have to be disposed off, there can be delays in the deliveries to customers.

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[17] Lost sales of the oilmilling industry: soybean meal EUR 500 m, soybean oil EUR 200m; replacement costs of food and feed producers: of soybean meal EUR 430 m, of soybean oil EUR 100 m; extra costs for livestock farmers: EUR 440 m.

- At the retail level: Potentially there will be empty shelves for concerned products, incidents will be reported in the EU's Rapid Alert system, there will be damage to consumer confidence in general and to companies' profiles and brands in particular, there can be a drop in confidence in the overall food sector.
- In the aftermath: There can be lengthy litigations with suppliers (to recoup costs), there will me more administrative and legal costs, relationships with suppliers can be damaged, overall there can be heightened uncertainty about the future of the business.

Solutions to the problem of LLP that were forwarded by the experts were to approve applications for the import and processing of GM crops at EU level in timely manner and in better synchrony between cultivating and importing countries. Furthermore the reality of LLP should be acknowledged and workable thresholds should be established for GM crops that were already risk-assessed elsewhere. There should also be legal certainty regarding LLP and its consequences, greater transparency and a better flow of information between technology providers, the competent authorities and the operators in the food and feed chain, and where necessary technical assistance for the latter.

The European farmers and agri-cooperatives (COPA-COGECA) pointed out that AA is a normal situation in a global market and not an isolated or minor question. They saw the need for this issue to be tackled properly as otherwise the "situation may well lead to the collapse of the EU livestock production and its replacement by large-scale imports of meat from animals fed with not-yet EU authorised GMO feed and raised according to lower production standards". The solution put forward by this representative to mitigate the impact of LLP in the short term is to – exceptionally and temporarily – authorise the imports of GM crops once they have received a favourable opinion from EFSA. Furthermore COPA-COGECA also demanded greater certainty for importers and an end of the EU's "zero tolerance" policy as this is likely to interrupt imports; instead a tolerance threshold should be established for the adventitious and unavoidable presence of traces of GMOs grown in third countries. In the longer term the EU's protein dependency should be decreased by increasing the production of protein crops, using more by-products from the biomass production and re-opening the debate on processed animal proteins. Altogether this representative saw the competitiveness of the EU's agri-food sector at stake.

Also for **the European seed industry** (ESA) the issue in the context of AA is its competitiveness: with intensifying competition in a growing market for GM seeds, ESA sees the European seed industry faced with restrictions in its access to the technology and for the exchange of germplasm – which puts EU companies at a disadvantage. At the same time ESA highlighted the significant economic costs and legal risks that the breeding and field trialling of GM varieties pose, it criticised the unpredictability and unreliability of the full authorisation of GM crops (i.e. including planting), and it sees its intellectual property protection reduced by delays in the authorisation of the crops. Moreover, ESA underlined that seed production with zero tolerance for impurities is impossible and that, therefore, economically viable thresholds and requirements are needed (both for LLP from GM crops in Europe and third countries). ESA also demanded practical coexistence measures and liability rules. Otherwise ESA sees the freedom to operate for Europe‘s breeders and the freedom of choice for its customers endangered.

The US rice industry (USA Rice Federation) presented the lessons learned from the "Liberty-Link case" (see Box 1). USA Rice explained that the response of the US rice industry was to restore the marketability and competitiveness of US rice by complying with third country regulatory requirements and provide confidence to customers; this meant the removal of LLRICE601 from the rice supply. To this end all rice seed was tested before planting in 2007 and 2008 (and will be in 2009), following EU protocols. Additional testing takes place of the rice destined for export to the EU; this rice is tested (1) when delivered from the field, (2) when moved from silo to the milling operation, (3) when it is milled, and (4) when it is loaded on barges, which are then sealed. Finally, the negative test certificates and statements by the US inspection administration accompany the rice shipments to the EU. However, as EU importers are not willing to take the risk that comes with a zero tolerance threshold for imports (see the view of the "EU food and feed chain" above), US rice exports are resuming only slowly, being down 70 percent in 2007/08 compared to 2005/06, meaning continuing lawsuits, lost revenues and trade policy friction. And although USA Rice declared that also in 2009 seed and crop testing will continue, it nevertheless stressed that it is unrealistic to expect a GM-free environment. USA Rice explained that the current extensive testing and segregation are voluntary actions by the US rice industry and that their implementation is a function of the cost of these measures and of the size of the target market – and that the EU is an important but not an essential market. Hence, EU importers and US exporters could shift to other markets and Europe could lose access to a reliable and safe supply of food and feed. Therefore an appropriate LLP policy would be crucial to maintaining supply and allowing agricultural trade to continue.

The American Soybean Association (ASA) also highlighted the commodity character of GM soybean crops, explaining that on the farm the soybean crop is often planted with many varieties and that it is harvested as a commodity crop with no separation of varieties, that during transport the harvested crop is hauled via personal or contracted truck where it will have been co-mingled with other soybean varieties, that at the elevator the soybeans are unloaded and stored in bulk via a common handling system, that they are then often mixed with harvested crops from other farms before being loaded via a common system onto barges or trains as a bulk commodity for transport to ocean ports where they would either be discharged into common storage or loaded direct into bulk holds of ocean-going ships that can carry 50,000-100,000 metric tons. At the port of discharge the soybeans are unloaded via common machinery into common storage before further transportation via coastal vessel, barge, truck or rail. The processor also will have common storage facilities for bulk commodities and common lines for production, processing and packaging. Finally, transportation to customers is again common and not segregated. Against this background ASA noted that in 2007 over 95 percent of the soybean acreage in the USA was planted with GM varieties and that use of the technology had helped maintain US soybean growers' competitiveness in their overseas markets. ASA noted that the EU represented 8 percent of the overseas market for US soybeans (compared to 32 percent for China, 14 percent for Mexico 10 percent for Japan). In their opinion, since 1996 US soybean growers' experience in cultivating GM soybeans was that the crop was more productive (due to increased use of no-tillage practices, less use of herbicides and more effective weed control), more profitable (due to less use of fuel and labour savings – which between 1996-2006 represented average savings of 43 USD/ha) and more sustainable (due to an improved soil structure, less CO_2 emissions and increased birdlife). Therefore, US soybean growers would continue to use GM soybeans, particularly those of the next generation that promise further benefits, not only for farmers but also for consumers. ASA noted its long-standing policy regarding commercialisation of new GM soybean traits. Should ASA decide to support the commercialization in the USA of a new biotech product which lacks relevant overseas regulatory clearance, that decision will be based on the potential benefits of the new biotech product and its projected effects on the profitability and competitiveness of US soybean farmers. Other important considerations include the size of a potential export market and whether or not it has a functioning and timely biotech approval system. In this context, ASA voiced concern over delays EU approval process that could lead to market access issues. Furthermore, ASA criticised the zero tolerance towards EU-unapproved traits and what in their opinion are discriminatory and unrealistic GM labelling laws.

The Canola Council of Canada also pointed out the commodity character of the canola trade where many participants operate within a bulk handling system – which in Canada would be dominated by GM canola as more than 80 percent of the canola acreage in Canada is sown with GM varieties. The Canola Council explained this high adoption rate by the benefits GM canola offers, like better weed control, higher yields and more profits – reporting in particular yield advantages of 10 percent, revenue increases of over 14 CAD/ha, significant fuel savings and reductions in the use of herbicides, plus reductions in tillage of one million hectares per year due to conservation tillage, more flexible rotations and summer fallows. Furthermore the Canola Council indicated that new GM traits would be coming up, like new herbicide tolerances, drought tolerance, nitrogen use efficiency, disease resistance, insect resistance and improved crop composition.

The North American Export Grain Association (NAEGA) acknowledged that agricultural biotechnology increasingly requires additional actions that add cost and increase risk for the management of export supply chains. Biotechnology policies impact the trade in commodities through, a lack of synchronised authorisations, LLP regulations for unauthorised events, mandatory labelling, or the setting of thresholds for the adventitious presence of (authorized) GM material in non-GM products. Given that in general there is zero tolerance for unapproved events and that events are usually approved (i.e. found safe) first in exporting countries and not in importing countries, NAEGA explained that trade is often restricted because neither IP systems nor grain channelling can achieve compliance with zero tolerance or with an approach based on testing limits. NAEGA highlighted that adventitious presence of GMOs will occur in all trans-boundary shipments of all commodities (both GM and non-GM) including shipments from countries that do not have GMOs in commercial production as well as from countries having GMOs in commercial production. In this context also NAEGA described the characteristics of the world grain system, where most grain used for food, feed or processing is shipped by bulk handling systems to realise economies of scale and achieve low costs. NAEGA also pointed out that most of the world's grain is utilised as feed (72 percent of the maize production and 60 percent of the oilseed production), but that both food and feed grains move through the same infrastructure. Giving an example of the traded volumes, NAEGA explained that one Panamax ship can hold 50,000 tons of grain, which corresponds to 38 barges, 2,200 semi-trailers, 2 million bushels – or 330 trillion soybeans. NAEGA underlined that within such a system and a zero tolerance approach, destination testing creates unmanageable commercial risks for importers and exporters (i.e. the risk of a – binding – positive test at the port of destination after a negative test at the port of origin cannot be managed effectively by the supply chain). Therefore NAEGA encouraged governments to develop policies that minimise impacts of agricultural biotechnology on the food and feed supply chains, to develop risk assessment policies and processes that minimise AA gaps between trading partners, to establish compliance policies for agricultural biotechnology that create access and predictability for global supply chains, and to support the development of practical and achievable standards for LLP.

Complementing the points by NAEGA, **the International Grain Trade Coalition** (IGTC) explained that the major four crops (wheat, rice, maize and soybeans) account for over half the global production, while the next four crops (barley, sorghum, cotton and canola) only account for 15 percent. With a volume of over 300 million tons, these same four crops also dominate global trade. For half of the major eight crops (namely for maize, cotton, soybeans and canola) GM varieties are available – and for these crops adoption levels of the GM varieties are increasing rapidly. The IGTC then projected further growth in the world grain demand (e.g. due to global economic growth or increasing use of biofuels) and warned that the "easiest" markets will get the most attention, i.e. producers and traders will prefer to supply grains for biofuel production over supplying grains for use as food and feed, they will prefer to supply grains domestically over exporting them – and they will prefer to supply bulk grains over specialty grains. What is in particular influencing this migration of exports towards "preferred buyers", according to IGTC, are compliance risks, supply chain disruptions and the predictability and timeliness of regulatory frameworks – with zero tolerance for LLP being considered one of the most disruptive biotechnology policies. Another effect highlighted by IGTC was that the price of grain is determined through supply and demand in the "bid and offer" system of grain exchanges; there price competition is based on quality and quantity specifications in the tender and there is a strong relationship between price, specifications and risk – the latter of which is increased by the uncertainty whether the grains can and will be in compliance with LLP regulations (if tested again). The tighter and more demanding the specifications and the bigger the risk are, the higher the prices will be. However, the IGTC clearly stated that if the risk cannot be measured or managed, there simply will be no trade. It also repeated that adventitious presence of GMOs will occur in all trans-boundary shipments of all commodities (both GM and non-GM) shipped from countries having GMOs in commercial production – and that neither IP systems nor grain channelling can manage these events to zero tolerance. IGTC does not consider testing to be a solution and also "limit of detection" thresholds do little to improve destination risks. IGTC sees the best risk management policy in the implementation of fully functioning regulatory systems where approvals are completed within 24 months from the date of submission. Furthermore, the validity of the risk assessment conducted by an exporting country should be recognised or at least considered. Events should be granted full authorisation, and zero tolerance thresholds should be replaced by low-level marketing thresholds. IGTC suggests the proactive use of the Codex LLP Annex (Codex 2008) when these policies are not possible, conducting a LLP risk assessment for the unapproved event and assigning a manageable LLP threshold. For guidance on where to fix these thresholds IGTC recommends looking at existing marketing thresholds (for crops destined for industrial use, the organic market, etc.). IGTC affirms that marketing thresholds allow grain customers to maximise the value of the grain product while minimising cost inefficiencies and handling costs. In concrete, IGTC recommends a 5 percent threshold for LLP of products of modern biotechnology.

Moving the focus from trade issues, **the Food and Agriculture Organization** of the United Nations (FAO) addressed the preconditions for carrying out genetic engineering on a global level, namely having access to suitable plant genetic resources (PGRs) and having the capacity and the knowledge base to develop GMOs. FAO highlighted that the centres of diversity for some of the world's major crops are spread all over the world and that these crops' PGRs have been widely shared and adapted by farmers, so that nowadays on average about 70 percent of the calorie intake in national diets is from crops coming from outside the respective region. Seeing both the need to conserve and to use PGRs, FAO favours an integrated approach to maximise technology benefits for food security that is embedded in international and collaborative agreements. Describing the uneven diffusion of GM crops and the related level of research activities, FAO explained that its focus is on the strengthening of capabilities in developing countries by expanding the knowledge base and by fostering effective linkages among stakeholders. While modern biotechnology has the potential to address many agriculture problems and to enhance the conservation and use of PGRs, biotech research must meet the needs of resource poor farmers in developing countries. In this context national capacities for managing biotech outputs must be strengthened, and access to scientific information and infrastructures together with dialogues among stakeholders should be promoted so that countries can make informed decisions with regard to these products and adjust their economic expectations.

5.2 Previous reports and studies on asynchronous approval

The economic impact of LLP has begun to catch the attention of experts working in government institutions or research centres in the EU. Below are summaries of two recent papers on the subject.

DG AGRI of the European Commission

In June 2007 the Directorate-General for Agriculture and Rural Development of the European Commission published a report on the "Economic impact of unapproved GMOs on EU feed imports and livestock production" (EC 2007). This report analysed the question of how severely animal feed imports could be affected by the presence of EU-non approved GMOs in maize and soybean products, and it looked at the potential consequences this would have for EU meat production, consumption and trade.

