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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 Treaty establishing the European Community,
- having regard to the Commission Communication on Life Sciences and Biotechnology – a Strategy for Europe¹,
- having regard to Council Decision No 2004/869/EC of 24 February 2004 concerning the conclusion, on behalf of the European Community, of the International Treaty on Plant Genetic Resources for Food and Agriculture²
- the International Treaty on Plant Genetic Resources for Food and Agriculture,
- having regard to Council Directive 98/95/EC of 14 December 1998, amending Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/457/EEC and 70/458/EEC, which introduced a legal basis enabling genetic variability,
- having regard to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity of 29 January 2000³, 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/EEC⁴,
- 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 feed⁵ 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/EC⁶,
- having regard to the Communication from the Commission to the Council and the

¹ OJ C 55, 2.3.2002, p. 3.

² OJ L 378, 23.12.2004, p. 1.

³ OJ L 201, 31.7.2002, p. 50.

⁴ 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).

⁵ OJ L 268, 18.10.2003, p. 1.

⁶ OJ L 268, 18.10.2003, p. 24.

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 Industry¹,
- having regard to its resolution of 21 November 2002 on the Commission Communication on Life Sciences and Biotechnology – a Strategy for Europe²,
- having regard to its resolution of 18 December 2003 on coexistence between genetically modified crops and conventional and organic crops³,
- having regard to the conclusions and recommendations of the Austrian Presidency Conference on the co-existence of genetically modified, conventional and organic crops held in Vienna on 4-6 April 2006, and the subsequent recommendations from the Agriculture Council in May 2006 that the Commission must develop a proposal establishing labelling thresholds for the adventitious presence of approved GM seeds in non-GM seeds,
- having regard to Rule 45 of the Rules of Procedure,
- having regard to the report of the Committee on Agriculture and Rural Development and the opinions of the Committee on International Trade and the Committee on Industry, Research and Energy (A6-0032/2007),

A. whereas (the biotechnology sector includes several fields of research concerning agriculture, the environment and food; whereas biotechnology also concern many fields other than GMOs, including those concerning the use of biomass (from agriculture, forestry and organic waste), biomolecules and microbial genomes which should in the coming years develop as part of a global approach to sustainable development, with economic, social, environmental and health implications in Europe and globally,

B. whereas the Lisbon and Gothenburg Strategies both aim to steer Europe towards sustainable development based on dynamic growth that ensures more jobs, increased social cohesion and greater respect for the environment by 2010 and a modern agricultural sector with market-oriented production could serve as a major contributor to achieving this; innovation, research and development activities in various sectors of biotechnology could contribute towards that sustainable development objective,

C. whereas no mechanism has been set up to detect and protect against unauthorised

¹ OJ C 343, 5.12.2001, p. 292.

² OJ C 25 E, 29.1.2004, p.384.

³ OJ C 91 E, 15.4.2004, p.680.

transgenics, and the food chain may be contaminated with such unauthorised transgenics which have not yet been detected because the analytical methods necessary to detect them are not yet available,

- D. whereas the development and use of agricultural biotechnology offers an opportunity to develop both economically and environmentally sustainable farming and food production,
- E. whereas developments in biotechnologies, provided these meet a need in the general interest, have the potential to yield many benefits for agriculture, such as increased yields, better product quality, reduced use of chemical fertilisers, herbicides, pesticides and fossil fuels and reduced soil erosion and pollution,
- F. whereas advances made in biotechnology have the potential to create new openings for agriculture and silviculture and, more broadly, to contribute to a better use of all biomass from renewable sources; and whereas these innovations concern the fields of green chemistry, food and health,
- G. whereas there is a growing demand for healthier, safer and higher-quality food, at the same time taking account of animal welfare and rural conservation,
- H. whereas the mid-term review shows that progress has been made towards achieving the goals set out 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 and so far is not very tangible,
- I. whereas Community legislation is interpreted differently by Member States and its implementation is therefore not consistent across all Member States; whereas there is a clear need to develop a common approach, particularly with regard to the coexistence of genetically modified crops and conventional and organic crops which provides the basis for choice for both farmers and consumers,
- J. whereas modern biotechnology could help to respond to the challenges brought about by poverty, population growth and changing environmental conditions in the developing world,
- K. whereas the use of new technologies, for example in new crops for medicinal or other non-food purposes, offers new production opportunities, particularly in sectors where conventional production has ceased to be economically profitable,
- L. 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,
- M. whereas bioenergy offers the possibility of increasing the share of renewable energy in overall EU energy consumption, which

is a strategic goal of the Union, and some energy crops can present challenging opportunities,

