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REPORT

on the Commission communication on Life sciences and biotechnology - A Strategy for Europe
(COM(2002) 27 – C5-0260/2002 – 2002/2123(COS))

Committee on Industry, External Trade, Research and Energy

Rapporteur: Elisa Maria Damião

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PROCEDURAL PAGE

By letter of 24 January 2002, the Commission forwarded to Parliament a communication on Life sciences and biotechnology - A Strategy for Europe (COM(2002) 27 – 2002/2123(COS)).

At the sitting of 10 June 2002 the President of Parliament announced that he had referred the communication to the Committee on Industry, External Trade, Research and Energy as the committee responsible and the Committee on Legal Affairs and the Internal Market, the Committee on the Environment, Public Health and Consumer Policy, the Committee on Agriculture and Rural Development and the Committee on Culture, Youth, Education, the Media and Sport for their opinions (C5-0260/2002).

The Committee on Industry, External Trade, Research and Energy had appointed Elisa Maria Damião rapporteur at its meeting of 19 February 2002.

It considered the Commission communication and the draft report at its meetings of 9 July, 11 September, 7 and 21 October 2002.

At the last meeting it adopted the motion for a resolution by 28 votes to 7, with 3 abstentions.

The following were present for the vote: Carlos Westendorp y Cabeza chairman; Yves Piétrasanta, vice-chairman, Konstantinos Alyssandrakis, Sir Robert Atkins, Luis Berenguer Fuster, Felipe Camisón Asensio (for Alejo Vidal-Quadras Roca), Gérard Caudron, Giles Bryan Chichester, Thierry de La Perriere (for Marco Cappato), Harlem Désir, Carlo Fatuzzo (for Paolo Pastorelli), Concepció Ferrer, Marialiese Flemming (for Paul Rübig pursuant to Rule 153(2)), Norbert Glante, Hans Karlsson, Bernd Lange (for Massimo Carraro), Peter Liese (for Werner Langen), Rolf Linkohr, Giorgio Lisi (for Michel Hansenne pursuant to Rule 153(2)), Hans-Peter Martin (for Erika Mann), Eryl Margaret McNally, Elizabeth Montfort, Bill Newton Dunn (for Nicholas Clegg), Seán Ó Neachtain, Reino Paasilinna, Elly Plooij-van Gorsel, John Purvis, Bernhard Rapkay (for Gary Titley), Imelda Mary Read, Didier Rod (for Nuala Ahern pursuant to Rule 153(2)), Mechtild Rothe, Guido Sacconi (for Olga Zrihen Zaari pursuant to Rule 153(2)), Inger Schörling (for Caroline Lucas pursuant to Rule 153(2)), Esko Olavi Seppänen, Antonios Trakatellis (for Bashir Khanbhai pursuant to Rule 153(2)), Claude Turmes, W.G. van Velzen and Myrsini Zorba.

The opinion of the Committee on Agriculture and Rural Development is attached; the Committee on Legal Affairs and the Internal Market and the Committee on the Environment, Public Health and Consumer Policy decided on 27 March 2002 not to deliver an opinion; the Committee on Culture, Youth, Education, the Media and Sport decided on 23 May 2002 not to deliver an opinion.

The report was tabled on 23 October 2002.

MOTION FOR A RESOLUTION

European Parliament resolution on the Commission communication on Life sciences and biotechnology - A Strategy for Europe (COM(2002) 27 – C5-0260/2002 – 2002/2123(COS))

The European Parliament,

– having regard to the Commission communication (COM(2002) 27 – C5-0260/2002[1]),

– 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[2],

– having regard to its resolution of 15 March 2001 on the Future of the Biotechnology Industry[3],

– having regard to the European Charter of Fundamental Rights proclaimed by the European Council on 7 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 its legislative resolutions on the proposal for a European Parliament and Council regulation on genetically modified food and feed[4] and on the proposal for a European Parliament and Council regulation on traceability and labelling of genetically modified organisms and traceability of food and feed derived from genetically modified organisms[5], which were adopted at first reading by the European Parliament,

– having regard to Rule 47(1) of the Rules of Procedure,

– having regard to the report of the Committee on Industry, External Trade, Research and Energy and the opinion of the Committee on Agriculture and Rural Development (A5-0359/2002).