The report found that new GMOs are being developed in feed exporting countries at a high rate, but that the **regulatory procedures for the approval of GMOs in the EU differ significantly from those of exporting third countries** – in particular regarding the time it takes for authorisations to be completed, which in the EU takes more than 2.5 years while the US average is 15 months. The persistent disagreement among Member States in the respective Regulatory Committees and in the Council adds to this situation of AA. Furthermore the report underlines that the presence of an EU-unapproved GM material has the same implications for imports, irrespective of whether it is approved or not in the exporting country, with **no legal provisions in the EU for tolerance levels for the accidental LLP of EU-unapproved GMOs** that have received approval in other countries. In this context the report states that with the more widespread cultivation of GMOs in exporting countries, AA could cause trade disruptions that become more severe, more frequent, and affect more products. Because although some third countries appear to make the granting of authorisation for new GMOs dependent on the impact that this could have on their exports, the report confirms that unwanted mixing of GMOs resulting from illegal or experimental cultivation in some of these countries, in combination with a lack of co-existence policies, could undermine efforts of third countries to supply feed to the EU that is free of LLP. In particular, **traders could be unwilling to assume the risk of having LLP of EU-unapproved GM material detected in their shipments** that would result in import stops (EC 2007).

In the case of **trade in soybeans and soybean meal**, the imports are much higher than EU domestic production (also see Figure 16), and soybean products are crucial for the EU livestock sector. The report stated that few alternatives exist to replace these imports and that an (aid-supported) domestic increase in the production of oilseeds and protein crops could replace at most 10-20 percent of the EU imports of soybeans and soybean meal.

Therefore, to assess the economic implications of an uptake of EU-unapproved GM soybeans in exporting countries, the report used an economic modelling approach to describe three different impact scenarios. This was done for the specific case of Monsanto's RR2 soybeans (MON89788), which at the time of the report were not yet authorised in the EU; the assumption of DG AGRI was that any potential interruption of soybean and soybean meal imports would only take place during 2009 and 2010 because the expectation was that the latest after that period MON89788 would be authorised. Eventually MON89788 was already authorised in late 2008 so that there will be no disruptions of soybean imports due to AA of MON89788. However, in the meantime there are two other GM soybeans that are already authorised in the USA but not yet in the EU (namely Bayer's other LibertyLink soybeans and Pioneer's Optimum GAT soybeans), with three more GM soybeans being in the global regulatory pipeline (see Table 1) and nine GM soybeans being at an advanced stage of R&D (see Table 2). Hence, the report scenarios may not apply for the specific case of RR2 soybeans, but comparable situations are likely to arise repeatedly in future.

In its "minimal impact" scenario, the report assumed that EU-unapproved GM soybeans would only be planted in the USA. In this case US soybean exports to the EU could be diverted to other destinations and be replaced by imports from Brazil and Argentina – the net effect in this scenario was considered to be low and no further analysis was carried out by DG AGRI.

In its "medium impact" scenario, the report assumed that EU-unapproved GM soybeans would be planted both in the USA and in Argentina. While DG AGRI assumed that part of the loss of these two suppliers of soybeans could be compensated by increased imports from Brazil, it estimated that an import deficit of about 10 million tonnes of soybean meal equivalent would emerge – which could be reduced to about 3 million tonnes through increased production and imports of rapeseed meal and sunflower meal.

Finally, in its "worst case" scenario, the report assumed that imports from the USA, Argentina and Brazil would cease, without compensation from other exporting countries. Again assuming an increase in the production and import of rapeseed meal and sunflower meal, DG AGRI still found a remaining net shortage of soybean meal of over 25 million tonnes.

Both the medium impact and worst case scenarios would obviously lead to high price increases of soybeans and soybean meal in the EU. The report expects that this, together with further repercussions on the prices of substitute products, would raise feed expenditures by more than 20 percent in the medium impact scenario and by more than 600 percent in the worst case. Higher feed prices, in turn, are expected to severely affect the EU meat sector. The report projected a short-term fall of up to 35 percent in the production of pork and a fall of up to 44 percent in poultry production – which would result in very significant increases in imports. These imports would most likely come from overseas where animals would be fed with cheap feed from (EU-unapproved) GM soybeans. The report furthermore concluded that a loss in competitiveness of the EU livestock sector would have important implications for agricultural incomes and employment, with considerable knock-on effects in the upstream and downstream industries, and significant increases in meat prices for the consumer and it suggested that the EU's authorisation procedure of GMOs should be accelerated and that the handling of LLP of events that are approved according to internationally agreed standards should be reconsidered.[18]

In the case of maize and maize products, (grains, CGF and DDGS), the report suggested that imports with potential LLP of EU-unapproved GMOs could eventually be replaced by maize products form within the EU-27, by imports from other trade partners or by other domestic cereals or alternative feed ingredients (also see Figure 12). Therefore the report concluded that "an interruption is unlikely to have a strong economic impact on future feed imports and livestock production at the overall EU level." However, the report concluded that there could be substantial economic consequences for individual Member States with access to cheap imports by sea (like Spain, the UK, Portugal, the Netherlands or Ireland).

LEI of Wageningen University and Research Centre

LEI, the agricultural economics research institute of Wageningen University, also published a report on the economic consequences of the EU's policy on GMOs (Backus et al. 2008), confirming that the cultivation of GM crops has seen a rapid growth since 1996, especially in the Americas, but that in the EU the cultivation of GM crops is still rather limited – despite a rapid increase in the use of GM crops in the EU. It also finds that the AA of GM crops, coupled with a zero tolerance policy for LLP of EU-unapproved GM material, has led to difficulties for the EU with the import of food and feedstuffs from major exporting countries. In this context Backus et al. highlight the common practice in food safety legislation that minute presence of unwanted materials (like dirt, weed or mycotoxins) is allowed and contrasts this with the EU requirement to take imports from that market that contain unintentional and hardly avoidable LLP of EU-unapproved GM material, even if the corresponding GMOs may have been approved for commercialisation in other countries. Backus et al. also expect that with the more widespread cultivation of GMOs that are approved in the exporting countries but not in the EU, potential trade disruptions could become more severe and that importers may become unwilling to assume the risk of LLP of EU-unapproved GMOs in their shipments. In particular, Backus et al. point out that as a consequence of trade disruptions EU livestock producers face the risk of being cut off from high-

[18] Providing more details on these implications, FEFAC (2007) states that a damaging loss of feed ingredients due to asynchronous approval would put the EU's livestock sector even more under pressure. A large part of the EU livestock industry and related industries would no longer be able to produce because of the lack of sufficient feed supply. The pig and poultry chains, representing 1,250,000 direct jobs in the EU-25, would be affected the most, with a potential production drop of 50%, which could mean loosing 600,000 jobs. FEFAC continues that this would be a high price to pay with no benefit for EU consumers and citizens as the EU livestock production deficit would be offset by imports from third countries of animal productions derived from animals likely fed with the same GMOs that the EU could not import even as traces.

quality, protein rich feedstuffs – feedstuffs than can never be produced within the EU in sufficient quantities. The resulting loss in competitiveness of the EU livestock sector could then have implications for agricultural incomes and employment, with knock-on effects in the upstream and downstream industries, and significant increases in meat prices for consumers – and potentially resulting in a situation where the EU import its meat from countries where animals are fed on GM crops that EU producers are not allowed to use. For the food industry Backus et al. find that the problems of LLP lie in the sourcing of conventional raw materials, especially when a zero tolerance policy is followed. In any case they expect that conventional raw material will have to be bought at a considerable additional cost.

While in their discussion of the economic impacts of AA they mostly drew on results of the study by DG AGRI (EC 2007) and an industry study by Brookes (2008), Backus et al. also reported additional data and results. Referring to a study by FEFAC, they indicated that the loss of cheap US maize imports – i.e. the need to fall back on more costly alternatives – may have cost the EU livestock sector an extra EUR 1.58 billion in 2007/08 (EUR 865 million for the substitution of maize and maize products and EUR 710 million in indirect costs due to feed import restrictions). Moreover, these cost increases would fall disproportionally on countries that so far used large amounts of CGF and DDGS, like the Netherlands, Germany, Ireland, Portugal and Spain. For EU-unapproved GM soybeans Backus et al. quote a presentation by the Secretary General of the "Fédération Européenne des Fabricants d'Aliments Composés pour Animaux" (FEFAC) who estimates that with the EU's current zero tolerance approach costs could increase by as much as EUR 200 billion if new GM soybeans would be approved and cultivated in all three main exporting countries (USA, Argentina and Brazil); with a tolerance threshold of 0.1 percent, the additional costs could be kept below EUR 3 billion.

Discussing the consequences for the food industry of avoiding GM soy products, Backus et al. pointed out that where possible the industry has already changed recipes. However, as the complete avoidance of soy products would not be feasible in all cases, continued sourcing of conventional soy will be necessary. Yet, even with full proof IP systems, LLP of EU-unapproved events in soybean shipments cannot be excluded. With a zero tolerance approach in the EU this will necessitate refusal of shipments. Backus et al. (2008: 33) therefore conclude that "the zero tolerance level of the EU is perhaps more of a problem than the sourcing of conventional soy." Reporting estimates of the "Confédération des industries agro-alimentaires " (CIAA) for an imaginary incident with soybean imports – one shipment with LLP of EU-unapproved events that affects fifty companies – Backus et al. provide cost estimates in the range of EUR 80-160 million only for testing stocks, financial charges, staff time and legal costs; if the GM material should only be found at a later stage, during processing, costs of over EUR 1 billion could arise (because of the low incorporation rates of soy-based derivatives in many food products).

6 Conclusion

In this report we described the current status of GM crops approved worldwide and the likely future developments for the short to medium term, for all relevant crops from all countries. Everywhere the commercialisation of these new GM crops is normally a regulated activity and different countries have different authorisation procedures. Therefore new GM crops do not get simultaneously approved in all countries. This "asynchronous approval" (AA) of GM crops is of growing concern for its potential economic impact on international trade, especially if crop importing countries operate a "zero tolerance" policy that may result in rejections of imports that contain only traces of not yet authorised GMOs; similar problems of "low-level presence" (LLP) of unapproved GM material in imports arise when developers of new GM crops did not seek approval for commercialisation in export markets in the first place, i.e. when there is "isolated foreign approval" (IFA), or when there is LLP of research events due to accidental admixture of commercial crops and GM crops from field trials. In the EU LLP has already caused trade disruption and economic problems, in particular for the EU feed and livestock production sectors.

To forecast the future evolution of LLP of GM crops for the EU agri-food sector, expected new GM crops were classified in five categories according to their proximity to market, they were discussed crop-wise, and their possible authorisation by the different trading partners of the EU were considered. Based on expert inputs that were obtained during a related workshop and on subsequent desk research, the prediction is that while currently there are around 30 commercial GM events cultivated worldwide, by 2015 there will be over 120. Therefore, if problems of LLP have occurred with 30 events in the market, these are likely to intensify when moving from 30 to 120 available events. Moreover, individual GM events can easily be combined ("stacked") by conventional cross-breeding to generate new GMOs with multiple desirable traits. Given the growing pipeline of individual events, it is evident that in countries where stacked GM crops are required to go through the regulatory system as a new GM crop, this will create an increasingly large number of new "approvable" GMOs. In these countries stacked GM crops will increase the workload of regulatory systems and contribute to the problem of AA. However, apart from AA, also the issue of IFA is bound to increase with more of the new GM crops being developed by national technology providers in Asia for their domestic agricultural markets, because these developers may not submit all of their GM crops for approval in potential export markets. In these cases detection of the events may pose additional problems.

Overall it is expected that next to the current major GM crops (soybeans, maize, rapeseed and cotton) and some minor ones, in the medium term also GM potatoes and GM rice will be commercialised. Apart from the current main traits (insect resistance, herbicide tolerance or a combination of both), new commercial traits covering crop composition and abiotic stress tolerance will become available. While for all these crops LLP issues are possible, potential problems are most relevant for those crops for which the EU depends on imports or for which there is substantial trade. For instance for soybeans there are already five new GM events in the commercial and regulatory pipeline that, within the next 2-3 years could result in potential situations of AA with the concomitant impacts on the EU agri-food sector. And as most of the new GM rice that is developed worldwide is not even submitted for EU approval, future problems due to LLP of unapproved GM material in rice imports are likely.

For the participants from the global food and feed chain the main problem of LLP is the economic risk of rejections of shipments at the EU border. Part of this problem consists of the "destination risk", i.e. the official testing for unauthorised GM material in imports in the port of destination only – when a cancellation of the shipment is impossible and when its re-direction is costly. Also, given the bulk handling of grains in international trade, experts confirm that compliance with a zero tolerance policy for LLP of unauthorised material is impossible, even under identity preservation systems. Therefore exporters may choose to sell their grain to "preferred buyers", i.e. to countries that have found concerns about LLP not justified and to importers that are known to create little problems. Moreover, the price of grain is determined through "bid and offer" systems of grain exchanges where prices are based on quality and quantity, with a strong relationship between price, specifications and risk – the latter of which is increased if there is uncertainty whether imported grains will be in compliance with LLP regulations. Hence, unless the risk cannot be measured or managed, in which case there will be no trade at all, bigger risks mean higher prices. Higher prices and potential supply bottlenecks in the EU due to LLP, in turn mean that EU businesses that are dependent on cheap imports of agricultural commodities, like livestock farming, may have to relocate abroad.

Solutions suggested by the participants are a replacement of the zero tolerance thresholds by low-level marketing thresholds higher than the detection limit to be practical (one tentative suggestion based on existing marketing thresholds for specialty crops is to use a five percent threshold). In addition, participants highlight the need to address the "destination risk", e.g. by official testing of shipments already at the port of loading. Other solutions proposed by the participants are the streamlining of the regulatory systems, mutual recognition of risk assessments of new GM crops and the implementation of Codex Alimentarius guidelines.

