Available online at www.sciencedirect.com
SCIENCE DIRECT®
Regulatory Toxicology and Pharmacology 44 (2006) 43–48
Regulatory Toxicology and Pharmacology
www.elsevier.com/locate/yrtph

Science, politics, and the GM debate in Europe

Francesca Tencalla *

Monsanto Europe S.A., Avenue de Tervuren 270–272, B–1150 Brussels, Belgium

Received 18 July 2004
Available online 26 September 2005

Abstract

Europe today stands at a crossroad, facing challenges but also opportunities. In its intent to make Europe a leading technology-based economy by 2010, the European Commission has identified biotechnology and genomics as fields for future growth, crucial for supporting the agricultural and food processing industry. Since first commercialization in 1996, GM crop areas have grown at double-digit rates, making this one of the most rapidly adopted technologies in agriculture. However, in contrast to other world areas and despite European Commission support, Europe has found itself 'bogged-down' in a polemic between opponents and supporters of plant biotechnology. As a result, planted areas have remained small. This stalemate is due to a lack of political leadership, especially at the Member State level, all the more surprising in light of European early development and competitive advantage with crop biotechnology. This situation proves once again that, for cutting-edge innovations, a solid science base alone is not sufficient. Acceptance or rejection of new technologies depends on interlinked political, economic, and societal factors that create a favorable or unfavorable situation at a given time. This article will look at GM crops in Europe and the role science and politics have played in the introduction of crop biotechnology.

Keywords: Plant biotechnology; Genomics; Research and development; Politics; Europe

1. Vision 2010: Europe as a leader in technical innovation

Today, Europe faces many challenges of political, economic, and social nature. At a time of intense competition from other world areas, the European Union (EU) is reshaping itself, expanding and continuously adapting its legal and environmental framework.

In a recent publication (European Commission, 2004), European Research Commissioner Phillippe Busquin restated the EU's March 2000 Lisbon European Council objective of becoming the "*most competitive and sustained knowledge-based economy by 2010*." One of the key elements to achieving this is maintaining and building on the EU's scientific and technological diversity and excellence, acting as a magnet for top researchers and innovative companies that would otherwise develop their activities elsewhere.

Two fields identified as crucial in this context, not only by the EU but also by individual Member State governments (see Boxes 1 and 2), are biotechnology and genomics.

Box 1—Tony Blair at the European Bioscience Conference (November 2000)

"The science of biotechnology is likely to be to the first half of the 21st century what the computer was to the second half of the 20th century. Its implications are profound, its potential benefits massive... Britain is well placed to keep our lead in Europe. I want to make it clear: we don't intend to let our leadership fall behind and are prepared to back that commitment with investment."

* Fax: +32 2 776 76 42.
E-mail address: francesca.tencalla@monsanto.com.

0273-2300/$ - see front matter © 2005 Elsevier Inc. All rights reserved.
doi:10.1016/j.yrtph.2005.04.011

Box 2—Edelgard Bulmahn, German Minister for Education and Research (November 2003)

"Biotechnology is one of the most innovative fields of the 21st century. We expect that, from now to 2020, biotechnological methods will be involved in about half of all important innovations."

Applied to crops and food singly and in combination, these technologies will determine the future competitiveness of Europe's agricultural and food processing industries. This is of no small importance given that the agri-food industry is the leading industrial sector in the EU. It represents a €600 billion annual turnover, utilizing a fifth of the Union's land. It is also the continent's third largest employer, with 2.6 million jobs (excluding farmers) mainly in small to medium-sized enterprises (SMEs) (CIAA, 2004).

Let us therefore take a closer look at plant biotechnology and the increasing role it plays in Europe.

2. What is plant biotechnology?

Biotechnology can be defined as the application of biological knowledge and techniques to develop products. The term encompasses classical methods used for plant and animal breeding, for example, fermentation and enzyme purification. It also refers to newer biotechnological methods to modify the genetic material of living cells so that they produce new substances or new functions.

Since the 1980's, biotechnology has been applied to plants, in particular crops, as a new method of breeding which helps add or switch off particular genes to improve crops in ways not possible with classical systems. At the outset, this was a response to farmer demand for simpler and more efficient methods of cultivation. The first genetically modified (GM) crops therefore carried agricultural traits, mainly tolerance to specific herbicides or resistance to a number of pests. For certain types of crops, this new technology represented the opportunity to move from chemical-based pesticide control systems to more sustainable biological methods, replacing older technologies with more environmentally friendly ones.

