

**RESPONSE BY THE EUROPEAN LIFE SCIENCES FORUM  
TO THE EC CONSULTATION:  
TOWARDS A STRATEGIC VISION OF LIFE SCIENCES AND BIOTECHNOLOGY**

The European Life Sciences Forum is a coalition of independent organisations representative or supportive of the life sciences, biotechnology and biomedical research communities in Europe. Its mission is to increase their visibility and impact in the public and policy-making arenas, as a continuing priority, to advance research and to improve scientists' positions in European society.

The membership of the European Life Sciences Forum (ELSF) comprises the European Society for Arteriosclerosis (EAS), the European Life Scientist Organisation (ELSO), the European Molecular Biology Laboratory (EMBL), the European Molecular Biology Organisation (EMBO), the European Plant Sciences Organisation (EPSO), the European Society of Gene Therapy (ESGT), the Federation of European Biochemical Societies (FEBS), and the Federation of European Neuroscience Societies (FENS).

**CONTACT:**

Dr Luc Van Dyck

Executive Co-ordinator, European Life Sciences Forum  
Meyerhofstrasse 1, D-69117 Heidelberg  
Tel.: +49 (0)6221 8891 552  
Fax: +49 (0)6221 8891 200  
E-mail: [luc.vandyck@elsf.org](mailto:luc.vandyck@elsf.org)  
[http: www.elsf.org](http://www.elsf.org)

## 1. GENERAL COMMENTS

### *Consultation questions*

- The European Life Sciences Forum (ELSF), whose membership represents several tens of thousands of researchers in Europe, has committed itself to answer systematically the Consultation questionnaire. This effort has been undertaken to emphasise the interest of the scientific community in public debate as well as in the consultation process itself.
- ELSF praises the efforts made by the European Commission to consult all stakeholders of the life sciences and biotechnology through the stakeholders' conference and the present questionnaire. Consultation with stakeholders is a first and essential step towards the establishment of a European Research Area, and the EC must ensure continuity of this process. In order to improve further steps of this process, ELSF recommends that:
  - conferences and consultations be widely advertised in due time;
  - the EC should ensure that all important scientific organisations are invited to contribute. This was not the case for the stakeholders' conference; and,
  - more time be allocated to answer consultation questionnaires in order to allow wide consultation of organisations' members.
- The short time period between the present deadline for submission of contributions and the announced term for the publication of the EC Policy Paper, due at the end of 2001, makes it unlikely that all contributions can be fully analysed and possibly incorporated in the Policy Paper. ELSF considers the consultation and the resulting Policy Paper as a preliminary step that should be followed by the articulation of an Action Plan for Biotechnology in Europe, to which stakeholders should be associated. The EC should invite contributions for such an action plan in a very near future, to allow sufficient time to analyse and integrate stakeholders' suggestions and ideas into the Action Plan.
- The EC consultation document emphasises rightly the potential of life sciences and biotechnology and the crucial role of research. ELSF acknowledges the visionary ideas of the ERA concept and some aspects of the proposal for the

Sixth Framework Programme, which are detailed in this response. ELSF however warns the European Institutions against too much self-satisfaction. In contrast to the general tone of the EC Consultation document, Europe is still a “Giant with clay feet” in a global context, due to a lack of genuine integration. In the same context of global competition, the total amount of public funding for basic research, the true motor of innovation, in Europe lags way behind the public spending of its main competitors, as confirmed by the benchmarking exercise of the EC. Major investments in research have therefore to be made, chiefly in some members-states, if the decision of the Lisbon Summit – becoming the most competitive knowledge-based economy in the world - is to become a reality.

- ELSF believes that the Consultation document would benefit greatly from a more balanced and positive approach to plant and animal science, and to biotechnology in the agricultural sector. ELSF considers that the report overly focuses on the concerns of the public towards products derived from first generation GM plants, and does not discuss adequately the potentially enormous long-range benefits of future products. ELSF nonetheless believes that GM products should be rigorously tested before commercialisation and that this process be based on scientifically definable standards.
- ELSF’s mission is to advance research and to improve scientists’ positions, and the Forum, therefore, wishes to emphasise two issues of major importance:
  1. In its Sixth Framework Programme (FP6) the EC apparently seeks not to sponsor basic research, but simply to integrate it at a European level, notably through the Networks of Excellence. If this is true, the EC should publicly acknowledge it, and two major conclusions should be drawn from it: Firstly, the selection of priority areas should not lead to the abandonment of major and key areas of basic research, e.g. plant and (non-model) animal science, microbiology, areas which also require more integration at the European level. This is especially important because some national funding agencies increasingly design their granting schemes to improve access to EU funding, which can have a long-term detrimental effect on research quality and continuity. Secondly, if the EC FP6 is not to be seen as a real source of funding but as a ‘topping-up’ mechanism to encourage integration, the implementation of a European Research Council should be considered. This Council would not replace national agencies, which have a crucial role in maintaining national strengths and priorities, but should be seen as an opportunity to provide funding for excellent trans-European research through

a flexible scheme, free from constraints. In the light of the example of EMBO programmes, fears pertaining to a fair re-distribution of grants to contributing states could be easily overcome.

2. The availability of human resources is a major concern in Europe. This phenomenon is currently exacerbated by the observed brain drain, loss of female scientists early in their career, loss of scientists to other sectors, and the anticipated generation shift among senior scientists throughout Europe. A narrow interpretation of the principle of subsidiarity had led the EC to restrict to the concept of mobility its response to these specific challenges. The Marie Curie fellowship programme is a very successful initiative, but so far the EC had not addressed the major problem: the lack of career perspectives for young scientists after the post-doctoral level. Provisions are made in the FP6 proposal to implement re-integration and repatriation mechanisms, however details are still missing to assess the quality of these new instruments. Similarly, the announced Marie Curie Excellence Grants may also be a step in the right direction. The EC however must be aware that these mechanisms will be successful only if the best young scientists are offered genuine perspectives to establish their own independent research group with an appropriate level of funding. One might argue that this is a national responsibility; several member states and most of the scientific organisations of Europe, however, have stressed the need for such opportunities in their response to the FP6 proposal. Following its own strategy to identify and encourage best practices, the EC could make a constructive move in this direction through the establishment of new, adequately-funded research group leader positions (Euro-Chairs) in order to encourage and facilitate the independence of the best young European researchers. This could be a joint initiative based on a co-funding mechanism, European and national or regional.