- N. whereas the success of the production of second-generation biomass-based biofuels is conditional on support for biotechnological research into processing,
- O. whereas 90 million hectares of GM crops were grown worldwide in 2005 and this hectareage is very likely to be substantially increased in the following years, while the area under GM cultivation in the EU is comparatively low, in the region of 65 thousand hectares,P. whereas there must be no discrimination against GMOs by comparison with conventional crops,
- Q. whereas farmers in the EU have the right to benefit from advances in modern biotechnology in exactly the same way as farmers in third states,

General

1. Understands that biotechnology has different meanings for different people; it encompasses a collection of scientific techniques that are used to create or modify plants, animals and organisms, which can range from brewing to modern day transgenic plants; for the purpose of this resolution, the term biotechnology is used to mean the application of scientific technology to living organisms as well as parts, products and models thereof, in order to alter living or non-living materials to obtain knowledge, goods and services; it is a body of methods and techniques that employ as tools the living cells of organisms or part or products of those cells (such as genes and enzymes); biotechnology includes modern biotechnology techniques such as genetic engineering technology, but does not exclusively relate to transgenic technology, which is used to create GMOs;
2. Encourages efforts to develop biotechnologies in the EU as one way of making agriculture viable and liveable, and takes the view that these biotechnologies facilitate the development of sustainable methods of production, increased yield, higher quality and more diverse products with less use of nitrates and other fertilisers and rational use of water ; underlines the need for conventional and organic agriculture to remain successful on its markets; points out that the use of new methods in agriculture must be geared first and foremost to market demand if this is to secure the sustained viability of agricultural holdings;3. Stresses therefore that more agricultural funds must be allocated from the CAP to the biotechnology sector, including funds for the education of farmers about the possibilities of biotechnology within the framework of sustainable agriculture;
4. Considers it important to acknowledge that biotechnology could present real opportunities in various fields; believes that beyond the traditional agricultural products of food, feed and fibre, entirely novel products will emerge, including pharmaceutical products such as oral vaccines, products with higher levels of essential amino acids or vitamins or with improved fatty acid content, and that the removal of allergens and anti-

nutrients from products will also become possible;

5. Believes that biotechnology applications may help to reduce the use of pesticides, herbicides and fertilisers in crop cultivation, thus contributing to the protection of the environment and human health;
6. Notes that the EU is a major importer of GM soya in particular; and that Member States which do not grow GM crops use imported GM feed ingredients;
7. Considers that the replacement of non-renewable raw materials with new products consisting of fine chemicals and a large variety of degradable materials offers new opportunities for farmers and helps the European agricultural sector to comply with WTO obligations; believes that research and development can find ways to improve wood and fibre structures and create new possibilities for renewable products, replacing non-renewable raw materials; is of the opinion that the impact of biotechnology on the economics of production of and trade in agricultural products must be assessed in a broad manner, including the possible effects on non-biotech agri-food production and on the economics of current and future non-food production such as biomass and biofuels, biodegradable packaging, medicinal products, etc.;8. Appeals to the Member States to guarantee the right of all people producing conventional crops not to have those crops contaminated by GMOs and to guarantee the right of all consumers to choose between food products produced without GMO technology and those produced with GMO technology;
9. Emphasises the need to work to ensure that, in the near future, an increased variety of better and healthier food and feedstuffs could also be produced in less favoured areas, such as in restricted climate conditions, in dry or moist conditions and on harsh soil, and notes that the correct use of biotechnology could be one of the keys to these developments;
10. Supports the view that biotechnologies may offer attractive alternative methods of energy production in rural areas and that biomass, biogas and biofuels can help in the diversification of the energy required for heating, electricity production and transport, thus increasing income in rural areas; emphasises that these possibilities should be considered in the light of the overriding considerations of food safety and supply, protection of health and the environment and management of the countryside;
11. Calls on the Commission to establish a high-level group composed of representatives of the Commission, Council and Parliament with transparent membership and work programmes to which all stakeholders (such as scientists, industry representatives, farmers, consumers and environmentalists) would be invited to contribute in an equal manner to plan a strategy on biotechnology and agriculture in the EU that takes into account the environmental and socio-economic diversity of the States and regions of the EU; calls for the work and composition of the group regularly to be made public;
12. . . Is aware of the existing as well as the potential impact of biotechnology on the competitiveness of plant breeding, farming and food production, in particular in view of

the very different rates of uptake of the technology in Europe, in comparison with its main competitors on the international agricultural markets, and calls on the Commission to pay specific attention to this impact in its forthcoming studies, to inform the European Parliament in detail on this matter and to put forward specific legislative proposals if and where required;

