



# Green Biotechnology Manifesto



EUROPA<sup>BIO</sup>

The European Association for Bioindustries

## Introduction to Green Biotechnology

Agricultural or “green” biotechnology is being adopted at record speed around the world - in 2006, 10.3 million farmers in 22 countries cultivated genetically modified (biotech) crops on 102 million hectares. The adoption rate is seeing double-digit annual growth since 1996. Planting in Europe has been much slower, but is accelerating as farmers start realizing the benefits of biotech crops. In 2006, six European countries (Portugal, Spain, Germany, France, Czech Republic, Slovakia, Romania) grew biotech crops as opposed to only one a few years ago<sup>1</sup>. The number of hectares of biotech crops in Europe, although modest, is also growing significantly. 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 or not to consume and plant biotech crops.

Agricultural biotechnology offers tremendous opportunities across key European public policy goals, including innovation, education, development, health, renewable resources and energy, and trade. Biotechnology is being exploited at an accelerating rate by Europe’s competitors, but if allowed to flourish, it will contribute to the increased economic and environmental sustainability of European agriculture and to efforts to ensure world food stocks keep 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 freeing up land for other uses than agricultural production;
- offer efficient protection against insect damage to crops; while significantly reducing the need to spray crops;
- result in permanent reductions in fuel use and resultant CO<sub>2</sub> emissions due to less tillage;
- have already reduced the global environmental ‘foot print’ of production agriculture by 14%<sup>2</sup> including reductions of CO<sub>2</sub> emissions in 2004 equivalent to taking 5 million cars off the road for one year;



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- produce better, safer and healthier food and feedstuffs, such as healthier vegetable oils; produce containing less harmful natural toxins such as mycotoxins;
- increase the economic viability of biofuels by reducing production costs of raw materials;
- allow farmers to grow more food more reliably in harsher climatic conditions;
- reduce water use and help us meet the Millennium Development Goals;
- protect soils from erosion and compaction through less ploughing;
- create jobs e.g. over 1 million new jobs were created in Argentina over a period of 10 years from the adoption of biotech crops<sup>3</sup>.

## Green Biotechnology, the Lisbon goals and beyond

In March 2000, the European Union set itself the ambitious goal of *“becoming the most dynamic and competitive knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and great social cohesion, and respect for the environment, by 2010.”* To underline the importance of science and research, Europe’s political leaders launched a *“knowledge for growth”* initiative in 2005 recognising that Biotechnology plays an essential role and reiterating the importance of the 2002 EU Strategy on Life Sciences and Biotechnology, stating *‘Life sciences and biotech can foster growth, create new jobs and benefit a wide range of sectors such as health and agriculture, while at the same time contributing to broader goals, such as sustainable development.’*<sup>4</sup>

The specific role of green biotechnology was emphasized by the Commission in 2004: *“Life science research can help European agriculture tackle its three main challenges: the shift in economic power away from primary producers (countries); the huge changes needed in agricultural infrastructure and systems; and the effect of trade globalisation and liberalisation that could lead to a 20% to 30% cut in EU agricultural output in the very near future.”*<sup>5</sup>

The European Commission and the Member States have put in place the world’s most stringent regulatory system for the assessment, the approval and monitoring of agricultural biotech products of which the main features are:

1. the safety assessment of biotech crops is carried out by an independent European authority, the European Food Safety Authority (EFSA), and 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. the tracing and labelling of biotech crop-derived ingredients is required throughout the food chain for maximum transparency towards consumers thus guaranteeing freedom of choice;



3. a set of European level recommendations (known as coexistence guidelines) on how to cultivate biotech crops alongside conventional and organic crops to ensure no discrimination against any type of agriculture;
4. Member States competent authorities are fully involved in the safety assessment of biotech crops.

**Notwithstanding the above, the authorisation for the cultivation and use of agricultural biotech products is facing a number of substantial hindrances.**

**These hindrances are setting the sector back in Europe with respect to the rest of the world and are impeding the contribution of agricultural biotech to Europe's Lisbon goals.**

**This Manifesto aims to present the practical hindrances in the five main areas in need of urgent attention and action, as well as suggested solutions.**

## Implement the biotech crop authorization process

In 2001, the European Commission published a report based on 81 research projects funded by the Commission (€70 million) over 15 years. The report found that biotech crops did not have “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<sup>6</sup>”.

Despite the 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 polarised and increasingly heated debate between opponents and advocates...” As a consequence of this political inertia, the stringent system for authorizing new biotech crops in the EU is not working as intended.

In spite of the fact that companies are complying with regulatory requirements and that the body responsible for scientific assessment, the European Food Safety Authority (EFSA), has issued a number of positive opinions on product safety, 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.
2. The European Commission Directorates responsible for managing the approval process are 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 not following EFSA opinions on product safety.



## **Suggested solutions**

1. As a matter of priority, the EFSA GMO Panel should focus its capacity on applications for product approvals, and deliver opinions in timeframes consistent with those prescribed in the regulations. Ad hoc self-tasking activities should be reduced until the backlog of applications is removed. Additional resources should be provided to EFSA to manage the increasing number of applications.
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 they established by making decisions on the basis of EFSA's scientific opinions.
4. The European Commission should ensure that, for biotech products authorized in the EU, Member States do not restrict farmers' access to such products through the use of arbitrary and illegal bans or through the adoption of discriminatory national or local coexistence rules.

