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Subject : Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions entitled:  
"Life sciences and biotechnology - A strategy for Europe"

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COMMISSION OF THE EUROPEAN COMMUNITIES

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**COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE  
EUROPEAN PARLIAMENT, THE ECONOMIC AND SOCIAL  
COMMITTEE AND THE COMMITTEE OF THE REGIONS**

**Life sciences and biotechnology – A Strategy for Europe**

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#### Part II : Action plan

## 1. THE STRATEGIC CHALLENGES

Life sciences and biotechnology are widely recognised to be, after information technology, the next wave of the knowledge-based economy, creating new opportunities for our societies and economies.

They also raise important policy and societal issues and have given rise to a broad public debate, as confirmed in the comprehensive public consultation carried out by the Commission during autumn 2001<sup>1</sup>. These issues must be addressed with great care and sensitivity. In Europe, however, the relevant responsibilities fall across a broad range of policies and actors. In the absence of a shared vision of what is at stake and without common objectives and effective coordination, Europe has therefore only slowly and with difficulty addressed the challenges and opportunities of these new technologies.

Our democratic societies should offer the necessary safeguards and channels of dialogue to ensure that the development and application of life sciences and biotechnology take place respecting the fundamental values recognised by the EU in the Charter of Fundamental Rights.

Europe is faced with a major policy choice: either accept a passive and re-active role, and bear the implications of the development of these technologies elsewhere, or develop pro-active policies to exploit them in a responsible manner, consistent with European values and standards. The longer Europe hesitates, the less realistic this second option will be.

The Community is competent on important policy aspects of relevance, and the Commission therefore has a particular responsibility to assist in finding ways forward. The present initiative proposes a framework for this.

### 1.1. Technology revolution and policy response

*Broad and  
profound  
impacts which  
need policy  
responses*

A revolution is taking place in the knowledge base of life sciences and biotechnology, opening up new applications in health care, agriculture and food production, environmental protection, as well as new scientific discoveries. This is happening globally. The common knowledge base relating to living organisms and ecosystems is producing new scientific disciplines such as genomics and bioinformatics and novel applications, such as gene testing and regeneration of human organs or tissues. These in turn offer the prospect of applications with profound impacts throughout our societies and economies, far beyond uses such as genetically modified plant crops.

The expansion of the knowledge base is accompanied by an unprecedented speed in transformation of frontier scientific inventions into practical use and products and

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<sup>1</sup> Commission Communication "Towards a Strategic Vision of Life Sciences and Biotechnology: Consultation Document", COM (2001) 454 of 4.9.2001. The Communication, public web-comments and results of a Commission Stakeholder Conference held 27-28 September 2001 are available at <http://europa.eu.int/comm/biotechnology>.

thus also represents a potential for new wealth creation: old industries are being regenerated and new enterprises are emerging, offering the kind of skill-based jobs that sustain knowledge-based economies. As probably the most promising of the frontier technologies, life sciences and biotechnology can provide a major contribution to achieve the European Community's Lisbon Summit's objective of becoming a leading knowledge-based economy. The European Council in Stockholm in March 2001 confirmed this and invited the Commission, together with the Council, *to examine measures required to utilise the full potential of biotechnology and strengthen the European biotechnology sector's competitiveness in order to match leading competitors while ensuring that those developments occur in a manner which is healthy and safe for consumers and the environment, and consistent with common fundamental values and ethical principles.*

Europe's current performance in life sciences and biotechnology is not facilitating the achievement of that objective.

*Europe seems to be hesitating*

In Europe and elsewhere, intensive public debate has emerged. While the public debate has contributed to awareness and concrete improvements on important issues, it has also focused narrowly on genetically modified organisms (GMOs) and specific ethical questions, on which public opinion has become polarised. In the Community, like in other regions and countries, the scientific and technological progress in these areas raises difficult policy issues and complex regulatory challenges. Uncertainty about societal acceptance has contributed to detract attention in Europe for the factors that determine our capacity for innovation and technology development and uptake. This has stifled our competitive position, weakened our research capability and could limit our policy options in the longer term.

Europe is currently at a crossroads: we need to actively develop responsible policies in a forward-looking and global perspective, or we will be confronted by policies shaped by others, in Europe and globally. The technology and its applications are developing rapidly – the Commission believes that Europe's policy choice is, therefore, not whether, but how to deal with the challenges posed by the new knowledge and its applications.

## **1.2. A European Strategy**

*Dispersed responsibility – but the Commission can contribute*

The European Commission wishes to contribute actively to the reflection on these issues and to address the challenges. In September 2001, it launched a broad public consultation on the wide range of issues at stake<sup>2</sup>. These issues can only in part be addressed by the Community - most depend on many other public and private actors. In some areas such as product approvals, safeguarding the internal market, agricultural and trade policies, the Community has exclusive competence. On other aspects, the Community has no competence or shares it with Member States. The ultimate responsibility for success or failure is therefore a shared one.

But respecting the subsidiarity principle should not prevent Europeans from working together towards common goals. Within a shared vision of the long-term and global opportunities and challenges, we can develop clear strategic objectives and coherent and holistic approaches, relying also on new forms of collaboration and monitoring,

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<sup>2</sup> COM(2001) 454 of 4.9.2001

in particular through open coordination and benchmarking which underpins the Lisbon Strategy.

*The strategic priorities*

With the present initiative, the European Commission proposes a **strategy** for Europe to develop sustainable and responsible policies to address the following three broad questions:

- Life sciences and biotechnology offer **opportunities** to address many of the global needs relating to health, ageing, food and the environment, and to sustainable development. How can Europe best attract the human, industrial and financial resources to develop and apply these technologies to meet society's needs and increase its competitiveness?
- Broad **public support** is essential, and ethical and societal implications and concerns must be addressed. How can Europe deliver effective, credible and responsible policies which enjoy the confidence and support of its citizens?
- The scientific and technological revolution is a **global** reality which creates new opportunities and challenges for all countries in the world, rich or poor. How can Europe best respond to the global challenges, develop its domestic policies with a clear international perspective and act internationally to pursue its interests?

*A strategy and an action plan*

The Commission proposes a strategy to respond with responsible, science-based, and people-centred policies on an ethical basis. This strategy aims to allow Europe to benefit from the positive potential of life sciences and biotechnology (sections 2 and 3), to ensure proper governance (section 4), and to meet Europe's global responsibilities (section 5). This is a proposal for an integrated strategy – its different elements are interdependent and mutually reinforcing.

Implementing this strategy requires an open, collaborative and sustained process to develop coherent and credible policies (section 6). The Commission also proposes an **action plan** for concrete measures by the Commission and the Community, as well as recommendations for other public and private actors, respecting the subsidiarity principle.

## 2. THE POTENTIAL OF LIFE SCIENCES AND BIOTECHNOLOGY

*New solutions to real problems*

Life sciences and biotechnology are widely regarded as one of the most promising frontier technologies for the coming decades. Life sciences and biotechnology are enabling technologies - like information technology, they may be applied for a wide range of purposes for private and public benefits. On the basis of scientific breakthroughs in recent years, the explosion in the knowledge on living systems is set to deliver a continuous stream of new applications.

There is a huge need in global **health care** for novel and innovative approaches to meet the needs of ageing populations and poor countries. There are still no known cures for half of the world's diseases, and even existing cures such as antibiotics are becoming less effective due to resistance to treatments. Biotechnology already enables cheaper, safer and more ethical production of a growing number of traditional as well as new drugs and medical services (e.g. human growth hormone without risk of Creutzfeldt-Jacobs Disease, treatment for haemophiliacs with

unlimited sources of coagulation factors free from AIDS and hepatitis *C* virus, human insulin, and vaccines against hepatitis *B* and rabies). Biotechnology is behind the paradigm shift in disease management towards both personalised and preventive medicine based on genetic predisposition, targeted screening, diagnosis, and innovative drug treatments. Pharmacogenomics, which applies information about the human genome to drug design, discovery and development, will further support this radical change. Stem cell research and xenotransplantation offer the prospect of replacement tissues and organs to treat degenerative diseases and injury resulting from stroke, Alzheimer's and Parkinson's diseases, burns and spinal-cord injuries.

