Approvals of GMOs in the European Union

Analysis • Global Comparison •
Forward Projection • Impacts • Improvements

EuropaBio™
The European Association for Bioindustries

October 2011

COMMENTS ON THE EU AUTHORISATION SYSTEM

"...we've created a state-of-the-art machinery for handling GMOs, we're really struggling to use it as well as we could be ... vital time is being lost in procedures... The result is that a growing number of GM products are widely used in other parts of the world, but are not yet authorised in the European Union."

Mariann Fischer Boel
EU Commissioner for Agriculture and Rural Development Speech, 15 October 2009

—

It is: *"...necessary to look for improvement of the implementation of this legal framework in order to better meet the objectives of the EC legislation, taking into consideration the necessity of continuing processing applications without undue delays..."*

2912th Environment Council Conclusions
Unanimously agreed on 4 December 2008

—

"One possibility to avoid the situation above from occurring is to speed up the authorisation processes for novel GM products."

"Study on the Implications of Asynchronous GMO Approvals for EU Imports of Animal Feed Products".
2010 Report financed,
presented by the European Commission.

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

TABLES

FIGURES

The data in this report represents the authorisation system status as of 1 September 2011.

LIST OF ABBREVIATIONS

ARM	Antibiotic Resistance Marker
CFIA	Canadian Food Inspection Agency
DG SANCO	The European Commission's Directorate General for Health and Consumer Policy
DNA	Deoxyribonucleic acid
EC	European Commission
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EPA	U.S. Environmental Protection Agency
ERA	Environmental Risk Assessment
FDA	U.S. Food and Drug Administration
GMFF	GM Food and Feed
GMO	Genetically Modified Organism
JRC	Joint Research Centre
LLP	Low Level Presence
MS	Member States
OECD	Organisation for Economic Co-operation and Development
R&D	Research and Development
SCFCAH	Standing Committee on the Food Chain and Animal Health
USDA	U.S. Department of Agriculture
WTO	World Trade Organisation

1. EXECUTIVE SUMMARY

Introduction

The European Union (EU) has a thorough and comprehensive system for the assessment and authorisation of Genetically Modified Organisms (GMOs) for import and processing, consumption as food or feed, and cultivation. The European Food Safety Authority (EFSA) issues a GM product specific safety assessment, focusing on impacts on human and animal health and the environment. Based on this EFSA assessment, the European Commission, together with the EU Member States, decides whether or not to authorise a GM product.

Although the regulatory framework, as well as the scope of the assessment, is broadly similar to other parts of the world, there are significant differences in the functioning and results of GM authorisation regimes worldwide.

The objective of this report is to raise awareness of the need for the system to work better. The report identifies specific challenges to applicants due to the way the regulatory framework is implemented in the EU and proposes clear constructive solutions geared at addressing those problems. All solutions offered maintain the strict, thorough and independent EU authorisation system.

This report was drafted on own initiative for the benefit of all parties involved in the EU authorisation process: EU Member States, the European Commission and the European Food Safety Authority (EFSA), and stakeholders who rely on an efficient and workable authorisation system for GM products: trait developers, seed companies, grain traders, food and feed industry and farmers.

Notes
The data in this report is updated until 31 August 2011. Predictions are based on the situation of end 2010.

The main points of this report are available in a PowerPoint slide deck. The report and the PowerPoint slide deck are available from EuropaBio upon request. All information in this report is publicly available. Interested parties are invited to contact EuropaBio regarding any information requests related to any data or calculations presented in this report.

The authors of this report have endeavoured to ensure that all information in this report is correct and up to date. In no event are the authors liable for any loss or damage arising out of, or in connection with, the use of data in this report.

CONCLUSIONS

State of play

1. The EU authorisation process for GM products takes substantially longer than comparable systems around the world. One third of the average 45 months it takes to receive approval for a GM product for import in the EU is spent on processing by the European Commission and voting procedures. The European Commission waits over 11 months on average before it asks Member States to vote on a GM product, disregarding the 3 month deadline set in EU legislation.

2. The EU is taking longer and longer to assess products (measured in averages over years). It is becoming increasingly difficult for applicants to receive authorisations within acceptable and predictable timelines. While data requirements for applicants have continued to change and increase, the efficiency and the speed of the approvals process has declined. In the case of GM products for cultivation, the authorisation process has never been correctly implemented - only two GM products have been authorised in the past 13 years. Some products have been in the system even longer. Farmers in other regions have upwards of 20 GM products to choose from.

3. Some Member States vote against the opinion of the independent safety assessors for political reasons. Nonetheless, since 2010, a majority of votes (more than 50% of available votes) cast by Member States in authorisation votes favoured authorisation. A minority of countries that represent less than 30% of the votes is slowing approvals by voting against the scientific opinion.

4. Every year, more GM products enter the EU authorisation system than exit it. Even by conservative estimates, 93 GM products are expected to be in the authorisation process by 2015.

Impacts

5. If the current EU approval rate does not improve, there will be serious trade repercussions. Countries around the world approve and allow farmers to plant products in a more timely fashion. Some are making efforts to make their authorisation systems more efficient. The EU's main suppliers of protein are less inclined to wait for EU approvals prior to approving and planting in their country. Challenges resulting from asynchronous authorisations as a result of a slower authorisation rate have caused trade problems costing billions to importers, food/feed processors and farmers. The number of such incidents is likely to increase.

6. EU farmers suffer economic losses as a result of the delays in the authorisation process. The absence of EU decisions on cultivation applications due to the failure to advance products through the system means that European farmers are being denied the choice of products available to farmers around the world. The high cost and unpredictability of the EU system means SMEs are not able to commercialise GM products. The problematic authorisation system has a negative effect on investment in innovation, which affects other R&D areas.

Looking ahead

7. A thorough science-based assessment is necessary, and it is legitimate to consider new facts. There is, however, an increasing tendency by risk managers to introduce new requirements into the risk assessment phase for political reasons. Such measures often do not have a scientific basis and do not contribute to an improved safety assessment.

8. There is potential for efficiency gains during the risk assessment and management phases without impacting thoroughness, completeness or independence. The gains lie in processing product applications more efficiently. In the case of a number of products that were causing trading problems in the past, the EU followed the timelines required by the legislation for product without delays. This showed that it is possible to operate within the timeframe set-up in the legislation.

RECOMMENDATIONS

1. **Put products to vote**. As prescribed in EU law, the European Commission should put GM products to the vote without delay. There are close to 20 import and cultivation files with a positive assessment waiting to be voted upon by Member States.

2. **Increasing efficiency and predictability is needed during risk management**. More efficient processing of applications should be a higher political priority. Legally prescribed timelines should be respected by the European Commission. Targets should be set to deal with the increasing backlog of applications in the EU authorisation system. Each application should be listed on a Standing Committee agenda for voting at the first or second available meeting. Any new scientific considerations on a product provided after the EFSA opinion should be duly and critically considered but should not lead to undue delays. Resources dedicated to processing authorisations should be significantly increased.

3. **Member States' votes should be based on the EFSA opinion**. Member States should be made aware of the implications of a non-approval, in particular the economic costs for farmers who require approved feed and farmers who are less globally competitive due to their lack of access to beneficial GM products. The Commission should find a sound path forward that is accepted by a majority of Member States and grants freedom of choice for farmers within a science-based system.

4. **Commission and Member States should guard over EFSA independence**. It is recommended that the Commission only add new requirements to the risk assessment if EFSA scientists, after consultation with Member States, deem this necessary. Risk managers should aim to inject more public confidence into the system through effective communication, not by undermining the work of risk assessors by adding additional requirements deemed unnecessary by EFSA scientists.

5. **More certainty is needed in EFSA Guidance**. New elements of EFSA guidance should not be applied retroactively to dossiers already in the process. New requirements for applicants should only apply when clearly formulated in a formally adopted, updated guidance document. Sufficient transition time should be foreseen. Clear endpoints and a rationale for case-by-case recommendations should be provided to avoid different interpretations and delays.

6. **Efficiency improvements are possible during EFSA risk assessment**. A transparent work plan should be designed for each application to help structure the risk assessment process. Risk assessment by different EFSA working groups, by the different Member States, should be carried out in parallel and in an independent way, and the procedures followed should be auditable. A better and more structured process for information exchange between applicants, EFSA and Member States' experts is recommended to improve efficiency. The accumulation of applications should be dealt with through a specific action plan implemented by EFSA.

   Regarding stand alone applications, new applications should only require data on new products and a format to update data packages for single products should be agreed. Regarding stacked products, applications should be reviewed in parallel with individual component single applications. Alternatively, another viable option could be a simplified procedure or notification (including necessary information to assess absence of interactions and cross-referencing). Regarding renewals, a fast-track safety assessment should be performed for products which have already been assessed and on the market for a number of years. Regarding full scope, for products that already received an EFSA opinion, a new application that follows a simplified procedure can be submitted following agreement between the applicant and the Commission.

2. COMPARISON OF INTERNATIONAL GMO ASSESSMENT FRAMEWORKS AND OUTPUTS

Introduction
Different GMO assessment frameworks are in place around the world. A brief comparison is made between the regulatory systems in the EU, and some of the main GM exporting countries: Canada, Brazil and the United States.

A functional regulatory system meets clear and defining characteristics. These are:

- **Clarity** about scope and objectives and division of responsibilities between ministries and agencies and clarity about the interrelation with other existing regulatory systems
- **Predictability** of processes and decision timelines
- **Transparency** about the application system for authorisations; how science advice is provided, taken into account and reviewed; consistent implementation between applications
- **Science-based** processes of safety/risk assessment; scientific assessment provides evidence to decision-makers
- **Workability** and practicability: requirements must be achievable, data requirements must be tailored to address specific risk hypotheses; complexity should be proportional with activity and level of risk and should be cost-effective and consistent with available human and financial resources
- **Adaptability** where new applications are evolving rapidly and regulatory requirements and/or guidelines must be able to quickly adapt

See Annex 5 for a more detailed description.

European Union

The EU's GM authorisation framework[1] has two distinct and separate phases. The first is the risk assessment phase. This involves a scientific assessment of human and environmental risks by independent scientists operating under the auspices of the European Food Safety Authority (EFSA), in collaboration with Member State experts. At the end of this case-by-case and step-by-step assessment, EFSA provides a scientific opinion to the European Commission on a specific product.

The second phase, risk management, is a political decision-making phase during which the European Commission and the Member States take into account EFSA's scientific opinion together with other considerations (so-called 'other legitimate factors'), and make a decision whether or not to authorise the GM product. Once a GM product is approved, the authorisation is valid for ten years. Authorised GM products are added to the public register, which can be found at: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

As of August 2011 there are 39 GM products approved in the EU. 37 GM crop products have been approved for import (7 cotton, 23 maize, 3 oilseed rape, 3 soybean and 1 sugar beet). Currently, only 2 GM products are approved for cultivation (1 type of maize and 1 potato for industrial use).

However, many GM products are currently stuck somewhere in the approval system. At the end of 2007, the number of products pending in the system was 51. By August 2011, this number already increased further to 72. Among the GM products currently in this backlog, there are 51 GM products for import/processing and 21 for cultivation.
A full overview is provided in Annex 1.

The comparison with the regulatory frameworks of the US, Brazil and Canada is made below. These countries are primary GM cultivation markets exporting to the EU.

United States

Crops derived from modern biotechnology are among the most stringently regulated agricultural products. They are not approved for commercialisation until three U.S. Federal agencies have determined that they are as safe for consumers and the environment as conventional crops. The three agencies that assess the safety of the products are the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA). Each plant variety is subject to extensive field-testing under the oversight of the USDA and as appropriate the EPA. 90 products have been approved for cultivation in the United States.

Brazil

The most important body in the authorisation process of GMOs in Brazil is CTNBio (Biosafety National Technical Committee), which consists of publicly acknowledged specialists in Science & Technology and representatives of each Ministry. Currently there are 28 GM products approved for cultivation in Brazil since 2005. It is worth highlighting that the Congress passed a Biosafety Bill in March 2005, which provided a legal framework to facilitate the approval of biotech crops in Brazil[2].

Canada

The Canadian authorisation system is noteworthy since it is product-based rather than process-based. This means that it is the presence of a novel trait in a plant, irrespective of the method used to introduce it, which will trigger the notification and authorisation requirements under the *Seeds Regulations*[3]. In Canada, both Health Canada and the Canadian Food Inspection Agency (CFIA) share responsibility for regulating novel agricultural products. The CFIA is responsible for regulating the safety of novel plants and novel livestock feeds. Health Canada is responsible for ensuring that novel foods are as safe and nutritious for humans as foods already on the marketplace[4]. Because of the product-based approach, a direct comparison is more challenging. Approved plants with a novel trait (GM or not) include 85 for food use, 81 for feed use and 66 for environmental release[5].

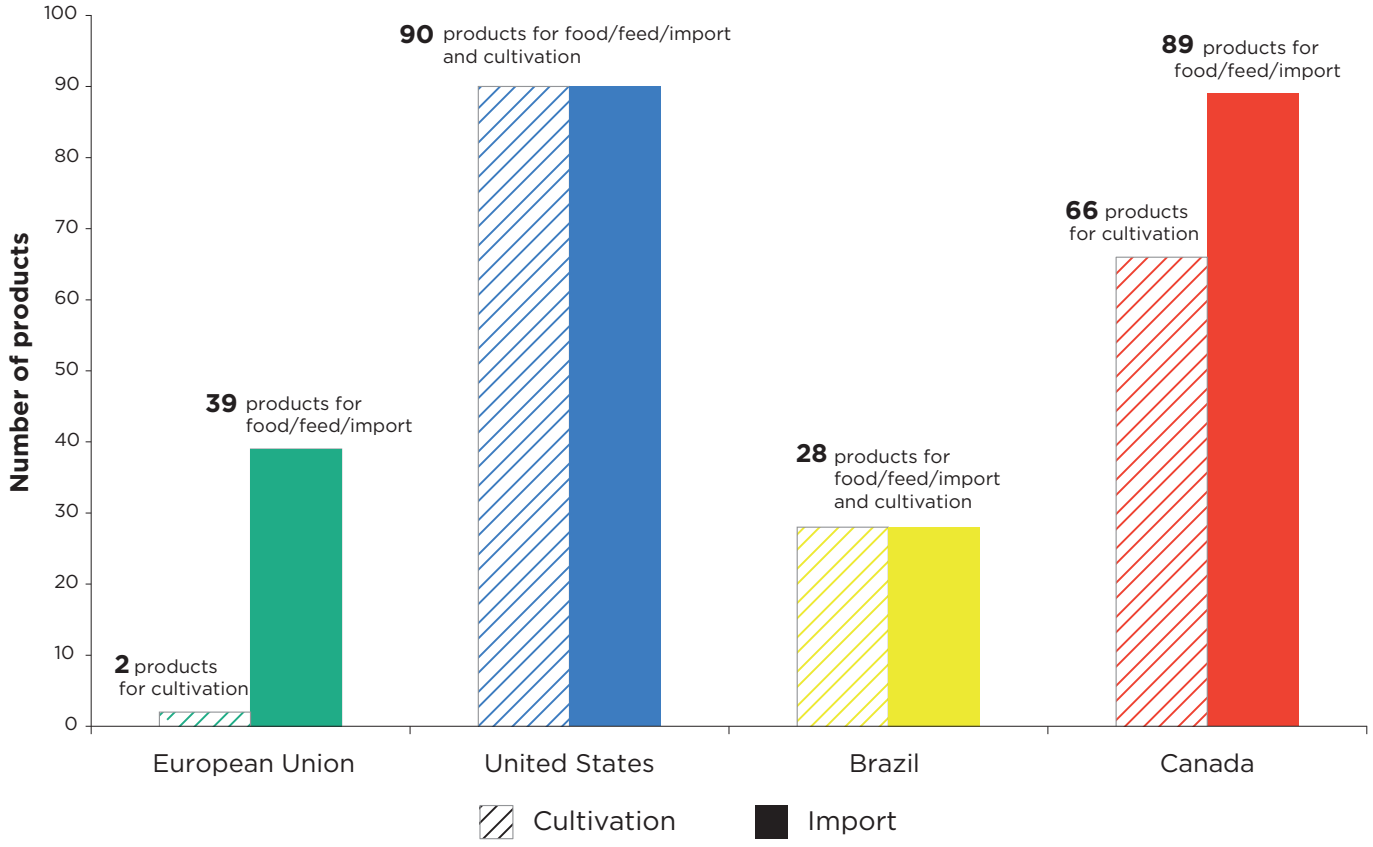
Outputs of four authorisation frameworks
These four countries/regions have different numbers of approved GM products, as shown in the chart below.

It is worth noting that in Brazil, 27 of the 28 products were approved after 2005 (when the Biosafety Bill passed)[6]. The products in Brazil were approved over 6 years.

Of the 39 approved GM products in the EU 12 are stacked products, GM products with more than one GM trait and 2 are renewals. The EU is one of the few regions where it is compulsory to submit separate applications for stacks and renewals.

In the US and Brazil, the products approved for food/feed uses and import are also authorised for cultivation.

FIGURE 1: Number of approved GM products in the EU, US, Brazil and Canada



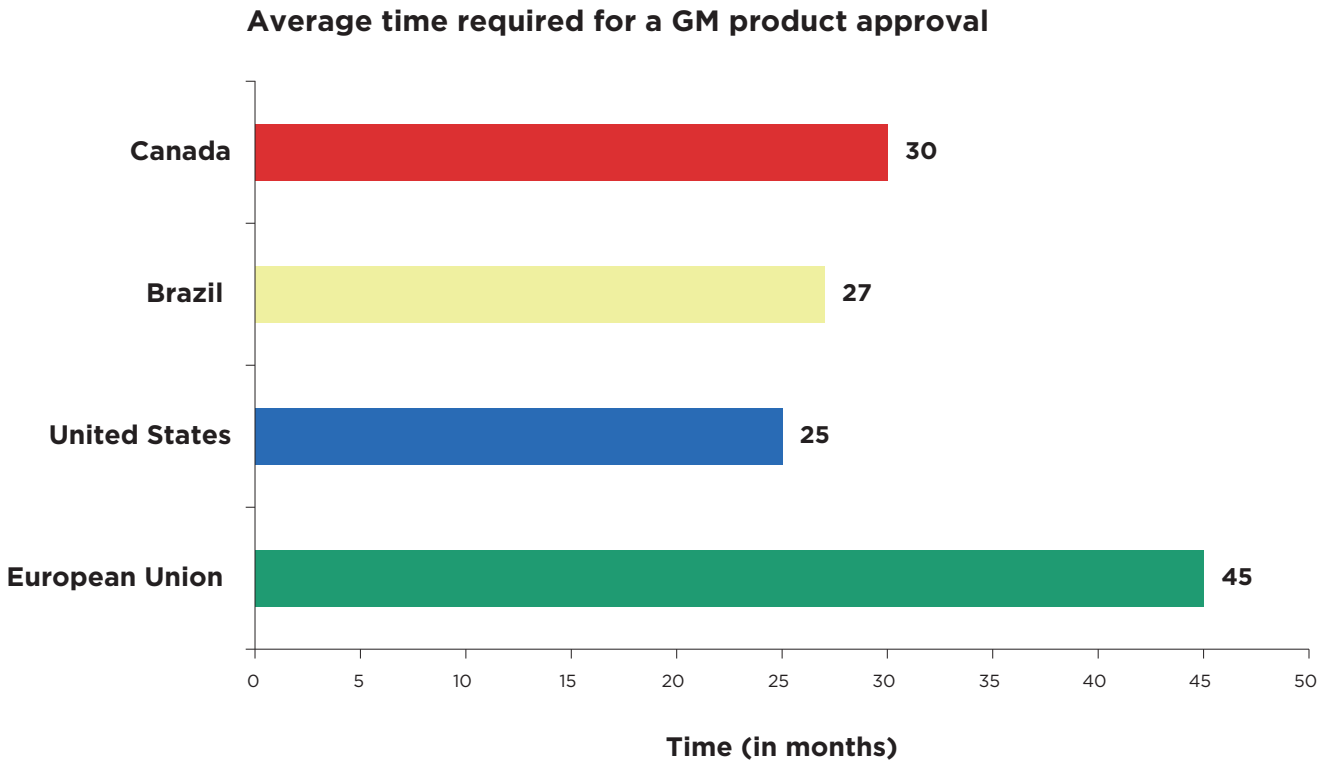
Note 1:
Canada includes Plant Novel Traits (PNT), some of which are not GM[7].

Time required in four different authorisation frameworks

Even if GM dossiers are submitted at the same time in different parts of the world, authorisations are not granted simultaneously. GM product authorisations in the EU take substantially longer than in the GM exporting countries. On average a GM import dossier takes almost four years to pass through the EU approval process.

It is noteworthy that the EU differentiates between an import and a cultivation dossier, while in Brazil and the US, and with some exceptions, in Canada, the distinction is not made; authorisations are given for the full scope of planting, import and consumption. Contrary to these other countries, the EU requires new approval for stacked products, even if those traits were previously authorised separately.

FIGURE 2: Average time required for a GM product approval in the EU, US, Brazil and Canada



3. THE EU APPROVAL SYSTEM: A PROJECTION FOR 2015

How many products are currently in the EU approval system?
In August 2011, there were 72 GM crop products in the EU authorisation process, either with EFSA or awaiting votes. Of these 72 GM applications, 12 are renewals and 27 are stacked products, GM products that include more than one GM trait (14 double stacked products, eight triple stacked products, four quadruple stacked products and one quintuple stacked product). Since the GM authorisation is valid for ten years, a new submission must be provided every decade. This new submission, called a renewal, must again be subjected to a safety assessment in which any new scientific findings are considered. Stacked products are products that are a combination of two or more GM traits, which allow growers to maximise the benefits of individual traits in a single plant.

Which products are expected to be in the approval system in 2015?
Besides the 72 products already submitted for the authorisation process, new products will be submitted in the coming years. This section provides an overview of the number of products expected to enter the authorisation process by 2015. These predictions are based on a report by the European Commission's Joint Research Centre (JRC): *"The global pipeline of new GM crops. Implications of asynchronous approval for international trade"*[8]

Since the JRC report was published end of 2009, and these new products were calculated on top of the products already in the authorisation system at the end of 2010, a future assessment was performed to make sure products were not double-counted. Five products, which were already submitted in 2010, were included in the JRC report, and as such, they were not taken into account into any projections below. It is acknowledged when performing this analysis that the list of products in the pipeline of the JRC report is not complete and deviations from this list may exist.

The following four definitions are used:

- **Commercial crop**: commercialised GM products marketed in at least one country worldwide
- **Commercial pipeline**: GM product authorised in at least one country but not yet commercialised (commercialisation only depends on the decision by the developer)
- **Regulatory pipeline**: GM product in the regulatory process to be marketed in at least one country
- **Advanced R&D pipeline**: GM products not yet in the regulatory process but in late stages of development (large-scale multi-location field trials, data generation for the authorisation dossier)

FORECAST 1:
At least 20 new individual GM products will enter the authorisation process by 2015.

These products are projected to be:

SOYBEAN: At the end of 2009, there were nine GM soybean products in the R&D pipeline. The assumption is made that all nine GM soybean applications will be submitted in the EU as the EU is a net soybean importer. Two of these nine products were submitted in 2010 and so are not taken up in the calculation. In total, it is expected that 7 GM soybean products will enter the authorisation system.

MAIZE: Based on the pattern of GM maize submissions in the commercial or regulatory pipeline worldwide (European and US developers submit in the EU; Asian developers do not submit in the EU), the assumption was made that six out of seven GM maize products in the R&D pipeline at the end of 2009 will be submitted in the EU. One of these GM maize products was already submitted in the meantime, so five more GM maize products will enter the authorisation system by 2015.

