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**COMMUNICATION FROM THE COMMISSION**

**TOWARDS A STRATEGIC VISION OF LIFE SCIENCES AND BIOTECHNOLOGY:  
CONSULTATION DOCUMENT**

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### TOWARDS A STRATEGIC VISION OF LIFE SCIENCES AND BIOTECHNOLOGY: CONSULTATION DOCUMENT

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# Towards a strategic vision of life sciences and biotechnology:

## Consultation document

### 1. TOWARDS A COMPREHENSIVE AND STRATEGIC VISION

Scientific and technological progress in the life sciences and modern biotechnology is continuing at a breathtaking pace. At the same time, the potential benefits and implications for individuals, society and the environment have given rise to intense public debate.

At the European Council in Lisbon in March 2000, the European Union 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.

In its follow-up report of February 2001 to the Stockholm European Council under the so-called Lisbon strategy, the Commission recalled the economic, social and environmental potential of life sciences and biotechnology and, in consequence, the strategic and long-term importance for Europe of mastering these sciences and technologies and their applications. The Commission also announced its intention to present, by the end of 2001, a strategic vision of life sciences and biotechnology up to 2010 and beyond. That initiative should take a comprehensive and forward-looking perspective and propose concrete actions in the short-term to meet the challenges of tomorrow, to achieve the Lisbon objectives and to contribute to the continued public dialogue and consensus building.

Life sciences and biotechnology raise different types of issues which should be addressed at the appropriate level in accordance with the subsidiarity principle. In some areas, the Community has a clear responsibility (for example concerning trade and internal market implications as well as handling the implications of life sciences and biotechnology on existing Community policies), in others, the responsibility lies overwhelmingly with the Member States (e.g. on setting the ethical principles). The cross-cutting nature and importance of life sciences and biotechnology and their implications call for a careful reflection on overall coherence and on the involvement of civil society and stakeholders.

Life sciences and biotechnology have entered a stage of exponential growth, opening up a vast **potential** to move economies in Europe and globally towards more sustainable development and improved quality of life. They are therefore of strategic importance in Europe's quest to become a leading knowledge-based economy. Europe cannot afford to miss the opportunity that these new sciences and technologies offer.

We therefore need to address all the relevant questions, including where necessary broader and generic issues that may not be specific to life sciences and biotechnology.

We need to strengthen **competitiveness** to permit growth and the creation of highly skilled jobs. The driving factor is primarily **research** which expands the new knowledge base in life sciences and biotechnology. A main challenge will be to ensure that **innovation** successfully transforms research and inventions into viable new products and services.

Most importantly, this potential can only be realised if there is broad public support. Consequently, there is increasingly a need for awareness and enlightened policy decisions on the societal priorities, and in particular on the **societal framework** and the **ethical basis** for development and applications of the new sciences and technologies. Development and application of life sciences and biotechnology raise fundamental ethical questions such as the definition and nature of the human being and the use and control of genetic information. Some applications may also have social and economic implications, for example in terms of access to health and life insurance or through implications for agricultural practices. It is fundamental that these questions, of key importance to **public perception**, be properly addressed.

**Regulatory oversight** of biotechnology and focused **public research** must, first and foremost, ensure that the development and application of life sciences and biotechnology is safe for humans, animals and the environment (including biodiversity), taking into account all the other concerns to ensure the safe and socially acceptable development and application of life sciences and biotechnology.

The scientific and technological revolution is a **global** reality which creates new opportunities and challenges for all countries in the world, rich or poor. Europe needs to develop its policies with a clear international perspective, contributing constructively to international cooperation while defending its own interests.

The European Commission is committed to the development of sound and coherent policies in the general interest of Europe, but the key to success lies with **all stakeholders in Europe** - public authorities, science, economic operators and consumers as well as the general public.

This approach is fully in line with the proposals set out in its recent White Paper on European Governance<sup>1</sup>. There the Commission highlighted the need to open up policy-making to make it more inclusive and accountable. In particular, it focussed on improving involvement of European citizens in shaping EU policy. Democracy depends on people being able to take part in public debate. To do this, they must have access to reliable information on European issues and be able to scrutinise the policy process in its various stages. Hence, the need for institutions to communicate more actively with the general public on European issues, in particular if they are of such a sensitive nature as life sciences and biotechnology. Moreover, consultation helps the Commission and other institutions to arbitrate between competing claims and priorities and assists in developing a longer term policy perspective. As pointed out in the White Paper, this will enable the Union to guard against decisions on future policies which are inspired by short-term thinking on long-term challenges.

In preparing the policy paper, the Commission draws on 25 years of experience of developing policies and instruments related to life sciences and biotechnology. It also draws on the rich public debate which is already taking place, including in the other Community institutions and bodies and in the Member States, and input from the many professional stakeholders. In accordance with the recent White Paper on Governance, the Commission will pay specific attention to the quality of the consultative process, and to the accountability of scientific expertise.

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<sup>1</sup> COM(2001)428 final of 25.7.2001

That is why the Commission now invites comments from citizens, consumers, as well as organised civil society, scientists, public authorities and operators with economic interests in industry, agriculture or services to contribute to the Commission's reflections before finalising the policy paper by the end of 2001. But the dialogue and consultation will continue; the Commission's policy paper will itself be a base for further dialogue, and the Commission envisages to include, in the action plan, specific proposals to support and develop the dialogue.

This consultation document lays out some of the Commission's current thinking, and suggests specific questions and issues on which the Commission would particularly welcome comments. The consultation is not limited to these questions and all contributions are therefore welcome.

Comments and contributions, in this first consultation phase, must be submitted no later than **23 November 2001**. They can be addressed to the Commission by mail to "Biotechnology, BREY 7/329, European Commission, Rue de la Loi 200, B-1049 Brussels, Belgium" or via the Internet on [ec-biotechnology@cec.eu.int](mailto:ec-biotechnology@cec.eu.int). To stimulate the dialogue, comments can be published on a new dedicated Commission website <http://europa.eu.int/comm/biotechnology> upon request.

The Commission is also organising a conference in September 2001 to consult with invited stakeholders.

## **2. POTENTIAL AND IMPACTS OF LIFE SCIENCES AND BIOTECHNOLOGY**

Progress in the life sciences and biotechnology<sup>2</sup> has continuously improved the quality of life for European citizens during the last century. Europeans can expect to live longer and healthier lives than earlier generations. The supply, safety, variety and quality of food available to European consumers has never been better. Our ability to prevent pollution and other human impacts on the environment has improved enormously. However, challenges and needs in these areas remain very large and the European position needs to be set in the context of the state of the world and international competitiveness. Challenges related to health, ageing, food and the environment and the developing world all have a strong biological component and it is the new knowledge base in life sciences and biotechnology that has the potential to address the needs and expectations of society in these areas.

### ***The potential of the new knowledge base in life sciences and biotechnology***

Recent decades have seen enormous strides in the understanding of the biology, molecular structures and mechanisms, genetic basis and ecology of all living things. The new knowledge base has enabled technical innovations such as genetic engineering, cloning (however, reproductive human cloning is prohibited by the Charter of Fundamental Rights of the European Union), biocatalysis, gene testing, gene therapy and monoclonal antibodies, collectively known as biotechnology. Many commentators believe that life sciences and biotechnology following Information Technology, will be the basis for the next wave of knowledge-based economies with huge potential for improving the quality of life through the creation of highly skilled jobs, improved competitiveness and economic growth in Europe, better healthcare and new tools to address the different challenges such as protection of the environment.

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<sup>2</sup> See glossary in annex

In health care, the "post genomic" era will enable the invention and production of new diagnostic tools and treatments capable of combating human diseases which at present are uncontrollable. A revolution in health-care is anticipated through a move towards prevention rather than cure and personalised medical treatments by means of genetic medicines, genetic testing etc. This may affect the prevalence of chronic illnesses and the ability of people to cope better with chronic illnesses and thereby impact on the future health status and quality of life of older Europeans and on the cost implications of population ageing. The EU Member States spend about 1.2% of their annual GDP on pharmaceuticals or roughly €100 bn. As preventive treatment continues to replace hospital care we can expect these figures to increase over the coming years. The potential of a number of new technologies such as stem cell applications and xenotransplantation requires further investigation.