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,

B. whereas biotechnology contributes to healthcare, helps to protect the environment and can be used in industrial production processes, while respecting the preventive and precautionary principles,

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[1] OJ C 55, 2.3.2002, p. 3.
[2] OJ L 213, 30.7.1998, p. 13.
[3] OJ C 343, 5.12.2001, p. 205.
[4] OJ C 304 E, 31.10.2001, p. 221.
[5] OJ C 304 E, 31.10.2001, p. 327.

C. whereas the European Union is not merely an economic area, but is also an area of shared fundamental values based on respect for human dignity,

D. whereas awareness of biotechnology and the principles of genetics is not widely known,

E. whereas in spite of increasing efforts in the biotech sector in recent years, the EU is lagging behind its global competitors, the situation can be demonstrated by insufficient levels of R&D expenditure, particularly from the private sector, the geographical migration of researchers outside the EU (brain-drain) and of companies, mainly to the US, the difficulty of access to investment and venture capital and cumbersome patenting legislation and bureaucracy;

F. whereas the European Union has only limited competencies in the field of education.

G. whereas, although genetics specialists and professional organisations make efforts to promote quality assessment, genetic testing services are provided under widely varying conditions and regulatory frameworks in the individual Member States;

H. whereas there exists no EU legislation to guarantee a minimum standard of genetic testing and analysis services in conformity with other provisions;

1. Welcomes the European Commission's Action Plan on Life sciences and Biotechnology and its vision for a long term, competitive and responsible European model for biotechnology with all its benefits and opportunities for our society, while respecting the cultural diversity of each Member State;

2. Welcomes the Commission's willingness to explore areas where common views on fundamental guidelines are possible, to promote an inter-institutional dialogue, and to ensure that ethical implications are taken into account at the earliest possible stage of EU-supported research;

3. Calls for major responsibility for coordinating the biotechnology strategy to be conferred on one Commissioner in particular and on a directorate-general created to that end so as to ensure greater consistency in Community activities;

4. Considers it important to inform the public that biotechnology offers opportunities in various fields: from health to agriculture, from industry to alternative energy resources; opposes the view that, in medicine, genetic 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;

5. Calls on the European Commission to launch a 'B-Europe' policy which lays down the specific political agenda for the next few years in the field of biotechnology;

6. Stresses that further basic statistical information is also required on the industry's structure and development in Europe;

7. Recalls that better statistics, e.g. on epidemiological data or on ongoing research projects, etc. will help to better focus target R&D projects on real needs of citizens;

Knowledge, Education and Workforce

8. Calls on the governments of the Member States, as the European Union has only limited competencies in the field of education, to improve basic education in schools, higher education and education for adults in the field of biology with a particular focus on genomics and microbiology, not only to improve the knowledge of the workforce but also to improve the knowledge base on which consumers can take their decisions;

9. Calls on the Commission to hasten its review of Regulation 1408/71 and to draft a proposal for a harmonised procedure to transfer pension rights also for supplementary pensions between different Member States to provide an incentive for the mobility of the workforce;

10. Calls on the Member States to increase the proportion of women in science, research and development by supporting educational programmes and by changing working conditions and improving the availability and the quality of childcare;

Public information and debate

11. Observes the need to enhance and enlarge public debate, the access to objective information and the level of scientific knowledge; emphasises the need for consumers to have the opportunity to address questions to scientists and to receive answers from them;

12. Calls for the public authorities and industry to pursue a transparent information policy based on scientific data; reminds the media of the major role which they play in this field and calls on them to cover the issue impartially and fairly;

13. Calls for an increased influence in the nomination of members of the European Group on Ethics in support of the Commission's proposal to strengthen the EP's role in exploring and informing about European ethical guidelines and stresses that the work of this group must be transparent and that consumers are involved at an early stage;

International cooperation

14. States that biotechnology alone will not help to overcome hunger in the world and that other methods, for example a better distribution of available food, are currently more important, but underlines that given the ever increasing world population it might also be necessary to use genetically modified crops to produce enough food;

15. Recalls that the European Union is the largest development aid partner world-wide, and calls on the Commission and Member States to promote international guidelines towards the co-operation role of biotechnology for the improvement of health, nutrition and environment, respecting human dignity in developing countries;

16. Considers that Community rules concerning the welfare and protection of consumers in the field of the life sciences and biotechnology should also be promoted at international level but without creating barriers to commerce and trade since many aspects are related

to the world's trading system, which is governed by WTO agreements;

