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REPORT

on the Future of the Biotechnology Industry
(2000/2100(INI))

Committee on Industry, External Trade, Research and Energy

Rapporteur: John Purvis

CONTENTS

Page

PROCEDURAL PAGE

At the sitting of 19 May 2000 the President of Parliament announced that the Committee on Industry, External Trade, Research and Energy had been authorised to draw up an own-initiative report, pursuant to Rule 163 of the Rules of Procedure, on the Future of the Biotechnology Industry and that the Committee on Legal Affairs and the Internal Market and the Committee on the Environment, Public Health and Consumer Policy had been asked for their opinions.

At the sitting of 21 September 2000 the President of Parliament announced that she had also referred the matter to the Committee on Agriculture and Rural Development for its opinion.

The Committee on Industry, External Trade, Research and Energy had appointed John Purvis rapporteur at its meeting of 19 April 2000.

It considered its draft report at its meetings of 14 September 2000, 25 January, 26 and 27 February 2001.

At the last meeting it adopted the motion for a resolution by 28 votes to 3, with 0 abstentions.

The following were present for the vote: Carlos Westendorp y Cabeza, chairman; Renato Brunetta, vice-chairman; John Purvis, rapporteur; Gordon J. Adam (for Glyn Ford), Guido Bodrato, Massimo Carraro, Giles Bryan Chichester, Gérard M.J. Deprez (for Christos Folias pursuant to Rule 153(2)), Concepció Ferrer, Norbert Glante, Lisbeth Grönfeldt Bergman (for Anders Wijkman), Cristina Gutiérrez Cortines (for Christian Foldberg Rovsing), Malcolm Harbour (for W.G. van Velzen), Roger Helmer, Helmut Kuhne (for Hans Karlsson), Werner Langen, Peter Liese (for Peter Michael Mombaur), Rolf Linkohr, Eryl Margaret McNally, Erika Mann, Angelika Niebler, Giuseppe Nisticò (for Jaime Valdivielso de Cué), Reino Paasilinna, Samuli Pohjamo (for Astrid Thors), Godelieve Quisthoudt-Rowohl, Imelda Mary Read, Paul Rübig, Ilka Schröder, Konrad K. Schwaiger, Elena Valenciano Martínez-Orozco and Alejo Vidal-Quadras Roca.

The opinions of the Committee on the Environment, Public Health and Consumer Policy and the Committee on Agriculture and Rural Development are attached; the Committee on Legal Affairs and the Internal Market decided on 21 June 2000 not to deliver an opinion.

The report was tabled on 28 February 2001.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

MOTION FOR A RESOLUTION

European Parliament resolution on the Future of the Biotechnology Industry (2000/2100(INI))

The European Parliament,

– having regard to the Presidency Conclusions of the Lisbon European Council of 23-24 March 2000[1],

– having regard to its resolution of 18 May 2000 on the communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions "Towards a European research area"[2],

– having regard to its resolution of 12 April 2000 on the Council common position for adopting a European Parliament and Council directive on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC[3],

– having regard to European Parliament and Council Decision No 182/1999/EC of 22 December 1998 on the fifth framework programme of the European Community for research, technological development and demonstration activities (1998 to 2002)[4],

– having regard to the Communication of the Commission on 'Making a reality of the European Research Area: Guidelines for EU research activities (2002-2006)' [COM(2000) 612][5],

– having regard to Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions[6],

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

– having regard to the European Charter of Fundamental Rights proclaimed by the European Council in December 2000,

– having regard to the European Convention on Human Rights and Biomedicine of the Council of Europe, signed on 4 April 1997,

– having regard to the document of the OECD entitled "Intellectual Property Practices in the Field of Biotechnology" of 1 February 1999[7],

– having regard to Rule 163 of its Rules of Procedure,

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[1] Council Press Release, Lisbon, 24.3.2000.
[2] OJ C59, 23.2.2001, p. 250.
[3] OJ C40, 7.2.2001, p. 123.
[4] OJ L213, 30.7.1998, p.13.
[5] Not yet published in OJ/OJ C.
[6] OJ L26, 1.2.1999, p.1.
[7] OECD, TD/TC/WP(98)15/FINAL.

– having regard to the report of the Committee on Industry, External Trade, Research and Energy and the opinions of the Committee on the Environment, Public Health and Consumer Policy and the Committee on Agriculture and Rural Development (A5-0080/2001),

Objectives

A. whereas the Lisbon European Council set the European Union the new strategic goal of becoming the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion,

B. whereas developments in biotechnology promise benefits for healthcare, agriculture, the protection and restoration of our environment, and in helping to combat the problems brought about by population growth and changing environmental conditions in the developing world,

C. whereas biotechnology has the ability to increase our understanding of living organisms and natural processes and of opening the possibility of designing more sustainable solutions to food production, the treatment of disease and industrial production,

D. whereas applications of biotechnology are likely to develop rapidly over the next few years and have major economic, industrial and social implications in Europe and globally,

E. whereas the policy of encouraging high-tech knowledge-based industries is especially relevant to the biotechnology industry, which has been singled out as an area with great potential for growth and for creating prosperity and employment, and whereas action taken by some Member States and regions to help the industry prosper has had positive results,

Structures

F. whereas there needs to be in place a legal and regulatory framework which is efficient, transparent, effective and predictable at EU and national levels in order for the industry to operate and develop in an orderly manner,

G. whereas GM healthcare and plant products necessarily have to pass very stringent tests to be authorised, but the present authorisation process is slow, cumbersome and inefficient and lacks transparency,

H. whereas biotechnology is not a narrowly specific sector but crosses boundaries in science and industry (molecular biology, chemistry, physics, medicine, informatics, pharmaceuticals, agriculture) and therefore involves several departments in the Commission and Member State governments,

I. whereas the success of biotech start-ups would be greatly increased by provision of high quality infrastructure and support and advice networks,

J. whereas it is necessary for biotechnology research to be given an ethical dimension because of the implications it may have, in particular, for the field of genetics,

Industry, research and employment

K. whereas basic research, applied research and development are essential to this industry and the costs of these are considerable and long-term,

L. whereas many biotechnology companies are SMEs which need incentives to invest in research, to have access to research funding and encouragement to co-operate and collaborate with universities and industry, including internationally,

M. whereas patents and intellectual property rights are essential to encourage research, innovation, investment and placing products on the market,

N. whereas the success of the industry in the US has benefited greatly from attracting scientists, entrepreneurs and experienced managers from around the world including from the EU,

O. whereas there is a shortage of skilled persons in European science, information technology, business and finance,

Finance

P. whereas European financial markets have improved but are still inadequate as regards initial funding for high-risk start-up companies and providing exit facilities for early-stage investors; whereas the European Investment Bank and its fund the EIF, as well as the Innovation 2000 Initiative, have nonetheless contributed much,

Q. whereas financial and fiscal incentives are important for the encouragement of innovation and marketing in biotechnology,

Healthcare

R. whereas the pharmaceutical market in Europe is not sufficiently open and competitive and thereby discourages innovation and reduces consumer choice and public health standards,

S. whereas a clear assessment of the current situation of the healthcare biotechnology industry in Europe is required, similar to that carried out on the pharmaceutical industry as a whole and whereas the importance of biotechnology requires a dialogue between interested parties,