As reported by the OECD<sup>3</sup>, it appears too early to draw conclusions about the economic and environmental benefits of the current generation of genetically modified food crops. In developed countries, consumers are demanding ever-higher standards of food safety throughout the food chain as well as improved nutrition. The challenge here is to address evolving consumer demands, while ensuring that primary production and processing methods are competitive and yet safe and compatible with sustainable agricultural practices with reduced environmental impact.

In order to better protect the environment, novel approaches to industrial sustainability are urgently required. Biotechnology offers the prospect of reductions in raw material and energy consumption, as well as less pollution and recyclable and biodegradable waste, for the same level of industrial production. Biotechnology is considered to be a powerful enabling technology for developing clean industrial products and processes such as biocatalysis. Benefits have been shown for traditional industries like textiles, leather and paper. Bioremediation also has the potential to clean-up polluted air, soil and water: bacteria have been used for a number of years to clean up oil spills and purify waste water. In the energy sector, processes currently under development such as biodesulphurisation and the use of biodiesel and bioethanol seek to replace energy-intensive and polluting technologies. It appears that this positive potential remains unexploited - OECD studies suggest that many manufacturing companies could reduce their environmental impact while improving their profitability through adopting biotechnology-based processes. On the other hand, the potential long-term risks to the environment, particularly to biodiversity, of some applications of biotechnology should be taken into account.

The Food and Agriculture Organisation estimates that 80% of the increase in world food production required by population growth in the developing world will come from intensification of agriculture while 20% will come from expansion of arable land. Agronomically improved crops produced through biotechnology are likely to be important tools, although not a panacea, in solving these problems. The contribution of biotechnology to health in the third world will be dramatic with new cures for poverty-related diseases being tantalisingly near, but will depend on improved health care systems to administer them.

### ***Societal challenges***

The emerging applications of life sciences and biotechnology also coincide with and reinforce on-going societal developments and even create new and specific economic, social and legal

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<sup>3</sup> Modern biotechnology and agricultural markets: Selected issues, OECD 2000

challenges. Some of these command enthusiasm, others raise concerns among the public or with particular interest groups. In addition to safety concerns, modern biotechnology has been opposed due to the fear that it could disrupt existing socio-economic patterns. And while Europe may be faced with one set of challenges, life science and biotechnology applications pose different challenges in other socio-economic contexts elsewhere in the world, in particular in developing countries.

### *Consultation questions*

- How can the potential of life sciences and biotechnology best be harnessed while at the same time ensuring that this occurs in a manner which is safe for consumers and the environment and consistent with fundamental societal values? How can socio-economic impact best be assessed? Should a more structured approach be used to weigh societal benefits against disadvantages? To what extent should such considerations be taken into account in the regulatory approach to life sciences and biotechnology?
- Biotechnology has already delivered clear benefits for improved **medicines and healthcare**. The promise of the "post genomics era" is significant but still very much research driven. What are the prospects in the medium and long term? How can we best address ethical and socio-economic implications, such as the use of genetic testing in determining individuals' access to employment, insurance and healthcare?
- **Europe's population** is ageing. How can advances in life sciences and biotechnology help improve the health status and quality of life of ageing Europeans?
- How may the twin objectives of competitiveness of EU **agriculture** and the trend towards sustainable practices be reconciled? What may be the implications for biodiversity? What are the likely impacts of biotechnology applications on the farming community and rural development, and on agro-industrial production. How can agricultural policies best take into account application of biotechnology (at the level of inputs such as seeds and pesticides, methods of production and quality and safety of food production)? To what extent might agricultural biotechnology innovations harm the viability of conventional and organic farming and increase farmer dependency on fewer suppliers for integrated crop management and protection systems? What are the prospects for the co-existence of genetically modified, conventional and organic crops, or the assimilation of the techniques of modern biotechnology into conventional and organic farming?
- Biotechnology applications in the **food sector** have posed particular challenges, in particular because consumers have perceived few benefits from GM crops. What kind of benefits might be expected in 2<sup>nd</sup> generation crops? How can consumers best be given information and choice? Are the market mechanisms working efficiently to match supply and demand?
- The European Commission White Paper on renewable energy<sup>4</sup> stated "12% of primary energy should come from **renewable energy resources** by the year 2010". What contribution will bioprocesses make to renewable energy in the next decade and how might this sector be stimulated?

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<sup>4</sup> COM (97) 599 final

- An OECD report<sup>5</sup> indicates that many manufacturing firms are unaware of the potential of biotechnology for **cleaner production and improved efficiency and profitability**. What are the reasons for this and how can the private sector's awareness of biotechnology's potential be raised?
- What are the implications of progress in life sciences and biotechnology on **job creation**? What are the characteristics of such jobs (level of skills, duration, mobility) and what related implications are there for human resources development and in particular for education and training?
- European policies in relation to life sciences and biotechnology will reflect European values and choices. In the global context, policies may diverge in some aspects. What could be the implications of such divergencies, hereunder the prospects for the EU to achieve the strategic goal set in Lisbon in March 2000 of becoming the most competitive and dynamic knowledge-based economy in the world?

### 3. INNOVATION AND COMPETITIVENESS

The European Union must harness the new technologies at the core of the knowledge-based economy if it is to achieve the target set in Lisbon. The e-Europe programme has given a strategic dimension to information and communication technology, but in the 21<sup>st</sup> century biotechnology may become even more economically important.

#### *Commercial applications*

Commercial applications of biotechnology occur in activities related to human, animal and plant life: principally healthcare, agriculture and environmental protection. By and large, commercial biotechnology differs from conventional technologies by using biological action in place of chemical reactions; thus it can also be used in some industrial processes. In the EU the main area of commercial biotechnology research is healthcare (primarily pharmaceuticals and genomics research); in several other technologically-advanced countries, commercial biotechnology research is significantly agriculture-related. The commercial applications of biotechnology are diverse: the common factor is the technological expertise in life sciences that is needed for upstream innovation.

#### *Industrial Structure*

Commercial biotechnology is often described as being characterised by a division between “upstream” dedicated biotechnology firms (considered to represent the hard core of biotechnology innovation) and “downstream” corporations. Most dedicated biotechnology firms lack the resources that are necessary to bring a product all the way to its final market. Consequently their customers tend to be large, financially strong corporations with a deep knowledge of regulatory and legal matters. As intellectual property can cross borders freely at a click of a mouse, the downstream “market” for discoveries has a global character: corporations in the US and Europe are capable of forming trans-Atlantic partnerships with dedicated biotechnology firms.

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<sup>5</sup> Biotechnology for clean industrial products and processes: Towards industrial sustainability, OECD 1998

The further down the value chain a dedicated biotechnology firm can develop its products, the higher the costs but the greater the potential profit. In particular, a large share of biopharmaceutical costs is incurred up to the end of pre-clinical trials but as much as 75% of value is added after that point. Consequently downstream biopharmaceuticals tends to be much more profitable than the upstream sector. The structure is the same (albeit less dramatic) in other markets.

A few dedicated biotechnology firms may become large vertically-integrated companies, using their specialised knowledge to develop and market new products. But most are likely to remain small, providing services or tools for research or doing contract research for clients; some may even be constituted to develop a single idea for a set time before being voluntarily wound up. Europe's corporate regulations and fiscal frameworks need to become more flexible in order to accommodate such structural changes if the development of commercial biotechnology is not to be unnecessarily constrained.

### ***Human resources***

To an even greater extent than information and communication technology, biotechnological innovation is people-centred. Dedicated biotechnology firms need managers capable of running high-risk/high-cost enterprises, patent lawyers and technical support staff such as laboratory assistants and computer and engineering specialists. However, their greatest need is for expertise in life sciences, and this is why they tend to be located in "clusters" around technological centres of excellence such as major universities. Moreover, the presence of academic biotechnology is valuable in itself to dedicated biotechnology firms, both for basic research and for the production of new generations of biotechnology graduates. Facilities for further training and up-grading of skills will also be called for to sustain supply and qualifications of scientists and support staff.