## 2. POTENTIAL AND IMPACT OF THE LIFE SCIENCES AND BIOTECHNOLOGY

### **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 that 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?

*The progress of life sciences and biotechnology, and therefore the delivery of their promises, is research driven and, by definition, unpredictable. In order to harness their full potential in Europe research must become a major investment priority and, at the same time, the industrial fabric has to be developed. The only measure to assess safety and environment-friendliness of biotechnology products is a regulatory framework based on sound science. This framework must be determined by experts and endorsed by policy-makers through legislation. The use (and misuse) of the precautionary principle must be looked at with great care. Ensuring adherence to fundamental values is strictly a political process to which society must be associated through wide consultation.*

*Public perception and acceptance is essential to harness the potential of life sciences and biotechnology. In this respect a distinction must be made between red biotechnology, for which immediate perception of personal benefit is more accessible, and green biotechnology, which requires comprehensive information. It has little sense to develop alternative approaches to assess societal benefits and disadvantages. Acceptance cannot be imposed on society. Freedom of choice must be the rule and both stakeholders and public authorities must ensure that society is provided with the input necessary to make informed choices. All parties should be given fair representation. Notably, activist groups like animal rights groups and pro-environmentalist groups should not be over-influential in public consultation. These groups are essential components of democracy and raise important questions that need to be addressed, however their implications must be clearly explained to the public, for instance the need for animal testing of pharmaceutical products.*

*The question of the impact of socio-economic and societal benefits on the regulatory approach is ambiguous. If it refers to regulatory processes establishing safety and environmental-friendliness of biotech products, these benefits must not interfere with the scientific assessment. If reference is made to regulations guiding research, then the framework must be established by policy-makers following wide consultation of all stakeholders and society at large. This reflection cannot be restricted to Europe and must include the global context of research, which has no boundaries, and its implications worldwide.*

*The EU should be prepared for a new legal system to deal with possible lawsuits arising from suspected harm due to GM products. Indemnity must be guaranteed for the marketers and producers, while providing for compensation in the event that a genuine or strongly suspected case arises. This would be an essential element to generate a framework in which the possible benefits of GM products can be realised by the public and commercially.*

- 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?

*There is no doubt that genetics and biotechnologies are going to change significantly the way in which medical care will be administered in the future, whilst also reducing healthcare costs. The post genomics era is actually a functional genomics era. The medical and healthcare benefits in the long term will include more predictive testing and personalised forms of therapies. It is likely that responders and non-responders to specific forms of treatment can be predicted with some accuracy, and, hence, the most effective forms of treatment with the lowest side effects determined for individual patients. This new way of doing medicine will require a re-assessment of clinical trials to target better variable patient groups on the basis of genetic susceptibility or resistance to a drug. It will also require a closer regulation of patient drug regime by doctors. Faster approval of life saving drugs for terminally ill patients is already needed.*

*As stated in the question, the promise of the post genomics era is research driven. It notably implies the systematic use of healthcare information and community-based*

*genetic research seeking to identify shared characteristics among family members and larger groups. A wide debate must be open, and a legal frame must be established to avoid discrimination and to find the right balance between privacy and access to information required to conducting research. It is necessary to ensure community consent in addition to individual consent. The issue of informed consent of people with severe mental illness must also be addressed. All stakeholders must therefore be included in public consultation, notably educators, social scientists, lawyers, ethicists, clergy, doctors and nurses, and community leaders. Considering the various cultural and philosophical backgrounds the consultation process may take different forms in countries across Europe, but a European and worldwide dimension is needed. As public acceptance will be a crucial factor for the access to information, the legal frame must ensure that ethical principles of beneficence, justice and respect for persons are upheld. Equal access to health treatment and employment must be ensured irrespective of genetic background. Other issues revealed by the advances of science are also at stake and must be addressed, e.g. pre-natal testing and the selection of embryos, and improved early diagnosis without cure, for which more counselling will be needed.*

- **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?

*Early identification of genetic risk factors could imply life style changes rather than targeted drug treatment or in combination with targeted drug treatment. Many of the diseases of the elderly are multi-system disorders, degenerative diseases and neoplastic diseases. Complex diseases are still poorly understood at the molecular and cellular level. Basic and applied biotechnology research is specifically addressing these issues, and major advances and breakthroughs are expected from functional genomics, pharmacogenetics and stem cell research. New treatments in cardiovascular, neurological and neoplastic diseases are expected to come from the application of this knowledge to tissue and cell transplantation and gene therapy.*

- 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?

*Rules for sustainability should be made on a worldwide basis, such that approaches taking sustainability into account do not lead to (short- or long-term) disadvantages in competitiveness. This should be accompanied by measures to protect biodiversity. Collections of plants and animals should be maintained, and national parks and protected regions be defined and rigorously protected. These measures are independent of whether a new crop variety to be introduced is derived from classical breeding or from GM technology. Crop rotation and intelligent crop management should be strongly encouraged. Crop varieties that are transgenic for insect resistance should have multiple resistance genes (equivalent to the multiple drug application in medicine, e.g. triple therapy for AIDS) and should be planted together with non-transgenic crops to avoid generation of resistant insects. Biotechnology and organic farming should be combined, because their common goal is to reduce chemicals in foods. The increasing dependence of farmers on fewer and larger companies is a general problem created by globalisation, and is not a consequence of biotechnological innovation. The impact of the co-existence of GM and traditional crops must be further studied, notably through field studies.*

- 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 lack of perception of the potential benefits of GM crops is largely due to a deficit of communication by industry when these products were put on the market. It should be realised that, currently, farmers have benefits from GM crops and that consumers have at least no disadvantages. But in the future consumers could have the chance to obtain food derived from GM crops that is less polluted with chemicals and less contaminated with mycotoxins. Furthermore, consumers in developing countries could benefit from a more balanced diet and from a more guaranteed harvest. Biotechnology can also contribute to a better environment and to a reduction of*

*energy consumption. Better scientific education of the consumers will make them more receptive to rational rather than emotional arguments. The availability of 2nd and 3rd generation products, e.g. multi-subunit oral vaccines from plants, iron- and vitamin-enriched rice, plants for bioremediation, will support this change in public perception.*

*Food supply is not an issue in Europe given the large surplus of agricultural products resulting from the past Common Agricultural Policy (CAP). It appears that there is now a strong interest from society towards more sustainable practices. In this context there is room for biotechnology products and technologies to improve the nutritional value of agricultural products and promote environment-friendly practices. The CAP should probably be altered in this direction.*

- The European Commission White Paper on renewable energy 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?

*Bioprocesses can reduce energy use. An obvious example is the use of algae to convert atmospheric carbon dioxide into carbohydrates through photosynthesis. Such projects have been actively pursued in Japan and similar approaches could be supported in Europe.*

- An OECD report 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?

