EU-U.S. High Level Working Group on Jobs and Growth

Response to Consultation by EuropaBio and BIO

Introduction

This submission is jointly put forward by EuropaBio and the Biotechnology Industry Organization (BIO) in response to the request for comments regarding regulatory cooperation activities that would help eliminate or reduce barriers to trade. Both EuropaBio and BIO welcome and support the continued coordination between the U.S. and EU on trade issues. Persistent and scientifically unjustified barriers to products derived from agricultural biotechnology continue to inhibit innovation and growth of companies with limited resources, unnecessarily restrict trade, and increase the risk of trade disruption of key agricultural commodities. It is of mutual interest for trade of products derived from agricultural biotechnology is normalized.

In 2006, a World Trade Organization (WTO) dispute panel found that the EU's de facto moratorium on agricultural biotechnology product approvals and several Member States' bans on cultivation were inconsistent with their commitments under the WTO Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures. This dispute remains unresolved, and the potential for resolution is increasingly uncertain.

EuropaBio is the voice of the European biotech industry. Membership includes a wide range of corporate members and industry associations involved in biotechnology throughout Europe. EuropaBio has 56 corporate and 14 associate members and BIO Regions and 19 national biotechnology associations - representing some 1800 small and medium sized enterprises across Europe. EuropaBio's primary focus is the European Union but we also represent our members in transatlantic and worldwide discussions. EuropaBio represents all 9 seed and breeding companies, including the producers of all commercial GM varieties in the EU approval system or of those that have already been approved. **Contact:** Carel du Marchie Sarvaas, Director - Green Biotechnology Europe, EuropaBio, Tel: +32-2-739 11 85, c.dmsarvaas@europabio.org www.europabio.org

The **Biotechnology Industry Organization** (BIO) is the world's largest biotechnology trade association. BIO provides advocacy, business development, and communications services for more than 1,100 members worldwide. Its mission is to be the champion of biotechnology and the advocate for its member organizations - both large and small. BIO members are involved in research and development of innovative healthcare, agricultural, industrial and environmental biotechnology. Corporate members range from entrepreneurial companies developing their first product to Fortune 100 multinationals, as well as state and regional biotechnology associations, service providers to the industry, and academic centers. **Contact:** Cathleen Enright, PhD, Executive Vice President, Food & Agriculture, Biotechnology Industry Organization (BIO), Tel: +1 202-962-6644/9200, cenright@bio.org, www.bio.org

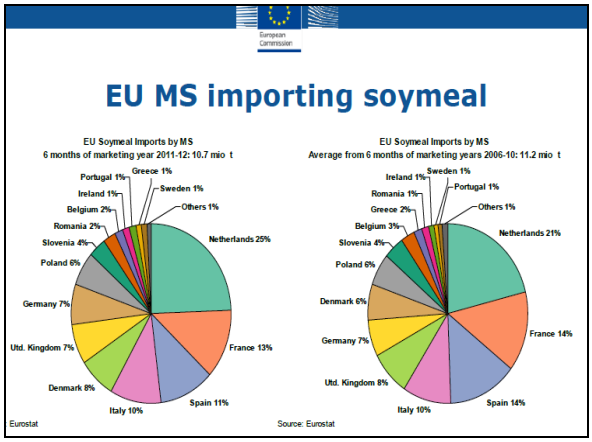
This submission has five sections:

1. Growing trade of agricultural commodities with genetically modified (GM) origin
2. Asynchronous global GM crops approval systems
3. Trade impacts
4. Steps that EU and the U.S. should consider
5. Conclusions

1. Growing trade of agricultural commodities with genetically modified (GM) origin

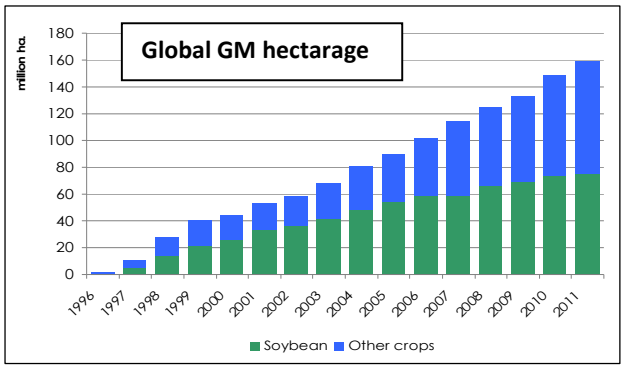
The EU is the biggest net importer of agricultural commodities (unprocessed products that are mainly traded in bulk, such as grains and oilseeds). The EU is also by far the biggest importer of agricultural products in general, which include intermediate and final products. Agricultural imports reached €98 billion in 2011[1]. The biggest exporters are North and South American countries, where modern biotechnology crops are widely grown and have contributed to higher productivity. European import dependency is particularly high for soya where EU domestic production covers only 7% of demand.

