COUNCIL OF THE EUROPEAN UNION

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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject :	Council conclusions and roadmap for a strategy on life sciences and biotechnology

COUNCIL CONCLUSIONS AND ROADMAP

of 26 November 2002

for a strategy on life sciences and biotechnology

THE COUNCIL OF THE EUROPEAN UNION,

1. RECALLS

– the European Council's conclusions of Stockholm recognising the important contribution that biotechnology can make towards achieving the target set at the Lisbon European Council for Europe to become the most competitive knowledge-based economy with thus more and better jobs while ensuring that those developments occur in a manner which is healthy and safe for consumers and the environment, and consistent with common fundamental values and ethical principles and in full compliance with the existing legislative framework;

– the European Council's conclusions of Barcelona calling for the development of measures and a timetable which enable Community businesses to exploit the potential of biotechnology while taking due account of the precautionary principle and meeting ethical and social concerns; and recalling that overall spending on R&D and innovation in the Union should be increased with the aim of approaching 3% of GDP by 2010 and that two-thirds of this new investment should come from the private sector;

– the Council conclusions of June 2002 requesting an operational roadmap of measures to this end, indicating priorities, the various actors' responsibilities and a timetable for implementation;

2. WELCOMES the Commission Communication on a life sciences and biotechnology strategy and action plan that provides a comprehensive basis for implementation of a roadmap; AGREES with the main lines of the Commission's analysis of strengths and weaknesses of the European Union biotechnology sector and of policies and actions related hereto, as well as the identification of main areas that need action to improve further policy coherence;

3. UNDERLINES the necessity for adequate and appropriate approaches, taking into account biosafety issues related to new technologies and societal needs as well as the aim to ensure consumer freedom of choice and the safety of consumers;

4. RECOGNISES that life sciences and biotechnology offer a considerable potential in areas such as health care, agriculture/food, industrial products and processes and environmental protection, and may contribute to sustainable development; UNDERLINES that this potential should be continuously assessed on the basis of benefits and risks anticipating health, economic, social and environmental consequences and ethical aspects and that the successful development of a competitive biotechnology sector in the European Union requires a comprehensive and coordinated approach covering all major areas of application of biotechnology;

5. ACKNOWLEDGES that any effective approach which would allow harvesting the potential of biotechnology in Europe should engage all Member States and encompass all policy areas and instruments available for the sector's promotion taking into account international aspects, be balanced, including a continuing societal dialogue, a high-standard regulatory framework which is science-based, and respect diversity of views and freedom of choice;

6. ACKNOWLEDGES that the European research and innovation area will be particularly helpful in providing a structuring effect and in overcoming the fragmentation of resources and the lack of critical mass. It will also stimulate – on a voluntary basis – enhanced coordination of research and development policies and actions and greater involvement of the private sector. Research in life sciences and biotechnology may serve as a model for integrating activities addressing ethical and social aspects from the earliest possible stage;

7. ACKNOWLEDGES that a science-based, transparent, effective and proportionate regulatory framework respecting the precautionary principle is a major requirement for establishing societal, in particular, consumer confidence, which should prevent unnecessary administrative burdens in particular on small and medium-sized enterprises and stimulate responsible innovation;

8. UNDERLINES that biotechnology could, to a certain degree, contribute to sustainable progress and economic growth in developing countries while decreasing the use of resources and environmental degradation; however, the biotechnology applications must correspond to the desires of the countries concerned;

9. ACKNOWLEDGES that the Cartagena Protocol on Biosafety represents an important global legal instrument to secure the protection of biodiversity while taking into account human health and ACKNOWLEDGES the importance of the Community's participation in capacity building in third countries;

10. UNDERLINES that a comprehensive strategy needs a continuous effort to ensure policy coherence and monitoring; RECOGNISES the need for a monitoring and a regular exchange of views and experiences between Member States about creating framework conditions for the biotechnology industry and the well-functioning of markets; WELCOMES the Commission's intention to present its regular life sciences and biotechnology report including a report on the implementation of the following roadmap for the strategy on life sciences and biotechnology, together incorporating the elements listed in the following roadmap;

11. INVITES the Commission to coordinate – with the active contribution of Member States – the implementation of the road map including:

– monitoring the competitiveness of the European Union biotechnology sector and related industries, in particular the European Union framework conditions, entrepreneurship and functioning of markets, the legal framework, access to and dissemination of knowledge and technological counselling, research and innovation, access to capital, including venture capital, and public – private cooperation, societal dialogue and ethical concerns;

– monitoring and driving the implementation of the following roadmap for the strategy on life sciences and biotechnology, taking into account its social, health, environmental, safety and ethical aspects;

– working for cross-sectoral co-ordination within fields of relevance to biotechnology.