*The lack of information in this sector is primarily observed at the level of SMEs and can only be counter-balanced by proactive information campaigns. For any kind of awareness-raising action, it is essential to bring together experts, scientists, and companies, to provide information, find common interests and identify niches where a shift to modern biotechnology would make sense. Funding agencies but also local and regional authorities are probably the most adequate level to undertake these actions.*

- 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?

*The development of biotechnology can have a positive impact on job creation, similarly to what has been observed in the US. A more aggressive policy towards development of the science and technology sectors, both public and private, would most likely increase the size and quality of a highly educated and skilled European workforce. There is however a hiatus between the announced lack of qualified human resources and the current difficulties that are met by many young scientists in finding a job. Development of human resources - the implications for education and training are discussed elsewhere in this document - and development of the industrial fabric that will provide jobs must be tackled at once. However, if the fruits of biotechnology in terms of job creation were to be harvested, it would be suicidal to sacrifice the current generation of researchers, which is planting the trees. The EC document raises several times the question of brain drain and loss of scientists to other sectors. Actions have to be taken to provide young promising scientists with career perspectives in order to reverse this trend (see section 4. Research). Among these actions, re-qualifying the scientific careers in universities and research institutes, and removing the obstacles to extensive and bi-directional exchange of human resources between academia and industry, are crucial ones.*

- 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?

*European policies must reflect European values and choices, but a stand-alone position is not a viable option in the global context. A self-determined policy on biotechnology is therefore extremely risky for Europe, which must rather seek global agreements. Thus, the EU must ensure that its voice is heard in all fora, including the WTO and other international organisations, in order to preserve the interests of its citizens and companies, and ensure that its ethical and societal values are not harmed but also that specific needs of the poorest countries are correctly addressed.*

### 3. INNOVATION AND COMPETITIVENESS

#### **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 establishment of a Community Patent is crucial. It appears that many large companies are primarily seeking protection in the US because R&D efforts and the commercial market are more important there. Seeking intellectual property rights is also tedious and expensive in Europe, which acts as a major disincentive especially for SMEs and the academic sector and thus militate against their development. A global European legal protection combined with lower costs of patent application and infringement procedures and, above all, a grace period for publication that would uniform the European system with that of the US is essential to strengthen R&D and biotechnology business in Europe. Several measures can contribute to solving the current problems. Global protection and costs, notably those incurred through translation, must find a legislative answer and thus require a political agreement at the European Council level. A simplification of the patent application procedure and faster granting of patents may be achieved by the European Patent Office. The report of the Patinova 2001 Conference highlights some original measures that could be implemented by public authorities to address litigation and agent costs (<http://www.patinova.org>).*

- 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?

*Public funds must support primarily academic, open-ended basic research, which is the major motor for true innovation. Technological progress cannot continue without the input of basic research and the conceptual breakthroughs it makes possible. Like any exploratory process, it is not possible to predict what one will find or what its eventual utility might be. Shareholders of companies cannot be expected to pour*

*money into research that delivers only in the very long-term; it is therefore the responsibility of governments to make the appropriate investments. It is also the responsibility of governments to make sure that steps are taken by public research institutions and scientists to acquire, where appropriate, intellectual property rights (IPRs) on research that is publicly funded and to promote technology transfer and licensing activities from public institutions, thereby, indirectly reaping the benefits of their investment.*

*Concerning research done in public institutions and sponsored by the private sector, guidelines on agreements to reach when entering into collaboration should be provided to ensure that public research institutions benefit from their work while at the same time the legitimate interests of companies with regard to IPRs are taken into consideration. In this regard, guidelines or regulation should be implemented to enforce disclosure of conflict of interests by scientists involved in any privately funded research activity.*

- 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?

*Capital availability, tax incentives, and risk-taking and entrepreneurial spirit certainly have different impact on both sides of the Atlantic. However, the boom of biotech companies in the US finds its origin primarily in the development of intellectual property in the academic sector, as discussed in depth by Lita Nelsen, director of the Technology Licensing Office of the Massachusetts Institute of Technology (Nelsen (1998) *The Rise of Intellectual Property Protection in The American University. Science* **279**, 1460), and this could serve as a model in Europe. In 1980 the Bayh-Dole Act allowed American universities to own the patents that arose from federally sponsored research. The universities themselves would not develop the patented technologies, but would license the patents to industry. A provision of the law allows the universities to retain royalties, which must be allocated to research and educational activities, from such licensing, and specifies that a fraction of the royalties be shared as personal income with the inventors. Now almost all research universities in the United States have technology licensing operations, and the number of patents granted to American universities has risen dramatically. More than 250 new companies were formed directly through university licenses in 1996 and a total of more than 1900 companies between the inception of the Bayh-Dole Act in*

*1980 and 1998. It has been estimated that more than 200,000 jobs have been created in the United States in product development and manufacturing of products from university licenses.*

*It should be noted however that the direct economic impact of technology licensing on the universities themselves has been relatively small as, with very few exceptions, most university licensing offices barely break even. This strategy should therefore not be seen as an alternative to public funding of research.*

*Another important aspect is the way academic success is rated in Europe, especially in the life sciences where it is almost exclusively measured on the number and quality of publications, and how it impacts on career developments. A more balanced approach taking into consideration patents owned but also elements like the presence on advisory boards could contribute to raising awareness on intellectual property and trigger a stronger involvement of scientists in public debate.*

- 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?

*This question is addressed in various parts of this document. In summary, it seems essential to take actions to: raise the interest in science and scientific careers; design education and training programmes for both scientists and technical staff that take into consideration the needs of industry; introduce elements of business development, intellectual property and technology transfer in scientific curricula; and address the problems leading to the loss of female scientists. Life scientists should also be made aware, at an early stage in their training, that there are many fields in which they can work within the life sciences that are not necessarily what they have studied; otherwise, we risk life scientists drifting out into service industries instead of making a small retraining step to a related area of science, e.g. bioinformatics and scientific database management, scientific facility management etc.*

*In order to avoid brain drain and career shift, it is essential to seriously address the lack of career perspective in Europe (see section 4. Research), a question that seems to be constantly overlooked in EC programmes for 'subsidiarity' reasons.*

*Education and opportunities, some aspects of which can be modulated by public authorities' actions, but also the personality of the scientist are instrumental in the choice of an entrepreneurial career. Undertaking an academic career is a passionate choice that is often tempered by the availability of positions and the lack of career perspectives. In both cases, the factors for geographical preference are a balance between opportunities, perspectives, and constraints, notably at the family level.*

- 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?

*No comment.*

- In view of the aim to foster European competitiveness, what could be done to develop a broader **downstream industry**?