As research progresses, many new traits are being worked on, including crops with enhanced nutritional profiles (e.g., increased levels of essential amino acids or vitamins, improved oil composition) or increased resistance to environmental stress (e.g., drought, heat or cold). Promising advances are also occurring in the medical field, with plants being used as substrate for the production of pharmaceutical products (Cockburn, 2003).

3. The rapid adoption of plant biotechnology worldwide

The benefits of GM crops are numerous; ease of use for the farmer, decrease in the amount of pesticides needed for weed or insect control, lower energy use and possibility to adopt soil-preserving conservation tillage techniques are just a few examples. This was recognized early on by farmers and GM crops became one of the most rapidly adopted technologies in the history of agriculture. Since their first commercialization in 1996, planted areas have grown steadily at double-digit rates, reaching 67.7 million hectares worldwide in 2003 (James, 2003). Today, seven million farmers, approximately one third from developing countries, cultivate GM crops in 18 countries. More than 99% of plantings occur outside of Europe, where only Romania, Spain, Bulgaria, and Germany grow GM plants, on surfaces reported at around 50,000 hectares or less in 2003 (Table 1).

Table 1
GM crops planted worldwide in 2003 (in million hectares)

Country	GM crop area	% of total	Country	GM crop area	% of total
USA	42.8	63	Uruguay	>0.05	<0.07
Argentina	13.9	21	Mexico	<0.05	<0.07
Canada	4.4	6	Bulgaria	<0.05	<0.07
Brazil	3	4	Indonesia	<0.05	<0.07
China	2.8	4	Columbia	<0.05	<0.07
S. Africa	0.4	1	Honduras	<0.05	<0.07
Australia	0.1	0.1	Germany	<0.05	<0.07
India	0.1	0.1	Philippines	<0.05	<0.07
Romania	>0.05	>0.07			
Spain	<0.05	<0.07	Total	67.7	

Source: James, 2003.

4. Regulation of GM plants

Worldwide, strict regulatory frameworks are in place in many countries to ensure that all candidate GM crops are evaluated according to the latest standards of scientific knowledge for impacts on human health, animal health, and the environment before authorizations for marketing are granted. There is a high level of international harmonization (König et al., 2004); the safety assessment is extremely rigorous and varies only slightly from country to country (Jaffe, 2004). It involves a case by case basis analysis, taking into account the crop, the trait and the region of intended commercialization. In contrast, new crop varieties developed by conventional breeding methods (these include not only traditional hybridization but also embryo rescue, chemical or ionizing radiation-induced mutation and protoplast fusion for example) are not extensively tested before commercialization.

Assessments of the GM crops currently on the market have uncovered no adverse health or environmental effects. Also, there have been no validated adverse findings during their consumption over the last 8 years (UK GM Science Review Panel, 2003, 2004).

5. Plant biotechnology: Europe compared to other world areas

Because of its huge commercial success, plant biotechnology is today a rapidly expanding field of research and development (R&D) around the world. Investments are largest in the US where the biotechnology sector for example raised €13 billion in 2000 (Ernst and Young, 2001) and the government launches programs such as the National Plant Genome Initiative with a total budget of €1.1 billion from 2003 to 2008. Investments in Canada, Asia, India, and South America are also increasing rapidly as these countries look to capture a bigger share of the agricultural trade and solve not only their own food security problems but many global needs, for example, cereal shortfalls resulting from increased meat consumption in developing countries (Pinstrup-Andresen et al., 1999).

Historically, Europe has played a leading role in biotechnology and genomics research, with European scientists involved in critical steps ranging from the unraveling of the structure of DNA at Cambridge's Cavendish Laboratory 50 years ago (Watson and Crick, 1953) to the assembly of a practical system for the genetic engineering of plants at the University of Ghent in Belgium (Schell et al., 1983). Nevertheless, the situation in Europe with regard to plant biotechnology is currently anything but positive. Europe does not have a single shared vision for biotechnology but an assemblage of various sector-specific, EU, Member State, and local policies. In 2000, although the number of biotechnology companies in the EU was higher than in the US (many SMEs versus fewer larger US companies), employment, expenditure on R&D, and the importance of the sector in terms of % GDP were all lower (Table 2). Probably the most pressing issue facing biotechnology companies is funding. The average total public and private research effort in the EU today amounts to 1.8% of GDP, against 2.7% in the US and 3.1% in Japan. Despite its larger economy, the EU's industrial biotechnology R&D has remained at only half the levels of the US over the last 25 years; in 2000, the EU biotechnology sector raised €6 billion for investments, compared to the €13 billion mentioned above for the US (Ernst and Young, 2001).