T. whereas the Orphan Drug Regulation has been shown to be a powerful piece of legislation able to promote innovation in healthcare biotechnology and the development of new drugs for patients with rare diseases,

Environment, agriculture and food

U. whereas in some cases GM plants cannot be isolated, and controlled environmental assessments in laboratory and field are essential to promote understanding of their impact,

V. whereas organic production of food is not at present a viable alternative for adequately feeding and nurturing everyone in the EU and in the developing world at acceptable cost,

W. whereas the present effective moratorium on GM plant introductions and trials damages SMEs more than multinationals which are better able to outlive the delays,

International

X. whereas the de facto moratorium on genetically modified products has brought about a trade dispute with the United States of America where GM foods are not considered to be unacceptable or significantly different from conventional varieties,

Y. whereas developing countries identify GM crops as one means of meeting the needs of their increasing populations, of countering desertification and water shortage and of eliminating disabilities such as blindness caused by Vitamin A deficiency,

Z. whereas in applicant countries there is potential for biotechnology as long as EU-compatible legislation and regulatory frameworks are established,

AA. whereas the Cartagena protocol established strict international regulations regarding the movement of GM crops across borders,

Public information and debate

AB. whereas it is the responsibility of policy-makers, as well as industry, to ensure that the benefits outweigh the risks, and to provide citizens with information on the subject,

AC. whereas some developments and applications of this technology raise new and difficult ethical, religious, environmental and animal welfare concerns that need to be addressed,

AD. whereas there is a cultural tendency to risk-aversion in Europe, especially in comparison to the USA, and this has an inhibiting effect on the European biotechnology industry,

AE. whereas support from European citizens is essential for the industry to prosper and at present that support is sceptical, if not negative,

Objectives

1. Resolves to support the development of biotechnology in the European Union to the benefit of its citizens, with a higher quality of life in the form of better foods, cleaner environment and improved health, and calls on the other EU institutions and Member States to do likewise;

2. Expects the biotechnology industry to be placed prominently on the agenda of the next European Council; expects the European Council in Stockholm to designate biotechnology as an important economic sector and an integral part of the Lisbon process to create a competitive and dynamic knowledge-based economy offering sustainable economic growth;

3. Calls on the Commission to draw up a Bio-Europe Action Plan, coordinated by DG Enterprise, for consideration by the European Parliament and the Council;

4. Calls on the Commission to report on the present state of the biotechnology industry in the Member States and on this basis to develop an action plan for Bio-Europe to make the EU competitive for the biotechnology industry;

5. Calls upon the Commission to revive the relevant Advisory and Scientific Committees; specifically urges the Commission to consult industry within the Advisory Committees prior to its proposals and to state the reasons for action taken contrary to the scientific advice of the Scientific Committees;

6. Urges Member States to designate an enterprise orientated ministry to promote and co-ordinate biotechnology policy at national level; recommends also that the Commission co-ordinate, at European level, the biotechnology policies of the Member States;

Research

7. Considers the idea of the European Research Area very relevant to the biotechnology industry: notably the need to spend more on research at national level and co-ordinate efforts at EU level, to develop centres of excellence, to enhance infrastructure and encourage inter-disciplinary research;

8. Supports continued and increased EU research funding of life sciences and other areas of potential advance in biotechnology and genetics;

9. Calls on the Member States of the European Union to increase funding for universities for the creation of new degree courses, research doctorates and short degree courses in biotechnology and to upgrade those that already exist;

10. Calls on the Member States to make the career of researcher attractive in both financial and social terms so as to reflect the important role they play in the progress of civil society; in particular, calls on the Member States to ensure that researchers receive salaries and recognition equivalent to and/or competitive with those in economically more advanced countries outside Europe;

11. Sees the need to encourage young people to enter the field of biotechnology by offering more degree courses and research fellowships;

12. Urges the streamlining of administrative procedures for EU-funded research programmes;

13. Urges Member States to encourage collaboration and investment by industry in biotechnology research in universities and public institutes; while at the same time tax concessions are required to provide an incentive to enterprises; considers that the public sector should now assign priority to fundamental research;

Industry, employment and SMEs

14. Supports moves to encourage academics and entrepreneurs to set up companies and to promote collaboration and mobility between universities, SMEs and industry by means of a helpful financial, fiscal and intellectual-property environment;

15. Urges all Member States speedily to ratify the directive on the legal protection of biotechnological inventions and to support moves towards a single EC patent;

16. Urges Europe to attract top foreign scientists, managers and entrepreneurs by ample quotas for immigration and work permits;

17. Stresses the role of regional government in providing infrastructure, networks, support and advice mechanisms and science-orientated education;

18. Calls on the Commission to ensure that SMEs can participate fully in European research programmes;

Finance

19. Welcomes the development of financial markets, in particular venture capital, but stresses the need for further steps to facilitate the funding of biotechnology start-ups;

20. Urges, therefore, the creation and availability of new financial resources for start-ups at the early stage (seed stage) in order to increase the survival rate of start-ups;

21. Urges further rationalisation of European stock markets so as to encourage investment

in biotechnology and provide an exit route for early stage investors;

22. Calls on Member States to introduce an environment friendly to risk-taking, inter alia by amending bankruptcy law, with tax incentives for science-related investment and the take-up of stock options;

Healthcare

23. Believes that biotechnological industries have the potential to make a major contribution to human health and wellbeing; congratulates researchers in the field who have made enormous strides towards finding effective genetically based treatments for numerous conditions; further notes, however, that the promise of such techniques can be realised only if public concerns over safety, ethics and social justice are addressed.

24. Reiterates its support for the European Medicines Evaluation Agency, but also welcomes the review of the authorisation and clinical trials procedures as a means to streamline the process;

25. Urges the EMEA to institute a process of pre-approval discussions with developers of new medicines in order to ease the procedure and reduce costs;

26. Calls on the European Commission to develop proposals for EU 'fast track review' and 'conditional approval' legislation that will facilitate patient access to innovative treatments for life-threatening, chronic, seriously debilitating or rare diseases;

27. Believes that EU pharmaceutical markets throughout the development chain must be more competitive to encourage the development of new medical products,

28. Calls on the Commission to carry out regular assessments of the current situation of the healthcare biotechnology industry in Europe and to put in place a regular dialogue with interested parties to discuss the future of the industry;

29. Urges the Community and Member States to maintain their commitment to reducing the use of animals in medical experiments as rapidly as possible, *inter alia* by ensuring that biotechnology's potential to develop alternative testing techniques is fully exploited, while the development of new animal-based testing methods in pursuit of biotechnological research should be allowed only when no alternatives can be found and where the benefits are clear and substantial.

Environment, agriculture and food

30. Strongly supports reducing the use of pesticides and herbicides through the application of biotechnology provided this reduction is reached through mechanism and technologies which do not pose new long- or short- term risks to the environment or human health;

31. Supports efforts to develop biotechnological and genetic engineering procedures in the EU as one way of improving the economic viability of agriculture and food production in a manner which is at the same time environmentally sustainable; considers that the use of biotechnology and genetic engineering should be developed in a customer-based and environmentally sound manner with the aim of producing higher-quality and more diverse products, from which farmers who are currently facing viability problems will also derive more economic benefit;

32. Opposes the view that, in medicine, gene technology and biotechnology are primarily associated with opportunities, whereas in agriculture they are primarily associated with risks. Is much more inclined to believe that in both areas there are major opportunities which should be taken advantage of, but also significant risks which need to be reduced by means of appropriate legislation.