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Relevant links and sources

Websites of the European Commission and EU authorities

Regulation on cultivation of GMOs and their use for food and feed:
http://ec.europa.eu/food/food/biotechnology/authorisation/

EFSA register of questions on GMOs:
http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=ALL

Community register of GM food and feed:
http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

EC information website on the deliberate release into the environment of GMOs:
http://gmoinfo.jrc.ec.europa.eu/

Community Reference Laboratory for GM food and feed:
http://gmo-crl.jrc.ec.europa.eu/

Websites of national regulators

USA – database of completed regulatory agency reviews of GM crops:
http://usbiotechreg.nbii.gov/database_pub.asp

USA – overview of petitions of nonregulated status received by USDA-APHIS:
http://www.aphis.usda.gov/brs/not_reg.html

USA – overview of EPA registrations of GM crops with plant incorporated protectants:
http://www.epa.gov/pesticides/biopesticides/pips/pip_list.htm

USA – list of completed consultations on bioengineered foods by the FDA:
http://www.cfsan.fda.gov/~lrd/biocon.html

USA – database of field test release applications:
http://www.nbiap.vt.edu/cfdocs/fieldtests1.cfm

Canada – database with information on the status of regulated plants with novel traits:
http://active.inspection.gc.ca/eng/plaveg/bio/pntvcne.asp

India – database on activities involving the use of GMOs and biosafety rules & regulations:
http://www.igmoris.nic.in/ and http://dbtbiosafety.nic.in/

Australia – list of applications and licences for intentional releases of GMOs:
http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1

Japan – list of approved living modified organisms (incl. field trials):
http://www.bch.biodic.go.jp/english/lmo.html

Websites by international organisations and secretariats

OECD database on products derived from the use of modern biotechnology:
http://www2.oecd.org/biotech/

Database of the Biosafety Clearing-House on living modified organisms:
http://bch.cbd.int/database/organisms/

Industry websites and private information websites

Database on the authorisation of GM food and feed in the EU:
http://www.gmo-compass.org/eng/gmo/db/

Database of approved GM crops with an international scope:
http://www.agbios.com/dbase.php

Database on the commercial status of "certain agricultural biotechnology products":
http://www.biotradestatus.com/

Monsanto Company, product overview:
http://www.monsanto.com/products/

Pioneer Hi-Bred International, Inc., product overview:
http://www.pioneer.com/web/site/portal/menuitem.0128f8e2dab251f7bc0c0a03d10093a0/

Bayer CropScience AG, product overview:
http://www.bayercropscience.com/bcsweb/cropprotection.nsf/id/BioScience

Syngenta AG, product overview:
http://www.syngenta.com/en/products_brands/fieldcrops.html
and http://www.agrisuretraits.com/Traits.aspx

Dow AgroSciences LLC, product overview:
http://www.dowagro.com/usag/prod/

BASF Plant Science, project overview:
http://www.basf.com/plantscience

Biotechnology Industry Organization, food & agriculture highlights:
http://www.bio.org/foodag/

European Association for Bioindustries, agrifood biotech overview:
http://www.europabio.org/green_biotech.htm

Appendix

List of participants

European Commission DGs and EU Authorities

- JRC Institute for Prospective Technological Studies:
  Per Sørup, Emilio Rodríguez-Cerezo, Alexander J. Stein, Anne-Katrin Bock, Marta Czarnak-Klos, Stephen Langrell, Thomas Fellmann
- DG Health and Consumers: Sébastien Goux, Sabine Pelsser
- DG Environment: Ioana-Rodica Ispas
- DG Trade: Beata Molendowska
- DG Research: Jens Hoegel
- JRC Joint Research Centre: Jean-Paul Malingreau, Sigrid Weiland
- JRC Institute for Health and Consumer Protection: Maddalena Querci
- European Food Safety Authority: Reinhilde Schoonjans

National regulators

- United States Department of Agriculture: Beverly Simmons
- Secretaría de Agricultura, Argentina: Moisés Burachik
- Ministério da Agricultura, Brazil: Marcus Vinícius Segurado Coelho
- Canadian Food Inspection Agency: Stephen Yarrow
- Department of Biotechnology, India: (represented by R. Tuli)
- Ministry of Agriculture, P.R. China: (absent)
- Department of Health and Ageing, Australia: Elizabeth Flynn
- Ministry of Agriculture, Japan: Koh-ichi Kadowaki
- Ministry of Economy, Ukraine: Zhanna Pastovenska

Private technology providers

- Monsanto Europe: Jonathan Ramsay
- Pioneer Overseas: (presentation submitted)
- Bayer CropScience: William H. Hensley
- Syngenta: Suzy Renckens
- Dow AgroSciences: Thomas W. Lyall
- BASF Plant Science: Matthias Pohl
- Biotechnology Industry Organization: Sarah Lukie
- European Association for Bioindustries: Nathalie Moll

Public technology providers

- Brazilian Agricultural Research Corporation: Francisco Aragão
- National Botanical Research Institute, India: Rakesh Tuli
- Chinese Academy of Sciences: Ruifa Hu
- Agricultural Research Council, South Africa: Gurling Bothma
- International Rice Research Institute: Gerard Barry
- Molecular Plant Breeding CRC, Australia: Keith Alcock
- International Food Policy Research Institute: José Falck-Zepeda
- Spanish National Research Council: Antonio Leyva

Supply-chain actors and users

- Coceral: Klaus Schumacher
- European Feed Manufacturers' Federation: Alexander Döring
- EU Oil and Proteinmeal Industry: Sonia Goetz
- Confederation of the Food and Drink Industries in the EU: Beate Kettlitz
- Federation of European Rice Millers: Chris Downes
- Grain & Feed Trade Association: Pamela Kirby-Johnson
- COPA-COGECA: Marie-Christine Ribera
- European Seed Association: Garlich v. Essen
- USA Rice Federation: Bob Cummings
- American Soybean Association, USA: David Green
- Canola Council of Canada: JoAnne Buth
- North American Export Grain Association: (represented by R. Giroux)
- International Grain Trade Coalition: Randal Giroux
- Food and Agriculture Organization: Kakoli Ghosh

Workshop programme

Day 1	***Wednesday, 12 November 2008***	
09:00	**Introduction**	
	Welcome	Per Sørup
	Rationale of the workshop	Emilio Rodríguez-Cerezo
09:30	**National regulators**	
	EU: Directorate General for Health and Consumers	Sébastian Goux
	United States Department of Agriculture	Beverly Simmons
	Argentina: Secretaría de Agricultura	Moisés Burachik
	Brazil: Ministério da Agricultura	Marcus Coelho
	Canadian Food Inspection Agency	Stephen Yarrow
	Morning coffee day 1	
	India: Department of Biotechnology	(K.K. Tripathi)
	P.R. China: Ministry of Agriculture	(Li Ning)
	Australia: Department of Health and Ageing	Elizabeth Flynn
	Japan: Ministry of Agriculture	Koh-ichi Kadowaki
	Ukraine: Ministry of Economy	Zhanna Pastovenska
	Summary	Chair
12:30	**Private technology providers**	
	Monsanto Europe	Jonathan Ramsay
	Pioneer Overseas Corporation	(Zsolt Jekkel)
13:00	*Lunch break day 1*	
	Bayer CropScience	William H. Hensley
	Syngenta	Suzy Renckens
	Dow AgroSciences	Thomas W. Lyall
	BASF Plant Science	Matthias Pohl
	Other ag biotech companies (BIO, EuropaBio)	Sarah Lukie, Nathalie Moll
	Summary	Chair
	Afternoon break day 1	
15:45	**Public technology providers**	
	Brazilian Agricultural Research Corporation	Francisco Aragão
	National Botanical Research Institute, India	Rakesh Tuli
	Chinese Academy of Sciences	Ruifa Hu
	Agricultural Research Council, South Africa	Gurling Bothma
	International Rice Research Institute	Gerard Barry
	Molecular Plant Breeding CRC, Australia	Keith Alcock
	International Food Policy Research Institute	José Falck-Zepeda
	European public research institute	Antonio Leyva
	Summary	Chair
18:00	**End day 1**	

Day 2 Thursday, 13 November 2008

09:00	**Supply-chain actors and users**	
	Coceral (EU commodity traders)	Klaus Schumacher
	European Feed Manufacturers' Federation	Alexander Döring
	CIAA (EU food and drink industries)	Beate Kettlitz
	Federation of European Rice Millers	Chris Downes
	USA Rice Federation	Bob Cummings
	EU Oil and Proteinmeal Industry	Sonia Goetz
	American Soybean Association, USA	David Green
	Canola Council of Canada	JoAnne Buth
	Morning coffee day 2	
	COPA-COGECA (EU farmers)	Marie-Christine Ribera
	North American Export Grain Association	(Gary C. Martin)
	International Grain Trade Coalition	Randal Giroux
	Grain & Feed Trade Association	Pamela Kirby-Johnson
	European Seed Association	Garlich v. Essen
	Food and Agriculture Organization	Kakoli Ghosh
11:45	**Discussion**	
	Soybeans	
	Maize	
	Cotton	
13:00	*Lunch break day 2*	
	Rapeseed	
	Rice	
	Wheat	
	Afternoon break day 2	
	Potato	
	Vegetables and other crops	
16:15	**Final discussion**	
	Final discussion	
16:30	**End of workshop**	

Glossary

Given that various parties contributed to the workshop and to this report, a consistent use of the terms cannot be assured in all cases. For general explanations of the technical terms (like event, trait, transgene, etc.) please refer to relevant glossaries that are freely accessible online, e.g.:

The glossary of Co-Extra (a project of the European Commission's 6th Framework Programme) at http://www.coextra.eu/glossary/

FAO's list of terms and acronyms in applied biotechnology at http://www.fao.org/biotech/index_glossary.asp

The agricultural biotechnology glossary of the USDA's Economic Research Service at http://www.ers.usda.gov/Briefing/Biotechnology/glossary.htm

The Canadian Food Inspection Agency's definition of commonly used terms in biotechnology at http://www.inspection.gc.ca/english/sci/biotech/gen/terexpe.shtml

The glossary of the portal on GMO Safety (supported by the German Ministry of Research) at http://www.gmo-safety.eu/en/glossary/

The glossary of the GMO-Compass at http://www.gmo-compass.org/eng/glossary/

Monsanto's biotechnology glossary at http://www.monsanto.com/biotech-gmo/asp/glossary.asp

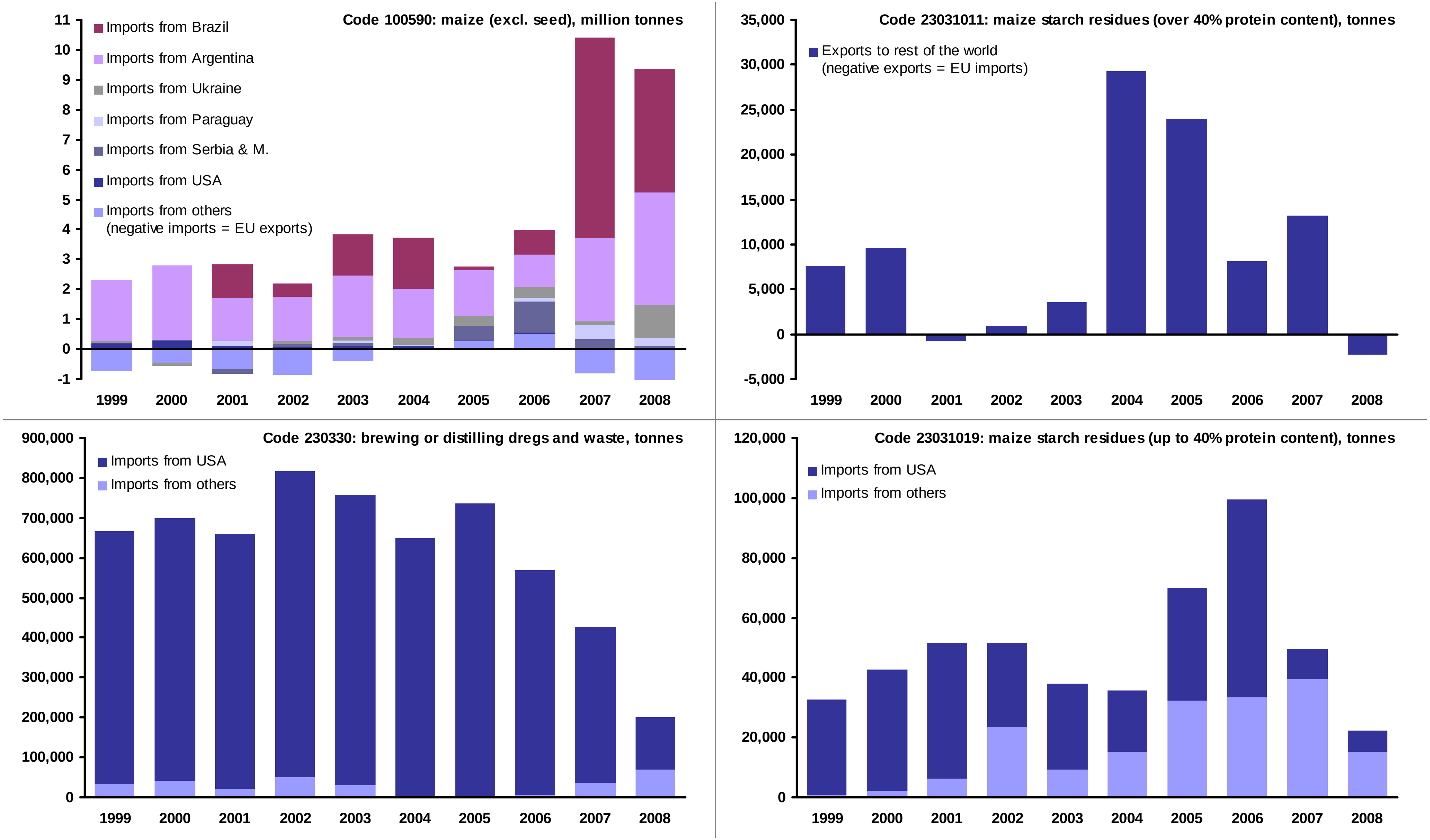
Overview figures of production and trade flows of maize, rice and soybeans

Figure 11 illustrates how – after the Herculex incident (see Section 2.21.2) – the reductions of EU imports of maize products for feed from the USA from 2006 onwards (lower quadrants) has been compensated by EU operators by importing more high grade maize grains (top left quadrant) and by exporting less of protein-rich maize residues (top right quadrant). However, altogether it can be seen in Figure 12 that the EU produces most of the maize it needs, even if on a global scale the USA are an important supplier of maize (Figure 13).