In the **agro-food** area, biotechnology has the potential to deliver improved food quality and environmental benefits through agronomically improved crops. Since 1998, the area cultivated with genetically modified (GM) crops world-wide has nearly doubled to reach some 50 million hectares in 2001 (in comparison with about 12.000 hectares in Europe). Food and feed quality may be linked to disease prevention and reduced health risks. Foods with enhanced qualities ("functional foods") are likely to become increasingly important as part of life-style and nutritional benefits. Plant genome analysis, supported by a FAIR research project, has already led to the genetic improvement of a traditional European cereal crop (called Spelt) with an increased protein yield (18%) which may be used as an alternative source of protein for animal feed<sup>3</sup>. Considerable reductions in pesticide use have been recorded in crops with modified resistance. The enhancement of natural resistance to disease or stress in plants and animals can lead to reduced use of chemical pesticides, fertilisers and drugs, and increased use of conservation tillage - and hence more sustainable agricultural practices, reducing soil erosion and benefiting the environment. Life sciences and biotechnology are likely to be one of the important tools in fighting hunger and malnutrition and feeding an increasing human population on the currently cultivated land area, with reduced environmental impact.

Biotechnology also has the potential to improve **non-food uses of crops** as sources of industrial feedstocks or new materials such as biodegradable plastics. Plant-based materials can provide both molecular building blocks and more complex molecules for the manufacturing, and energy and pharmaceutical industries. Modifications under development include alterations to carbohydrates, oils, fats and proteins, fibre and new polymer production. Under the appropriate economic and fiscal conditions, biomass could contribute to alternative energy with both liquid and solid biofuels such as biodiesel and bioethanol as well as processes such as bio-desulphurisation. Plant genomics also contributes to conventional improvements through the use of marker-assisted breeding.

New ways to protect and improve the **environment** are offered by biotechnology including bioremediation of polluted air, soil, water and waste as well as development of cleaner industrial products and processes, e.g. based on use of enzymes (biocatalysis).

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<sup>3</sup> <http://europa.eu.int/comm/research/agro/fair/en/be1569.html>

### 3. HARVESTING THE POTENTIAL

*The economic dimension*

The potential of life sciences and biotechnology is being exploited at an accelerating rate and is likely to engender a new economy with creation of wealth and skilled jobs. Less certain is the time profile and orientations of this development and whether Europe will fully participate.

Some estimates suggest that by the year 2005 the European biotechnology market could be worth over € 100 billion. By the end of the decade, global markets, including sectors where life sciences and biotechnology constitute a major portion of new technology applied, could amount to over € 2000 billion.

#### **Direct and indirect market potential of life sciences and biotechnology<sup>1</sup>**

Industrial	€1500 bn market globally in 2010 in sustainable industrial and environmental technology (only partly biotech) with environmental technology estimated at €90-120 bn <sup>2</sup>
Pharmaceutical	€506 bn world market in 2004 (€818 bn in 2010 assuming constant increase) <sup>3</sup>
Agricultural	Although there is a steady increase in area sown with genetically modified seeds, the future market value is difficult to predict, as it would depend on the possible development of a non-GM feed market. Million hectares world-wide <sup>4</sup> :

1998	1999	2000	2001
28	40	44	53

Allowing for the uncertainty of estimates from different sources, the above would imply that in 2010 there would be a total world market (excluding agriculture) of above 2.000 billion Euro in sectors where a major portion of the new technology and a substantial part of the total technology comes from biotechnology companies.

- 1 Beyond quoted figures, comparative data on international competitiveness in biotechnology are difficult to establish: The main value factor is knowledge, and the usual statistical data on turnover/sales/exports do not reveal the location where value in terms of intellectual property has been added
- 2 UK gov. data: from DTI's Bio-Wise programme launched in 1999: OECD: POST Report 136, April 2000
- 3 IMS Health, ([www.imshealth.com](http://www.imshealth.com))
- 4 ISAAA: International Service for the Acquisition of Agri-Biotech Applications

Europeans are also likely to become major beneficiaries of solutions offered by life sciences and biotechnology - in the form of products and services for consumers, for public benefits and throughout the production system. But to manage this development, to give us options, to project our values and policy choices internationally, and to reap the benefits of a new emerging economy, Europe should also command the knowledge base and its transformation into new products, processes and services.

### 3.1. The knowledge-base

*Mastering the  
knowledge  
base through*

...

The life sciences revolution was born in, and is fed and nurtured by, research. Public research laboratories and institutions of higher education are at the core of the science base interacting also with enterprise-based research and that of other private bodies.

The success of any knowledge-based economy rests upon the generation, diffusion and application of new knowledge. Investments in research and development, education and training and new managerial approaches are therefore of key importance in meeting the challenges posed by life sciences and biotechnology.

*- effective and  
innovative  
research*

One of Europe's main strengths is its science base; centres of scientific excellence in specific technologies exist and are at the core of regional clusters of biotechnology development. However, total European investment in R&D is lagging behind the US. Moreover, Europe suffers from fragmentation of public research support, and from the low level of interregional co-operation in R&D, among companies and institutions from different regions of several states.

The Commission aims to restore European leadership in life sciences and biotechnology research. The 6<sup>th</sup> Community Framework Programme for Research, Technological development and Demonstration activities (2002-2006) proposes this area as the first priority and will provide a solid platform for constructing, in collaboration with the Member States, a European Research Area. This should reinforce R&D capacity and help overcome existing fragmentation of research policies and efforts. When Europeans work together, maximising collaboration and minimising duplication, we can better meet major challenges such as the handling of the ever-increasing volumes of data and information and ensuring full participation in global scientific initiatives.

Moreover, European research efforts should focus on the new prospects that are opening up through multi-disciplinary research. New discoveries are made most often in when biological research is carried out in conjunction with other sciences and disciplines such as information technology, chemistry and process engineering. For example, human genome analysis into so-called "gluten allergy" may ultimately lead to the development of allergen-reduced cereals. A first fully integrated Community project has recently been launched to ensure leadership at the genomes-medicine interface where biotechnology is yielding innovative approaches to treatments of human and animal diseases.

*- research to  
meet society's  
needs*

Europe's research agenda for life sciences should be based on the needs of its citizens and attuned to our particular requirements. This calls for an approach which actively identifies the needs and opportunities presented by European societies and seeks to address them through innovative research. We need to further strengthen the links between research and other Community policies, including the scientific basis for health and safety regulations. In the same logic, it is also of utmost importance to involve scientists and researchers as closely as possible in societal consensus building. New research partnerships should also be encouraged amongst developed and developing nations to take full advantage of promising technologies and biodiversity potential, the basis for future progress.

### 3.2. Europe's capacity to offer scientific and technological solutions

*Transforming science into applications*

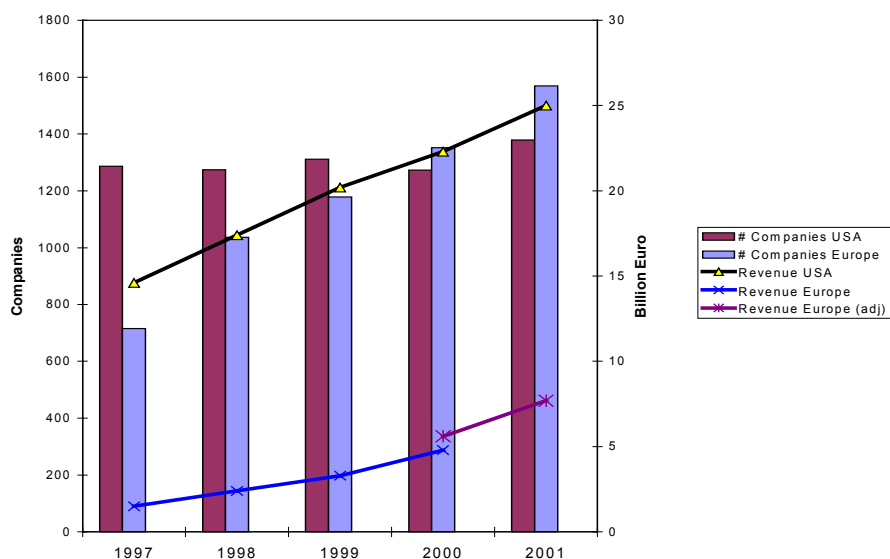
The potential for applications of life sciences and biotechnology promises to be a growing source of wealth creation in the future, leading to the creation of jobs, many of which will be highly skilled ones, and new opportunities for investment in further research.