Legislative framework

13. Supports the current precautionary approach to the approval of new biotechnology products and accepts that practices based on the existing procedure cannot always be justified by objective scientific criteria, and points out that socio-economic factors, as well as the protection of human health and the environment, should be taken into account as part of the approval process;
14. 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;
15. Calls on the Commission to put forward a proposal establishing workable and proportionate labelling thresholds for the adventitious presence of EU-approved GM seeds in non-GM seeds;
16. 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 to establish clear, uniform and transparent coexistence measures that enable farmers to coexist with neighbours using different farming methods;
17. Calls for all holdings whose 'GM-free' quality label has given them a higher-priced market to be safeguarded by adequate and clearly defined coexistence measures against contamination from GMOs and for the market position they have won, and hence their economic stability, not to be jeopardised;
18. Stresses that there is a need for common labelling rules and better consumer information in accordance with WTO rules;
19. Calls on the Commission, within the framework already established in Commission Recommendation 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming¹, to provide more detailed guidelines, on a crop-by-crop basis, of the coexistence measures which Member States may take without going

¹ OJ L 189, 29.7.2003, p. 36.

beyond what is proportionate;

20. Asks for clarification concerning 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;

Research and development

21. Calls on the Commission and Member States to promote research and development in the field of biotechnology, other crop methods and agricultural product quality by increasing funds for work and further enhancing cooperation and coordination between public sector research and companies at European, national and regional level;
22. Calls on the Commission and Member States to support research on biotechnology applications offering clear social or environmental benefits, including the development of GM micro-organisms for water purification, land regeneration, the replacement of hazardous chemical substances currently in use and the development of sustainable and environmentally favourable energy sources (including biogas, hydrogen and second-generation biofuels);
23. Emphasises the need for research and comparative studies, not least as regards food safety, allergens and human nutrition and health, which must be conducted systematically; also emphasises that more comparative studies and research are also needed into the complex issues of sustainable farming practices, food security, allergenicity, nutrition and public health;
24. Stresses that the existence of publicly funded research must be guaranteed and R&D activity in small biotechnology undertakings and plant-technology centres must be supported in order to maintain maximum competitiveness at the various levels of the food production chain;
25. 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 are creating real obstacles to European research and may lead to research activities and human resources being moved outside the EU;
26. Also suspects that these may be contributing to a strong concentration of research, inventions and immaterial rights among a few large global players, thus increasing their influence and power to the detriment of smaller companies and making countries and people more dependent on them;
27. Fears that the complex and comprehensive arrangements for recognising agricultural crop varieties and the rules on marketing them currently constitute genuine obstacles to seed research and varietal conservation within small-scale farming and could lead to impoverished varietal diversity in Europe; fears also that this may help to considerably concentrate intellectual property rights among a small number of concerns and hence increase their influence and power over food safety and the dependence of countries and populations on those concerns; calls therefore for the immediate establishment of the

legal basis, called for in Directive 98/95/EC, which would make it possible, under seed marketing legislation, to preserve varieties at threat from genetic erosion, through in situ and on-farm use;

28. Calls on the Commission and Member States to conduct, under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities(2007-2013), a sweeping socio-economic study at European level that includes a comparison of different methods of agricultural production;
29. Calls for intellectual property to be protected in the field of agricultural and food biotechnology in order to stimulate private investment in this area;
30. Considers that GMO research should be in line with Parliament's legislative resolution concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013), which stresses that research will aim to integrate the diversity of scientific knowledge in order to develop balanced, sustainable and socially acceptable solutions and approaches;
31. Welcomes new developments including the recent development of the Rapid Trait Development System (RTDS) – which uses the plant's own genetic machinery to change its DNA, through a process known as site-directed mutagenesis;
32. Reaffirms its support for guidelines and legislation to be used to safeguard experiments needed for field trials when new products are developed and points to the legal obligations regarding the transparency of those trials and public access to information;^{33.}
Stresses that the legislation and guidelines referred to in carrying out experiments must seriously take into account the protection of consumers and the environment;
34. Underscores the fact that, also in the case of GMOs, liability rules based on the originator principle must be applied;