OILSEED RAPE: Since all previous GM rapeseed products were submitted in the EU, the assumption was made that all five GM oilseed rape products in the R&D pipeline at the end of 2009 will be submitted in the EU. One of these GM rapeseed products was already submitted in the meantime, and so in total, four more GM oilseed rape products will enter the authorisation system by 2015.

- **COTTON:** Based on the pattern of GM cotton submissions in the commercial or regulatory pipeline worldwide, the assumption was that the two GM cotton products, in the R&D pipeline at the end of 2009, developed by major technology developers will be submitted in the EU. We have assumed that the eight GM cotton products developed in India will most likely not be submitted in the EU.

- **RICE:** Since eight out of 10 GM rice products in the R&D pipeline at the end of 2009 are developed by Asian providers for the domestic agricultural market, it is most likely that only two GM rice products will be submitted in the EU.

- **POTATOES:** Compared to the JRC report, one of the products has received approval and one was submitted in the meantime. Another potato product not on the JRC report has been submitted in 2010 so that currently 2 products undergo EFSA assessment. An additional potato product also not listed at JRC is in advanced R&D and is expected to be submitted in the EU for cultivation and food/feed use.

More detailed information on the specific products can be found in Annex 3.

FORECAST 2:
Beside the new individual products, four requests for renewals can be expected by 2015.

The assumption that there will be four renewals by 2015 is based on the authorisation date of products approved in the EU. Since the authorisation is valid for ten years, it can be expected that products approved between 2001 and 2005 will require a renewal of the authorisation before 2015. This also depends on the commercial interest of the applicant, but looking back, it can be assumed that for the vast majority of products a renewal dossier will be submitted.

Based on the products currently approved in the EU, there are 10 products which received approval between 2001 and 2007. For 6 of these a renewal application has been submitted. It is to be expected that for the four remaining products a renewal application will be submitted before 2015.

FORECAST 3:
At least 22 more stacked products are expected to enter the approval process by 2015.

The process of stacking GM products can create a tremendous amount of possible combinations. According to the JRC report, with the 24 individual GM maize products by 2015, it would be theoretically possible to create 12,926 maize stacks. Of course not all these combinations would make agronomic sense, but this gives a clear image of how the number of possible stacked crops increases dramatically with the number of new products and the number of stacked products that can be put into one plant. The first quintuple stack was submitted in the EU in July 2011.

The estimate for the number of stacks is based on an analysis of applications in the authorisation process between 2006 and 2010[9]. In this period, 22 individual GM products entered the authorisation process, together with 25 stacked products. The ratio of stacked products to single at the time was 1.14. Applying this conservative ratio to the 20 new unique single applications which are expected by 2015, at least 22 more stacked products are expected to enter the authorisation process. Stacked products are increasingly being developed and cultivated around the world.

Therefore, the real number of stacks submitted is likely to be markedly higher and the number of 22 is an overly conservative estimate.

FORECAST 4:
It is likely that there will be 12 GM products for which no approval will be requested but for which the European Commission may seek an assessment.

Currently there are five GM rice products in the commercial and regulatory pipelines worldwide. None of them are authorised in the EU and four of these products, developed by national technology providers in Asia and designed for domestic agricultural markets, will most likely never be submitted for approval in the EU. In the advanced R&D pipeline worldwide, there are also currently at least 10 new GM rice products. Again, eight of these are developed by Asian providers. Based on the assumption that these products are for domestic agricultural markets, they will most likely not be submitted for EU approval.

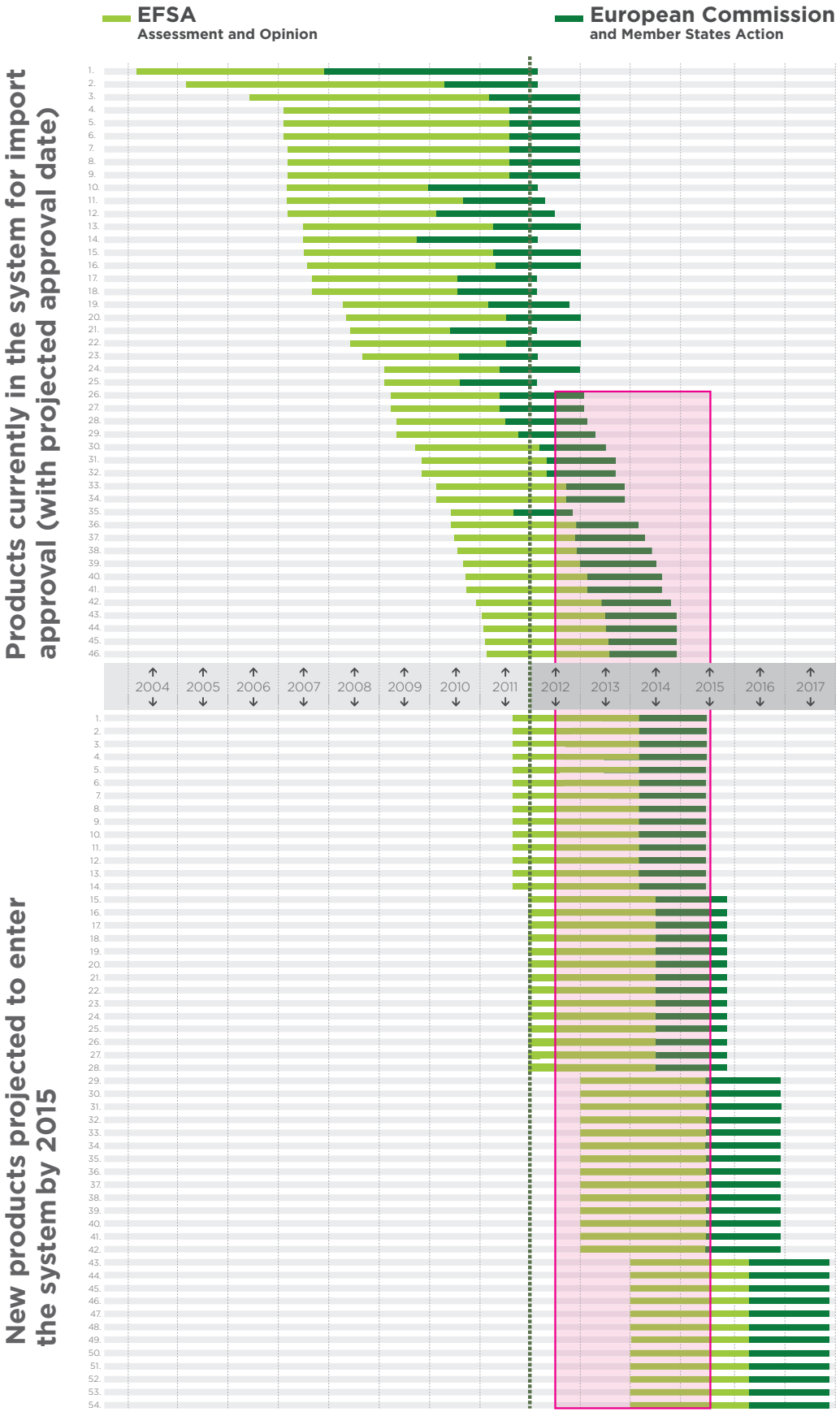
These products, though not intended for the EU, may give rise to problems of low level presence (LLP). LLP refers to the incidental and unavoidable presence of GM material, authorised in other parts of the world but not yet in Europe, in food, feed or grain at levels that are consistent with generally accepted agricultural and manufacturing practices. These already occur in rice imports (49 recorded notifications of unapproved GM rice in 2010) and will increasingly occur in future as a result of the advanced R&D rice pipelines in various Asian countries. Therefore, it is expected that EFSA will be requested by the Commission to perform safety assessments of these products. This would lead to another 12 applications (four already in regulatory pipelines and eight in R&D pipeline).

Rice is only one example, however. There are crops in Asia and other parts of the world, developed for the domestic market but that may be present in exports. In September 2011 Brazil's CTNBio gave the green light for a GM virus-resistant bean, destined for the internal market. There are upwards of 40 products that fall into this category according to the JRC. In order not to make an overestimation, these products are not taken into account in the calculations below.

TABLE 1: State of play and what's to be expected for the EU approval system by 2015

State of play (end 2010)	**Number of products**
Total products submitted in the authorisation system (end 2010)	101
Total products approved (status end 2010) (note 3 were approved in 2011)	36
Total products in the EU authorisation process (in addition, there have been 8 new submissions in 2011, bringing the actual total to 73)	65
What the EU can expect by 2015	**Number of products**
Individual new products	20
Renewals	4
Stacked products	22
Products developed for local markets, not seeking an approval in the EU	12
Total number of products projected that will have been submitted to the EU authorisation process by 2015	159
Total number of products projected to be in the system in 2015 (assuming an average of 6 authorisations per year)	**93**

FIGURE 3: Current and projected GM products in the EU Authorisation System 2010-2015

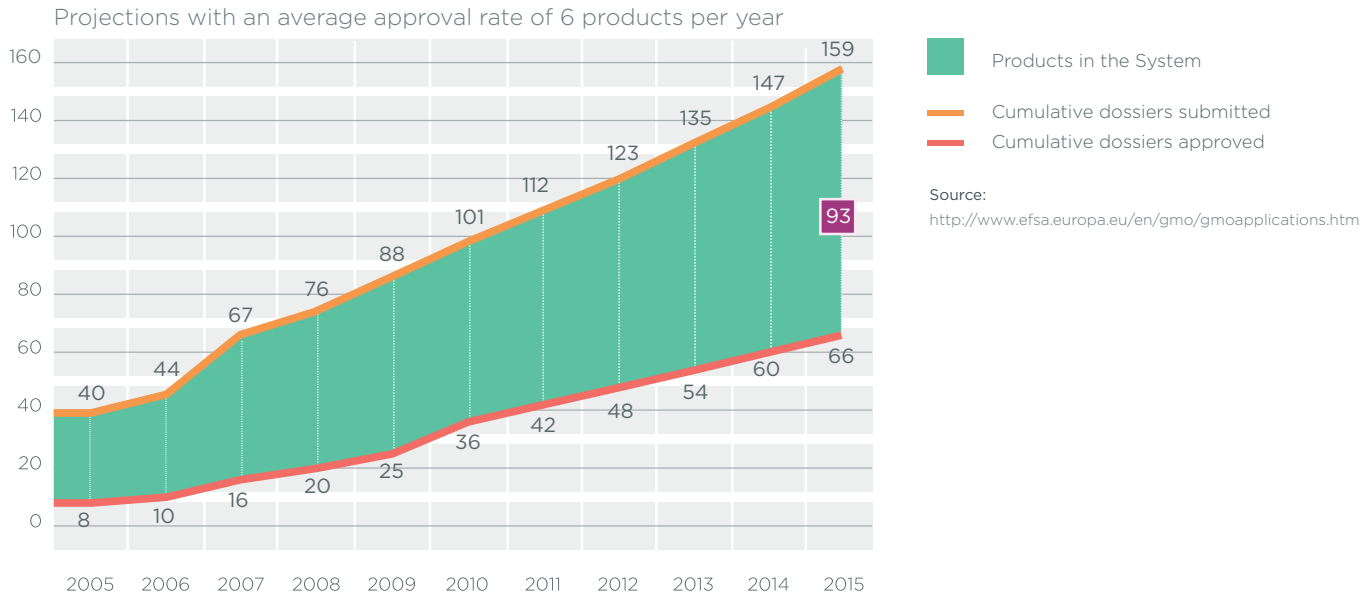


The chart shows:

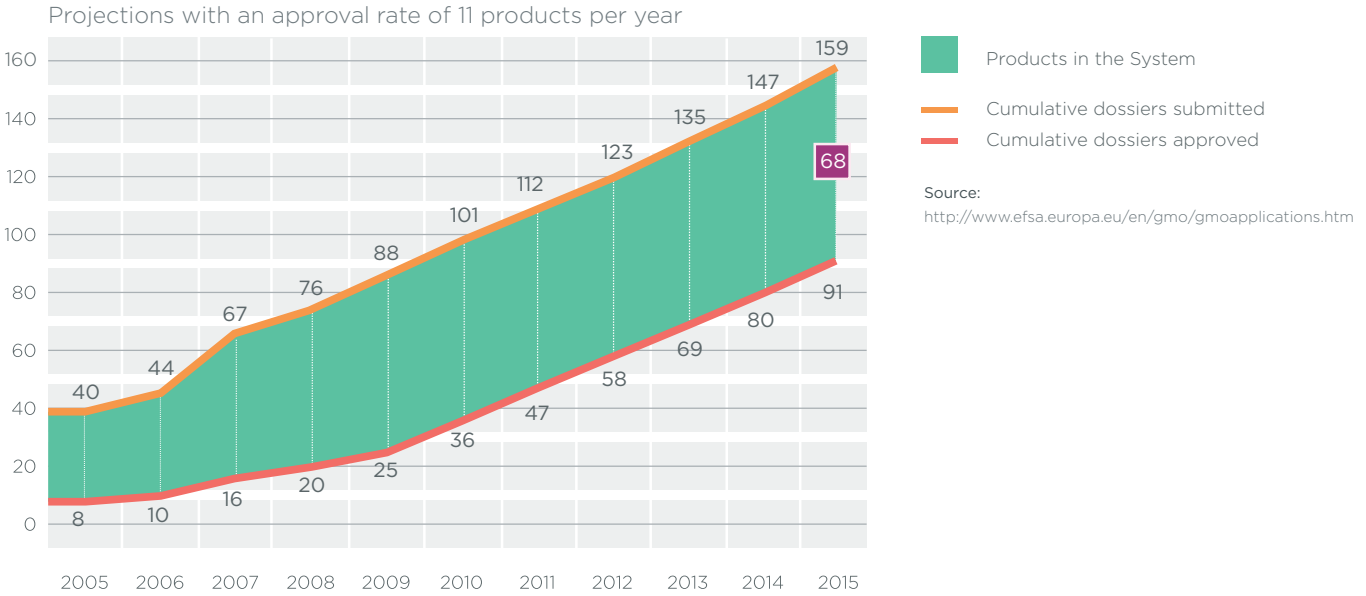
- Between 2012-15, many products (area in red box) will need to be assessed by EFSA and the European Commission concurrently.
- Without efficiency gains and increased outputs, significant blockages will result.

The list with the products shown in this graph can be found in Annex 4.

FIGURE 4: EU authorisation system: Products in the system under 2 scenarios



ABOVE: The chart shows that if the average annual authorisation rate of 6 products remains unchanged, there will be at least **93 products** in the system by 2015. 6 products per year is the average approval rate over the last 5 years.



ABOVE: The chart shows that if the authorisation rate is 11 products per year there will be **68 products** in the system by 2015 - the same total as in the start of 2011. 11 products per year is the rate of 2010, which was a record.

4. THE IMPACTS OF THE EU AUTHORISATION SYSTEM FOR GMOS

EU authorisation process in global context

The EU authorisation system for GMOs is substantially slower than comparable systems, such as those in the countries exporting commodities to the EU. Although the EU system is seen as the strictest in the world, GM products also undergo rigorous reviews in other countries that broadly assess the same elements as in the EU. In a recent legal opinion from the Council (8994/11) on a related issue, it was admitted that *"...it is common knowledge that the authorisation process....(has) become problematic in practice."* The EU authorisation system does not meet the basic requirements of good governance and regulation set out by the European Commission.

The number of products in the EU authorisation system is increasing rapidly. While in 2007 the number was 51, it increased to 72 in August 2011, and the total is projected not to decrease unless active measures are taken. Even if the overall average output of the approval process almost doubled, there would still be a large backlog of products projected for 2015 and beyond. Each year, more products are entering the system than are approved.

Measured in averages over years, the EU process is slowing down (it takes longer and longer to approve a product). If the current rate and timing continues, significant trade problems can be expected due to asynchronous authorisations in main exporting countries.

The EU authorisation system is highly unpredictable as a result of the politicisation of the science-based system. After EFSA produces a positive opinion, it currently takes an average of 11 months before the European Commission puts a product to the vote in the Standing Committee. With the proliferation of stacked traits, the EU will need to think of a more pragmatic way of regulating such products that often combine already approved GMOs, instead of considering them as completely new.

Governments in many parts of the world are stepping up efforts and dedicating resources to approve GM products more efficiently in order to maintain their competitive advantage and to ensure a place in the global market by giving their farmers access to the newest varieties available. Bolivia stated in June 2011 that it was improving the approval process for GM with the goal of increasing food production. Russia announced an ambitious biotechnology development programme in spring 2011. Argentina introduced measures in September 2011 to accelerate the approval system (see below).

Argentina authorisations no longer reflect European authorisations

The Ministry of Agriculture in Argentina recently approved the cultivation of an insect-resistant maize that is not yet approved in the EU. The technology, which is already approved for cultivation in the USA, Canada, and Brazil, will be available to Argentine growers in the 2011/2012 season. The maize product is still being assessed by EFSA, and so will not be authorised for import in the EU in the near future. The decision by Argentina shows that it is not prepared to wait for the EU to approve products, prior to approving them in their own country, though it tries to limit any trade disruptions.

The government also indicated that it intends to approve 4 new GM corn and soy products in 2011, including one soy product that is at least a year away from approval in Europe.

In September 2011, the Argentinean government unveiled a new plan for the commercial registration of GM products that would cut Argentine approval times by 50%, bringing it in line with Brazilian and US systems. The new system will facilitate the production and availability of seed for commercial launch and allow more certain anticipation of approval times of new products. The reactions in Argentina to this new approach were positive. Argentinean stakeholders had asked the government to break the so-called 'mirror policy' – where it waited to approve products until the EU finished the authorisations. The decision of the Argentinean government is based in part on the fact that the GM crop was already being planted in Brazil, that the government wants to improve the regulatory process and have more products approved for cultivation and that it wants to work closely with its neighbours to achieve synchronous authorisations.

In the past, the EU has shown repeatedly that it is possible to achieve a more reasonable timeframe for product authorisations. For example, two specific products, a maize and a soy product, were approved in 30 and 27 months respectively. The risk management phase (Commission and Member States) took 6 and 5 months respectively. These products were approved faster than average, because they were already being grown in countries exporting maize and soy to the EU, and they were causing trade disruptions.
The message these 2 authorisations sent was twofold. First, the EU is able to approve products more quickly. The second message is that the presence of a not yet approved product in traded commodities will influence the priority setting leading to a more rapid EU approval.

International trade aspects
Presence of unauthorised GM material can cause trade disruptions and therefore economic problems. The EU feed and livestock production sectors are affected particularly by such disruptions. As the EU's relative importance in global commodity trade (maize and soy) decreases, it loses political weight and influence on the approval decisions of the exporting countries. A report[10] released in early 2011 by the European Commission stated:

> *"...The demand for maize and soybean, and their derived products, is growing rapidly around the world, especially in China. At the same time the relative importance of the EU market...inevitably diminishes. This will discourage efforts by producers and traders in exporting countries to invest in segregating EU approved from non-approved GM material and to continue trading with the EU."*

Governments of exporting countries and farmers are paying less heed to the decisions in the EU because they can sell their products elsewhere.

CASE STUDY 1:
How traces of unapproved GM varieties cost farmers billions in 2009

In June 2009 several bulk shipments of soy from the US were turned away from Germany. They were found to contain barely detectable traces of GM maize not yet approved in the EU and left in the ships from previous shipments. The same happened to ships coming into Spain in August 2009 and to the Netherlands in September 2009. Overall three unauthorised GM maize products were found in different soy shipments.

In 2009, hundreds of thousands of tons of GM soy were refused entry in Europe because of this problem. Grain traders, who had their ships stuck in EU ports or had to re-route them at high cost, decided to avert any risk and stopped all imports of soybeans and soybean meal from the US to Europe. Prices for soybeans instantly rose after detection of the unauthorised products. In Rotterdam and Hamburg prices after the incidents jumped to about €30-35 per metric ton. Droughts in South America and increased demand from China had led to low soy stocks. After the GM products were authorised in the EU (October, November 2009) soybean prices returned to normal levels within two months. The extra economic cost of feed imports for the livestock sector was estimated by the feed industry to be between €3.5 billion and €5.5 billion.[11]

The combination of a severe backlog in the EU process, together with long approval times, is one of the main causes of asynchronous approval for GM products. Due to asynchronous approval, shipments can be rejected if they contain traces of new GM crops that can appear in agricultural commodities exported to countries where these new products have not yet been authorised. Such trade disruptions can have major consequences. Rejections of shipments cause economic losses, price increases for farmers and consumers, and can lead to closing the access to specific markets. This not only negatively impacts applicants, but more importantly EU farmers, livestock breeders, importers of commodities and their users, the food companies. A report commissioned by the European Commission's DG Agriculture states:

"EU soybeans/soymeal imports are very high, supplies to the world market are dominated by USA, Brazil and Argentina and supplies from alternative suppliers are limited. When trade disruptions occur between the EU and the USA, price impacts are in the order of 25%. With trade disruptions involving three or more of the major exporters, the supplies to the EU are severely curtailed and prices of soybeans and soy meal increase by 210% or more over the short run (one to two years)."

The likelihood of presence of non-authorised GMOs in imports is increasing continuously because:

1. New GM varieties are developed.
2. GM acreage is increasing.
3. Some exporting countries are no longer following a mirror policy with regard to approvals
4. Exporters cannot cope with the logistical capacity of segregating GM material that is EU-authorised from material that is not yet authorised in the EU.

The same European Commission DG Agriculture report on the issue stated that global traders have less and less possibility to separate different GM varieties:

"The logistical capacity of segregation in the main exporting countries to the EU, as far as infrastructure logistics are concerned, is not able to cope with the requirement of segregating GM material that is EU authorised from unauthorised."

The "technical solution" achieved in 2011 for the presence of traces of as yet unapproved GM varieties in imported commodities for feed use is a good start, but it is only part of a global solution. The technical solution makes zero-tolerance more operational and can avoid some trade problems in the short term. However, more action will be needed to address: 1) higher unintended trace levels, and 2) the presence of traces of unapproved GM varieties in imports for food and commercial seeds.

Regarding higher unintended trace levels, given the rate of planting of GM varieties outside the EU and the consequent increasingly likely presence of trace amounts of unintended GM products in commodity exports to the EU, both the scope (feed only) and the threshold level (0.1%) will be insufficient to cover the problems associated with asynchronous authorisations. This is best illustrated by reviewing the most recent planting figures in the three countries that supply the overwhelming bulk of soy for feed and food in Europe. In Brazil 83% of soy acreage is GM in 2011-2012, an increase of over 13% compared to the previous season, over four times greater than initially predicted.[12] In the US the soy acreage is 91-93% GM and in Argentina 99% is GM.[13] The numbers for maize are upwards of 60%.

Given these trends, the EU needs to develop a longer-term strategy to deal with the presence of GM in non-GM imports. Such a strategy would: 1) Recognize the ongoing acceleration of GM authorisations around the world, 2) Anticipate the rapid uptake of new GM varieties around the world, 3) Recognize EU dependence on imports of raw materials and protein for use in food and feed.

In addition, the issue of discontinued products and the presence of these products in commodity trade present a significant challenge.

CASE STUDY 2:
A past problem caused by asynchronous authorisations

In 2006 a new GM maize product was introduced in the US. The product was approved in the USA, Japan and other areas but not in the EU. It entered the EU authorisation system in 2005. About 1% of total US maize area was planted with this type of GM maize. In anticipation of possible trade disruptions, a comprehensive plan was developed and implemented with farmers, traders and authorities to segregate product flows in transport, storage and in the fields.

