

November 19th 2009

AmCham EU Position Paper on Agricultural Biotechnology

The American Chamber of Commerce to the European Union (AmCham EU) represents European companies of American parentage across all industry sectors. The Agro-Food Committee encompasses the whole of the food chain, from the seed breeders and animal health suppliers, to food retailers. With this unique, horizontal and global perspective, AmCham EU would like to comment on the EU policies on agricultural biotechnology from both a competitiveness and a practical point of view. More than 10 years on from the day the first biotech crop was approved in the EU, where do we stand?

Agricultural biotechnology has not been allowed to find its place in the EU because of a number of legislative and technical barriers. Without prejudging the size and character of that market in any way, AmCham EU believes that the market should be given a chance to develop, to weigh and to evaluate the various interests involved, on products whose safety has been tested and unequivocally confirmed. To witness this lack of progress, this AmCham EU Position Paper on Agricultural Biotechnology was first written in September 2007. This version has been updated to include the latest data (where relevant) and positioning of AmCham EU.

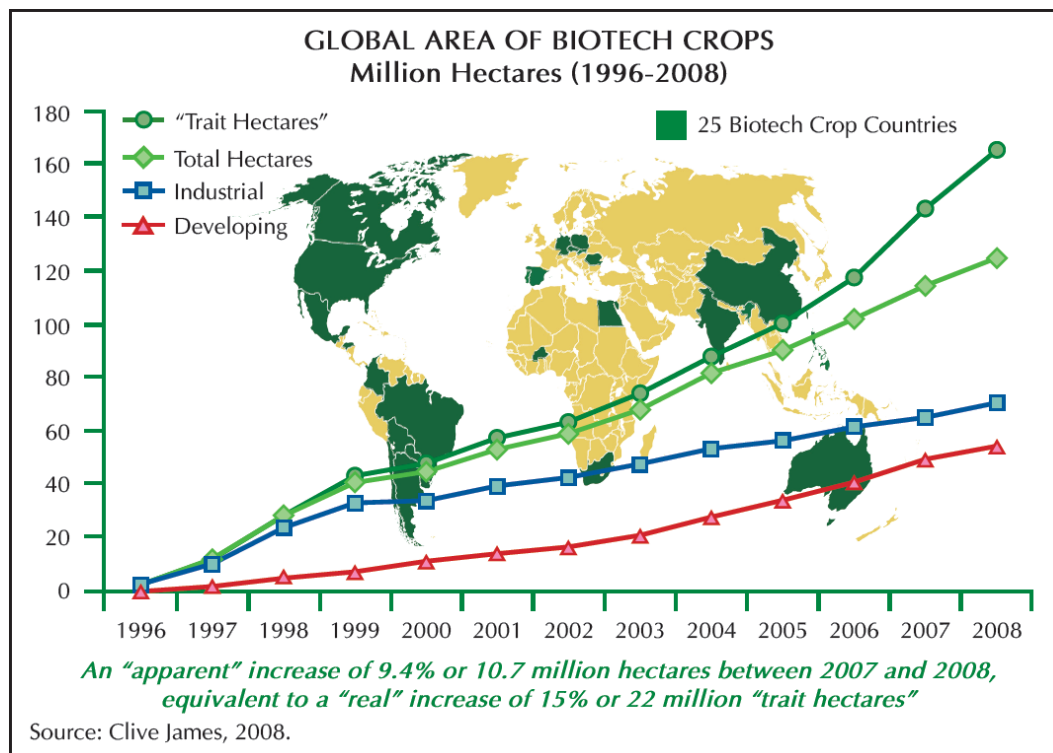
AmCham EU recommends:

- Better regulation: apply existing EU legislation in a timely and efficient manner, so as to promote innovation and the legal certainty needed for a favourable investment climate
- Regulatory & trade harmonisation: approve products with positive scientific assessments
- WTO compliance: lift Member State and regional bans on approved biotech crops
- Sustainable agriculture: establish practical, workable, national cultivation guidelines for approved crops
- Freedom of choice: allow European farmers to plant approved biotech crops if they so wish, and to offer consumers the ability to access both genetically modified and non genetically modified products, and thus exercise choice.