Table 2
Comparison of the biotechnology sectors in the EU and the US (2000)

Measurable	EU	US
Number of companies	1570	1273
Number of employees	61,000	162,000
Number of researchers, in % of industrial workforce	2.5	6.7
R&D effort, in % of GDP[a]	1.8	2.7
R&D expenditure, in million Euros	4977	11,400

Source: Ernst and Young, 2001.
[a] The value for Japan is 3.1%.

The introduction of the first GM product on the European market—paste from Flavr Savr delayed-ripening GM tomatoes sold by the UK retailers Sainsbury and Safeway in 1996—was largely successful. However, this preceded a multiple wave of food scandals (BSE, *Escherichia coli* 157, and others) that generated a context of distrust towards policy-makers, industry, and scientists. Moreover, each time science overcomes a barrier, it is normal that parts of society feel threatened; just the pace of change can be worrying. If, additionally, conditions are unfavorable, this unease may translate into the type of generalized "zero risk" approach towards new innovations experienced today in some EU countries with regard to biotechnology. It is therefore not surprising that, when the next GM crops reached the European markets (herbicide tolerant soybeans), these were met with resistance by certain pressure groups. Since then, a heated debate between opponents and supporters of plant biotechnology has developed (weighing up GM and organic products against each other), leading to near political inertia, and trapping a skeptical and confused public in the crossfire.

6. The European approval system

The ongoing debate in Europe is having a series of wide-ranging consequences that directly impact the objective of becoming a leader in technical innovation. Although the European Commission and certain governments strongly support moving forward with plant biotechnology, not all Member States stand united behind the decision. This has brought the regulatory system in place to a grinding halt. In 1998, six countries installed a "*de facto*" moratorium, stopping all new product approvals until the existing legislation governing questions relating to environmental monitoring, traceability, and labeling were revised. Since 2003, new rules and guidelines are in place to address these questions but the system is still moving forward only very slowly. Where required, implementation into national laws has not been timely. In some cases, national measures have been inconsistent with the stated objective to support plant biotechnology and/or much more restrictive than required by EU legislation (see Box 3). In addition, there have been repeated destructions of field trials by anti GMO campaigners who have seldom been held to account by the law. In consequence companies and even public bodies have found it to be effectively impossible to conduct research or development with any real prospect of bringing a product to market in Europe in a timely fashion. This has led to biotech companies closing their European operations and moving R&D facilities to other world areas more receptive to GM research and offering real opportunities to place new products into the market. The net consequence of this is a loss of investment in Europe with a knock-on effect for university students, employment, and overall competitiveness.

Box 3—Statement of the DFG (German Research Foundation) on the draft legislation to reform the law on genetic engineering in Germany (August 2004)

This draft legislation is intended to implement EU Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMOs). The Directive requires Member States to take the precautionary principle into account (Article 8) when implementing the "appropriate control of risks" when GMOs are released. As part of the regulation of the release and placing on the market of GMOs, the draft legislation introduces an extension of the objectives of the law (Article 1 clause 2 new version), namely the principle of "co-existence," which is defined as co-existence of "agriculture using genetic engineering with conventional and ecological agriculture."

The vast majority of the following individual regulations nevertheless contradict the stated objective of the law. They present obstacles due to disproportionate conditions, which in practice—as the sum of the direct and indirect consequences of the planned regulations—will affect only one of these three forms of agriculture, namely the use of genetic engineering. Not only the agricultural use of "green genetic engineering," but also its use in research will be excluded, not according to the law, but by the predictable effects of the new regulations.

Today, a few crops recently received, or are on the verge of receiving, approval for import into Europe but actual planting of new GM crop varieties remains far on the horizon. This situation is contradictory; although the imports provide essential grains often at a lower price than home production, the lack of planting approvals sends a negative message to European farmers who are not able to take advantage of the benefits of the technology.

7. What are the consequences?

As a result of this complex situation, Europe is progressively losing market share and, due to declining investments from large organizations, any near-term ability to be competitive in the field of biotechnology. The emerging gap between the EU and its main competitors will affect not only the European science and technology base, but also industry, consumers and farmers.

There are many different measurable parameters to demonstrate the already considerable impact on European research. The number of notifications for field trials in across the EU15 (JRC, 2004) peaked at 264 in 1997, then fell to only 56 in 2002 (Fig. 1) and 23 in 2004. In contrast, there are around 900–1000 notifications of GM trials in the US each year (Mitchell, 2003). According to a recent Commission survey of private biotech companies and public research institutes (European Commission, 2003), 39% of European research projects in this field have been aborted in recent years. In the private sector alone, the figure was as high as 61%.

