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on Biotechnology: Prospects and Challenges for Agriculture in Europe
(2006/2059(INI))

Committee on Agriculture and Rural Development

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MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

on Biotechnology: Prospects and Challenges for Agriculture in Europe (2006/2059(INI))

The European Parliament,

– having regard to the Commission Communication on Life Sciences and Biotechnology - a Strategy for Europe[1],

– having regard to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity of 29 January 2000[2], signed by the European Community on 24 May 2000,

– having regard to the Proposal for a decision of the European Parliament and of the Council concerning the seventh framework programme of the European Community for research, technological development and demonstration activities (2007 to 2013) (COM(2005)0119),

– having regard to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC[3],

– having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[4] and to Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC[5],

– having regard to the Communication from the Commission to the Council and the European Parliament on the report on the implementation of national measures on the coexistence of genetically modified crops with conventional and organic farming (COM(2006)0104),

– having regard to its resolution of 15 March 2001 on the Future of the Biotechnology Industry[6],

– having regard to its resolution of 21 November 2002 on the Commission Communication on Life Sciences and Biotechnology - a Strategy for Europe[7],

– having regard to its resolution of 18 December 2003 on coexistence between genetically modified crops and conventional and organic crops[8],

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[1] OJ C 55, 2.3.2002, p. 3.
[2] OJ L 201, 31.7.2002, p. 50.
[3] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Decision 2002/623/EC (OJ L 200, 30.7.2002, p. 22).
[4] OJ L 268, 18.10.2003, p. 1.
[5] OJ L 268, 18.10.2003, p. 24.
[6] OJ C 343, 5.12.2001, p. 292.
[7] OJ C 25 E, 29.1.2004, p.384.
[8] OJ C 91 E, 15.4.2004, p.680.

– having regard to Rule 45 of the Rules of Procedure,

– having regard to the report of the Committee on Agriculture and Rural Development (A6-0000/2006),

A. whereas modern biotechnology is one of the leading new technologies that is likely to develop tremendously over the next few years and has huge economic, commercial, social and environmental implications in Europe and globally,

B. whereas the Lisbon Strategy, which aims to make Europe more dynamic and competitive, sets as targets an average economic growth of 3% and the creation of 20 million jobs by 2010 and modern biotechnology could serve as a major contributor to achieving European Union policy goals on growth, competitiveness and job creation,

C. whereas developments in biotechnology have the potential to yield many benefits for agriculture, such as increased yields, reduced use of herbicides and pesticides, less fossil fuel use and reduced soil erosion,

D. whereas the mid-term review shows that much progress has been made towards achieving the goals set in "Life Sciences and Biotechnology — A strategy for Europe" with respect to establishing regulatory principles and promoting a strong public life sciences research base and healthcare applications; whereas progress towards the specific goals established for the agricultural biotechnology applications is lagging behind these achievements,

E. whereas implementation of Community legislation is not consistent across all Member States and there is a clear need to develop a common approach, particularly with regard to coexistence between genetically modified crops and conventional and organic crops which provides the basis for choice for both farmers and consumers,

F. whereas GM products for use in agriculture necessarily have to pass very stringent assessments and the present authorisation process is slow and bureaucratic, contributing to the EU lagging behind its global competitors,

G. whereas modern biotechnology can help to respond to the challenges brought about by poverty, population growth and changing environmental conditions in the developing world,

H. whereas the EU strongly wants to increase the share of renewable energy in its energy consumption and bioenergy presents challenging opportunities,

I. whereas 90 million hectares of GM crops were grown worldwide in 2005 and this hectarage is very likely to be substantially increased in the following years,

General

1. Encourages efforts to develop biotechnology in the EU as one way of improving the economic viability and environmental sustainability of agriculture; considers that the use of biotechnology and genetic engineering should be developed in order to facilitate more sustainable farming practices, better food, increased yield and higher-quality and more

diverse products with less use of nitrates and other fertilisers and less use of water;

2. Considers it important to acknowledge that biotechnology presents real opportunities in various fields; believes that beyond the traditional agricultural products of food, feed and fibre, entirely novel products for agriculture will emerge, including pharmaceutical products such as oral vaccines, products with higher levels of essential amino acid or vitamins, improved fatty acid content and the removal of allergens and anti-nutrients;

3. Is convinced that biotechnology applications can help to reduce the use of pesticides, herbicides and fertilisers in crop cultivation, thus contributing to the protection of the environment and of human health;