*Academic/industry think tanks on future directions, needs, and prospects could be established in order to try to predict markets and needs. The standardisation of regulations between different fields of application of basic research knowledge would also be helpful.*

- 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?

*No comment.*

- 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?

*Clustering companies around centres of excellence is a critical factor for success, broad distribution is a prescription for ineffective use of resources. The successful*

*companies in the US essentially all come from such centres of excellence, and a community as large as the US has only a handful of them. There is no equal geographical spread of centres of excellence across Europe, and it is a regional and national responsibility to tackle this situation and perform the necessary investments. The number of incubators and academic technology transfer departments is steadily increasing, however again, there are wide discrepancies between countries and regions across Europe; the European Commission, and also national and regional authorities should therefore aim to stimulate these practises.*

*Shared use of equipment at reasonable cost, challenging environment providing opportunities for easy exchange of ideas and continued training of staff members, and qualified human resources are among the clear benefits that can be expected from company clustering. Some disadvantages may be found in the fact that intellectual property is drained into company, and in issues of confidentiality that may result in a less open academic atmosphere.*

- **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?

*Elements contributing to the success of an incubator overlap the advantages for clustering companies around centres of excellence: incubators must be immersed in a high-class modern basic research environment, have the possibility to benefit from common infrastructure at reasonable costs (canteen, library, material storage, parking space, administration), and have opportunities to provide lab equipment adjusted to the individual needs of each company. There must also be room for expansion with the growth of the enterprise. However, the success of an incubator primarily depends on the quality of its employees, on their education and training, and on their relationships with the scientific community and investors.*

## 4. RESEARCH

### **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 **priority areas for public research** in Europe and are sufficient resources foreseen?

*Fragmentation and lack of coordination of European research is a reality and one of the greatest challenges to Europe. In this respect, the establishment of a European Research Area (ERA) is an initiative that has long been awaited. ERA however should not be just a slogan; it has to be a signpost to the future. A narrow interpretation of the Treaty of Amsterdam, notably the principle of subsidiarity and the articles governing the Community action with respect to research, must be avoided if the conclusions of the Lisbon Summit are to become a reality.*

*The benchmarking exercises undertaken by the EC have revealed a number of sectors where national and European initiatives are needed. At the European level, the Sixth Framework Programme (FP6) is considered to be the major instrument to implement ERA. Through FP6 the EU aims to integrate research, and structure and strengthen its bases. Several issues of the EC proposal - support for SMEs, development of a European industrial fabric, ethical and societal issues, public perception of science and technology, guidelines for best practices, intellectual property etc. – are addressed throughout this document. Here, we wish to focus on the research policy of the EC.*

1. *Infrastructures. There is a lack of research infrastructures in Europe. Facilitating trans-national and private sector access to the existing infrastructures, and supporting steps to establish new ones, are valuable initiatives of the EC.*
2. *EC applications and evaluations. The preparation of an application to EC programmes is a tedious process that requires a lot of investment in time and human resources for a very low success rate, a problem that may be exacerbated in the case of the larger consortia involved in Networks of*

*Excellence and Integrated projects. The EC cannot reduce its administrative workload at the expenses of the researchers. A simplified, two-step application procedure must be systematically implemented. The EC must also ensure the transparency of the evaluation process. The expert selection procedure, the composition of the evaluation panels, and the mode of operation of these panels have to be modified in such a way that the best scientists are recruited and given optimal conditions to perform the evaluation. In the fourth and fifth Framework Programs the EC has progressively worsen its grant reviewing system, by establishing a politically-driven and a top-down approach in choosing priorities, by forcing an “applicative” focus in all areas of academic research, and by introducing unprecedented and ineffective practices such as self-nomination in the expert database, anonymity in the proposals, and the use of pondered scores that give too much weight to elusive parameters such as “management”, “European added value” and “exploitation plans” and too little to expertise and quality. Finally, a cumbersome closed-door approach to the reviewing process, and a fundamentally faulted interpretation of concepts such as country representation and conflict of interest, has effectively deprived the expert panels of the best and most experienced European scientists. As a result, many excellent scientists have been discouraged to apply to EC funds, and an industry of consultants and professional grant writers has flourished and drained resources from the whole system. Ultimately, the system neither funds basic science nor promotes practical application. Again, the example of much more successful funding systems, such as the National Institutes of Health in the United States, should inspire and drive any future action of the EC. A simplification of the administrative procedures following granting of a project is also urgently required.*

3. *Human resources. The Marie Curie fellowship programme is a greatly needed and successful programme. However, several issues have long been identified, where harmonisation across Europe is required to facilitate mobility: pension scheme, social security, maternity leave, child support, working permit for the partner etc. The EC has been proactive in trying to address these issues but it seems that the European Council is far from considering this as a priority! As stated several times in this document, mobility is also not the appropriate answer to the major problem of young academic scientists: the lack of career perspectives at the post-doctoral level. The concept of Euro-Chair, a scheme establishing research group leader*

*positions that could be co-funded by the EC and national or regional authorities, has received wide support in the scientific community. These Euro-Chairs should provide sufficient funding to allow the best, young scientists to establish their own, independent research group. Such a mechanism would be the best incentive to repatriate researchers and to address the anticipated generation shift among senior scientists throughout Europe. The announced Marie Curie Excellence Grants may be a step in the right direction, but this programme should be assessed in due course to see whether it meets the needs and expectations of the scientific community.*

- 4. Priority areas for research. There are three aspects in the selection of research priority areas in the life sciences at the European level. Firstly, public funding is required to address crucial public health and environmental issues. Poverty-related diseases, and food quality and supply in the third world must also be tackled through public action or within consortia involving charities, small companies and public research groups, when the involvement of industry is deficient. Secondly, public funding must aim to palliate current deficiencies and respond to specific needs, e.g. in bio-informatics, proteomics, patients databases etc. Thirdly, at both the European and national level, public research sponsored by public funds must focus on high quality long-term, basic or fundamental research. If it has a strategic element that can be defined, it is an advantage, however, this is not always the case nor is it true that all research that has a strategic flavour end up delivering on this strategy nor is it true that all research that does not have such label, ends up being of no strategic benefit. The choice of priority areas also implies a transient character, whilst a key element of good research is continuity.*
- 5. New instruments. It seems unlikely that long-lasting integration of research can be obtained through Networks of Excellence if the integration is not duly justified by the research itself. Research is of its very nature a flexible process. The decision of the European Research Council and the European Parliament to maintain instruments of smaller size and accessible to all kinds of research groups is viewed positively.*
- 6. Public funding of industrial research. The use of the public system to support R&D that is properly the domain of industry should be looked at with great care. It would seem more appropriate to give the industries the money through other means such as tax incentives to carry out research, or subcontract it to the public sector. Public money should go towards research*