The EU's livestock sector comprises approximately 40% of total EU agricultural production. Livestock farmers depend on the availability of quality feed at good prices. EU livestock feed contains ingredients made from GM crops. Compound feed consumption represents ca. 150 million tons[2]. Soy meal accounts for 55% of protein-rich animal feed. Roughly half of the approximately 40 million tons of raw soy products imported into the EU per year is used in animal feed. Almost two thirds of EU maize production is used in animal feed, with some GM maize being grown in EU countries.

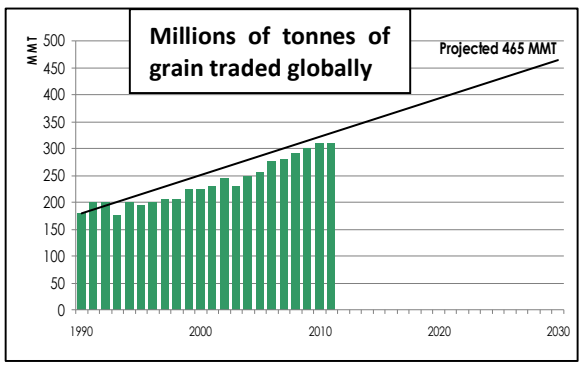


Source: Eurostat, European Commission

There is a rapid increase of GM cultivation in the U.S. and other countries that export to the EU. In 2011, 16.7 million farmers planted 160 million hectares of biotech crops in 29 countries, up 8% from 2010. Soy, harvested in the three main countries from which the EU imports, is mostly GM: in the U.S., Brazil and Argentina, GM adoption rates for soy stand at 92%, 83% and 99% respectively, and continue to increase.



Source: EuropaBio derived from ISAAA data



Source: USDA, USTR and European Commission data

There is rapid growth of internationally traded commodities, most notably soy and maize products, most of which contain more GM products. The EU imports upwards of 30 million tons annually - equivalent to 60kg per EU citizen per year (500 million). Asian nations demand for soy and maize products is increasing even faster than EU demand, which increases the competition for supply.

[1] EU Commission, MAP, May 2012 http://ec.europa.eu/agriculture/publi/map/index_en.htm
[2] FEFAC, http://www.fefac.eu/file.pdf?FileID=34736

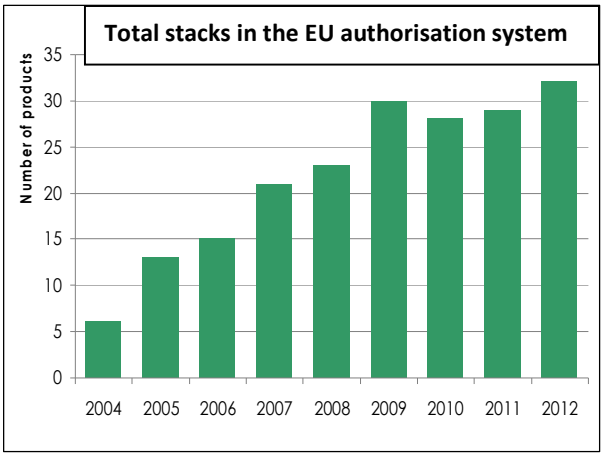
2. Asynchronous global GM crops approval

The number of GM product approval requests in the EU is increasing, and more products will enter the EU system. In 2007, 51 products were in the system; in 2012, it is 75. At current rates, this is projected to rise beyond 100 products in the system by 2015. Currently, twice as many products enter the EU approval system than exit it on average each year.