If Europe is to benefit from this, excellence in the science-base is not enough: it is essential to have the capacity to translate knowledge into new products, processes and services, that in turn will generate benefits to society, skilled jobs and prosperity. The development of new capacity involves the encouragement of the entire research and innovation process to attract and train researchers, to attract investment and resources, and to provide a balanced and responsible legal, regulatory and policy framework.

*Europe's fragile biotechnology sector*

During the 1980s, biotechnology in Europe developed primarily within large companies whereas, unlike the US, the small company sector remained mostly stagnant. While large companies in the pharmaceutical and chemical sectors continue to exploit the technology to provide innovative products, we have seen a rapid expansion of the small companies sector in Europe in the recent past. There are now more dedicated biotechnology companies in Europe (1570), than in the US (1273). This is an encouraging demonstration of entrepreneurial potential in Europe.

**Biotechnology Industry in Europe compared to the US**



Note: European data for 2000 and 2001 are adjusted by the inclusion of the Swiss biotech company Serono

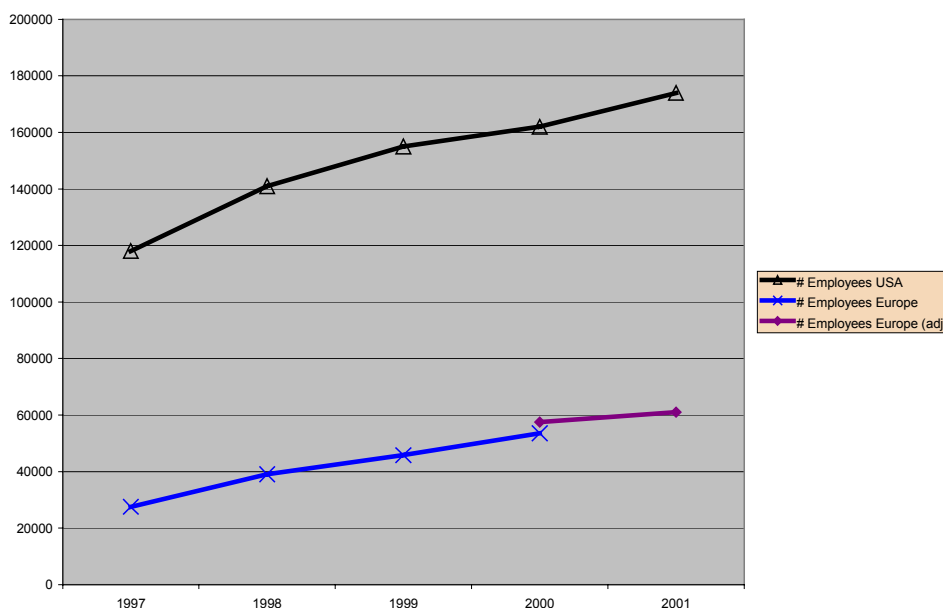
However, the European SMEs are relatively small companies, whereas the US biotechnology industry started earlier, produces more than three times the revenues of the European industry, employs many more people (162.000 against 61.000), is much more strongly capitalised and in particular has many more products in the pipeline.

The Commission's 2001 report on Competitiveness (Chapter V) analysed in detail why commercial development of EU industry currently lags behind that of the US in

the biotechnology sector. Intellectual property rights were identified as a relevant factor to be taken into account.

Structurally, biotechnology SMEs are very capital-intensive, and investments have long payback periods. Risk capital funding has been increasingly available, but does not appear to be sufficient at all stages of the long company development process. Insufficient supply of skilled personnel may develop into a major constraint for industry development.

**Comparison of Employment**



*Action for Europe's biotechnology sector*

Eliminating such bottlenecks is as important as fostering an entrepreneurial Europe with sufficient incentives for innovation and economic risk-taking to create the necessary dynamics. Europe's competitiveness should be enhanced through three main pillars for action: the resource base, networks and a pro-active role for public authorities.

- Reinforcing the **resource base** is of prime importance for this knowledge-based industry; this calls first of all for enhancing life sciences education (life-long learning for scientists, general awareness of the public). We also need training across disciplines and specialisation, including the potential for take-up of information and communication technologies in biotechnology; new ideas tend to emerge at the junction of specialisation. Scientific and engineering knowledge has to be matched with entrepreneurial management skills for successful company operation. This action pillar contributes directly to Europe's education<sup>4</sup> and employment<sup>5</sup> objectives. Comprehensive, up-to-date and publicly and freely available bioinformatics data is the basis for advances in biotechnology. In order

<sup>4</sup> 10 year-objectives in education and life-long learning

<sup>5</sup> Employment policy guidelines for 2002: improving employability; developing entrepreneurship and job creation; encouraging adaptability of businesses and their employees.

to flourish, companies need access to high quality public and private databases and tools. While maintaining strong public research, public support and intellectual property rules should encourage collaboration, especially public/private ones, that mobilise resources and support innovation. In the border region between research and application, the conditions for exploitation of knowledge, in particular well-managed risk capital and Europe-wide rules for intellectual property rights, make all the difference. The full implementation of Directive 98/44 on the legal protection of biotechnological inventions will considerably improve legal certainty for industry. The clarification of the legislative environment within the EC will provide innovative firms in the various industries using biotechnology with an incentive to continue or even increase their investments in research. In addition, the adoption of the Community patent would promote the competitiveness of the EC companies.

- We need to **network Europe's Biotechnology Communities** to facilitate open access to knowledge, skills and best practises, and to create a close community of actors and institutions involved in biotechnology. European-wide intellectual property protection must be completed to provide an affordable basis for technology transfer and co-operation. Links between the university and the industry spheres need to be strengthened. Research co-operation and technology transfer among regions and member states must be enhanced. There is a need to promote and facilitate different forms of networking and linking-up to overcome current fragmentation. Benchmarking allows the sharing of knowledge of good practices (e.g. on business clusters and incubators). An intelligent management of diversity may exploit the network benefits of regional clusters that are specialised in specific technologies.
- The fast development of biotechnology and the broad range of potential applications requires a **pro-active role for public authorities** to monitor the impact on competitiveness of the existing policy framework and to anticipate emerging issues and pro-actively adapt policies. This will need a pooling of the knowledge available to public decision-makers, through information exchange and networking.

#### 4. A KEY ELEMENT FOR RESPONSIBLE POLICY: GOVERNING LIFE SCIENCES AND BIOTECHNOLOGY

*The technology revolution calls for governance through ....*

The public debate on life sciences and biotechnology and the fundamental values affected highlight the need for responsible and coherent policies to govern these fast-moving technologies. All key stakeholders have stressed the importance of governance, i.e. attention to the way public authorities prepare, decide, implement and explain policies and actions.

The Commission proposes to apply the highest standards of governance of life sciences and biotechnology along 5 main action lines:

- Societal dialogue and scrutiny should accompany and guide the development of life sciences and biotechnology
- Life sciences and biotechnology should be developed in a responsible way in harmony with ethical values and societal goals

- Informed choice should facilitate demand-driven applications
- Science-based regulatory oversight should enhance public confidence
- Basic regulatory principles and legal obligations should be respected to safeguard the Community single market and international obligations.

#### 4.1. Societal scrutiny and dialogue

*- inclusive, informed and structured dialogue*

Life sciences and biotechnology have given rise to significant public attention and debate. The Commission welcomes this public debate as a sign of civic responsibility and involvement. Life sciences and biotechnology should continue to be accompanied and guided by societal dialogue.

Dialogue in our democratic societies should be **inclusive, comprehensive, well informed and structured**. Constructive dialogue requires mutual respect between participants, innovative approaches, and time. It should be structured in agreement with stakeholders to allow progress, for example in the provision of better information and mutual understanding. Experience also shows how important it is that dialogue takes place at the local and national levels, as well as internationally, and the Commission invites Member States and local actors to take relevant initiatives.

Dialogue should be open for **all stakeholders**. Public authorities should help to ensure participation by stakeholders with limited resources. Economic operators, industry and users, who have economic interests at stake, as well as the scientific community, bear a particular responsibility for active participation. The Commission invites these parties to respond to public concerns, for example through transparency of their visions, policies and ethical standards.