*that is of a different nature. Are there sufficient funds or resources for this? Clearly no! How Europe expects to be on a par with America or Japan when spending half the amount of money is a mystery. European researchers are neither twice as intelligent, nor twice as well interlinked, nor twice as innovative. Europe therefore will end up inevitably second or third in any world competition if similar resources are not provided.*

*The Fifth Framework Programme has been a source of disappointment for the academic community, and at the origin of a misunderstanding between this community and the EC. In its FP6 the EC now apparently seeks not to sponsor basic research, but simply to integrate it at a European level through the provision of 'topping-up' incentives. This move may be justified to obtain a finer tuning of national research policies at a European level. However, if it is true, the EC should publicly acknowledge it in order to avoid further misunderstandings with the scientific community. It should also make the decision not to choose basic research priority areas, since all disciplines of the life science need more networking, and because some national funding agencies increasingly design their granting schemes to improve access to EU funding.*

*The use of Article 169 to facilitate networking of the European research community through the opening-up of national programmes can be very positive but could be very slow, and result in a bureaucratic cacophony for the researchers. The implementation of an independent European Research Council could help to address the question and would constitute a major breakthrough at the European level. The purpose of this Council would not be to replace national agencies, which have a crucial role in maintaining national strengths and priorities, but to provide funding for excellent trans-European research through a flexible, constraints-free scheme. A certain level of resistance is to be expected from some countries, and their scientists, where research support is more generous, if they are to contribute part of their research funds to the budget of this Council. However, the example of EMBO programmes indicates that a fair re-distribution of grants to contributing states is obtained.*

- 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?

*Searching for intellectual property protection is a legitimate right for researchers and companies. Furthermore, this is increasingly emphasised in EU and national research funding programmes, and the substitution of deficient public funding by private sector sponsoring will contribute to this trend. It is the duty of the European Patent Office and the national patent offices to ensure that the criteria for granting patents are met for pre-competitive knowledge as for any other invention: novelty, inventive step and industrial applicability. The fact that the Community Patent would include a grace period for publication, similar to US patent provisions, would facilitate dissemination of knowledge. Access to protected pre-competitive knowledge in developing countries who cannot afford to pay high prices for the acquisition of essential knowledge could be dealt with separately in global agreements including governments as well as public and private sectors.*

- **Private sector research** in Europe is often considered to be less than in the US. If so, how may private sector research be encouraged?

*Private sector research is indeed significantly less than that in the US, where it has benefited from an enlightened transfer of technology from academic institutes to industry. The origin and the dynamism of the biotechnology industry in the US find its sources within the flourishing basic research community, in its physical and intellectual interactions with academic research, and in the availability of financial instruments. The European Commission has pointed out some important measures that have to be taken, e.g. in order to facilitate freedom of movement of academics to and from industry, and to encourage entrepreneurship. It is deemed essential to establish and/or develop proactive technology transfer departments in academia and to stimulate actions to raise awareness on new discoveries. Tax incentives supporting R&D investments, facilitated access to capital, and better administrative assistance should be implemented. Many of these actions could be initiated at a national and/or regional level. Public acceptance of research and technologies, and the adverse role of activist groups in this, should also not be overlooked if private research is to be encouraged.*

*Initiatives aiming to encourage private sector sponsoring of public research must also be viewed positively and supported at the European, national and regional levels. Private sponsoring must, however, not be seen as a potential alternative to public*

*spending by governments, but as an additional way to strengthen research. Furthermore, companies' spending is not a philanthropic action but an economy-driven investment directed towards companies' needs. The disadvantages of these practices, e.g. lab management problems related to the continuity of the funding, impact on the training of young researchers who have to publish, short-term contracts for scientists, must therefore be carefully analysed and considered.*

- 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 reasons for the observed disinterest in science and scientific careers in Europe are manifold, and several measures have to be taken to reverse this trend. At the public level, perception of and trust in science have to be restored. At the education level, science teaching could be improved through re-design of school and university programmes and continuous training of teachers, who have to be made aware of the most recent scientific and technological development. Research community and industry should be associated to the elaboration of university curriculum in order to make sure that education and training meet the real needs, notably the need for more multi-disciplinarity. The problem created by the excessive length of university studies and PhD trainings in some European countries may have to be addressed in order to recruit more young people.*

*Mobility is an essential component of the quality of training; social, fiscal, and legal aspects (e.g. maternity leave, pension, social security etc.) have to be addressed urgently at a European level. Mobility, however, is not going to solve the problem of scarce human resources. Making scientific careers more attractive is a more crucial issue to retain in Europe or to repatriate high-level scientists and to stimulate new vocations. The lack of career structure is in this respect a major problem. The pay level for highly skilled people who have spent many years training to be researchers, allied to the uncertainty of job security, all militate against maintaining a highly trained scientific cadre in Europe. This must be addressed at every level including the amount of the grants that are provided, the security that is provided, the incentives that are provided and the independence that is given. The latter point is a particular problem that is accentuated in Europe. The need to encourage the leading scientists at the postdoctoral level or beyond is an essential action. The response to the EMBO Young Investigator Programme demonstrates the need for support of this sector of*

*the community. The comparison of the way in which young investigators are treated in Europe compared to the US is a major disincentive for those who wish to stay in science in Europe. Everything should be done to refocus the equilibrium of decision-making, leadership etc. such that a better balance is achieved between the senior members of the scientific community and their apprentices.*

- 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?

*Current education curricula programmes are not adequately adapted to the task of preparing individuals for their participation in an informed debate on the integration of new technologies into and the utilisation by society. The response to ethical and societal issues is very much related to the philosophical and cultural background of each society, and, therefore, there is no single recipe to address the question. A 'minimal' background covering all facets of scientific disciplines is required to perceive the importance and implications of science and technology developments. A revision of the school and university education programmes is required if this is to be addressed successfully. Politicians themselves probably need assistance to be able to grasp issues. There is also a need to start a really solid and enduring approach to teachers training and updating of knowledge in the life sciences through workshops and opportunities to visit basic research and industrial establishments regularly.*

*Scientists engaged in research have a major role to play in stimulating and nurturing public debate on complex scientific issues, however, they are themselves not well prepared to face these challenges. Bioethics could be incorporated in PhD programmes to stimulate thoughts and to raise awareness of ethical issues in the scientific community, especially amongst the young generation of researchers.*

- 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?