There is a growing gap between approval timelines in major markets. Global approval timelines are increasingly asynchronous. The U.S. Government and most other North and South American nations operate faster approvals systems than the EU, and they have decided to accelerate further. While the EU takes close to 3.5 years on average for an import approval, the U.S. is aiming at 1.5 years (Brazil currently takes just over 2 years and Argentina introduced measures in 2011 to cut approval times by 50% (currently about 1.5 years for single events). The EU spends almost a third of the total time in the approval process on administrative processing, rather than on safety assessments. The burgeoning backlog of GM products awaiting approval/processing represents a major barrier to trade.

In the EU there is a failure to act as prescribed by EU law. After receipt of an EFSA Positive Opinion for products for import, the Commission often fails to respect the timeline set in Article 7 of Regulation 1829/2003 about GM products for import and food/feed use. This states that after EFSA has issued a Positive Opinion on a GM product, the European Commission must act: "*Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committee ….a draft of the decision to be taken in respect of the application….*" Rarely has this deadline been met. Currently 18 products have a positive opinion from EFSA and are waiting for Commission action – some already for many months. The actions, or lack thereof, of the Commission and its motivations lack transparency and predictability and are the main cause for late, slow or no decisions. This has allowed the creation of a bureaucratic limbo, which was identified by the Commission's evaluation report about 2001/18 which states that "*…the process has been able to stall without any legal implication*" (page 51).

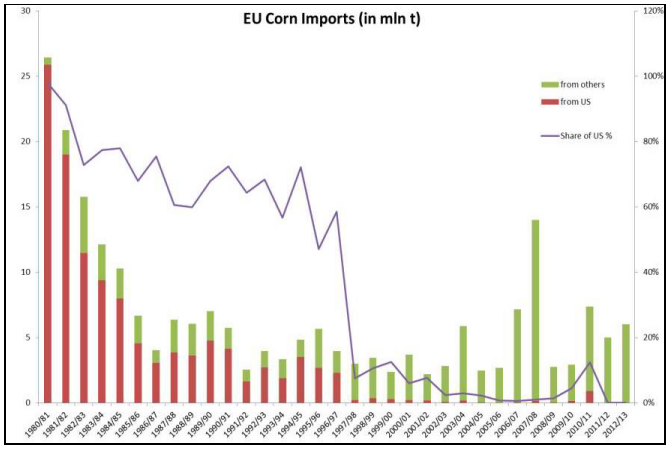
More complex stacked products will need to be approved. Most GMOs entering the market today are stacked events, in which two or more GM traits are combined by means of conventional crossing. Therefore, the number of stacks to be approved in the EU is growing. Different handling of stacks by different jurisdictions is a cause for concern. With the exception of the EU, most governments do not assess stacks separately as new products. When a stacked event is approved in most markets, any sub combination of that event with other approved singles is also approved (or is approved thereafter with a rapid procedure). The EU has a policy of only starting the risk assessment of a stacked product after the risk assessment of the single events composing that stack is completed. The data requirements for stacked products are also higher in the EU. These three factors slow down EU approvals of stacks, often by more than a year compared to approvals of single events.



Source: EuropaBio

3. Trade impacts

The chart shows the decline of U.S. to EU corn exports. The large drop in the middle of the chart in 1997/1998 coincides with the introduction of GM in the U.S. market. Trade has never picked up again to the same levels. Similar trends can be seen in other commodities like rice.



Source: Coceral 2012

100% purity is impossible in the production of food, feed and seed. Agricultural commodities inevitably become inter-mixed to a small extent. This mixing results in adventitious presence (technically unavoidable presence) of impurities without affecting quality or saleability of the crop. EU regulations usually reflect the inevitability of admixtures – except when it comes to GM crops. The zero-tolerance policy in the EU implies that imports containing minute traces of GM varieties that are as yet unapproved in the EU are not allowed into the EU. It has become increasingly difficult over the last years to import commodity grains from countries that widely use GM varieties.

It is commonly the case that a GM trait is already authorized for commercial use or sale in one or more exporting countries, but not or not yet covered by an authorization in the country of import. Due to asynchronous approval, shipments that contain traces of GM crops can be rejected at the port of entry, or diverted to other continents (see case studies overleaf). The likelihood of presence of not yet EU-authorised GMOs in imports is increasing continuously. In addition, the ability to manage this issue is more challenging. *"The logistical capacity of segregation in the main exporting countries to the EU… is not able to cope with the requirement of segregating GM material that is EU authorised from unauthorised",* according to a Commission report. This is less a problem in the U.S. because GM products are approved faster and earlier in the U.S. than in the EU.

