EuropaBio™

Green Biotechnology Manifesto

Green Biotechnology Manifesto

Contents

Introduction to Green Biotechnology

Agricultural or "green" biotechnology is being adopted at record speed around the world. In 2008:

- 13.3 million farmers in 25 countries cultivated genetically modified (biotech) crops on 125 million hectares[1]
- This is a 9.4% increase in global biotech crop acreage compared to 2007, demonstrating that farmers around the world, especially in developing countries where 90% of cultivation takes place, recognize the benefits plant technology can bring.

  Planting in Europe is on a smaller scale, but has accelerated over the last 11 years as farmers start realizing the benefits of biotech crops; lower costs and lower mycotoxins levels being the drivers for insect-resistant maize. In 2008:
- 107,719 hectares of biotech crops were planted in seven EU countries. The technology is safe and regulatory systems, if applied correctly in the countries of the European Union, guarantee consumers and farmers the choice of whether to consume and plant GM food and GM crops, respectively.

Agricultural biotechnology offers tremendous opportunities across key European public policy goals, including sustainability, CO_2 emissions reductions, energy efficiency, innovation, education, development, promotion of scientific research, retention of skills, health and trade. Biotechnology is being exploited at an accelerating rate by Europe's competitors. When allowed to flourish in the EU, it can improve environmental sustainability and competitiveness and would help to ensure that world food production keeps up with rising demand.

The benefits of green biotechnology to farmers, the environment, consumers and society are many.

Biotech crops are able to:

- increase yields by 6% - 30% on the same amount of land, thereby avoiding the need to plough up land that is currently a haven for biodiversity and used for conservation;
- offer efficient protection against insect damage to crops resulting in a significant reduction in spraying;
- result in permanent reductions in fuel use and CO_2 emissions due to less tillage; in 2007 this led to global emissions reductions of 14.2 billion kg of CO_2, equivalent to 6.3 million fewer cars on the road for one year[2];
- produce better, safer and healthier food and feedstuffs, including crops with an altered oil content and composition;
- produce food and feed containing fewer cancer-causing natural toxins such as mycotoxins;
- increase the economic viability of biofuels by reducing production costs of raw materials;
- mitigate the impact of climate change by enabling farmers to grow more food, more reliably, in harsher climatic conditions;
- help to meet the Millennium Development Goals on reducing poverty - 90%, or 12.3 million farmers cultivating biotech crops in 2008 were small and resource-poor farmers in developing countries;
- protect soils from erosion and compaction through less ploughing, with a concomitant conservation of soil moisture;
- contribute to sustainable economic benefits; Farmers earned an extra €34 billion from 1996 to 2007, 44% of which resulted from substantial yield gains and 56% from a reduction in production costs;
- increase the efficiency of water usage. Field trials have shown that drought-tolerant crops can yield up to 20% more than their non-GM counterparts;

[1, 2] *ISAAA Executive Summary 2008 – page 13*
http://www.isaaa.org/resources/publications/briefs/39/executivesummary/pdf/Brief%2039%20-%20Executive%20Summary%20-%20English.pdf

Competitiveness, sustainability and beyond

On 20 May 2008 the EU Commission proposed new rules aimed at European agriculture to respond to the growing demand for food and rising prices without compromising on environmental standards. The ***Health Check on European Agriculture*** was devised to ensure that the sector could keep up with the growing demand for food in a sustainable way. The Commission also aimed to clear obstacles that hinder farmers from responding to market signals.

While the ***Health Check*** aimed to counter rising food prices in the short-term by stimulating European production, the Commission insisted that long-term measures, including more co-ordinated international cooperation and investment in agricultural research, would also be required.

But sadly, as the 10 year anniversary of the *de-facto* moratorium on new GM crop approvals for cultivation in the EU has now come and gone, opportunities continue to be missed to allow European farmers to take advantage of the benefits of agricultural biotechnology and be as competitive and environmentally friendly as their global counterparts.