4. Considers that the replacement of non-renewable raw materials with new products of fine chemicals and a large variety of degradable materials offers new opportunities;

5. Expects that, in the future, an increased variety of better and healthier food and feedstuffs could be produced also in less favoured areas, in restricted climate conditions, in dry or moist conditions and on harsh soil, and notes that biotechnology is key to these developments;

6. Supports the view that biotechnology can offer attractive alternatives to energy production in rural areas and that biomass, biogas and biofuels could replace increasingly scarce oil reserves for heating, electricity production and traffic fuels, thus increasing income in rural areas;

7. Calls on the Commission to establish a high level group of the Commission, Council and European Parliament and to plan a strategy on biotechnology for agriculture in the EU;

Legislative framework

8. Regrets the current complexity of the approval of new biotechnology products and doubts that practices based on the existing procedure are always justified only by objective scientific criteria and not rather by political positions; points out that other factors than protecting human health and the environment should be clearly identified and separated from other aspects in the approval process;

9. Stresses the decisive importance of protecting human health and the environment in the approval process and underlines the use of objective scientific criteria in this respect; points out that the precautionary principle cannot be used as an excuse to delay the process;

10. Notes the Commission's recent report on the implementation of national measures on the coexistence of genetically modified crops with conventional and organic farming and urges better harmonisation of rules and conditions within the EU; emphasises the importance of farmers having the right to choose between traditional, organic and GMO production and therefore the need for establishing clear, uniform and transparent coexistence measures that enable GM farmers to coexist with neighbours using different farming methods;

11. Asks for clarification of liability for damages incurred in the growing and use of biotechnological products: who is liable, what can be claimed and under what circumstances a claim can be made; in emphasising the importance of proportionality and fair play, considers that overly stringent rules can create real obstacles to the use of biotechnological inventions;

Research and development

12. Calls on the Commission and Member States to promote research and development in the biotechnology field by increasing funds for work and further enhancing public and private networking amongst European, national and regional biotechnology research units, clusters and companies; suspects that a lack of private-public partnership would create a real obstacle to European research;

13. Fears that the existing complex and extensive implementation of the Community legislation on biotechnological trials and the lengthy approval procedure for placing inventions on the market is are creating real obstacles to European research and may lead to research activities and human resources being moved outside the EU; fears also that these may be contributing to a strong concentration of research, inventions and immaterial rights among a few big global players, thus increasing their influence and power to the detriment of smaller companies and making countries and people more dependant on them;

14. Reaffirms its support for guidelines and legislation to be used to safeguard experiments needed for field trials when new products are developed;

Global developments

15. Considers that biotechnology can contribute towards finding genuine solutions to global challenges such as constantly increasing need for food, environmental problems, sustainable development and energy sufficiency, and can help developing countries to reduce poverty, thus helping to achieve the Millennium Development Goals;

16. Notes with concern the WTO's ruling of 29 September 2006 on the Community approval procedures for genetically modified crops; stresses that the Commission and Member States must respond and react accordingly;

Responding to public concerns

17. Observes the need to enhance and broaden public debate, access to objective information and the improvement of the level of scientific knowledge; considers that it is the responsibility of policy-makers, as well as industry, the scientific community and non-governmental organisations, to communicate to citizens in a clear and transparent manner the benefits and risks of biotechnology;

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18. Instructs its President to forward this resolution to the Council and Commission.

EXPLANATORY STATEMENT

Biotechnology

Biotechnology is a modern branch of science. It has developed dramatically in the recent fifty years, but its future seems to be even more attractive. In fact, many scientists speak about us facing a biotechnological revolution, compared to the revolution in electronics that we have experienced in recent decades. The existing inventions and applications seem to be only the very first steps of this development.

Current GM cropping

In 2005 commercial GM crop production was calculated to be about 90 million ha involving 8.5m growers in 21 countries. The US, Argentina, Brazil, Canada & China are the principal global growers of which the US represents 55% of total GM cropping area. In the EU, those Member States commercialising modest areas of GM maize comprise: Spain, Germany, Portugal, France and Czech Republic.

Over the last decade, farmers have increased their plantings of GM crops by 11% every year, with the number of countries cultivating GM crops increasing from 6 to 21 in the same period.