Despite the unprecedented and extensive measures, and the relatively low level of adoption in the first year, 54.5% of all tested samples taken on US barges were positive and shipments entering Europe were found to contain the maize. The cost of the resulting trade blockages was estimated at tens of millions of Euros for exporters, traders and European farmers. The maize was finally approved in the EU in September 2007.

National research institutes in Brazil, China and others, also develop GM seeds. Because in many cases they do not intend to export those products to Europe, they have little commercial interest to submit products for approval in the EU. Nonetheless traces will appear in commodities in Europe, as they already do today.

As foreign governments become seed developers, trade disruptions will also be caused by products resulting from public research, not the products of private companies. This means that trade disputes will have to be dealt with directly between national governments, which adds a new dimension. As food security becomes a national issue in many countries, these countries will focus more on domestic food production than on possible trade issues.

CASE STUDY 3:
A looming problem caused by asynchronous approvals

A GM maize product X was approved for cultivation in Brazil in 2009. A triple stack, containing product X and products Y and Z, submitted by the same applicant to the Brazilian authorities was approved for cultivation in early 2011. This commercial product X.Y.Z is cultivated commercially in Brazil in 2011.

This same GM triple stack product X.Y.Z was submitted to EFSA in the beginning of 2009, together with a full data package on product X whereas products Y and Z were already approved in the past in the EU. However, due to the new policy of EFSA to assess all single products before starting the assessment of the stack, the applicant was requested by the European Commission in April 2010 to submit also a separate dossier for the single product X to EFSA, although all safety data was already with EFSA since early 2009. The applicant did so in July 2010, even though the intended commercial product was the triple stack, not the single product.
Since EFSA has decided to start the assessment of the stacked product only when the assessment of all the singles therein has been completed, it will still take many years before this triple stack can be authorised in the EU. Given the average time of 45 months to approve the GM import file, the single product is not expected to get an approval before the end of 2012/ beginning of 2013.

Following the new EFSA policy, the assessment of the stacked product will only start after the assessment of the single product and the timelines for final authorisation of this stack would run well into 2014. By that time this triple stack will already be cultivated in Brazil and in other countries (US, Argentina) for several years. This can have an important impact on trade of maize commodities with the EU.

EU farmers, competitiveness and innovation climate

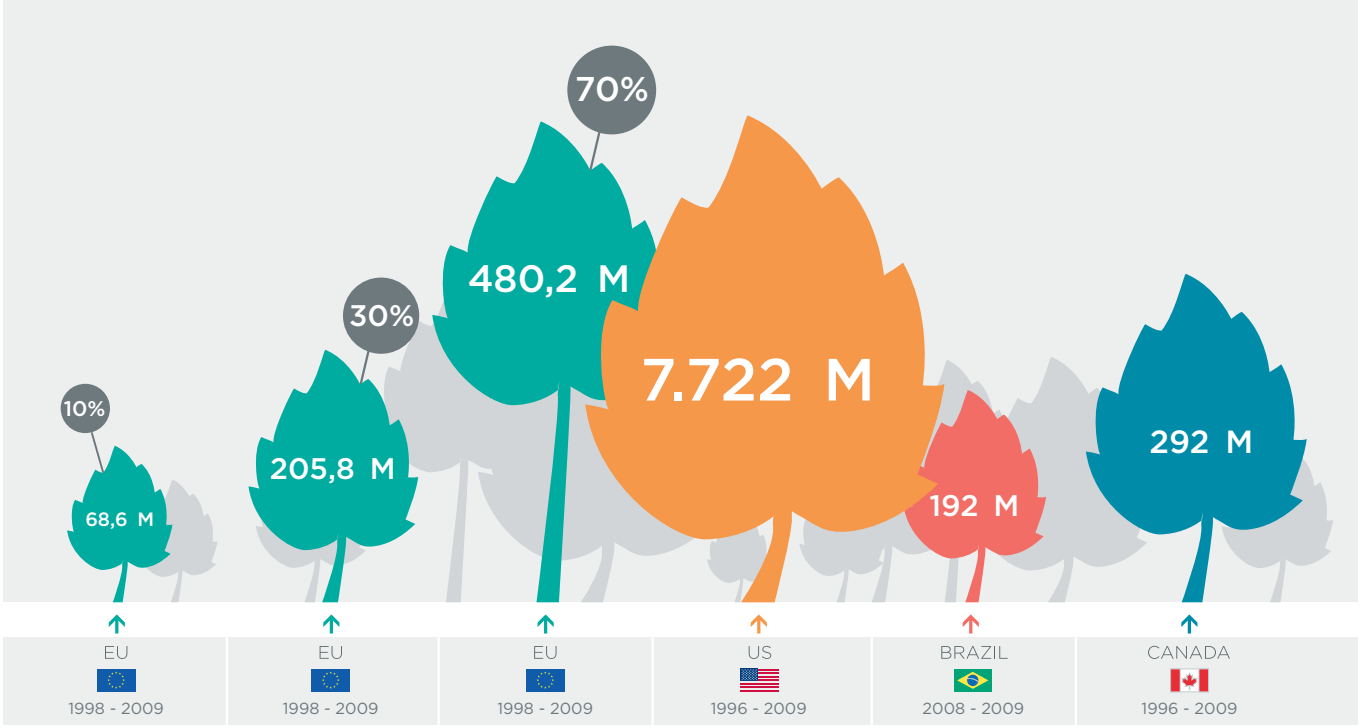
Farmers in the EU are experiencing negative impacts by being denied access to GM plants. GM crops give farmers competitive benefits by reducing costs due to more targeted use of plant protection products and being more resource effective. EU farmers are not allowed to grow the same GM products that the EU has said are safe to eat and that are being imported from abroad. A recent report from the University of Reading calculated that European farmer margins would increase by an estimated €443 to €929 million each year, were they allowed to grow GM maize, cotton, soya bean, oilseed rape and sugar beet, where there is agronomic need.[14] The chart shows estimates of lost revenues.

The prohibitively high cost of developing a new GM product is caused in large part by the high regulatory costs. The unpredictability and high cost of the EU authorisation system has made it nearly impossible for smaller companies or universities to commercialise new GM products. Because of the uncertain market prospects for biotechnology in the EU, many scientists and professionals from the EU find better employment in more technology-friendly environments in other parts of the world.

Research projects on GMOs sponsored by the Commission have almost exclusively dealt with issues of food and environment safety and management (detection methods, coexistence) whereas there is little focus on research on developing new innovative solutions for agriculture to address the global challenges of food security and climate change or to boost competitiveness of EU farmers, though this may be changing.

FIGURE 5: GM crop farm income benefits in the EU under three scenarios

(10%, 30%, 70%) compared with the US, Brazil and Canada



% Percentage of area where farmers would gain an economic benefit from growing GMOs

Source:
Park et al. The impact of the EU regulatory constraint of transgenic crops on farm income http://www.sciencedirect.com/science?_ob=PG Economics GM crops: global socio-economic and environmental impacts 1996-2009 www.pgeconomics.co.uk/pdf/2

The chart shows additional farmer revenues for four areas due to the use of GM crops.

For EU farmers, the chart shows three potential scenarios of additional revenues had they been allowed to adopt available GM crops there where it would be useful (1998-2009).

- At a **10% adoption rate** they could have accrued benefits of €68 million.
- At a **30% adoption rate** they could have accrued benefits of €205 million.
- At a **70% adoption rate** they could have accrued benefits of €480 million.

Through the use of GM crops
US farmers earned an extra €7,722 million between 1996-2009.
Brazilian farmers earned an extra €192 million in 2008-2009 alone.
Canadian farmers earned an extra €292 million between 1996-2009.

Data in this chart based on Park, J., (2011) The impact of the EU regulatory constraint of transgenic crops on farm income.

CASE STUDY 4:
Lost income for Romanian farmers

Before its accession to the EU in 2007, Romania gained extensive experience with the cultivation of herbicide tolerant (HT) GM soybeans. These were grown commercially in Romania from 1999-2006 and accounted for 68% (about 137,000 ha) of all soybeans planted there in 2006. Cultivation then had to be stop because the crop had not yet been approved for cultivation by the EU. Romania is still waiting for the authorisation of this GM soya bean which has been undergoing EFSA assessment since 2005.[15]

Farmers who used HT GM soybeans indicated that it was the most profitable arable crop grown in Romania, with gains derived from higher yields and improved quality of seed coupled with lower costs of production. In 2006, the profit margin per hectare ranked between €100 and €187, while in the same year conventional soya bean growers were running losses. The increase in income was the result of herbicide cost reduction as well as the higher yields (3-3.5t/ha for HT versus 2 t/ha for the conventional product). According to the Romanian agriculture minister, Romania's annual loss from not cultivating GM soybeans amounted to approximately €1 billion.[16]

CASE STUDY 5:
The Spanish Bt maize experience

Spain is the country with the largest GM cultivation in the EU, all of it being Bt maize. Additional farm income since introduction of the technology in Spain has been calculated at $93.5 million. Average additional earnings in Spain were €186/ha. The average yield increase is 6.3% and depends heavily on the intensity of pest infestation (with low infestation, yield increases of up to 1%, with high infestation, yield increases of 10 to 20% have been reported). In a recent survey, 93% of Spanish farmers who planted Bt maize in 2010 said they would do so in the next season. Indeed, according to the Ministry of Agriculture in Spain in 2011, 97,326 hectares (26,5% of the total of maize grain sowed) was GM, an increase of 27% over 2010.

In Spain, GM adoption is not statistically related to farm size and there was no impact on the amount of farm labour employed. Yield gains on Bt maize translated directly into revenues increase, as there is no difference in the crop price paid to Bt or conventional maize farmers. The economic welfare resulting from adoption of Bt maize in Spain is shared between farmers and seed companies, including the seed developer, seed producers and seed distributors. The largest share of welfare (74.4% on average) went to Bt maize farmers and the rest to the seed companies (25.6% on average).[17]

5. THE AUTHORISATION PROCESS: ISSUES AND RECOMMENDED IMPROVEMENTS

Compared to the general characteristics of a functioning regulatory system (see Annex 5), there are a number of issues related to the EU authorisation process which make it challenging for: 1) authorisations to be achieved within acceptable timelines and 2) applicants to live up to the regulatory requirements.

These issues are set out in this chapter. Eight issue areas are defined and 22 recommended improvements are proposed. All recommendations are intended to: increase the efficiency of the system and decrease the time required during the administrative parts of the EU regulatory framework. None of the recommendations in any way decrease the independence and the rigour of the scientific assessment.

ISSUE AREA 1
High levels of unpredictability of timing in the EU authorisation system resulting from political decisions made by the European Commission. Process efficiencies are possible.

Issue

There are currently (31 August 2011) 51 GM products for import/processing and 21 for cultivation in different stages of the approval system. In general, timelines for GM product authorisations in the EU are substantially longer than in other parts of the world. Moreover, there are big differences in the EU authorisation timelines for different products.

On average, a GM import authorisation takes 45 months to go through the process. This is one and a half to two years longer than for authorisations in other countries. Over 16 months out of these 45 are directly dependent on Commission action and Member State voting. However, past evidence shows that this average time frame of 45 months can be 25 months or can be as long as 73 months.

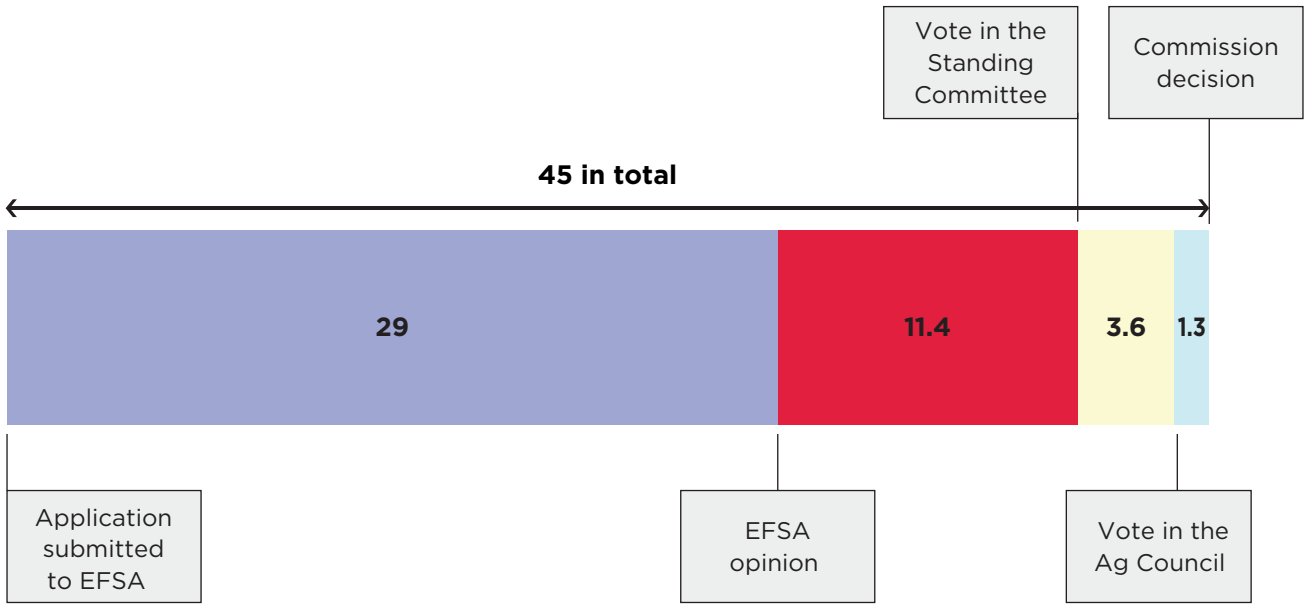
These extreme variations in timing show the lack of predictability. Moreover, products with a positive EFSA opinion do not follow a chronological order whilst going through the voting process. For the applicant, this prediction is pivotal to understand the potential impact on trade and when planting of the GM crop in third countries is envisaged.

Voting opportunities are very often cancelled. Despite the long waiting list of products that should be voted on, in 2010 almost 50% of Standing Committees for Member States to vote on products were cancelled (five out of 11 meetings were cancelled and three two-day meetings were reduced to one-day meetings). By summer 2011, five out of six Standing Committee meetings scheduled for the first half of 2011 were cancelled. One additional Standing Committee was organised in 2011, which was originally not scheduled. However, no product votes were put on the agenda.

The practice of grouping product votes (collecting 3 or more products to vote on only a few times a year) is a major cause of the delays. This practice is not in line with the legislation which prescribes 3 months as the period the European Commission should take at maximum between EFSA opinion and vote in the Standing Committee.[18]

It has been argued that this practice leads to more consistent voting results. However, detailed analysis of the product voting at Standing Committee and Council does not show any noticeable difference in voting results. The voting results confirm that countries vote per product and that grouping them does not lead to any change.

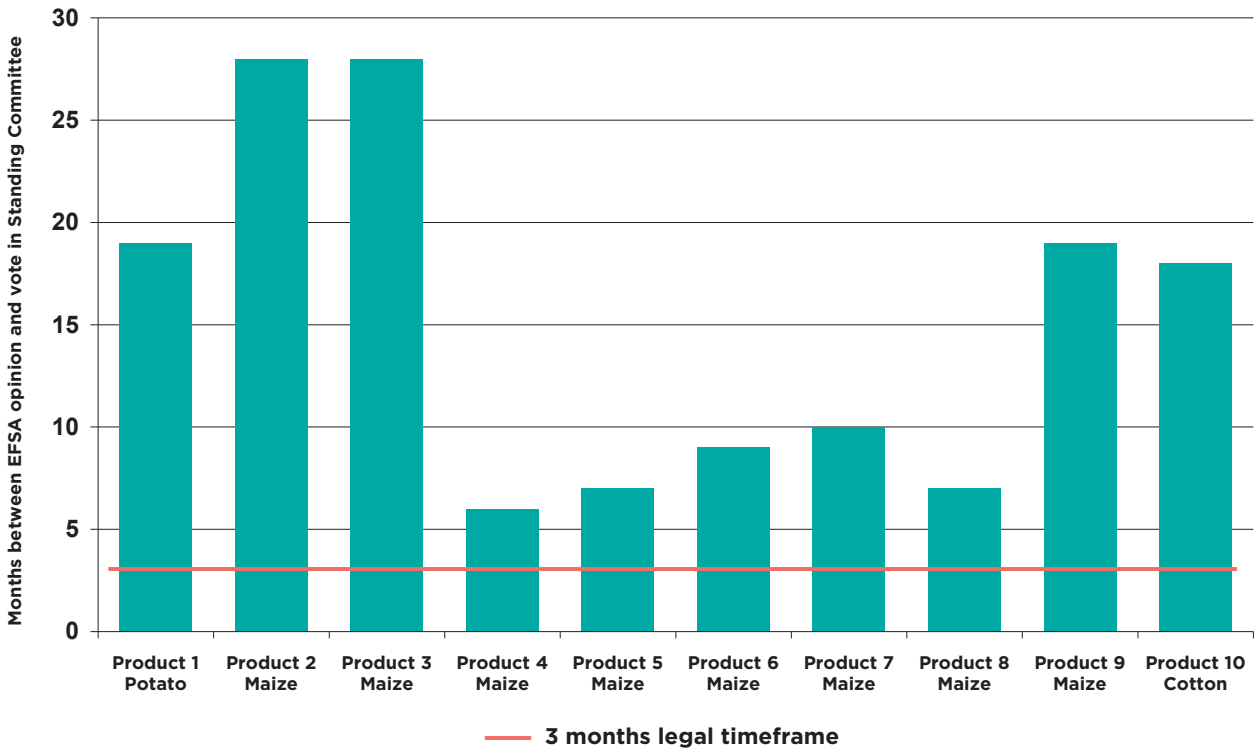
FIGURE 6: Average duration of GM food and feed products authorisation in the EU (in months)



The chart shows that of **the average time it takes to assess and process an import application** (45 months) approximately one third of the time (16+ months) is spent on file processing and voting related procedures rather than safety assessment at EFSA.

On average, over **11 months** pass between a receipt of an opinion from EFSA and the first Member State vote. The law prescribes **3 months**.

FIGURE 7: Months between EFSA opinion and voting of the last 10 GM products approved for import (excluding renewals)



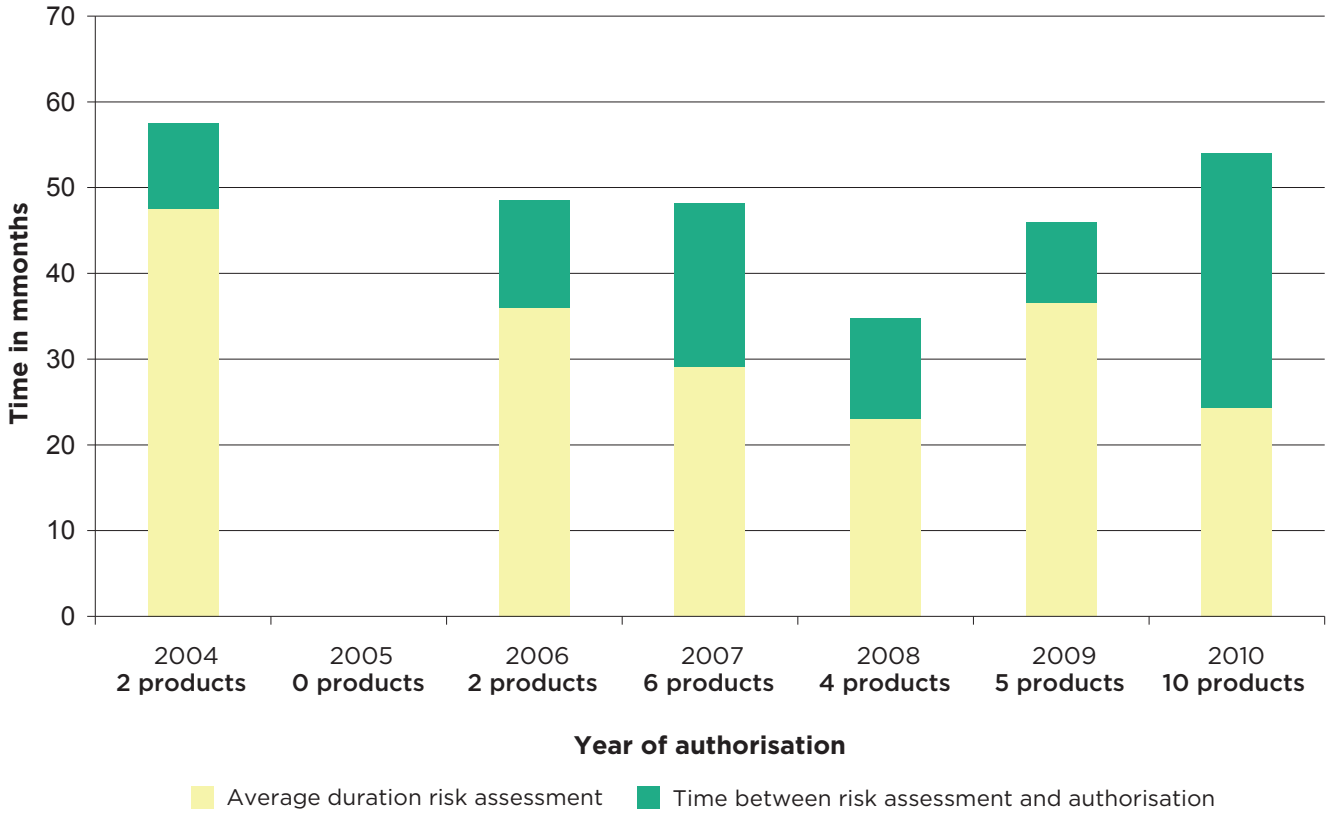
Timelines of the last 10 GM products approved for import.
The bars show the number of months between the EFSA opinion and the first vote by Member States. In all case the legal timeframe of 3 months – the red line – was exceeded. Even for products that move faster than average the number of months is more than double of the legal timeframe. Note this chart excludes renewals.

TABLE 2: Timelines for the last 10 GM products approved for import (excluding renewals)

Product	EFSA Positive opinion given	First time voted by MS (Standing committee)	Months	Months over legal deadline
Product 1 POTATO	24/02/2006	10/10/2007	19	16
Product 2 MAIZE	12/07/2005	10/10/2007	28	25
Product 3 MAIZE	12/07/2005	10/10/2007	28	25
Product 4 MAIZE	21/07/2009	10/02/2010	6	3
Product 5 MAIZE	29/09/2009	19/04/2010	7	4
Product 6 MAIZE	06/05/2009	10/02/2010	9	6
Product 7 MAIZE	08/04/2009	10/02/2010	10	7
Product 8 MAIZE	22/09/2009	19/04/2010	7	4
Product 9 MAIZE	30/03/2010	15/11/2011	19	16
Product 10 COTTON	10/03/2009	24/09/2011	18	15

In 2010, the European Commission approved 11 GM products, including 5 products that had been pending for a long time. But even when these files are not taken into account in the calculations, the average time taken by the Commission to approve a GM import product was still higher in 2010 than in 2009 (14 and 10 months respectively).
At the time of writing, 18 GM products (14 for import, 4 for cultivation) have received a positive opinion from EFSA and await direct action by the European Commission.

FIGURE 8: Average time for approval of GM import applications in 2004-2010



The chart shows that the average time it takes to approve a GM product is increasing. In 2008, it was less than 40 months on average. By 2010, it had increased to 52 months. Despite these long timelines in 2010, eight out of the 10 products approved were stacks and one was a renewal. Only one new product for import was approved in 2010. Some products with a positive EFSA opinion have been waiting for years for Commission action.

Notes: This chart includes all import products (not products for cultivation). No products were approved in 2005. 2011 it is not included in the graph. Three products were approved in the first 9 months.