Global developments

35. Considers that biotechnology may have a role to play in finding genuine solutions to global challenges such as a constantly increasing need for food, environmental problems, sustainable development and energy sufficiency, which are urgently needed; emphasizes the importance of biotechnology for the future of sustainable agriculture, for example in developing bio-energy, substitutes for oil products such as plastics and new sustainable methods for growing crops; considers that this should include helping developing countries in need to achieve the implementation of the Millennium Development Goals;
36. Notes the WTO's ruling of 29 September 2006 on the Community approval procedures for GMOs, which did not find in favour of any one single party, and notes that unapproved GMOs have been detected in commodity imports into the EU and emphasizes that the EU approach to the regulation of GMOs is justified;

Responding to public concerns

37. Observes the need to enhance and broaden public debate and improve the level of scientific knowledge; points out that the vast majority of the European public are not in favour of GMOs, while not being opposed to biotechnology in principle; considers that it is the responsibility of policy-makers, as well as industry, the scientific community and non-governmental organisations to communicate with citizens in a clear and transparent manner on the benefits and risks of biotechnologies; regrets that to date the debate about GM foods has been unduly polarised;³⁸. Notes that over 50% of citizens believe that biotechnology will improve their quality of life (Eurobarometer survey 2005) but that the public is still mostly sceptical about agricultural (green) biotechnology, and will continue to be so unless new crops and products are seen to have consumer benefits;
39. Emphasises the need to conduct balanced and transparent discussions and assessments involving all the parties concerned, including the European public;

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40. 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 hectareage 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 Alimentarius (produced by WHO) approach to evaluating food and feed safety and quality by evaluating substantial equivalence and a detailed 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/EEC. 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 caused. 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.

24.1.2007

MINORITY OPINION

pursuant to Rule 48(3) of the Rules of Procedure
Diamanto Manolakou and Ilda Figueiredo
on behalf of GUE/NGL

Whereas according to a recent Eurobarometer study 70% of the population in the EU rejects the consumption of GM food and that many regions and entire member states are declaring themselves "GM free",

Whereas different studies, show that coexistence between transgenic and conventional/organic crops is impossible, considers that genetic engineering is a defective and uncontrollable technology incompatible with agricultural sustainability,

Considers that intellectual property rights (e.g. patented seeds) concentrate in a few multinational corporations' increases their power and control over food sovereignty, food safety and farmers, leading to impoverished varietal diversity in Europe, reduce biodiversity, as well the concentration and intensification of production and abandonment of rural areas.

Stresses the need to apply the precautionary principle and considers that information on the risks from GMOs have been supplied essentially by the GMO industry. More comparative studies and research are needed.

Urges the Member States to take the necessary measures to ban the use of GMOs on agriculture/food and provide incentives for the declaration of GMO-free zones, preserving their traditional products and conventional/organic farming, to guarantee the right of all people producing conventional crops not to be contaminated by GMOs and to guarantee the right of all consumers to food products without GMOs.

15.9.2006

OPINION OF THE COMMITTEE ON INTERNATIONAL TRADE

for the Committee on Agriculture and Rural Development

on Biotechnology: prospects and challenges for agriculture in Europe
(2006/2059(INI))

Draftsman: Enrique Barón Crespo

SUGGESTIONS

The Committee on International Trade calls on the Committee on Agriculture and Rural Development, as the committee responsible, to incorporate the following suggestions in its motion for a resolution:

1. considers that genetically modified organisms may represent a key element in the multi-functional European agriculture;
2. notes that the global market for genetically modified organisms continues to grow and considers that this ought to be an important growth sector for Europe;
3. considers that, in the long run, the international competitiveness of European agriculture depends to a significant extent on the development of the biotechnology industry and the spillover of its achievement into the economy;
4. believes that genetically modified organisms can help resolve several of the major challenges and problems of our times, e.g. food and energy supplies; the trade in such products is therefore an important instrument for ensuring that countries and people throughout the world can benefit from their potential; this applies not least to poor countries for which genetically modified crops can be an important instrument of development;
5. regrets that as a consequence of the restrictive policy and regulatory approach applied by the Commission and some Member States, the European biotechnology sector is at risk of lagging behind;
6. emphasises that the Commission and the Member States should not adopt or apply less

strict rules concerning imported biotechnology products than those applied to similar goods produced in the EU;