17. Emphasises that developing countries themselves must decide if and to what extent they want to use GMOs. Should a developing country want to use biotechnology, the EU and Member States should provide support so that it can strengthen its own capacities;

18. Considers that biotechnology can contribute towards finding genuine solutions to environmental problems, sustainable development and food sufficiency, which would help to combat chronic hunger and to improve human health; considers, therefore, that this technology should be promoted with caution and its applications supported, taking full account of environmental and health safeguards;

19. Calls on the Commission and the Member States to promote the Johannesburg process for sustainable development and include technology transfer as one of the preconditions for sustainable development in the developing countries, underlines that biotechnology if applied prudently is a contribution to sustainable development because it helps to save energy and raw material and can lead to less pollution;

20. Supports the Commission's idea to play a leading role in developing international guidelines but regrets that this action is focused mainly on the food sector; points out that the establishment of international guidelines for the application of biotechnology are necessary and also further enhances human dignity;

Legislation and enforcement of existing legislation

21. Emphasises the urgency to complete a harmonised, knowledge-based, predictable and ethical legal framework for biotechnology companies and farmers, which aims to secure consumer safety, competitiveness, the prevention of both a 'brain-drain' in this field and a future dependency on the import of biotech products;

22. Calls on the Member States to implement existing legislation (e.g. Clinical Trials Directive, Directive on the legal protection of biological inventions) in a way that preserves citizens' interests but which does not jeopardise research activities in Europe at the same time;

23. Calls for the introduction of a European patent which meets the requirements of research workers and innovators in both public research institutes and industry;

Consumer Protection

24. Considers that users of biotechnological developments should bear no risk of liability under the relevant European Union legislation;

25. Recalls the need for information based on reliable scientific assessments and studies to enable consumers to make their choice on a sound basis, emphasises that new technologies often have been met with doubt and that some of these doubts are not really rational and that the precautionary principle should be applied in a rational manner so as to provide consumer and environmental protection and not serve as a barrier to political decision-making and technological innovation;

26. Stresses that the use of genetically modified products and genetic engineering in production must be accompanied by research, particularly into the long-term effects;

27. Stresses the need to ensure that consumers receive reliable information about GMOs, products, and food and animal feed produced from GMOs so that they can choose a product on the basis of prior information and can acquire confidence in GMO products and technology;

28. Supports the view that, when new products and production methods are introduced, the potential risks to human health and the environment should be minimised and that, therefore, transparent, knowledge-based risk assessment and risk management procedures must be used, taking account of the precautionary principle;

29. Notes that the cautious attitude of consumers towards GMOs and their products recorded in various European surveys (Eurobarometer, December 2001, ITPS Report, etc.) is in large measure attributable to insufficient provision of information about GMO technology; considers it essential, therefore, that consumers receive reliable and full information;

Research and development, Industry, employment and SMEs

30. Calls on the European Commission to promote Public and Private networking within the 6th Framework Programme and elsewhere amongst European, national and regional biotech research units, clusters and companies;

31. Calls on the European Union to continue research in particular with regard to the development of foodstuffs that are beneficial for consumers, the definition of consumer benefit shall always include the nutritional and toxicological consequences of a product;

32. Calls on the European Union to continue research into the improvement of risk assessment, taking into consideration the latest scientific findings;

33. Takes the view that policy, together with the industry and research, must produce better information as to risks for consumers, the environment and animals and launch a carefully formulated accompanying programme for growing genetically modified plants;

34. Asks the Member States to implement the Directive 98/44/EC[1] of the European Parliament and the Council of the 6 July 1998 on the legal protection of biotechnological interventions and to recognise that the decision of the European Patents Office, on the so-called Edinburgh Patent in July 2002, shows that ethical concerns are respected by the European Patents Office; regrets on the other hand that the earlier mistake on this patent by the Patents Office was discovered by Greenpeace (and not by the Patents Office itself); asks the European Patents Office to review its working methods, so that such mistakes will not be repeated and, refers to its resolution of 30 March 2000 on the 'Decision of the Patents Office on the cloning of Human beings'[2];

[1] OJ L 213, 30.07.1998, p. 13.
[2] OJ C 378, 29.12.2000, p. 20.