*It should be recalled that scientists are constantly disclosing information about their work to their colleagues. It would therefore be wrong to indicate that they are not open about their research. It may however be difficult for the general public to understand it and perceive its implications. The scientific community is aware that it*

*has to engage in public dialogue, as it is accountable to society, in collaboration with other stakeholders like the media.*

*The communication policy of companies on their research as well as the communication on public research subsidised by companies must be assessed with different criteria as competition implies a certain level of secrecy.*

*Without prejudice, but in order to ensure transparency, scientists should be encouraged to disclose their sources of funding, as the work they publish may have a dramatic impact on some regulatory processes, e.g. in the approval of new drugs, but also as members of advisory committees or when they are involved in public debate.*

- 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 need for research to improve scientific advice in support of public policies is essential and should be implemented at all level of public action. EU Institutions and national governments must establish guidelines on best practices in seeking and using scientific advice in policy making. Advisory boards should be composed of leading scientists selected through a transparent and open process. Proceedings of their meetings must be widely publicised, and public authorities and administrations should justify the use or non-use of their recommendations.*

- 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**?

*Research can contribute to address social impacts and ethical issues through the provision of scientifically established facts, and the analysis of perspectives created by scientific and technological progress. The impact of the research community depends on its involvement within the public debate, and incentives may be provided to facilitate interactions between scientists and scientific organisations and society at large.*

- What specific actions could be launched in order to raise **awareness in industry of the potential** of life sciences and biotechnology?

*The awareness in pharmaceutical industry of the potential of life sciences and biotechnology does not need to be further stressed. It is a false assumption that industry is not making progress because of its lack of awareness of scientific research. As indicated by the Animal Cell Technology Industrial Platform (ACTIP) in its position paper on research, what needs to be addressed at a national and European level is the fact that there is not enough high quality basic research being supported in public research centres and the problems related to human resources.*

*Awareness-raising actions for more specific aspects of the potential of life sciences and biotechnology have been discussed in section 2. Potential and impacts 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?

*Horizontal activities in support of SMEs have no impact whatsoever, and should be abolished. The only way to foster and stimulate creation and development of SMEs in the biotech sector is through fiscal measures, incentives to investment, and building of infrastructures such as science parks and incubators. Other types of funding are essentially government subsidies, and as such are ineffective and often counterproductive.*

## 5. ETHICAL IMPLICATIONS

### **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?

*The role of expert or advisory bodies in consultation is crucial as they focus their attention on the matters in hand, and because, occasionally, there is a divergence between the reality as viewed by the expert and the concern as expressed by the pressure group. The composition of the expert advisory groups however is of some importance because in selecting the experts, the outcome can be prejudiced. Great efforts must be made to ensure that experts are truly representative and that the composition of the body is well balanced by cross-community checking of the expert bodies that are appointed. In this respect, moving from the area of Ethics to the manner in which the EU chose to receive advice on research through EURAD, there is an example that could give rise to some concern. Competence of the experts, transparency when establishing advisory boards and wide dissemination of the proceedings of their meetings must thus be the guiding principles. If this is achieved, there will be no need to strengthen networking of advisory bodies, as information will be systematically shared.*

- 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?

*The role of the European Group on Ethics will only be strengthened by its performance in providing wide information and advice. If this is not its mission, the European Group on Ethics cannot be imposed on society. The issues to be addressed by the European Group on Ethics are well defined in the Consultation document.*

- 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?

*It may appear that it is not a possibility to reach European-wide agreements on ethical principles, given the diversity of background in Europe on all topics. One should neither try to homogenise this diversity, which must be respected, nor systematically search for compromises on minimal common values.*

- What role could **democratically elected bodies** play in defining such European ethical principles and rules?

*Democratically elected bodies must stimulate open discussions on ethical principles and rules in fora gathering together life scientists and influential representatives of all facets of society, including lawyers, social scientists, and community and religious leaders. They also have to undertake wide consultations and receive advice from the expert advisory groups that they establish. At the end of the day, however, it is essential that democratically elected bodies take decisions, establish regulation in a timely fashion, and renounce the practice of imposing moratoria or delay crucial decisions on politically and socially sensitive issues. The misinterpretation and misuse of the precautionary principle is an example of such a “time buying” strategy, which has direct and negative effects on the European system. Uncertainty on rules and legislation is a major factor in discouraging capital investment, diverting human and financial resources elsewhere, and ultimately affecting the overall competitiveness of European science and technology.*

## 6. PUBLIC VIEWS AND PUBLIC INVOLVEMENT

### **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?

*There is no single solution to meet information needs. The population can be divided into several categories depending on perception and acceptance of science and technology, and therefore a different approach is needed to communicate with each. Furthermore, information needs to be qualitatively suitable for consumption. A preliminary step is actually to establish mechanisms allowing the formulation of public information needs.*

*Media are of prime importance in guiding public perception of biotechnology. Considering the primary characteristic of journalism – publish an appealing story – two kinds of actions should be encouraged. Firstly, communication strategies should be included in the education and training programmes of scientists. Secondly, best journalistic practices, including balanced presentation of facts, arguments, and interpretations, must be promoted. Initiatives taken by scientific organisations, like courses and workshops in gene technology for journalists, should be fostered and financially supported. Strategies and material for ‘virtual learning’ via the Internet have to be developed through collaborations between public research institutions and the media. Given the role of information in raising awareness and public acceptance of science, public outreach must be maximised. Internet alone cannot do the job; additional communication means, including broadcasting of science programmes, have to be developed.*

*It would be useful to set up information service that supplies fast reactions to the public and the media. Indeed, rapid reactions from scientists may be needed to compete with organisations whose aim is to block a technology. In this respect, the creation of positions in science communication and facilitation would be a first step: scientists are too busy to do this themselves, but young scientists wishing to go into communication at present do not have many obvious openings.*

- 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)?

*Public debate is a democratic process and, therefore, all players have to be involved and encouraged to participate. There is no optimal level of dialogue to be recommended; each one is having its own specificities and should be used to maximise public outreach and involvement.*

- 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?

*Dialogue is needed in all forms, but the anticipation that there has to be consensus after dialogue is, however, very optimistic. Consultations and other initiatives must be widely advertised to ensure that information reaches all stakeholders in due time. There is a clear need for an unbiased selection of truly representative organisations and personalities. Therefore, it is essential to avoid cryptic selection mechanisms and to ensure that the panel composition is cross-community checked. Avoiding over-representation of pressure groups is a challenge because these groups are extremely proactive, but it is a key factor for a fair representation of all stakeholders. The best way to reach most of the public in the various stakeholder sectors is to stipulate certain follow-up functions of dissemination and multiplication of the discussion and conclusions via these groups' representatives after the meetings.*

*Scientists have a major role to play as independent and credible experts in the public debate. The weak trans-disciplinary organisation of the research community, combined with the fact that time and money are often limiting factors for scientists, contribute to make it a 'low-profile' stakeholder in some consultation processes. This*

*is a challenge that needs to be tackled; public authorities must encourage a better trans-disciplinary networking of scientific organisations and should provide financial incentives to facilitate this process.*

- 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?