GM soybean continued to be the principal GM crop in 2005, occupying 54.4 million hectares (60% of global GM area), followed by maize (21.2 million hectares at 24%), cotton (9.8 million hectares at 11%) and rapeseed (4.6 million hectares at 5% of global GM crop area).

During the first decade, 1996 to 2005, herbicide tolerance has consistently been the dominant trait followed by insect resistance and stacked genes for the two traits. In 2005, herbicide tolerance, deployed in soybean, maize, rapeseed and cotton occupied 71% or 63.7 million hectares of the global GM 90.0 million hectares, with 16.2 million hectares (18%) planted to insect resistant crops and 10.1 million hectares (11%) to the stacked genes.

The accumulative reduction in pesticides for the period 1996 to 2004 was estimated at 172,500 MT of active ingredient, which is equivalent to a 14% reduction in the associated environmental impact of pesticide use on these crops.

GM crops were grown by approximately 8.5 million farmers in 21 countries in 2005, up from 8.25 million farmers in 17 countries in 2004. Notably, 90% of the farmers were resource-poor farmers from developing countries, many of whom received increased incomes from GM crops to alleviation of their poverty. In 2005, approximately 7.7 million (7.5 million in 2004) poor subsistence farmers utilized biotech crops – the majority in China with 6.4 million farmers, 1 million in India, thousands in South Africa, more than 50,000 in the Philippines, with the balance in the seven developing countries which grew biotech crops in 2005.

In 2005, the global market value of biotech crops is estimated to be $5.25 billion representing 18% of the ~$30 billion 2005 global commercial seed market. The $5.25 billion biotech crop market comprised of $2.42 billion for biotech soybean (equivalent to 46% of global biotech crop market), $1.91 billion for biotech maize (36%), $0.72 billion for biotech cotton (14%),

and $0.21 billion for biotech canola (4%). The accumulated global value for the ten-year period, since biotech crops were first commercialised in 1996, is estimated at $29.3 billion. The global value of the biotech crop market is projected at over $5.5 billion for 2006.

Future trends

It is likely that the increases in GM crop area seen during the first decade of commercialisation, 1996 to 2005, will continue and possibly be surpassed in the second decade 2006-2015. The number of countries adopting the four current major biotech crops is expected to grow. An increase in the global hectarage will be accompanied by an increase in the number of farmers planting biotech crops as the first generation of biotech crops is more widely adopted and the second generation of new applications becomes available.

Beyond the traditional agricultural products of food, feed and fibre, entirely novel products to agriculture will emerge including the production of pharmaceutical products, oral vaccines, specialty and fine chemicals and the use of renewable crop resources to replace non-renewable, polluting, and increasingly expensive fossil fuels.

Adherence to good farming practices with biotech crops will remain critical as it has been during the first decade and continued responsible stewardship must be practiced, particularly by the countries of the South, which will be the major deployers of biotech crops in the coming decade.

Regulatory framework

Regulations on the import, processing and consumption of GM products are well developed in most developed and many developing countries. All developed countries have regulatory systems in place and are conducting biosafety assessments. The basis for these regulations and the methods used for determining biosafety vary according to country, but all are based on a precautionary approach to food and feed safety and the Codex Alimentarus (produced by WHO) approach to evaluating food and feed safety and quality by evaluating substantial equivalence and a detaiIed analysis of differences.

Internationally

Many developing countries also have regulatory systems following models developed in US, Europe or elsewhere. International agencies such as OECD, UN (FAO, UNEP), WHO, WTO etc. are all involved in capacity building and attempting to harmonise regulations in order to allow free movement and trade in products once their food/feed safety has been established by the regulatory authorities of various countries. UNEP established a Biosafety Clearing House (an information exchange mechanism for GMOs) which provides a database of biosafety data and risk assessments of each GMO application (both experimental and commercialisation) in all countries involved in the scheme. The Cartagena protocol of the CBD was partly established in order to provide protection for countries from importation of GM foods/feeds and products for processing where relevant biosafety evaluations had not been conducted. It enables an importing country to declare, via the Biosafety Clearing House, that it wishes to take a decision based on risk assessment information before agreeing to accept an import.

In the European Union

In February 2001, the EP adopted Directive 2001/18/EC, which defined new GM crop rules which came into force in October 2002. It presents a substantially revised version of the previous Directives. Central in these regulations is that GM is considered something new and special for which existing legislation is not sufficient. The EU regulatory system is therefore process-based rather than product-based: the way something is made determines the regulatory framework.