7. acknowledges the rapid and growing uptake of biotechnology in general, and GM crops in particular, in farming throughout the world and specifically in countries which are important trading partners of the EU in agricultural products; notes that in 2005, some nine million farmers in Brazil, India, China, South Africa, Canada, the United States and in a growing number of developed and developing countries cultivated almost 90 million hectares of genetically modified products which is the equivalent of the land area cultivated in the EU;
8. is convinced that, on the basis of existing legislation covering approvals for and uses of biotechnology in agriculture in Europe and third countries, enhanced exchanges of information and cooperation will be required in future to safeguard unhampered trade without prejudice to environmental and public safety;
9. acknowledges that the Cartagena Protocol on Biosafety to the United Nations Convention on Biological Diversity, which is based on the precautionary principle, constitutes an important forum for addressing the implications of cross-border movement of GMOs; which are only one application of biotechnology; nevertheless, does not believe that the precautionary principle can be used to block all scientific innovation including in the area of genetic engineering; and considers that the rules governing trade in genetically modified organisms must be laid down within the framework of the WTO; moreover, the rules that are laid down there should be complied with by WTO member countries; considers also that a better balance will need to be found between the WTO system and MEAs;
10. calls on the Commission and the Member States to keep Community and national legislation in line with WTO rules and obligations;
11. stresses that biotechnology, and, in particular GMOs, have had a growing importance in international trade disputes; in the light of the practice of the WTO Dispute Settlement Body, these disputes are solely judged by their conformity with the relevant WTO rules which, as far as trade is concerned, prevail over any other instrument of international law;
12. takes note of the WTO's preliminary ruling on the EU's approval process for GMOs;
13. considers it important that the Commission and the Member States address the final WTO ruling and its findings in an appropriate manner;
14. considers that in view of the interim report of the WTO Panel and the Commission's recent report on the implementation of national measures on the coexistence of genetically modified crops with conventional and organic farming, a total ban on GMO crops is not a viable option; considers that commonly agreed approval processes and/or mutual recognition systems may facilitate the international exchange of goods derived from biotechnology, provided such systems safeguard the necessary high level of environmental and consumer protection and do not prejudice specific requirements as to labelling or traceability as provided for by Community legislation;

15. believes that in the EU coexistence must be organised between conventional agriculture, organic farming and agriculture using genetically modified organisms; considers that clear and transparent coexistence rules, based on solid scientific evidence, are needed; stresses that, in order to avoid further WTO dispute settlement procedures against the Community, coexistence rules must not result in a de facto moratorium in relation to GMO crops;
16. stresses that there is a need for common labelling rules and better consumer information in conformity with WTO rules;
17. considers that by promoting the use of agricultural products for non-food purposes (such as raw materials in pharmaceutical and other industries), biotechnology offers additional outlets for farmers, and helps the European agricultural sector to comply with WTO obligations;
18. regrets the fact that Europe has fallen behind in the development of GM crops; calls therefore for higher priority to be given to support for adequate research and democratic control of genetic resources; and asks Member States to transpose rapidly all the European directives in this area;
19. believes that the use of genetically engineered seeds has made it possible in many parts of the world to reduce the use of pesticides and herbicides, which is in the interests of protecting the environment and biodiversity; therefore, encourages the Commission to play an active role in, and where required initiate, international discussions for dealing with the practical use of biotechnology in farming and food production, including actions against biopiracy in the developing countries;
20. welcomes the EU's commitment to an ambitious European research policy in the area of plant seeds and, more generally, agricultural biotechnology, the outcome of which will play a fundamental part not only in cutting agricultural pollution but also in meeting the world's constantly growing food requirements; and considers this commitment to be a precondition for achieving its goal to become the world's leading bio-economy in this particular area of application;
21. is of the opinion that the impact of biotechnology on the economics of production of and trade in agricultural products must be assessed in a broad manner, including the possible effects on non-biotech agri-food production, the possible impact of biotechnology on the economics of current and future non-food production such as biomass and biofuels, bio-degradable packaging, medicinal products, etc.; supports an ambitious European research policy in the area of biofuels and, more generally, biomass use, which is of key importance in the present energy context, allowing the EU to boost its exports and limit its imports in order to improve the EU's trade balance;
22. is aware of the existing as well as the potential impact of biotechnology on the competitiveness of plant breeding, farming and food production, in particular in view of the very different rates of uptake of the technology in Europe, in comparison with its main competitors on the international agricultural markets, and calls on the Commission to pay specific attention to this impact in its forthcoming related studies, to inform the European Parliament extensively about it and to put forward specific legislative proposals

if and where required;