The European Commission and Member States have put in place the world's most stringent science-based regulatory system for the assessment, approval and monitoring of agricultural biotechnology products which includes:

1. A safety assessment of biotech crops that is carried out by an independent European authority, the European Food Safety Authority (EFSA). Assessment is a continuous process which remains in place even after the authorisation of a product, through careful monitoring and the requirement to renew the approval of a biotech product every ten years;

2. Tracing and labelling of GM crop-derived ingredients that is required throughout the food chain for informing consumers thus guaranteeing freedom of choice;

3. A set of European level recommendations on how GM crops can coexist alongside conventional and organic crops to ensure no discrimination against any type of agriculture;

4. The involvement of Member State's Competent Authorities in the safety assessment of biotech crops throughout the process.

Notwithstanding all of the above, the authorisation of cultivation and use of agricultural biotechnology products is facing a number of substantial hurdles.

These barriers are setting the sector back in Europe with respect to the rest of the world and are impeding the contribution of agricultural biotechnology to Europe's long-term sustainability goals across a wide range of policy sectors including environmental, developmental, competitiveness and trade, in addition to the more obvious area of agriculture.

This Manifesto aims to:

- ***Highlight the five main problem areas in need of urgent attention and action***
- ***Indicate solutions to these problems***

1. Implement the GM crop authorization process effectively

In 2001, the European Commission published a report based on 81 research projects that it had funded (€70 million) over 15 years. The report found that GM crops did not pose *"any new risks to human health or the environment beyond the usual uncertainties of conventional plant breeding. Indeed, the use of more precise technology and the greater regulatory scrutiny probably make them even safer than conventional plants and foods"*[3].

Despite those scientific findings, in 2004 the European Commission acknowledged that as far as agricultural biotechnology is concerned: *"...Europe's position is declining as a consequence of the political inertia caused by the polarized and increasingly heated debate between opponents and advocates..."*[4]. As a consequence of this political inertia, the stringent system for authorizing new biotech crops in the EU is not working as intended.

Indeed, in spite of the fact that companies are complying with those regulatory requirements and that the body responsible for scientific assessment, the European Food Safety Authority (EFSA), has issued numerous positive opinions on product safety, to date, no product has yet been approved in the EU for cultivation since the new regulatory framework was adopted in 2001. In addition, approvals of products for use in animal feed and food also face undue delays in spite of positive opinions on safety from EFSA.

The approval process is not working properly for three main reasons:

1. The safety assessment part of the approval process managed by the EFSA GMO Panel is functioning very slowly. More product dossiers enter the EFSA than exit in a one year period and a backlog of around 40 products has been accumulated over the past 6 years.
2. The European Commission's Environment Directorate, which is responsible for managing the approval process, is not submitting proposals for decisions to the Regulatory (Member State) Committees within the times prescribed by the regulations.
3. Member State representatives at the Regulatory Committee and Council levels are ignoring EFSA opinions on product safety and are voting against the approval of products in Comitology. This has the serious, knock-on consequence, of eroding public confidence in the scientific evaluations of EFSA as well as in the approval process itself.

Suggested solutions

1. As a matter of priority, the EFSA GMO Panel should focus on applications for product approvals, and deliver opinions in timeframes consistent with those prescribed in the regulations. A specific short-term action plan should be put in place to eliminate the accumulated back-log and until then other activities should be reduced.
2. The European Commission should propose draft approval decisions to Member States according to their regulatory obligations with respect to legally binding timelines.
3. Member States should act in a manner consistent with their EU and International obligations, and demonstrate confidence in the regulatory process, that they themselves established, by making decisions on the basis of sound science and the EFSA opinions.
4. The European Commission should ensure that, for biotech products authorized in the EU, Member States do not restrict farmer's access to such products through the use of arbitrary and illegal bans or through the adoption of discriminatory and disabling national or local coexistence rules.