Biotechnology clusters are only sustainable in places that succeed in producing, retaining and attracting life scientists. Producing life scientists is basically a question of education and career choice: good teaching of life sciences at pre-university level is a pre-requisite; applicants for degree courses in the life sciences then need to be encouraged by the prospect of attractive academic or professional careers in biotechnology. Retaining and attracting life scientists depends on a number of factors such as professional satisfaction, remuneration and social preferences.

Europe benefits from a very strong academic science base, with a world-class presence in many science fields. European scientists produce about  $\frac{3}{4}$  as many publicised articles and scientific citations as their American counterparts. This is encouraging, considering that US public spending on biotechnology research is some four times greater than the combined total of the comparable Member States' and Community's programmes. Nevertheless the strength of US commercial biotechnology, stimulated by high public spending on biotechnology research, has led to strong demand for life scientists there. This has stimulated a significant "brain drain" from Europe, which still has insufficient commercial biotechnology activity in comparison with academic activity.

### ***Competitiveness***

The EU's competitiveness in biotechnology can be assessed qualitatively: by the strengths of EU-based dedicated biotechnology firms and of downstream users of biotechnology, as well as by the extent to which commercial biotechnology activity adds value in the economy.

The EU now has more dedicated biotechnology firms (DBFs) than the US, but they tend to be much smaller with lower employment and research expenditure per firm. Germany has the most in the EU, followed by the UK, France and Sweden.

	<b>United States</b>	<b>European Union</b>
Number of DBFs	1273	1570
Employment in DBFs	162000	61000
Expenditure on biotech R&D	€11.4 billion	€5.0 billion
Main regional “clusters” (in approximate order of size, most DBFs first)	<b>California</b> (S.Fran’co, LA, S.Diego) <b>North-East</b> (Ma, NY, NJ, Md) <b>Others</b> (N.Carolina, Texas, Washington)	<b>Germany</b> (Berlin, Hesse/BW, Munich), <b>UK</b> (London, “Oxbridge”, C.Scotland) <b>France</b> (Paris and C.France) <b>Baltic</b> (S.Finland, Denmark/Sweden) <b>Others</b> (Eire, Milan, NL/Flanders),

Sources: Ernst & Young; associations of biotech industries

One problem is that, in comparison with the US, the EU is a poor business environment for the development of high-risk/high-gain ventures such as dedicated biotechnology firms. While Europe now has the entrepreneurs themselves, the social and legal framework still tends to discourage risk-taking and business-creation. Obstacles include bankruptcy rules that may preclude further ventures, regulatory uncertainty, lack of liquidity in the risk capital markets as well as more mundane problems such as stigmatisation of failed entrepreneurs and barriers to the reintegration of entrepreneurial scientists into academic careers.

Policy-makers should not only promote the competitiveness of dedicated biotechnology firms in Europe but also encourage other companies in Europe to use biotechnology to create value throughout the economy.

### ***Intellectual Property***

Economic value in the biotechnology industry is mainly knowledge-based. The major cost in the biotech-related industry is original research and development, a substantial part of which is pre-market clinical or safety testing required by regulation. As the costs of production and distribution are relatively low, innovators need protection from copycat competitors to stimulate research and discovery. The method used is the same intellectual protection system of patents that has served the developed world well over the last two centuries. This provides for a temporary right to exclude others from developing a product, while requiring that the information becomes publicly available. Protection of knowledge is thus vital to any innovative biotechnology company.

Directive 98/44/EC<sup>6</sup> on the legal protection of biotechnological inventions establishes a sound legal framework notably concerning the criteria that have to be fulfilled to obtain a patent in this field. In addition, the proposed Community Patent Regulation<sup>7</sup> will, when adopted, increase the competitiveness of the European companies in providing for an effective, affordable and legally sound protection and counter the present trend of biotechnology companies to prefer to patent in the US.

<sup>6</sup> OJ L 213 of 30.7.1998, p. 13

<sup>7</sup> OJ C 337 E/2000, p. 278

### *Consultation questions*

- How much difference would the establishment of a **European patents system** make to the way that innovative (upstream) biotechnology companies do business in Europe? To what extent may it encourage/facilitate the use of their inventions by other companies in Europe?
- The relationship between **academic research and actual products** lies at the heart of biotechnology development. Given that public funds only can cover a small portion of research & development needs, how should those funds be targeted? What should the continuing interest of public research institutions be in their own inventions?
- What explains the gap between Europe and the US in terms of small **start-up companies**? Is this gap related to different models of private investment in commercial biotechnology and different approaches to technology transfer? What are the policy implications?
- Are the **human resources** available adequate to man the entrepreneurial companies being set up in Europe? If not, in what fields is the shortage and, in particular, what is the implication of the increasing outflow of European life-scientists to other careers and other parts of the world? How may training, and upgrading and updating of skills, help to ensure supply and how do we recycle experience? What are the deciding factors for life science scientists choosing an **academic or entrepreneurial career**? What are the factors for their geographical preference?
- Do the **regulatory and fiscal systems** in Europe sufficiently promote innovation and competitiveness? What determines industrial **investment and location decisions**? In particular, what is the role of availability of skilled resources, the geographical proximity of the knowledge base, capital availability or the regulatory framework?
- In view of the aim to foster European competitiveness, what could be done to develop a broader **downstream industry**?
- Biotechnology product development is a long and expensive process, compared to other new technologies. Does this warrant a targeted approach to **public innovation, financing and support** measures?
- It is claimed that **clustering** companies around a research institution or a university strengthens cross-fertilisation of ideas from both. What are the benefits and disadvantages of clustering and which best practices may be established?
- Business **incubators** (public or private facilitators to host and aid start-ups in their early years) are held up as a model for successful technology transfer from academia to commercial use. What elements constitute a good incubator for biotechnology enterprises?

## **4. RESEARCH**

The life sciences revolution was born and is fed and nurtured by research. Research gives rise to questions which spur the development of new technologies which, in turn, provide the

tools that lead to new discoveries - in the cycle of research and innovation. There is an undisputed link between research, innovation, the competitiveness of industry and the generation of wealth and social prosperity. Public sector support for research stimulates academic centres of expertise which provide the ideas and creative resources that attract new and established companies alike, drawing in private sector investments. Strong European research is an essential component of a strategic vision for life sciences and biotechnology.

The issues raised by modern biotechnology and the controversy about some of its applications has also increased attention on the scientific basis for public decision-making and, in particular, its impartiality, relevance and credibility. This has underscored the recognition that science is by nature continuously evolving and not always value-free and the importance for public confidence of transparent, impartial and credible public research and scientific advice in support of public policies.

### ***Developing a European research agenda***

The Commission has proposed to restore European leadership in life sciences and biotechnology research through actions aimed at constructing a European Research area and enhancing industrial competitiveness. This effort must overcome concrete challenges such as the handling of the ever-increasing volumes of data and information and ensuring full European participation in global scientific initiatives (for example, the human or the rice genome programmes, brain research and biodiversity research), as well as address societal needs and concerns in a comprehensive way through seeking a European consensus, particularly on ethical issues. It is of utmost importance to involve scientists and researchers as closely as possible in this consensus building. This effort will adopt a global perspective, comparing European research with that of our major trading partners and pay particular attention to the complexity of living systems through multidisciplinary research. A European research agenda should address emerging needs and strengthen links to other Community policies (health, food, environment, competitiveness).

The Commission proposes to focus on the following actions:

1. Adopting the next framework programme; enhancing support for life sciences and biotechnology research; establishing a critical mass of financial and human resources; networking centres of excellence; support for infrastructures; establishing public/private partnerships; integrated training schemes; support for innovation and SMEs; finance and research; science parks. Areas of activity are the priority thematic areas of the Framework Programme proposals i.e. genomics and biotechnology for health; nanotechnologies, intelligent materials and new production processes; Food safety and health risks; sustainable development and global change; citizens and governance in the European knowledge-based society; anticipating the EU's scientific and technological needs and strengthening links to other EU policies.
2. Engaging in public dialogue; matching societal needs with research; addressing ethical aspects and fostering ethics in research, addressing socio-economic aspects; enhancing public understanding. Areas of activity: Human genetics, cloning, genetic testing, gene therapy, embryo research, stem cells, transgenic animals, genetic modification in agriculture and food production.