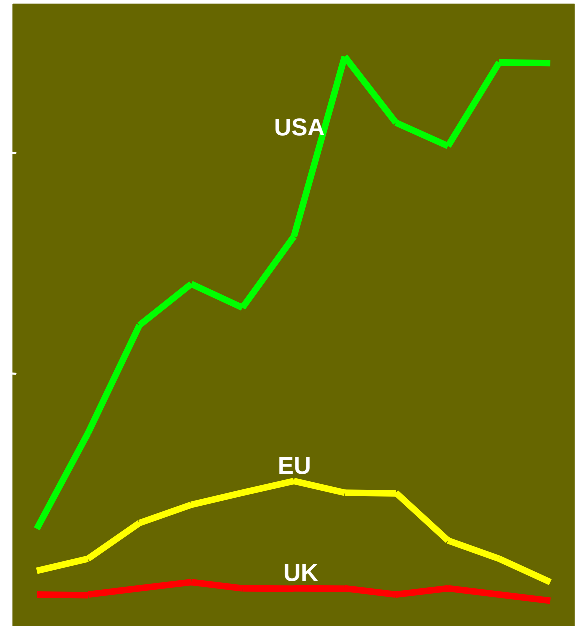

Fig. 1. Approvals for biotech research and development field trials (1992–2002).

Faced with overly strict political and regulatory frameworks, university and industry R&D is moving to other world areas such as the USA, Japan, and China where long-term strategies for exploiting the potential of plant genomics and strengthening the positions in related markets are in place. Each year, thousands of Europeans go to study in the US and over 70% remain there to pursue their careers; it is estimated that nearly 40% of the scientists working in the US today are of European origin (Mettler, 2004). European biotechnology SMEs are more likely to enter into research collaborations with US companies that their EU counterparts and are also turning more and more to customers outside the EU (Bioscience Law Review, 2004). Furthermore, companies of all sizes are relocating their research activities and investments to these countries, as well as India and Argentina.

Recent examples include the Swiss agrochemical company Syngenta, which announced in July 2004 its intention to relocate its UK agricultural biotechnology research operations to North Carolina (US). Also, BASF, the world's largest chemical company, has threatened to move its GM crop research to the USA unless Europe becomes more receptive to new technologies. In an interview with the Financial Times (12 July 2004), Jurgen Hambrecht, chief executive BASF, said the German chemicals giant could not afford to keep investing in research if there was no market for its products. He further added that "*the EU's 'Lisbon' aim to make Europe the world's most competitive economy by 2010 stood no chance of becoming a reality unless politicians were prepared to accept that the benefits of a new technology inevitable carry some risks.*"

Finally, the recalcitrant attitude towards biotechnology is expected to affect also the 15 million European farms in the 25 Member States and the European food industry. In a situation where agricultural output is less technologically competitive and Common Agricultural Policy subsidies are decreased and even eliminated, the growth of alternative niches such as the organic food market will not be able to compensate for a shrinking share of conventional and GM markets in Europe. Strong price competition coupled with loss of import protection and tariff reductions could lead to a shift from European products to imports, effectively limiting the range of EU consumer lifestyle and health choices. In the near future, European consumers including farmers themselves risk being left with the choice of either buying local products at much higher prices or going for cheaper imports, all because of an unsubstantiated fear of GM products.

Rather than a leading position in the biotechnology and genomics field, Europe therefore faces the deterioration of its R&D base, the loss of markets for European agricultural products and an increased dependence on food and feed imports (Mitchell, 2003). European industry's ability to contribute to agricultural innovations and a biotechnology-based economy may see itself severely restricted.

8. Conclusion

Europe is at a crossroads and there are enormous opportunities to be grasped. Biotechnology and genomics, in particular relating to plants, have been identified as fields for future growth, crucial for supporting the agricultural and food processing industry, Europe's main economic sector. However, in contrast to other world areas which are moving ahead and investing heavily, Europe has found itself 'bogged-down' in a heated, long-winded, and often acrimonious debate between opponents and supporters of these technologies. In the meantime it is losing its competitive edge to other regions of the developed and developing world.

The situation in Europe proves once again that, for all cutting-edge innovations, a solid science base alone is not sufficient. Acceptance or rejection of the new technology depends on many interlinked political, economic, and social factors that create a favorable or unfavorable climate at a given time. Clearly more research is required on societal responses to the application of new technological innovations. Overall a better understanding of peoples' attitudes and values is needed. Despite the competitive advantage Europe once had in the field of plant biotechnology, the first GM products to reach the market came at a time of confusion and strong skepticism towards politicians, industry, and scientists. As a result, the debate concerning GM crops has been dominated by the risks, while the positive economic, environmental, and health aspects have been ignored. The direct consequences are a lack of unanimous and consistent political support throughout the various European Member States, directly impacting new research initiatives, and market opportunities.