35. Encourages the initiative of the European Commission to identify with appropriate European experts how to overcome the issue of insufficient funding regarding biotech start-ups, asks the European Investment Bank to favourably consider recommendations resulting from that initiative;

36. Stresses the importance of giving SME easier access to innovation, training and risk capital in line with the spirit of the European Charter for Small Enterprises;

37. Encourages the Commission, Member States, the European Investment Bank and the Committee of the Regions to actively support setting-up bio-clusters, where appropriate support them with finance skills and other means, and encourage networking of bio-clusters throughout Europe to exchange experiences and establish best practices; calls for the development of bioclusters and other models for technological transfer to be promoted in the European Union and in the applicant countries in order to stimulate investment.

Environment, agriculture and food

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

39. Asks the Commission to support the potential of biotechnology regarding sustainable development and to support the development and selection of adequate assessment techniques allowing a quantitative measurement of sustainability, including all three pillars: environmental, economical and social;

40. Calls on the Commission and the Member States to review legislation on fuels, in particular Directive 98/70/EC on the quality of fuels, so as to allow biological energy sources to be economically explored and products to be placed on the market in the short term, e.g. blending ethanol with traditional engine fuels, in particular because current limitations are not economically or scientifically justified, they favour pollutant fossil fuels and impair significant environmental improvement through reduction of CO_2;

41. Strongly supports the view that the existing de-facto moratorium on GM foods in force since 1998 and due to end in 2003 should cease, in order to increase consumer choice and benefits, and to promote innovation; the current situation has particularly harmed SMEs that are main originators of innovation;

42. Supports the establishment of legal thresholds for the adventitious presence of GM foods and feeds which enable consumer choice, which are set at practically appropriate levels and are based on scientific assessment, provided these products have been established as safe by EU standards;

43. Calls for the adoption of practicable thresholds and the immediate implementation of the Directive on the deliberate release of GMOs into the environment within the framework of an overall strategy for green genetic engineering in which products containing genetically modified material or produced therefrom must be clearly and unambiguously labelled and traceability ensured in order to give consumer the greatest possible transparency and full

freedom of choice;

44. Strongly supports the reduction in the use of pesticides and herbicides through biotechnology if it is achieved without risk to the environment or human health;

45. Expects that higher consumer confidence in the regulatory process is achievable through centralised scientific review procedures performed by the European Food Safety Authority; therefore asks the Commission to make a proposal in this direction;

Health and Reproductive Medicine

46. Calls on the Commission to draft a legislative regulation for the introduction of a standard for genetic tests, since these services lie outside the scope of Council Regulation (EEC) N° 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and Directive 98/79/EC on in-vitro diagnostic medical devices, which applies only to products to be marketed;

47. States that genetic testing and analysis must be conducted under clear rules within the frame of competent, independent and personal counselling which must cover medical, ethical, social, psychological and legal aspects;

48. Solemnly reaffirms that the life and dignity of all human beings, whatever their stage of development and state of health, must be respected and is opposed to any form of research or use of life sciences and biotechnology that runs counter to this fundamental principle;

49. Notes that genetic testing analysis and diagnosis data must remain confidential and should be used only for the benefit of the person requiring such tests, with the exception of tests undertaken for clearly defined scientific or criminal investigation purposes, therefore such tests should be inadmissible for social or recruitment purposes, and should not jeopardise personal privacy and dignity;

50. Calls on the Commission to take the necessary steps for an EU-wide regulation on DNA-testing, choosing, if possible, a legal basis (e.g. Article 152 (health) or Article 153 (consumer protection)) which leaves Member States free to introduce more stringent protection measures and asks its competent Committee, subject to prior authorisation by the Conference of Presidents, to consider drafting an own-initiative report on the legal aspects of DNA testing;

51. Considers it particularly important to ensure that no woman is compelled to have prenatal diagnosis carried out and that any decision not to resort to such diagnosis is respected and supported;

52. Takes the view that determination of sex in connection with prenatal diagnosis should be permitted only - if at all - if there is a risk of serious gender specific hereditary diseases;

53. Instructs its President to forward this resolution to the Council and the Commission and the parliaments of the Member States.

EXPLANATORY STATEMENT

1. Definitions

a) What is biotechnology and Life Sciences?

The provisional single definition of biotechnology according to the OECD is as follows: *"The application of S&T to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services."*
No "official" definition of Life sciences has been found and its are often used as a synonym for biotechnology.