In the case of milled rice, the EU imports over a third of the rice it consumes (Figure 14). As has been discussed in Section 1.2, after the incident with unapproved LibertyLink rice 601 in the USA, the share of US rice in EU imports has dropped dramatically and the EU has sourced its rice from other countries, mainly in Asia (Figure 5). This was possible because on a global scale the USA are only a small producer (Figure 15) and therefore alternative suppliers could fill the gap. However, searching new suppliers and re-directing trade flows is not cost neutral. Moreover, with this approach LLP in rice may only be avoided as long as these alternative suppliers do not cultivate GM rice (and even then LLP through comingling during transportation and storage cannot be excluded). And given the relatively small EU market for rice, in future the big producers in Asia and the rest of the world may not be willing to change their policy on GM rice because of EU concerns.

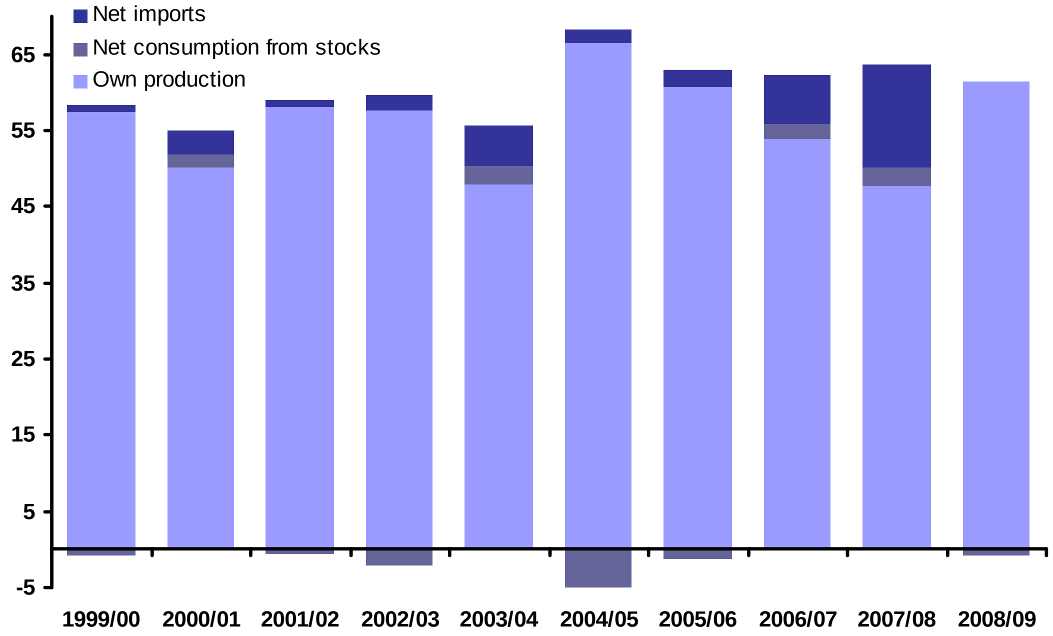
Finally, the data on soybeans show that the EU is fully dependent on soybean imports, relying for its consumption on over 90 percent on soybeans from abroad (Figure 16). At the same time the USA produce about one third of all soybeans worldwide (Figure 17). And even though the share of soybean imports from the USA has been declining constantly over the last 10 years (Figure 18), AA in soybeans may nevertheless pose the biggest threat to the EU supply of food and feed – beyond the considerable economic losses that arise from any LLP incident – as there are few alternative suppliers (Figure 18).

Figure 11: Net trade flows in maize and derived products between the EU-25 and the rest of the world, 1999-2008



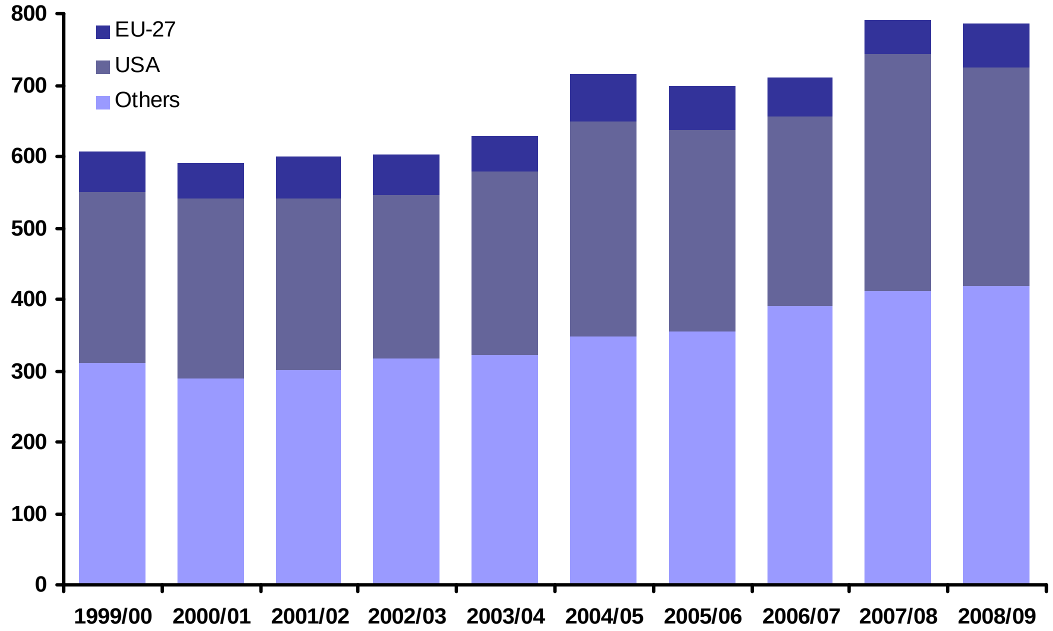
Note: The codes for the trade indicators are those of the Combined Nomenclature (HS2, HS4, HS6 and CN8). *Source*: Based on data from Eurostat (2009).

Figure 12: Consumption of maize in the EU-27, by sources in million tonnes



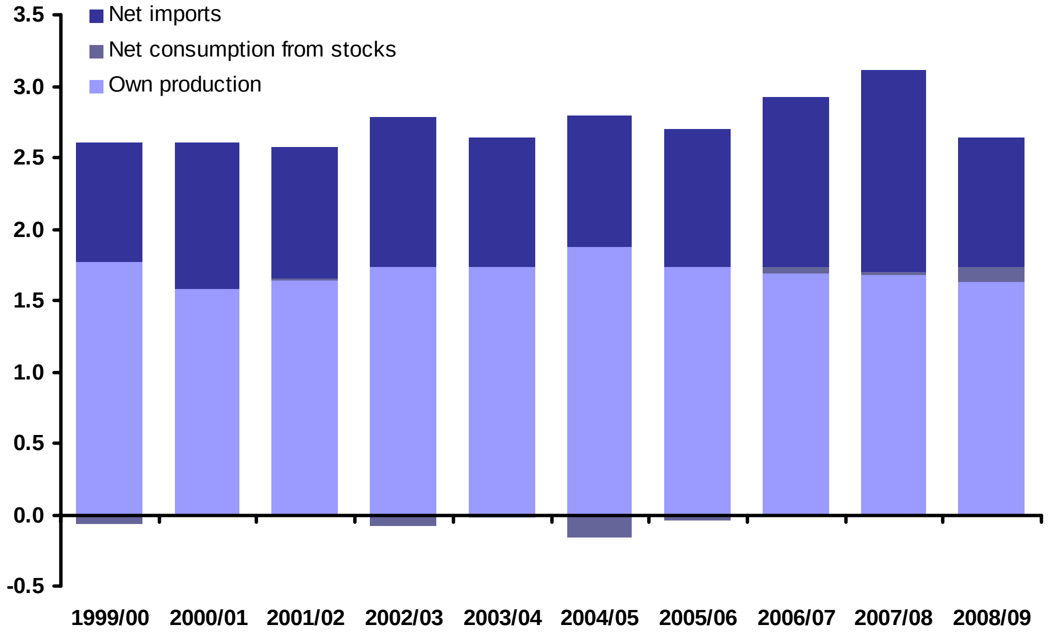
Source: Based on data from USDA (2009).

Figure 13: Production of maize worldwide, by producer in million tonnes



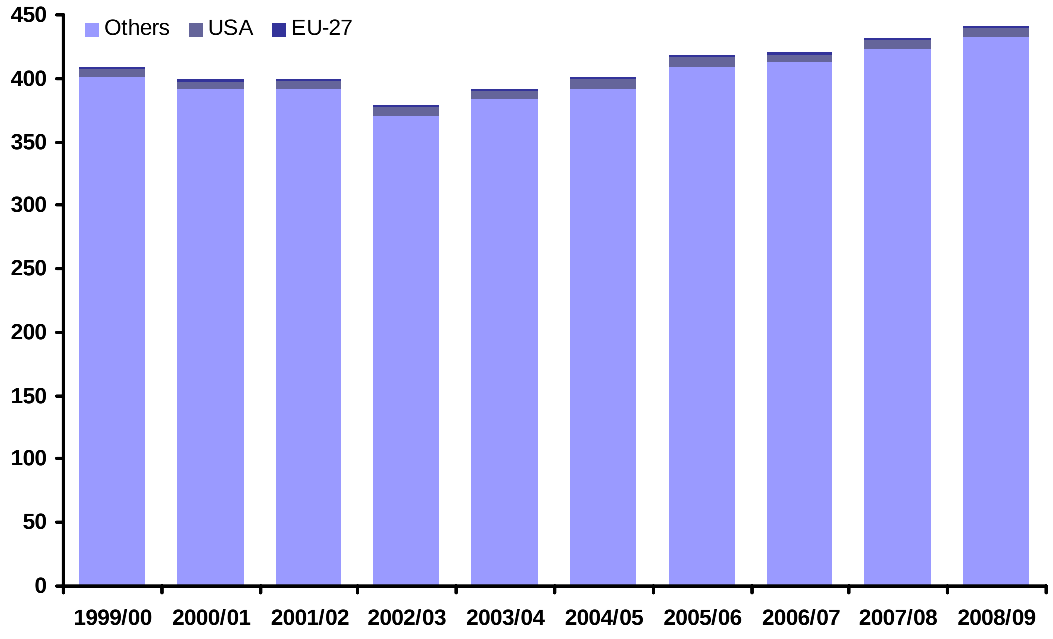
Source: Based on data from USDA (2009).

Figure 14: Consumption of milled rice in the EU-27, by sources in million tonnes



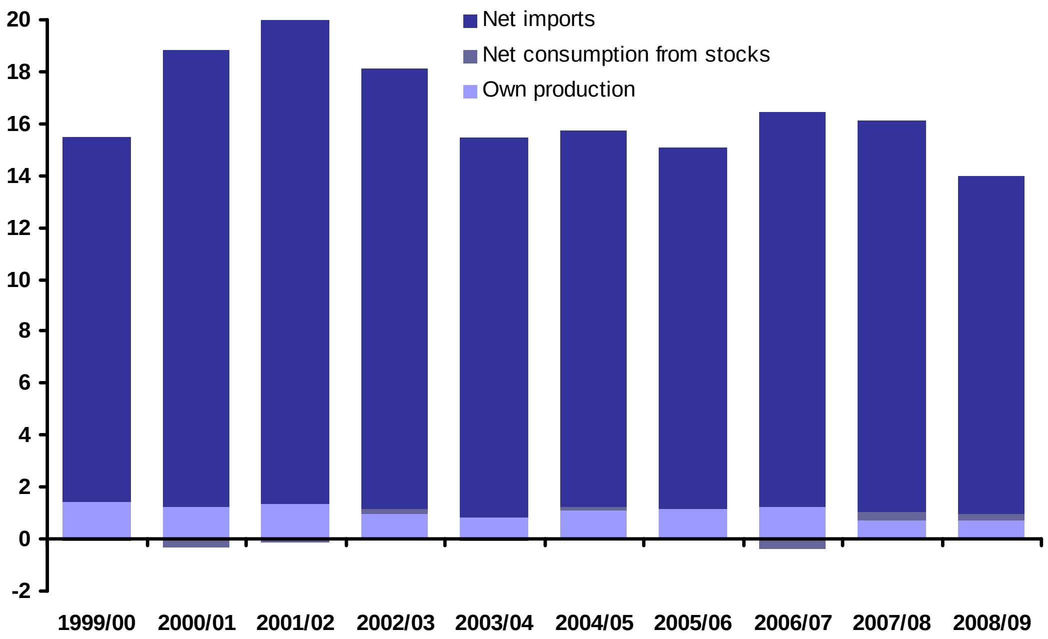
Source: Based on data from USDA (2009).

Figure 15: Production of milled rice worldwide, by producer in million tonnes



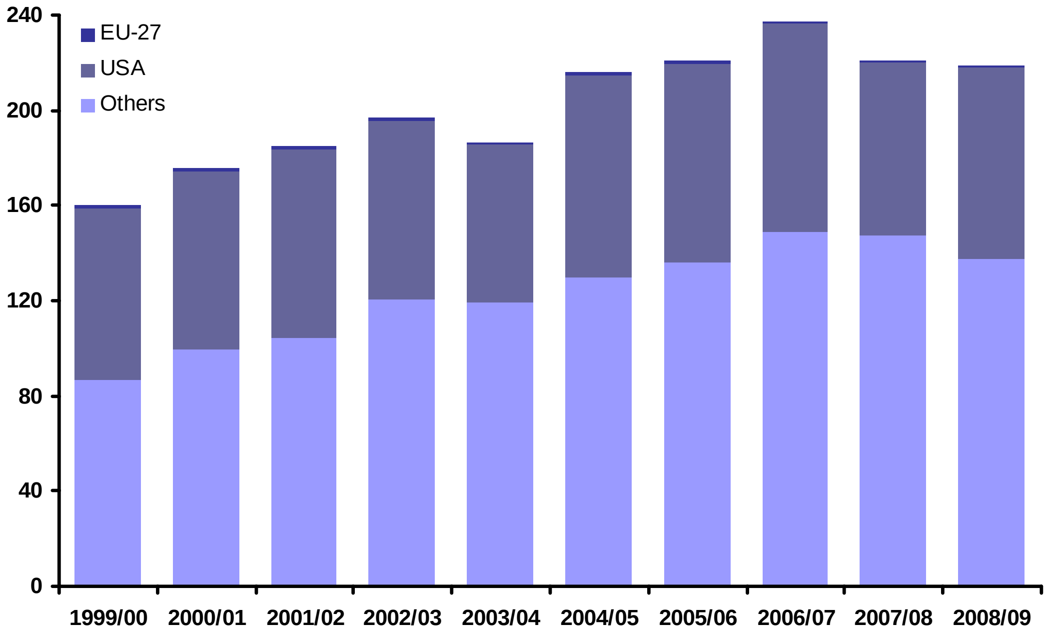
Source: Based on data from USDA (2009).