If these steps are implemented, the marketplace will then be able to make its own decisions on the size and character of the market for agricultural biotechnology in the EU, rather than the regulators continuing to second-guess and stifle the market

Global trends in agricultural biotechnology

The use of modern biotechnology in agriculture is a global success story. Since their introduction in 1996, biotech crops have been grown on more than 800 million hectares cumulatively. In 2008, 25 countries, representing more than half of the global population, saw the cultivation of biotech crops on 125 million hectares, grown by more than 10 million farmers, 90% of whom live in developing countries¹.



¹ Clive James, Global Status of Commercialized Biotech/GM Crops: 2008, ISAAA Briefs 39, 2008: www.isaaa.org/resources/publications/briefs/39/executivesummary/default.html.

The first generation of biotech crops has yielded significant socio-economic and environmental benefits at the farm level, mainly through higher yields and better yield protection, fuel use and greenhouse gas emissions and through the implementation of effective and environmentally-friendly farming practices like conservation tillage².

- Since 1996, farm incomes have benefited by US\$ 24.2 billion globally, 47% of which has been in developing countries.
- Reduced fuel consumption led to savings of 962.000 t of carbon dioxide (CO²), equivalent to removing 2 million cars from the road for one year.
- There has been a 15% net reduction in the environmental impact of the cropping area.

EU participation in global agricultural biotechnology trends

In the EU, these beneficial trends have been severely muted because of continuing opposition in certain Member States, legislative barriers, and the lack of choice for farmers.

Trade realities

At the same time, the EU has benefited from major imports of biotech crops. EU Member States import over 50 million tons of animal feed ingredients every year, principally protein-rich materials for livestock. These imported materials have to meet three-quarters of the EU's consumption needs. The majority of these materials are biotech-derived soybeans or soybean meal or by-products of the corn (maize) milling industry, such as corn gluten feed or distillers' dried grains (from ethanol production)³.

While the main exporting countries – US, Brazil and Argentina – continue to embrace innovations of agricultural biotechnology, and steadily approve new traits for cultivation, the EU has significantly fallen behind global agricultural biotechnology developments. By continuously delaying approval of new biotech products, the EU now risks being cut off from critical imported supplies since the new traits are grown alongside the old ones and all are harvested together. A supply cut could result in

² Graham Brookes & Peter Barfoot, GM Crops: The First Ten Years - Global Socio-Economic and Environmental Impacts, ISAAA Briefs 36, 2006: www.isaaa.org/resources/publications/briefs/36/download/isaaa-brief-36-2006.pdf; Sujatha Sankula, Quantification of the Impacts on US Agriculture of Biotechnology-Derived Crops Planted in 2005, National Center for Food and Agricultural Policy 2006: www.ncfap.org/whatwedo/pdf/2005biotechimpacts-finalversion.pdf.

³ The share of biotech-derived EU imports amounts to 90% for soy and to 70% for maize products, given that the main exporting countries have widely adopted GM crops (US: 90% of soy, 60% of maize; Argentina: 99% of soy, 60% of maize; Brazil: 55% of soy).

important shortages of necessary raw material, sharply increased feed expenditure, and a significant loss in competitiveness for the European livestock sector⁴. AmCham EU would like to see a re-evaluation of the risks and benefits of biotech crops for Europe, taking such factors into account.

Application of EU legislation

With a series of new legislative measures for the approval and use of genetically modified organisms (GMOs), the EU has further developed the most comprehensive approval system for biotech products in the world. It includes science-based risk assessment and monitoring, and ensures the safety of agricultural biotech products for human and animal health and the environment.

Further, AmCham EU notes that the US and EU approaches to safety assessments are fundamentally based on identical science-based criteria. So the question naturally arises, “Why is the EU failing so obviously to capture its share of the benefits of the global trends in agricultural biotechnology?”

A first observation is that EU decisions tend to put more emphasis on a wider array of factors, including political and socio-economic factors. This reflects current political realities but one such factor which does not appear to have been considered is the long term economic impact of the EU falling further and further behind the world’s other major agricultural producers in this area. This impact affects more than just the EU biotech sector itself – it is particularly important, for example, for the future of Europe’s livestock industry.

AmCham EU also notes that there is a significant backlog of agricultural biotech products awaiting approval in the EU. Indeed, only a small number of biotech products have been approved for import, processing, and/or use in food or feed since the new legislation came into force in 2004, and there has been no new cultivation approval since the declaration of the moratorium on biotech crops in 1998⁵.