The OECD distinguishes between the following five categories:

- **DNA (the coding)**: genomics, pharmaco-genetics, gene probes, DNA sequencing/synthesis/amplification, and genetic engineering.
- **Proteins and molecules (the functional blocks)**: protein/peptide sequencing/synthesis, lipid/protein engineering, proteomics, hormones, and growth factors, cell receptors/signalling/pheromones.
- **Cell and tissue culture and engineerin**g: cell/tissue culture, tissue engineering, hybridisation, cellular fusion, vaccine/immune stimulants, embryo manipulation
- **Process biotechnology**: Bioreactors, fermentation, bioprocessing, bioleaching, bio-pulping, bio-bleaching, biodesulphurization, bioremediation, and biofiltration.
- **Sub-cellular organisms: gene therapy, viral vectors.**

b) Categories of biotechnology and life sciences

Three main categories can be distinguished at this time:

1. white: in industrial processes
2. green: in agriculture
3. red: healthcare

2. Why is biotechnology important?

At the European summit in Lisbon, Heads of State and Government have decided: "The Union has today set itself a ***new strategic goal*** for the next decade: *to become 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*. " Biotechnology has been clearly identified as a component of that knowledge-based economy.

Biotechnology has the potential to contribute to food production sustainability and safety, to maintain biodiversity and to minimise land use and deforestation. It can be used to protect the environment as an alternative complementary energy and industrial processes. It can enhance the quality of life of patients, extend life expectancy and deliver medical solutions to some of the world's rare as well as incurable diseases.

Biotechnology is one of the most promising emerging technologies. It is predictable to be one of the fastest growing areas within the next decade. It is of critical importance to allow Europe to evolve its full potential by developing a stable regulatory and economic framework for the biotechnology sector, while promoting confidence of the public and consumers.

3. What are the concerns associated with Biotechnology? Why is a public debate so important?

According to 2001 Eurobarometer survey, the European public has become increasingly sceptical as to the benefits of biotech.The same survey shows, however, that European's knowledge about genetics and biotechnology is poor and only slightly improved since 1993. This negative perception must be reversed by a continuous knowledge-based, responsible dialogue and use information vetted by all stakeholders.

4. Biotechnology - what is the situation in Europe?

	Year	EU	US	world
Companies	2001	1.570	1.273	
Direct employees		61.000	162.000	
Market capitalisation		€ 42 billion	€ 376 billion	
Private venture capital	2000	€ 1 billion	€ 3 billion	
Surface of GMO crops	2001	12.000 ha		50 million ha

The European Commission's report "Innovation and competitiveness in European biotechnology (Enterprise papers No 7 - 2002, ISBN 92-894-1805-2) states that Europe lags behind the US for various reasons:

- late entry
- less networking
- unattractiveness to researchers
- fragmentation
- less funding for research
- less pluralism in funding.

Funding seems to be the most urgent problem are younger than their US counterparts and most of them are in a phase of development where they are currently extremely vulnerable; their capital demands far exceeds current supply, furthermore without own resources, they depend largely on outside capital. With the Basel-II agreement, it has become much more difficult for them to access funding from the banking sector. The current economic situation also does not make it easy to raise funds. The above-mentioned Innovation report states that *"the availability of venture capital is commonly invoked as a fundamental ingredient of American leadership in biotechnology"*. The report explains that the conventional stereotype that American financial institutions are short-sighted is not true in this case and that venture capitalists can be characterised as having *"an extremely strong long run approach."* Contrary to the situation in Europe, a significant number of biologists with PhDs are working in venture capital firms and can actually evaluate applications for funding.

Regarding green biotechnology in particular, the situation is very complicated in Europe. There is an illegal de-facto moratorium for product approvals to prevent further GMO crops being placed in the market. The European Parliament has just tightened a Commission proposal for GMO labelling and tracebility. This has been welcomed by certain pressure

groups, but has been widely criticised by the research and industry community, who believe the amendments forwarded by the EP are not practicable creating administrative burden without enhancing safety.

5. What is the action plan?

The Action Plan has been drawn up by the Commission as a follow-up of the Lisbon summit - at the request of the Council - and as a consequence of the European Parliament's own initiative report on the future of the biotechnology industry[1] . The Action Plan contains 30 actions (see annex) that cover all areas of importance in developing the social and economic potential of the industry. The final goal is to reap its benefits in a shared European vision, achievable, only, by policy coherence between all areas affecting and affected by biotechnology..

6. Is the Action plan improving the situation?

The action plan is a good initiative and it should be welcomed. However, two questions remain: Will it be enough? And in the long term, can we afford not to have a European biotechnology?