Figure 16: Consumption of soybeans in the EU-27, by sources in million tonnes



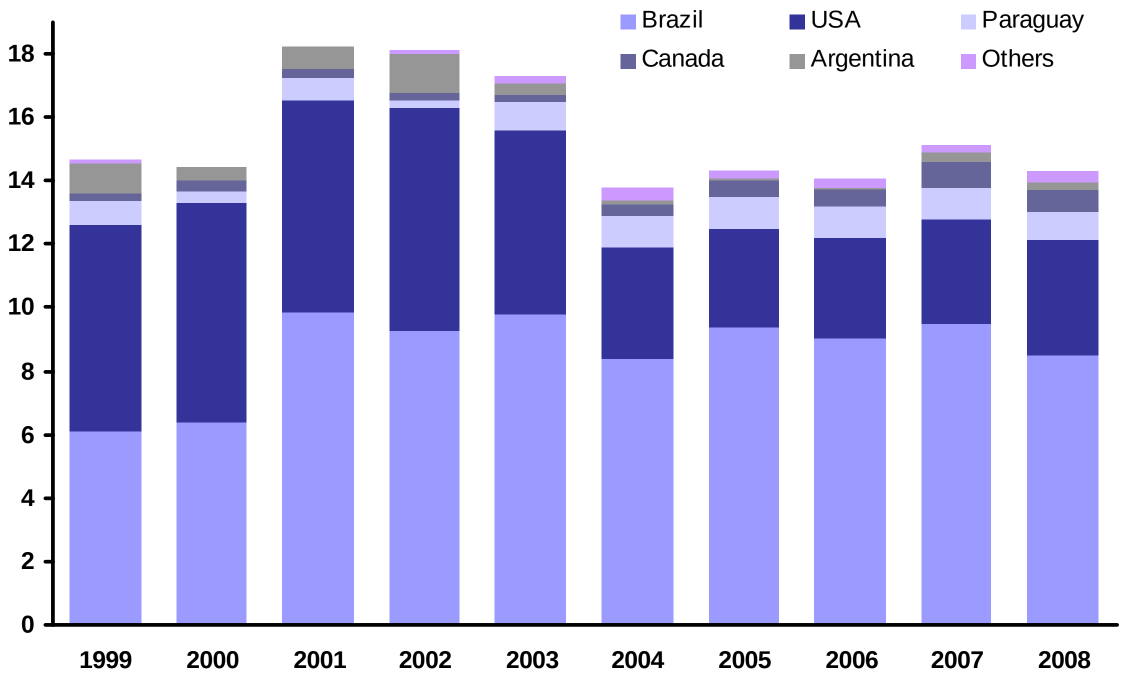
Source: Based on data from USDA (2009).

Figure 17: Production of soybeans worldwide, by producer in million tonnes



Source: Based on data from USDA (2009).

Figure 18: Net imports of soybeans into the EU-25 from the rest of the world, 1999-2008, by country in million tonnes (excl. soybeans for sowing)



Source: Based on data from Eurostat (2009).

Overview tables of current and future GM crops

On November 12-13, 2008, a workshop on "The global commercial pipeline of new GM crops" was organised by the European Commission's Joint Research Centre, Institute for Prospective Technological Studies (JRC-IPTS). The workshop gathered scientists from private and public institutions, regulators and experts involved in the development, authorisation and commercialisation of GM crops worldwide. One of the main outcomes of this workshop is a database on the global pipeline of GM crops that may be commercialised in the short to medium term worldwide (Stein and Rodríguez-Cerezo 2009). The database was compiled for the crops for which GM varieties exist or are likely to be marketed in the near future (mainly soybeans, maize, rapeseed, cotton, sugar beet, potatoes and rice). Information was obtained from participants of the workshop; additional information was taken from the websites of government authorities, as well as from databases of the OECD, AGBIOS, BIO and the Biosafety Clearing-House.

In the following overview tables the information of this database is reproduced by crop. To classify the pipeline, five categories were established according to the proximity of the respective GM "event" to market:

- **Commercial crop**: commercialised GM events (those currently marketed in at least one country worldwide).
- **Commercial pipeline**: GM events authorised in at least one country but not yet commercialised (commercialisation only depends on the decision by the developer).
- **Regulatory pipeline**: GM events already in the regulatory process to be marketed in at least one country.
- **Advanced R&D pipeline**: GM events not yet in the regulatory process but at late stages of development (large-scale multi-location field trials, generation of data for the authorisation dossier).
- **Other crops**: GM events authorised in at least one country, but not commercialised or commercialised once but "phased out" commercially or legally afterwards.

These categories only provide the **short to medium term pipeline** of commercial or "soon-to-be" commercial GM events (until 2015). We have not included GM crops at early stages of R&D because of the inherent uncertainties relating to their eventual commercialisation – and one reason underlying the workshop was the focus on the issue of LLP and trade, for which a more precise pipeline is required.

The tables only list the status of individual GM "events"; so-called **stacked GM crops** – i.e. those obtained by conventional crossings of existing GM events – are not included. As discussed in the workshop, the regulatory approach to these stacked GM crops differs across the world. In the EU, a new risk assessment and authorisation dossier is required even if the "parental" GM events are already authorised, making stacked GM crops a particular case in the context of AA and trade. The case and regulatory situation of stacked crops is discussed in detail in Section 4.3.

Regarding the **country** information, in addition to the EU, countries included in the overview tables are those relevant in the context of LLP and trade, i.e. the main net exporters and net importers of each crop (according to FAOSTAT data from 2004/05; for cotton data on cotton seed was used, for sugar beet the information provided by the developer). Also, countries with relevance as **developers** or growers of GM crops are included. In any case the list of countries is not exhaustive. The **timeline** given for events that are not yet commercialised represents only an estimate by the developer or the experts present at the workshop of when the crop in question may first be commercialised in any one country. If the estimation is made by the authors due to lack of information during the workshop, the year is given in brackets.

These overview tables were circulated among the workshop participants and, combining all the data, represent the most authoritative information in this report. However, given the complexity and the dynamic development of the information, errors and mistakes can still occur and are, of course, entirely assumed by the authors. To double-check individual pieces of information, an overview of the most important publicly available sources on the commercialisation and regulation of GM crops is given in the list of "Relevant links and sources" on p. 54. Also, the information in the tables only reflects the **status until January 2009**; again more up-to-date information on new GM crops may be found in the "Relevant links and sources". In parallel to this report this information is also published in the form of an Excel database (Stein and Rodríguez-Cerezo 2009), which is planned to be updated on http://agrilife.jrc.ec.europa.eu/pipeline.htm.

Development stage: legend of the terms used

Field trials	-	Field trials with the GM crop have been carried out (and no further or more detailed information is available).
Planned [year]	-	First year (or period) when the developer of a new GM crop expects to commercialise the GM crop.
Environmental release	-	For China there are three steps prior to the authorisation of a GM crop for commercialisation: field trials, environmental release trials and pre-production trials.
Pre-production trials	-	For China there are three steps prior to the authorisation of a GM crop for commercialisation: field trials, environmental release trials and pre-production trials.
Biosafety research (level I)	-	For India the contained field trials for regulatory studies – which are required for the authorisation of a GM crop – comprise three steps: trials for event selection, trials for biosafety research (level I) and trials for biosafety research (level II).
Phase 3	-	For Monsanto there are four R&D phases between "discovery" and "launch": Phase 1 (proof of concept), Phase 2 (early development), Phase 3 (advanced development) and Phase 4 (pre-launch).
Old research event	-	The GM crop had been authorised (in the country where the R&D took place) but subsequently it has not been commercialised.

Regulatory status: legend of the terms used

[Blank field]	-	A dossier for authorisation of the GM crop has not yet been submitted or there is no information available. For stacked GM crops some countries do not require a new authorisation if their parental lines are authorised already.
Target	-	The developer of a new GM crop plans to commercialise the crop in the given country.
Planned	-	The developer of a new GM crop plans to submit a dossier for authorisation.
Expected	-	Regulators know about a new GM crop and expect that the developer eventually submits a dossier for authorisation of the crop.
Assessment	-	The developer has submitted a dossier that is currently under assessment by the authorities.
Withdrawn	-	The developer has withdrawn the application.
Pending	-	The authorities have finalised their assessment of the dossier and the final decision is pending
Rejected	-	The decision makers have rejected the approval of the GM crop.
Field	-	The decision makers have authorised field tests with the GM crop.
Feed	-	The GM crop has been authorised to be used for feed.
Food & feed	-	The GM crop has been authorised to be used for food and feed.
Planting	-	The GM crop has been authorised to be used for planting / cultivation.
All	-	The GM crop has been authorised to be used for all purposes.
[year]-[year]	-	The GM crop has been authorised to be used for the given time period only. (Time limits are reported for the EU only – even though e.g. in the USA the approval of a GM crop can also have time limits; for these please see http://www.epa.gov/pesticides/biopesticides/pips/.)
Renewal	-	The developer of a GM crop has requested a renewal of the authorisation of the crop after the authorisation has expired and the process of authorising the crop again is currently ongoing.
Expired [year]	-	The authorisation of the GM crop has expired in the given year.
[Colour code]	-	The commercial use of the GM crop has been authorised in the respective country in some way (planting, food or feed).
[Colour code]	-	In the respective country, some form of commercial use of the GM crop (planting, food or feed) is due to be authorised soon.
[Colour code]	-	The commercial use of the GM crop is not authorised in the respective country; LLP of the corresponding event may not be tolerated (according to current regulations this is for instance the case in the EU).

Notes: (i) In some cases with overlapping authorisation requests only the current status or the status of the most advanced dossier is reported (e.g. if there is request for a renewal of an authorisation for a crop that is still authorised, then only the current status is reported, or if there is a request for a renewal and a parallel authorisation request under a different regulatory process, then only the renewal is reported).
(ii) If there are different years of approval for the various purposes (e.g. for "planting" and "food & feed"), here only the last year in which any of the approvals was made is reported. Only in case one of the decisions is till pending this is noted separately.

Abbreviations used in the tables

ALS	-	acetolactate synthase
CAAS	-	Chinese Academy of Agricultural Sciences
CICR	-	Central Institute for Cotton Research, India
cont.	-	content
HPPD inhib.	-	hydroxyphenylpyruvate dioxygenase inhibitors
IRRI	-	International Rice Research Institute, Philippines
LLP	-	low-level presence
n/a	-	not available
PLRV	-	potato leaf roll virus
PVY	-	potato virus Y
R&D	-	research and development
res. / resist.	-	resistance
tol.	-	tolerance

List of overview tables

Overview 1: Commercial GM soybeans and GM soybeans in the commercial and regulatory pipeline worldwide

Unique identifier	MON-Ø4Ø32-6	MON-89788-1	ACS-GMØØ5-3	ACS-GMØØ6-4	DP356Ø43-5	DP-3Ø5423-1	BPS-CV127-9	
Event name / gene(s)	MON 40-3-2 *	MON89788	A2704-12	A5547-127	356043	305423 *	CV127	Gna
Product name	Roundup Ready	Roundup Ready 2	LibertyLink	LibertyLink	Optimum GAT	High oleic	Imi	
Developer	Monsanto	Monsanto	Bayer	Bayer	Pioneer	Pioneer	BASF / Embrapa	China
Trait	Glyphosate tol.	Glyphosate tol.	Glufosinate tol.	Glufosinate tol.	Glyphosate tol., ALS tol.	Oleic acid cont.	Imidazolinone tol.	Insect resist.
Timeline	commercialised	2009	2009	(2012)	2011	2010	2011	(2010)
Development stage								Pre-production trials
Regulatory status in								
EU (net importer)	Food & feed: renewal, planting: assessment	Food & feed: 2008-18	Food & feed: 2008-18	Food & feed: assessment	Food & feed: assessment	Food & feed: assessment	Food & feed: assessment	
Net exporters								
USA	All: 1994	All: 2007	All: 1998	All: 1998	All: 2008	Assessment	All: assessment	
Brazil	All: 1998		Assessment				All: assessment	
Argentina	All: 1996		Pending	Pending			Planned	
Paraguay	All: 2004							
Canada	All: 1996	All: 2007	All: 2000	All: 2000	Expected	Expected	All: assessment	
Uruguay	All: 1997							
Ukraine								
Net importers								
China	Food & feed: 2004						Planned	Assessment
Japan	All: 2005	All: 2008	All: 2006	All: 2006	Field: till 2007	Field: till 2009	Food & feed: assessment	
Mexico	All: 1998		Food & feed: 2003	Food & feed: 2003			Planned	

* A stack of DP-3Ø5423-1x MON-Ø4Ø32-6 is under assessment for use as food & feed in the EU.