33. Points out the importance of field trials to assess environmental impact and of the legal protection of those undertaking these trials; calls on the Commission to develop tools for measuring the net environmental impact when new technology is introduced; calls on the Commission to perform comparative research to ascertain whether it is possible to attain more sustainable results with the aid of the new technology than by means of conventional intensive farming;

34. Regrets government actions to block or delay authorisation of GM products for reasons not based on objective scientific opinion;

35. Observes that the existing de facto moratorium particularly harms small and medium-sized enterprises which, unlike multinational corporations, are often unable to perform their research work in countries outside the EU;

36. Welcomes the agreement reached between Council and Parliament in the conciliation committee on the amendment of the directive on the release of genetically modified organisms and the assurances given by the Commission in that connection with regard to labelling and traceability, and considers that a clear framework now exists for the release of genetically modified organisms in Europe which will ensure maximum consumer protection and environmental protection, and that it would therefore not be justified to continue the de facto moratorium on the release of GMOs;

37. Welcomes the establishment of the European Food Safety Authority which should restore consumer confidence, reduce international conflicts and have overall responsibility for the approval of GM products; stresses that the critical ingredients of any credible and successful system for assessing food safety are its technical-scientific competence in risk assessment and its independence from improper interference in decision-making in individual cases; emphasises that independence cannot be assured if decision-making remains in the hands of political bodies;

38. Calls for obligatory mutagenicity, carcinogenicity and toxicity tests to be carried out on transgenic foods before they are placed on the market;

39. Stresses the importance of informing the public truthfully and openly about the safety checks which are made and the extent of any residual risk;

40. Affirms the right of EU citizens to information about food products and calls on the Commission to complete the rules on labelling of genetically modified organisms and to allow de minimis exceptions only where they are technically unavoidable;

41. Emphasises the need to establish a centralised procedure for the assessment of GM products which is able to provide an authoritative EU wide scientific consensus on the risk assessment of new products; these assessments should form the basis for risk management decisions;

42. Calls on the Commission and the Member States to support research into biotechnological applications offering clear social or environmental benefits, including the development of genetically modified micro-organisms for use in water purification, soil restoration, replacing dangerous chemicals currently in use, and developing sustainable and environmentally friendly energy sources (including biogas, hydrogen and ethanol);

43. Considers that in order to prevent centralisation which would render farmers dependent on large food businesses, sufficient publicly funded research must be ensured, R&D by small biotechnology enterprises and by plant-breeding institutes must be supported, and maximum competitiveness must be maintained at the various stages in the food chain;

44. Considers that the use of new technologies, for example for medicinal purposes or other non-food production, affords new opportunities for production, particularly in regions where bulk production is not economically viable because of environmental conditions.

45. Considers that the new crop varieties could alleviate the adverse impact of agriculture on the environment, and calls on the Commission to develop instruments for measuring the net environmental impact of introducing new technology.

46. Calls on the Commission to assess carefully the phenomena, the cycles and the possible waste products resulting from biotechnological applications so that biotechnological products can be assessed at every stage, from initial research to actual use.

47. Urges the authorities of the Community and Member States to outlaw techniques which could pose a threat to health or the environment, including the use of antibiotic-resistant genes that could spread into the environment.

International and enlargement

48. Believes that biotech applications can help reduce agricultural, environmental and health problems in developing countries; therefore considers that they should be encouraged to develop their own biotech industries and supports their involvement in the prioritising of relevant EU research programmes and in trade debates;

49. Believes that, in order to avoid a growing gap between rich and poor countries in utilising the benefits of biotechnology, the latter require technical assistance in order to develop their own skills, industries and markets;

50. Urges the Commission to make an assessment of the biotechnology industry in applicant countries and of the adequacy of their regulatory arrangements;

51. Supports involving of EU applicant countries in biotechnological research networks and debates;

52. Urges the Commission to work on establishing an internationally agreed system of equivalence as regards the authorisation of GMOs in order to put in place a scientifically sound, economically viable and practical system safeguarding environmental protection, public health and the undisrupted international trade of such products;

53. Calls for greater collaboration between the EMEA, the future EFA and the FDA in the area of biotechnologies and GM foods;

54. Welcomes the EU-US biotechnology forum as a means to obviate and resolve disputes;

55. Identifies the CODEX ALIMENTARIUS as the forum in which disputes over biotechnologies are voiced;

Public information and debate

56. Stresses the importance of improving the quality of scientific education and the level of knowledge in the field of biotechnology, not only in terms of fundamental principles but also of their applications to various sectors (such as the biomedical sector, the food industry and the environment), both in secondary schools and in universities and of graduates in specific disciplines (medicine, biology, pharmacy, agriculture and industrial chemistry);

57. Recommends that, in order to provide students with scientifically sound and objective information in the biotechnology field, the Member States should introduce university training courses for secondary school biology teachers;

58. Calls on the industry to take an active role in informing the public of the benefits and risks of genetic engineering;

59. Calls on Member States and the Commission to organise public fora on biotechnology in order to explain the benefits and to discuss the issues related thereto whereby all viewpoints are respected so that it may become possible to reach a common understanding between industry, the public and politicians on how we want to use this technology to the benefit of society;

60. Wishes the technology to be exploited to the benefit of society in accordance with the fundamental values and ethical principles of European citizens, their culture and civilisation, and to this end sees the need to develop ethical guidelines;

61. Stresses that the public's wish for ethically motivated limits on genetic engineering and biotechnology is justified and that the European Union has already set certain limits, for example in the Charter of Fundamental Rights, the directive on clinical tests and the Fifth Framework Programme of Research; undertakes, particularly after the conclusion of the work of the Temporary Committee on Human Genetics and Other New Technologies of Modern Medicine, to consider whether further limits are necessary and appropriate at European level;

62. Considers that the use of and access to personal genetic information by third parties be debated with a view to legislation, which should particularly focus on protecting the individual's personal integrity and on the requirement to obtain his consent;

63. Urges Member States to protect individuals' right to genetic confidentiality and ensure that genetic profiling is used for purposes beneficial to individual patients and society as a whole; there should be an exception to this general principle of confidentiality where the genetic fingerprints held in DNA databases are used to identify and convict criminals.

64. Instructs its President to forward this resolution to the Council and the Commission, to the Member States governments and the applicant countries, and to the World Trade Organisation.

EXPLANATORY STATEMENT

The European Union and biotechnology

Europe has a long and distinguished history in the application of biotechnology, which (thanks to recent dramatic scientific advances) has been singled out as an industry with great potential for renewed growth, wealth creation and employment - key aims of the Union. Biotechnology has the potential to improve quality of life through medical applications, for improved food and a cleaner environment. It could also help the EU meet environmental emissions targets. In a knowledge-driven economy, this is one industry that turns ideas into products.