The major philosophical shift in Directive 2001/18/EC compared to its predecessors is the explicit adoption of the precautionary approach as a guide, rather than or in addition to the concepts of familiarity and substantial equivalence. The EC realises that the precautionary approach may be difficult to apply. Therefore, it is stated that reliance on the precautionary approach is no excuse for detracting from the general principles of risk management such as proportionality, non discrimination, consistency, examination of the benefits and costs of action or lack of action and examination of scientific developments (CEC, 2000). This is being interpreted in different ways by member states and also different EC Directorate Generals.

A public registry of all approved products will allow consumers to trace GM products. Although the basic philosophy of the regulation is quite different, the data requirements for assessing safety of GM plants and plant products are similar to the USA. The information required in the EU tends to be more extensive, mainly with respect to molecular characterisation, impacts of the specific cultivation and management requirements of the GM crops, post market monitoring and traceability.

In addition to Directive 2001/18/EC, a range of other legislative documents deals with aspects of GM crop regulation in the EU. The placing on the market of GMOs intended for food or feed and of food or feed products containing, consisting of or produced from GMOs is governed by Regulation (EC) 1829/2003 on genetically modified food and feed. Where a food product contains or consists of GMOs, the applicant has a choice: either the application as a whole is subject solely to Regulation (EC) 1829/2003, in application of the principle of "one door, one key", in order to obtain authorisation for the deliberate release of a GMO into the environment - in accordance with the criteria laid down by Directive 2001/18/EC - and for the use of this GMO in food products - in accordance with the criteria laid down by Regulation (EC) 1829/2003; or the application - or part of it - is subject both to Directive 2001/18/EC and to Regulation (EC) 1829/2003.

In addition, GM crop cultivars must pass a variety registration procedure and be listed in the Community Common Catalogue, before they are allowed to be grown commercially. This is no different from the regulation for any new cultivar resulting from traditional breeding. In Regulation EC/1139/98, the presence of DNA or protein resulting from genetic modification is used as a criterion to trigger labelling of food or food ingredients derived from GM maize and soybean. These labelling provisions were amended by Regulation EC/49/2000 to provide a 0.9%-labelling threshold for “adventitious”, “accidental” or “technically unavoidable” presence of GM material in food (during cultivation, harvest, handling, transport or processing). In addition, Regulation EC/50/2000 defines specific labelling requirements for food and food ingredients containing additives, colourings and flavourings derived from GM material. Also, seed of GM crops must be labelled in accordance with Directive 98/95/EE**C.** This label has to show clearly that it is a GM cultivar.

The EC has presented legislation on traceability and labelling of GM organisms and products derived from GM organisms and for GM food and feed. These require traceability throughout the whole production chain at all stages of the market. It will provide consumers with information by labelling all GM food and feed. All foods in which GM organisms are contained, or have been produced from GM organisms, should be labelled.

In the United States

In the USA the regulation focuses primarily on the characteristics of the product, rather than the way in which the product is produced. This product-based assessment is a major difference with the philosophy of regulation in for example the European Union, which is process-based. This process-product difference of philosophy has sparked considerable controversy over recent years.

In the USA regulation of the environmental release is based on the concept of "familiarity". This concept can be considered the ecological counterpart of the concept of "substantial equivalence", although in some publications these two concepts are also considered separately for environmental release. Familiarity considers whether the GM plant is comparable to its traditionally bred counterpart in environmental safety. Such comparison may assess the relevant issues in a GM crop without direct experience. Familiarity considers the biology of the plant species, the trait introduced, and the agricultural practices and environment used for crop production.

USA has separate regulations governing releases of plants for pharmaceutical and bioremediation purposes but has no regulations concerning labelling and traceability of GM crops.

Farming of GM crops

The approval of GM crops is quite long-lasting and complex. But the practical farming also faces many rules and restrictions. They concern labelling, traceability, co-existence, liability and compensations. These rules have no counterparts if you grow conventionally bred crops.

Labelling and traceability have already been dealt with previously. Since the publication of the Commission Recommendations and guidelines for co-existence of genetically modified, conventional and organic farming in July 2003 all Member States are developing co-existence strategies under the subsidiarity principle.