Relevant public **information** is essential for meaningful dialogue. Providing it requires focused and pro-active efforts. It is especially important that the information needs formulated by the broad public are taken seriously and responded to. We shall also strive for a balanced and rational approach, distinguishing between real issues, on which we must act, and false claims.

#### 4.2. Developing life sciences and biotechnology in harmony with ethical values and societal goals

*- balancing benefits against disadvantages*

Without broad public acceptance and support, the development and use of life sciences and biotechnology in Europe will be contentious, benefits will be delayed and competitiveness will be likely to suffer.

The debate and the public consultation carried out by the Commission<sup>6</sup> indicate that the European public is quite prepared and capable to enter into complex weighting of benefits against disadvantages, guided by fundamental values. Although sometimes polarised, the public debate demonstrates many points of converging views.

Public opinion depends crucially on the perceived benefits of life sciences and biotechnology. Eurobarometer surveys reveal that public expectations of

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<sup>6</sup> The Commission intends to publish these comments on the Internet

biotechnology, apart from medical advances, are moderate. And there is also considerable public uncertainty about some applications, and aversion towards their distributional impacts and the risks involved.

There is broad support for many guiding values and goals. Some of these, such as the freedom of research, intrinsic value of new knowledge and the moral obligations to help alleviate illness or hunger, tend to favour the development and application of these new technologies. Others help to clarify the criteria and conditions for the development and applications of life sciences and biotechnology, in particular the need to take into account the ethical and societal implications, and the importance of transparency and accountability in decision-making, minimising risk, and freedom of choice.

It is therefore of key importance to support information and dialogue to help the public and stakeholders better understand and appreciate these complex issues and to develop methods and criteria for assessing benefits against disadvantages or risks, including the distribution of impacts among different parts of society.

Our democratic societies should offer the necessary safeguards to ensure that the development and application of life sciences and biotechnology take place respecting the fundamental values recognised by the EU in the **Charter of Fundamental Rights**, in particular by confirming the respect for human life and dignity. The Community has also banned funding of research into human reproductive cloning. Support should be given to the Franco-German initiative, addressed to the UN, for a world-wide convention on the prohibition of human reproductive cloning. Other issues such as stem cell research clearly require attention and further debate. Europe has also taken clear positions on the importance of freedom of choice for consumers as well as for economic operators with respect to GM foods, and we have established broad societal agreement on the need to safeguard European agricultural practices.

However, scientific and technological progress will continue to give rise to new ethical or societal implications. The Commission considers that these issues should be addressed pro-actively and with a broad perspective, taking into account the moral obligations towards present and future generations and the rest of the world. We should not content ourselves with acting defensively only when our core values are being transgressed.

These issues cannot be adequately addressed within the narrow context of regulatory product approvals but require more flexible and forward-looking approaches. Europe needs an active and on-going public dialogue, accompanied by focused fact-finding on both benefits and disadvantages to allow the public to contribute to the complex process of setting priorities. In the context of its Science & Society initiative<sup>7</sup>, the Commission has already proposed a series of actions intended to strengthen the ethical dimension in sciences and new technologies.

To be at the front of developments, Europe should have the capacity for foresight/prospective analysis and the necessary expertise to help clarify the often complex issues for policy makers and the public, and to place them in their scientific and socio-economic context. The Commission welcomes the key role played by the

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<sup>7</sup> COM(2001)714 of 4.12.2001

**European Group on Ethics in Science and New Technologies** since its creation in the early 1990s and proposes, as part of the present strategy, to enhance its role and to reinforce the networking with and between national ethical bodies. To this end, an additional targeted consultation of the other Community institutions is envisaged.

Moreover, transparency, accountability and participatory approaches in public policy-making need to be reinforced. These objectives coincide with those of the Commission's White Paper on European Governance<sup>8</sup> and will be pursued through the actions proposed therein.

#### 4.3. Demand-driven applications through informed choice

*- giving  
consumers and  
economic  
operators  
informed choice*

The regulatory oversight applied to the development and use of life sciences and biotechnology is the expression of societal choices. Regulation and other public policy measures set the rules and conditions, under which life sciences and biotechnology may be developed and applied. Regulation should therefore ensure that market mechanisms function effectively to obtain the stated objectives. This is the purpose of Europe's policy of mandatory labelling which aims to ensure that consumer's preferences are translated into incentives for producers to adapt supply.

As far back as 1990 and after lengthy discussions, the Community opted for a science-based regulatory approach that subjects all commercial uses of genetically modified organisms to ex-ante public scrutiny and safety approval on a case-by-case basis, prior to any application, release into the environment or marketing. As a result of this approach, a revised framework legislation on GMOs has been adopted and will enter into force in October 2002. The new legislation provides a sound basis to overcome the present standstill in authorising new products.

- Under the Community's regulatory approach in sectors where pre-marketing authorisation is required, authorisation is granted after a scientific evaluation of the risks which the product may present for human and animal health or for the environment, taking into account other factors legitimate to the matter under consideration. In the logic of this approach, it is for the markets to determine whether products survive. But it is essential to ensure that the market mechanisms work effectively so that **consumers can exercise choice** and thus send clear signals to suppliers. Over the last 5 years, Europe has pioneered solutions to ensure informed consumer choice through labelling – these need urgently to be completed and put into application.
- In order to fully apply the principle of **freedom of choice for economic operators** and to safeguard sustainability and diversity of agriculture in Europe, public authorities in partnership with farmers and other private operators need to develop agronomical and other measures to facilitate the co-existence of different agricultural practices without excluding GM crops.

#### 4.4. Confidence in science-based regulatory oversight

*- fostering  
public  
confidence in  
science and  
regulation*

Where safety is an issue, Community legislation is science-based and its application with respect to specific decisions will be in accordance with the precautionary

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<sup>8</sup> COM(2001)428 final of 25.7.2001

principle<sup>9</sup>. The European Agency for Evaluation of Medicinal Products is a successful example of setting high standards of scientific advice and effective risk communication. With the creation of the European Food Safety Authority (EFSA), the already high standards of excellence, independence and transparency of scientific advice in that field will be taken further and new emphasis will be placed on risk communication. EFSA will be responsible for scientific assessments of environmental, human and animal health effects of GMOs and GM food and feed, and will have a forward-looking responsibility for identifying emerging risks, including those potentially arising from the application of biotechnology in agri-food production. These are essential contributions to public trust in the scientific basis for regulatory oversight for the safety of existing foods and medicines as well as new applications. Building public confidence and understanding must be a permanent concern.

- There is a general need to enhance public trust in the **role of science in our societies**. The Commission has proposed an action plan on Science & Society to promote scientific culture, to better take into account public needs in setting the scientific agenda, and to place science at the heart of European policies. Public authorities, economic operators and the scientific community should actively present relevant knowledge and facilitate understanding on key issues, including that scientific knowledge is always advancing and therefore regularly improves our reference points. Moreover, it is an essential part of the process of public understanding and policy formulation to also evaluate the risks of not taking action, for example against the evolution of new or drug-resistant diseases and in areas where current agricultural practices are unsustainable.
- Biotechnological inventions require high capital investment, long development cycles and comprehensive regulatory approval. Effective **patent protection** is a crucial incentive to R&D and innovation and an essential means of guaranteeing return on investment. Moreover, the disclosure of information in patent publication has been important in contributing to the overall development of biotechnology. In view of the rapid scientific progress, legislation on intellectual property needs to be monitored very closely. Regular assessments need to be made on whether the patent regime satisfies the needs of researchers and companies. In this respect, the EC and its Member States should ensure that the interpretation of the essential criteria of novelty, invention and utility in the field of life sciences is not left exclusively to courts and patent offices. As regards the international context, there is a need to work towards a level playing field in patent protection in industrialised countries. Steps need to be taken in view of promoting international dialogue on this issue.
- The basis for **Community regulation** of these new technologies should be more transparent and better communicated. For example, we should be clearer about how regulators deal with risk - potential risk, scientific uncertainty (e.g. the absence of zero-risk, the application of the precautionary principle), weighing of comparative risks, the role of the different stages of risk analysis, the role of risk management measures such as monitoring and safeguards, and their proportionality with risk. In addition, whilst underlining the importance of legal

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<sup>9</sup> Commission's Communication on the Precautionary Principle COM (2000)1 final of 2.2.2000, and the Nice European Council conclusions

certainty and predictability, we need to stress the reversibility of regulatory decisions when justified and highlight the on-going work on international convergence of risk analysis methodologies and development of anticipatory risk analysis methodologies. Publicly funded research in support of regulatory oversight is of particular importance for public confidence.