The European biotechnology industry has been growing fast:-

	1995	1997	1999
Number of companies	584	1036	1351
Employees	17200	39045	53511
Revenues (€ millions)	1471	2725	5368
R & D expense (€ millions)	1252	1910	3164

Source: Ernst & Young Bio Business (2000)

However, the USA still dominates the industry. The EU lags far behind in the size of biotech companies, in revenues, R & D expenditure and persons employed. In 1998 the position was:-

European Union		USA	Ratio US:EU
3709	Revenues (€ millions)	15777	4.2
2334	R & D expenditure(€ millions)	8398	3.6
45823	Employees	153000	3.3

Source: Ernst & Young Bio Business (1999)

Many other countries are investing in biotechnology – Brazil, Canada, China, India, Israel, Japan, Thailand, etc. The EU risks being left behind and becoming a customer of others. We may even lose the industry altogether. This would have a knock-on effect on other industries, most notably the key pharmaceutical industry, where biotech is likely to become the growth area for the future. Already there are signs of emigration by companies involved in seeds and plants due to the negative attitude in Europe to GM crops.

Action is required from Member States and the EU to create the right environment for the industry to prosper. For this an Action Plan, similar to the e-Europe initiative, is required to co-ordinate national initiatives, exchange best practice and identify where European action would be valuable. We suggest that one Commission DG, probably Enterprise, be responsible for and act as champion of the biotechnology industry. The future of the biotechnology industry should also be placed prominently on the agenda of the next European Council in Stockholm with the objective of providing a renewed impetus to its development.

Research

The biotechnology industries spend an estimated 45% of income on R&D. Many biotech companies are SMEs, which find it difficult to follow through their research, owing to the time needed to develop, test and bring biotech products to market. As rewards in Europe are often lower than in the USA, the industry has correspondingly less to invest in research and

development. Enhancing profitability is therefore vital.

Research effort in the EU accounts for a lower percentage of GDP (1.8%) than the USA (2.8%) or Japan (2.9%)[1]. The estimated weight of biotech in national R&D expenditure differs considerably (3.3% in Sweden, 2.4% in France, 1.2% in Italy, 0.5% in Greece[2]). State funded research at national and EU levels is important for biotechnology, especially in basic research (such as gene sequencing). DG Research has invested in a number of biotechnology programmes over the past decade. It is important that EU research in this area should continue, particularly at the pre-competitive stage. Member States could invest more in research and an increased percentage in biotechnology research specifically.

Interdisciplinary and multinational research collaborations should be supported but must genuinely add value. Centres of excellence, with satellites in other locations, could work well. It is vital that researchers' intellectual property within such alliances is protected.

Industry and SME involvement in EU research should continue to be encouraged. Researchers have complained about the cumbersome application process. While accepting that applications must be properly screened and EU funds must be safeguarded, application procedures for EU research programmes should be as straightforward as possible. Payments must also be made on time.

The success of biotech in the US is often attributed to the interconnected industrial, financial, and academic networks. In the EU there are still barriers between industry and universities and between private and public sector research. The biotech industry has been more successful in member states where companies are involved in deciding on biotech research policy and where public-private research collaboration is encouraged.

Biotechnology is a broad subject. Therefore, numerous Commission departments and national ministries are involved. Designating one Directorate General at EU level and one ministry at national level with overall responsibility would help drive the industry forward and better co-ordinate EU and national government efforts.

Agriculture and Development

Through genetic modification, biotechnologists aim to create plants that have better flavour, are more nutritious, are cheaper, and require fewer chemicals to grow and to conserve. Better transport resistance and longer shelf life benefit the consumer as well as the farmer and trader. Researchers also aim to create farm animals which are healthier, less vulnerable to disease, better tasting and more nutritious. This could correct genetic deficiencies and improve growth rates, yields, resistance to bacteria and behaviour.

The first GM crops were introduced onto the market in the mid-1990s. 70% of world-wide sowings are in the U.S.A.; an estimated 35% of corn and about half the cotton grown in 1999 was GM.[3] Between 1997 and June 1999, China approved 26 applications for

[1] COM(2000)6 "Towards a European Research Area"
[2] Inventory of public biotechnology R&D programmes in Europe, EUR 18886/1, Vol.1 Analytical Report, p.10,DG Research 1999
[3] DG Agriculture Working Document "Economic Impacts of Genetically Modified Crops on the Agri-Food Sector" shttp://europa.eu.int/comm/dg06/publi/gmo/fullrep/cover.htm

commercialisation of transgenic organisms, 59 for environmental release and 73 for field trials[1]. In the EU only 4 varieties of maize, 1 variety of soybean and 3 varieties of oilseed rape have been approved under 90/220.

Soya beans are self-fertile and there are no wild varieties of maize in Europe, so the risk of contamination is negligible. With rapeseed, there is risk of gene transfer via cross pollination. Controlled field trials are essential in order to have a thorough assessment of any risks, and trials of such products must be authorised only after safety tests at the laboratory stage.

There is as yet no scientific evidence that GM foods have any human health implications. They have to pass extremely stringent tests to show that they are as safe as conventional varieties. GM products first appeared without consumers being aware what they were. The result was a backlash, from which the industry is still suffering. Consumers must be given information so that they can choose for themselves. In order to do this, food containing GM material should be labelled as such.

It is becoming increasingly difficult to claim that any foodstuff is wholly GM free. Allowing "GM free" claims to encompass minimal GM content is likely to be unacceptable to those wanting genuinely GM free produce. Therefore "GM free" labels should mean just that. Alternative labels could be "May Contain" or "Does Contain".

Feeding a growing world population is a major challenge. Added to this are land overuse, pests/diseases, water scarcity, soil degradation, and desertification in the developing countries. Research is being carried out into salt and drought-resistant crops and healthier food such as "Golden rice" which is genetically modified to redress Vitamin A deficiency, a cause of blindness in Asia. Scientists from developing countries are involved in research programmes on transgenic plants and local companies are taking part.

Trade

GM foods are major trading commodities. Under WTO rules, members can fix the level of sanitary protection that they judge to be appropriate, but not as a form of trade protection. The level of acceptable risk must be defined and there should be no discrimination between domestic and foreign goods. In the United States GM foods are not considered to be essentially different from conventional foods and therefore present no safety concerns. The position in Europe is very different. Dialogue under WTO aegis or directly is essential to avoid further trade disputes. To this end, the EU-US Biotechnology Consultative Forum and the involvement of OECD in biotech issues is to be welcomed.

Health

Genetics have a role in many diseases. Knowledge about genes could lead to the development of new forms of treatment and the creation of 'designer' medicines for application to very specific cells in specific individuals. Genetic diagnostics are already being used to check for predisposition to diseases. Gene therapy, replacing a faulty gene with a good one, is in development. Scientists are working on ways to successfully introduce a corrective cell or

[1] Internet Service for the Acquisition of Agri-biotech Applications Brief no. 17-2000 "Global Status of Commercialised Transgenic Crops:1999"

cells.

There has also been research into using GMOs to create vaccines and safer treatments. Progress in this area is moving quickly and we can anticipate further developments in the next few years.

The pharmaceutical industry is a key EU industry and is a major investor in biopharmaceutical R&D. 100 biotech medicines are in clinical trials in the EU, of which 14 are in the last phase. With over 350 in clinical trials in the USA, of which 107 are in the last phase, the EU lags behind drastically.[1] The European industry is hindered mainly by the Community regulatory system and national price and profit controls in state-run health services. As a result, the industry prefers to develop and trial products in the US. A more open, competitive market and a less costly and more efficient regulatory system would attract business to Europe, improve the industry's competitiveness and benefit patients.