Concerning co-existence there are great demands to create GM-free regions or member states in the EU. Until now the general position has been that these are not legal, if there is no scientific evidence, not according to the EU law or under international agreements. There are some cases in the Court of European Justice waiting for decision.

It might be worth mentioning that at the same time when several regions have announced their intention to be a GM- free region, imported GM – feed is used in animal husbandry.

There is also a diverse variety of applications of the co-existence in different member states. A single European model does not exist, which will probably cause disputes and difficulties in

the single markets. The Commission has left the issue as a matter of subsidiary to the hands of member states and tries to promote best practices in this matter. The results are not very promising.

A big issue is liability re co-existence. The main issue is who is liable, who can claim, what can be claimed and under what circumstances and whether there is a compensation fund or insurance to cover any claims. Only Spain has previously applied general law to liability, but now nearly all member states are approaching the issue on the bases of the way of breeding separating GM crops from conventionally bred crops. When conventionally bred crops are grown, general law is applied on liability and compensations, if damage has been causes. The somewhat unclear question of liability may provoke complaints that are expensive to investigate and in that way discourage some farmers from starting the cultivation of GM crops.

GMO and international agreements

In 29 September 2006 the WTO made public the dispute panel verdict on the European Union's six-year moratorium on imports of genetically modified food and crops.

Regarding the alleged moratorium on the approval of GMOs, the Panel found that the EC had applied a de facto moratorium between June 1999 and August 2003. As a legal matter, this moratorium was considered to be inconsistent with the EC's obligation under Annex C(1)(a) of the SPS (Sanitary and phytosanitary agreement on international standards for harmonised food safety standards), which requires parties to complete testing and approval procedures without undue delay.

Regarding the complaint that the EC had failed to consider specific GMOs for approval, the Panel ruled that the EC had acted inconsistently with its obligation under Annex C(1)(a) to undertake and complete such procedures without undue delay with respect to numerous GMOs. Under the U.S. complaint, the Panel found undue delay in the EC's consideration of 21 out of 25 specified GMOs. For Canada, the inconsistent treatment was found for all four GMOs identified.

Regarding the individual European country bans on GMO products (including Safeguard Measures), the Panel condemned the ban by six EU members (Austria, Belgium, France, Germany, Italy and Luxembourg) on a number of individual products. The Panel ruled that the bans were not based on risk assessments as required by Article 5.1 of the SPS Agreement, and were therefore inconsistent with the countries' WTO obligations. The conclusions reached in this aspect of the decision were the only ones in which the Panel found breaches of substantive, rather than merely procedural, provisions of the SPS Agreement. Significantly, the Panel found that the bans were not consistent with Article 5.7 of the SPS, which permits parties to adopt provisional measures (such as product bans) where there is insufficient scientific evidence to assess the risk of the product. The EC Scientific Committee on Plants and competent national authorities had carried out assessments of each of the products in question, and each was approved as safe. These assessments were deemed to be proper risk assessments as defined in the SPS Agreement. The studies relied upon by the individual countries for their bans were found not to constitute sufficient risk assessments and, because acceptable risk assessments were available, Article 5.7 could not be relied upon.

This in turn led the Panel to conclude that these country bans were also inconsistent with Articles 2.2 and 2.3 of the SPS, which prohibit a party from maintaining a restrictive measure without sufficient scientific evidence to justify it (Article 2.2), and from applying such measures in a way to constitute a disguised restriction on international trade (Article 2.3). The Panel recommended that the individual countries bring their safeguard measures into compliance, and remove the bans on the specified GMO products.

While the WTO Panel did not pronounce on the validity of the EC's regulatory system for GMOs, it did rule that bans on GMO products that are not based on risk assessments, as defined in the SPS, are inconsistent with WTO rules. On the other hand, the Panel confirmed the right of individual countries to impose bans if risk assessments support such measures. Regarding the moratorium on approvals of GMO products, the Panel did find that the 1999-2003 moratorium was inconsistent with the SPS Agreement, as it had the effect of unduly delaying the results of the approvals process. The Panel did not suggest that future moratoria would necessarily also be inconsistent. If additional scientific evidence were brought to light that would justify restrictions, the EC would be permitted to impose them, provided decisions were made without undue delay.

In its ruling, the Panel interpreted the obligations of the SPS agreement without reference to any precautionary approach and reaffirmed that restrictive measures said to be based on health or environmental concerns have to be justified by science, and not on concerns or desires to be cautious.