3. Furthering international collaborations; tackling global problems; harmonisation of standards and data validation. Areas of activity: Bioinformatics, poverty-related diseases, developing country collaboration, vaccines, TSE, clinical trials, biosafety research including improved methodologies for risk assessment, biodiversity, neuroinformatics.
4. Encouraging multidisciplinary; molecules-organisms-populations-ecosystems; multifunctionality. Areas of activity: Functional genomics; proteomics; metabolomics for human health, improved food and feed safety, functional foods; better control of pathogens (humans, animals and crops); tissue engineering and development; systems analysis of models.
5. Organising foresight; observations; surveillance. Areas of activity: All areas; prenormative biosafety research; alternatives to animal testing; genetic testing; other socio-economic questions.

### *Consultation questions*

- European research is often described as 15+1 indicating that it is fragmented and uncoordinated. Initiatives aimed at creating a **European Research Area** seek to overcome this disadvantage. How real are these problems for life sciences and biotechnology research and what is needed to ensure that we move fast enough in co-ordinating European research? What should be the **priorities for public research** in Europe within the area of life sciences and biotechnology?
- The technology is pervasive and like information technology it has potential in many sectors and applications ranging from genetic medicine to renewable sources of energy and safer and nutritionally improved foods. How may the **pre-competitive knowledge base be made freely available** to different sectors world-wide while respecting the rights of companies and researchers to receive a fair return on their investments in research?
- **Private sector research** in Europe is often considered to be less than in the US. If so, how may private sector research be encouraged?
- A strong **skill resource** is essential for the full potential of the technology to be met but there is an increasing outflow of European life-scientists to other careers and to other parts of the world. How may the supply and retention of skilled and mobile expertise be best strengthened?
- The interaction between **science and society** poses a wide range of challenges. Are our education systems sufficient to adequately prepare future generations? How can public debate be encouraged on complex and future-oriented issues, including the emerging global scientific initiatives?
- Are scientists and companies sufficiently **open about their research**, and is there a need to encourage scientists to disclose their sources of funding when publishing scientific work?
- How may research contribute to improve **scientific advice in support of public policies** in the face of a range of new challenges? How can convergence of scientific references and technical standards be encouraged, and how can openness and communication on risk and policy choices best be ensured?

- The potential of the technology also depends on an environment that is conducive to its uptake. How may research contribute to address **social impacts and ethical issues**?
- What specific actions could be launched in order to raise **awareness in industry of the potential** of life sciences and biotechnology?
- The Framework Programmes and other Community policies support a number of **horizontal activities in support of SMEs**. How can these be designed to suit the life sciences sector?

## 5. ETHICAL IMPLICATIONS

Life sciences and biotechnology address issues involving the life and death of living organisms. They raise fundamental questions of human existence and life on Earth, the very factors that have shaped the deepest religious, ethical and cultural heritage of humanity.

The EU is a community of law and of shared fundamental values and human rights while respecting differences in cultural and ethical values and public morality. This is also reflected in the EU Charter on Fundamental Rights, which contains several provisions of relevance for the subject matter of this Communication<sup>8</sup>. Consideration of ethical issues and respect for cultural and ethical values should therefore be an integral part of Community action.

The rapid progress of scientific knowledge and technological potential of life sciences and biotechnology oblige us to continuously set priorities and encourage some developments while placing restrictions on others. To do so, we need to identify, and even anticipate, the ethical issues, provide focused advice on the often technically complex matters, and make available the relevant facts to facilitate societal scrutiny and debate. In responding to ethical implications of scientific and technological progress, policy makers need to find the right balance between those issues that belong to individual conscience and decision making, and issues that call for societal responses. Within the limits of its competencies, the Community must take into account the ethical bases of Member States (which are often integrated into their constitutional and legal systems) while also promoting shared values. This process will continue to evolve with scientific and technological progress, and the challenge for all actors is therefore to maintain mechanisms and procedures to address emerging ethical issues.

The Commission's main contributions has been the establishment of the European Group on Ethics in Science and New Technologies<sup>9</sup>, the support for research in bio-ethics and the introduction of ethical principles and evaluation for Community research support. The European Group on Ethics has contributed actively to clarify the public debate, to dialogue with Member States and other interested parties and to give specific advice to guide the Community legislative process. Cross-border co-operation on research in ethics has initiated a true reflection on fundamental values and the reasons for diversity of viewpoints in Europe leading to a better mutual understanding.

<sup>8</sup> E.g. Article 3 on the protection of the integrity of the person; Article 13 on freedom of the arts and sciences; Article 17 on property rights and Article 22 on cultural, religious and linguistic diversity.

<sup>9</sup> See website of the European Group on Ethics in Science and New Technologies, [http://europa.eu.int/comm/european\\_group\\_ethics/gee1\\_en.htm](http://europa.eu.int/comm/european_group_ethics/gee1_en.htm)

### *Consultation questions*

- Member State governments and elected bodies, local authorities as well as professional and business associations have increasingly established **expert or advisory bodies**, sometimes with some executive competencies. What are the best practices for facilitating the work of such bodies, for providing useful clarifications and contributions, and for disseminating and integrating their work into policies and action? What is the potential for better networking between such bodies and what particular contribution could the Community make?
- Should the role of the **European Group on Ethics** be strengthened and are there particular issues or areas in need of advice from the Group?
- What are the prospects for developing **agreed ethical principles** and rules at the European level while at the same time respecting national, cultural and ideological differences that constitute the richness of Europe?
- What role could **democratically elected bodies** play in defining such European ethical principles and rules?

## **6. PUBLIC VIEWS AND PUBLIC INVOLVEMENT**

Over the last decade, Europe has experienced a lively public debate on a wide range of issues related to life sciences and biotechnology and with participation from all levels (ordinary citizens and consumers, NGOs, the media, commercial, professional and academic circles as well as public authorities, including at the Community level).

The defining characteristics of this debate include strong position taking and polarisation of views, but also the involvement, interest and participation of wide segments of organised civil society as well as ordinary citizens and consumers.

Divergent views and public debate demonstrate the complexity of the issues facing modern society as well as the societal, religious and cultural legitimacy of different views. It is to be welcomed that the viewpoints of the public have received growing attention along with the views and positions of professional actors and stakeholders.

This reflects the fact that life sciences and biotechnology have raised fundamental religious, ethical and cultural questions, as well as issues related to the safety for humans and the environment. Moreover, the debate on life sciences and biotechnology has coincided with - and even stimulated - growing public awareness of wider generic societal issues such as industrial food production and food safety, governance, globalisation, development policy etc. That is the reason why, in its White Paper on European Governance, the Commission noted the unprecedented moral and ethical issues thrown up by technology, which underline the need for a wide range of disciplines and experience beyond the purely scientific

In addition to the underlying issues at stake, **public perception** in the sense of ordinary citizens' interest, knowledge of and attitudes towards life sciences and biotechnology represent a challenge for all public authorities and stakeholders. The White Paper on

European Governance already stressed the importance of informing people about what is known and where uncertainty persists and the need of increasing public confidence in expert-based policy making. It is not always clear to the public who is actually deciding – experts or those with political authority. The White Paper, therefore, announces guidelines on collection and use of expert advice to provide for the accountability, plurality and integrity of the expertise used.

- **Information/knowledge:** Informed position-taking and debate is essential. Life sciences and biotechnology, their applications and wider implications, represent complex and evolving issues and there is a clear desire on the part of the public to be better informed. The question is not limited to improving the scientific knowledge base but calls for ensuring the availability of relevant information and promoting understanding on the wider issues at stake. This challenge that must be met by all interested parties, including the Commission.
- **Public dialogue:** A broad public dialogue has developed in Europe on issues related specifically to life sciences and biotechnology and has also contributed to awareness and dialogue about wider societal issues. The Commission has consistently welcomed public dialogue and has contributed where possible through dissemination of information, creation of platforms for dialogue, contributions to stakeholder events and, occasionally, by setting out its own views. The Commission believes that public dialogue can benefit further from exchange of best practices between stakeholders and actors involved.
- **Taking public concerns into account:** All parties are faced with the challenge of taking into account divergent public views in their on-going action. Public authorities, in particular, have an obligation to consult and listen to the views of stakeholders as well as to explain and justify their own action to constituents.