Societal scrutiny and ethics:
Promoting dialogue among stakeholders and organising public debates are necessary to accompany the development of Biotechnology and insure it is in harmony with societal values. In this respect, the action plan initiates an essential European debate about biotechnology in order not to lose more ground to competitors - if it is lost in the short term, it may be so forever.

Support for the biotechnology community:
The biotechnology community urgently needs a predictable and supportive legal and policy framework. It also needs a better access to venture capital and overall co-ordination (both public and private) that unifies research and investment efforts for international and regional mutual benefit, therefore aiming both at competitiveness and quality benchmarking.

According to the European biotechnology industry itself, companies are suffering from massive under-funding since Basel-II. The Commission urgently needs to examine public financing mechanisms, which might assist the industry during the current economic conditions.

Patenting should be connected with product development and testing; A EU centralised co-ordination body is needed with public and private support, especially for SME's, to minimise repetition of testing costs and offering conditions for patent holders to develop and test their products in Europe.

Consumer protection:
The need for a high level of consumer safety, a rigorous risk assessment and extensive, clear information is paramount for any product under EU's legislation. Scientists, companies, the European Commission and Member States should be able to provide consumers with an

[1] Purvis report, adopted on 15.03.2001

informed choice concerning biotech products, keeping consumers from falling into misinformation and producers from market ostracism.

Protection of personal data should be enforced by the prohibition of genetic testing results for non-therapeutic and non-research uses.

Legislation and enforcement of existing legislation:
It is important that a knowledge-based legal framework for biotechnology is created promptly, limiting administrative burdens for researchers and industry, with enforceable requirements.

The Commission should initiate infringement procedures at an earlier stage. The European Parliament could regularly monitor enforcement of important directives, e.g. during its plenary meetings. The EP itself must discuss biotechnology thoroughly to overcome the schizophrenic situation of half supporting it and half condemning it.

The flight of inventions and researchers implies the need of a supported European patent with minimal bureaucracy, achievable through the harmonisation of National Legislations.

International co-operation:
Co-operation with developing countries should always take their needs into consideration and not simply transfer European ideas on foreign ground. The co-decision of these countries is not underlined in the action plan.

Research and development:
The EP has played an important role in adopting legislation for FP6 in due time so that the calls for tender can be made soon and research can be funded from the beginning of 2003 onwards.

Education and workforce:
Europe has no power in the drafting of curricula for schools. The exchange of scientists can be encouraged, but how can young people be encouraged to study biosciences? How can common knowledge about biotechnology or genomics be improved? These questions are not answered by the Commission text. Nor is the question of acceptance solved.

The loss of European biotech researchers (brain-drain) and companies is unacceptable. This is a direct consequence of EU´s inaptitude to decide goals for the sector. In the long run it will greatly benefit our global competitors rendering EU a dependent importer economy and leave our consumers without freedom of choice.

22 October 2002

OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT

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

on the communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions entitled 'Life sciences and biotechnology - A Strategy for Europe'
(COM(2002) 27 – C5-0260/02 – 2002/2123(COS))

Draftsman: Emilia Franziska Müller

PROCEDURE

The Committee on Agriculture and Rural Development appointed Emilia Franziska Müller draftsman at its meeting of 19 June 2002.

The committee considered the draft opinion at its meeting of 10 September 2002, 2 October 2002 and 21 October 2002.

At the last meeting it adopted the following conclusions unanimously.

The following were present for the vote: Joseph Daul, chairman; Friedrich-Wilhelm Graefe zu Baringdorf and María Rodríguez Ramos, vice-chairmen; Emilia Franziska Müller, draftsman (for Michl Ebner); Carlos Bautista Ojeda, Niels Busk, Arlindo Cunha, Christel Fiebiger, Jean-Claude Fruteau, Georges Garot, Lutz Goepel, Willi Görlach, María Esther Herranz García (for Christos Folias), Liam Hyland, María Izquierdo Rojo, Elisabeth Jeggle, Heinz Kindermann, Dimitrios Koulourianos, Wolfgang Kreissl-Dörfler (for Gordon J. Adam), Maria Martens (for Albert Jan Maat pursuant to Rule 153(2)), Véronique Mathieu, Xaver Mayer, Manuel Medina Ortega (for António Campos pursuant to Rule 153(2)), Karl Erik Olsson, Mikko Pesälä, Christa Prets (for Vincenzo Lavarra), Encarnación Redondo Jiménez, Isidoro Sánchez García (for Giovanni Procacci), Agnes Schierhuber, Eurig Wyn (for Danielle Auroi).