Environmental/Industrial applications

Biotech processes can protect the environment e.g. in sewage treatment, removing nitrates from water, breaking down oil spills. They can also make industry cleaner and more productive with new products and processes. Industry should be encouraged to invest in this type of research.

GM crops can replace fossil fuels: plastics from GM oilseed rape, natural oils to replace petroleum. Incentives could be given to industry and farmers to grow these crops and develop uses.

Legal instruments

The industry needs a legal and regulatory framework that is efficient, transparent, effective and predictable. This is not the case in the EU.

Directives 90/219 on the Contained Use of GMOs and 90/220 on the deliberate release into the environment of GMOs affect the "green" biotech industries. 90/220 requires an assessment of the risks to human health, animal health and the environment prior to a release. The manufacturer or importer must notify the competent authority of the Member State, where the product is to be placed on the market, with a risk assessment. If accepted, the information is sent to the European Commission and all the other Member States, who may raise objections. If there are any objections, the Commission can put forward a favourable opinion to be decided by the Regulatory Committee, composed of representatives of Member States, or a proposal is put forward to the Council which requires a qualified majority. A similar procedure is in place under Regulation (EC) 258/97 on Novel Foods and Novel Food Ingredients for authorisation and labelling of GMO derived food products.

Under this system approval takes an unacceptably long time. Article 16 of Directive 90/220 has been invoked by Member States to put a temporary ban on GM products for safety reasons. In some of these cases the Commission's Scientific Committees have judged that the ban was unjustified. Furthermore, no authorisations have been approved under this directive

[1] DuPont Government Affairs

since October 1998. This demonstrates a lack of mutual recognition between Member States and a de facto moratorium on all development. It calls into question the political will in Europe to support this industry.

The lack of trust of the public in the regulatory system is an important factor in public opposition to GM crops and foods. EU institutions clearly need to respond to safety and environmental concerns, but it is hoped that the conciliation procedure on the revision of Directive 90/220 will restore confidence. Making the proposed European Food Safety Authority responsible would provide a more systematic and independent approach to testing and approval, one that is transparent and recognised. It is fundamental that approvals and non-approvals must be firmly and solely science-based.

On the pharmaceutical side, the European Medicines Evaluation Agency (EMEA) evaluates all applications, submits its conclusions to the Commission which then consults Member States. This system is a distinct improvement, but the Member State consultation stage adds to the time and cost. This must be streamlined to speed up the procedure, such as by notifying the EMEA of clinical trials early on and instituting collaborative discussion fora with medicine developers, as is common practice with the American FDA. Eventually there must be a move towards a single EU system using EMEA. Once approved, products will have access to a truly EU-wide single market. This would have a major impact by encouraging development and trials in Europe.

Patents

Under Directive 98/44 on the legal protection of biotechnological inventions, the production of plants and animals by crossing or selection alone is not patentable, but transgenic plants and animals are. There is a difference in law with the US where, "the term 'invention' means invention or discovery. *In European law 'discovery' is distinguished from 'invention' and is unpatentable… A discovery involves new knowledge whereas an invention is a practical application of knowledge."*[1] A patent must also have an industrial application. There is concern that biotechnology companies (especially in the U.S.) are using patents to keep particular genes or gene sequences from general release and application. Patents are necessary for profitability and as an incentive to invest. It costs €800-1000 million to develop a new product. A patent does not give ownership but prevents others from commercialising the item patented. As patents are published the knowledge becomes accessible. For these reasons, the European Parliament voted to adopt the Directive. Member States should have brought their legislation in line by 30 July 2000. Eleven member states have still not transposed the directive with serious implications for the industry.

The industry is still hindered by the lack of an EU-wide patent. Because the European Patent Office is not controlled by the Community, a patent is subject to different national legislations and courts for validity and enforcement. It takes an average of 46 months to get a patent granted by EPO, almost double the time in the US. It is also very expensive, especially due to translation costs into 11 languages.[2] A single EU-wide patent system with a limit of three languages would make Europe a more attractive environment for research and biotechnology companies.

[1] European Federation of Biotechnology briefing paper no.1, September 1996 "Patenting in Biotechnology"
[2] The Financial Times 17/11/00

Enlargement

In 1998 R&D expenditure in the candidate countries represented less than 1% of GDP although there are signs that this is improving. The share of the business sector in R&D expenditure was much lower than the EU average (63.7%) e.g. Poland (41.5%) and Estonia (19.6%)[1]. The EU should assess the current situation and future potential with recommendations for action.

Harmonised regulation is needed to avoid trade problems and encourage collaboration with EU businesses. Applicant countries should be involved in the biotech debate and be encouraged to participate in information sharing and research programmes.

Finance/business environment

The industry depends on the interest of investors. Financial markets and access to risk capital in Europe have greatly improved, but it still remains easier in the US. In 1995 €5bn was invested in the EU, rising to €25bn in 1999, but this is still significantly less than in the US (€45bn invested in 1999). Investment in biotech involves higher risk because the success rate is low (estimated 13%) and the process lengthy - 5-10 years to go public and provide early investors with an exit[2].

Typically institutional investors do not provide funds in the very early stages. Support by family and private business angels for the earliest stages is therefore essential. Such investors need incentives to take risks, notably a favourable fiscal environment in the relatively unlikely event of a major success. The European Investment Fund has increased investment via private sector venture capital funds for early stage biotech companies.

The situation would also improve if Member States gave tax relief on R&D expenditure and introduced attractive capital gains tax regimes for stock options. Academic researchers should be permitted to set up their own companies and be encouraged with good infrastructure – research and manufacturing facilities, science parks, structures to bring scientists, entrepreneurs and business people together and support with business and financial aspects. Executives, who have succeeded abroad, should be attracted to work in the EU and provide management for biotech companies.

A culture of enterprise could be fostered in the right regulatory and fiscal environment and through courses in schools and universities. Immigration quotas for foreign nationals with essential skills and resources would help Europe become more innovative and competitive.

Local and regional government

The biotechnology industry in Europe is widespread geographically. Typically there are clusters located around centres of academic excellence, the most significant around Munich, Cambridge, Central Scotland and Paris.

Local and regional governments have an important rôle in encouraging links between universities and business, between different regions and developing infrastructures for support and advice. Co-ordination between European, national and regional government is important, with a successful biotech industry being the key to regional prosperity and job creation over

[1] Eurostat News Release no.130/2000, 20 November 2000

[2] M.Shublin (EIF) and J.Peeters (Capricorn Venture Partners), Roundtable, 8 November 2000

the next few decades. It is therefore desirable for regional authorities to develop a policy for biotech and provide the requisite conditions. A notable example of this was the German BIO-REGI competition, which has catapulted Munich into first place among European biotechnology centres.

Education and Training

There is a shortfall in people skilled in science, finance and business. Biotechnology covers many different areas including molecular biology, chemistry, physics, mathematics, medicine and IT. There is also a chronic shortage of middle level technicians, who are vital to day-to-day working. Schools and universities need to increase cross-disciplinary research and training. Industry could be encouraged to invest more in universities by directing research into areas of greater business potential and providing the business know-how to potential entrepreneurs among academic scientists. Awareness must be raised among managers and entrepreneurs of the commercial potential of scientific research.

Public opinion and biotechnology

To have an informed debate on biotechnology, it is important that the public has an understanding of the science through education systems and public media.