The EU has adopted a 0.1% tolerance threshold for testing, which applies to feed only. This entered into force in 2011. This so-called 'technical solution' does not replace the EU's zero-tolerance policy, but it simply addresses the uncertainties related to methods of sampling and analysis. It is unlikely that a 0.1% tolerance threshold will be able to cope with quantities and varieties of GM products being planted around the world.

Trade disruptions have major consequences. First, there is the increased cost of raw materials to the EU. Cost increases have run into the billions of euros. This negatively impacts EU farmers, livestock breeders, commodity importers and their users, food companies. If there is doubt, grain traders will avert the risk that their ships will be denied from unloading in the EU and reroute to locations where they will not encounter problems and where they are welcomed. National and EU authorities are responsible for managing such preventable high profile incidents. These incidents decrease public trust in both the

capacity of authorities and in the technology. They may lead to recalls of consumer products, as happened with the rice incidents in 2006.

Blockage of soymeal from the EU's main suppliers as a result of traces of non-authorized GMOs would result in a soybean price increase of over 200% and could see farm profits drop by around € 3 billion for the beef sector, € 1.2bn for the dairy sector and € 1bn for the pig meat sector. Despite possible gains for domestic feed producers, the overall cost to the economy of such disruptions could total € 9.6 billion, according to a recent European Commission report. [3]

Case Study 1: Trade Disruption: Unauthorized GM maize in imports. In 2006, a new GM maize product was introduced in the U.S. It entered the EU authorization system in 2005. About 1% of total U.S. maize area was planted with this type of maize. A comprehensive plan was implemented among farmers, traders and authorities to segregate product flows in transport, storage and in the fields. The EU authorities were fully informed of the plan. Despite the unprecedented and extensive measures, 54.5% of all tested samples on U.S. barges were positive, and shipments entering Europe were found to contain the maize. The cost of the resulting trade blockages was tens of millions of Euros. The maize was finally approved in the EU in September 2007.

Case Study 2: Trade Disruption: Maize dust in soy shipments. In 2009, bulk shipments of soy from the U.S. were turned away from European ports because they contained detectable traces of GM maize not yet approved in the EU and left in the ships from previous shipments. Three unauthorized GM maize products were found. Hundreds of thousands of tons of GM soy were refused entry. Grain traders, who had their ships stuck in EU ports or had to re-route them at high cost, decided to avert risk and stopped all imports of soy products from the U.S. Soybean prices jumped. After the products were authorized, soybean prices returned to normal. The extra cost of feed imports was estimated to be between euro 3.5 -5.5 billion.

[3] Study on the Implications of Asynchronous GMO Approvals, executed on behalf of DG AGRI, December 2010: http://ec.europa.eu/agriculture/analysis/external/asynchronous-gmo-approvals/summary_en.pdf

4. Steps that the EU and U.S. should consider

To find a long-term solution to current barriers to agricultural biotechnology, the U.S. and EU must consider a systematic approach to normalize trade. The WTO SPS agreement calls on Members to initiate negotiations. Unless the outcome of these discussions becomes more productive, the unacceptable status quo is likely to be perpetuated.

The starting point is a more efficient EU authorization system with data requirements and approval timeframes more in line with the U.S. and other comparable systems. Requests for additional, unnecessary data and information are particularly burdensome to smaller, innovative developers with limited resources and staffs. The European Commission should first and foremost implement EU legislation - it should put forward all products that have received an EFSA Positive Opinion for voting within the legally foreseen timeline of 3 months.