Overview 2: GM soybeans in the advanced R&D pipeline worldwide

Unique identifier	MON-87769-7			MON-87754-1					
Event name / gene(s)	MON87769			MON87754					
Product name	Omega-3 enriched	Dicamba-tolerant	Insect protected & RR2	Vistive III	Nematode	HPPD	DHT	GlyTol + HPPD	Glufosinate + HPPD
Developer	Monsanto	Monsanto	Monsanto	Monsanto	Syngenta	Syngenta	Dow	Bayer	Bayer
Trait	Stearidonic acid cont.	Dicamba tol.	Insect res., Glyphosate tol.	Oleic acid cont.	Nematode res.	HPPD inhib. tol.	Herbicide tol.	Glyphosate tol., HPPD inhib. tol.	Glufosinate tol., HPPD inhib. tol.
Timeline	(2012)	(2012)	(2013)	(2014)	(2011)	(2014)	2013	2015	2015
Development stage	Phase 3	Phase 3	Phase 3	Phase 3				Planned 2015	Planned 2015
Regulatory status in									
EU (net importer)								Planned	Planned
Net exporters									
USA	Target	Target		Target			Planned 2013	Planned	Planned
Brazil		Target	Target					Planned	Planned
Argentina		Target						Planned	Planned
Paraguay									
Canada		Expected						Planned	Planned
Uruguay									
Ukraine									
Net importers									
China									
Japan	Field: till 2010			Field: till 2010				Planned	Planned
Mexico									

Overview 3: Other GM soybeans (never commercialised or phased out)

Unique identifier	DD-Ø26ØØ5-3	ACS-GMØØ1-8	ACS-GMØØ2-9	ACS-GMØØ3-1	ACS-GMØØ4-2	(ACS-GMØØ5-3)
Event name / gene(s)	260-05	W62	W98	GU262	A2704-21	A5547-35
Product name					LibertyLink	LibertyLink
Developer	Pioneer	Bayer	Bayer	Bayer	Bayer	Bayer
Trait	Oleic acid cont.	Glufosinate tol.	Glufosinate tol.	Glufosinate tol.	Glufosinate tol.	Glufosinate tol.
Timeline	-- not commercialised --					
Regulatory status in						
EU (net importer)					Field: in 2004	Field: in 2004
Net exporters						
USA	All: 1997	Planting: 1996	Planting: 1996	Planting: 1998	Planting: 1996	Planting: 1996
Brazil						
Argentina						
Paraguay						
Canada	All: 2000					
Uruguay						
Ukraine						
Net importers						
China						
Japan	All: 2007					
Mexico					Food & feed: 2003	Food & feed: 2003

Overview 4: Commercial GM maize and GM maize in the commercial and regulatory pipeline worldwide

Unique identifier	DAS-Ø15Ø7-1	DAS-59122-7	MON-ØØ81Ø-6	MON-ØØ863-5	MON-ØØ6Ø3-6	MON-88Ø17-3	MON-ØØØ21-9
Event name / gene(s)	1507	59122	MON810	MON863	NK603	MON88017	GA21
Product name	Herculex I	Herculex RW	YieldGard Corn Borer	YieldGard Rootworm	Roundup Ready Corn 2	YieldGard VT	Agrisure GT
Developer	Dow / Pioneer	Dow / Pioneer	Monsanto	Monsanto	Monsanto	Monsanto	Syngenta
Trait	Lepidopteran resist.	Coleopteran resist.	Lepidopteran resist.	Coleopteran resist.	Glyphosate tol.	Coleopteran res.	Glyphosate tol.
Timeline	commercialised	commercialised	commercialised	commercialised	commercialised	commercialised	commercialised
Regulatory status in							
EU (net importer)	Food & feed: 2006-16	Food & feed: 2007-17, planting: assessment	All: renewal	Food & feed: 2006-16	Food & feed: 2005-15, planting: assessment	All: assessment	Food & feed: 2008-18, planting: assessment
Net exporters							
USA	All: 2001	All: 2005	All: 1996	All: 2002	All: 2000	All: 2005	All: 1997
Argentina	All: 2005		All: 1998		All: 2004	Assessment	All: 2005
Brazil	All: 2008		All: 2007		All: 2008		All: 2008
Ukraine							
South Africa	Food & feed: 2002		All: 1997		Food & feed: 2002		Food & feed: 2002
India							
China		Food & feed: 2006	Food & feed: 2004	Food & feed: 2004	Food & feed: 2005		Food & feed: 2004
Serbia and Monte.							
Thailand							
Paraguay							
Net importers							
Japan	All: 2005	All: 2006	All: 2004	All: 2004	All: 2004	All: 2006	All: 2005
South Korea	Food & feed: 2004	Food & feed: 2005	Food & feed: 2004	Food & feed: 2004	Food & feed: 2004	Food & feed: 2006	Food & feed: 2005
Mexico	Food & feed: 2003	Food & feed: 2004	Food & feed: 2002	Food & feed: 2003	Food & feed: 2002	Food & feed: 2006	Food & feed: 2002
Egypt							
Malaysia							
Colombia							Assessment
Algeria							
Iran							
Canada	All: 2002	All: 2005	All: 1997	All: 2003	All: 2001	All: 2006	All: 1999

Overview 4 (cont.): Commercial GM maize and GM maize in the commercial and regulatory pipeline worldwide

Unique identifier	SYN-BTØ11-1	SYN-IR6Ø4-5	MON-89Ø34-3	REN-ØØØ38-3	SYN-E3272-5	SYN-IR162-4	DP-Ø9814Ø-6
Event name	Bt11	MIR604	MON89034	LY038	3272	MIR162	98140
Product name	Agrisure CB	Agrisure RW	YieldGard VT PRO			Agrisure Viptera	Optimum GAT
Developer	Syngenta	Syngenta	Monsanto	Monsanto	Syngenta	Syngenta	Pioneer
Trait	Lepidopteran resist.	Coleopteran resist.	Lepidopteran resist.	High lysine cont.	Amylase cont.	Lepidopteran resist.	Glyphosate tol., ALS-inhib. tol.
Timeline	commercialised	commercialised	2009	(2010)	2009	2009	2010
Regulatory status in							
EU (net importer)	Food & feed: 2004-14	Food & feed: assessment	Food & feed: pending	Food & feed: assessment	Food & feed: assessment		Food & feed: assessment
Net exporters							
USA	All: 1996	All: 2007	All: 2008	All: 2006	Food & feed: 2007, planting: assessment	Pending	Food & feed: 2008, planting: assessment
Argentina	All: 2001		Assessment	Withdrawn		Assessment	Assessment
Brazil	All: 2007		Assessment			Assessment	
Ukraine							
South Africa	All: 2003						
India							
China	Food & feed: 2004						
Serbia and Monte.							
Thailand							
Paraguay							
Net importers							
Japan	All: 2007	All: 2007	All: 2008	All: 2007	All: 2005	Assessment	Field: till 2009
South Korea	Food & feed: 2006	Food: 2007			Assessment	Assessment	
Mexico	Food & feed: 2007	Food & feed: 2007		Feed: 2007	Food & feed: 2008	Assessment	
Egypt							
Malaysia							
Colombia	All: 2007					Assessment	
Algeria							
Iran							
Canada	All: 1996	All: 2007	All: 2008	All: 2006	All: 2008	Pending	Expected

Overview 4 (cont.): Commercial GM maize and GM maize in the commercial and regulatory pipeline worldwide

Unique identifier			
Event name / gene(s)	Cry1A	Lysine	Phytase
Product name			
Developer	China	China	China
Trait	Insect resist.	Lysine cont.	Phytase cont.
Timeline	(2009)	(2010)	(2010)
Development stage	Pre-production trials	Pre-production trials	Pre-production trials
Regulatory status in			
EU (net importer)			
Net exporters			
USA			
Argentina			
Brazil			
Ukraine			
South Africa			
India			
China	Assessment	Assessment	Assessment
Serbia and Monte.			
Thailand			
Paraguay			
Net importers			
Japan			
South Korea			
Mexico			
Egypt			
Malaysia			
Colombia			
Algeria			
Iran			
Canada			

Overview 5: Commercial GM maize stacks and GM maize stacks in the commercial and regulatory pipeline worldwide

Unique identifier	MON-ØØ863-5 x MON-ØØ6Ø3-6	MON-ØØ863-5 x MON-ØØ81Ø-6	MON-ØØ6Ø3-6 x MON-ØØ81Ø-6	DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6	DAS-59122-7 x MON-ØØ6Ø3-6	MON-ØØ863-5 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6
Event name / gene(s)	MON863 x NK603	MON863 x MON810	NK603 x MON810	1507 x NK603	59122 x NK603	MON863 x MON810 x NK603
Product name	-- See parental lines --					
Trait						
Timeline						
Regulatory status in						
EU (net importer)	Food & feed: renewal	Feed: renewal	Food & feed: 2007-17, planting: assessment	Food & feed: 2007-17, planting: assessment	Food & feed: pending	Food & feed: pending
Net exporters						
USA						
Argentina			All: 2007	All: 2008		
Brazil						
Ukraine						
South Africa			All: 2007			
India						
China						
Serbia and Monte.						
Thailand						
Paraguay						
Net importers						
Japan	All: 2004	All: 2005	All: 2004	All: 2005	All: 2006	All: 2004
South Korea	Food: 2004	Food: 2004	Food: 2004	Food: 2004	Food: 2006	Food: 2004
Mexico	Food & feed: 2004	Food & feed: 2006	Food & feed: 2004	Food & feed: 2004	Food & feed: 2006	Food & feed: 2006
Egypt						
Malaysia						
Colombia						
Algeria						
Iran						
Canada		All: 2004				

Overview 5 (cont.): Commercial GM maize stacks and GM maize stacks in the commercial and regulatory pipeline worldwide

Unique identifier	REN-ØØØ38-3 x MON-ØØ81Ø-6	MON-88Ø17-3 x MON-ØØ81Ø-6	MON-89Ø34-3 x MON-ØØ6Ø3-6	MON-89Ø34-3 x MON-88Ø17-3	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7
Event name / gene(s)	LY038 x MON810	MON88017 x MON810	MON89034 x NK603	MON89034 x MON88017	MON89034 x 1507 x MON88017 x 59122
Product name					
Developer					
Trait			-- See parental lines --		
Timeline					
Regulatory status in					
EU (net importer)	Food & feed: assessment	Food & feed: assessment	Food & feed: assessment	Food & feed: assessment	Food & feed: assessment
Net exporters					
USA					
Argentina	Withdrawn			Assessment	
Brazil					
Ukraine					
South Africa					
India					
China					
Serbia and Monte.					
Thailand					
Paraguay					
Net importers					
Japan	All: 2007	All: 2006	All: 2008	All: 2008	
South Korea		Food: 2006			
Mexico		Food & feed: 2006			
Egypt					
Malaysia					
Colombia					
Algeria					
Iran					
Canada					

Overview 5 (cont.): Commercial GM maize stacks and GM maize stacks in the commercial and regulatory pipeline worldwide

Unique identifier	DAS-Ø15Ø7-1 x DAS-59122-7	DAS-59122-7 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6	SYN-IR6Ø4-5 x MON-ØØØ21-9	SYN-BTØ11-1 x MON-ØØØ21-9	SYN-BTØ11-1 x SYN-IR6Ø4-5	SYN-BTØ11-1 x SYN-IR6Ø4-5 x MON-ØØØ21-9
Event name / gene(s)	1507 x 59122	59122 x 1507 x NK603	MIR604 x GA21	Bt11 x GA21	Bt11 x MIR604	Bt11 x MIR604 x GA21
Product name	Herculex XTRA		Agrisure GT/RW	Agrisure GT/CB	Agrisure CB/RW	Agrisure 3000GT
Developer						
Trait	-- See parental lines --					
Timeline						
Regulatory status in						
EU (net importer)	All: assessment	All: assessment	Food & feed: assessment	Food & feed: assessment	Food & feed: assessment	Food & feed: assessment
Net exporters						
USA			All: 2006	All: 1997	All: 2006	All: 2006
Argentina				Pending		
Brazil				Assessment		
Ukraine						
South Africa			Assessment	Assessment	Assessment	Assessment
India						
China						
Serbia and Monte.						
Thailand						
Paraguay						
Net importers						
Japan	All: 2006	All: 2006	All: 2007	All: 2007	All: 2008	All: 2008
South Korea	Food: 2006	Food: 2006	Food: 2008	Food: 2006	Food: 2008	Food: 2008
Mexico	Food & feed: 2006	Food & feed: 2006	Food & feed: 2007	Food & feed: 2007	Food & feed: 2007	Food & feed: 2008
Egypt						
Malaysia						
Colombia						
Algeria						
Iran						
Canada			All: 2007	All: 1997	All: 2007	All: 2007

Overview 6: GM maize in the advanced R&D pipeline worldwide *

Unique identifier	MON-87754-1						
Event name / gene(s)	MON87754						cry1Ac + cp4epsp4
Product name	High-oil	Drought tolerant	DHT	Optimum AcreMax 1	Drought tolerant	NutriDense	
Developer	Monsanto	Monsanto / BASF	Dow	Pioneer	Syngenta	BASF	India
Trait	High oil cont.	Drought tol.	Herbicide tol.	Coleopteran resist.	Drought tol.	Protein cont., Amino acid cont., Phytase cont.	Insect resist.
Timeline	(2010)	2012	2012	2010	(2015)	(2015)	(2014)
Development stage	Phase 3	Phase 3					Biosafety research (level I)
Regulatory status in							
EU (net importer)							
Net exporters							
USA	Target		Planned 2012				
Argentina	Target						
Brazil	Target						
Ukraine							
South Africa							
India							
China							
Serbia and Monte.							
Thailand							
Paraguay							
Net importers							
Japan	Field: till 2010						
South Korea							
Mexico							
Egypt							
Malaysia							
Colombia							
Algeria							
Iran							
Canada	Expected						

* Apart from developing new events, especially for maize there is a growing tendency of stacking more and more existing events in one variety (triple stacking, quadruple stacking, etc.).