Scares such as BSE, and the ways in which such situations have been handled, have made the public sceptical about assurances received from scientific advisory bodies and politicians. Public support is essential for the biotechnology industry to develop. Efforts must be made to restore confidence by providing information on benefits and risks. Public discussion fora could open up the debate and increase transparency.

Ethical and social issues

There are moral objections to biotechnology in agriculture because it involves fundamental changes in our relationship with nature. There are concerns about the genetic modification of animals and the animal testing of products. There are fears that GM crops in developing countries will make them dependant on multinational seed companies or change farming practices and their way of life. On the other hand, it is inconceivable not to give such countries access to new technology. Involvement of scientists from developing countries in research and of their politicians in trade discussions would allow more informed decisions.

The availability of personal genetic information brings risks of new forms of discrimination. There are concerns that insurance companies and employers could use this information to deny cover or jobs. Access to this information needs to be debated further so that appropriate legislation can be adopted.

Accounts of ‘designer babies’ have emphasised the need to decide how far the application of science should go on the eugenics scale. Stem cell research is much debated. It is thought that cells from early stage embryos (typically up to six days old), which are still undifferentiated, could provide information leading to the production of replacement tissues and organs by means of nucleus replacement with the patient's own cells. The aim is to give scientists a better understanding of nuclear reprogramming, so that alternative methods of stem cell production (i.e. without the use of embryo cells) could be developed, thereby providing non-rejectable organ transplants and novel cures for injuries, disorders and diseases. Those opposed to any research, which involves the death or manipulation of embryos, hope that this

end can be reached by direct research on adult stem cells from umbilical cords and placenta. Some scientists claim that this route will take much longer to reach the objective - if it ever will. Member States vary in research policy on embryos from completely forbidden (Germany) to partially permitted subject to regulatory approval (U.K.). Often this is related to the strength of the Roman Catholic and Evangelical Protestant churches versus secular society. The basic argument revolves around the status of the embryo as a living organism with the rights and dignity of a living person. The pro-life activists consider this begins at the moment of conception. Others consider this untenable while the cells are still undifferentiated and there are potential benefits to those suffering from disease.

Nine EU countries have national ethics committees and the rest have other ethics structures. At EU level the European Group on Ethics in Science and New Technologies (EGE) has independent status and advises the European Commission, Parliament and Council of Ministers on ethical values in scientific and technological developments within Community policies. It recently published an authoritative report on stem cell research.[1] Further debate on such ethical issues by these committees and in the European Parliament under the aegis of the Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine is to be welcomed. It is likely and proper that such decisions will continue to be made at member state level while the EU decides on where and how its research priorities and funding should be directed.

Conclusion

The Lisbon summit declared its ambition to make Europe the most dynamic and competitive knowledge-based economy in the world. In parallel with the electronic information technology revolution, development of the biotechnology industry must be of the highest priority. The EU institutions owe it to the people of Europe to turn this promise into successful prosperous industries, added wealth and fulfilling jobs. Leadership and positive action must replace ambivalence and procrastination urgently, with the Swedish Presidency and the President of the Commission having particular responsibility.

[1] The European Group on Ethics "Adoption of an Opinion on Ethical Aspects of Human Stem Cell Research and Use" Paris, 14 November 2000

26 February 2001

OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND CONSUMER POLICY

for the Committee on Industry, External Trade, Research and Energy

on the Future of the Biotechnology Industry
(2000/2100(INI))

Draftsman: Jonas Sjöstedt

PROCEDURE

At its meeting of 12 July 2000 the Committee on the Environment, Public Health and Consumer Policy appointed Jonas Sjöstedt draftsman.

It considered the draft opinion at its meetings of 24 January and 26 February 2001.

At last meeting it adopted the following conclusions by 41 votes to 2.

The following were present for the vote: Guido Sacconi, acting chairman; Alexander De Roo and Ria G.H.C. Oomen-Ruijten, vice-chairmen; Jonas Sjöstedt, draftsman; Emmanouil Bakopoulos (for Mihail Papayannakis), Jean-Louis Bernié (for Jean Saint-Josse), Hans Blokland, David Robert Bowe, John Bowis, Hiltrud Breyer, Martin Callanan, Dorette Corbey, Chris Davies, Avril Doyle, Jillian Evans (for Marie Anne Isler Béguin), Karl-Heinz Florenz, Cristina García-Orcoyen Tormo, Laura González Álvarez, Robert Goodwill, Mary Honeyball (for Béatrice Patrie), Anneli Hulthén, Eija-Riitta Anneli Korhola, Bernd Lange, Peter Liese, Torben Lund, Jules Maaten, Minerva Melpomeni Malliori, Patricia McKenna, Emilia Franziska Müller, Rosemarie Müller, Riitta Myller, Giuseppe Nisticò, Karl Erik Olsson, Marit Paulsen, Dagmar Roth-Behrendt, Karin Scheele, Ursula Schleicher (for Per-Arne Arvidsson), Horst Schnellhardt, Dirk Sterckx (for Frédérique Ries), Marianne L.P. Thyssen (for Maria del Pilar Ayuso González), Antonios Trakatellis, Kathleen Van Brempt (for Catherine Stihler), Phillip Whitehead.

CONCLUSIONS

The Committee on the Environment, Public Health and Consumer Policy calls on the Committee on Industry, External Trade, Research and Energy, as the committee responsible, to incorporate the following points in its motion for a resolution:

1. Believes that biotechnological industries have the potential to make a major contribution to human health and wellbeing. Congratulates researchers in the field who have made enormous strides towards finding effective genetically based treatments for numerous conditions. Further notes, however, that the promise of such techniques can be realised only if public concerns over safety, ethics and social justice are addressed.

2. Is concerned about the increased concentration of biotechnology research to a few very large corporations and calls on the public authorities at Member State, Community and international level to:

   (a) monitor the effects of such concentration as they may affect the public interest
   (b) protect the position of smaller firms and non-profit making organisations,
   (c) ensure the development of a strong, independent and publicly-funded research effort, focussing in particular on those areas which offer little potential for worthwhile short- or medium-term financial returns and which therefore tend to be under-researched by private industry, such as treatments for illnesses which mainly afflict poor people or children or are found predominantly in poorer countries; cures for conditions currently treated through expensive long-term maintenance regimes; and treatments for rare illnesses and for childhood illnesses,
   (d) promote research on the risks of biotechnology and possible ways to avoid these risks,
   (e) encourage the establishment of public-private partnerships which aim to carry out more extensive and more detailed study and research into applications which are of particular importance in local terms, either because they focus on specific crops or because they are innovative in nature.

3. Notes the significant opposition to GM crops in several developing countries, manifested in the demand for clearer rules by these countries within the framework of the Biosafety protocol; also notes that the use of GM crops could lead to a situation in which individual farmers or entire nations become dependent on certain large corporations; believes that unequal development must be counter-balanced by active technology transfer, scientific co-operation, fair rules governing patents and promotion of efforts to discourage the flight of expertise from developing countries to the north.

4. Urges Member States to protect individuals' right to genetic confidentiality and ensure that genetic profiling is used for purposes beneficial to individual patients and society as a whole, and never as grounds for refusing insurance or employment or for any purpose which is unethical, socially divisive or otherwise undesirable. There should be an exception to this general principle of confidentiality where the genetic fingerprints held in DNA databases are used to identify and convict criminals.