[3] *Press Release from the European Commission, DG Research: http://ec.europa.eu/research/biosociety/pdf/gmo_press_release.pdf "GMOs: are there any risks ? – Launch of a European Round Table on GMO safety, 9 oct 2001" page 1*

[4] *European Commission, "Plants for the Future: The Vision Paper: "2025: a European vision for plant genomics and biotechnology" page 8, 2004 http://www.epsoweb.org/Catalog/TP/Plants%20for%20the%20future-Dec04.pdf*

2. Enable a European single market in seeds

The term *Adventitious Presence* (AP) refers to the unintentional and incidental commingling of trace amounts of one type of seed or grain with another. AP may occur in all arable farming at every step in the production of seed or grain or at any stage of further processing in the agri-food chain. Since plant breeding, seed production and commercial farming are conducted in the same open farming environment, it is impossible to achieve 100% purity in any of these products. There may be cross pollination from other plants or mixing during harvesting, cleaning or packaging. Low impurities in conventional or organic seeds of any crop have therefore always been accepted and the EU's seed legislation defines acceptable and economically practicable levels for such AP.

This is what Europe's seed industry demands for adventitious presence of biotech seeds in its conventional seed as well - a practicable threshold. Despite a series of explicit requests over the last decade from Europe's seed producers, farmers, many individual Member States and from the full Council on several occasions, and despite numerous assurances by the Commission that it would deliver a workable proposal, the Commission has delivered nothing but broken commitments.

Since no EU seed thresholds for biotech seeds have been set, some Member States have sought to impose their own, often extremely costly, conditions on the seed industry. As a consequence, crops in fields have had to be destroyed and seed companies and their staff even face criminal proceedings because of extremely low level presence of GMOs in their seed. Of even greater consequence for the EU as a whole, the single Market for seeds continues to be eroded through restrictions to seed trade and limited availability of varieties to farmers. The continued failure of the Commission to follow through on its proposals with concrete action has deprived Europe's seed industry of legal certainty, its single market and its economic future.

Suggested solutions

Europe's plant breeders and seed producers need the Commission to end the era of inaction. After 10 problematic years of increasing uncertainty for the industry the time for reflection is over. The Commission should put forward a proposal for EU-wide thresholds for AP of GM seeds in conventional seed. This proposal must be proportionate and economically sustainable for Europe's large number of small and medium sized seed businesses. The Commission should take its responsibility to end the years of legal and economic uncertainty for plant breeders and seed producers and re-establish the Single Market for the EU's seed industry and for its customers – Europe's farmers.

3. Respect other countries' freedom to trade in commodities

New GM products and crops continue to be approved, cultivated and commercialized at a faster speed and in greater numbers in North America, South America, Asia, Africa and Australia.

This leads to the lawful presence of GM products on those markets and despite product channeling, it is inevitable that low levels of these products will be present in traded commodities such as grains and derived products that are exported from those countries to Europe. At the moment, the EU does not permit any presence of GM material, approved outside the EU, to be present in traded commodities entering the EU, unless they have full approval for use within the EU, irrespective of how small a presence the GM material makes up of the total.

The huge, chronic delay in product approvals in the EU leads to a continued asynchronous approval speed compared with the rest of the world. The net effect of this is that the EU is increasingly exposed to the potential for incidents where low level presence of GM material, already approved outside the EU, appears in traded commodities entering the EU leading to trade disruptions. This issue of asynchronous approvals was highlighted as a critical problem by a recent WTO case[5].

Without an urgent solution to address this problem, given the uncertainty in international commodity markets, it is likely that many food and feed industries in the EU will suffer from insufficient quantities of imported raw materials and will face increasing costs that sooner or later will impact consumers as well as effecting investment and employment in this critical sector of the economy.

Suggested solutions

1. The European Commission and Member States should ensure that the science-based approval system for GM products works in a timely fashion and that the undue delays are solved to reduce approval gaps with the rest of the world in order to avoid trade disruptions.
2. In the immediate term, the European Commission should consider finding a pragmatic approach to manage the presence of low levels of GM products and derived products in a traded commodity where these have been evaluated as safe in accordance with internationally recognized criteria, commercialized in third countries, but not yet approved in the EU. This would significantly minimize tensions and reduce trade disruptions on the international market.
3. The European Commission and Member States should appropriately adopt the Codex guidelines on Low-level presence which were approved in July 2008.

[5] *WTO reports issued on 29 September 2006 from the panel that had examined complaints by the United States, Canada and Argentina, respectively, against "European Communities — Measures affecting the approval and marketing of biotech products" (DS291, DS292 and DS293). http://www.wto.org/english/news_e/news06_e/291r_e.htm*

4. Promote coherence of policies and public information on green biotech

More and more farmers are increasingly supporting and growing biotech crops around Europe.