The European Commission's DG Agriculture released an extensive analytical report about asynchronous authorisations that concluded that: *"One possibility to avoid the situation above from occurring is to speed up the authorisation processes for novel GM products."*[19] At the time of writing, few envisaged improvements aimed at streamlining or accelerating the administrative parts of the process are known. In 2011 there have been only 3 product authorisations so far (September 2011) and the last approvals before date from 11 months earlier in July 2010.

Impact of issue

The regular cancellation of opportunities to vote has an immediate and negative impact on the timing of pending procedures and on the number of authorisations. By cancelling Standing Committee meetings, timelines become longer and the backlog waiting for Commission action increases.

While products are pending in the process, they do not have a commercial value for applicants and users. For the user (e.g. farmer), each delay

is a loss of another planting season with negative economic implications. For farmers who use imported grains to feed their animals, undue delays can and have in the past caused unnecessary price increases. For applicants, it is increasingly difficult to make any predictions about timelines for their product authorisations.

The backlog is detrimental to farmers. The slow approval process in the EU hampers the commercial introduction of safe and innovative GM products and denies their benefits to farmers.

The backlog causes trade problems. The countries from which the EU imports commodities are eager to provide the benefits of new GM varieties to their farmers. The pace of authorisations in the EU has until now had a slowing effect on the adoption of beneficial new varieties in their countries.

Due to the limited resources devoted to processing product applications, the responsible Commission unit is burdened unduly. The unit is also required to fulfil policy requirements (consultations, reviews, reports, parliamentary questions, public events, etc).

In the whole Commission less than 20 people are responsible for all authorisations and policy issues. DG Agriculture has very few people dealing with GM issues. These factors are an indication of the low priority attached to GM products, and do not reflect the importance of GM in agriculture – namely the fastest adopted agricultural technology ever. 10% of global arable land is planted with GM crops, and it expands each year in the double digits.

There is no holistic approach to GM authorisations that incorporates strategic input of all affected DGs (Health, Environment, Agriculture, Research, Trade, and Enterprise).

Examples

1. The European Commission rarely submits an application to the Standing Committee within the legally prescribed timeframe of 3 months.
2. Some products have been waiting for many years.
3. The Commission has cancelled a large number of voting opportunities.

Recommended solution 1
Efficient processing of product applications should be a higher political priority. The first step to achieve this would be that the legally prescribed timelines should be respected. In addition, each year clear targets should be set to reduce the backlog and to approve a sufficient number of GM products. A specific list of time indicators of progress could be established in order to measure progress. Moreover, a chronological order should be followed when products with a positive EFSA opinion go through the voting process. The most logical would be to follow a *"first in, first out"* approach.

Recommended solution 2
Standing Committee meetings should not be cancelled anymore with the reason that there are not enough items on the agenda as long as there is a long list of products waiting for a vote. A new rule of thumb should be set: each dossier should be put on a Standing Committee agenda for voting at the first or second available meeting after finalization of the public consultation.

Any scientific considerations on a product provided during the process (or after approval), should be duly and thoroughly considered by the Commission and EFSA if deemed appropriate, but should not lead to undue delays. If considerations are submitted outside of the legally foreseen consultation periods, these should not prevent the Commission to progress the application, in the same way as authorised products are not automatically revoked by each allegation.

Recommended solution 3
More working time should be devoted to processing authorisations. Given the projected workload, it is also recommended to increase the number of staff in the relevant Commission unit dealing with authorisations. In addition, it is recommended that a dedicated number of man-hours be devoted exclusively to furthering authorisations.

ISSUE AREA 2
The European Commission recommends risk management measures deemed unnecessary by the scientists at EFSA.

Issue
The European Commission has recommended some risk management measures deemed unnecessary by EFSA scientists. This is done to assuage political needs and not because the scientific community has deemed such measures necessary to assess safety. It is argued that such (non-scientific) measures are needed to increase public confidence in the risk assessment process and in GMOs. However, creating new requirements that have no legitimate scientific basis has the exact opposite effect. They create the impression that political considerations will overrule scientific facts, and that the current risk assessment process is not robust.

Ultimately, measures for political sake without scientific basis detract from the credibility and legitimacy of EFSA and EFSA assessments, and this weakens public confidence in EFSA. The existing strict system should be defended. Risk management measures deemed politically convenient but scientifically unjustified should be avoided.

Impact of issue
It slows down authorisations and increases costs. Moreover, it undermines EFSA's credibility.

Examples
Example 1: 90-day rat studies
Existing EFSA guidance on GM Food Feed risk assessment requires a 90-day rat feeding study to be carried out on a case-by-case basis. According to EFSA guidance, the need for a 90-day rat feeding study is only justified when the composition of the GM plant is modified substantially, or if there are any indications for the potential occurrence of unintended effects. Therefore, recent indications that the European Commission will request a 90-day rat feeding study in all or many more cases go against the science behind the existing EFSA guidance.

Example 2: Antibiotic resistance markers (ARMs)
Antibiotic resistance markers (ARMs) make it easy to recognize the transformed plant cells among the multitude of untransformed ones. EFSA reconfirmed the safety for humans, animals and the environment of specific ARM gene(s) used for the development of genetically modified plants. For example, an EFSA opinion on 11 June 2009 concluded that:

1) The current state of knowledge indicates that adverse effects on human health and the environment resulting from the transfer of two antibiotic resistance genes from GM plants to bacteria, associated with use of GM plants, are unlikely.
2) Its previous assessments on GMOs containing an antibiotic resistance marker gene are in line with the risk assessment strategy - that no new scientific evidence has become available that would prompt the Panel to change its opinions.

Nonetheless, there are moves to phase out ARMs. ARMs are widely used by public scientists, and as other selection methods are far more expensive, this will make it even more difficult for public scientist or SMEs to develop new products. No other nations have indicated any issues – scientifically or politically with ARMs. EFSA has consistently confirmed the safety of ARMs in different reports[20].

Recommended solution 4
In order to maintain EFSA's autonomy in the tasks under its responsibility, and to keep the scientific and political components of the process separate, it is recommended that the Commission only adds new requirements in the risk assessment procedure if EFSA deems this necessary.

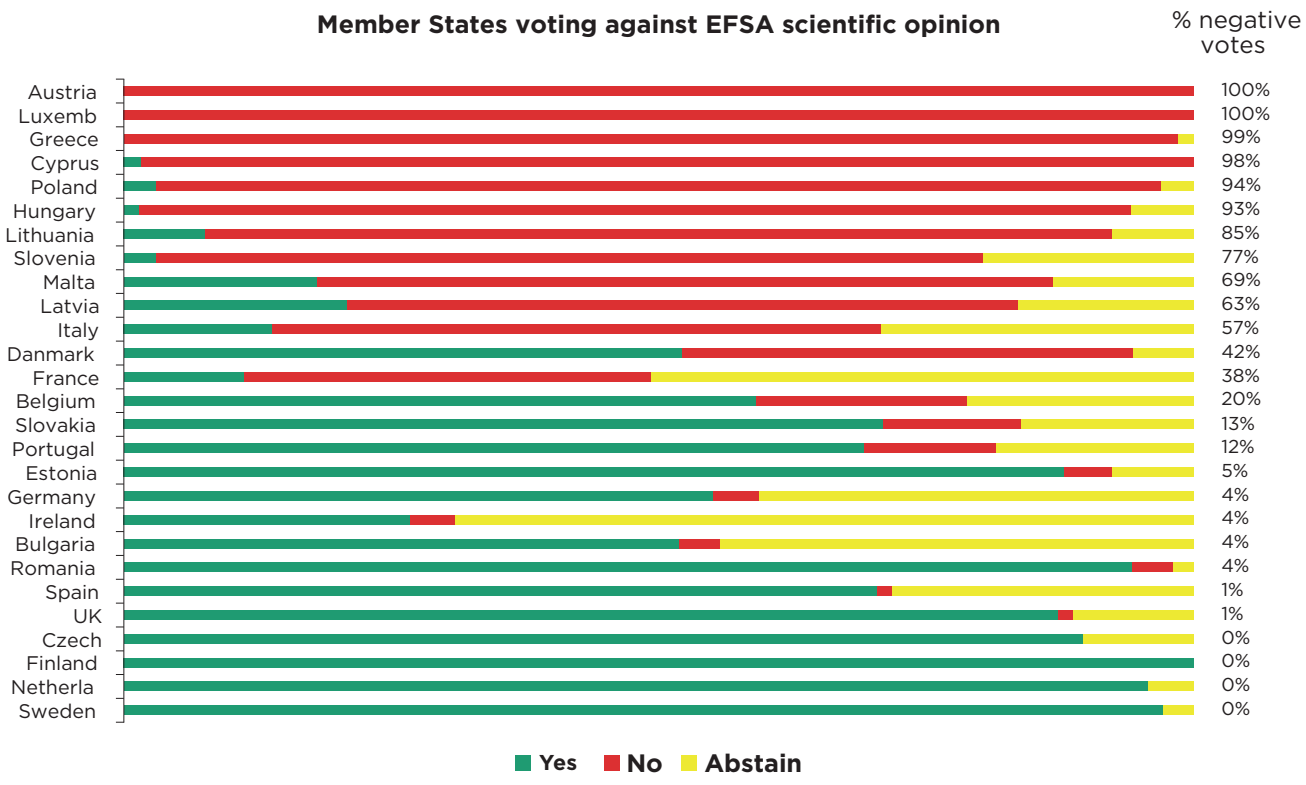
ISSUE AREA 3
Member States vote against scientific opinions, but are not required to justify their decision.

Issue
There is a minority of 10 Member States that consistently vote against the scientific opinions of EFSA. This minority does not want to grant new GM authorisations or fears political damage if they vote in favour of an application.

These 10 countries represent only 15% of the total EU population, less than a fifth of EU cereal production, about a fifth of EU oilseed production and only a quarter of the total votes in Council.[21]

The six smallest of these countries, because of their limited market size, are commercially less interesting. Most of these countries import GM feed to feed their animals.

FIGURE 9: Detailed voting pattern of each Member State



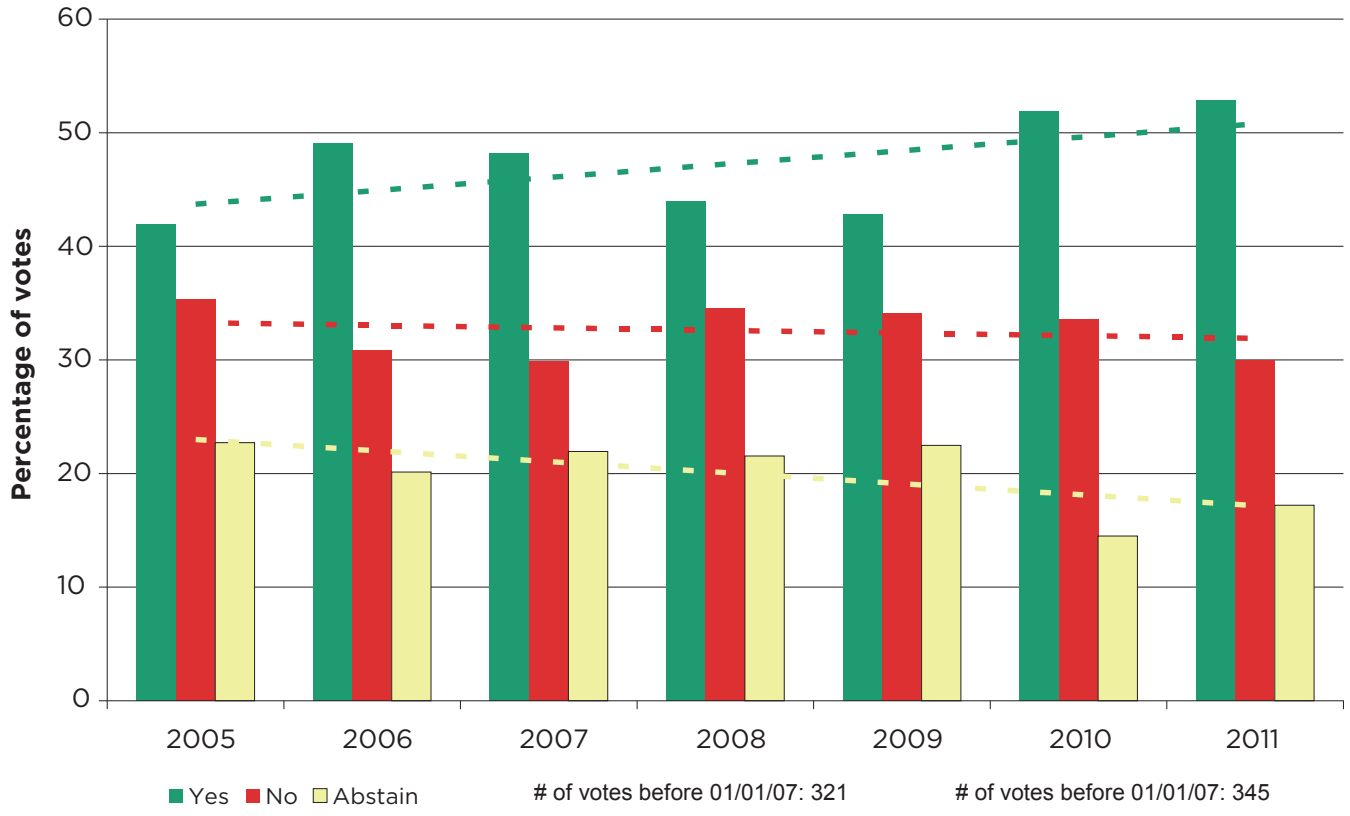
The chart shows that 10 countries vote against the EFSA scientific opinion ranging upwards of 63% of the time. The percentages incorporate all votes made in Standing Committee and Council (upwards of 60 votes for some countries).

Impact of issue

Voting against the EFSA scientific opinion slows down the approval process. It also politicises the scientific opinion. Several countries openly admit that their vote is political and not based on scientific considerations. By disregarding the scientific opinion, they prevent the GM regulatory framework, which was agreed in full co-decision between Member States and European Parliament from working as intended. This voting pattern is preventing new GM product authorisations and stopping other Member States from providing access to new products to their farmers.

Since 2010, over 50% of votes cast are in favour of approvals.

FIGURE 10: Member States voting patterns between 2005-2011



There is a clear increase in the percentage of positive votes cast in favour of GMOs, reaching more than 50% since 2010. The votes against GM approvals and abstentions have decreased.

TABLE 3: Member States voting trends over the last 10 votes (indicating Council voting weight)

Country	Trend measured over the last 10 votes
Germany (29)	Positive
UK(29)	Positive
Italy (29)	Positive
Spain (27)	Positive
Romania (14)	Positive
Netherlands(13)	Positive
Portugal (12)	Positive
Belgium (12)	Positive
Czech R.(12)	Positive
Sweden (10)	Positive
Slovakia (7)	Positive
Finland (7)	Positive
Denmark (7)	Positive
Ireland (7)	Positive
Estonia (4)	Positive

Country	Trend measured over the last 10 votes
France (29)	Negative/Mixed
Bulgaria (10)	Negative/Mixed
Poland (27)	Negative
Hungary (12)	Negative
Greece (12)	Negative
Austria (10)	Negative
Lithuania (7)	Negative
Latvia (4)	Negative
Slovenia (4)	Negative
Luxembourg (4)	Negative
Cyprus (4)	Negative
Malta (3)	Negative

The chart shows the most recent voting behaviour per country of the last 10 GM product votes.

Recommended solution 5
Prior to the vote the Commission should set out the direct implications of a non-approval vote, including an overview of lost economic value and other drawbacks of a negative result.

Recommended solution 6
Specifically with respect to GM cultivation dossiers, the Commission should find a legitimate path forward allowing freedom of choice and the possibility for those Member States that want to adopt GM crops to move ahead. Figure 10 shows that over the years, more and more countries vote in favour of GMOs so ways must be found to let them progress.
Setting aside the discussions related to the nationalisation proposal, it is clear that a political solution must be found to break the current deadlock. Industry has offered ideas to achieve this without many of the negative secondary effects many Member States associate with the current proposal.

ISSUE AREA 4

Efficiency improvements are possible at EFSA, without in any way affecting the thoroughness, completeness, independence or strictness of the safety assessment process.

Issue

In addition to the scientific quality standards (past and current scientific opinions are of high quality), operational standards need to be established. Operational standards will reinforce the scientific standards and enhance the reputation of EFSA as a centralized and independent scientific authority.

The high workload at EFSA, in part caused by high numbers of questions, consultations and additional mandates, comes at the cost of time that could be spent assessing applications. The reorganisation of EFSA made public in May 2011 is a promising start. Additional suggestions are proposed below.

It has been noted that, in the past, the GM application dossiers have not always been as robust and comprehensive as desired by EFSA. This situation has changed and the quality of GM applications has improved noticeably. This has not resulted in shorter timelines, nor fewer questions asked to the applicants.

Impact of issue

Operational adaptations in procedures and in interaction with applicants could lead to increased efficiency and considerable time savings in the assessment of applications without compromising on their current scientific quality.

Recommended solution 7

A transparent implementation of a work plan for each application would help to structure the risk assessment process. This could eliminate delays at the start of the risk assessment immediately after the applicant has submitted any additional information requested.

Recommended solution 8

The risk assessment by different working groups and by the different Member States should all be carried out in parallel and in an independent way, and the procedures followed should be auditable.

Recommended solution 9

Clarifications on content or terminology play an important role in enhancing the understanding of additional requests. Exchanges between applicant experts and EFSA experts are essential, especially when costly and time-consuming additional studies are envisaged.

A better, more structured process is desirable for information exchange between applicants and the EFSA Secretariat and experts in order to resolve questions and find acceptable solutions. Such meetings will enable technical discussions and consultations on methodologies used.

Questions from EFSA to applicants should be clearly formulated to avoid misunderstandings and to help applicants to respond effectively. Often the questions posed require unexpected additional information. In such cases applicants should be given the flexibility to offer pragmatic and timely solutions without compromising safety.

ISSUE AREA 5

EFSA re-interprets its guidance or retroactively applies its guidance.

Issue

On a regular basis, EFSA has reinterpreted existing EFSA guidance on GM Food and Feed Risk assessment. Such a new interpretation of an existing, published guidance document is first communicated to individual applicants in light of the ongoing risk assessment of a specific application. Eventually such a new interpretation becomes the new 'rule', communicated more formally to all applicants in a joint meeting, or becoming part of a new, updated guidance document. As a consequence, applicants are faced with the challenge of 'moving goalposts'. They are expected to fulfil unforeseeable, new requirements which are often not yet officially prescribed, during the EFSA scientific risk assessment of their applications.

New EFSA requirements or updated guidance documents, which are applied retroactively to all applications under the EFSA review, change interpretations over time.

Impact of issue
For applicants, it is difficult to foresee and fulfil all the requirements of an application, which usually takes several years to put together before it can be submitted to EFSA, if requirements change throughout. As applicants need to provide additional data and information in order to meet new requirements, the risk assessment process is slowed.

Given the time that some of these applications spend in EFSA (on average 2,5 years for import applications and many years longer for cultivation applications), retroactive changes create a situation of constantly 'moving goalposts'. Applicants cannot foresee what data package is required for a complete application and are requested repeatedly to update their dossiers with new information.

Examples
Example 1: From the time EFSA published its first guidance document up until now, EFSA gradually increased its requirements with regards to bioinformatic analyses. One particular requirement that first was requested for individual products was to use current databases. This later became more specific when EFSA required bioinformatics analyses to be performed with databases that were not more than one year old at the time of submission. Knowing that product applications for import on average remain 2.5 years with EFSA, the applicants now face the request to update their bioinformatic analyses for the same product at least twice during the same assessment.

A second requirement which is a moving target is EFSA's request to use *E*-score cut-offs of 10 (make use of default settings). Initially, it was requested for some products and not for others, but currently it is EFSA's preferred way of doing this type of analysis. The main issue with this request is the lack of scientific rationale provided by EFSA. These increased requirements now apply to all applications. Moreover, a request to re-do the bioinformatics analyses also applies to the already risk assessed single (and approved) products in the framework of a stacked trait application.

Example 2: For most of the studies, EFSA currently wants to receive the raw data. This is also a requirement that gradually appeared. Whereas little attention was given to it when the first products were submitted, the question started to come (for individual products and not by official communication) for protein expression and composition data, for example. More recently, the question is also asked for agronomic/phenotypic data. EuropaBio was only informed in September 2010 about this requirement during an EFSA presentation.

Example 3: The new EFSA guidance on Environmental Risk Assessment (ERA) proposes a new tiered approach that is different from the tiered approach used in other risk assessment schemes worldwide for decision-making. Sub-tiers within tiers have been introduced that force applicants to generate more and more data. It is interpreted by applicants that data is required in all different tiers, meaning that in planta data is compulsory even if lower tiers indicate no risk (e.g. honey-bee study with pollen being asked for all cultivation dossiers). The applicant is forced to dismiss its protein base studies and instead do in planta studies which are not always needed nor easy to perform or useful in terms of quality of results to assess risk of the GM to non-target organisms.

The new EFSA guidance on ERA asks to begin to use modelling for exposure assessment in the surrounding field environment, though the specific examples that applicants are to follow are not made clear.

The new EFSA guidance on ERA asks for a consideration of the effects of natural stacking (in the field), which takes into account all other traits to be approved for cultivation.

Recommended solution 10
New requirements should only apply once they are clearly formulated in a newly adopted, updated guidance document. Any changed interpretations should be clearly communicated and the scientific rationale explained to all applicants, including the date as of which these changes enter into effect. A transition period should be foreseen according to the context of the proposed change. It should be kept in mind that certain studies may take years to complete.

Recommended solution 11
EFSA should include, wherever possible, clear endpoints and a rationale for certain case-by-case recommendations. Absence of these can lead to different interpretations of the possibility for a case-by-case risk assessment and thus potentially to long delays in the progress of an application, if additional data need to be generated.

Recommended solution 12
EFSA guidance should not be applied retroactively to applications already in the process, and should clearly stipulate when new data requirements come into effect. A transition period should be allowed for applicants to prepare the appropriate data package.

ISSUE AREA 6
The EU approach to stacks, scope, stand alone applications and renewals can be more efficient without compromising on safety.

STACKS

Issue
Until recently, applicants only submitted applications for products intended to be placed on the market. In a situation where only a stack and not the individual single products were to be commercialised, EFSA accepted stack applications in the past, provided that the information on singles was included in the dossier. However, a recent EFSA rule now says that the risk assessment of stacked products can only start after the risk assessment of the respective single products.

The Commission's approach to stacks allows applicants to submit a single application for the highest order stack, covering all sub-combinations of products which could be put on the market[22] (assuming that each single product was assessed).

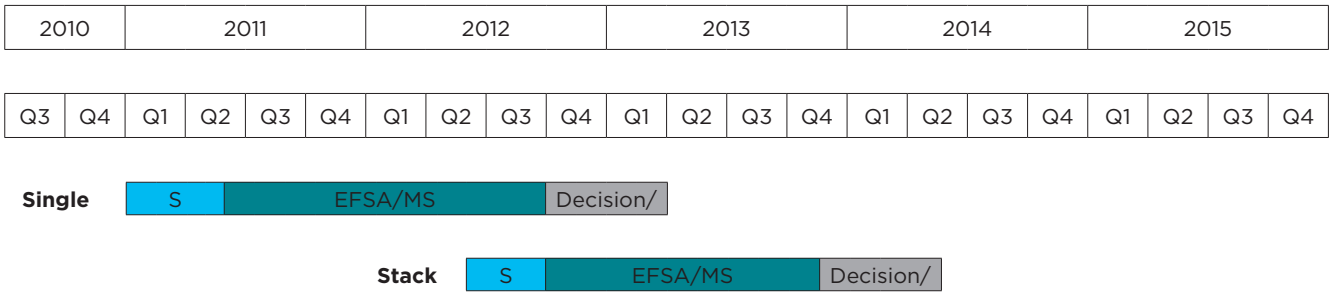
The Commission recently started to ask for separate applications for all singles, independent of whether they are intended to be commercialised or not. Following the Commission's lead, EFSA now recommends submitting all applications for stacked products at a later stage, once the assessments of all single products are close to finalisation. The EFSA scientific review of the data supplied for the stack even goes beyond what is stipulated as necessary by EFSA, namely verifying absence of interactions based on: a) stability of the inserts, b) expression of the introduced genes and their products and c) potential synergistic or antagonistic effects resulting from the combination of the products.