*A greater use of existing media, notably local media, is necessary to involve the public via their representatives. The public should also be made more aware of exactly who their representatives are, and what they actually stand for, in order to ensure that consumers' associations and pressure groups really represent the public.*

*A policy that will please all will emerge is unlikely to happen. The responsibility of politicians, and through them the policy makers, is to give a lead based on consultation and expert analysis of the facts in order to avoid confusion.*

- 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. labeling)?

*Smaller groups should be convened, that bring conflicting stakeholders together in the absence of the others, in order to tackle a specific lack of agreement. If this disagreement cannot be solved, trading of requirements may lead to a compromise. If not, a temporary conclusion must be drawn that explicitly states that one party's concerns have not completely been remedied, and that consultation will continue at the next given opportunity. It is important to address all issues democratically, for a whitewash that ignores unsettled disagreements leads eventually to a radical reaction.*

<b>7.1 REGULATION AND GOVERNANCE: REGULATORY ISSUES FOR GMOs, INCLUDING SEEDS, GM FOOD AND FEED</b>
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**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 challenge that faces the Community is clearly outlined in the statement that there is a need for a "continuous updating of assessment methods", notably towards more multi-disciplinary approaches. Increased investment has therefore to be made in assessment methods such that they remain appropriate for the new products and at the forefront of technological developments, and to ensure the safety as defined objectively of all new elements coming into contact with society. Consumers' perception and acceptance rather than the regulatory framework could curb R&D and innovation, and this can only be tackled by an appropriate communication of risks and policy choices.*

- 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?

*Facts and scientific data must lead in the discussion. Communication must involve all stakeholders, including member states, the Community, scientists, industry, and informed consumer and environmental groups, because a recipe that leaves the task to a single group would be either inadequate or would not be adhered to. In the case of the scientists, any ties to pressure and opinion groups or to industry have to be publicly disclosed in order to guarantee fair communication.*

*The main features of appropriate communication include simple explanations of exactly how the GM product differs from other products, and comparisons in all respects, including risk/benefit. The establishment of a body that can respond with timely information to consumer fears and request for advice is necessary. Risk/benefit communication must be done at the lowest possible level, e.g. in the supermarket, with the stamp of approval of the European Food Authority. To ensure its credibility the European Food Authority will have to demonstrate its impartiality and its independence from any industrial, economic and political pressure.*

- 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 and if so, how could the potential benefits be weighed against any risks?

*The introduction of a consumer benefit factor in assessing GMOs should be avoided. The consumer is not an individual respondent but a range of individuals with different perspectives of what their interests are and of what is of concern to them. Scientific facts correctly adjudicated are the only way of ensuring that an informed decision is based on the consumer's perception of its own needs.*

- 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?

*The implication in this statement is that there is scientific consensus rather than scientific facts. The reality is that there are scientific facts and there are modulating components that can give rise to an alternate interpretation. Ultimately the facts become consolidated by repeated experiments that in a fair-minded scientific debate are accepted by all parties. There is no place for minority opinions that do not have a very solid scientific basis. In other words, it is not the fact that being in a minority that should allow it to be included, but it is appropriate to include a minority opinion if there is a basis for this different interpretation of the scientific facts.*

- Based on the information about the Commission's short-term regulatory intentions, which **other actions at the Community level** may be needed?

*The Commission's short-term regulatory intentions are well balanced and the ELSF has no specific item to suggest.*

- 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?

*Risk assessment and regulatory measures have to be based on the most relevant and reliable scientific data available. They must be used to inform consumers but not to force or to restrict their choice. It would appear that the public likes to know whether they are dealing with organic, conventional or genetically modified foods; as a consequence proper labelling is essential.*

*Whilst the definition of GMOs is one area that has been addressed by the community, the definition of organic agriculture has received less attention. In this respect, comparative studies on the respective advantages and disadvantages of GM farming and traditional and organic farming on food production, health, environment or development must be carried out and communicated. There should be no presumption, however, that their products are in anyway different in terms of safety and nutritional and other benefits unless it has proven to be the case.*

- 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?

*No comment.*

- 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?

*Generally speaking the principles are fine but detail aspects remain unclear. For instance, when will risk assessment be proven to be sufficient, conclusive or certain? Does this allow all tests involving GMOs to be placed in a zone of non-decision forever? There is also a question as to whether the same test would be required for all conventional or organic foods. The GMO question is one that has two elements to*

*it: the impact to the consumer, and the impact on the environment. Both of these have to be studied carefully and scientifically while accepting that risk does not mean certain non-event. The same is true of conventional foods. Herbicide resistant plants are now being produced by conventional methods that fall outside the scope of the EC Directive, whilst these categories of genetically modified products are being used in food and feed. If one searches for a truly safe food environment, all components of the food chain have to be studied equally and vigorously.*

## 7.2 REGULATION AND GOVERNANCE: REGULATIONS AND OTHER APPLICATIONS

### **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?

*Regulatory constraints should be limited to scientific assessment of safety for humans in the environment. Many of the other issues are wide open for manipulation by pressure groups and may restrict the development of useful compounds for spurious reasons.*

- To what extent, if any, does European legislation that affects biopharmaceuticals unnecessarily impede **competition and the marketing of new medicines**?

*A major factor in reducing the potential of the European biotechnology and pharmaceutical industry in developing new drugs and therapies is the fragmentation of the rules governing clinical trials, and the lack of a single European agency authorizing and overlooking early clinical experimentation (phase I/II trials). This causes uncertainty and imposes an unnecessary administrative burden on biotech companies trying to develop new or highly experimental treatments, such as cell or gene therapy, and ultimately discourages the use of European clinical centers for developing new therapies. Europe should acknowledge the role of the Federal Drug Administration as a major factor in governing, stabilizing, and ultimately promoting drug development in the US, and accelerate the establishment of the European Agency for the Evaluation of Medicinal Products (EMA) as its European counterpart.*

- Should European pharmaceuticals legislation be reformed further to ensure the effective development of **Orphan drugs**? If so, how?