23. is convinced that Marker Assisted Selection (MAS), which allows the improvement of crops through "smart breeding", i.e. the crossing of plants of similar families rather than their genetic modification through the integration of foreign genes, must provide a major contribution to the development of energy-intensive and at the same time environmentally safe biomass;
24. asks the Commission to contemplate an evaluation system which would ascertain on scientific bases the advantages and risks associated with the use of biotechnologies both for human and animal health and the impact of their use on the environment;
25. backs the right of consumers to be informed and to choose between conventional products and transgenic products;
26. emphasises the importance of biotechnology for the future of sustainable agriculture, for example in developing bioenergy, substitutes for oil products such as plastics and new sustainable methods for growing crops; stresses therefore that more agricultural funds must be allocated out of the CAP to the biotechnology sector, including funds for the education of farmers about the possibilities of biotechnology within the framework of sustainable agriculture.

PROCEDURE

Title	Biotechnology: prospects and challenges for agriculture in Europe
Procedure number	2006/2059(INI)
Committee responsible	AGRI
Opinion by Date announced in plenary	INTA 16.3.2006
Enhanced cooperation – date announced in plenary	NO
Drafts(wo)man Date appointed	Enrique Barón Crespo 12.09.2006
Previous drafts(wo)man	Jonas Sjöstedt 22.2.2006
Discussed in committee	3.5.2006 11.7.2006
Date adopted	12.9.2006
Result of final vote	+: 20 -: 4 0: 0
Members present for the final vote	Jean-Pierre Audy, Daniel Caspary, Giulietto Chiesa, Christofer Fjellner, Béla Glattfelder, Jacky Henin, Alain Lipietz, Caroline Lucas, Erika Mann, Georgios Papastamkos, Godelieve Quisthoudt-Rowohl, Tokia Saïfi, Peter Št'astný, Johan Van Hecke, Daniel Varela Suanzes-Carpegna, Zbigniew Zaleski
Substitute(s) present for the final vote	Margrietus van den Berg, Jorgo Chatzimarkakis, Robert Goebbels, Maria Martens, Antolín Sánchez Presedo, Jonas Sjöstedt, Mauro Zani
Substitute(s) under Rule 178(2) present for the final vote	Filip Kaczmarek
Comments (available in one language only)	

14.9.2006

OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

for the Committee on Agriculture and Rural Development

on Biotechnology: prospects and challenges for agriculture in Europe
2006/2059(INI)

Draftswoman: María del Pilar Ayuso González

SUGGESTIONS

The Committee on Industry, Research and Energy calls on the Committee on Agriculture and Rural Development, as the committee responsible, to incorporate the following suggestions in its motion for a resolution:

1. Welcomes the fact that the Seventh Framework Programme for Research includes the application of agricultural biotechnology for non-food purposes;
2. Takes the view that biotechnology is opening up new opportunities, particularly in regions where the production of agri-foodstuffs is not proving economically viable;
3. Considers that research financed from public funds must be provided in particular to support the R & D activity of small biotechnology businesses;
4. Gives its backing to research projects designed to improve the economic viability of agriculture and non-food agricultural products (including biofuels), the sustainable production of foodstuffs and disease prevention;
5. Calls on the Commission to look into the economic, social and environmental implications of applied biotechnology, so that biotechnological production practices and products can be evaluated at every stage, from initial research to end use;
6. Urges the Member States to ban technologies that involve a threat to health and the environment, including the use of genes resistant to antibiotics for human use that may be propagated in the environment;
7. Strongly supports reducing the use of pesticides, herbicides and fertilisers through the application of biotechnology, with special reference to avoiding the propagation of diseases due to resistance to herbicides;

8. Calls for transgenic foodstuffs to undergo compulsory testing before marketing, to establish that they are harmless before they are marketed;
9. Considers that biotechnology offers excellent opportunities for making better use of organic waste material and energy resources; expresses interest in research to look into new vegetable varieties that are adapted to adverse conditions such as drought or extreme temperatures;
10. Calls on the Commission to carry out an assessment of the present situation of the European biotechnology industry for discussion on its future.