For the approach to the stacks, EFSA does not take into account sufficiently all the past experience gained from the individual risk assessments of the products that make up the stack . The EU is one of the few regions in the world requiring separate applications for stacked products.

Impact of issue
Compared to other parts of the world, the data requirements for stacked products are disproportionate in the European Union. As a consequence of its sequential approach based on separate submissions, single products are assessed many different times: first for the single authorisation, afterwards as part of (one or more) stack applications, and possibly a third time as part of renewals or cultivation files. This recurring reassessment produces new questions for products that are already approved in the EU.

Because the single products have to be assessed prior to the assessment of the stack applications, the current approach makes the review timelines for the actual commercial product even longer and increases the workload significantly. As a result in most of the cases this will mean at least one year difference in the approval timelines of singles and stacks.

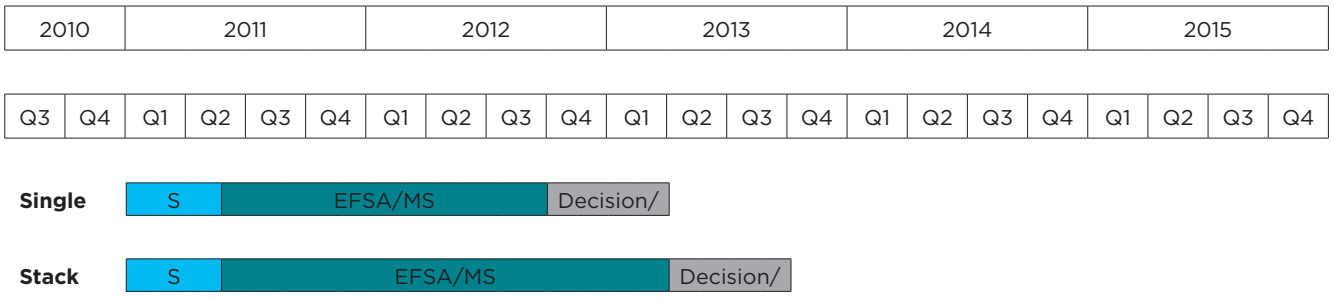
FIGURE 11: Current EU approach to stacks
Current process: Stack being reviewed after the scientific opinion of singles



Recommended solution 13
If the EU framework and approach to scientific review for stacks remains as it is, the following solution can increase efficiency: stack applications should be reviewed in parallel with their individual single applications. There is no scientific reason why the review of a stack cannot start at the same time as the one for its individual single review; the core part of a stack dossier consists of stack-specific risk assessment data.

After the opinions of the singles have been completed, EFSA can - in collaboration with the applicant - upgrade the stack dossier with the additional information provided during scientific review of the singles and EFSA can complete its assessment by verifying an absence of interactions. In this way the approval times for singles and stacks can be achieved in shorter timeframes, particularly in those cases where the comparative risk assessment data for stacks compares the test article against a conventional comparator. This change in approach can reduce the delay in the approval by many months.

FIGURE 12: Recommendation for EU approach to stacks
Best case scenario: Stack being reviewed in parallel to single applications



In order to reduce timelines to the minimum, two alternative solutions can be proposed, their applicability depending on the Commission's and EFSA's willingness to change the current approach to scientific review of stacks.

If the Commission and EFSA are willing to accept that the risk assessment information for the singles is attached to the stack application, the number of applications would be reduced. This would mean that fewer resources would need to be dedicated to the completeness check and the upgrading of applications with information requested in the context of single applications. In this way, it is expected that the approval times for the commercial stack product can be reduced by 6 months.

Recommended solution 14
Failing the above preferred option, if the Commission and EFSA prefer separate applications, then reducing the stack application to a simplified procedure or a notification including the necessary information to assess absence of interactions and cross-referring (rather than including) the single applications would be a second option. It is expected that this would be the most efficient process which would result in a smaller difference of approval timelines between singles and stacks.

However, the recommendation from the European Commission and EFSA, to submit the stack applications only close to finalisation of the single opinion is commercially unacceptable as it is delaying the approval of the only products that will be placed on the market, namely the stacked products. It is also a significant contributor to the problems associated with asynchronous approvals.

SCOPE OF APPLICATIONS

Issue
The European Commission recommends submitting only applications with a comprehensive scope. This means that the scope of an application should not be restricted or limited to specific uses. For products for which authorisations have been granted in the past for specific uses only, additional applications need to be submitted to cover all uses, independent of whether the use is intended or unintended. In some cases, this relates to products that already have been positively assessed by EFSA on several occasions over the last years.

Although these additional applications require the broadening of the scope, there are no changes in the hazard characterisation for the specific products, i.e. no new hazards have been identified by EFSA.

As a consequence, the risk assessment for these additional scope applications should only focus on the exposure, which in these specific cases will be negligible. However, even for these additional scope applications, EFSA requests a full and independent stand-alone application including all scientific data that has been reviewed by EFSA in the past.

Impact of issue
Timelines increase even further as EFSA reviews the already assessed applications again and again and comes with new questions on the dossiers that have already been positively assessed and in some cases already approved.

Examples
Example 1: Cottonseed contains the toxic compound gossypol and is therefore not intended for consumption by humans. However, the Commission asks applicants to include a toxic use ("food containing and consisting of GM cottonseed") into the scope of a GM cotton application.

Example 2: Applicants were requested by the Commission to also include possible unintended uses into the scope of the GMO application. This meant in practice that a new application had to be submitted to EFSA to complement the scope for a given trait, which had already been assessed by EFSA in the past. The data package remains the same, since in this issue of scope the use – or in other words, the exposure component of the risk assessment – is the only variable that changes.

From the perspective of process, it is not efficient to ask for a complete review of a product because its scope is different, especially as the fundamental risk assessment has already been done and remains the same. The data from comparative studies (composition, agronomic/phenotypic, animal feeding) show that GM and control are the same without unintended effect, safety data of the new protein do not change, and molecular characterization does not change.

Recommended solution 15
For products that have already received an EFSA opinion, a new application can be submitted following a mutual agreement between the applicant and the Commission. This application can follow a simplified procedure, in which the Commission mandates EFSA to perform an exposure assessment of the missing scope and to assess safety by combining the conclusions

from the exposure assessment with the hazard conclusions from their previous safety assessment on the product. The applicant can provide information on exposure of the specific uses which are not covered in the previous applications. This way, all uses are covered.

STAND ALONE APPLICATIONS

Issue
EFSA requests all applications to be 'stand alone' applications, i.e. individual dossiers that include all available information. Therefore, applicants have to resubmit data that was already submitted and assessed by EFSA in the past. Cross-referencing to earlier submissions is not accepted. Single products are therefore assessed many different times: first for the single authorisation, afterwards as part of stack applications, then as renewals or cultivation files. This recurring assessment results in new questions for products that have already been approved in the EU.

Impact of issue
Applications become unnecessarily voluminous and complex. The risk assessment process is further slowed down. As a consequence, timelines continue to lengthen. Since several applications are being assessed for risk simultaneously, additional information on a single product may have to be submitted several times.

Example
When an applicant submits an application for cultivation of a product that was already approved for import, the regulatory data have to be resubmitted (and updated). Similarly, for a renewal of a product, the data have to be resubmitted. The situation becomes increasingly complex with stack applications where EFSA requests information on single products that have already been assessed or even approved.

Recommended solution 16
EFSA and applicants should agree on a format to centralise and update the data package for single products. New applications should only require data on new products.

RENEWALS OF APPLICATIONS

Issue
A disproportionate amount of specific information is required for products that have been lawfully placed on the EU market for several years. Moreover, these products benefit from a long history of safe use in the EU and/or other world areas, and for which extensive data packages have been provided at the time of their original notification and whose safety has already been assessed positively by the former Scientific Committees of the Commission or by the EFSA GMO panel.

In asking for renewal applications to be accompanied by a "stand-alone dossier containing all of the information required for a risk assessment", the EFSA draft guidance document exceeds the legal requirements of Regulation (EC) No. 1829/2003. One should expect that the renewal of dossiers would be far more efficient than the processing of new dossiers, but this is currently not the case.

Impact of issue
The EU approach to renewals of applications causes higher workloads and longer timelines since the already positively assessed dossiers need to go through a full risk assessment again.

Examples
This is the case for all renewals in the EU approval process. Recent analysis shows there is little reason for optimism that a renewal application can move more efficiently through the approval process. Timelines are still long and voting outcomes remain inconclusive.

Recommended solution 17
For renewals of products, which have been already on the market for 10 years, a simplified safety assessment should be performed, that takes into account previous safety assessments. Most, if not all of these products have also been assessed by the regulatory authorities of many other countries. Whereas EU authorisations are granted for 10 years, other countries grant indefinite authorisations (called deregulation in some countries). These products have a history of safe use. EFSA should only assess if all requirements according to the legislation (Copy of authorisation, monitoring reports, any new information, literature review, etc) are fulfilled.

Recommended solution 18
If the Commission maintains it's approach to stacks, where the stack dossier includes all the information of the single products, and therefore the single products are assessed again, it would be logical that a renewal is also given for the single products.

ISSUE AREA 7
There is an ongoing escalation of data requirements.

Issue
Applicants receive requests to submit extra clarification on issues that are not specific requirements in the guidelines. The updated guidance documents also demonstrate that the difference between 'need to know' versus 'nice to know' is blurring, which makes it difficult for applicants to know what the exact requirements are.

Impact of issue
The escalation of data requirements causes more delays, additional workload and higher costs to all parties involved, without any benefits with regard to higher assurances regarding safety.

Examples
Example 1: EFSA guidance states that:
"In cases where molecular, compositional, phenotypic, agronomic and other analyses have demonstrated equivalence between the GM plant and derived food and feed and its comparator, except for the inserted trait(s), and have not indicated unintended effects, the performance of animal feeding trials with rodents or other (target) animal species (e.g. broilers) is of little additional value if any, and is therefore not deemed necessary on a routine basis."

In cases where such supplementary information is provided by the applicants, EFSA requests additional information on the supplied information. The requested information is far from being 'need to know' especially considering that the animal feeding trials are not considered to be necessary on a routine basis by EFSA.

Example 2: Applicants are requested to provide information, gathered from expensive and time-consuming tests, for products that will not be commercialised. As single products need to be assessed before the stack product, which is the product of commercial interest, it is requested to provide data, such as compositional data, for all the single products. It is unclear why this information is needed for the single products that will never be commercialised.

Recommended solution 19
EFSA should aim to harmonise its guidance with requirements globally. Interaction with major regulatory bodies outside the EU on guidance would help to ensure that the resulting harmonisation of principles and study requirements offer benefits to all parties involved. Therefore EFSA should compare its data requirements with those agreed at international level, in particular at Codex, to ensure proportionality.

Recommended solution 20
EFSA should organise pre-consultation meetings with applicants when new data requirements will be requested. Through these pre-consultations, there could be a dialogue established which could enlighten all parties regarding which requirements should be added and the reasons for adding these requirements.

ISSUE AREA 8
Numerous late and questionable mandates to EFSA cause additional delays.

Issue
According to Regulation (EC) 1829/2003 on genetically modified food and feed, the general public may make comments on the EFSA opinion within 30 days of its publication. The European Commission analyses all the comments received and consults EFSA to determine whether they have an impact on the opinion.

However, the consultation process is being exploited by some parties with the aim of obstructing and slowing the authorisation system. Irrespective of the legally foreseen period for commenting and without a check for the validity of the claims, inputs into the consultation with broad-ranging allegations regarding the safety of GMOs are routinely forwarded by the Commission to EFSA. Mandates are sent for GM products that are waiting for a vote in the Standing Committee or the Council, or even for those products which already have received authorisation.

Impact of issue
The accumulation of new mandates to EFSA results in considerable additional workload for the EFSA GMO Panel, forcing EFSA to shift resources away from reviewing new applications. This slows down the processing of applications and contributes further to the increasing backlog in the GM authorisation system. In addition, since these new mandates are sent to EFSA at all possible stages, irrespective of the foreseen 30-day consultation period, the further processing of the involved applications is put on hold until EFSA has again validated the outcome of the original risk assessment.

Example
Reports are consistently sent with intimidating claims regarding safety concerns to the Commission, once they become aware of an application for a specific GM product to be discussed and voted in the Standing Committee and Council. Without a specific validation system, the Commission drafts a new mandate to EFSA to verify the claims and stops the processing of the application until a further EFSA confirmation is received. This can lead to additional delays of 6-9 months.

Recommended solution 21
The 30-day window for commenting by the general public should be respected. Moreover, new information received during or outside the commenting period should be checked for relevance and quality and not routinely forwarded to EFSA in the form of a new mandate. This can be done by staff of the EFSA GMO Unit or designated experts.

Recommended solution 22
A dedicated *ad hoc* panel of GMO experts in EFSA should be set up to assess the validity of the issues raised and deal with parliamentary questions and safeguard clauses. Only when a real concern is identified, should the GMO Panel be involved. This would absorb the additional burden of the GMO Panel dealing with GM product applications and avoid further delays.

PRINCIPLES THE BIOTECH INDUSTRY SUPPORTS AND PROMOTES

1. **Freedom of choice**
   Farmers and consumers should be free to decide whether they want to cultivate or consume GM products or not. When the product is found to be safe, politicians should not decide whether farmers and consumers will have free choice.

2. **Science-based, transparent decision-making**
   An objective scientific evaluation of the safety of GM products is rightfully the basis for authorisations in the EU and in other parts of the world. Safe products should be allowed onto the market.

3. **Workable and working authorisation system**
   There is clear potential to make the EU authorisation system more efficient. Currently, applicants have to comply with all requirements but have no certainty about how many years it will take until a decision is made. Even the strictest authorisation system should offer applicants predictability.

4. **Public engagement and political responsibility**
   The biotech industry plays an important role in increasing public understanding of the technology. Industry has always been and continues to be committed to communicating about all aspects of GM food and crops. Politicians, food manufacturers, traders, farmers, scientists and consumer, development and environmental groups, should engage in responsible public communication.

6. ANNEXES

ANNEX 1: Applications for import/processing and cultivation dossiers – status on 31 August 2011

FF — FOOD AND FEED
IP — IMPORT AND PROCESSING
C — CULTIVATION

Products waiting EFSA completeness check	Application received by EFSA			
Bayer MS8, RF3& MS8x RF3 oilseed rape (ffip) (scope extension)	23/06/2010			
Bayer/Monsanto MS8xRF3xGT73 oilseed rape (ffip)	20/10/2009			
Bayer GHB614 x LLCotton25 x MON15985 cotton (ffip)	18/02/2011			
Bayer GHB119 cotton (ffip)	07/04/2011			
Bayer T304-40 cotton (ffip)	07/04/2011			
Bayer FG72 Soybean (ffip)	24/06/2011			
Dow DAS-68416-4 soybean (ffip)	19/01/2011			
Monsanto GT 73 oilseed rape (ip) (extension of scope)	31/08/2010			
Monsanto MON89034 maize (c)	03/01/2011			
Pioneer 1507 x 59122 x MON810 x NK603 maize (ffip)	03/02/2011			
Syngenta Bt11x MIR604 x GA21 maize (c)	27/07/2010			
Syngenta Bt11xMIR162x1507xGA21 Maize (ffip)	10/08/2010			
Syngenta MIR604 maize (c)	27/07/2010			
Syngenta Bt11x59122xMIR604x1507xGA21 maize (ffip)	07/07/2011			

Products waiting EFSA assessment	Application received by EFSA	EFSA validity statement	Months for complete-ness check	
BASF(former AVEBE) AV43-6-G7 potato (ffc)	08/04/2009	17/01/2011	22	
BASF BPS-CV127-9 soybean (ffip)	15/01/2009	13/07/2009	6	
BASF Amylopectin Potato AM04-1020 (ffipc)	10/09/2010	15/04/2011	7	
Bayer GHB614xLLCotton25 (ffip)	04/02/2010	26/01/2011	11	
Bayer T25 maize (ffipc) (renewal)	29/06/2007	09/10/2008	15	
Dow 281-24-236x3006-210-23xMON88913 cotton (ffip)	19/03/2009	03/03/2010	11	
Dow DAS-40728-9 maize (ffip)	11/11/2010	11/03/2011	4	
Monsanto MON 1445 cotton (ffip) (renewal)	29/06/2007	03/07/2008	12	
Monsanto MON 15985 cotton (ffip) (renewal)	22/05/2008	20/08/2008	3	
Monsanto MON 15985xMON1445 cotton (ffip) (renewal)	29/06/2007	09/04/2008	9	
Monsanto MON 40-3-2 soybean (c)	04/11/2005	29/09/2006	11	
Monsanto MON 531 cotton (ffip) (renewal)	29/06/2007	11/06/2008	12	
Monsanto MON 531xMON1445 cotton (ff) (renewal)	29/06/2007	12/03/2008	8	
Monsanto MON 88017 maize (c)	21/04/2008	12/09/2008	5	
Monsanto MON 88913 cotton (ffip)	11/04/2007	19/10/2007	6	
Monsanto MON 88913xMON 15985 cotton (ffi)	11/04/2007	28/01/2008	10	
Monsanto MON87460 maize (ffip)	29/05/2009	28/01/2010	8	
Monsanto MON87701xMON89788 soybean (ffip)	27/08/2009	08/12/2009	3	
Monsanto MON87705 soybean (ffip)	25/02/2010	13/08/2010	6	
Monsanto MON87769 soybean (ffip)	20/10/2009	15/02/2010	4	
Monsanto MON87769 x MON89788 Soybean (ffip)	30/07/2010	26/11/2010	4	
Monsanto MON89034xMON88017 maize (c)	03/06/2009	04/11/2009	5	
Monsanto MON89034xNK603 maize (c)	03/06/2009	09/10/2009	4	
Monsanto MON87708 soybean (ffip)	09/02/2011	13/05/2011	3	
Monsanto NK 603xMON 810 maize (c)	08/11/2005	10/01/2007	14	
Monsanto NK603xT25 maize (ffip)	21/05/2010	12/10/2010	5	
Monsanto/KWS H7-1 sugarbeet (ffc)	10/12/2008	25/08/2009	8	
Pioneer 305423 (High Oleic) soybean (ffi)	18/06/2007	22/10/2007	4	
Pioneer 98140 (GAT) in maize (ffi)	15/04/2008	12/11/2008	7	
Pioneer HO 305423x40-3-2 soybean (ffi)	24/09/2007	19/02/2008	5	

Pioneer/Dow 1507x59122 maize (ffc)	20/12/2005	31/08/2007	20	
Pioneer/Dow 1507xNK 603 maize (ffcip)	29/06/2005	10/03/2006	8	
Pioneer/Dow 59122 maize (ffc)	21/10/2005	09/03/2007	16	
Pioneer/Dow 59122x1507xNK603 maize (ffipc)	03/01/2006	27/07/2007	19	
Syngenta Amylase 3272 maize (ffip)	09/03/2006	06/07/2007	16	
Syngenta Bt11xMIR162xGA21 maize (ffip)	20/02/2009	13/07/2009	5	
Syngenta Bt11xMIR162xMIR604xGA21 maize (ffip)	20/02/2009	13/07/2009	5	
Syngenta GA21 maize (ffipc)	16/07/2008	21/10/2008	3	
Syngenta 5307 Maize (ffip)	07/04/2011	21/06/2011	2	
Syngenta MIR162 maize (ffip)	12/07/2010	24/08/2010	1	

Products waiting Commission Action (SCFCAH vote)	**Application received by EFSA**	**EFSA opinion**	**Months from submission until EFSA opinion**	**Months from EFSA opinion until 01/08/2011**
Bayer LLrice62 (ffip)	20/08/2004	30/10/2007	38	45
Bayer MS8xRF3 rapeseed (ff) (renewal)	29/06/2007	22/09/2009	27	22
Bayer A5547-127 soybean (ffip)	03/04/2008	10/05/2011	37	3
Monsanto GT 73 oilseed rape (ffip) (renewal)	29/06/2007	15/12/2009	30	19
Monsanto MON 40-3-2 soybean (ff) (renewal)	29/06/2007	01/12/2010	41	8
Monsanto MON 810 maize (ffipc) (renewal)	29/06/2007	30/06/2009	24	25
Monsanto MON 863 maize (ffip) (renewal)	29/06/2007	30/03/2010	33	15
Monsanto MON87701 soybean (ffip)	17/05/2010	26/07/2011	14	1
Monsanto NK603 maize (ffipc)	04/08/2005	11/06/2009	46	25
Monsanto/Dow MON 89034 x 1507 x MON 88017 x 59122 maize (ffip)	28/10/2008	27/09/2010	23	10
Monsanto/Dow MON89034 x 1507 x NK603 maize (ffip)	06/02/2009	27/09/2010	20	10
Pioneer 356043 (GAT) soybean (ffi)	11/04/2007	26/07/2011	52	1

Products waiting Council Action (Council Vote)	**Application received by EFSA**	**EFSA opinion**	**Months from submission until EFSA opinion**	**Months from SCFCAH until 01/08/2011**
Dow 281-24-236x3006-210-23 cotton (ff)	28/06/2005	15/06/2010	60	14
Pioneer/Dow 1507 maize (c)	2001*	03/03/2005	48	77
Syngenta Bt11 maize (ipc) (submitted to MS 1996)	2003*	19/05/2005	24	73
Syngenta Bt11xMIR604 maize (ffi)	14/11/2007	18/05/2010	30	15
Syngenta Bt11xMIR604xGA21 maize (ffip)	21/05/2008	15/06/2010	25	14
Syngenta MIR604xGA21 maize (ffi)	14/11/2007	18/05/2010	30	15

Products waiting Commission Action (final approval)	**Application received by EFSA**	**EFSA opinion**	**Months from submission until EFSA opinion**	**Months from Council Vote until 01/08/2011**
none				

Products approved in EU under Reg 1829/2003 or Dir 2001/18/EC	Application received by EFSA	EFSA opinion	Months from submission until EFSA opinion	Authorisation in EU	Total time in months from submission till authorisation
Monsanto NK 603 maize (ff)	01/04/2001*	01/03/2004	35	26/10/2004	43
Monsanto MON 863 maize (ff)	2002*	16/04/2004	24	13/01/2006	35
Pioneer/Dow 1507 maize (ffip)	2001*	19/01/2005	48	03/03/2006	62
Monsanto GT 73 oilseed rape (ip)	01/11/1998*	01/03/2004	64	21/02/2007	100
Bayer MS8, RF3, MS8xRF3 oilseed rape (ffip)	2003*	12/10/2005	24	25/05/2007	43
Monsanto/KWS H71 sugarbeet (ff)	26/11/2004	14/12/2006	25	24/10/2007	35
Monsanto NK 603xMON 810 maize (ff)	10/06/2004	21/12/2005	18	24/10/2007	41
Pioneer/Dow 1507xNK603 maize (ff)	01/10/2004	12/05/2006	20	24/10/2007	37
Pioneer/Dow 59122 maize (ff)	27/01/2005	03/04/2007	26	24/10/2007	33
Syngenta GA21 maize (ff)	08/08/2005	02/10/2007	26	28/03/2008	32
Bayer A2704-12 soybean (ff)	13/07/2005	20/07/2007	25	08/09/2008	38
Bayer LLCotton25 cotton	07/03/2005	14/12/2006	21	29/10/2008	44
Monsanto MON 89788 soybean (ff)	07/11/2006	11/07/2008	20	04/12/2008	25
Bayer T45 oilseed rape (ff)	04/11/2005	05/03/2008	28	26/03/2009	41
Monsanto MON 88017 maize (ffi)	10/11/2005	06/05/2009	41	30/10/2009	48
Monsanto MON 89034 maize (ffi)	31/01/2007	18/12/2008	22	30/10/2009	33
Pioneer 59122xNK 603 maize (ffi)	19/09/2005	01/12/2008	38	30/10/2009	49
Syngenta MIR 604 maize (ffi)	12/01/2005	21/07/2009	54	30/11/2009	59
BASF Amylopectin Potato EH92-527-1 (c)	03/02/2003	24/02/2006	37	02/03/2010	84
BASF Amylopectin Potato Event EH92-527-1 (ff)	25/04/2005	24/02/2006	10	02/03/2010	58
Monsanto MON 863xMON 810 maize (ff)	02/07/2004	12/07/2005	12	02/03/2010	68
Monsanto MON 863xMON 810xNK 603 maize (ffip)	23/11/2004	12/07/2005	7	02/03/2010	63
Monsanto MON 863xNK 603 maize (ff)	10/11/2004	12/07/2005	8	02/03/2010	64
Monsanto MON 88017xMON 810 maize (ffip)	03/01/2006	21/07/2009	43	28/07/2010	55
Monsanto MON 89034xNK 603 maize (ffip)	01/02/2007	29/09/2009	32	28/07/2010	42
Pioneer/Dow 1507x59122 maize (ffip)	30/05/2005	06/05/2009	47	28/07/2010	62
Pioneer/Dow 59122x1507xNK603 maize (ffip)	19/09/2005	08/04/2009	42	28/07/2010	58
Syngenta Bt11 maize (ff) (renewal, first approval see next page)	29/06/2007	17/02/2009	19	28/07/2010	37
Syngenta Bt11xGA21 maize (ffip)	14/11/2007	22/09/2009	23	28/07/2010	33
Monsanto MON 89034xMON 88017 maize (ffip)	12/02/2007	30/03/2010	38	17/06/2011	52
Bayer GHB 614 cotton (ffip)	25/01/2008	10/03/2009	13	17/06/2011	41
Pioneer/Dow 1507 maize (ff) (renewal, first approval see before)	29/06/2007	11/06/2009	23	17/06/2011	48

* Products entered the system before EFSA was set up and were risk assessed by Member States.