## Enable a European single market in seeds

Although it has been globally agreed that a low level adventitious presence of biotech seeds is acceptable in conventional and organic seed lots and therefore for trade, one issue that is not addressed by the EU regulatory regime concerns the establishment of threshold levels for that adventitious presence.

Since 1998, industry and governments have requested that labeling thresholds for the adventitious presence of biotech seeds in seed lots be established in order to safeguard the EU single market in traded seeds.

Given that no EU thresholds in seeds have been set so far by the European Commission, Member States have taken the liberty to interpret locally how to deal with this issue, thus setting ad hoc and variable thresholds for labeling and trade in the different Member States. This has created new trade barriers and led to significant disruptions of the single market.

The political will for developing a proposal has been recently re-stated by the highest levels of the institutions:

- In March 2005 during its orientation debate on GMOs, the European Commission stressed the urgency of establishing thresholds – and agreed to do so.
- In April 2006, the Austrian Presidency concluded that the setting of thresholds was a priority.
- In May 2006, the EU Council of Agriculture Ministers asked for a proposal on EU thresholds as soon as possible.

The science and data on economic and environmental impacts on which to base a proposal exists.

- In December 2005, the seed industry provided extensive information about economic impacts.
- In February 2006, the Commission's Joint Research Centre produced a scientific study with environmental impacts of different threshold levels.
- Throughout 2006, seed companies provided further information about economic impact.





## **Suggested solutions**

As a matter of urgency, the European Commission should publish a proposal to establish technically practical, proportionate and economically viable EU-level labeling thresholds for the adventitious presence of biotech seeds in seed lots.

This matter should be given the utmost priority in order to reestablish the single market for the free movement of seeds within the European Union.

## **Respect other countries' freedom to trade in commodities**

New biotech products and crops continue to be approved, cultivated and commercialised at a higher speed and in greater numbers in other parts of the world such as North America, South America, Asia, and South Africa.

This leads to the lawful presence of biotech products on those markets and despite strong 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 biotech material, approved outside the EU, to be present in traded commodities entering the EU.

Huge delays in product approvals in the EU are the result of both Europe's de facto moratorium as well as the 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 biotech material approved outside the EU, appears in traded commodities consequently leading to trade disruptions. This issue of asynchronous approvals was highlighted as an important issue in the recent WTO case.

Without an urgent solution to address this problem and given the uncertainty in international commodity markets, it is likely that many industries in the EU will suffer from insufficient quantities of traditionally imported raw materials.



## **Suggested solutions**

1. The European Commission and Member States should ensure that the approval system for biotech 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 biotech products and derived products in a traded commodity where these have been evaluated as safe in accordance with internationally recognized criteria, commercialised in third countries but not yet approved in the EU. This would significantly minimise tensions and reduce disruptions on the international market.
3. The European Commission and Member States should continue to support the Codex work project on the presence of low levels of biotech grains and derived products in traded commodities.

## Promote coherence of policies and public information on green biotech

Farmers are increasingly supporting and growing biotech crops around Europe. One group representing European farmers stated that Europe's slow adoption ... "leaves Europe in a very uncomfortable position compared to its international competitors<sup>8</sup>". Most farmers support Agriculture Commissioner Fischer Boel's statement in 2005 that ... "Farmers should be given choice in order to reflect and adapt to the needs of the market. The decision on the use of biotech crops should be for the farmer<sup>9</sup>." As the UK National Farmers Union said "... farmers should have access to technologies that have received regulatory approval and should therefore be free to choose their preferred production systems<sup>10</sup>."

Public opinion is also changing. Recent polling and reports show growing support for agricultural biotech, especially where spraying of crops can be reduced or healthier food choices can be obtained<sup>11</sup>. Europeans rank biotech at the bottom of the list of all concerns about foods, and a large majority of consumers says that biotech content is not important in purchasing decisions<sup>12</sup>.

### Suggested solutions

1. Societal and political leaders need to make a greater contribution towards educating citizens about the technology, its safety, its advantages and the stringent regulatory framework that is in place in Europe.
2. Europe's political leadership needs to nurture a coherence pro-growth policy that supports sustainable agriculture and is both science-based and non-discriminatory towards proven technologies.
3. Remove the uncertainties in the approvals process which only undermine citizens' confidence in European institutions and the regulatory framework.



## Promote coherence of policies with development goals

Cultivation of biotech crops is gaining momentum in the EU and has reached 65 000 hectares in 2006 with 6 European countries cultivating approved biotech crops (Portugal, Spain, Germany, Czech Republic, Slovakia and France)<sup>13</sup>. With improvements in policies, there is great potential for further opportunities for biotech crops in the EU. However, the ambivalent position of the EU hinders such opportunities and negatively influences developing countries from the adoption of biotech crops.

In 2006, 90% of the farmers who benefited from biotech crops were resource poor farmers from developing countries, whose increased income from these crops contributed to the alleviation of poverty<sup>14</sup>.