#### *Consultation questions*

- What are the best practices for meeting **information needs**, in particular the specific information needs as formulated by the public? How can a shared information and knowledge base be promoted?
- How can a fair representation in the **consultative process** of the different stakeholders and the transparency of their contributions best be ensured?
- What is, and what should be, the **role of different actors** such as industry, NGOs, scientists and public authorities in providing information and contributing to the public dialogue, and what can be achieved at the different levels of dialogue (local, Member State, Community and international levels)?
- What are the most useful platforms for **dialogue** (media, conferences including innovative efforts such as consensus conferences), and what possibilities exist for structuring dialogue to achieve constructive interaction between parties, to build consensus, and to ensure follow-up? How can the dialogue best address both the specific life science and biotechnology issues and their wider context? How can dialogue be organised to take into account the pluralism of views and to ensure that all legitimate interests can participate or be properly represented? In particular, what can be done to ensure appropriate participation of relatively low-profile stakeholders?

- What are the best practices for key actors such as public authorities for **consultation and involvement of the public**, and for integrating divergent public views into policy formulation and implementation?
- Although consensus-building may be an objective, public authorities normally have to act despite **stakeholder disagreement**. How can public authorities best identify the appropriate balance between societal solutions (that may impose unwanted restrictions on significant minorities) and frameworks/mechanisms that allow for freedom of choice of individuals and stakeholder groups (e.g. labelling)?

## 7. REGULATION AND GOVERNANCE

### 7.1. Regulatory issues for GMOs, including seeds, GM food and feed

In the decades after the Second World War food policy was determined by the need to increase output and efficiency in order to achieve food security. While this scenario still applies in many parts of the world, general affluence and surplus in the food supply in Europe has resulted in a gradual change in public policy focus away from efficiency and productivity towards quality and diversity in agri-food production and sustainable, environmental friendly agriculture. Modern food production methods themselves have raised matters of public concern beyond human health and safety in relation to environmental and ethical aspects of agri-food production, including sustainable development, animal health and welfare.

Recent food scares such as BSE and the dioxin crises have reinforced the change in public policy focus and also resulted in a further strengthening of regulations and safety criteria in the food and feed sectors. In the White Paper on Food Safety<sup>10</sup>, the Commission identified the need to address the issue of securing the confidence of consumers and trading partners in the European food supply. This was reconfirmed in the proposal on the General Food Law and establishing the European Food Authority<sup>11</sup> which lays down the general objectives of European food law and a number of principles, including precaution, traceability, liability and protection of consumers' interests.

Increasing concerns have also been expressed with regard to potential risks from the deliberate release of GMOs into the environment and the application of modern biotechnology to seed, food and feed although no peer-reviewed scientific evidence exists for any adverse effects to human health or the environment of the GMOs which have so far been authorised for marketing. Whilst medical applications of biotechnology have only lately become the subject of public debate, intense public and political debate has focused on GM plants and potential long-term and unintended effects on human health and the environment, including bio-diversity. Community legislation governing gene technology (as a special set of techniques of modern biotechnology) aims to ensure a high level of protection for human health and the environment (including biodiversity) as well as providing confidence for the public and legal certainty for researchers and industry.

<sup>10</sup> COM (1999) 719 final

<sup>11</sup> COM (2000) 716 final - 2000/0286 (COD)

### *Short-term regulatory issues*

The short-term regulatory issues revolve around the establishment of an efficient, effective, transparent, harmonised, stable and predictable regulatory framework governing biotechnology in the EU. This requires a consistent and coherent approach across both ‘horizontal’ and sector based legislation.

The early regulatory framework for biotechnology was founded on a ‘horizontal’ approach, which took account of the protection of both human health and the environment across relevant sectors. Directive 90/220/EEC<sup>12</sup> governed the deliberate release into the environment of genetically modified organisms (GMOs) and the placing on the market of products containing or consisting of GMOs for use as foods, feeds and seeds as well as pharmaceuticals. Directive 90/219/EEC<sup>13</sup> governs work activities involving the contained use of genetically modified micro-organisms (GMMs) (extended by the majority of Member States to include all use of GMOs under contained conditions in national laws).

As the individual sectors have continued to expand, a progressive move towards a more sector-based approach has developed, particularly in terms of the commercialisation of products. For example, pharmaceutical and medicinal applications are now largely governed under Regulation (EEC) 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products<sup>14</sup>, GM foods under Regulation (EC) 258/97<sup>15</sup> and GM seeds under the various seed Directives<sup>16</sup>. In this context, the sector-based legislation has introduced provisions to specifically address risk and other issues relevant to the sector in question although the environmental elements remain linked to Directive 90/220/EEC.

The inter-play between ‘horizontal’ and sector based legislation remains of fundamental importance in ensuring a coherent and rational regulatory approach, not least to ensure a ‘one door – one key principle’, where authorisation for all uses of a GMO may be granted via a single consent.

The current regulatory framework has been improved by the recent adoption of Directive 2001/18/EC<sup>17</sup>, which will replace Directive 90/220/EEC in October 2002. The Commission aims to complete the regulatory framework for GMOs and derived products by:

- Introducing the appropriate implementing measures and guidance as required under the provisions of Directive 2001/18/EC,
- Introducing a comprehensive traceability regime based on Directive 2001/18/EC,

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<sup>12</sup> OJ L 117 of 8.5.1990, p. 15

<sup>13</sup> OJ L 117 of 8.5.1990, p. 1

<sup>14</sup> OJ L 214 of 24.8.1993, p. 1

<sup>15</sup> OJ L 43 of 14.2.1997, p. 1

<sup>16</sup> Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/457/EEC and 70/458/EEC on the marketing of seeds; codified versions available in COM(2001) 177, 193, 196, 192, 195, 191 and 194.

<sup>17</sup> OJ L 106 of 17.4.2001, p. 1

- Ensuring a harmonised framework for authorisation and labelling of feed consisting of, containing or produced from GMOs,
- Setting up a comprehensive labelling regime which would allow consumer/users to fully exercise their choice,
- Ensuring that provisions equivalent to those in Directive 2001/18/EC are in place for all sectors (food, feed, seed etc.),
- Addressing the issue of adventitious presence of traces of GMOs and GM material, including standardised sampling and detection methodology,
- Addressing the issue of liability with respect to significant environmental damage arising from contained use of genetically modified micro-organisms within the scope of Directive 90/219/EC and deliberate release into the environment of GMOs within the scope of Directive 2001/18/EC,
- Ensuring that the provisions of the Biosafety Protocol<sup>18</sup> are appropriately implemented in Community legislation.
- When appropriate, taking into account the orientations on co-regulation included in the White Paper on Governance, executive provisions of the legislation should take proper account of the knowledge and self-regulatory capacity of the stakeholders, when they meet the criteria of general public interest.

To this end, the Commission presented in July:

- a proposal for a Regulation on traceability and labelling of GMOs and traceability of food and feed products derived from GMOs,
- a proposal for a Regulation which introduces a Community-wide authorisation system for GM food and feed, with a risk assessment performed by the European Food Authority, and a labelling scheme which will cover all GM food and feed, including derived products where no modified DNA or protein are present,

Moreover, the Commission intends to present in the near future:

- a proposal for the amendment of the seeds legislation introducing purity criteria for the adventitious presence of traces of GMOs in conventional seed lots and the labelling requirements for seeds of GM varieties,
- a proposal for a Regulation concerning the environmental risk assessment in respect of genetically modified plant varieties,
- a proposal for a Directive on the prevention and restoration of significant environmental damage to include damage from GMOs and GMMs,
- a proposal for a legal instrument implementing the provisions of the Biosafety Protocol.

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<sup>18</sup>

COM (2000) 182 final

### *Principles for future regulation and implementation*

The development of future Community legislation should remain consistent with the major objective of protecting human health and the environment and of being revised according to technical progress and new scientific findings. Moreover, other legitimate factors may be taken into account such as ethical, societal and economic factors, including innovation and competitiveness.