Overview 7: Other GM maize (never commercialised or phased out)

Unique identifier	MON-ØØØ21-9 x MON-ØØ81Ø-6		MON-8Ø2ØØ-7	PH-MON8Ø9-2	DKB-8979Ø-5	DKB-89614-9
Event name / gene(s)	GA21 x MON810	MON801	MON802	MON809	DLL25 (B16)	DBT418
Product name			YieldGard			Bt Xtra
Developer	Stack – see parental lines	Monsanto	Monsanto	Monsanto	Monsanto	Monsanto
Trait		Lepidopteran resist.	Lepidopt. res., Glyphosate tol.	Lepidopteran resist.	Glufosinate tol.	Lepidopteran res., Glufosinate tol.
Timeline	-- not commercialised --					
Regulatory status in						
EU (net importer)	Food & feed: expired 2007					
Net exporters						
USA		Food & feed: 1995	All: 1997	All: 1996	All: 1996	All: 1997
Argentina						All: 1998
Brazil						
Ukraine						
South Africa						
India						
China						
Serbia and Monte.						
Thailand						
Paraguay						
Net importers						
Japan	All: 2005				All: 2006	All: 2007
South Korea					Food: 2004	Food: 2004
Mexico						
Egypt						
Malaysia						
Colombia						
Algeria						
Iran						
Canada			All: 1997	All: 1996	All: 1996	All: 1997

Overview 7 (cont.): Other GM maize (never commercialised or phased out)

Unique identifier	SYN-EV176-9		PH-ØØØ676-7	PH-ØØØ678-9	PH-ØØØ68Ø-2
Event name / gene(s)	Bt176	Bt10	676	678	680
Product name	NaturGard KnockOut				
Developer	Syngenta	Syngenta	Pioneer	Pioneer	Pioneer
Trait	Lepidopteran resist.	Lepidopt. res., Glufosinate tol.	Male fertility, Glufosinate tol.	Male fertility, Glufosinate tol.	Male fertility, Glufosinate tol.
Timeline	-- not commercialised --				
Regulatory status in					
EU (net importer)	All: expired 2007				
Net exporters					
USA	All: 1995		All: 1998	All: 1998	All: 1998
Argentina	All: 1998				
Brazil					
Ukraine					
South Africa	Food & feed: 2001				
India					
China	Food & feed: 2004				
Serbia and Monte.					
Thailand					
Paraguay					
Net importers					
Japan	All: 2007	Field: till 2008			
South Korea	Food & feed: 2006				
Mexico					
Egypt					
Malaysia					
Colombia					
Algeria					
Iran					
Canada	All: 1996				

Overview 7 (cont.): Other GM maize (never commercialised or phased out)

Unique identifier	ACS-ZMØØ1-9	ACS-ZMØØ2-1	ACS-ZMØØ3-2	ACS-ZMØØ4-3	ACS-ZMØØ5-4	DAS-Ø6275-8
Event name / gene(s)	MS3	T14	T25	CBH-351	MS6	TC6275 (CBH-351)
Product name		LibertyLink	LibertyLink	Starlink	InVigor	
Developer	Bayer	Bayer	Bayer	Bayer	Bayer	Dow
Trait	Male fertility, Glufosinate tol.	Glufosinate tol.	Glufosinate tol.	Lepidopt. res., Glufosinate tol.	Male fertility, Glufosinate tol.	Lepidopteran resist.
Timeline	-- not commercialised --					
Regulatory status in						
EU (net importer)	All: renewal *					
Net exporters						
USA	All: 1996	All: 1995	All: 1995	Feed: 1998	All: 1999	All: 2004
Argentina		All: 1999	All: 1998			
Brazil			All: 2007			
Ukraine						
South Africa			Food & feed: 2001			
India						
China			Food & feed: 2004			
Serbia and Monte.						
Thailand						
Paraguay						
Net importers						
Japan		All: 2006	All: 2004			All: 2008
South Korea			Food & feed: 2004			
Mexico		Food & feed: 2007	Food & feed: 2007			
Egypt						
Malaysia						
Colombia						
Algeria						
Iran						
Canada	All: 1998	All: 1997	All: 1997			All: 2006

* Authorisation of this GM maize is only renewed in the EU to avoid problems with traces (LLP) of the event in seeds and imports.

Overview 8: Commercial GM rapeseed and GM rapeseed in the regulatory and advanced R&D pipeline worldwide

Unique identifier	MON-ØØØ73-7	ACS-BNØØ5-8 x ACS-BNØØ3-6	ACS-BNØØ8-2						
Event name / gene(s)	GT73 (RT73)	MS8 x RF3	T45 (HCN28)*	GM					
Product name	Roundup Ready	InVigor	LibertyLink						
Developer	Monsanto	Bayer	Bayer	China	Bayer	Bayer	Bayer	BASF	BASF
Trait	Glyphosate tol.	Male fertility, Glufosinate tol.	Glufosinate tol.	n/a	Herbicide tol.	Disease resist.	Oil cont.	Fatty acid cont.	Oil cont.
Timeline	commercialised	commercialised	commercialised	(2011)	2011-2013	2011-2013	(2014)	(2013)	(2015)
Development stage				Pre-production trials					
Regulatory status in									
EU (net exporter)	Food & feed: renewal	Food & feed: renewal	Food & feed: 2009-19						
Net exporters									
Canada	All: 1995	All: 1997	All: 1997						
Australia	All: 2003	All: 2003	All: 2003						
Ukraine									
Russia									
Net importers									
Japan	All: 2006	All: 2007	All: 2007						
Mexico	Food & feed: 1996	Food & feed: 2004	Food & feed: 2001						
Pakistan									
China	Food & feed: 2004	Food & feed: 2004	Food & feed: 2004	Assessment					
USA	All: 1999	All: 1999	All: 1998						
Bangladesh									

* Authorisation of this event was only renewed in the EU to avoid problems with traces (LLP) of the event in seeds and imports as this event is currently being phased out.

Overview 9: Other GM rapeseed (never commercialised or phased out)

Unique identifier	ACS-BNØØ4-7, ACS-BNØØ1-4, ACS-BNØØ4-7 x ACS-BNØØ1-4	ACS-BNØØ4-7, ACS-BNØØ2-5, ACS-BNØØ4-7 x ACS-BNØØ2-5	ACS-BNØØ7-1	ACS-BNØ11-5	MON-89249-2	
Event name / gene(s)	MS1, RF1, MS1xRF1	MS1, RF2, MS1xRF2	TOPAS19 / 2 (HCN92)	OXY-235	RT200 (GT200)	ZSR500, ZSR502, ZSR503
Product name	SeedLink	SeedLink		BXN Canola		
Developer	Bayer	Bayer	Bayer	Bayer	Monsanto	Monsanto
Trait	Male fertility, Glufosinate tol.	Male fertility, Glufosinate tol.	Glufosinate tol.	Oxynil tol.	Glyphosate tol.	Glyphosate tol.
Timeline	-- not commercialised --					
Regulatory status in						
EU (net exporter)	All: expired 2007	All: expired 2007	Food & feed: expired 2007		All: 1997	All: 1997
Net exporters						
Canada	All: 1995	All: 1995	All: 1995	All: 1997		
Australia	All: 2003	All: 2003	All: 2003			
Ukraine					All: 2006	
Russia						
Net importers						
Japan	All: 2007	All: 2007	All: 2007	All: 2008		
Mexico			Food & feed: 1996		All: 2002	
Pakistan						
China	Food & feed: 2004	Food & feed: 2004	Food & feed: 2004	Food & feed: 2004		
USA	All: 2002	All: 2002	All: 2002	Food & feed: 1999		
Bangladesh						

Overview 9 (cont.): Other GM rapeseed (never commercialised or phased out)

Unique identifier	CGN-89111-8	CGN-89465-2					
Event name	pCGN3828-212 / 86-18	pCGN3828-212 / 86-23 (23-198, 23-18-17)	MPS961	MPS962	MPS963	MPS964	MPS965
Product name			Phytaseed	Phytaseed	Phytaseed	Phytaseed	Phytaseed
Developer	Monsanto	Monsanto	BASF	BASF	BASF	BASF	BASF
Trait	Laurate cont.	Laurate cont., Myristate cont.	Phytase cont.	Phytase cont.	Phytase cont.	Phytase cont.	Phytase cont.
Timeline	-- not commercialised --						
Regulatory status in							
EU (net exporter)							
Net exporters							
Canada		All: 1996					
Australia							
Ukraine							
Russia							
Net importers							
Japan							
Mexico							
Pakistan							
China							
USA	Planting: 1994	All: 1995	Food & feed: 1999	Food & feed: 1999	Food & feed: 1999	Food & feed: 1999	Food & feed: 1999
Bangladesh							

Overview 10: Commercial GM cotton worldwide

Unique identifier	MON-ØØ531-6	MON-15985-7	MON-Ø1445-2	MON-88913-8	DAS-24236-5	DAS-21Ø23-5	ACS-GHØØ1-3
Event name / gene(s)	MON531	MON15985	MON1445	MON88913	281-24-236	3006-210-23	LLCotton25
Product name	Bollgard	Bollgard II	Roundup Ready	Roundup Ready Flex	Widestrike (*stack*)		LibertyLink
Developer	Monsanto	Monsanto	Monsanto	Monsanto	Dow		Bayer
Trait	Lepidopteran resist.	Lepidopteran resist.	Glyphosate tol.	Glyphosate tol.	Lepidopteran resist.		Glufosinate tol.
Timeline	commercialised	commercialised	commercialised	commercialised	commercialised		commercialised
Regulatory status in							
EU (net importer)	Food & feed: renewal	Food & feed: renewal	Food & feed: renewal	Food & feed: assessment	Food & feed: assessment		Food & feed: 2008-18
Net exporters*							
USA	All: 1995	All: 2002	All: 1995	All: 2005	All: 2004	All: 2004	All: 2003
Australia	All: 2003	All: 2002	All: 2003	All: 2006			All: 2006
Brazil	All: 2005	Assessment	All: 2008		Assessment		All: 2008
Côte d'Ivoire							
Zambia							
Burkina Faso		Planting: 2008					
Turkmenistan							
Net importers*							
Mexico	All: 1997	Food & feed: 2003	Food & feed: 2000	Food & feed: 2006	Food & feed: 2004	Food & feed: 2004	Food & feed: 2006
Japan	All: 2004	All: 2004	All: 2004	All: 2006	All: 2006		All: 2006
South Korea	Food & feed: 2004	Food & feed: 2004	Food & feed: 2004	Food & feed: 2006			Food & feed: 2005
Turkey							
South Africa	All: 1997	All: 2003	All: 2000	All: 2007			
Saudi Arabia							
GM countries							
India	All: 2002	All: 2006		Assessment	Assessment		
China	Food & feed: 2004	Food & feed: 2006	Food & feed: 2004				Food & feed: 2006
Argentina	All: 1998		All: 2001				

* Trade status relates to cotton seed.

Overview 10 (cont.): Commercial GM cotton worldwide

Unique identifier					
Event name / gene(s)	Cry1A + CpTI	Cry1Ab - Cry1Ac	Cry1A	Event 1	Cry1Ac
Product name	SGK321	GK19	GFM Cry 1A	JK-1	CICR
Developer	China (CAAS)	China (CAAS)	India (Nath Seeds)	India (JK Agrigenetics)	India (CICR)
Trait	Lepidopteran resist.	Lepidopteran resist.	Lepidopteran resist.	Lepidopteran resist.	Lepidopteran resist.
Timeline	commercialised	commercialised	commercialised	commercialised	commercialised
Regulatory status in					
EU (net importer)					
Net exporters					
USA					
Australia					
Brazil					
Côte d'Ivoire					
Zambia					
Burkina Faso					
Turkmenistan					
Net importers					
Mexico					
Japan					
South Korea					
Turkey					
South Africa					
Saudi Arabia					
GM countries					
India			All	All	All
China	All	All			
Argentina					

Overview 11: GM cotton in the commercial and regulatory pipeline worldwide

Unique identifier	SYN-IR1Ø2-7	SYN-IR67B-1	BCS-GHØØ2-5		
Event name / gene(s)	COT102	COT67B	GHB614	Event 9124	Event 24
Product name			GlyTol		
Developer	Syngenta	Syngenta	Bayer	India (Metahelix)	India (JK Agrigenetics)
Trait	Lepidopteran resist.	Lepidopteran resist.	Glyphosate tol.	Lepidopteran resist.	Lepidopteran resist.
Timeline	(2009)	2009	2009	(2009)	(2009)
Regulatory status in					
EU (net importer)			Food & feed: assessment		
Net exporters					
USA	Pending	Pending	Assessment		
Australia	Food & feed: 2005	Assessment			
Brazil			Target		
Côte d'Ivoire					
Zambia					
Burkina Faso					
Turkmenistan					
Net importers					
Mexico	Pending	Assessment	Target		
Japan	Assessment	Assessment	Field: till 2010		
South Korea					
Turkey					
South Africa					
Saudi Arabia					
GM countries					
India			Target	Assessment	Assessment
China					
Argentina					

Overview 12: Commercial GM cotton stacks and GM cotton stacks in the commercial and regulatory pipeline worldwide

Unique identifier	MON-15985-7 x MON-Ø1445-2	MON-ØØ531-6 x MON-Ø1445-2	MON-88913-8 x MON-15985-7	ACS-GHØØ1-3 x MON-15985-7	DAS-24236-5 x DAS-21Ø23-5	DAS-24236-5 x DAS-21Ø23-5 x MON-88913-8	DAS-24236-5 x DAS-21Ø23-5 x MON-Ø1445-2	
Event name / gene(s)	MON15985 x MON1445	MON531 x MON1445	MON88913 x MON15985	LL25 x MON15985	281-24-236 / 3006-210-23	281 x 3006 x MON88913	281 x 3006 x MON1445	Event 1 x Event 24
Product name					Widestrike			JK Stack
Developer								
Trait					-- See parental lines --			
Timeline								
Regulatory status in								
EU (net importer)	Food & feed: renewal	Food & feed: renewal	Food & feed: assessment	Food & feed: assessment	Food & feed: assessment			
Net exporters								
USA					All: 2004			
Australia	All: 2006	All: 2006	All: 2006					
Brazil					Assessment			
Côte d'Ivoire								
Zambia								
Burkina Faso								
Turkmenistan								
Net importers								
Mexico	Food & feed: 2006	Food & feed: 2002			Food & feed: 2004	Food & feed: 2006	Food & feed: 2005	
Japan	All: 2005	All: 2004	All: 2006	All: 2007	All: 2006	All: 2006	All: 2006	
South Korea	Food: 2004	Food: 2004	Food: 2006	Food: 2007		Food: 2006	Food: 2006	
Turkey								
South Africa		All: 2005	All: 2007					
Saudi Arabia								
GM countries								
India			Assessment		Assessment			Assessment
China								
Argentina		All: 2009						

Overview 13: GM cotton in the advanced R&D pipeline worldwide *

Unique identifier										
Event name / gene(s)			cry1Ac	cry2Ab	cry2Ax1	cry1Ia5	vip	cry1Aa3	cry1F	asal
Product name	TwinLink	DHT								
Developer	Bayer	Dow	India	India	India	India	India	India	India	India
Trait	Lepidopt. res., Glufosinate tol.	Herbicide tol.	Insect resist.	Insect resist.	Insect resist.	Insect resist.	Insect resist.	Insect resist.	Insect resist.	Insect resist.
Timeline	2012	2013	2013	2013	2013	2013	2013	2013	2013	2013
Development stage										
Regulatory status in										
EU (net importer)										
Net exporters										
USA	Target	Target								
Australia										
Brazil	Target									
Côte d'Ivoire										
Zambia										
Burkina Faso										
Turkmenistan										
Net importers										
Mexico	Target									
Japan										
South Korea										
Turkey										
South Africa										
Saudi Arabia										
GM countries										
India	Target									
China										
Argentina										

* Apart from developing new events, especially for cotton there is a growing tendency of stacking more and more existing events in one variety (triple stacking, quadruple stacking, etc.).