"European farmers are increasingly interested in using new technologies such as agricultural biotechnology to meet the multiple challenges of feeding a growing population whilst minimizing the impact on the environment" said James Ede of the National Farmers Union of the United Kingdom, speaking at the press conference in Brussels in February 2009. *"Europe's political leaders should respond to the demands of their farmers and offer them the freedom to choose the same tools available to their competitors globally"* he added.

These comments echo those of Agriculture Commissioner Marianne Fischer Boel in 2009 who stated that *"[The EU] needs to be confident in a science-based approach to genetically modified organisms (GMOs). It's beyond question that we must authorise only GMOs which are safe for people, animals and the environment. But within this framework, let's be open to what GM technology can do for us – for example, GM crops which are more resistant to heat or drought."*[6]

Public opinion is also changing. Recent polling and reports show growing support for agricultural biotechnology, especially where spraying of crops can be reduced or healthier food choices can be obtained[7]. Europeans rank biotechnology low down on the list of all concerns about foods, and a large majority of consumers says that GM content is not important in purchasing decisions[8]. Indeed, when they are offered on the shelves of food stores, European consumers buy foodstuffs labeled as derived from or containing ingredients from GMOs[9]. Overall recent consumer survey findings indicate that general acceptance of gene technology is on the increase[10].

Writing in the journal, Feedstuffs, in March 2009, the former Commissioner for Health, David Byrne said: *"It is nonetheless disappointing that the political leadership in Europe has failed to emphasize the consistent scientific advice, which is that GM food and feed are as safe as conventional varieties. Politicians must take a more courageous approach and encourage a more balanced understanding of GM food among European consumers."*

Suggested solutions

1. Societal and political leaders need to make a greater concerted contribution towards informing and reassuring citizens about the technology, its safety, and the stringent regulatory framework that is in place in Europe.
2. Europe's political leadership needs to nurture a coherent pro-growth policy that supports sustainable agriculture and is both science-based and non-discriminatory towards proven and well-regulated technologies.
3. The Commission and the Member States need to remove the uncertainties in the approvals process which only serve to undermine citizens' confidence in European institutions and the regulatory framework. Voting against positive EFSA opinions confirming safety of GMs undermines both the products and the regulatory system in the minds of consumers.

6 *European Commissioner Marian Fischer Boel, 04 May 2009, http://www.teatronaturale.com/article/488.html*

7 *Europeans and Biotechnology in 2005: Patterns and Trends http://ec.europa.eu/research/press/2006/pdf/pr1906_eb_64_3_final_report-may2006_en.pdf page 22*

8 *Peter Hutton, "GM Foods: What Europeans Really Think", August 2006, http://www.actu-ogm.fr/dlm/1/37 , page 3*

9 *"Do European Consumers buy GM foods?" European Commission Survey for The King's College of London http://www.whybiotech.com/resources/tps/DoConsumersBuyGMFoods.pdf page 6, October 2008*

10 *GMO Compass Survey, April 2009 'Opposition decreasing or acceptance increasing? http://www.gmo-compass.org/eng/news/stories/415.an_overview_european_consumer_polls_attitudes_gmos.html*

5. Promote coherence of policies with development goals

Although cultivation of biotech crops is gaining momentum in the EU, reaching 107,719 hectares in 2008, it has been far surpassed in other countries around the world. Indeed, cultivation in the EU accounts for less than 0.1% of global cultivation of GM crops.

In 2008, the number of biotech crop farmers increased by 1.3 million, reaching 13.3 million globally in 25 countries. Notably, 90% or 12.3 million were small and resource-poor farmers in developing countries whose increased income from these crops contributed to the alleviation of poverty[11].

So far, globally the cultivation of Agricultural Biotechnology crops has contributed to sustainable economic benefits worth €34 billion from 1996 to 2007. 44% of this was due to substantial yield gains and 56% due to a reduction in production costs.