Products approved in EU under Reg 1829/2003 or Dir 2001/18/EC	Application received by EFSA
Monsanto MON40-3-2 soybean (ff)	03/04/1996
Monsanto MON810 maize (c)	22/04/1998
Bayer T25 maize (ff)	22/04/1998
Monsanto MON1445 cotton (ff)	18/12/2001
Syngenta Bt11 maize (ff)	19/05/2004
Monsanto MON15985 cotton (ff)	18/04/2005**
Monsanto MON15985xMON1445 cotton (ff)	18/04/2005**
Monsanto MON531 cotton (i)	01/01/1997
Monsanto MON531xMON1445 (ff)	18/04/2005**

** Notified as an existing product under Reg 1829/2003

Annex 2: EU, US, Brazil and Canada GM authorisation processes

European Union

STEP 1: **Submitting an application (risk assessment)**

An application for a product that consists of or is made from a GMO must be submitted to a Member State Authority. Supporting documents must accompany the application, including:

- Studies showing that the GM food causes no risk to human and animal health or the environment
- Analyses showing that the GM food is substantially equivalent to conventional counterparts (e.g. by a compositional analysis)
- Suggestions for product labelling
- Methods and sample material for detecting GM content
- A proposal for post-market monitoring
- A summary of the application dossier

The MS then forwards the application to EFSA, who subsequently notifies all the other Member States and allows them to access the application. EFSA also makes the application summary available to the public.

STEP 2: **Risk assessment**

Once all the required documentation is present, EFSA has six months to provide an opinion. The decision time can be extended by stopping the clock, if supplementary documentation is requested. The application is evaluated by a panel of scientific experts, the GMO Panel. Along with a scientific safety assessment, EFSA's official opinion includes:

- A suggestion for product labelling
- The recommendation may include restrictions or conditions such as post-market monitoring in response to results of the safety assessment
- Detection methods confirmed by the EU Reference Laboratory (EURL)
- Environmental monitoring plan for the GM plant

EFSA submits its opinion to the European Commission and MS and the opinion is made available to the public on the EFSA website.

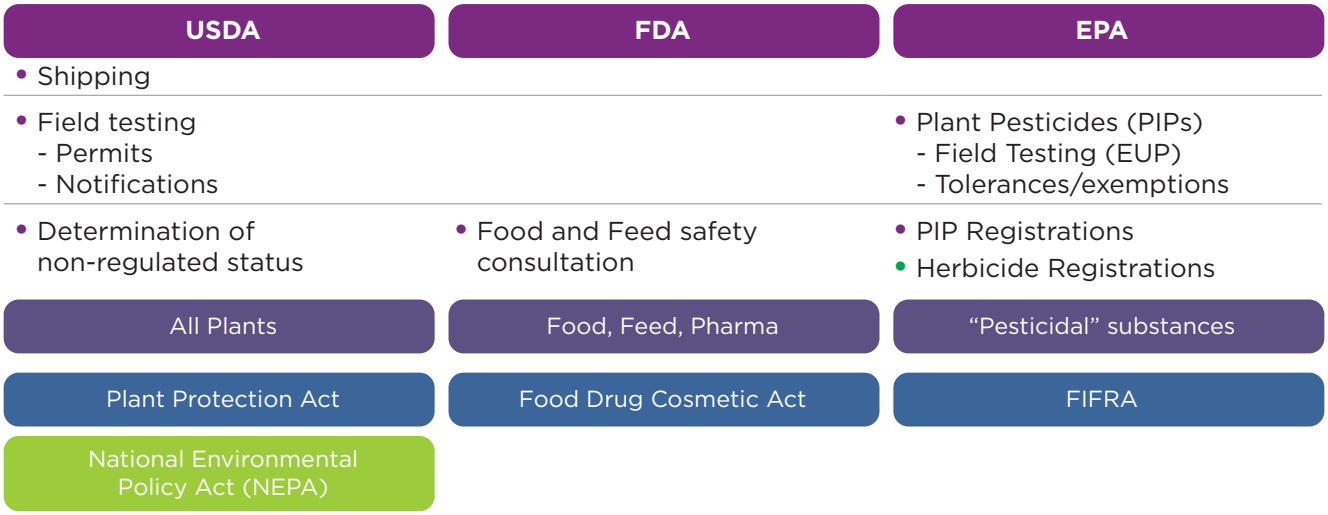
STEP 3: **Final Decision (risk management)**

After receiving EFSA's opinion, the EC has three months to produce a draft decision. If the European Commission's draft for a decision is different from EFSA's opinion, written justification is required. The decision process is delineated in the Treaty on European Union and in other legal documents. This process applies not only to GMO regulation, it is the general process used in all legislative decision-making.

- The EC submits its draft for a decision to the "Standing Committee on the Food Chain and Animal Health" (SCFCAH). The committee consists of representatives from all Member States and may approve or reject the EC's draft with a qualified majority.
- If the SCFCAH does not agree with the EC's draft, or if a decision with qualified majority cannot be reached, the EC can either submit an amended draft to the committee (within two months) or submit the same measure for a second deliberation to the Appeal Committee (within one month).
- The composition of the Appeal Committee can be flexible, adapted to the political sensitivity and the difficulty of the negotiations. In principle it will consist of representatives appointed by the Member States and will be chaired by the EC whilst it will not have a voting right.
- In order to reach a qualified majority, 232 out of 321 votes are needed. Additionally, a qualified majority must represent at least 62 percent of the EU population.
- If the Appeal Committee cannot reach a qualified majority, the Commission may adopt the proposal.

United States

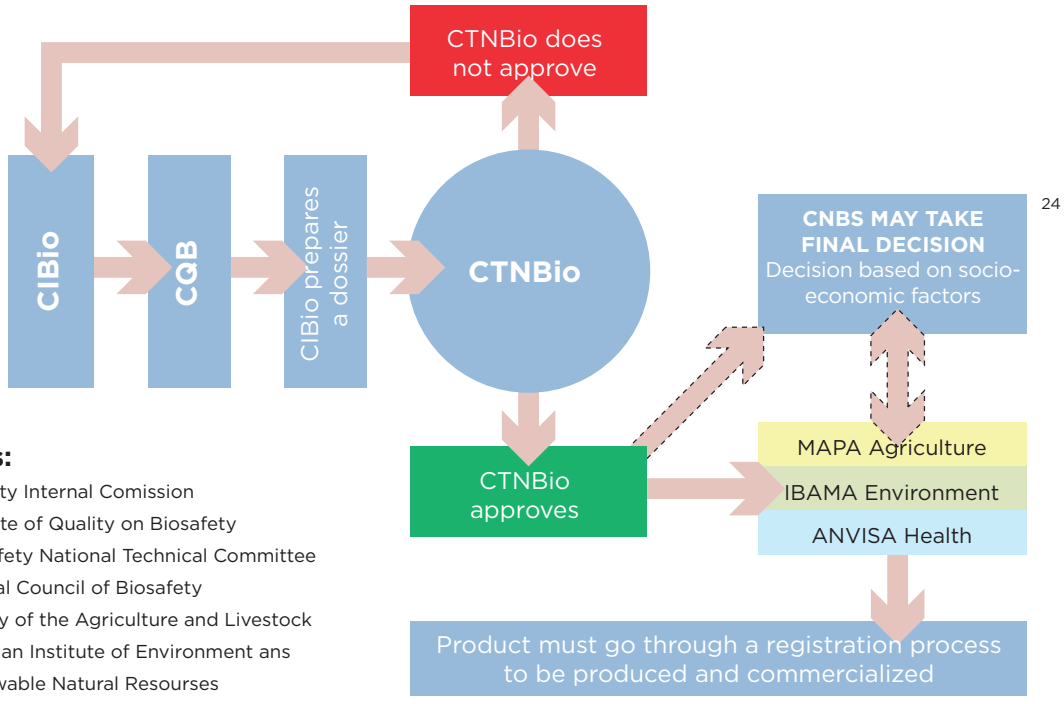
Federal agencies are the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA). Each plant variety is subject to extensive field-testing under the oversight of the U.S. Department of Agriculture (USDA) and as appropriate the Environmental Protection Agency (EPA). In the US, the term used when a GMO has been approved is "deregulated".



[23]

Brazil

The CTNBio (Biosafety National Technical Committee) which consists of publicly acknowledged specialists in Science & Technology and representatives of each ministry.



[24]

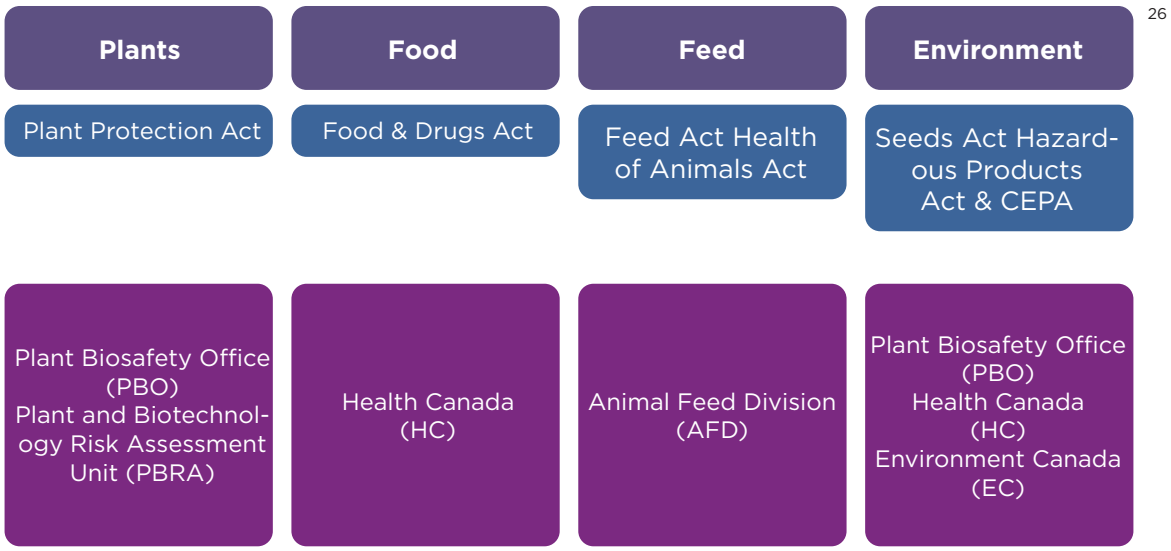
Acronyms:

CIBio: Biosafety Internal Comission
CQB: Certificate of Quality on Biosafety
CTNBio: Bosafety National Technical Committee
CNBS: National Council of Biosafety
MAPA: Ministry of the Agriculture and Livestock
IBAMA: Brazilian Institute of Environment ans Renewable Natural Resourses
ANVISA: Health National Agency

Canada

Health Canada and the Canadian Food Inspection Agency (CFIA) share responsibility for regulating novel agricultural products. The CFIA is responsible for regulating the safety of novel plants and novel livestock feeds. Health Canada is responsible for ensuring that all novel foods are as safe and nutritious for humans as foods already on the market[25].

- CFIA defines a plant with a novel trait as a plant that contains a trait that is both new to the Canadian environment and has the potential to affect the specific use and safety of the plant with respect to the environment, human and animal health.
- Health Canada defines novel foods as products that have never been used as a food; foods which result from a process that has not previously been used for food; or, foods that have been modified by genetic modification.



[26]

Annex 3: GM Products in the pipeline worldwide

In this overview GM products in the worldwide pipeline are shown. A broader overview is given in the JRC report[27].

SOYBEAN

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

MAIZE

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)							

RAPESEED

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	In Vigor	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						

COTTON

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)										

RICE

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	2-3 Bt events	Several Bt events	cry1Aa3	cry1F	asal
Product name			Golden Rice 1	Golden Rice 2						
Developer	Bayer	Bayer	IRRI	IRRI	China	Indonesia	Pakistan	India	India	India
Trait	Herbicide tol.	Insect resist.	Betacarotene cont.	Betacarotene cont.	Glufosinate tol.	Insect resist.	Insect resist.	Insect resist.	Insect resist.	Insect resist.
Timeline	2011-2013	2011-2013	2011	2012	(2011)	2012	(2013)	2013	2013	2013
Development stage	Planned 2011 2013	Planned 2011 2013			Environmental release	Field trials	Field trials			
Regulatory status in										
EU (net importer)										

RICE

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

Unique identifier										
Event name / gene(s)	CP iORF-IV	RTBV-ODs2	chi11 tlp	cry1Ac	cry1Ab, cry1C & bar	Glyoxalase I & II	Osmotin	cry1Aa3	cry1F	asal
Product name										
Developer	India	India	India	India	India	India	India	India	India	India
Trait	Virus resist.	Tungro resist.	Disease resist.	Insect resist.	Insect resist.	Salinity tol.	Drought tol.	Insect resist.	Insect resist.	Insect resist.
Timeline	2012	2012	2013	2013-2015	2013-2015	2015	2015	2013	2013	2013
Development stage				Biosafety research (level I)						
Regulatory status in										
EU (net importer)										

POTATO

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	BASF
Trait	Amylopectin cont.	PVY resist.	PVY resist.	Starch cont.	Late blight resist.	Reduction in cold-induced sweetening	Dwarfness	GM	Oil cont.
Timeline	(2009)	(2012)	(2012)	(2014)	2011	2012	2012	(2014)	(2015)
Development stage				Dossier ready for submission				Environmental release	
Regulatory status in									
EU (net exporter)	All: pending			Target					

Annex 4: List of GM products in Figure 3

Products currently in the system for import approval

1. Bayer LLrice62 (ffip)
2. Dow 281-24-236x3006-210-23 cotton (ff)
3. Syngenta Amylase 3272 maize (ffip)
4. Monsanto MON 88913 cotton (ffip)
5. Monsanto MON 88913xMON 15985 cotton (ffi)
6. Pioneer 356043 (GAT) soybean (ffi)
7. Monsanto MON 1445 cotton (ffip) (renewal)
8. Monsanto MON 531 cotton (ffip) (renewal)
9. Monsanto MON 531xMON 1445 cotton (ff) (renewal)
10. Monsanto GT 73 oilseed rape (ffip) (renewal)
11. Monsanto MON 40-3-2 soybean (ff) (renewal)
12. Monsanto MON863 maize (ffip) (renewal)
13. Monsanto MON 15985xMON 1445 cotton (ffip) (renewal)
14. Bayer MS8xRF3 rapeseed (ff) (renewal)
15. Pioneer 305423 (High Oleic) soybean (ffi)
16. Pioneer HO 305423x40-3-2 soybean (ffi)
17. Syngenta Bt11xMIR604 maize (ffi)
18. Syngenta MIR604xGA21 maize (ffi)
19. Bayer A5547-127 soybean (ffip)
20. Pioneer 98140 (Gly ALS tolerance in) maize (ffi)
21. Syngenta Bt11xMIR604xGA21 maize (ffip)
22. Monsanto MON 15985 cotton (ffip) (renewal)
23. Monsanto/Dow MON 89034 x 1507 x MON 88017 x 59122 maize (ffip)
24. BASF BPS-CV127-9 soybean (ffip)
25. Monsanto/Dow MON89034 x 1507 x NK603 maize (ffip)
26. Syngenta Bt11xMIR162xGA21 maize (ffip)
27. Syngenta Bt11xMIR162xMIR604xGA21 maize (ffip)
28. Dow 281-24-236x3006-210-23 xMON88913 cotton (ffip)
29. Monsanto MON 87460 maize (ffip)
30. Monsanto MON87701xMON89788 soybean (ffip)
31. Bayer/Monsanto MS8xRF3xGT73 oilseed rape (ffip)
32. Monsanto MON 87769 soybean (ffip)
33. Bayer GHB614xLLCotton25 (ffip)
34. Monsanto MON87705 soybean (ffip)
35. Monsanto MON87701 soybean (ffip)
36. Monsanto NK603xT25 maize (ffip)
37. Bayer MS8, RF3& MS8x RF3 oilseed rape (ffip) (extension of scope)
38. Syngenta MIR162 maize (ffip)
39. Monsanto MON87769 x MON89788 Soybean (ffip)
40. Monsanto GT 73 oilseed rape (ip) (extension of scope)
41. Syngenta Bt11xMIR162x1507xGA21Maize (ffip)
42. Dow DAS-40728-9 maize (ffip)
43. Dow DAS-68416-4 soybean (ffip)
44. Pioneer 1507 x 59122 x MON810 x NK603 maize (ffip)
45. Monsanto MON87708 soybean (ffip)
46. Bayer GHB614 x LLCotton25 x MON15985 cotton (ffip

New products projected to enter the system by 2015

1. Renewal 1
2. Renewal 2
3. Renewal 3
4. Renewal 4
5. New event 1
6. New event 2
7. New event 3
8. New event 4
9. New event 5
10. Stack 1
11. Stack 2
12. Stack 3
13. Stack 4
14. Stack 5
15. New event 6
16. New event 7
17. New event 8
18. New event 9
19. New event 10
20. New event 11
21. New event 12
22. Stack 6
23. Stack 7
24. Stack 8
25. Stack 9
26. Stack 10
27. Stack 11
28. Stack 12
29. Product for which no approval is asked 1
30. Product for which no approval is asked 2
31. Product for which no approval is asked 3
32. Product for which no approval is asked 4
33. Product for which no approval is asked 5
34. Product for which no approval is asked 6
35. New event 13
36. New event 14
37. New event 15
38. New event 16
39. Stack 13
40. Stack 14
41. Stack 15
42. Stack 16
43. Product for which no approval is asked 7
44. Product for which no approval is asked 8
45. Product for which no approval is asked 9
46. Product for which no approval is asked 10
47. Product for which no approval is asked 11
48. Product for which no approval is asked 12
49. New event 17
50. New event 17
51. Stack 17
52. Stack 18
53. Stack 19
54. Stack 20

Annex 5: Characteristics of a functioning regulatory system

CLARITY

1. Scope and objectives must be unambiguous
2. There must be a clear *differentiation* regarding different activities: Contained use, Commodity imports/exports, Confined field trials, Unconfined (commercial) releases
3. Clarity as to the *division of responsibilities* between government ministries (Ag, Envi, Health, etc)
4. The *interrelation* with other *existing regulatory* systems must be clear (seeds regulations, plant import and quarantine, food safety, etc)

PREDICTABILITY

1. Regulatory roadmap and processes are clearly defined and streamlined
2. Timelines to decisions can be predicted; this does not mean the outcomes of decisions are predictable
3. Predictable regulatory systems allow business planning (seed manufacturing, supply chain management, grower preparation)
4. A functional system is able to improve itself over time to make it more streamlined and predictable

TRANSPARENCY

1. The *application system* for permits and/or authorisations must be clearly communicated
   - When and where to submit
     What is to be included (data and information requirements)
   - Pre-submission consultations
     Time standards for review and decision-making
2. How *science advice* is provided and taken into account
   - External review, expert panels, government science evaluators
3. Basis of regulatory *decision-making*
   - How and by whom
   - Independence and impartiality
4. What information is disclosed to the *public* and when
   - Treatment of confidential business information and data protection
5. *Consistent* implementation – system must work public and private sectors, domestic and foreign

SCIENCE-BASED

1. Assessment processes of safety/risks of the product should be science-based
2. The scientific assessment provides evidence to decision-makers to make decisions
3. Decisions are policy-based and must be supported by evidence
4. Decisions based on a lack of evidence are subject to WTO challenge because they are frequently arbitrary

WORKABILITY (PRACTICALITY)

1. Must be practical, effective and efficient
2. Triggers and procedures must work
3. *Requirements* and standards must be *achievable*
4. Data requirements must be tailored to address specific *risk hypotheses*
5. Complexity should be commensurate with activity and level of risk
6. *Cost-effective* – consistent with available resources – human, financial, infrastructure

ADAPTABILITY

1. New applications of biotechnology are evolving rapidly and regulatory requirements and/or guidelines must be able to *quickly adapt*
2. Technical requirements should be defined in guidelines or directives and not in statutory regulations or laws
6. Flexibility must exist to accommodate *case-by-case variation*
3. As confidence and experience grows with particular trait x species combinations, provisions for streamlined or 'short-track' reviews is desirable – particularly the case for commodity imports (food, feed, processing use)

Annex 6: Historical overview of key milestones in the assessment and authorisation system

In this chronological overview key milestones in the European legislative framework for GMOs, selected for those elements that have a direct influence on the commercialisation of GM crops, are given.