Overview 14: Other GM cotton (never commercialised or phased out)

Unique identifier			MON-ØØ757-7	MON-89924-2	MON-89383-1	DD-Ø1951A-7	SYN-IR1Ø2-7	SYN-IR67B-1
Event name / gene(s)	BXN	31807 / 31808	MON757	MON1076	MON1698	19-51a	COT102	COT67B
Product name			Bollgard	Bollgard				
Developer	Monsanto	Monsanto	Monsanto	Monsanto	Monsanto	Pioneer	Syngenta	Syngenta
Trait	Oxynil tol.	Oxynil tol., Lepidopt. res.	Lepidopteran resist.	Lepidopteran resist.	Glyphosate tol.	Sulfonylurea tol., ALS tol.	Lepidopteran resist.	Lepidopteran resist.
Timeline	-- not commercialised --							
Development stage								
Regulatory status in								
EU (net importer)								
Net exporters								
USA	All: 1994	All: 1997	Food & feed: 1995	Food & feed: 1995	All: 1995	All: 1996	Food & feed: 2005	Assessment
Australia								
Brazil								
Côte d'Ivoire								
Zambia								
Burkina Faso								
Turkmenistan								
Net importers								
Mexico	Food & feed: 1996							
Japan			All: 2005				Field: till 2009	Field: till 2009
South Korea								
Turkey								
South Africa								
Saudi Arabia								
GM countries								
India								
China								
Argentina								

Overview 15: GM rice in the commercial and regulatory pipeline worldwide (incl. "other" GM rice)

Unique identifier	ACS-OSØØ2-5					ACS-OSØØ1-4	BCS-OSØØ3-7
Event name / gene(s)	LLRICE62	Bt63	KMD1	Xa21	B827	LLRICE06	LLRICE601
Product name	LibertyLink					LibertyLink	LibertyLink
Developer	Bayer	China	China	China	Iran	Bayer	Bayer
Trait	Glufosinate tol.	Insect resist.	Insect resist.	Leaf blight resist.	Insect resist.	Glufosinate tol.	Glufosinate tol.
Timeline	(2010)	(2009)	(2010)	(2010)	(2010)	-- not commercialised --	
Development stage		Pre-production trials	Pre-production trials	Pre-production trials	Released 2005, recalled 2006 *	Old research event	Old research event
Regulatory status in							
EU (net importer)	Food & feed: pending						
Net exporters							
USA	All: 2000					All: 2000	Planting: 2006
Uruguay							
Argentina	Assessment						
Paraguay							
China		Assessment	Assessment	Assessment			
India							
Russia							
Net importers							
Mexico	Food & feed: 2007						
Costa Rica							
Honduras							
Brazil	Assessment						
Guatemala							
El Salvador							
Uzbekistan							
GM countries							
Iran					Pending		

* The rice was recalled because of an inter-Ministerial lack of consultation and had to undergo a re-review of the safety assessment; currently the final pan-Ministerial approval is pending.

Overview 16: GM rice in the advanced R&D pipeline worldwide

Unique identifier							
Event name / gene(s)	HT Bayer	Bt Bayer	GR1	GR2	Bar68-1	CP iORF-IV	RTBV-ODs2
Product name			Golden Rice 1	Golden Rice 2			
Developer	Bayer	Bayer	IRRI	IRRI	China	India	India
Trait	Herbicide tol.	Insect resist.	Betacarotene cont.	Betacarotene cont.	Glufosinate tol.	Virus resist.	Tungro resist.
Timeline	2011-2013	2011-2013	2011	2012	(2012)	2012	2012
Development stage	Planned 2011-2013	Planned 2011-2013			Environmental release		
Regulatory status in							
EU (net importer)							
Net exporters							
USA							
Uruguay							
Argentina							
Paraguay							
China							
India			Planned 2011-2013	Planned 2014		Planned 2012	Planned 2012
Russia							
Net importers							
Mexico							
Costa Rica							
Honduras							
Brazil							
Guatemala							
El Salvador							
Uzbekistan							
GM countries							
Philippines			Planned 2011	Planned 2012			
Bangladesh			Planned 2013	Planned 2013			
Indonesia							
Pakistan							

Overview 16 (cont.): GM rice in the advanced R&D pipeline worldwide

Unique identifier							
Event name / gene(s)	chi11 tlp	cry1Ac	cry1Ab, cry1C & bar	Glyoxalase I & II	Osmotin	2-3 Bt events	Several Bt events
Product name							
Developer	India	India	India	India	India	Indonesia	Pakistan
Trait	Disease resist.	Insect resist.	Insect resist.	Salinity tol.	Drought tol.	Insect resist.	Insect resist.
Timeline	2013	2013-2015	2013-2015	2015+	2015+	(2015+)	(2015+)
Development stage		Biosafety research (level I)				Field trials	Field trials
Regulatory status in							
EU (net importer)							
Net exporters							
USA							
Uruguay							
Argentina							
Paraguay							
China							
India	Planned 2013	Planned 2013-2015	Planned 2013-2015	Planned 2015	Planned 2015		
Russia							
Net importers							
Mexico							
Costa Rica							
Honduras							
Brazil							
Guatemala							
El Salvador							
Uzbekistan							
GM countries							
Philippines							
Bangladesh							
Indonesia						Planned 2011+	
Pakistan							

Overview 17: GM potatoes in the regulatory and advanced R&D pipeline worldwide

Unique identifier	BPS-25271-9							
Event name / gene(s)	EH92-527-1	SY230	SY233		RB	Nt-Inhh, iIR-INV	A20 oxidase	GM
Product name	Amflora			Cisgenic				
Developer	BASF	Argentina (Tecnoplant)	Argentina (Tecnoplant)	AVEBE	India	India	India	China
Trait	Amylopectin cont.	PVY resist.	PVY resist.	Starch cont.	Late blight resist.	Reduction in cold-induced sweetening	Dwarfness	GM
Timeline	(2009)	(2012)	(2012)	(2014)	2011	2012	2012	(2014)
Development stage				Dossier ready for submission				Environmental release
Regulatory status in								
EU (net exporter)	All: pending			Target				
Net exporters								
Egypt								
Israel								
Canada								
China								
Turkey								
Iran								
India								
Lebanon								
Australia								
Net importers								
Russia								
Iraq								
Malaysia								
USA								
Algeria								
El Salvador								
Mexico								
GM countries								
Argentina		Planting: assessment	Planting: assessment					

Overview 18: Other GM potatoes (never commercialised or phased out)

Unique identifier	NMK-89761-6	NMK-89367-8	NMK-89613-2	NMK-8917Ø-9	NMK-89279-1	NMK-89576-1	NMK-89724-5	NMK-89812-3	NMK-89175-5	NMK-896Ø1-8	NMK-89167-6	NMK-89593-9	NMK-899Ø6-7	NMK-89675-1
Event name / gene(s)	ATBT04 -6, -27, -30, -31, -36					SBT02-5	SBT02-7	BT6	BT10	BT12	BT16	BT17	BT18	BT23
Product name	-- Newleaf --													
Developer	-- Monsanto --													
Trait	-- Coleopteran resist. --													
Timeline	-- not commercialised --													
Regulatory status in														
EU (net exporter)														
Net exporters														
Egypt														
Israel														
Canada	-- All: 1997 --					-- All: 1996 --								
China														
Turkey														
Iran														
India														
Lebanon														
Australia														
Net importers														
Russia														
Iraq														
Malaysia														
USA	-- Food & feed: 1996 --					-- All: 2001 --								
Algeria														
El Salvador														
Mexico								-- Food & feed: 1996 --						

Overview 18 (cont.): Other GM potatoes (never commercialised or phased out)

Unique identifier	NMK-89653-6	NMK-89935-9	NMK-8993Ø-4					NMK-89684-1	NMK-89185-6	NMK-89896-6
Event name / gene(s)	RBMT15-101	SEMT15-02	SEMT15-15	RBMT21-152	RBMT22-186	RBMT22-238	RBMT22-262	RBMT21-129	RBMT21-350	RBMT22-82
Product name		-- Newleaf Y --					-- Newleaf Plus --			
Developer					-- Monsanto --					
Trait		-- Coleopt. res., PVY resist. --					-- Coleopt. res., PLRV resist. --			
Timeline					-- not commercialised --					
Regulatory status in										
EU (net exporter)										
Net exporters										
Egypt										
Israel										
Canada		-- All: 2001 --						All: 1999	All: 1999	All: 2001
China										
Turkey										
Iran										
India										
Lebanon										
Australia										
Net importers										
Russia										
Iraq										
Malaysia										
USA		-- All: 2001 --			-- Food & feed: 2001 --				-- All: 2001 --	
Algeria										
El Salvador										
Mexico		-- Food & feed: 2001 --							-- Food & feed: 2001 --	

Overview 19: Commercial GM sugar beet worldwide (incl. "other" GM sugar beet events)

Unique identifier	KM-ØØØH71-4		ACS-BVØØ1-3
Event name / gene(s)	H7-1	GTSB77	T120-7
Product name	Roundup Ready		
Developer	KWS / Monsanto	Monsanto	Bayer
Trait	Glyphosate tol.	Glyphosate tol.	Glufosinate tol.
Timeline	commercialised	-- not commercialised --	
Regulatory status in			
EU	Food & feed: 2007-17, planting: assessment		
USA	All: 2005	All: 1998	All: 1998
Canada	All: 2005		All: 2001
Mexico	Food & Feed: 2006		
Japan	All: 2007		
South Korea	Food: 2006		
Australia	Food: 2005		
China	Food: pending		
Philippines	Food & Feed: 2005		

Overview 20: Other commercial GM crops and other GM crops in the regulatory and R&D pipelines worldwide

For information on other GM crops, please see Section 3.7 (Table 14, Table 15 and Table 16) in the main body of the report.

European Commission

EUR 23486 EN – Joint Research Centre – Institute for Prospective Technological Studies
Title: The global pipeline of new GM crops: implications of asynchronous approval for international trade
Authors: Alexander J. Stein and Emilio Rodríguez-Cerezo
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Abstract:

In this report we described the current status of GM crops approved worldwide and the likely future developments for the short to medium term, for all relevant crops from all countries. Everywhere the commercialisation of these new GM crops is a regulated activity and different countries have different authorisation procedures. Therefore new GM crops do not get simultaneously approved in all countries. This "asynchronous approval" (AA) of GM crops is of growing concern for its potential economic impact on international trade, especially if crop importing countries operate a "zero tolerance" policy that may result in rejections of imports that contain only traces of not yet authorised GMOs; a similar problem of "low-level presence" (LLP) of unapproved GM material in imports arises when developers of new GM crops did not seek approval for commercialisation in export markets in the first place, i.e. when there is "isolated foreign approval" (IFA). In the EU LLP incidents have already caused trade disruption and economic problems, in particular for the EU feed and livestock sectors.

To forecast the future evolution of LLP, expected new GM crops were classified in five categories according to their proximity to market, they were discussed crop-wise, and their possible authorisation by the different trading partners of the EU were considered. The prediction is that while currently there are around 30 commercial GM events cultivated worldwide, by 2015 there will be over 120. Therefore, if problems with LLP have occurred with 30 events in the market, these are likely to intensify when moving from 30 to 120 available events. Moreover, individual GM events can easily be combined ("stacked") by conventional cross-breeding. Given the growing pipeline of individual events, it is evident that in countries where stacked GM crops are required to go through the regulatory system as a new GM crop, this will create an increasingly large number of new "approvable" GMOs. Yet, apart from AA, also the issue of IFA of is bound to increase with more of the new GM crops being developed by national technology providers in Asia for their domestic agricultural markets, as these developers may not submit all of their GM crops for approval in potential export markets.

Overall it is expected that next to the current major GM crops (soybeans, maize, rapeseed and cotton) and some minor ones, in the medium term also GM potatoes and GM rice will be commercialised. Apart from the current main traits (insect resistance, herbicide tolerance or a combination of both), new commercial traits covering crop composition and abiotic stress tolerance will become available.

For actors in the global food and feed chain the main problem of LLP is the economic risk of rejections of shipments at the EU border. Part of this problem consists of the "destination risk", i.e. the official testing for unauthorised GM material in the port of destination only – when a cancellation of the shipment is impossible and when its re-direction is costly. Also, given the bulk handling of grains in international trade, compliance with a zero tolerance policy for LLP is impossible. Therefore exporters may choose to sell their grain to "preferred buyers" who are known to create little problems. Moreover, the price of grain is determined based on quality and quantity with a strong relationship between price, specifications and risk – the latter of which is increased if there is uncertainty whether compliance with LLP regulations is possible. Or, if the risk cannot be managed, there will be no trade at all. Higher prices and potential supply bottlenecks also mean that EU businesses that are dependent on cheap imports of agricultural commodities, like livestock farming, may have to relocate abroad.

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