- Specific initiatives proposed in the Commission's White Paper on **European Governance** are particularly relevant for enhancing public confidence, in particular the planned improvements for openness and accountability in risk governance and in use of expertise.
- Confidence in our regulatory oversight is a responsibility of public authorities but also requires the **responsible participation of other stakeholders** such as the biotechnology industry, other economic operators, the scientific community, NGOs and the media.

#### 4.5. Regulatory principles

*- reconciling policy objectives in regulation of life sciences*

Community regulation currently governs such diverse aspects such as the patenting of biotechnological inventions, the authorisation of pharmaceutical products, contained use of genetically modified microorganisms, and release and marketing of products consisting of or derived from GMOs, including foods, feeds and seeds. This regulatory framework has evolved gradually over the last 25 years, with major developments in recent years.

In order to improve the coherence, transparency and efficiency of Community regulation, the Commission suggests that Community regulatory activity should respect the following principles:

- **Risk governance and product authorisation:** Products of biotechnology should, in accordance with the established regulatory principles and frameworks, be authorised on the basis of a comprehensive scientific risk assessment if found to be safe for human, animal or plant life and health and the environment. In cases where scientific evidence is insufficient, inconclusive or uncertain, and where possible risks are judged to be unacceptable, risk management measures should be based on the precautionary principle. Risk management should take into account the results of risk assessment and other factors legitimate to the matter under consideration in order to achieve the chosen level of protection.. Procedures for authorisation should be transparent, risk assessments should be published and made available for public comment as part of the authorisation procedures. Communication needs to be an integral part of risk assessment and risk management activity.
- **Safeguarding the Internal Market:** To secure the functioning of the Internal Market and legal certainty, Community legislation should be drafted and periodically reviewed to ensure coherence and efficiency, including with regard to its practical feasibility and enforceability. Implementation of and compliance with Community law should be carefully monitored, and any problem of compliance should be addressed and resolved among concerned parties according to existing procedures in a transparent and predictable manner.

- **Proportionality and consumer choice:** Community regulatory requirements should be proportionate to the degree of identified risk and should conform with the Community's international obligations. As proposed by the Commission, Community legislation should facilitate consumer choice through ensuring that consumers/users are informed in cases where a food, feed or seed is genetically modified or derived from GMOs.
- **Predictability, modernisation and impact assessment:** The Commission should periodically publish a rolling regulatory work programme (see point 6 below) to improve predictability, transparency and quality of regulation. Regulation should continue to be regularly reviewed to be up-to-date with scientific and technological progress, for evaluation of impacts and for conformity with the present principles.

## 5. EUROPE IN THE WORLD - RESPONDING TO GLOBAL CHALLENGES

*A global reality*

The revolution in life sciences and biotechnology is global. Research is fundamentally international - knowledge and experts circulate throughout the world. A growing number of countries are actively pursuing biotechnologies, and the resulting products and services will increasingly be traded on global markets, with a premium for first innovators.

It is also clear that great diversity exists between countries and regions with respect to their capacities to develop, regulate and apply the new products and services. Even greater diversity may emerge with respect to the priorities and societal values that will shape the approaches and choices to developing and using these new technologies.

*... which should be reflected in our policies and priorities*

European policies should not be developed in isolation. We need to embrace the wider international context which shapes both challenges and opportunities for Europe, and we must respond with responsible and proactive policies at the global level. A main objective must be to ensure that the EU maintains competitiveness vis-à-vis major industrialised countries such as the US and Japan. Moreover, whatever policies Europe will decide regarding life sciences and biotechnology, they will have important international impacts, in particular for developing countries. The interests of these countries must also be taken into account. We must integrate the international dimension into all relevant policies, and we need to develop an international agenda, based on our fundamental values and long-term objectives, to actively promote balanced and responsible policies globally, in particular towards the developing world.

### 5.1. A European agenda for international collaboration

*Managing international diversity*

International collaboration is required to manage the novel issues raised by life sciences and biotechnology and the diversity of capacities and policies in different countries and regions towards their applications.

Trade in goods and services is already being affected due to divergent product approval rates. International trade friction may also emerge if countries and regions adopt divergent regulatory frameworks. There is a need for international dialogue on

regulatory issues to develop mutual understanding of basic principles and values underlying regulatory developments in different countries.

The Community is committed to open, multilateral, and rules-based trading systems. We should therefore promote respect and implementation of existing international agreements. Given the particular issues raised by life sciences and biotechnology, the Community should promote solutions and dialogue at international level that:

- Ensure **mutual supportiveness between relevant international agreements** and in particular between the WTO agreements and the Biosafety Protocol.
- Support a coherent, comprehensive, effective, transparent and inclusive approach to biotechnology across the relevant **international fora** in order to avoid overlaps and make the best use of their respective expertise (including FAO, UNEP, CBD, WTO, WHO and UNCTAD<sup>10</sup>). Europe should continue to play a full part, in particular in the OECD and the Codex Alimentarius, and notably its *Ad Hoc* Intergovernmental Task-Force on Biotechnology, to promote within these organisations the development and periodic review of harmonised guidelines with respect to the risk analysis, the labelling and the traceability of products derived from modern biotechnology. The role and efficiency of EU participation in international discussions should be enhanced, including through discussions with developed and developing countries. Dialogue should promote mutual understanding of concerns and objectives of different countries and regions, such as the EU/US Biotechnology Forum which delivered its final report in December 2000<sup>11</sup>. Early policy dialogue about forthcoming legislation may reduce the potential for international friction.

## 5.2. Europe's responsibilities towards the developing world

*Potential to meet the urgent needs of the developing world*

Life sciences and biotechnology hold the promise of meeting some of the fundamental needs for food and health facing the developing world. The UNDP, in its 2001 Human Development Report, highlights the potential of biotechnology for the developing world<sup>12</sup>. Some emerging economies such as China, India and Mexico have already initiated ambitious national development programmes.

Life sciences and biotechnology are not a panacea and will not resolve the distributional problems of the developing world – but they will be one of the important tools. New capacities should help developing countries reconcile yield increases, sustainable use of natural resources, economic efficiency and social acceptability. Potential applications must 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 and nutritional quality.

*Putting European capacities to the service of developing countries*

As a major actor in life sciences and technologies, Europe has a particular responsibility to help the developing world deal with the risks, challenges and

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<sup>10</sup> Food and Agriculture Organisation, United Nations Environmental Programme, Convention on Biological Diversity, World Trade Organisation, World Health Organisation, United Nations Convention on Trade and Development

<sup>11</sup> [http://europa.eu.int/comm/external\\_relations/us/biotech/biotech.htm](http://europa.eu.int/comm/external_relations/us/biotech/biotech.htm)

<sup>12</sup> <http://www.undp.org/hdr2001/>

opportunities, and to facilitate the safe and orderly development of these technologies at the global level. Europe already holds an influential position in international deliberations on life sciences and biotechnology. This needs to be taken forward with responsible policies to achieve our strategic objectives and to allow the safe and efficient use of life sciences and biotechnology in developing countries.

- Europe should continue to promote protection of biodiversity and the implementation of the Biosafety Protocol for international trade in living modified organisms. Moreover, Europe should continue to support **negotiated multilateral frameworks** such as the Convention on Biological Diversity and the FAO International Undertaking on Plant Genetic Resources. These international instruments regulate access to genetic resources and the sharing of the benefits arising from their use, in view of providing compensation to the centres of origin of genetic resources and the holders of traditional knowledge used in biotechnological inventions. The EC should contribute to ensure that the benefits generated by biotechnological inventions, including intellectual property income, are properly shared with the providers of genetic resources or traditional knowledge.
- Europe should contribute to **technical assistance, capacity-building and technology transfer** to allow developing countries to participate in negotiating and implementing international agreements and standards, notably on risk governance, and to safely develop and apply these new technologies if they so wish. Europe should support local initiatives for dialogue on biotechnology among public and private stakeholders and civil society in partner countries.
- Europe should encourage equitable and balanced **North-South partnerships and public research** for demand-driven applications of life sciences and biotechnology.
- **Domestic European policies** with regard to life sciences and biotechnology are bound to have major impacts on developing countries. Whilst not compromising EU food safety requirements or consumer information policies, we should provide technical assistance and capacity building to ensure that our policies do not, unwittingly, prevent developing countries from harvesting desired benefits. In particular, we should guard against regulatory requirements that may be manageable only in the industrial world but are unachievable by developing countries, thereby either upsetting existing trade or effectively blocking developing countries from developing life sciences and biotechnology at their own wish and pace.