The Commission suggests that future regulation on GMOs should be based on the following principles:

- GMOs, including seeds, and GM derived food and feed should only be authorised if they have undergone a comprehensive scientific risk assessment and concluded to be safe for human health, animal health and the environment,
- Risk assessment should continue to be science-based and in cases where scientific evidence is insufficient, inconclusive or uncertain, and where possible risks to human health, animal health or the environment are judged to be unacceptable, measures should be based on the precautionary principle,
- Decisions to authorise GMOs, including seeds, and GM derived food and feed should be based on the outcome of the risk assessment. As with all risk management measures, other legitimate factors, such as societal, economic, traditional, ethical and environmental and the feasibility of controls, may be relevant to and taken into account in reaching such decisions,
- Community legislation should provide that consumers/users should be informed in cases where a food, feed or seed is genetically modified or derived from a GMO in order to facilitate choice,
- Risk assessments should be published and made available for public comment as part of the authorisation procedures,
- Procedures for authorisation should be transparent and should include mechanisms to address issues of concern, such as ethical and socio-economic questions,
- Community regulatory requirements should be proportionate and commensurate with the degree of identified risk and in conformity with the Community's international obligations,
- Community legislation should be feasible and enforceable.

The complexity of genetic modifications to plants is rapidly increasing. In further development and implementation of the legislative framework, it will be important to anticipate future GMOs and products derived therefrom and to develop appropriate methodologies for risk assessment, risk management and risk communication.

#### *Consultation questions*

- The speed and range of technological innovation, including gene technology, requires the continuous updating of **assessment methods**. How can the regulatory framework be developed to cater for the introduction of new GMOs, including rigorous scientific safety

assessment before placing on the market and at the same time avoid curbing innovation, research and development and thereby preventing consumers from reaping the potential benefits of future GM products?

- The **communication of risk and policy choices** is of key importance and, in particular, it must make an essential contribution to reassuring public confidence in the regulatory framework and the associated use of the technology. What are the main features of appropriate risk/benefit communication on GMO and GM products? How is risk/benefit communication most efficiently carried out and at what level - Member State level or Community level (European Food Authority) or a combination of both?
- Data from the Eurobarometer survey of 1999 could be interpreted to imply that risk evaluations should be augmented with additional **criteria that reflect the public's concern**. One of the main impediments for public acceptance of GMOs is the perceived lack of consumer benefits. Should the potential benefits of a GMO be assessed<sup>19</sup> and if so, how could the potential benefits be weighed against any risks?
- Common scientific and technical standards are essential for credible and authoritative **science-based decisions** at the Community level. How may the provision of scientific advice be improved? What steps might be taken to ensure a broad scientific consensus without ignoring minority opinions?
- Based on the information about the Commission's short-term regulatory intentions, which **other actions at the Community level** may be needed?
- Are regulatory measures needed to safeguard the multifunctionality of rural areas and the **co-existence of genetically modified, conventional and organic agriculture** and which measures could be envisaged?
- What are the benefits and disadvantages of the Community's **regulatory architecture** for authorisation of GMOs and derived products, in particular the inter-play between 'horizontal' and sector based legislation?
- Do you agree with the suggested **principles for future Community legislation** on the application of biotechnology in the agri-food sector? Are there important principles that should be added?

## 7.2. Regulation of other applications

### *Industrial biotechnology and bioremediation*

Europe is a world leader in harnessing genetically modified micro-organisms (GMM) to produce pharmaceutical compounds and industrial enzymes. The main pharmaceutical uses are production of therapeutic protein products such as insulin and growth hormones, while the industrial uses are mainly within the food and detergent industries and bioremediation. This is done in sealed systems and the final product is neither a GMM nor directly derived from one.

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<sup>19</sup> Proposals to this effect have i.a. been made by the EU/US Consultative Forum on Biotechnology in December 2000 ([http://europa.eu.int/comm/external\\_relations/us/biotech/biotech.htm](http://europa.eu.int/comm/external_relations/us/biotech/biotech.htm))

The approval procedure for such activities is covered by Directive 90/219/EEC on contained use of genetically modified micro-organisms.

To the extent that genetically modified organisms are released into the environment, e.g. for bioremediation purposes, they will have to go through the approval procedure under Directive 2001/18/EC.

### ***Non-food agricultural and silvicultural biotechnology***

Non-food agricultural GMOs need to be approved under the horizontal Directive 2001/18/EC. Trees have been developed but not yet planted commercially, with the aim of producing paper more efficiently. Such trees would be subject to prior authorisation in accordance with Directive 1999/105/EC<sup>20</sup> on the marketing of forest reproductive material. Outside the EU, cotton is already a major GM crop. Cotton does not have any food use in Europe beyond the small (and economically irrelevant) quantities consumed as cotton seed oil. Fibre and wood/paper will probably remain the main candidates in this category for some time.

There are other plants that have dual uses. Conventional rape is already used for diesel production, apart from feed and oil. If a food/feed plant is genetically modified to replace petroleum products by producing fine chemicals, but not to be used for food/feed, it will have to be approved under 2001/18/EC. If it would also be used for food or feed, a further approval under the proposed GM Food and Feed regulation would also be necessary.

A further example is a plant modified to contain and be consumed as a pharmaceutical compound, for example a plant vaccine. This modification would have to be approved by the European Agency for the Evaluation of Medicinal Products (EMA) under the Regulation 2309/93<sup>21</sup> laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use. EMA would also have to perform an environmental risk assessment equivalent to that under Directive 2001/18/EC.

### ***Pharmaceuticals***

Biotechnology is a key driver of progress in the pharmaceuticals sector, whose end-user benefits are easy to identify. Biotechnology makes possible the development of new cures; it also permits yields and quality to be improved and enables existing pharmaceutical products to be manufactured with a lesser impact on the environment.

The pharmaceuticals sector is highly regulated and is already covered by substantial Community legislation; new pharmaceutical products are subject to regulation under Directive 65/65<sup>22</sup> and its supporting legislation, notably Regulation 2309/93. Any product (whether or not a biotechnology product) that makes medicinal claims is required to meet stringent standards of quality, safety and efficacy; under Regulation 2309/93 all new products with a major biotechnological component are subject to centralised assessment by the EMA.

Given the considerable barriers to market entry of these products, the regulatory system should seek to avoid unnecessary difficulties that would impede biotechnology companies' efforts to compete and bring pharmaceutical products to market. For example, there may be

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<sup>20</sup> OJ L 011 of 15.1.2000, p. 17

<sup>21</sup> OJ L 214 of 24.8.1993, p. 1

<sup>22</sup> OJ B 022 of 9.2.1965, p. 369

scope for streamlining the approvals system in order to eliminate overlap between the new Clinical Trials Directive<sup>23</sup>, Community regulation on GMOs, and continuing local level ethics committee and regional approvals.

It costs an estimated €250 million to develop a new drug. Consequently pharmaceutical companies tend to concentrate on potential best-sellers that can be sold to millions of people: there is relatively little research into “orphan drugs” (treatments for rare diseases) and drugs to treat diseases that are common only in low-income countries. But changes in legal constraints can create incentives for pharmaceutical companies to develop “orphan drugs”: in 2000 the Commission introduced such regulation<sup>24</sup>, which, though still in the early stages of utilisation, is already having a positive impact on the use of biotechnology.

### *Consultation questions*

- The potential of the technology depends on a number of factors for its uptake. Should European **regulatory constraints** on biotechnology research and applications be limited mainly to scientific assessments of safety for humans and the environment? What role should other considerations such as social impacts, ethical issues, and public opinion play in regulatory decisions?
- To what extent, if any, does European legislation that affects biopharmaceuticals unnecessarily impede **competition and the marketing of new medicines**?
- Should European pharmaceuticals legislation be reformed further to ensure the effective development of **Orphan drugs**? If so, how?
- Should Member States and Community **tax credits and research grants** for pharmaceuticals research be more closely linked to the coverage of the costs of clinical trials, as is the case in the United States?