⁴ European Commission, Directorate-General for Agriculture and Rural Development, Economic Impact of Unapproved GMOs on EU Feed Imports and Livestock Production, July 2007: http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf

⁵ Since the new EU biotech legislation came into force in 2004, only 18 agricultural biotech products have been authorised for import and food and feed use. 65 products are currently pending authorisation (status of Nov

As a result of the manner in which the EU legislation is being applied, at both the EU and Member State levels, the EU has been extremely slow to embrace innovation, which has created *de facto* barriers for companies investing in new technologies and processes in the EU, as well as barriers to international trade in commodities. The fact that some Member States have refused to implement and/or apply legislation already adopted at EU level only frustrates further the legitimate expectations of market operators to a minimum level of legal certainty, so as to permit them to take rational business investment decisions.

November 2009; see http://ec.europa.eu/food/food/biotechnology/authorisation/index_en.htm), with numerous new applications to be expected in the nearer future.

Making the European life sciences and biotech strategy work in agriculture as well

In this difficult context, AmCham EU congratulates the European Commission for its overall efforts to advance the European strategy on life sciences and biotechnology⁶. AmCham EU welcomes and strongly supports the Commission's plans to "ensure a sustainable contribution of modern biotechnology to agriculture" and to "improve the implementation of the legislation and its impact on competitiveness" by 2010, as expressed in the Commission's midterm strategy review⁷.

AmCham EU agrees with the Commission that considerable progress has been achieved in the fields of pharmaceutical (red) and industrial (white), but regrettably not in the area of agricultural (green) biotechnology. Therefore, AmCham EU would like to submit recommendations to help achieve the goal of a competitive, knowledge-based European economy in this important sector as well.

As a first step, AmCham EU would recommend that the EU and Member State authorities apply existing EU legislation in a timely and efficient manner, and approve products which have received positive scientific opinions from the European Food Safety Authority (EFSA). Removing the current backlog and approving new requests would send a clear signal to EU consumers, to operators and potential investors in Europe, and to supply sources in other parts of the world that the new EU model is workable, efficient and sustainable. That in turn would create a climate in the EU which encourages innovation and investment, while also providing a secure environment for the placing of products on the market which are known to be scientifically safe.

As a second step, Member State and regional bans on approved biotech crops should be lifted and practical, workable, national cultivation guidelines established to allow European farmers to plant approved biotech crops if they so wish.

In relation to each of these steps, AmCham EU would like to see those Member States whose decision-making has moved away from the science-based risk assessment undertake serious consideration of their approach and its effects. We suggest they reconsider in particular their approach of consistently voting against the approval of new products which have received a positive safety assessment, and recognise that by introducing insurmountable technical requirements for cultivation and/or prohibiting

⁷ Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: Life Sciences and Biotechnology – A Strategy for Europe, COM (2002) 27: http://eur-lex.europa.eu/LexUriServ/site/en/com/2002/com2002_0027en01.pdf.

the use of certain products without scientific justification, they are irrationally denying their own citizens a share in global agricultural biotechnology benefits.

In order to avoid barriers to international trade, the EU and its trading partners should further explore how operators can best function and consumers can benefit within the realities of today's global markets. Among other things, this will require that low levels of biotech grain and derived products which are commercialised in third countries, but not yet authorised in the EU, should be deemed acceptable as imports if they have been approved according to safety assessment criteria determined by the Organisation for Economic Co-operation and Development (OECD). This is an important issue resulting from delayed approvals of biotech crops in the EU; increasing trade problems have arisen this year because this issue has not been properly addressed, the situation in the future can be expected to worsen. Most importantly in the EU-US context, the two sides should actively seek mutual recognition for GMO approvals. Progress in this area would signal a real breakthrough in EU-US economic and regulatory cooperation.

Conclusion

More than ten years on, we are in a position to reassess agricultural biotechnology and view it in a more rounded manner. Millions of tons of products from biotech crops have been eaten by livestock and humans, without adverse health effects, but rather with significant economic and environmental gain. As agricultural biotech gains worldwide acceptance, the EU is left behind partly because it is not implementing its own laws. AmCham EU strongly advocates that the EU and its Member States systematically and consistently apply the existing legislation to approve products, remove legislative and technical barriers, and allow the marketplace in Europe to determine the extent of the development and use of agricultural biotechnology which is known to be safe.

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled €1.2 trillion in 2008 and currently supports 4.8 million direct jobs in Europe.

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