## 6. IMPLEMENTATION AND COHERENCE ACROSS POLICIES, SECTORS AND ACTORS

*Overcoming dispersed responsibilities through collaboration*

Europe does not have a single policy for life sciences and biotechnology but a patchwork of specific regulation, overlaid by many sectoral and horizontal policies at international, Community, Member State and local levels. If, with so many actors and policies involved, Europe is to successfully manage life sciences and biotechnology and reap the benefits for society, we should proceed on the basis of a shared vision for a co-operative approach and with effective implementing mechanisms to compensate for absence of overall responsibility and control. Without

such mechanisms, life sciences and biotechnology risk to continue to suffer indecision or short-sighted and local solutions.

*Implementation through ...* The Commission proposes to structure and support implementation of the present strategy and the enclosed action plan through the following measures:

- *monitoring*
  - To **monitor progress** in policy development and on the ground, and to **anticipate emerging issues** in this fast-developing area, the Commission will, starting in 2002 and ending in 2010, present a regular Life Science and Biotechnology Report, including a rolling work programme for legislation.
- *coherence of EU policies*
  - We need to ensure **coherence across Community legislation and policies** directly regulating, or indirectly impacting on, the development and application of life sciences and biotechnology. The Commission will, as part of its Life Science and Biotechnology Reports, review the coherence of Community policies and legislation affecting life sciences and biotechnology and launch initiatives and proposals as appropriate. Particular attention will be given to ensure that regulation on life sciences and biotechnology adequately integrates our international objectives and facilitates innovation and international competitiveness, that Community research contributes coherently and effectively to Community objectives, and that other Community policies and objectives (e.g. in environment, public health and consumer protection, education, employment, agriculture, trade and development policies) adequately reflect the long-term and global importance of life sciences and biotechnology. The Commission will evaluate whether existing international fora and bilateral dialogues are sufficiently effective and provide adequate flow of information, and whether the domestic coordination mechanisms can be improved.
- *coordination and benchmarking*
  - Where **different levels of competence** apply, the strategy should be a reference for collaboration between different actors (Community, national and local public authorities, economic operators, the scientific community etc). As part of the Lisbon strategy, coherent action for life sciences and biotechnology should be pursued through the established methods of coordination and benchmarking. In addition, new forms of collaboration and partnerships between stakeholders should be encouraged. Together with Member States, the Commission will also assess whether current patterns of competence and mechanisms of co-operation allow the effective achievement of the strategic objectives, incl. reassess whether there is a need for reinforcing Community competence in accordance with the Treaty.
- *political attention*
  - The Commission invites all institutions and public actors to strive for better coherence in their action. For its own part, it will seek to provide the **vigilance and political impetus** to keep momentum in implementing the present strategy, through its own action or through recommendations and invitations to other parties. The Commission intends to hold more regular orientation debates, coinciding with the adoption of the above mentioned Commission Life Science and Biotechnology Report.
  - In order to facilitate transparency and structured dialogue on the further development and implementation of the proposed strategy for life sciences and biotechnology, the Commission will organise a broadly based **Stakeholders' Forum**, including representatives of the candidate countries and third countries.

## 7. A FRAMEWORK FOR DIALOGUE AND ACTION

*A framework  
for action now  
and for  
developing  
future action*

It is time to clarify the strategic opportunities and challenges facing Europe. Life sciences and biotechnology are a global reality and essential for the objective of developing dynamic and innovative knowledge-based economies. We have to face the difficult questions and identify our strategic objectives to avoid the pitfalls of short-term solutions to long-term challenges and of local solutions to global challenges.

Recognising that life sciences and biotechnology raise particular challenges, the Commission undertook to propose a strategy and concrete actions. It now presents this initiative for a coherent, collaborative and sustained effort.

The present initiative draws on a thorough analysis<sup>13</sup> of the strengths and weaknesses of European biotechnology, and a broad public debate and the specific public consultation launched by the Commission in September 2001. The initiative should, in turn, itself inspire further dialogue. The attached action plan suggests a broad scope of measures according to the orientations set out in chapters 3 to 6 of this Communication. It constitutes a framework, within which some actions can be launched in the short-term while other actions for the medium and longer term are identified and suggested for further development in collaboration with Member States and stakeholders.

The Commission now invites the Community institutions and bodies, the Member States, protagonists and the public to contribute to refine and implement the proposed strategy by defining detailed measures under both short- and medium-term actions and the time-plan for their deliverables, as a first decisive step towards an effective and coherent European biotechnology policy.

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<sup>13</sup> European Competitiveness Report 2001, Luxembourg 2001; ["Innovation and Competitiveness in European biotechnology"](#), Enterprise Papers - N° 7, 2002, European Commission

## PART II: ACTION PLAN

### 1. HARVESTING THE POTENTIAL

#### THE RESOURCE BASE

#### Investing in People

##### Action 1

The Commission will together with competent authorities in Member States<sup>1</sup> identify the education needs in life sciences within the *10-year Objectives for Learning in the Knowledge Society*<sup>2</sup> and:

- a) **strengthen a broad education** and understanding of life sciences,
- b) **develop and train a skilled workforce** in life sciences,

by issuing recommendations for curricula and teacher training. Community support can be provided under the Comenius and Erasmus programmes.

- c) As set out in its *Communication on the European area of Lifelong learning*<sup>3</sup>, the Commission will work with Member States, industry, academia and others to identify measures to promote **continuing education** and refresh the current competence of the scientific workforce. Community support can be provided under the Leonardo programme.
- d) The Commission and Member States should support discussion fora for specialist scientists, with the objective of stimulating **an exchange across disciplines**. Vital discoveries frequently happen at the point where disciplines intersect. Community support can be provided under the Erasmus programme.

**Implementer: Member States, Commission, private sector**

**Timeframe: 2003-2010**

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<sup>1</sup> Where reference is being made to the Member States in the action plan, the Commission will examine with interested candidate countries their participation.

<sup>2</sup> Education Council Report to the European Council 5980/01

<sup>3</sup> COM(2001) 678

## Action 2

The Commission will explore with Member States

- a) the opportunity and best way to establish efficient methods **to match a skilled workforce with job opportunities**, involving effective communication of open positions, collaboration with established companies and a labour force aware of available employment options.
- b) possible measures to **attract and retain scientists** and avoid brain drain. In achieving this, specific reference will be paid to the initiatives launched under the Communication «A Mobility Strategy for the Research Area»<sup>4</sup>, which aims at improving the overall environment of researchers and their families in the EU. Due attention will also be paid to the increased mobility opportunities offered by the forthcoming Sixth Framework Programme (2002-2006), and more particularly to the measures aimed at attracting foreign researchers and supporting the return of EU researchers established in other parts of the world.

**Implementer: Member States, Commission**

**Timeframe: 2003 onwards**

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<sup>4</sup> COM(2001)331final, of 20 June 2001, as supplemented by the Council's Resolution of 20 December 2001 concerning «The Reinforcement of the Mobility Strategy within the European Research Area ».

## Generating and exploiting knowledge

### Research

#### **Action 3**

The Commission will enhance its **support for life sciences and biotechnology research, technological development, demonstration and training activities** under the next Framework Programme 2002-2006 aimed at contributing towards the creation of the European Research Area.

Biotechnology research will be supported under the thematic priorities, including:

- 1: Genomics and biotechnology for health
- 3: Nanotechnologies
- 5: Food quality and safety
- 6: Sustainable development
- 7: Citizens and governance

Specific measures will be provided to encourage SME participation, international cooperation and mobility and training of researchers.

The new instruments of Networks of Excellence and Integrated Projects will facilitate the objectives of Europe-wide collaborations, attaining critical mass and simplification of administrative procedures.