1982	**Early steps towards a Community framework for regulation of GMOs** The EC Council recommends[28] to the Member States that they adopt laws, regulations and administrative provisions concerning the registration of work involving recombinant deoxyribonucleic acid (DNA). The development of fundamental and applied biological research is expected to contribute to the economic expansion of the Member States; implying that recombinant DNA work will be performed in several sectors on diverse organisms. Yet as the Council recognizes that "conjectural" risks are associated with this work, registration should allow establishing protective measures. The requirement for notification of work involving recombinant DNA was reinforced by the Committee of Ministers in 1984[29].
1983	A communication[30] of the European Commission addresses the concept of regulating biotechnology under the following three headings: • biological safety, • the consumer and the bio-industry, • the regulation of products and their free circulation. The European Commission expresses its intention to attempt to "ensure regulatory provision to maintain rational standards".
1986	The EU Commission put forward to the European Council the concep[31] for a Community Framework for the regulation of biotechnology. It was a more restrictive approach than had been advocated by Member States with the greatest experience of biotechnology.
	Keeping pace with international developments In the same year, the OECD publication "Recombinant DNA safety considerations"[32], also known as the "OECD Blue Book", is the first international publication presenting comprehensive considerations on the environmental safety of recombinant DNA technology. The book introduces some of the key concepts, e.g. the "case-by-case" and "step-by- step" approaches. The publication highlights that recombinant DNA techniques open up new and promising possibilities in a wide range of applications and are expected to bring considerable benefits to mankind. By aiming for a common understanding of the safety issues raised by recombinant DNA techniques, OECD intends to provide the basis for international consensus, the protection of health and the environment, the promotion of international commerce and the reduction of national barriers to trade in the field of biotechnology. In subsequent publications[33],[34],[35], OECD confirms its role in international harmonisation and introduces several concepts that are used internationally in risk assessment of GMO's, such as "familiarity" and "substantial equivalence".
1988	The EU Commission published proposals[36] for two Council Directives: one "on the contained use of genetically modified microorganisms" and the other "on the deliberate release to the environment of genetically modified organisms".
1990	**Two environmental Directives at the basis of European GMO legislation** The two directives 90/219/EEC and 90/220/EEC are adopted on April 23, 1990. Directive 90/219/EEC dealt with the contained use of GM microorganisms, while Directive 90/220/EEC regulated the deliberate release of GMOs into the environment within the EU. Despite scientific advice to the contrary, both use the process of "genetic modification" as their regulatory trigger. Aspects of contained use are not further discussed in this overview as they are less relevant for the commercialisation of GM crops. Referring to the Treaty establishing the European Economic Community, and in particular Article 100a thereof, Directive 90/220/EEC aims to protect human health and the environment by controlling risks from the deliberate release of GMOs into the environment. In order to avoid that individual Member States would establish divergent rules and thereby create unequal conditions of competition or barriers to trade in products containing GMOs, the Directive is intended to approximate the laws of the Member States. A Community authorisation procedure for the placing on the market of products containing, or consisting of, GMOs where the intended use of the product involves the deliberate release of the organism(s) into the environment, is established following the case-by-case and step-by-step approach. Although the Annexes provide indications on the required information and the Directive requires a risk assessment to be conducted before any deliberate release, there is no indication on specific protection goals or methodology to be followed.
	Early attention to food use aspects. Following the initial attention on environmental impact, work had been established to develop scientific principles for food safety assessment of products of modern biotechnology. In 1990, a joint consultation[37] of FAO and WHO established that the comparison of a final product with one having an acceptable standard of safety provides an important element of safety assessment. This is the foundation for the comparative assessment as applied in supporting food safety.
1991	**Administrative considerations, but the core of risk assessment remains undefined.** Council Decision 91/596/EEC[38] describes the required templates to be used as **Summary Notification Information Format** for part B applications (introductions in the environment except for the placing on the market). While a purely administrative matter, it is one of the additional tasks that per se do not contribute to the safety evaluation. Directive 90/220/EEC indicates that these are information exchange documents between Competent Authorities and Commission, eventually applicants are asked to submit the completed SNIF in addition to the actual submission. The format[39] was modified in 1994 creating a specific format for GM higher plants and one for other GM organisms.
1992	Council Decision 92/146/EEC[40] describes the required templates to be used as Summary Notification Information Format when dealing with an application for a placing on the market according to Directive 90/220/EEC. During implementation by Member States, the administrative burden is again redirected to the applicants.

	Novel Foods are proposed to include food from a GM source In the same year, the Commission presents its proposal[41] for regulating novel foods and novel food ingredients. It describes the need to assess the safety of certain food products with no tradition of safe use. Using genetic technology is indicated as an important new field that will create opportunities beyond what is achievable via traditional breeding. Consequently the scope of the proposed regulation includes products produced from or consisting of, or containing an organism or part of an organism currently used in food production which have been modified by gene technology. Further reference is made to assessment principles developed by Codex Alimentarius and OECD.
1993	**Substantial equivalence as practical approach in food safety assessment** In 1993 the OECD[42] further elaborated the concept of comparative assessment and advocated the approach to safety assessment based on substantial equivalence as being the most practical approach to addressing the safety of foods and food components derived through modern biotechnology (as well as other methods of modifying a host genome, including tissue culture methods and chemical or radiation induced mutation).
	Simplified administrative procedures based on accumulated knowledge In the same year, criteria for simplified procedures[43] concerning the deliberate release into the environment of GM plants are established. Based on the finding that at that moment there was accumulated knowledge and data available concerning the necessary prerequisites for safety to human health and the environment for the release of certain types of GMOs; Member States can request application of a simplified procedure for dealing with Part B applications (releases other than the placing on the market). In 1994, based on requests from the United Kingdom and France, this procedure is used to allow[44] more than one release (possibly extending to a programme of development work) to be covered in a single application dossier.
1994	**Requirements for GM higher plants are specified.** On the basis of the experience gained with the releases of genetically modified higher plants, Annex II of the Directive 90/220/EEC which specifies the required information is adapted[45]. This results in two sub-Annexes: Annex II A outlining the information required in the notifications concerning releases of GMOs other than higher plants, and Annex II B outlining the information required in the notifications concerning releases of genetically modified higher plants. While this helps to make the information requirements more applicable for the majority of the applications, *i.e.* GM plants, it does not provide any further insights on protection goals and/or the methodology to be used for risk assessment.
1996	**Confirmation of substantial equivalence and comparative approach.** A Joint FAO/WHO Expert Consultation[46] on Biotechnology and Food Safety elaborated on compositional comparison as an important element in the determination of substantial equivalence. A comparison of critical components can be carried out at the level of the food source (*i.e.* species) or the specific food product. The comparison of critical components should be between the modified variety and non-modified comparators with an appropriate history of safe use. The data for the non-modified comparator can be the natural ranges published in the literature for commercial varieties or those measured levels in parental or other edible varieties of the species
1997	Extension of requirements: detection tools and labelling. Annex III of the Directive 90/220/EEC indicates additional information required in the case of a notification for placing on the market. Using the procedure for adapting to technical progress, this Annex is extended[47] to include: • information relating to the introduced genetic modification which could be of relevance to the establishment of a possible register of modifications introduced in organisms (species). This is considered the first step to establishing detection tools. • extended information on the label of the product. So far the label was expected to provide information on the technical aspects of the product. The adaptation requires that the label or the accompanying document includes an indication that the product contains, or consists of genetically modified organisms.
	Novel Food Regulation enters into force. Most GM plant products are notified on the basis of confirmed substantial equivalence. In the same year, Regulation (EC) No 258/97[48] concerning novel foods and novel food ingredients includes in its scope: • foods and food ingredients containing or consisting of GMOs within the meaning of Directive 90/220/EEC, and • foods and food ingredients produced from, but not containing GMOs. The Regulation foresees a pre-market approval procedure. A derogation of approval is foreseen for products that are confirmed by a competent body to be substantially equivalent to existing foods or food ingredients. The placing on the market of such products should only be notified. As the Regulation is limited to food use, other downstream uses (e.g. feed use) of GMOs remain covered within the scope of Directive 90/220/EEC. In addition to other technical aspects, presence of a GMO needs to be indicated on the label in order to ensure information of the final consumer.
	Later in the year, Recommendations[49] concerning scientific aspects of the information that is required for a novel food application are published. The recommendation confirms the concept of substantial equivalence, stressing the fact that establishment of substantial equivalence is not a safety or nutritional assessment in itself, but an approach to compare a potential new food with its conventional counterpart. In the specific guidance on GM Plants, it is of interest to note that *"the safety evaluation of a GM plant may be a simpler task than the evaluation of a novel non-GM plant, if the non-modified organism is a traditional food plant and the alteration has occurred by means of a precisely defined process of genetic modification. In this case, the safety assessment can focus on the results of the genetic modification".*
1998	An OECD Workshop[50] examined the effectiveness of the application of substantial equivalence in safety assessment. It was concluded that the determination of substantial equivalence provides equal or increased assurance of the safety of foods derived from genetically modified plants, as compared with foods derived through conventional methods

1998	**Labelling of already approved products imposed** In the EU, a Regulation[51] is adopted to require the labelling of foods and food ingredients produced, in whole or in part, from two GM plants that had been placed on the market before the entry into force of Regulation (EC) No 258/97. The Regulation provides very specific wording relating to the GM nature of the material. However, foodstuffs in which neither protein nor DNA resulting from genetic modification is present were not subject to the specific labelling requirements.
	The *de facto* moratorium obliging to return to the legislative process Following declarations from twelve (of then fifteen) Member States that they were opposed to further authorisations of GMOs, the Commission halted the GMO authorisation process; hence a ***de facto* moratorium** was established. During this period no new GMO authorisations were granted from April 1998 onwards. Failures within the regulatory policy system forced the EU into this de facto moratorium situation which stalled authorisations of GM products (predominantly GM crops). This stalemate situation occurred due to differing ideas of risk, some clear cultural and historical differences between Member States. Thus under renewed political pressure and with a de facto moratorium in place, the EU once again returned to the legislative process to put in place a new Directive relating to GMOs. The so-called de facto moratorium on GM authorisations did not lift until the final outcome of the political process that produced the new Directive 2001/18/EC.
	Still in 1998, a Proposal[52] for amending Directive 90/220/EEC is forwarded to the Council and the European Parliament. Eventually this will lead to Directive 2001/18/EC repealing Directive 90/220/EEC. This proposal introduces: • limiting consents to the placing on the market of GMOs as or in products to a fixed period • moving forward to a more centralised Community system of authorisation by establishing a common methodology to carry out the risk assessment based on independent scientific advice (as determined in Annex II – Principles for the Environmental Risk Assessment). • the obligation to carry out a monitoring in order to trace any direct or indirect, immediate or delayed effects on human health and the environment of GMOs as such or in products after they have been placed on the market (as outlined in Annex VII) • Confirming the GMO labelling requirements ("this product contains GMOs" or "this product may contain GMOs" depending on the situation)
1999	**Introduction of the Precautionary Principle** On 13 April 1999 the Council adopted a resolution urging the Commission inter alia "to be in the future even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer related activities and develop as priority clear and effective guidelines for the application of this principle". Until then the only explicit reference to the precautionary principle at Community level is found in the environment title of the EC Treaty, and more specifically Article 174.
2000	As part of the Commission's response to the indication of Council on the Precautionary Principle, a Communication[53] is issued, aiming to: • outline the Commission's approach to using the precautionary principle, • establish Commission guidelines for applying it, • build a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully, and • avoid unwarranted recourse to the precautionary principle, as a disguised form of protectionism. The precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk. Where action is deemed necessary, measures based on the precautionary principle should be, *inter alia*: • proportional to the chosen level of protection, • non-discriminatory in their application, • consistent with similar measures already taken, • based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis), • subject to review, in the light of new scientific data, and • capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment
	More labelling, but also recognition of the need for a threshold for adventitious presence Council Regulation (EC) No 1139/98 laid down the compulsory indication on the labelling of foods and food ingredients produced from certain genetically modified plants. It was understood that despite the fact that some operators avoid using genetically modified crops as a source for their food ingredients, material derived from the said genetically modified organisms may be present in them. In the cases in which the presence of such material is adventitious and represents only a small proportion of a food ingredient considered, this food ingredient should not be subject to the labelling requirements of Regulation (EC) No 1139/98. A *de minimis* threshold of for adventitious presence of 1% was introduced by Commission Regulation (EC) No 49/2000[54]. In order to establish that the presence of this material is adventitious, operators must be in a position to supply evidence to satisfy competent authorities that they have taken appropriate steps to avoid using as a GM source. The Regulation furthermore confirms that in any case, food ingredients are not subject to the labelling requirements when neither protein nor DNA resulting from the genetic modification is present. In parallel, Commission Regulation (EC) No 50/2000[55] provides for GMO specific additional labelling requirements for the use of additives or flavourings that have been genetically modified or have been produced through genetic engineering (these had not been included in the initial scope of GMO labelling).

2000	Also in 2000, the Joint FAO/WHO Expert Consultation[56] on Foods Derived from Biotechnology concluded that the safety assessment of genetically modified foods requires an integrated and stepwise, case-by-case approach, which can be aided by a structured series of questions. A comparative approach focusing on the determination of similarities and differences between the genetically modified food and its conventional counterpart aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy for the safety and nutritional assessment of genetically modified foods. The concept of substantial equivalence was developed as a practical approach to the safety assessment of genetically modified foods. The Consultation concluded that the application of the concept of substantial equivalence contributes to a robust safety assessment framework.
2001	**A thoroughly renewed deliberate release Directive and proposals for dealings with GM food and feed** Directive 2001/18/EC[57] is adopted, repealing Council Directive 90/220/EEC. In addition to Commission proposal of 1998 (see above), the following changes are included: • reference to the precautionary principle in drafting and implementing the Directive, • the possibility for Member States to take ethical aspects into consideration when GMOs are deliberately released or placed on the market as or in products. • an extended description of the principles for the environmental risk assessment, • an general outline of the monitoring plan, incorporating general surveillance for unanticipated adverse effects and, if necessary, (case-) specific monitoring focusing on adverse effects identified in the risk assessment, • inclusion of public consultation, • phasing out the use of certain antibiotic-resistance genes, • traceability at all stages of the placing on the market of GMOs as or in products authorised under part C, • consents for the placing on the market of GMOs as or in products are granted for a period fixed at maximum 10 years, following which a streamlined renewal procedure should be used, • consultation of the relevant Scientific Committee(s) on matters which are likely to have an impact on human health and/or the environment, • inclusion of a separate chapter regarding the socioeconomic advantages and disadvantages of each category of GMOs authorised for placing on the market, which will take due account of the interest of farmers and consumers, in the report to be issued every three years by the Commission, and • the option to establish a minimum threshold below which products shall not have to be labelled where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded.
	The Commission also presents its proposal[58] for regulating genetically modified food and feed. It is indicated that the authorisation procedure applicable for novel foods and novel food ingredients should be "streamlined" and made more transparent. This results in abandoning of the notification procedure in respect of genetically modified foods which are substantially equivalent to existing foods. It is noted that for other novel foods the substantial equivalence notification is not modified. Feed consisting of or containing genetically modified organisms (GMOs) had been authorised in accordance with Directive 90/220/EEC. The proposal introduces a single Community authorisation procedure for feed consisting of, containing or produced from GMOs.
	Another proposal[59] covers the traceability and labelling. Traceability requirements should serve distinct purposes: • facilitate the withdrawal of products where unforeseen adverse effects to human health, animal health or the environment are established, • target monitoring to examine potential effects on, in particular, the environment. • facilitate accurate labelling of such products, so as to enable operators and consumers to exercise their freedom of choice in an effective manner as well as control and verification of labelling claims. Whereas before foodstuffs in which neither protein nor DNA resulting from genetic modification is present were not subject to the specific labelling requirements, this is no longer the case. In fact, traceability requires that information on the GM origin of the material is passed between operators.
2002	**A strategy to benefit from the positive potential of life sciences and biotechnology, to ensure proper governance, and to meet Europe's global responsibilities.** In January 2002, the Commission adopted a Strategy for Europe on Life Sciences and Biotechnology[60], that aims to allow Europe to benefit from the positive potential of life sciences and biotechnology, to ensure proper governance, and to meet Europe's global responsibilities. It sets out what is needed from the Commission and the other European Institutions, while also recommending actions for other public and private stakeholders. The Commission proposes to apply the highest standards of governance of life sciences and biotechnology along 5 main action lines: • societal dialogue and scrutiny should accompany and guide the development of life sciences and biotechnology, • life sciences and biotechnology should be developed in a responsible way in harmony with ethical values and societal goals, • informed choice should facilitate demand-driven applications, • science-based regulatory oversight should enhance public confidence, and • basic regulatory principles and legal obligations should be respected to safeguard the Community single market and international obligations.
	Supplementing requirements for Risk Assessment & Post Market Environmental Monitoring In 2002, important clarification are published that supplement Annexes to Directive 2001/18/EC. *E.g.* Annex II to Directive 2001/18/EC provides indications on how to conduct and formulate conclusions in the required environmental risk assessment. This Annex was further supplemented by detailed guidance[61] on the objective, general principles, methodology (including a six step risk analysis), conclusions, review and adaptation.

2002	Annex VII to Directive 2001/18/EC is supplemented by detailed guidance notes[62] expanding on the objectives, general principles, design of the monitoring plan and reporting. The objectives of post-market monitoring, as detailed under Annex VII, are to: • confirm that any assumptions regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment are correct, and • identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment. Case-specific monitoring should, when included in the monitoring plan, focus on potential effects arising from the placing on the market of a GMO that have been highlighted as a result of the conclusions and assumptions of the environmental risk assessment. The design of the monitoring plan should incorporate general surveillance for unanticipated or unforeseen adverse effects. While it is considerably more difficult to plan for potential effects or variables that cannot be foreseen or predicted, it may, however, be possible through appropriate planning of monitoring and surveillance plans to optimise the chances for early detection of such effects.
	In the same year, also the Summary Notification Information Format[63] to be used in the framework of Directive 2001/18/EC is published.
	EFSA is established Finally, in 2002, the European Food Safety Authority[64] is established. EFSA provides scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It also provides independent information on all matters within these fields and communicate on risks Its mission includes the provision of scientific opinions on products other than food and feed relating to genetically modified organisms as defined by Directive 2001/18/EC. A specific Scientific Panel on genetically modified organisms is established.
2003	**Further international endorsement of the comparative approach and substantial equivalence.** Between 2000 and 2003, the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology undertook work to develop principles and guidelines for foods derived from biotechnology. The full report of the Codex Task Force to the Codex Alimentarius Commission in 2003 included: • Principles for the risk analysis of foods derived from modern biotechnology. • A Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants. • A Guideline for the conduct of food safety assessment of foods produced using recombinant- DNA micro-organisms. One notable feature is that they make reference to a safety assessment involving the comparative approach between the food derived from modern biotechnology and its conventional counterpart.
	In relation to Directive 2001/18/EC the report format is adopted[65] that needs to be used by the notifiers when presenting the results of the deliberate release into the environment of genetically modified higher plants to the competent authority.
	Establishing the complete framework for dealing with GM food and feed. In the same year, the Regulations dealing with food and feed aspects of GMOs are adopted. The genetically modified food and feed Regulation[66] applies to • GMOs for food and/or feed use; • food and/or feed containing or consisting of GMOs; • food and /or feed produced from GMOs • food containing ingredients produced from GMOs These products can only be placed on the market when an authorisation has been granted in accordance with the Regulation. When a product is likely to be used both for food and feed purposes; such products should only be authorised when fulfilling authorisation criteria for both food and feed. Furthermore, the authorisation is granted for ten years, following which a renewal needs to be applied for. The Regulation also fixes the threshold for the presence of traces of GMOs in food and feed products, that are adventitious or technically unavoidable. Traces of authorised GMOs in a proportion no higher than 0,9 %, provided that these should not trigger labelling and traceability requirements traces are adventitious or technically unavoidable. Additionally, a transitional measure (valid until 2006) allows under certain conditions the presence in food or feed of material which contains, consists of or is produced from GMOs that have benefited from a favourable opinion from the Community Scientific Committee(s) or the Authority before the date of application of the Regulation in a proportion no higher than 0,5 %.
	Also the traceability and labelling of genetically modified organisms Regulation[67] is adopted, applying to • products consisting of, or containing, GMOs, • food produced from GMOs; • feed produced from GMOs.
	Implementation of the Cartagena Protocol Still in 2003, a legal framework[68] is established for exports of GMOs to third countries. In this way the Community fulfils its obligations under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The Protocol had been signed by the Community and its Member States in 2000 and Council Decision 2002/628/EC[69] to conclude the Protocol, on behalf of the Community, had been taken on 25 June 2002. As existing Community legislation, and in particular Directive 2001/18/EC and sectoral legislation providing for a specific risk assessment to be carried out in accordance with the principles set out in that Directive, already contain rules which are in line with the objective of the Protocol, there is no need to adopt supplementary provisions with regard to imports of GMOs into the Community.

2003	**Coexistence of genetically modified crops with conventional and organic farming** Finally, the Commission issues guidelines[70] for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming. The starting point is that no form of agriculture, be it conventional, organic or agriculture using genetically modified organisms, should be excluded in the European Union. Coexistence refers to the ability of farmers to make a practical choice between conventional, organic and GM crop production, in compliance with the legal obligations for labelling and/or purity standards. The European Commission considers that measures for coexistence should be developed and implemented by the Member States. Subsequently, different Member States, sometimes even regions, have established legislation or other forms of rules to direct coexistence schemes. By imposing complex and unrealistic management schemes for GM crop farmers and by a high administrative burden, some Member States have misused coexistence as a way to hinder the deployment of GM crops.
2004	**Detection tools and reference materials** An additional Regulation[71] provides specific indications on: • applications for authorisations submitted in accordance with Regulation (EC) No 1829/2003, • implementing rules for transitional measures to the regime provided by Regulation (EC) No 1829/2003 for products falling within the scope of other Community legislation, • detailed rules on the preparation and presentation of notifications under Regulation (EC) No 1829/2003 of existing products placed on the market in the Community before the entry into force of the Regulation, and • detailed rules for implementing the transitional measures for the adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. Furthermore the Annexes describe in more detail the requirements for method(s) of detection, sampling and event specific identification of the transformation event, as well as the required samples of the food and feed and their control sample.
	In order to facilitate a coordinated approach for inspections and control measures in the framework of Regulation (EC) No 1830/200, A Commission Recommendation[72] provides technical guidance on sampling and testing for GMOs and food and feed material produced from GMOs in products.
	EFSA takes over the role for scientific guidance of risk assessment The EFSA Guidance Document[73] for the Risk Assessment of Genetically Modified Organisms and Derived Food and Feed provides guidance for the preparation and presentation of applications submitted within the framework of Regulation (EC) 1829/2003 on GM food and feed, and of Directive 2001/18/EC on the deliberate release into the environment of GMOs. This document covers the full risk assessment of GM plants and derived food and feed. The Guidance document was adopted in 2004. It was further completed with a new chapter on General surveillance of unanticipated effects of the GM Plant as part of the post market environmental monitoring, which was adopted on 7 December 2005 and published in May 2006. An update was proposed in 2008 by the GMO Panel in accordance with the experience gained during the risk assessment of the applications, the outcome of self tasking activities and additional guidance on stacked events. Although this update is still in draft status, the information has been integrated in the guidance.
2006	**Increasing requirements for detection tools, materials & Post Market Monitoring** Regulation (EC) No 1829/2003 provides for a Community reference laboratory (CRL) to carry out certain duties and tasks set out in that Regulation. It also provides that the CRL is to be assisted by national reference laboratories. Commission Regulation (EC) No 1981/2006[74] lays down detailed rules for: • the contribution to the costs of the tasks of the CRL and of the national reference laboratories, and • the establishment of national reference laboratories. For each application, a flat-rate contribution of € 30 000 shall be paid by the applicant to the CRL. Where a full validation procedure of a method of detection and identification for a single GMO event is required, the CRL shall request the applicant to pay an additional contribution of € 60 000.
	A 2006 Scientific Opinion[75] of the EFSA GMO Panel elaborates on the Post Market Environmental Monitoring (PMEM) plan that is mandatory in all applications for placing on the market. It is emphasised that case-specific monitoring is not obligatory but may be required to verify the environmental risk assessment, whereas a general surveillance plan must always be part of the application. The GMO Panel justifies this Opinion based on the fact that it is responsible for assessing the scientific quality of PMEM plans submitted with each application. The GMO Panel concludes that general surveillance cannot be hypothesis driven, but should, when possible, make use of existing monitoring systems in addition to more focused monitoring systems (e.g. farm questionnaires). Data quality, management and statistical analysis are of high importance in the design of general surveillance plans and comparison should be made with baseline data. In addition the EFSA GMO Panel explains the scientific rationale for this guidance and makes a number of recommendations for the management and conduct of PMEM by both applicants and risk managers.
	An EFSA GMO Panel guidance[76] aims to assist applicants in the preparation and presentation of applications for renewal of authorisation of existing products according to Articles 11 and 23 of Regulation (EC) No 1829/2003 on genetically modified food and feed. It introduces the need to update data packages according to the latest guidance, not taking into account the fact that the product has been safely used during the authorisation period.
2007	**More requirements for stacked products** The EFSA GMO Panel specifies the information required with respect to the risk assessment[77], under Regulation (EC) No 1829/2003 and Directive 2001/18/EC, of GM plants containing stacked transformation events, defined as those combined by conventional breeding. As globally GM events are integrated in breeding, a rapidly increasing number of stacked products are anticipated. In contrast to many other legislations, in the EU stacks need to be approved in addition to individual events.
	Safety of widely used antibiotic resistance genes confirmed Following an opinion from EMEA, the EFSA GMO Panel reiterates[78] its earlier conclusions that the use of the nptII gene as selectable marker in GM plants (and derived food or feed) does not pose a risk to human or animal health or to the environment. The GMO Panel also confirms earlier safety assessments of GM plants and derived food/feed comprising the nptII gene.