A G8 Leaders Statement on Global Food Security[12] issued in 2008 stated: *"We fully recognize the need for a wide range of mid- to long-term measures to tackle the issue of food security and poverty, inter alia, the importance of stimulating world food production and increasing investment in agriculture. To this end, we will … accelerate research and development and increase access to new agricultural technologies to boost agricultural production; we will promote science-based risk analysis including on the contribution of seed varieties developed through biotechnology, …"*

However, as a UN Human Development Report stated as far back as 2001 *"Opposition in richer countries to biotech crops may set back the ability of the poorest nations to feed growing populations… The world's richest nations must get over their fear of genetically engineered food if they want to help eradicate poverty in the world's poorest countries[13]". The same report also stated that "Biotechnology offers the only, or the best "tool of choice" for marginal ecological zones-left behind by the green revolution but home to more than half of the world's poorest people, dependent on agriculture and life stocks."*

This opinion was reaffirmed by the European Commission which in June 2008 Stated *"The use of GMO crops can increase productivity. This may be particularly important in regions of the world which suffer from difficult climatic conditions. GMOs can therefore play an important role in mitigating the effects of the food 'crisis'"*[14].

Refusals by countries facing widespread famine to accept GM food aid[15] even when the same product is eaten daily by millions of Americans, exemplifies the fact that Europe's "ambivalent position" negatively influences developing countries in their attitude towards agricultural biotechnology, with consequences that have at times been grave for those in need.

Suggested solutions

1. The European Union should nurture and promote coherent pro-development policy that does not discriminate against promising technology.
2. Europe's political leadership should openly communicate its support for its own regulatory system, and the products approved through this system, including GM products.

11 *ISAAA Executive Summary 2008, page 8 http://www.isaaa.org/resources/publications/briefs/39/executivesummary/pdf/Brief%2039%20-%20Executive%20Summary%20-%20English.pdf*

12 *http://www.issi.it/documents/G8%2008%20Hokkaido%20Declarations.pdf ,page 10*

13 *United Nations Development Programme, Human Development Report 2001 (: http://hdr.undp.org/en/media/completenew1.pdf) quoted by the NY Times on 8 July 2001: http://www.nytimes.com/2001/07/08/world/move-to-curb-biotech-crops-ignores-poor-un-finds.html*

14 *Commission's / EU's response to the high oil and food prices (Press release, 19 June 2008)*

15 *Zambia denies GM aid for refugees (http://news.bbc.co.uk/1/hi/world/africa/2250933.stm)*

Conclusion: Europe must move forward

In order for agricultural biotechnology to contribute actively to Europe meeting competitiveness, environmental and development goals, European political leaders and the European Commission should review their biotechnology and life sciences policies to ensure that they:

1. Publicly acknowledge agricultural biotechnology as a key tool in the challenge to respond to the growing demand for food without compromising on environmental standards.

2. Fulfil their legal obligations and properly apply EU legislation.

3. Enable EFSA to deliver safety opinions on biotech products within the times prescribed in EU legislation and stand by EFSA opinions when they are delivered.

4. Propose draft decisions for the placing on the market of biotech products in a timely manner as required by EU legislation.

5. Establish EU-wide pragmatic labelling thresholds for adventitious or technically unavoidable presence of biotech seeds in seed lots.

6. Establish a pragmatic approach towards managing the presence of low levels of biotech products and derived biotech material in traded commodities.

7. Monitor Member State's implementation of measures to ensure alignment with the 2003 EU recommendations on coexistence.

8. Listen to, and support more vocally, European farmers to help them benefit from the economic and environmental advantages of green biotechnology.

9. Nurture and promote coherent pro-growth and pro-development policies that do not discriminate against this promising technology.

10. Contribute more effectively toward informing citizens about the technology, its safety, its advantages and the existing regulatory framework.

EuropaBio's mission is to promote an innovative and dynamic biotechnology-based industry in Europe.

For further information, please contact:

EuropaBio Avenue de l'Armée, 6 - B-1040 Brussels
Tel: +32 2 735 03 13 - Fax: +32 2 735 49 60 - greenbiotech@europabio.org
www.europabio.org

Printed on 100% recycled paper

EUROPABIO™
The European Association for Bioindustries