The Commission and the Member States should also in collaboration with the European Investment Fund (EIF) develop **a competitive bioinformatics infrastructure** in support of biotechnology research and focus support for the development of research in computational biology and bio-medical informatics.

**Implementer: Member States, EIF, Commission**

**Timeframe: 2002-2006**

### Management and legal services

#### **Action 4**

Enhancing the supply of specific management and legal skills:

- a) Member States and national biotechnology associations should examine the opportunity of creating self-sustained **networks of biotechnology company managers** at the national level.
- b) Member States and the Commission should promote collaboration between law schools, law firms and companies for the **development of specific legal competence** needed by biotechnology companies.

**Implementer: Member States, academia, professional associations, Commission**

**Timeframe: 2003 onwards**

## Exploitation of intellectual property

### Action 5

**A strong, harmonised and affordable European intellectual property protection system, functioning as an incentive to R&D and innovation** will be finalised by:

- a) Member States urgently transposing into national laws the Directive on the Legal Protection of Biotechnological Inventions EC/98/44.
- b) Council adopting the Community Patent Regulation.
- c) Member States and the Commission clarifying rules on ownership of intellectual property stemming from public research and monitoring the effect of implementation of patent legislation on research and innovation.
- d) encouraging awareness training in the strategic use of IPR during the entire research and innovation process and raising awareness among academics of the commercial potential of their research, encouraging entrepreneurship and movement between academia and companies.
- e) taking steps to promote international dialogue and co-operation with a view to work towards a level playing field with industrialised countries in patent protection on biotechnology inventions, ensuring an effective level of protection for innovation in this field.

**Implementer: Member States, Council, Commission**

**Timeframe: 2002 onward**

## Capital base

### Action 6

The Commission should together with the European Investment Bank (EIB) and the European Investment fund (EIF) **strengthen the capital base for the biotechnology industry**, by:

- a) seeking to stimulate investments in research and technological innovation via complementary financing on the basis of the co-operation agreement signed in June 2001 between the Commission and the EIB group.
- b) seeking to stimulate investments in business incubators through the EIF Start Up Facility
- c) studying measures to support technology transfer mechanisms, such as financing of patent pools or other methods for patent exploitation.
- d) studying measures to encourage commercial financing of companies based on a medium-term investment perspective.

**Implementer: EIB Group, Commission**

**Timeframe: 2002 onwards**

### Action 7

The Commission will strengthen the work of the **Biotechnology and Finance Forum** by the inclusion of relevant major stakeholders to provide advice into policy development in the field of capital supply.

**Implementer: Commission**

**Timeframe: 2002**

## NETWORKING EUROPE'S BIOTECHNOLOGY COMMUNITIES

### Networks in Europe

#### Action 8

The Commission will:

- a) support creation of a **commercial biotechnology web portal for Europe** that will help free access to information and networking available Internet platforms. The contents of such a portal will have to be defined based on the requirement of economic viability and sustained demand.
- b) develop its newly created Commission web site to provide a **broad entry platform into the Commission's work on biotechnology**.

**Implementer: Commission**

**Timeframe: 2002-2003**

#### Action 9

Member States, their regions, the Commission and EIB should support:

- a) **stronger interregional co-operation**, e.g. through a network of biotechnology regions. Crossborder and interregional co-operation can receive funding from the Interreg programmes (notably Interreg IIIB and IIIC).
- b) **networks of biotechnology clusters**. In addition, the Commission will organise a European competition between Biotechnology Innovation clusters, to highlight their capability to develop a cluster with a focus of excellence in a specific scientific field.

**Implementer: Member States, Regions, EIB, Commission**

**Timeframe: 2003-2006**

## A PROACTIVE ROLE FOR PUBLIC AUTHORITIES

### Action 10

The Commission will establish

- a) a **competitiveness monitoring function and a contact network with Member States ministries with responsibility for competitiveness in biotechnology**. Monitoring should include impact on European competitiveness of legislation and policy measures.
- b) a **Competitiveness in Biotechnology advisory group** with industry and academia to assist in identification of issues affecting European competitiveness. The Group will provide input into the Commission's regular reports on Life Sciences and Biotechnology.

**Implementer: Member States, Commission**

**Timeframe: 2002**

### Action 11

Transparency in the administrative process:

- a) The Commission and Member States, as regulatory authorities, should **aid applicants**, especially from start-up companies and SME's, requesting approval through the regulatory process.
- b) The Commission will issue a **guide to Community regulation** for users and for entrepreneurs who have limited staff and expertise in the regulatory and legal fields. Such a guide should also benefit non-EU (e.g. developing world) applicants and the general public.

**Implementer: a) Member States, Commission. b) Commission**

**Timeframe: 2003 onwards**

### Action 12

In collaboration with the involved actors, the Commission will **benchmark good practices in clustering biotech companies and in the work of business incubators** and disseminate results. The Commission will also establish with Member States a programme for **benchmarking** relevant elements of **biotechnology policies**, in addition to existing benchmarking structures.

**Implementer: Commission**

**Timeframe: 2003 onwards**

## 2. A KEY ELEMENT FOR RESPONSIBLE POLICY: GOVERNING LIFE SCIENCES AND BIOTECHNOLOGY

### SOCIETAL SCRUTINY AND DIALOGUE

#### Action 13

The Commission, Member States, organisations, institutions and other actors should engage in a **structured dialogue at various levels to develop an understanding and information exchange on life sciences and biotechnology**. The Commission will in particular help mobilise all key actors in the public debate and facilitate participation of stakeholders with limited resources.

In particular:

- a) The Commission will propose a framework for a process of **dialogue and follow-up with stakeholders** as a result of the European strategy for life sciences and biotechnology. The framework will notably include a broadly based **Stakeholders' Forum**. In this process, the Commission will take the initiative to better explain Europe's regulatory approach (including the application of the precautionary principle, the role of risk management, monitoring, safeguards and reversibility of regulatory decisions).
- b) The Commission will take initiatives, and invites the scientific community and other stakeholders to assist, to **promote awareness of key scientific paradigms underlying regulatory oversight such as scientific uncertainty, absence of zero risk, comparative risks, that science is continuously evolving** and therefore continuously improves our reference points, and the articulation between the steps in the risk analysis process. Within their respective fields, the European Food Safety Authority and the European Agency for the Evaluation of Medicinal Products will play an important role in general risk communication, including the scientific background for their conclusions of risk assessments.
- c) Beyond these two specific initiatives, the Commission will also encourage **public debates on biotechnology between scientists, industry and civil society**, including specific interest groups, such as patients groups, farmers and consumers, focussing on specific technological developments, to raise public interest in such developments and offer early information on potential benefits and risks. Developers in the scientific community and in industry have a specific responsibility in actively explaining the background and the benefits of their products.

**Implementer: Member States, Industry, Academia, Civil society, EFSA, EMEA, Commission**

**Timeframe: 2002 onwards**

**DEVELOPING LIFE SCIENCES AND BIOTECHNOLOGY IN HARMONY WITH ETHICAL  
VALUES AND SOCIETAL GOALS**

**Action 14**

The Commission will **strengthen and focus Community support for research into socio-economic and ethical issues** and dissemination of results, including criteria for assessing the benefits of using biotechnology in agri-food production, to facilitate future reporting and to provide a good basis for societal decisions on the application of biotechnology and life sciences. The Commission will program research support to a more systematic mapping of benefits and disadvantages/risks which should include a strong component for dissemination of information and debate.

The Commission will ensure that **ethical, legal and social implications are taken into account at the earliest possible stages of Community supported research by means of funding bioethics research and of providing an ethical review of research proposals received.**

**Implementer: Commission**

**Timeframe: 2002-2006**

**Action 15**

The Commission proposes to **enhance the role of the European Group on Ethics**. In addition, the Commission will launch a separate consultation of the other Community institutions on possible structural and procedural improvements. The Commission will also promote collaboration between Community, national and local levels by **promoting networking of national and local ethical bodies and elected representatives**. The Commission will organise a **network of academic and professional experts** for ad-hoc advice on specific socio-economic aspects.

**Implementer: Ethical bodies, Legislatures, Commission**

**Timeframe: 2002**

**Action 16**

The Commission will **develop, jointly with the EP, outreach measures to inform about the analysis of ethical issues** at the EU level.