5. Further urges these authorities to outlaw all techniques involving the introduction of heritable characteristics into human beings.

6. Calls on the Commission and Member States to support research into biotechnological applications offering clear social or environmental benefits, including the development of genetically modified micro-organisms for use in water purification, soil restoration, to replace dangerous chemicals currently used in industry and also in agriculture, to develop sustainable and relatively environmentally friendly energy sources (including biogas, hydrogen and ethanol).

7. Calls on the Commission to assess carefully the phenomena, the cycles and the possible waste products resulting from biotechnological applications so that biotechnological products can be assessed at every stage, from initial research to actual use.

8. Accepts the right of private researchers to a degree of confidentiality necessary to prevent competitors from unfairly benefiting from their work, but insists that this right must be qualified by the prioritisation of the public interest. Believes that systems can and must be developed which enable these two considerations to be respected, but that where there is a conflict, the interests of public health, ethics and the environment must take precedence.

9. Urges the Community and Member States to maintain their commitment to reducing the use of animals in medical experiments as rapidly as possible, *inter alia* by ensuring that biotechnology's potential to develop alternative testing techniques is fully exploited, while the development of new animal-based testing methods in pursuit of biotechnological research should be allowed only when no alternatives can be found and where the benefits are clear and substantial.

10. Accepts the argument of private firms in the industry that patents must be available in order to protect the financial interests of inventors, developers and innovators and that in view of this the definition of what may be patented should be more precisely drawn. The award of patents which are too vague and far-reaching, can hinder research and should be avoided. The Community should follow these principles in international negotiations such as those regarding TRIPs; underlines its view that rules governing patents - both within the EU and internationally - must respect Article 15 of the United Nations Convention on Biodiversity, that biodiversity is a legitimate national resource and that the right of nations to benefit from any techniques or applications developed on the basis of their genetic heritage should be respected.

11. Opposes the view that, in medicine, gene technology and biotechnology are primarily associated with opportunities, whereas in agriculture they are primarily associated with risks. Is much more inclined to believe that in both areas there are major opportunities which should be taken advantage of, but also significant risks which need to be reduced by means of appropriate legislation.

12. Underlines its view that the precautionary principle must be applied to the use of GM crops and that the existing EU legislation is insufficient; only when an appropriate legal framework, such as rules on liability, labelling and traceability, is incorporated

into their legislation should Member States consider the introduction of new GM crops for commercial use; insists that those who manufacture and market GMOs should have full, unlimited liability for any damage to private or public property, human, animal or plant health or the general environment and that they must be fully insured.

13. Urges the authorities of the Community and Member States to outlaw techniques which could pose a threat to health or the environment, including the use of antibiotic-resistant genes that could spread into the environment. Research on potentially dangerous techniques which can be shown to offer potential social or environmental benefits should be confined to closed laboratory conditions until they can be shown to be safe.

30 January 2001

OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT

for the Committee on Industry, External Trade, Research and Energy

on the future of the Biotechnology Industry (2000/2100(INI))

Draftsman: Mikko Pesälä

PROCEDURE

At its meeting of 13 September 2000 the Committee on Agriculture and Rural Development appointed Mikko Pesälä draftsman.

It considered the draft opinion at its meeting of 23 January 2000.

At the last meeting it adopted the following conclusions by 24 votes to 4, with 1 abstention.

The following were present for the vote: Friedrich-Wilhem Graefe zu Baringdorf, chairman; and, Encarnación Redondo Jiménez vice-chairman; Mikko Pesälä, draftsman; Gordon J. Adam, Danielle Auroi, Alexandros Baltas (for Bernard Poignant), Carlos Bautista Ojeda, Niels Busk, António Campos, Giorgio Celli, Arlindo Cunha, Michl Ebner, Francesco Fiori, Carmen Fraga Estévez (for Joseph Daul), Georges Garot, Lutz Goepel, Willi Görlach, Elisabeth Jeggle, Salvador Jové Peres, Hedwig Keppelhoff-Wiechert, Heinz Kindermann, Efstratios Korakas (for Christel Fiebiger), Albert Jan Maat, Miguel Angel Martínez Martínez (for Michel J.M. Dary), Neil Parish, Agnes Schierhuber, Dominique F.C. Souchet, Struan Stevenson, Robert William Sturdy.

GENERAL COMMENTS

INTRODUCTION

Biotechnology, especially genetic engineering, is regarded as one of the key technologies of the immediate future. In agriculture and the food industry, strategies and parameters for research into the new technologies and their applications have likewise become burning issues calling for decision.

The Community has developed its legislation in an attempt to find a solution to the problems associated with the use of the new technologies. By means of risk assessment and risk management, and in accordance with the precautionary principle, it seeks to ensure that GM production chains are safe from the point of view of human and animal health and the environment.

In agriculture, genetic engineering has so far been used to increase the productivity of plants and animals and their resistance to various diseases and environmental stresses, as well as to improve quality. At present, research is also under way into the use of GM crops and animals in the production of medicines, vaccines and various replacement tissues.

Genetic engineering makes it possible to produce certain alterations in organisms with considerably greater precision than by means of traditional breeding. In addition, genetic-engineering techniques enable the desired proteins to be produced within micro-organisms or cell cultures and to make precisely targeted modifications in certain proteins.

New opportunities

The majority of GM varieties currently being cultivated are ‘first-wave’ products. ‘Second-wave’ products are currently being developed with the aim of attaining end-products of better quality, for example by modifying such constituents of plants as amino acids, proteins, fatty acids, starch, trace elements and vitamins.

The importance of raw materials of vegetable origin to industry is growing. It is estimated that, by means of genetic engineering, the oil content of oleiferous crops could be increased from current levels of 20-45% to as much as 70%. In addition, the fatty acid content of the oil could be altered to suit the needs of each industry or its nutritional value improved for use in food for human consumption or animal feed. Raw materials of vegetable origin could also replace current energy sources like diesel fuel and petrol, e.g. rapeseed could be processed to biofuels.

Human beings can synthesise only half of the twenty amino acids they require. The remainder have to be obtained from the food they eat. Using genetic engineering, efforts have been made to increase levels of important amino acids. Genetic engineering can also eliminate harmful substances which impede the absorption of nutrients in the intestines.

Transgenic livestock will be used for two main purposes: to produce biomedicines and to modify production or render it more efficient, for example to increase output, promote disease resistance or alter the characteristics of farm products.

Feedingstuffs can be made easier to digest by adding to them enzymes produced by genetically modified microbes. Enzymes produced by GM microbes are also used in cheese production.

The use of GM soil microbes for such purposes as remediation of polluted soil or to render production more efficient is a whole field of R&D by itself.

THE SIGNIFICANCE OF GENETIC ENGINEERING TO FARMERS

In the existing situation of falling producer prices, biotechnology could greatly assist farmers who wish to increase productivity and cut costs. First-wave GM varieties have not yet had a significant impact on the viability of farms. However, it will only be possible to make reliable analyses of viability on the basis of long-term results.

Second-wave GM products will be produced in response to demand. Some of them will be a response to consumer demands for a healthy diet, and consumers will presumably be willing to pay a higher price for them. This would improve the viability of producers.

Such products might include health foods, for example. This category also includes GM products whose characteristics have been modified in such a way as to render them suitable for new uses, for instance in non-food industries.