SHORT JUSTIFICATION

In recent years, the strategy to be adopted by the European Union as regards research and development in the field of biotechnology, and, in particular, the agri-food aspect thereof, has given rise to a large number of debates in Europe.

Public reaction has ranged turn and turn about between a degree of apprehension, based on fears more emotional than scientific about the impact on human health or on biodiversity in the environment, and a desire to remain part of the leading group of countries which know how to use the technologies of the future. That was shown in particular by the major study carried out by the European Commission in December 2001[1].

The European institutions, and, in particular, the European Parliament, have constantly reaffirmed that a mastery of biotechnology constitutes a priority strategic objective, provided that certain precautions are taken at ethical and technical levels, and that Europe must make up for lost time in this area and catch up with other international operators. This Commission communication forms part of that nexus and must be supported in the light of our vision of agriculture in Europe and of Europe in the world.

I. <u>New prospects for European agriculture thanks to biotechnology</u>

(a) In the countries of the European Union, consumers and the public in general are calling increasingly for agricultural production to involve fewer and fewer chemical fertilisers, pesticides and herbicides with a view to both limiting the amount of residues in the environment and protecting human health. At the same time, the pressure of international competition is requiring our farmers to maintain, or even increase, yields, while reducing inputs. Cultivation of pest-resistant plants developed with the use of biotechnology will enable us to satisfy both the expectations of our farmers and those of consumers and the general public[2].

(b) What is more, use of this technology will provide European agriculture with **new outlets** by enabling farmers to produce from plants or animals raw materials which currently have to be produced by chemical synthesis. Accordingly, the amount of energy and non-renewable raw materials used in the production process may be reduced as they are replaced by renewable resources produced by farmers (e.g. fuels, oils and lubricants, plastic substitutes, washing powders and pharmaceutical products).

(c) **The general public** will become more confident about the use of these techniques the more those techniques are properly regulated as regards research and traceability (Action 19) and backed up by a transparent information policy which will make these products and techniques much less mysterious.

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[1] 'Public perceptions of agricultural biotechnologies in Europe'. Final Report of the PABE research project, December 2001.

[2] Use of biotechnology leads to a reduction in the harmful impact of farming on the environment because the amount of pesticide used is lower. For example, the use of genetically-modified cotton in China has resulted in pesticide use being cut by three quarters.

Furthermore, in Action 17, the Commission gives a commitment that it will take measures to ensure the **sustainable co-existence** of conventional and organic farming with genetically-modified crops.

II. Strengthening the EU's role in the field of life sciences and biotechnology

(a) Biotechnology offers an opportunity to **respond to the challenges** which will confront the world in the next few decades: requirements connected with the environment, health and food.

(b) **World markets** for such products, as estimated in various studies quoted in the Commission communication, will be worth more than EUR 2 000 billion in 2010. In 2001, only 12 000 hectares of GM crops had been planted in Europe out of 53 million hectares world wide (ISAAA study 2001[1]). If Europe decides not to go for those markets, it will have to accept that it will be marginalised in less than 10 years.

(c) Each year, the European Union imports about 40 million tonnes of **animal feed**, of which 34 million tonnes are soya-based products. In the USA, more than 70% of the soya harvest comes from genetically-modified seed. We cannot ignore these facts.

(d) For more than 20 years now, a large amount of **research** involving tens of thousands of test fields has shown that the use of transgenic plants does not constitute any specific danger to mankind, animals or the environment[2].

(e) Europe already possesses the basic knowledge required to excel in this field, but that knowledge is applied in **small units**, public or private, which are unable to attract either the capital required to finance research or the best brains which they need if they are to be able to compete with the major American companies that dominate the market. What is therefore required is widespread **public support** at European level.

[1] ISAAA = International Service for the Acquisition of Agri-biotech Applications. Each year, the ISAAA publishes a global survey of commercialised transgenic crops.

[2] According to a report by Philippe Busquin, Commissioner with special responsibility for research, the EU has invested some EUR 70 million in 81 research projects into the safety of biotechnologies since 1985. More than 400 teams of scientists from various scientific disciplines have been involved in those projects. Their findings reveal that transgenic plants presented no danger to mankind, animals or the environment in any of the 81 projects.