Based on a yearly report from the Commission the Council once a year should hold an in depth discussion, beginning in 2003, on the implementation of the following roadmap for the strategy on life sciences and biotechnology;

12. CALLS UPON THE COMMISSION, THE MEMBER STATES AND THE PRIVATE SECTOR AS WELL AS OTHER STAKEHOLDERS, within their respective competencies and responsibilities, to engage in defining and implementing measures in a cooperative way within the framework of the following roadmap for the implementation of the strategy on life sciences and biotechnology which sets out priorities within an indicative timetable.

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I. STRENGTHENING THE VALUE CREATION CHAIN

A. HUMAN RESOURCES

Member States should keep under review and assess, before mid-2003, future requirements in specific skills in the European Union for scientists, technicians, engineers and managers within the various life science specialities.

Member States and the Commission should

– cooperate in identifying tools, such as education modules or curriculum elements, and compare best practices to fill those needs, particularly relating to:

  - initial education: life science education at secondary school level, university and technical education resources, strengthening science interest, reduction of drop-out rate;

  - continuous professional development and lifelong learning related to biotechnology, as well as management and legal skills needed by entrepreneurial companies;

  - mobility, attraction and retention of researchers;

– collaborate with academia and industry to establish and disseminate best practices to match workforce with available positions, and improve mobility.

These measures should be operational by 2004.

Member States and the Commission call upon industry and academia to assist in developing tools and contribute within their own areas of competence, e.g. staff exchanges and in-house training and "research academy" partnerships. The Commission is invited to monitor this process and report to the Council before the end of 2004.

B. FROM KNOWLEDGE TO MARKET

Research

The Council invites the Member States and the private sector to increase or continue to increase the research resources allocated to life sciences and biotechnology, and improve the efficiency and effectiveness of national research by working to implement the European Research Area in those aspects of science, technology and engineering which specifically underpin and support biotechnology developments.

Member states should make the best use of the areas which have been identified under the Sixth Framework Programme (2003-2006) to benefit of the European Union life sciences and biotechnology industries so as to enhance their competitiveness in a coordinated manner, while taking into account views on ethical standards and social, health and safety concerns.

Intellectual Property

The Council recognises the vital importance of the proposed Community Patent for a dynamic biotechnology sector and will – in line with the Barcelona conclusions of 2002 – resolve the outstanding issues as soon as possible and invites Member States to:

– continue the transposition of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnology inventions [1] taking into account the Commission report on the development and implications of patent law in the field of biotechnology and genetic engineering. The status of transposition and practical experience in application should be reported every year to the Council – beginning in 2003;

– discuss – in close cooperation with academia – national plans for increasing awareness of the strategic uses of intellectual property in a responsible manner.

Technology transfer

Member States and the Commission should in 2003 establish an inventory of best practices for the promotion of technology transfer and subsequent support of the dissemination through networks and pilot projects.

Finance

Member States, the Commission and financial institutions should consider how to improve the financial framework for biotechnologies, and in particular:

- use the results of the collaboration between the Commission and the European Investment Bank/Fund to improve innovation finance including venture capital availability in their own innovation policies and increase investments in this area, e.g. through EIB/EIF instruments supporting late stage investments or consolidation funds;

[1] OJ L 213, 30.7.1998, p. 13.

- intensify work on a cross-national basis, e.g. by building networks between existing structures, sharing experience and exploring best practices. Results will be reported before the end of 2004.

C. NETWORKING AND CLUSTERS

The Council welcomes the Commission support for the creation of a self financed biotechnology portal for Europe, providing free access to information on available networking Internet platforms. In addition, the Commission, as it has indicated, should further develop its own website in order to provide a broad entry platform into the Commission's work on biotechnology giving all relevant actors easy access to information. This portal and the entry platform should be operational before the end of 2003.

In order to create mutual learning and develop best practices, representatives from biotechnology clusters are encouraged to exchange experiences yearly. The Commission is invited to report yearly to the Council on best practices related to biotechnology clusters.

Member States, regions and the Commission should take initiatives to stimulate interregional cooperation between biotechnology companies and institutions – including biotechnology clusters and centres of excellence.

The Commission is invited to monitor the process and the development of clusters and cooperation between clusters and report yearly to the Council beginning in 2003.

D. A PROACTIVE ROLE FOR PUBLIC AUTHORITIES

Member States and the Commission should prepare and implement on a voluntary basis a benchmarking programme in 2003, highly focussed on areas of special relevance, to assist the development of biotechnology policy through identification and exchange of best practices. Such a programme may for example include measurement of the extent of commercial development of biotechnology: the resource base (human and financial), public policies (national and sub-national) to promote the development of commercial biotechnology (e.g. technology transfer and SME support), regulatory factors including transparency and other (national and sub-national) factors affecting the business climate for commercial biotechnology, and the use of the precautionary principle.

The programme should make full use of already existing measures and involve all interested stakeholders.

The Member States and the Commission should continuously monitor and assess economic, social, health, environmental, ethical and safety factors.