There is no doubt that, as with all technologies and human endeavors, genetic modification carries the potential for risk, therefore safety assessments are required to be performed for every new trait, within the context of a sound international broadly harmonized legislative framework. However, while the aim of regulatory systems is the same (protection of human health and the environment), innovation has continued to flourish under some (e.g., the US, Canada, Japan, and China) but not under others (e.g., Europe). If Europe is to remain a leader in this crucial area of innovation, the concerns of both critics and advocates need to be critically addressed and then Europe should move on; expending time and energy constructing legislative and regulatory hurdles to counter biotechnology without valid justification is counterproductive. Used in conjunction with other methods, plant biotechnology can be a positive addition to the current agricultural portfolio. Europe should therefore proceed responsibly in developing biotechnology, while taking all reasonable steps to minimize adverse effects. It is important to remember that, in some cases, not proceeding may be just as costly as moving ahead. This can be measured in negative impacts for each of the parameters essential for global sustainability, namely health, environment, and socio-economic development.

In the words of European Research Commissioner Philippe Busquin: "(…) *It is time to reverse this downward trend. If we do not react, we will be dependent on technology developed elsewhere in the world within the next ten years.*"

References

Bioscience Law Review, 2004. Europe's biotech vision, so far so good? http://pharmalicensing.com/features/disp/1075973829_40220ec5d94f5 (accessed August 2004).

CIAA (Confederation of the EU Food and Drink Industry), 2004. Key facts and figures about the food and drink industry in Europe. http://www.ciaa.be/navigation/frames_uk/frameset1.htm (accessed September 2004).

Cockburn, A., 2003. Commercial plant breeding: what is in the biotech pipeline? Journal of Commercial Biotechnology 10 (3), 209–223.

DFG (Deutsche Forschungsgemeindschaft), 2004. Statement of the German Research Foundation on the draft legislation to reform the law on genetic engineering in Germany. http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/2004/download/gentechnikrecht_en_0604.pdf (accessed August 2004).

Ernst and Young, 2001. 8th Annual Life Sciences Review 2001. http://www.ey.com/GLOBAL/content.nsf/UK/HS_-_Library_-_Integration (accessed September 2004).

European Commission, 2003. Commission calls on EU Member States to intensify efforts in life sciences and biotechnology. European Commission press release. http://europa.eu.int/rapid/press Releases Action.do ?reference = IP/03/313&format = HTML&aged = 1&language = EN &guiLanguage = en (accessed August 2004).

European Commission, 2004. Plants for the future: a European Vision for plant biotechnology towards 2025. http://www.europabio.org/plant_genomics_platform.htm (accessed August 2004).

Pinstrup-Andresen, P., et al., 1999. World food prospects: critical issues for the early 21st century. Food Policy Report IFPRI, Vision 2020.

Jaffe, G., 2004. Regulating transgenic crops: a comparative analysis of different regulatory processes. Transgenic Research 13, 5–19.

James, C., 2004. Preview: global status of commercialized transgenic crops: 2003. ISAAA publication no. 30 – 2003. http://www.isaaa.org (accessed August 2004).

JRC (Joint Research Center), 2004. Deliberate field trials. http://biotech.jrc.it/deliberate/dbcountries.asp (accessed August 2004).

König, A. et al., 2004. Assessment of the safety of food derived from genetically modified 5GM° crops. Food and Chemical Toxicology 42, 1047–1088.

Mettler, A., 2004. Europe is steadily losing its science elite. Financial Times, July 15 2004.

Mitchell, P., 2003. EU biotech firms drastically cut back research. Nature Biotechnology 21 (5), 468–469.

Schell, J. et al., 1983. Ti plasmids as experimental gene vectors for plants. Advances in gene technology: molecular genetics of plants and animals. Miami Winter Symposia 20, 191–209.

UK GM Science Review Panel, 2003. GM science review, first report. An open review of the science relevant to GM crops and food based on interests and concerns of the public. http://www.gmsciencedebate.org.uk/report/default.htm#first (accessed August 2004).

UK GM Science Review Panel, 2004. GM science review, second report. An open review of the science relevant to GM crops and food based on interests and concerns of the public. http://www.gmsciencedebate.org.uk/report/default.htm#second (accessed August 2004).

Watson, J.D., Crick, F.H.C., 1953. A structure for deoxyribose nucleic acid. Nature 171, 737.