## **8. THE INTERNATIONAL DIMENSION**

### **8.1. Trade and international collaboration**

Life sciences and biotechnology is likely to result in the development of a growing number and variety of applications globally, many of which also result in products traded on international markets.

This development has already revealed divergent approaches between regions and nations and impacted on trade. This, together with other issues raised by these technologies, has led to increased attention to the role and impacts of life sciences and biotechnology with bilateral partners of the EU and in the context of the many instruments and fora that govern international relations.

The EU, in this field as in most others, has favoured negotiated international solutions. In this particular field, the EU has very actively supported international solutions and consensus building and promoted acceptable and viable global solutions.

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<sup>23</sup> OJ L 121 of 1.5.2001, p. 34

<sup>24</sup> OJ L 018 of 22.1.2000, p. 1

The relevant key international discussions have so far taken place in the context of Codex Alimentarius, the OECD and the Biosafety Protocol where the recognition that many safety and consumer information issues associated with biotechnology applications are similar everywhere has led to efforts to develop common approaches to key elements of environmental and human health assessment and to jointly examine other related issues such as consumer information.

### ***International governance***

The number of intergovernmental organisations dealing with different questions related to biotechnology is now rapidly growing to include, in addition to the above, e.g. FAO, WHO, WTO, UNEP, CBD, UNIDO, ICGEB, and OIE<sup>25</sup>.

Although it is justified that different international organisations address aspects of biotechnology that fall within their respective mandates, the fact that biotechnology is being discussed by several international bodies may give rise to:

- Potential overlap and some lack of focus in the international process,
- Lack of transparency and inclusiveness of the international process for NGOs, developing countries and even some OECD countries, partly due to resource constraints. The OECD has within the last 18 months organised two international conferences on issues related to GM food and crops with participation of all stakeholders and developing countries. The discussions of the conferences show that the functioning of the international system needs to be based on inclusiveness, open and balanced dialogue, transparency and access to information.

### ***The contribution and role of the EU***

The EU's efforts during recent international discussions have been mainly guided by the internal EU priorities and policies, reflecting current European needs, values and experiences. The EU has striven to incorporate the issues of precaution and more informed choice for consumers, and the EU has successfully achieved a better global understanding of its regulatory approach which has also served as a model for other countries, in particular developing ones.

However, the influential position achieved by the EU on the international scene also brings with it increased responsibilities. For the EU to continue to play a leading role on these issues, it will have to take a broad outlook and account of the needs and development choices of other parts of the world, including those of other developed countries.

In view of the existing differences in regulatory approaches between the EU and some of its major trading partners, there is a need for international convergence towards common approaches. Balanced, viable and global solutions need to be found through consensus building between different approaches and experiences.

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<sup>25</sup> Food and Agriculture Organisation, World Health Organisation, World Trade Organisation, United Nations Environmental Programme, Convention on Biological Diversity, United Nations Industrial Development Organisation, International Centre for Genetic Engineering and Biotechnology, *Office International des Epizooties*

### *Consultation questions*

- Which areas and issues lend themselves best for efforts to **converge and harmonise approaches internationally**, and how?
- Are all relevant issues being addressed by the appropriate **international bodies**? Is the mode of operation of international/intergovernmental bodies satisfactory, also in terms of transparency and involvement of the different legitimate interests? Is there a need for better co-ordination of the different international discussions? How could this best be achieved?
- What are the **EU's medium and long-term interests** in the global context?
- What are the **competitiveness and trade** prospects for Europe in the global context? What would be the economic implications of Europe becoming dependent on imports of such products and services?

## **8.2. Development policy**

### *Using biotechnology to address specific needs of developing countries*

Developing countries will sovereignly determine whether and how life science and biotechnology can serve their interests. In the context of development policies, however, the potential of life sciences for alleviating some of the problems facing developing countries must be addressed.

Developing countries can benefit from biotechnology products designed for developed countries' (healthcare, agriculture, industrial processing and environmental bio-remediation) and, in addition, they have also specific needs that biotechnology can contribute to address.

The **healthcare applications** of biotechnology that are particularly relevant to developing countries are biopharmaceuticals and vaccines to combat tropical diseases. The standard way in which new pharmaceuticals are brought to market relies on the pharmaceuticals industry being able to recoup its R&D costs in developed countries. But, as there is little purchasing power in developing countries and little or no demand in developed countries for the treatment of tropical diseases, there is no effective incentive for the development of medicines to treat them. This problem applies as much to biopharmaceuticals as to conventional pharmaceuticals, and one of the solutions seems to lie in publicly funded research efforts, allied to other capabilities that could be mobilised for the benefit of developing countries.

The other main area in which biotechnology applications can be expected to make a major contribution to addressing the particular needs of developing countries is in the promotion of **sustainable agriculture**, including livestock, fisheries and forestry. Population projections imply that demand for food in developing countries will continue to grow, and consequently that production in those countries will similarly need to rise further if their food security is to keep pace. Lessons, particularly in terms of economic and environmental sustainability, have been drawn from the use of hybrid crop varieties. This has already led to major gains in crop productivity in developing countries (the "green revolution"). In light of this, the use of GM crops in these countries should not be considered a panacea, but as one of the ways to

sustainably improve agricultural production, provided that appropriate precautions have been taken.

Biotechnology applications in **industrial processing** (such as bio-mining) and **environmental bioremediation** may also be beneficial to many developing countries, provided that they are affordable.

### ***Research efforts to address the specific needs of developing countries***

As regards the treatment of tropical diseases, biotechnology now plays a major role in pharmaceuticals. The main policy issues are already being considered as part of the broader healthcare question of developing countries' "access to medicines". One proposal is the possibility of establishing an international fund to finance research into the treatment of tropical diseases that are common in developing countries. Such medical research, at least some of which would almost certainly be biopharmaceutical, would by necessity be financed mainly by the public resources of developed countries and incorporate a strong component of research in developed countries.

Research into GM crop varieties is already under way in several developing countries: indeed, it was in China that GM farming is believed to have first begun on a commercial scale. The strongest commercial demand is still likely to be for varieties that have been designed for monoculture. Biotechnology research efforts could and should also be used to develop new GM varieties to improve yields and enable cultivation by small-scale and poor farmers without major social and environmental impacts. For example, by enhancing traits that give resistance to drought and disease, the application of biotechnology to crop science could extend the progress made in raising crop yields in developing countries. It could also reduce farmers' over-reliance on costly and environmentally damaging technology such as intensive irrigation and reduce pesticide use. However, the same technology could also lead to the depletion of fragile and marginal lands with adverse impacts on the environment. Potential applications must therefore be adequately researched and assessed, taking full account of both the environmental safety issues and the needs expressed by the populations concerned to reduce poverty and strengthen food security. Such research could be supported by the EC and Member States' co-operation programs, in particular at the international and regional level.

Although the pathways and implementation strategies are likely to differ from one country to another, developing countries will need to adapt their organisation and legislation to maximise the benefits and minimise the risks of agricultural biotechnology. New models of partnerships have to be developed through social dialogue involving the private sector, which leads in every aspect of agricultural biotechnology. Such partnerships must be based upon mutual trust and common goals in order to develop products that are adapted not only to the agro-ecology of the poorest regions but also to their social and economic systems. In this context, disclosure and sharing of test-data is an important confidence building measure.

### ***Technology transfer and capacity building***

Developing countries tend to have much smaller science bases (and few have significant centres of technological excellence) than developed countries and countries in transition. Nevertheless, with the notable exception of biopharmaceutical R&D, the cost of much biotechnology research is low enough for some R&D to be done in developing countries.

A few newly emerging economies, notably India, China and Malaysia, have identified biotechnology as an area of significant economic potential and are already undertaking their own initiatives to encourage the development of biotechnology clusters. Development assistance has a key role to play in funding capacity-building at national and/or regional levels, aimed at an integrated policy encompassing both the application of biotechnology and the necessary risk assessment and risk management capacities and tools to ensure biosafety, incl. the protection of biodiversity.

Another area in which development policy should help institutional capacity building is in relation to Intellectual Property Rights (IPRs). Effective IPRs are a precondition for the development of commercial biotechnology, which has wider benefits for social and economic development. Technical assistance is likely to be effective in the establishment and strengthening of legal institutions to enforce IPRs (which are relatively weak in most developing countries) while also helping to devise workable arrangements such as licensing to enable innovators to make wider commercial use of their IPRs.