PROCEDURE

Title	Biotechnology: prospects and challenges for agriculture in Europe		
Procedure number	2006/2059(INI)		
Committee responsible	AGRI		
Opinion by Date announced in plenary	ITRE 16.3.2006		
Enhanced cooperation – date announced in plenary			
Drafts(wo)man Date appointed	María del Pilar Ayuso González 20.3.2006		
Previous drafts(wo)man			
Discussed in committee	3.5.2006	20.6.2006	12.9.2006
Date adopted	12.9.2006		
Result of final vote	+: 38	-: 3	0: 1
Members present for the final vote	John Attard-Montalto, Šarūnas Birutis, Jan Březina, Philippe Busquin, Jerzy Buzek, Pilar del Castillo Vera, Giles Chichester, Den Dover, Lena Ek, Nicole Fontaine, Adam Gierek, Norbert Glante, Umberto Guidoni, András Gyürk, Fiona Hall, David Hammerstein Mintz, Rebecca Harms, Erna Hennicot-Schoepges, Ján Hudacký, Romana Jordan Cizelj, Anne Laperrouze, Eluned Morgan, Reino Paasilinna, Aldo Patriciello, Miloslav Ransdorf, Vladimír Remek, Herbert Reul, Mechtild Rothe, Paul Rübig, Andres Tarand, Britta Thomsen, Patrizia Toia, Catherine Trautmann, Claude Turmes, Dominique Vlasto		
Substitute(s) present for the final vote	María del Pilar Ayuso González, Daniel Caspary, Neena Gill, Cristina Gutiérrez-Cortines, Edit Herczog, Lambert van Nistelrooij, Vittorio Prodi		
Substitute(s) under Rule 178(2) present for the final vote			
Comments (available in one language only)			

PROCEDURE

Title	Biotechnology: Prospects and challenges for Agriculture in Europe				
Procedure number	2006/2059(INI)				
Committee responsible Date authorisation announced in plenary	AGRI 16.3.2006				
Committee(s) asked for opinion(s) Date announced in plenary	INTA 16.3.2006	ITRE 16.3.2006	ENVI 16.3.2006		
Not delivering opinion(s) Date of decision	ENVI 25.4.2006				
Enhanced cooperation Date announced in plenary	-				
Rapporteur(s) Date appointed	Kyösti Virrankoski 26.1.2006				
Previous rapporteur(s)	-				
Discussed in committee	30.5.2006	11.9.2006	21.11.2006	18.12.2006	24.1.2007
Date adopted	24.1.2007				
Result of final vote	+ 22 - 15 0 6				
Members present for the final vote	Peter Baco, Katerina Batzeli, Thijs Berman, Niels Busk, Luis Manuel Capoulas Santos, Giuseppe Castiglione, Dumitru Gheorghe Mircea Coșea, Joseph Daul, Albert Deß, Carmen Fraga Estévez, Duarte Freitas, Lutz Goepel, Bogdan Golik, Friedrich-Wilhelm Graefe zu Baringdorf, Elisabeth Jeggle, Heinz Kindermann, Albert Jan Maat, Diamanto Manolakou, Mairead McGuinness, Rosa Miguélez Ramos, Neil Parish, Radu Podgorean, María Isabel Salinas García, Agnes Schierhuber, Willem Schuth, Czesław Adam Siekierski, Brian Simpson, Csaba Sándor Tabajdi, Marc Tarabella, Witold Tomczak, Kyösti Virrankoski, Janusz Wojciechowski, Andrzej Tomasz Zapałowski				
Substitute(s) present for the final vote	Pilar Ayuso, Bernadette Bourzai, Gábor Harangozó, Hynek Fajmon, Ilda Figueiredo, Zdzisław Zbigniew Podkański, Struan Stevenson, Armando Veneto				
Substitute(s) under Rule 178(2) present for the final vote	Jorgo Chatzimarkakis, Wiesław Stefan Kuc				
Date tabled	8.2.2006				
Comments (available in one language only)					