As the UN Human Development Report stated *"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"*.

A number of internationally recognized reports, including the 2002 FAO report<sup>16</sup>, state that agricultural biotechnology has a definite role to play in combating world hunger.

The United Nations Development Programme 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.<sup>17"</sup>*

Refusals to accept food aid containing GM traces and such exemplifies the perception that Europe's perceived *"ambivalent position"* negatively influences developing countries in their attitude towards agricultural biotechnology.

## Suggested solutions

1. The European Union as a whole should nurture and promote coherent pro-development policy that does not discriminate promising technology.
2. At the same time, Europe's political leadership should openly communicate its support for the policies it has agreed on so as to correctly reflect the trust it has in its own regulatory system and the products approved through this system.

- <sup>1</sup> Source: ISAAA, "Global Status of Commercialized Biotech/GM crops: 2006"
- <sup>2</sup> Brookes and Barfoot, "GM Crops: The Global and Environmental Impact – The First Nine Years 1996-2004", *Agbioforum* 8, (2\$3):187-196
- <sup>3</sup> Ten Years of Genetically Modified Crops in Argentine Agriculture
- <sup>4</sup> Eduardo J. Trigo (FORGES Foundation), Eugenio J. Cap (Institute of Economics and Sociology of the National Institute of Agricultural Technology), December 2006
- <sup>5</sup> European Commission, "Life Sciences and Biotechnology – A Strategy for Europe", 2002
- <sup>6</sup> European Commission, "Future Challenges for Life Sciences Research", European Group of Life Sciences (EGLS), Sep 2004
- <sup>7</sup> European Commission-sponsored research on the safety of Genetically Modified organisms – a review of results, <http://ec.europa.eu/research/quality-of-life/gmo/>
- <sup>8</sup> European Commission, "Plants for the Future", 2004
- <sup>9</sup> European Landowners Organisation, "The situation of biotechnologies in European Agriculture", 2004
- <sup>10</sup> Commissioner Fischer Boel, as quoted in "Farmers Guardian", 15 April 2005
- <sup>11</sup> NFU Statement: "Coexistence of GM crops with conventional/ organic production", October 2003  
June 2006 Eurobarometer on biotechnology
- <sup>12</sup> Peter Hutton, "GM Foods: What Europeans Really Think", August 2006
- <sup>13</sup> ISAAA Brief 35 Global Status of Commercialized Biotech/GM Crops: 2006
- <sup>14</sup> ISAAA Brief 35 Global Status of Commercialized Biotech/GM Crops: 2006
- <sup>15</sup> United Nations Organisation Human Development Report Increasingly, EU governments are taking a proactive approach so that their policies positively affect particularly African, development.
- <sup>16</sup> "Biotechnology provides powerful tools for the sustainable development of agriculture, fisheries and forestry, as well as the food industry. When appropriately integrated with other technologies for the production of food, agricultural products and services, biotechnology can be of significant assistance in meeting the needs of an expanding and increasingly urbanized population in the next millennium. FAO recognizes that genetic engineering has the potential to help increase production and productivity in agriculture, forestry and fisheries. It could lead to higher yields on marginal lands in countries that today cannot grow enough food to feed their people".
- <sup>17</sup> United Nations Development Programme, Human Development Report of 2001



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**EuropaBio** is the political voice of the biotechnology industry in Europe. Our association of bioindustries has some 70 corporate members operating worldwide, 11 associates, 5 regions and 25 national biotechnology associations, representing 1500 small and medium sized biotech companies in Europe.

Members of EuropaBio are involved in research, development, testing, manufacturing and commercialisation of biotechnology products and processes. Our corporate members have a wide range of activities: human and animal health care, diagnostics, bio-informatics, chemicals, crop protection, agriculture, food and environmental products and services.

EuropaBio also welcomes associate members such as international commercial, financial, asset management and other service-providing companies, regional biotechnology development organisations and scientific institutes. The common denominator among all our members is the use of biotechnology at any stage of research, development or manufacturing.



Avenue de l'Armée 6  
B-1040 Brussels - Belgium  
Tel : (+32.2) 735.03.13  
Fax : (+32.2) 735.49.60  
E-mail : [info@europabio.org](mailto:info@europabio.org)

# Conclusion

## Europe must move forward

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

1. Honour commitments aimed at achieving political and economic objectives.
2. Fulfil their legal obligations and properly implement Community legislation.
3. Encourage EFSA to deliver safety opinions on biotech products within the times prescribed in the Community legislation.
4. Propose draft decisions for placing on the market of biotech products in a timely manner as required by the Community legislation.
5. Establish pragmatic labelling thresholds for adventitious or technically unavoidable presence of biotech seeds in seed lots.
6. Establish pragmatic approach to manage the presence of low levels of biotech products and derived biotech material in traded commodities.
7. Enhance the co-ordination with Member States as far as co-existence is concerned.
8. Listen to, and more vocally support, European farmers to realize 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. Better contribute toward educating citizens about the technology, its safety, its advantages and the regulatory framework.



The European Association for Bioindustries

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