The impact of labelling and traceability systems on the prices of products

The introduction of traceability systems for products placed on the market will increase costs at all stages in the food production chain. Depending on the product and the system used, the extra costs are estimated at EUR 5-25 per ton of raw material, which is equivalent to 6-17% of the farmgate price.

Hitherto traceability has not been required of the first wave of 'bulk' products. In connection with the revision of Directive 90/220/EEC, a requirement has been introduced for traceability of GM products to be made compulsory. It may be assumed that the costs of labelling and traceability systems will have to be borne at the beginning of the production chain, in many cases by farmers.

If GM varieties yield a better return to the farmer despite the extra costs associated with them, they will come into general use. It will then be GM varieties which determine the market price, with the result that a higher price will have to be paid for non-GM varieties. In this situation it is whose consumers who opt for the 'special' product that will have to pay.

Second-wave products developed to meet consumers' needs will be quality products, which means that it will generally be primarily to the advantage of farmers and the food industry to label them and ensure that they are traceable. Such products will be cultivated under contract, and it will usually be consumers who pay the price for their higher quality. A similar pricing mechanism operates in the organic food sector, for instance. In all these cases, the price of the end product is significantly affected by the tolerance level set for admixtures. The lower the

tolerance, the greater the restrictions which will be needed and the more precise inspections will have to be at all stages of the food chain, and the more expensive the whole system will become.

Globalisation

The first GM products to appear on the market on a large scale were developed and marketed by centralised multinationals. The economic resources required for GM research and product development and the strict approval procedure are stimulating the concentration of development. Many small biotechnology firms do not have the economic resources to engage in it.

Farmers who introduce new GM varieties may become dependent on these businesses. This development will be advantageous to the businesses concerned, as it will make it possible to use the same distribution channels and to market different products jointly, an associated aspect being the regulation of seed and chemical prices.

OTHER FACTORS WHICH WILL AFFECT THE FUTURE OF BIOTECHNOLOGY

Under the European Union's Fifth Framework Programme, more than EUR 2 billion is being devoted to research in the life sciences. Public and private biotechnology research in the Member States has an even greater impact on the development of agriculture.

The aim of research should be to develop both GM and conventional products in an ethically and environmentally sustainable manner, taking account of the stringent requirements applicable to the quality and safety of foodstuffs.

The committee has previously stressed the following priorities for research:

- functional analysis of plant genomes as a means of locating, marking, identifying and isolating genes for economic and/or ecological exploitation,
- rendering isolated genes suitable for use by transferring them into plants which are of economic significance,
- ascertaining in full the biological production potential of plants and rendering them suitable for exploitation,
- bringing together scientific research findings and industry in order to ensure international competitiveness,
- promoting structural and financial incentives for new and existing biotechnology businesses.

The following points should be added to this list: research into genetic engineering of livestock, research into the safety and environmental impact of the whole GM food chain, and research concerned with risk assessment and GM legislation, particularly concerning the effects of various legal and other rights involved in the GM food chain.

Consumers' opinions

Consumers feel uncertain about GM foodstuffs. In general, they are significantly more in favour of medical applications of genetic engineering than of GM foods. They consider that GM foods should be clearly labelled.

Consumer concerns about the impact of GM products on health and the environment, problems with traceability and labelling, and uncertainty as to how legislation to promote the latter aspects is developing in the EU, have made retailers cautious. In the United States and Canada, some cereal merchants and plant-breeders have begun to separate GM products and non-GM products in order to be able to meet customers' wishes on both domestic and export markets.

CONCLUSIONS

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

Modernisation of agriculture

1. The development and use of biotechnology and genetic engineering is one possible way of developing agriculture and food production in an economically and environmentally sustainable manner, even though many things have yet to be verified in this area. To abandon these procedures would give other competitors a competitive advantage.

2. The development of biotechnology and genetic engineering processes and their use in agriculture must continue to respect the principle of a 'case-by-case' assessment. An objective and comprehensive examination must weigh up the advantages and disadvantages of introducing a genetically modified product.

3. The use of biotechnology and genetic engineering must be developed with the aim of producing higher-quality and more versatile products, which will be economically more beneficial to farmers, whilst taking into account the points of view of consumers and the need for sustainable agriculture.

4. The use of the new techniques, for example for medicinal purposes or non-food production, is creating new opportunities for production, particularly in regions where bulk production is not economically viable because of environmental conditions.

5. The European Union undertakes to promote and agree on standards and regulations governing intellectual property – relating to biotechnologies – which will allow and facilitate access to new technologies in developing countries.

6. Genetically modified plant and animal varieties are creating new opportunities for local farmers in developing countries to produce sufficient quantities of higher-quality food for the people who live there.

7. In order to combat the trend towards centralisation, which renders farmers dependent on the agricultural processing industry, it is important to ensure that sufficient research is carried out using public funds, support should be provided for R&D by small biotechnology firms and plant-breeders, and maximum competitiveness should be maintained in the various parts of the food chain.

8. The European Union considers it appropriate to promote the formation of public-private partnerships to pursue the aim of intensifying and developing the study of and research into applications of particular importance locally – either because they are focused on specific products or because they are innovative.

9. The European Union proposes to study appropriate legislation which will offer the opportunity of incorporating anti-trust legislation, not least as regards the aspects connected with patents, in the specific field of biotechnology and genetic material, in order not to distort the conditions of competition.

10. Considerably more resources are required for biotechnology research than are available from the EU's framework programme of research. The channelling of national research funding and particularly private research funding, and providing incentives for human resources – such as young researchers – to remain in Europe, are therefore keys to the development of the field.

Priority for safety over economic benefits

11. The possible dangers to human safety or the environment arising from genetic modification must always be scientifically assessed, and economic advantages must never take priority over safety. New biotechnology procedures must be used in a controlled manner and must make sustainable use of natural resources and be conducted openly and under effective supervision.

12. In order to ensure that information can be obtained and choices made, genetically modified products must be properly labelled. It must be possible to trace products, and they must be subject to comprehensive monitoring. More public information should be provided concerning genetic engineering, and more should be taught about it at school. Training and information programmes must be drawn up to manage these technologies, targeting the farming sector. Such programmes will, in particular, be aimed at farming techniques and logistic and marketing aspects.

13. In the absence of a standardised method of analysis and taking into account changing techniques, only documentary traceability guaranteeing a continual flow of information

will facilitate reliable labelling of the product reaching the final consumer in compliance with current legislation.

14. The committee calls on the Commission to study the problems associated with the existing authorisation procedure operated by the Member States. At the same time it should consider whether there is a need to establish a centralised marketing authorisation procedure at Community level.

15. In order to reach a practicable solution, a uniform threshold value for pollution caused by genetic engineering should be laid down for the whole EU.

16. The Commission is urged to devise more information programmes to make authorisation and the procedures for using biotechnologies more transparent.

A cleaner environment

17. The new crop varieties could alleviate the adverse impact of agriculture on the environment. The committee calls on the Commission to develop instruments for measuring the net environmental impact of introducing new technology.

18. The committee calls on the Commission's agriculture department to carry out comparative research to establish whether it is possible to achieve more sustainable results by means of the new technology than by means of conventional farming.

19. Biotechnology firms responsible for the introduction of GMOs must accept civil liability. Farmers must not be made liable for damage caused by GMOs and their derivatives.