While respecting cultural pluralism, the Commission will work with public and private partners to **identify areas where it is possible to establish consensus on ethical guidelines/standards or best practise**. Areas might include stem cell research, biobanks, xenotransplantation, genetic testing and use of animals in research. Such guidelines could, when appropriate, take the form of self-regulatory initiatives in the scientific community and industry.

**Implementer: European Parliament, Member States, Regions, Industry, Institutions, Commission**

**Timeframe: 2002 onwards**

## DEMAND-DRIVEN APPLICATIONS THROUGH INFORMED CHOICE

### **Action 17**

The Commission will take initiative to develop, in partnership with Member States, farmers and other private operators, research and pilot projects to clarify the need, and possible options, for agronomic and other **measures to ensure the viability of conventional and organic farming** and their sustainable co-existence with genetically modified crops. Moreover, the Commission recognises the importance of safeguarding the existing genetic resources in agriculture. It will launch a new action programme for the conservation, characterisation, collection and utilisation of genetic resources in agriculture in the Community.

**Implementer: Member States, professional associations, other operators, Commission**  
**Timeframe: 2002 onwards**

## CONFIDENCE IN SCIENCE-BASED REGULATORY OVERSIGHT

### Pharmaceutical legislation

### **Action 18**

Parliament and Council are invited to speed up the adoption of the three legislative proposals, revising the Community pharmaceutical legislation, including measures:

- a) to **develop and reinforce the system of giving scientific advice** and to increase the access of the European Agency for Evaluation of Medicinal Products' (EMA) scientific committees to high level expertise through the creation of expert panels and permanent working groups. The increased level of expertise will also help the revision and development of European guidelines on the quality, safety and efficacy aspects of biotechnological medicinal products.
- b) to introduce an **accelerated procedure for products with a major public health interest** that will allow the assessment and authorisation of a medicinal product within a shortened time scale
- c) to introduce **a procedure allowing a conditional authorisation** valid for one year, but renewable. This will allow products of major public health interest but for which certain studies are still in progress to be given a conditional access to the market during the finalisation of the studies.

**Implementer: European Parliament, Council**  
**Timeframe: 2002**

## **Genetically modified organisms (GMO) legislation**

### **Short-term regulatory actions**

#### **Action 19**

Parliament and Council are invited to speed up the adoption of the two following legislative proposals:

- a) Proposal for a European Parliament and Council **Regulation on Traceability and Labelling of Genetically Modified Organisms and Traceability of Food and Feed derives from Genetically Modified Organisms.**
- b) Proposal for a European Parliament and Council **Regulation on Genetically Modified Food and Feed.**

**Implementer: European Parliament, Council**

**Timeframe: 2002**

#### **Action 20**

The Commission continues its work with a view to finalising the legislative proposals which have already been announced, such as initiatives concerning GM plant propagating material, environmental liability and the implementation of the biosafety protocol.

**Implementer: European Parliament, Council, Commission**

**Timeframe: 2002-2003**

### **Implementation and enforcement activities**

#### **Action 21**

The Commission will **ensure that legislation is enforced in a uniform and effective way** across the Community and adopt **appropriate implementing measures required under relevant legislation, including the necessary guidance for detection and sampling methodology.** The Commission will also establish a **molecular register** that is accessible to the public, containing information on events of genetic modification.

**Implementer: Commission**

**Timeframe: 2002-2003**

### Specific long term regulatory actions

#### Action 22

The Commission will report on the feasibility of options to **improve further the consistency and efficiency of the framework for authorising GMO's for deliberate release into the environment**, including a centralised Community authorisation procedure.

**Implementer: Commission**

**Timeframe: 2003**

#### Action 23

The Commission will support the development of methodologies for monitoring potential **long-term environmental impacts of GMO's** as compared with conventional crops, and methodologies for the **monitoring of effects of genetically modified food and feed as compared with conventional food and feed**. With the establishment of the European Food Safety Authority, the work on the early identification of emerging risks will be reinforced and upgraded.

**Implementer: Commission**

**Timeframe: 2002 onwards**

### 3. EUROPE IN THE WORLD - RESPONDING TO GLOBAL CHALLENGES

#### A EUROPEAN AGENDA FOR INTERNATIONAL COLLABORATION

#### Action 24

The Commission should continue to play a **leading role in developing international guidelines**, standards and recommendations in relevant sectors, based on international scientific consensus and, in particular, push for the development of a consistent, science-based, focused, transparent, inclusive and integrated international system dealing with food safety issues.

**Implementer: Commission**

**Timeframe: 2002 onwards**

## EUROPE'S RESPONSIBILITIES TOWARDS THE DEVELOPING WORLD

### Agriculture

#### **Action 25**

The Commission will in co-operation with Member States support:

- a) the redefining of national research towards **an appropriate mix of traditional techniques and new technologies**, based on priorities developed with local farmers.
- b) the establishment of **effective research partnerships** between public and private research organisations in developing countries and in the EU, and the adequate **capacity and infrastructure for developing countries** to enter into such partnerships, in accordance with international commitments under the Conventions.
- c) **sub-regional, regional and international organisations**, in particular the International Agricultural Research Centres.

**Implementer: Member States, Commission**

**Timeframe: 2002 onwards**

### Genetic resources

#### **Action 26**

The Commission and the Member States will support the **conservation and sustainable use of genetic resources** in developing countries and their equitable sharing of benefits arising from their use by:

- a) supporting the development and enforcement of effective **measures to conserve, to use sustainably and to provide access to genetic resources and traditional knowledge**, as well as to share equitably the benefit arising from them, including income generated by intellectual property protection. Support for local communities is vital to **conserve indigenous knowledge and genetic resources**.
- b) supporting the **participation of delegates from developing countries in the negotiations of relevant International Conventions**.
- c) supporting measures to **promote greater regional co-ordination** in legislation to minimise disparities in access, benefits and also trade in products derived from genetic resources, in accordance with international commitments.

**Implementer: Member States, Commission**

**Timeframe: 2002 onwards**

## Health

### Action 27

The Commission and the Member States should work with the international community to **concretise the commitment to research to combat HIV/AIDS, Malaria, TB and other main poverty-related diseases** and also identify effective measures to support developing countries in establishing the structures needed to deploy a health policy.

**Implementer: Member States, Commission**

**Timeframe: 2002 onwards**

## Responsible and careful use

### Action 28

The Commission should support:

- a) the **safe and effective use of modern biotechnologies** in developing countries, based on their autonomous choice and on their national development strategies.
- b) **measures to increase the capacity of developing countries to assess and manage risk** for man and the environment, under conditions prevailing in the country.
- c) the development of appropriate administrative, legislative and regulatory measures in the developing countries, for the **proper implementation of the Cartagena Protocol**.
- d) that international research on social, economical and environmental impacts are effectively adapted to take into account conditions prevailing in developing countries and that the findings are subsequently disseminated to them in an appropriate format.
- e) that the international regulatory requirements remain manageable by developing countries, so as not to impede their trade and production prospects.

**Implementer: Commission**

**Timeframe: 2002 onwards**

#### 4. IMPLEMENTATION AND COHERENCE ACROSS POLICIES, SECTORS AND ACTORS

##### Action 29

The Commission will enhance

- a) the general **foresight function** across Commission services, and in particular its role in technology foresight through its Institute for Prospective Technological Studies (IPTS), **for early identification of newly emerging issues** and of elements of a policy response
- b) its **monitoring and review function** to assess
  - the relevance, coherence and effectiveness of legislation and policy
  - the extent to which policy objectives are achieved and legislation enforced
  - the societal and economic impact of legislation and policy measures.

In pursuit of these objectives and to further strengthen policy coherence, the Commission

- c) will reinforce continuous co-ordination between its services and calls upon Member States to also provide enhanced foresight/review functions and a co-ordinated interface for a dialogue on these issues.

**Implementer: Commission, Member States**

**Timeframe: From 2002 onwards**

##### Action 30

The Commission will present a **regular Report on Life Sciences and Biotechnology** to monitor progress and indicate possible specific proposals to ensure policy and legislative coherence. The report will draw on the conclusions under actions 11 and 30.

**Implementer: Commission**

**Timeframe: 2003 onwards**