2008	**Introduction of procedure with scrutiny** Directive 2001/18/EC provides that certain measures are to be adopted in accordance with Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission. Decision 1999/468/EC has been amended by Decision 2006/512/EC, which introduced the regulatory procedure with scrutiny for the adoption of measures of general scope and designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure referred to in Article 251 of the Treaty, *inter alia*, by deleting some of those elements or by supplementing the instrument with new non-essential elements. Directive 2008/27/EC[79] amends Directive 2001/18/EC so that it is adjusted in accordance with the applicable procedures and that the regulatory procedure with scrutiny is applicable. Similarly Regulation (EC) No 298/2008[80] amends Regulation (EC) No 1829/2003 to adjust the implementing powers.
	Animal feeding trials of limited value, comparative approach confirmed In a 2008 publication[81] the EFSA GMO Panel discusses various elements of the safety and nutritional assessment procedure for GM plant derived food and feed, in particular the potential and limitations of animal feeding trials for the safety and nutritional testing of whole GM food and feed. The GMO Panel considers that the comparative approach to safety and nutritional testing of food and feed derived from GM plants, using molecular, compositional, phenotypic, agronomic and other analyses, remains appropriate as the basis for deciding whether animal feeding studies are needed for the safety and nutritional assessment of GM food and feed. The comparative approach has been developed and accepted by international organisations like the FAO/WHO, Codex Alimentarius and OECD.
	Additional requirements for genetically modified herbicide tolerant plants The EFSA GMO Panel, requested to carry out the Environmental Risk Assessment of genetically modified herbicide tolerant (GM HT) plants, develops a working document[82] proposing different approaches on how to deal with the interplay between the risk assessment of GM HT crops and the risk assessment of the associated herbicides. While basing their involvement on the requirement to assess the environmental impact of changes in management, including, where applicable, in agricultural practices of GM crops. However, the guidance on risk assessment and risk management introduces unbalanced requirements compared with other applications of plant protection products.
2009	**Reporting on Post Market Monitoring** Guidance notes supplementing the information provided on Post Market Environmental Monitoring as described in Annex VII to Directive 2001/18/EC had already been published. In order to ensure that the objectives of Annex VII to Directive 2001/18/EC are fulfilled in the most consistent, transparent and thorough manner, that Annex is further supplemented by adopting formats[83] for the presentation of monitoring results for the placing on the market of GMOs, with a particular focus on genetically modified higher plants. Given the different requirements for monitoring the cultivation of GMOs and monitoring the import and processing and food and feed uses of GMOs, separate formats are established.
	Safety of two antibiotic resistance genes again confirmed Following a request from the European Commission to the European Food Safety Authority (EFSA) the Panel on Genetically Modified Organisms (GMO) and the Panel on Biological Hazards (BIOHAZ) were asked to deliver a joint scientific opinion[84] on the use of antibiotic resistance genes as marker genes in genetically modified (GM) plants. The Panels conclude that the current state of knowledge indicates that adverse effects on human health and the environment resulting from the transfer of the two antibiotic resistance genes (antibiotic resistance marker genes, aph(3')-IIa (*nptII*) and ant(3'')-Ia (*aadA*)) from GM plants to bacteria, associated with use of GM plants, are unlikely.
	Risk assessment of GM plants used for non-food or non-feed purposes. The EFSA GMO Panel issues a guidance document[85] for the risk assessment of genetically modified plants used for non-food or non-feed purposes. The scope of this opinion covers GM plants and plant parts deliberately released into the environment via cultivation, import or processing for a wide range of potential non-food or non-feed uses, such as the production of industrial or medicinal products, energy production, phytoremediation, landscape improvement and ornamental use.
2010	**Further expansion of the risk assessment methodology: will more data lead to better decisions?** In 2010, the EFSA GMO Panel publishes a guidance document and several scientific opinions in relation to risk assessment and data required for supporting it. All documents are characterised by a significant increase of the demanded information as well as a sophistication of the methodology. Nevertheless on important aspects like to identification of protection goals or the interpretation of unacceptable impacts, no clarity is provided. The scientific Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) publishes a guidance document[86] for the environmental risk assessment (ERA) of genetically modified (GM) plants submitted within the framework of Regulation (EC) No. 1829/2003 on GM food and feed or under Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMOs). It describes the six steps for the ERA of GM plants, as indicated in Directive 2001/18/EC: 1) problem formulation including hazard identification; 2) hazard characterisation; 3) exposure characterisation; 4) risk characterisation; 5) risk management strategies; and 6) an overall risk evaluation. Although for the first time problem formulation is included as a part of the procedure, the identification of protection goals remain vague and unpractical.

2010	Seven specific areas of concern to be addressed by applicants and risk assessors during the ERA are considered: 1) persistence and invasiveness of the GM plant , or its compatible relatives, including plant-to-plant gene transfer ; 2) plant-to-micro-organism gene transfer; 3) interaction of the GM plant with target organisms and 4) interaction of the GM plant with non-target organisms, including criteria for selection of appropriate species and relevant functional groups for risk assessment; 5) impact of the specific cultivation, management and harvesting techniques; including consideration of the production systems and the receiving environment(s); 6) effects on biogeochemical processes; and 7) effects on human and animal health. In addition, the guidance document is supplemented with several general cross-cutting considerations (e.g. choice of comparator, receiving environment(s), general statistical principles, long-term effects) that need to be considered in the ERA.
	The EFSA GMO Panel publishes a Scientific Opinion[87] on the assessment of allergenicity of GM plants and microorganisms and derived food and feed. The strategy summarised in this report for assessing the allergenicity of GM food and feed considers the allergenicity of the newly expressed proteins, the whole GM food and feed, and also other aspects, such as exposure. Particularly with regard to newly expressed proteins, it is based on a weight-of-evidence, case-by-case approach, in line with the approach followed in other EFSA guidance documents and the Codex Alimentarius guideline.
	The GMO Panel also publishes an opinion on statistical considerations proposing: 1) updated statistical guidelines and possible approaches for the analysis of compositional, agronomic and phenotypic data from field trials carried out for the risk assessment of GM plants and derived foods/feeds; 2) minimum requirements that should be met in the experimental design of field trials, such as the inclusion of commercial varieties, in order to ensure sufficient statistical power and reliable estimation of natural variability. The guidance imposes significant adjustments to designs of trials and studies without providing more information on safety. Furthermore, by imposing internal comparisons it complete neglects the familiarity concept, whereas at international level comparison with databases or literature is accepted as a valid approach.
	Disproportionate attention to non-target organisms. A specific 2010 Scientific Opinion of the GMO Panel addresses the assessment of potential impacts of GM plants on non-target organisms (NTO). It is indicated to provide guidance to risk assessors for assessing potential effects of GM plants on NTOs, together with rationale for data requirements in order to complete a comprehensive ERA for NTOs. However, the approach on NTO goes way beyond the concept of familiarity and sets new, disproportionate requirements for GM crops. Nevertheless, guidance to applicants as outlined in this opinion has been inserted in the updated Guidance Document of the EFSA GMO Panel for the ERA of GM plants.

REFERENCES

[1] A cartoon explaining the EU authorisation process can be found at http://www.gmo-compass.org/flash/popup.php?lang=eng
[2] James, Clive (2010) ISAAA Brief 42 Global Status of Commercialized Biotech/GM Crops: 2010 http://www.isaaa.org/resources/publications/briefs/42/default.asp
[3] http://www.inspection.gc.ca/english/plaveg/bio/dir/dir9408e.shtml
[4] Understanding Canadian Biotech Regulations. Council for Biotechnology Information. http://www.whybiotech.ca/resources/understanding_canadian_biotech_regulations.pdf
[5] http://www.inspection.gc.ca/english/plaveg/bio/pbopnte.shtml
[6] James, Clive (2010) ISAAA Brief 42 Global Status of Commercialized Biotech/GM Crops: 2010 http://www.isaaa.org/resources/publications/briefs/42/default.asp
[7] Understanding Canadian Biotech Regulations. Council for Biotechnology Information. http://www.whybiotech.ca/resources/understanding_canadian_biotech_regulations.pdf
[8] Stein, A.J. and Rodríguez-Cerezo, E. (2009) The global pipeline of new GM crops. Implications of asynchronous approval for international trade. European Commission, Joint Research Centre
[9] http://www.efsa.europa.eu/en/gmo/gmoapplications.htm
[10] "Study on the Implications of Asynchronous GMO Approvals, for EU Imports of Animal Feed Products" European Commission, DG Agriculture, http://ec.europa.eu/agriculture/analysis/external/asynchronous-gmo-approvals/full-text_en.pdf
[11] Food and feed chain dossier with regard to minute presence of GM events not yet authorised in the EU in imported raw materials, notably soya and soya beans" Product Board Animal Feed, Netherlands
[12] Celeres Biotechnology Report 2011, http://www.comunique-se.com.br/deliverer_homolog/arq/cli/arq_1198_76582.pdf
[13] USDA FAS GAIN Report 2011 http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%
[14] Park, J., Mc Farlane, I., Phipps, R., Ceddia, G. (2011) The impact of the EU regulatory constraint of transgenic crops on farm income., http://reading.academia.edu/grazianoceddia/Papers/405026/The_impact_of_EU_regulatory_constraint_of_transgenic_crops_on_farm_income
[15] Otiman, I.P., Badea, E.M., Buzdugan L. (2008) Roundup Ready Soybean, a Romanian story. Buletin USAMV-CN, 65(1-2)/2008, ISSN 1454-2382asse
[16] ACT Romanian Nes Agency, 12 April 2011 http://www.actmedia.eu/2011/04/12/top+story/agriculture+minister+valeriu+tabara%3A+i+hope+we+receive+approval+for+growing+gm+soybeans+after+2012+/33135
[17] Brookes, G., Barfoot, P., (2011) GM crops: global socio-economic and environmental impacts 1996-2009. Gómez-Barbero, M., Berbel, J., Rodríguez-Cerezo, E. (2008a) Adoption and performance of the first GM crop introduced in EU agriculture: Bt maize in Spain. Joint Recearch Centre report (http://ftp.jrc.es/EURdoc/JRC37046.pdf); Gómez-Barbero, M., Berbel, J., Rodríguez-Cerezo, E. (2008b) Bt corn in Spain—the performance of the EU's first GM crop. Nature Biotechnology 26, 384 – 386. Esteban, E. (2009) Experience with a GM crop cultivation by a Member State: Spain. Presentation at EFSA Conference – Assessing risks of GMOs, 14-15 September 2009. Antama (2009): Press release by fundacion Antama: http://fundacion-antama.org/wp-content/uploads/2011/01/20110110-NP-ANTAMA-estudio-markin-EN.pdf. Gomez-Barbero et al (2008a, 2008b) as well as Gómez-Barbero, M., Rodríguez-Cerezo, E. (2007) GM Crops in EU agriculture – A case study for the Bio4EU project (http://bio4eu.jrc.ec.europa.eu/documents/FINALGMcropsintheEUBIO4EU.pdf). Gómez-Barbero, M., Rodríguez-Cerezo, E. (2007) GM Crops in EU agriculture – A case study for the Bio4EU project (http://bio4eu.jrc.ec.europa.eu/documents/FINALGMcropsintheEUBIO4EU.pdf)o the seed companies (25.6% on average).
[18] Legislation 1829/2003 states "Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred in Article 35 a draft of the decision to be taken in respect of the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences...."
[19] "Study on the Implications of Asynchronous GMO Approvals, for EU Imports of Animal Feed Products"
[20] 'Consolidated presentation of the joint Scientific Opinion of the GMO and BIOHAZ Panels on the "Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants" and the Scientific Opinion of the GMO Panel on "Consequences of the Opinion on the Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants on Previous EFSA Assessments of Individual GM Plants", EFSA-Q-2009-00589 and EFSA-Q-2009-00593
[21] The Food Chain Research and Technology Network (2010) GM crops in Europe: Politics, Policies and Processes. http://www.foodchaintech.org/documents/GM%20Policy%200910.pdf
[22] This is the case for heterozygote GM plants containing stacked events. In the case of homozygote GM plants containing stacked events, in which the progeny will be genotypically uniform, EFSa requires the presentation of separate individual applications only for each sub-combination of events intended for marketing.
[23] US Biotechnology Industry Organisation http://www.bio.org
[24] Conselho de Informaçoes sobre Biotecnologia http://www.cib.org.br
[25] Understanding Canadian Biotech Regulations. Council for Biotechnology Information. http://www.whybiotech.ca/resources/understanding_canadian_biotech_regulations.pdf
[26] CropLife Canada www.croplife.ca
[27] Stein, A.J. and Rodríguez-Cerezo, E. (2009) The global pipeline of new GM crops. Implications of asynchronous approval for international trade. European Commission Joint Research Centre
[28] 82/472/EEC: Council Recommendation 30 June 1982 concerning the registration of work involving recombinant deoxyribonucleic acid (DNA) OJ L 213 , 21/07/1982, p. 15 - 16
[29] Recommendation n°. R (84) 16 of the Committee of Ministers to Member States concerning notification of work involving recombinant deoxyribonucleic acid (DNA)
[30] EU Commission Communication to the Council entitled "Biotechnology in the Community", COM (83) 672
[31] EU Commission Communication to the Council entitled "A Community Framework for the Regulation of Biotechnology", COM (86) 573.
[32] Recombinant DNA Safety Considerations : Safety considerations relating to the use of organisms obtained through DNA recombination techniques in industry, agriculture and the environment. Organisation for Economic Co-operation and Development (OECD); 1986. ISBN 92-64- 22857-8
[33] Safety Considerations for Biotechnology. Organisation for Economic Co-operation and Development (OECD); 1992. ISBN 92-64-23641-7.
[34] Safety considerations relating to biotechnology: Scale-up of crop plants. Organisation for Economic Co-operation and Development (OECD) 1993. ISBN 92-64-24044-6.
[35] Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and principles. (OECD); 1993. ISBN 92-64-23859-6.
[36] EU Commission Proposal for a Council Directive on the contained Use of genetically modified Microorganisms and Proposal for a Council Directive on the deliberate Release to the Environment of genetically modified Organisms, COM (88)160
[37] WHO. 1991. Strategies for assessing the safety of foods produced by biotechnology. Report of a Joint FAO/WHO Consultation. World Health Organisation, Geneva
[38] Council Decision of 4 November 1991 concerning the Summary Notification Information Format referred to in Article 9 of Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms (91/596/EEC) OJ L 322, 23.11.1991, p. 1-16
[39] 94/211/EC: Commission Decision of 15 April 1994 amending Council Decision 91/596/EEC concerning the summary notification information format referred to in Article 9 of Council Directive 90/220/EEC OJ L 105, 26.4.1994, p. 26–44
[40] Commission Decision 92/146/EEC of 11 February 1992 concerning the Summary Notification Information format referred to in Article 12 of Council Directive 90/220/EEC OJ L60, 05.03.1992, p. 19- 30
[41] Proposal for a Council Regulation (EEC) on novel foods and novel food ingredients. COM/92/295FINAL - SYN 426 OJ C 190, 29.7.1992, p. 3

[42] Organisation for Economic Co-operation and Development, Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles, OECD, Paris, 1993.
[43] 93/584/EEC: Commission Decision of 22 October 1993 establishing the criteria for simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6 (5) of Council Directive 90/220/EEC OJ L 279, 12.11.1993, p. 42–43
[44] 94/730/EC: Commission Decision of 4 November 1994 establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6.5 of Council Directive 90/220/EEC OJ L 292, 12.11.1994, p. 31–34
[45] Commission Directive 94/15/EC of 15 April 1994 adapting to technical progress for the first time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms OJ L 103, 22.4.1994, p. 20–27
[46] FAO/WHO, (1996) Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety.
[47] Commission Directive 97/35/EC of 18 June 1997 adapting to technical progress for the second time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms OJ L 169, 27.6.1997, p. 72–73
[48] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients OJ L 43, 14.2.1997, p. 1–6
[49] 97/618/EC: Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council (Text with EEA relevance) OJ L 253 , 16/09/1997 P. 0001 - 0036
[50] OECD (1998), Report of the OECD Workshop on the Toxicological and Nutritional Testing of Novel Foods (Aussois, France, 5-8 March 1997)
[51] Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC OJ L 159, 03/06/98, p.4
[52] A Proposal for a European Parliament and Council Directive amending Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms (COM (1998) 0085 - 1998/0072(COD)) was forwarded to the Council and the European Parliament on 23 February 1998 in accordance with the co-decision procedure under Article 95 (ex 100A) of the Treaty. OJ C139, 04/05/98, p. 1
[53] Commission Communication on the Precautionary Principle. COM (2000)1
[54] Commission Regulation (EC) No 49/2000 of 10 January 2000 amending Council Regulation (EC) No 1139/98 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC OJ L 6, 11/01/2000, p. 13
[55] Commission Regulation (EC) No 50/2000 of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms OJ L6, 11/01/2000, p.15
[56] FAO/WHO (2000) Safety aspects of genetically modified foods of plant origin, a joint FAO/WHO consultation on foods derived from biotechnology, Geneva, Switzerland 29 May - 2 June 2000
[57] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration OJ L 106, 17.4.2001, p. 1–39
[58] Proposal for a Regulation of the European Parliament and of the Council on genetically modified food and feed COM/2001/0425 final - COD 2001/0173 OJ C 304E , 30.10.2001, p. 221–240
[59] Proposal for a Regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (COM(2001) 182 final — 2001/0180(COD)) OJ C 304E , 30.10.2001, p. 327–330
[60] Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions entitled "Llife Sciences and Biotechnology – a strategy for Europe" 23.1.2002 com(2002) 27 final
[61] 2002/623/EC: Commission Decision of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC OJ L 200, 30.7.2002, p. 22–33
[62] 2002/811/EC: Council Decision of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC OJ L 280, 18.10.2002, p. 27–36
[63] Council Decision of 3 October 2002 establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market (2002/813/EC) OJ L 280, 18.10.2002, p. 62 – 83
[64] REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety OJ L31, 1.2.2002, p.1
[65] 2003/701/EC: Commission Decision of 29 September 2003 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market OJ L 254, 8.10.2003, p. 21–28
[66] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance) OJ L 268, 18.10.2003, p. 1–23
[67] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC OJ L 268, 18.10.2003, p. 24–28
[68] Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms OJ L 287, 5.11.2003, p. 1–10
[69] 2002/628/EC: Council Decision of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety OJ L 201, 31.7.2002, p. 48–49
[70] Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming OJ L 189 , 29/07/2003 P. 0036 - 0047
[71] Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation OJ L 102, 7.4.2004, p. 14–25
[72] Commission Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003 OJ L 348, 24/11/2004, p.18
[73] Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed, the EFSA Journal (2006) 99, 1-100.European Food Safety Authority 2006 - ISBN: 92-9199-019-1
[74] Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms OJ L 368, 23.12.2006, p. 99–109
[75] Opinion of the Scientific Panel on genetically modified organisms [GMO] on the Post Market Environmental Monitoring (PMEM) of genetically modified plants The EFSA Journal (2006) 319, 1-27

[76] Guidance document for the renewal of authorisations of existing GMO products by the Scientific Panel on Genetically Modified Organisms (GMOs) Guidance of the GMO Panel - The EFSA Journal (2006) 435, 1-4
[77] Guidance Document for the risk assessment of genetically modified plants containing stacked transformation events by the Scientific Panel on Genetically Modified Organisms (GMO) The EFSA Journal (2007) 512, 1-5
[78] Statement on the safe use of the nptII antibiotic resistance marker gene in genetically modified plants by the Scientific Panel on genetically modified organisms (GMO) Statement of the GMO Panel - Published: 13 April 2007 http://www.efsa.europa.eu/en/efsajournal/doc/742.pdf
[79] Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, as regards the implementing powers conferred on the Commission OJ L 81, 20.3.2008, p. 45–47
[80] Regulation (EC) No 298/2008 of the European Parliament and of the Council of 11 March 2008 amending Regulation (EC) No 1829/2003 on genetically modified food and feed, as regards the implementing powers conferred on the Commission OJ L 97, 9.4.2008, p. 64–66
[81] Scientific Opinion on Safety and Nutritional Assessment of GM Plants and derived food and feed: The role of animal feeding trials Food and Chemical Toxicology 46 (2008) S2–S70
[82] Working Document of the GMO Panel on the Environmental Risk Assessment of genetically modified herbicide tolerant plants and interplay between Directive 2001/18/EC (GMOs) and Directive 91/414/EEC (Plant Protection Products) - Published: 10 October 2008 http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902125247.htm
[83] 2009/770/EC: Commission Decision of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council OJ L 275, 21.10.2009, p. 9–27
[84] Consolidated presentation of the joint Scientific Opinion of the GMO and BIOHAZ Panels on the "Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants" and the Scientific Opinion of the GMO Panel on "Consequences of the Opinion on the Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants on Previous EFSA Assessments of Individual GM Plants" The EFSA Journal (2009) 1108, 1-8
[85] Scientific Opinion on Guidance for the risk assessment of genetically modified plants used for non-food or non-feed purposes, on request of EFSA. EFSA Journal 1164
[86] EFSA Guidance Document on the ERA of GM plants EFSA Journal 2010;8(11):p. 1879
[87] Scientific Opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed EFSA Journal 2010; 8(7):1700
[88] Scientific Opinion of Statistical considerations for GMOs safety EFSA Journal 2010; 8(1):1250
[89] Scientific opinion on the assessment of potential impacts of GM plants on non-target organisms EFSA Journal 2010;8(11):1877

NOTES

EuropaBio™
The European Association for Bioindustries

For further information, please contact:

EuropaBio
Avenue de l'Armée, 6
T. +32 2 735 03 13
F. +32 2 735 49 60

E-mail: gmoinfo@europabio.org
Website: www.europabio.org
Blog: www.seedfeedfood.eu
Twitter: @EuropaBio and
@SeedFeedFood