The chart below sets out many **specific efficiency recommendations**, most of which are explained in detail in three reports - two funded by the Commission: http://ec.europa.eu/food/food/biotechnology/evaluation/index_en.htm. Another by EuropaBio at: http://www.europabio.org/agricultural/positions/approvals-gmos-european-union

Process efficiencies in the European Commission (predictability and timing) • Legally prescribed timelines should be respected • Scfcah meetings should not be cancelled - votes should take place at the first available meeting • A specific action plan to address the backlog should be initiated. This will require more time and political weight to be devoted to processing authorizations efficiently.
Political risk assessment • Maintain EFSA's autonomy: new requirements to be added by EC only if EFSA deems necessary
Efficiency improvements for EFSA • A transparent implementation of a work plan for each application • Parallel and auditable risk assessment (by different working groups and by the different MS) • A more structured process for information exchange between applicants and the EFSA
EFSA guidance: re-interpretation/ retroactivity • Avoid retroactive requirements. Any change should be clearly communicated • EFSA should set clear endpoints and a rationale for certain case-by-case recommendations • EFSA guidance should not be applied retroactively • Need for clear date of entry into effect; need for a transition period
Stacks, scope, stand alone, renewals • **Stacks:** Applications to be reviewed in parallel with their singles. Failing the above preferred option, if separate applications: reduce stack application to a simplified procedure or a notification • **Scope:** For products with EFSA opinion, a new application can be submitted following a mutual agreement between the applicant and the Commission - simplified procedure • **Stand alone:** EFSA/applicants should agree a format to centralize/ update data packages for singles. • **Renewals**: For renewals, a simplified assessment should be performed that takes into account prior assessments. It would be logical that a renewal is also given for a single when a stack is approved.
Escalation of data requirements • Global harmonization of principles and study requirements (Codex) • Pre-consultation meetings with applicants before new requirements
Late and questionable mandates to EFSA • The 30 day window for comments by general public should be respected • Specific panel to deal with the validity of the issues raised should be instituted

The "technical solution" should be extended to include food. But, it should be clear that this remains a tool under the current "zero tolerance" policy. In order to take account of the dynamics of the international adoption of GMOs in agriculture, it should be recognized that such a "zero tolerance" policy is ultimately untenable, given the global trading trends. Zero tolerance of products assessed by multiple food safety agencies all operating basically the same approval approach around the world is unnecessary.

A LLP policy for EU unauthorized GM products in feed, food and seed is needed. The policy should consider practical approaches to: unauthorized products, discontinued events, off-license products and products not submitted for approval in the EU. The EU should contribute to ongoing international efforts to coordinate LLP policies worldwide,[4] and also consider the option of mutual recognition of safety assessment data. The establishment of LLP rules does not compensate for the serious asynchronicity in approval timing between production countries and the EU.

Another option that deserves more attention is the possibility of mutual recognition of approvals with third countries. But, as progress on both of the before mentioned options is very slow in the EU, there is an urgent need for workable thresholds for feed, food and seeds. As many commodities can easily find their way both into food and feed supply chain, and segregation between commodities for feed and those for food is not practically possible, an extension of the existing 'technical solution' to cover food is needed as a matter of urgency.

Adventitious presence of GM seeds can occur in non-GM seed – in just the same way as off-types have long been found in conventional varieties. Clearly, the widespread cultivation of GM crops in many non-European countries also increases the possibility of adventitious presence of these GMOs in the non-GM seed produced in these countries for export. Expecting an adventitious presence standard of "absolute zero" is neither realistic nor possible.

The European Commission has indicated that it want to companies to reduce the use ARMGs. In 2012 the EU notified the WTO of the Implementing Regulation for authorizations of GM food and feed, which 'recommends' applicants to develop products without ARMs. Any approach to limit ARMGs must be science-based and must respect product lifecycles. The implication of the EU's policy to regulating stacked events is that applicants are required to submit stacks that may contain singles that use ARMGs. The inclusion of a de facto limit on ARMGs could have seriously negative consequences on trade.

5. Conclusions

International trade increases everyone's livelihood. Trade allows each country to specialize in the activities according to comparative advantage. By trading with others, consumers and producers can buy a greater variety of goods or services. In this document, BIO and EuropaBio have presented concrete suggestions on how to make regulatory regimes on agricultural biotechnology more compatible across the Atlantic and therefore facilitate the international trade flow of key commodities to the EU.

The biotechnology industry is willing to assist and participate in any projects related to facilitating more positive and productive agricultural trade relationships. We would appreciate and welcome the opportunity to meet and engage in a discussion with authorities on both sides of the Atlantic on these matters, and offer our support and assistance as the EU and the U.S. government look to enhance their trade relationship.

[4] International declaration on LLP signed by 13 governments in September 2012: http://64.76.123.202/site/agregado_de_valor/biotecnologia/_archivos/DECLARACION06sep2012.pdf