Life sciences and biotechnology: a strategy for Europe

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The Council held an exchange of views on the basis of the Commission's communication "Life sciences and biotechnology - a strategy for Europe" and adopted the following conclusions: - The Council welcomes the Commission's communication on a life sciences and biotechnology strategy action plan that provides a comprehensive basis for implementation of a roadmap. It agrees with the main lines of the Commission's analysis of strengths and weaknesses of the EU 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. The Council also 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. It 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 EU requires a comprehensive and co-ordinated approach covering all major areas of application of biotechnology. The Council 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 sectors' 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. 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, on the basis of the following points: 1) Human resources : Member States should keep under review and assess, before mid-2003, future requirements in specific skills in the EU for scientists, technicians, engineers and managers within the various life science specialities. These measures should be operational by 2004. 2) From knowledge to market: 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. The Council recognises the vital importance of the proposed Community Patent for a dynamic biotechnology sector and will resolve the outstanding issues as soon as possible and invites Member States to continue the transposition of Directive 98/44/EC on the legal protection of biotechnology inventions. The Member States and the Commission should in 2003 establish an inventory of best practises for the promotion of technology transfer and subsequent support of the dissemination through networks and pilot projects. 3) 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. 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 frombiotechnology clusters are encouraged to exchange experiences yearly. The Commission is invited to monitor the process and the development of clusters and co-operation between clusters and report yearly to the Council beginning in 2003. 4) 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. 5) Participation of society : 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. 6) Regulatory Framework : the Council welcomes the Commission's efforts to improve the regulatory framework for medicinal products. 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. In this context, the Council is considering the outcome of the ongoing work concerning further GMO related legislation. 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; - precautionary principle; - risk management measures also taking into account other legitimate factors as appropriate; - proportionality of risk management measures; - transparency of procedures assessments and, as foreseen by the Aarhus Convention, public participation; - consumer information and choice; - testing and validation of control methods; - regular reviews of legislation; - the functioning of the approval system. 7) International cooperation : Member States and the Commission should provide strong EU 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 EU. By the end of 2003, the Commission should report on results in this respect.