II. RESPONSIBLE GOVERNANCE

A. PARTICIPATION OF SOCIETY

Societal scrutiny and dialogue

The Council joins the Commission's commitment to support an open and transparent as well as comprehensive, structured and focussed dialogue and information exchange, including all stakeholders, notably through a broadly-based Stakeholders Forum starting at the latest in 2003 as well as other targeted measures, as indicated in the Commission Science and Society Action Plan.

Member States, the Commission, academia, industry and civil society should take part in a continuous dialogue on issues of societal concern, by encouraging discussion-fora at the appropriate levels, starting at the latest in 2003.

Member States and the Commission should initiate and support the promotion of awareness of scientific paradigms underlying regulatory oversight, as well as an open and transparent public dialogue on biotechnology between all stakeholders, focussing on technological developments and potential benefits and risk. Balanced and informed debates should take place in each Member State starting at the latest before the end of 2003.

Member States and the Commission will take into account the output emerging from the abovementioned initiatives.

Ethics

The Council notes that the ethical acceptability of some areas of biotechnology is related to the diversity among Member States and is governed by national law in accordance with the principle of subsidiarity. An increased dialogue between ethical bodies in the European Union, including the European Group on Ethics in Science and New Technologies, and with the general public should facilitate the identification of different ethical standpoints and contribute to mutual understanding of their basis and exploration of where common views are possible and desirable. It is important to promote the understanding of ethical, legal and social aspects in the scientific community.

In that respect, the Council welcomes the Commission's intention to:

- before the end of 2004 strengthen and focus Community support for research into socio-economic and ethical issues and dissemination of results, including criteria for assessing the cost and benefit of using biotechnology, in order to facilitate future reporting and provide a good basis for societal decisions on the application of life sciences and biotechnology;

- fund bioethics research and ensure that the ethical, legal and social implications are taken into account at the earliest possible stages of Community-supported research by providing an ethical review of research proposals received;

- to promote the dialogue between national ethical bodies and private and public partners with a view to examine – on a case by case basis – where it might be possible to work towards Common approaches to be used e.g. in decision-making processes and as a basis for public consultation and information, taking into account the experience obtained under the Sixth Framework Programme.

B. REGULATORY FRAMEWORK

Pharmaceuticals

The Council welcomes the Commission's efforts to improve the regulatory framework for medicinal products that constitute one of the most important sectors of applied biotechnology, and will conclude discussion on the proposed review of the pharmaceutical legislation, including accelerated authorisation procedures, conditional approval and enforced scientific advice for applicant companies, in order to increase the competitiveness of the pharmaceutical sector with a high level of consumer confidence. The Commission is invited to yearly evaluate progress made in implementation and its impact.

The recommendations made by the High-Level Group on Innovation and Provision of Medicines, and the Commission's reaction to the recommendations should provide a basis to arrive at operational conclusions to be presented by 2003.

Genetically modified organisms (GMO) legislation

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release of genetically modified organisms [1] into the environment has been applicable since 17 October 2002. Its objectives are to strengthen the regulatory approval system and to provide a high level of health and environmental protection, as well as to ensure individual choice. In this context, the Council is considering the outcome of the ongoing work concerning further GMO related legislation.

[1] OJ L 106, 17.4.2001, p. 1. Directive as amended by Council Decision 2002/811/EC (OJ L 280, 18.10.2002, p. 27).

The Council encourages the Commission, Member States and other interested stakeholders to develop agronomic and other options to enable the coexistence of all different agricultural practices, considering the need to safeguard sustainability and diversity in Europe and fully apply the principle of freedom of choice for operators and consumers. Results in this respect should be included in the Commission annual report on the strategy for life sciences and biotechnology based on information coming notably from the Member States.

The Commission is invited to, as it has indicated, periodically – beginning in 2003 – publish a rolling regulatory work programme to further improve coherence, predictability, transparency and quality of the regulatory framework, applying notably the principles of:

– product authorisation on the basis of scientific risk management

– the precautionary principle

– risk management measures also taking into account other legitimate factors as appropriate

– the proportionality of risk management measures

– the transparency of procedures assessments and, as provided for by the Aarhus Convention, public participation

– consumer information and choice

– the testing and validation of control methods

– regular reviews of legislation

– the functioning of the approval system

C. INTERNATIONAL/DEVELOPMENT COOPERATION

Member States and the Commission should provide strong European Union support in order to enable developing countries and countries with economies in transition to assess and use the potential of biotechnology and to develop their own capacity for the adequate policy response, according to their needs and to the local conditions. Support should include international scientific cooperation, such as the establishment of effective research partnerships between public and private research organisations in developing countries and the European Union. Assistance should be based on the express preferences of the developing partner. Apart from assistance for application purposes, this should reinforce assistance to implement the relevant international Conventions and Agreements, for example the International Treaty on Plant Genetic Resources for Food and Agriculture, the Convention on Biological Diversity including the Cartagena Protocol on Biosafety. By the end of 2003, the Commission should report on results in this respect.