For a more equitable sharing of benefits arising from biotechnology research and development, IPRs of local communities and indigenous people in developing countries also need to be strengthened. For this, it is important that issues related to IPRs are addressed in development co-operation and international negotiations.

#### *Consultation questions*

- How, and how far, can biotechnology's potential be harnessed to address specific **needs of developing countries**: (a) treatment of (poverty-related) tropical diseases, (b) pressures on rural communities and increasing demand for food, (c) environmental problems, (d) other development needs?
- In what respect is the impact of biotechnology on **agriculture and rural development** in developing countries different from application of other modern production methods, e.g. the use of conventional high-yield varieties? Do these differences have particular implications for development policy?
- What are the prospects for **biotechnology research in developing countries**? What are the main obstacles to application of biotechnology in developing countries?
- What impact will the **Biosafety Protocol** have on the application of biotechnology in developing countries?
- How could the international **dissemination of research and testing results** be improved? Should developing countries have the right to access the results of GMO tests?
- What are the most effective and appropriate arrangements that could be promoted to secure a more **equitable sharing of the benefits** arising from the utilisation of traditional knowledge in biotechnology?

## **9. CONCLUSIONS**

Life sciences and biotechnology are of strategic importance in Europe's quest to become a leading knowledge-based economy. Europe cannot afford to miss the opportunity that these new sciences and technologies offer.

Over the last decade, Europe has experienced a broad public debate on a wide range of questions related to life sciences and biotechnology, demonstrating the complexity of the issues facing modern society and the challenge of finding socially acceptable solutions in our pluralistic societies.

The key to resolve the apparent dilemmas lies with Europe's citizens. That is why the Commission now invites comments from citizens, consumers, as well as organised civil society, scientists, public authorities and economic operators to contribute to the Commission's reflections before finalising its policy paper by the end of 2001.

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## GLOSSARY

The following terms are commonly used in discussion of life sciences and biotechnology. The explanations given are not (necessarily) legal or complete scientific definitions but intend to make the Communication easier for non-specialists to understand.

2 <sup>nd</sup> generation crops	New Genetically Modified (GM) varieties of plants that may have traits (such as enhanced nutritional properties) that appeal directly to consumers, in contrast to 1st generation GM crops that tend to benefit the producers
Adventitious presence	Low-level, technically-unavoidable and unintended presence (for example, traces of GM products found in cargoes of similar conventional products as a result of co-mingling)
Basic research	Research that can have many indirect commercial applications but that is not necessarily commercially applicable itself
Biocatalysis	The use of a biological process to begin or accelerate a biochemical change
Biodesulphurisation	Removal of sulphur (usually from coal) by biological processes
Biodiesel	A variety of ester-based oxygenated fuel, usually made from soybean oil or other vegetable oils or animal fats
Bioethanol	Ethanol (alcohol) derived from biological material
Bioinformatics	The use of computer-based analysis to understand complex biological systems: in relation to the human genome this means using computers to generate, store, manage and manipulate DNA sequences
Bio-mining	Using biological processes to extract minerals from ores
Bioprocesses	Processes that use biologically-based components or raw materials
Bioremediation	The use of organisms or enzymes to consume or otherwise help clean up pollutants from a contaminated site
Biotechnology	The application of organisms, biological systems or biological processes to manufacturing and service industries; modern biotechnology uses recombinant DNA technology to give GMOs desirable characteristics
BSE	Bovine Spongiform Encephalopathy ("mad cow" disease), a disease affecting the central nervous system of cattle

Cloning	Producing genetically identical organisms , cells or biological molecules from one individual cell through asexual processes that do not involve the interchange or combination of genetic material
Clusters	Distinct geographical groupings of companies (that could include dedicated biotechnology firms, specialist suppliers, specialist law firms, academic ventures, etc) in locations, where there is good access to leading universities and other research institutions
Co-existence	The cultivation in the same environment of GMOs, conventional non-GM crops, and organic non-GM crops
Community-wide authorisation system	System of granting consent, valid in all EC Member States, for placing a product on the market
Contained use of genetically modified micro-organisms	Use of GMMs in a sealed system
Copycat competitors	Parties that compete with an innovative producer by making unauthorised use of its innovation
Dedicated biotechnology firms (DBFs)	Firms that are exclusively or primarily involved in biotechnology innovation
Derived products	Products produced from GMOs but no longer containing or consisting of living GMOs
e-Europe programme	An EC action plan that identified key measures on electronic commerce to enter into force by the end of 2002
Functional genomics	The study of the function of individual genes in the genome
Gene	Basic unit of genetic information (consisting of DNA and sometimes RNA); the basis for the transmission of the characteristics of living organisms from one generation to another
Gene testing	Testing of a person's genetic material for abnormalities, defects and deficiencies, including carrier status (the possibility that a health person carries particular genes that may affect his/her descendants)
Gene therapy	The insertion of genes into selected cells in the body for medical reasons; addition of a functional gene or group of genes to a cell to correct an hereditary disease
Genetic engineering (or “gene technology”)	The process by which a living organism's genetic make-up is changed by eliminating, modifying or adding copies of specific genes from other organisms through modern molecular biology techniques

Genetic medicine	The application of biotechnology to treat genetically hereditary diseases
GM (genetically modified)	A product of genetic engineering
GM food and feed	Food and feed products containing or produced from GMOs
GMM (GM Microorganism)	GMO consisting of a microbe (microscopic organism)
GMO (genetically modified organism)	A living organism in which the genetic material has been altered by genetic engineering
High-risk/high-cost	Expensive and with a high probability of commercial failure
High-risk/high-gain	Potentially very profitable but with a high probability of commercial failure
Horizontal and sector based legislation	Legislation that applies (respectively) “across the board” and to specified sectors
Hybrid crop variety	The offspring of crossing of plants of different genotypes, varieties and species. When deliberately done, the controlled cross-breeding aims to produce plants with specific desirable characteristics. The tools used were first developed in the 1920s
Industrial biotechnology	Applications of biotechnology that are used in industry (rather than food, feed or medicine)
Knowledge base	Pool of intellectual expertise
Knowledge-based economies	Economies whose capacity to create value is based mainly on intellectual expertise
Lack of liquidity in the risk capital markets	Inadequate supply of savings to financial intermediaries that are prepared to invest in high-risk/high-gain projects
Metabolomics	The study of the cell metabolism, i.e. the products of the functioning of cells, given their genetic programme
Modified DNA or protein	Certain biological materials (DNA or protein) whose characteristics have been altered by genetic engineering
Monoclonal antibodies	Structurally identical antibodies that recognise only one kind of antigen (a large molecule or small organism whose entry into the body provokes an immune system response)
Neuroinformatics	The study of the functioning of the brain using advanced information technology
Orphan drugs	Pharmaceutical treatments for diseases that are rare

Peer-reviewed scientific evidence	Science-based information that has been examined by recognised experts in the field
Post genomic era	The present era, when the sequence information of genomes allows a linking of genes with their possible functions
Pre-clinical trials	Preliminary safety testing of medical products (before testing on patients)
Pre-market clinical or safety testing	Safety testing of regulated medical/food products before they are placed on the market
Proteomics	Study of proteins encoded and expressed by a defined genome and of their interactions
Regulatory architecture	Overall approach, organisation and application of the system of formal regulations
Risk assessment	Scientific assessment of possible harm that might be caused to the environment or to human or animal health
Risk-taking	Making economic decisions in the knowledge that there is a significant probability of commercial failure
Silvicultural	Concerned with the care and cultivation of forest trees
Stem cells	Cells that can grow or differentiate into different cells/tissues of the body
Traceability	The ability to trace certain products throughout the production and distribution chains facilitating quality control and also the possibility to withdraw products
Upstream/downstream model	Economic paradigm where “upstream” activity provides key inputs for the “downstream” to make into finished goods
Vertically-integrated companies	Companies that carry out both “upstream” and “downstream” parts of a process
Xenotransplantation	The implantation of an organ or limb from one species to another species