*The ELSF cannot assess the impact of the newly introduced regulation. The forum however feels that, as for poverty-related diseases, public research and the involvement of small biotech companies in the development of orphan drugs and therapies must be encouraged and facilitated. Public investment has a crucial role in*

*developing therapies for diseases that do not represent an attractive target for the pharmaceutical industry, and should more aggressively pursue policies of direct or indirect incentives for non-profit organisations, academic centres and biotechnology SMEs in developing such therapies.*

- 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?

*The linkage of research grants for pharmaceuticals research to anything other than the quality of their research should be seen as mistake. Linking the obtaining of grants or credits to the access of research products to clinical trials would result in a blockage of future research. Government funding for clinical trials should only be considered if there is a very major real alignment of the business policies of the pharmaceutical industry. In this case drug prices would have to be closely monitored, as the costs of clinical trials are normally used as a major justification for extremely high costs of compounds. On the other hand, public funding or financial measures such as tax credits should be concentrated on pharmaceutical or biotechnology companies willing to develop new treatments for rare, genetic, third-world, or otherwise orphan diseases, which impose high costs on the mostly public European healthcare systems, and do not represent an economically attractive alternative target for private investment.*

<b>8.1 THE INTERNATIONAL DIMENSION: TRADE AND INTERNATIONAL COLLABORATION</b>
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**Consultation questions**

- Which areas and issues lend themselves best for efforts to **converge and harmonise approaches internationally**, and how?

*All issues, scientific, ethical, societal and economic, related to the biotechnologies must be approached internationally.*

- 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?

*As stated in the Consultation document biotechnology issues concern many international bodies. In order to avoid duplication of efforts and reach higher efficiency networking of working groups would be desirable. Emphasis should be set on flexibility of the networking, and mega-events should be avoided. The mode of operation of international bodies such as the United Nations agencies (FAO, WHO) in terms of transparency and involvement of the different legitimate interests is usually quite satisfactory. In contrast, informal meetings of the G7 or the mode of operation of organizations like the WTO are questionable.*

- 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?

*Biotechnology and biotech products have a great economic potential. Given the globalisation of trade and the resulting increased competition, which may have dramatic social and economic implications, Europe cannot afford to miss the biotechnology revolution. Europe must meet the challenge of developing high technology industry and services, otherwise it will face the risk of its own decline. In*

*this respect, it seems well understood by the European Institutions that public acceptance of biotechnology is a key issue. Is it therefore necessary to reiterate that this acceptance can only come from better information strategies based on convincing scientific evidence?*

## 8.2 THE INTERNATIONAL DIMENSION: DEVELOPMENT POLICY

### **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?

*Biotechnology can be a major instrument to address specific needs of developing countries provided that some prerequisites are met. The balance between altering the current practices in the countries and bringing in new ones must be considered carefully. Specific solutions must be implemented for the lowest developed countries, and the responsibilities for governments worldwide must be established, as exemplified by the recent World Trade Organisation's agreement on medicaments. The role of public and private sectors must be clearly defined, and strong public funding for R&D programmes targeting specific needs of developing countries is required. The EU is planning to do so for poverty-related diseases like malaria, Aids and tuberculosis in its next Framework Programme. This policy could be extended to other fields of biotechnology, e.g. some aspects of green biotechnology, in order to make this technology and its products accessible to the poorest countries, thereby harnessing the full potential of biotechnology.*

- 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?

*Both improved traditional production methods and modern biotechnology can significantly contribute to tackling the specific needs of developing countries, and ultimately what may distinguish between these production methods is their capacity to increased yields such that it matches demand in a sustainable manner. It is important, however, to stress the need to improve and adjust native strains and organisms rather than importing optimal European animals or plants, as each environment requires a different complement of genetic factors. The selection that has been carried out in developing countries over many years against diseases and pests cannot be ignored by any theoretical solution such as bringing in higher*

*yielding animals or plants. The argument in favour of introducing a single gene into the native stock and plant varieties such that the new trait is added to the old should be viewed positively.*

- What are the prospects for **biotechnology research in developing countries**?  
What are the main obstacles to application of biotechnology in developing countries?

*The prospects for biotechnology research in developing countries are strictly related to the quality of the science that can be performed there. The lack of money therefore must be seen as the major obstacle. This allied with infrastructure gaps is a complicated combination that will make it difficult for the developing countries to reach parity with the developed countries in this area unless financial resources are provided.*

*The establishment of a knowledge-based society and economy relies on human resources. The development of the education systems in developing countries is therefore a prime objective. Networking of European universities and universities from developing countries should be encouraged. Europe also has a major role to play in educating and training young scientists from developing countries, and in providing them with genuine mechanisms to re-integrate their countries of origin. The EU could increase the number of research programmes carried out jointly by European and developing countries' research groups, and subsidises initiatives such as the Consultative Group on International Agricultural Research (CGIAR), which is directly addressing the needs of developing countries by supporting local biotechnological R&D, and through the provision of training opportunities and research infrastructures. Intellectual property rights have also an impact on research carried out in developing countries because genetic information is increasingly protected. To address these questions, the public and private sectors should negotiate a global licensing system that makes agricultural and healthcare biotechnologies available to developing countries.*

*The main obstacles to application of biotechnology in developing countries are the development of products with a true and perceived interest, and the access of sophisticated technology and biotechnology products at a reasonable price. Key factors for the success of biotechnology in developing countries are thus the financial and technological accessibility, farmers and consumers perceived benefits, and the necessary training and education of farmers.*

- What impact will the **Biosafety Protocol** have on the application of biotechnology in developing countries?

*The use and impact of biotechnology to address the needs of the poorest countries cannot be considered separately from other development policies and from global trade issues. For some developing countries agriculture represents a major source of income through export of their products. It may therefore be detrimental to foster a biotechnology-based agriculture in developing countries and at the same time ban the import of its products in Europe. The Biosafety Protocol requires the exporting country to provide enough scientific information to allow the importing country to judge risks. Two questions must thus be addressed: 1. Is it reasonable to develop agri-biotechnology applications in developing countries as long as a moratorium on GM products is in place in Europe? 2. Which mechanisms should be implemented to help developing countries to develop the scientific expertise and to face the costs incurred to respond to the requirements created by the Biosafety protocol?*

- 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?

*Transparency must be the guiding principle in terms of the dissemination of research and testing results. This of course would extend to the developing countries, and they like all other citizens should have access to the results of GMO tests, not least because this may be reassuring to them should the results be positive and benefits predicted for their agricultural systems.*

- 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?

*The concept that traditional knowledge in biotechnology has a value is well established. If this information were not available to other countries, then it would be a retrograde step for all. One of the most important aspects therefore may be to link studies of traditional knowledge with the provision of extra resources and facilities in the country such that their scientific skills, development, and protection of natural resources may be improved.*