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 on the Commission communication entitled 'Life sciences and biotechnology - A Strategy for Europe':

1. Welcomes the idea of a Commission action plan for life sciences and biotechnology and calls for the responsible use of green genetic engineering in the farming sector with consistent application of the precautionary principle;

2. Urges the institutions involved to facilitate the passage of the proposals for regulations on traceability and labelling of genetically modified organisms and on genetically modified food and feed so that, once these provisions are in force, a balanced assessment can be made of the moratorium on genetically modified organisms in the EU with a view to possibly lifting the moratorium in a way which offers scientific safeguards and does not generate public alarm;

3. Refers to the Joint Research Centre's recent study on coexistence of modified and non-modified crops, from which it emerges that coexistence will involve significant cost increases for non-modified agriculture, partly because of the structural adjustments that would be needed on farms with non-modified production; calls urgently for this kind of detrimental effect on normal agriculture to be avoided;

4. Calls for the public authorities and industry to pursue a **transparent information** policy based on scientific data; reminds the media of the major role which they play in this field and calls on them to cover the issue impartially and fairly;

5. Calls on the institutions of the European Union, and, in particular, on the Commission, to concentrate their efforts on the areas which fall within their remit, with due account being taken of the principle of subsidiarity;

6. Emphasises that the establishment of an effective, predictable and stable legal and regulatory framework constitutes a matter of urgency for biotechnology undertakings**,** farmers and consumers in the European Union if undertakings and agricultural producers are to enjoy a climate of confidence and be persuaded not to relocate to third countries and if, at the same time, consumer confidence is to be boosted;

7. Demands that products containing, consisting of or produced from GMOs are not introduced at the expense of farmers and food manufacturers who do not produce or use such products and stresses that it is therefore primarily the responsibility of the producers and users of such products to ensure that their products are not unintentionally introduced into other, conventional or organic products;

8. Calls, therefore, on the Commission and the Member States, in regard to Action 17 of the action plan, to ensure forthwith and in the context of potential market authorisation of new products containing, consisting of or produced from GMOs, that the applicants and users

of such products are responsible for taking, and do in fact take, all the necessary measures to prevent the unintentional presence of their products in other products;

9. Calls for the adoption of practicable thresholds and the immediate implementation of the Directive on the deliberate release of GMOs into the environment within the framework of an overall strategy for green genetic engineering in which products containing genetically modified material or produced therefrom must be clearly and unambiguously labelled and traceability ensured in order to give consumers the greatest possible transparency and full freedom of choice;

10. Calls on the Commission not to set thresholds for the labelling of seeds and propagating material which contain traces of genetically modified organisms, at least as long as no agreement has been reached on such thresholds for food and feed in the context of the proposal for a regulation on genetically modified food and feed (COM(2001) 425) and the proposal for a regulation on the traceability of food and feed produced from genetically modified organisms (COM(2001) 182), as otherwise Parliament's right of codecision would be nullified in respect of those regulations;

11. Notes that thresholds for the labelling of seed which exhibits adventitious or technically unavoidable traces of genetically modified organisms may be established, pursuant to Article 21(2) of Directive 2001/18/EC, only 'according to the product concerned' and only in accordance with the procedure set out in Article 30(2) of that Directive;

12. Calls on the European Commission to launch a **'B-Europe'** policy which lays down the specific political agenda for the next few years in the field of biotechnology;

13. Calls for major responsibility for coordinating the biotechnology strategy to be conferred on one Commissioner in particular and on a directorate-general created to that end so as to ensure greater consistency in Community activities;

14. Calls for the next framework research programme to give priority to research in the field of biotechnology and for more substantial financial resources to be allocated thereto;

15. Takes the view that policy, together with the industry and research, must produce better information as to risks for consumers, the environment and animals and launch a carefully formulated accompanying programme for growing genetically modified plants;

16. Calls for the introduction of a **European patent** which meets the requirements of research workers and innovators in both public research institutes and industry;

17. Calls for easier **access to risk capital**, especially for SMUs active in research into biotechnology and for public funding to become competitive with that allocated to private research;

18. Calls for the development of **bioclusters** and other models for technological transfer to be promoted in the European Union and in the applicant countries in order to stimulate investment.

19. Considers that users of biotechnological developments should bear no risk of liability under the relevant European Union legislation;

20. Calls for a practicable approach to labelling and traceability;