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Life Sciences and Biotechnology - A Strategic Vision

Commission stakeholder conference
Brussels, 27th - 28th of September 2001

Commission reports on the four workshops*

(Revised version 1)

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* The present reports are the Commission's *rapporteurs'* summaries of the discussions in the four workshops, drawing in particular on the contributions of chairs and panel members of each of the workshops (see the conference programme for chairs and panel members), as well as contributions from conference participants in general. As the conference and workshops are part of the wider public consultation launched by the Commission, the present reports do not represent definitive conclusions but elements for further reflection.

Report on Workshop 1: Potential and Research

Rapporteur: Bruno Hansen, Director DG RTD

Session 1 - potential

- Mapping the potential in healthcare, agriculture and environmental protection and anticipating the implications.

  Due to the time constraint the Chairman requested a focus on three areas of potential: healthcare, agro-food, developing world. Topics such as bioremediation and biocatalysis were therefore not included.

Healthcare

- A new paradigm is taking place with a move from disease management involving diagnosis, therapy and monitoring to personalised and preventive medicine based on genetic predisposition, targeted screening and preventive measures. Developments in pharmacogenomics will underpin this radical change in the approach to healthcare.

- The dose response of many common drugs, which can vary by a factor of 1000 from one individual to another, can now be related to the genetics of the patient hence allowing personalised and more appropriate medicine. Pharmacoeconomics research should also be supported as biotechnology derived drugs are often considered to be more expensive but may in the long term serve to reduce healthcare costs.

Agro-food

- Biotechnology has the potential to deliver improved food quality and environmental benefits through agronomically improved crops. Food and feed quality may be linked to disease prevention and reduced health risks. The enhancement of natural disease resistance may lead to reduced use of chemical pesticides and hence direct environmental benefits.

- Consumers are no longer considered the "end-point" for agriculture and they now play a critical and influential role from "fork to farm". However, more needs to be done to further consumer understanding of the role that biotechnology could play and facilitate real choice.

Developing world

- World population increases are faced with declining land and water resources. Existing agricultural practices will often have disastrous environmental impacts. The need for agricultural research has never been greater but it must be focused on topics that will save lives such as drought resistance, salt tolerance etc. Both private and public resources should be

drawn upon to tackle the problems that exist and North/South partnerships are of vital importance.

- Researchers will need to use all available tools including the new technologies which should be freely available to poor farmers and not restrained by intellectual property rights. Biotechnologies must be seen as a tool that is available to plant breeders to exploit the new genomics knowledge base and increase the speed and efficiency of traditional breeding.

Session 2 - Research and transfer of knowledge into practice

Research

- The need for a strong, shared knowledge base through the creation of a European Research Area was considered essential. The development of integrated and multidisciplinary teams across Europe will require highly trained scientific managers. Support should be provided for advanced training courses in management and bioinformatics.

- Data such as clinical trial information needs to be in a form that can be shared. Access to data will require standardisation including ethical standards in sharing personal data and samples.

- There is a real need to draw upon all available resources through private and public sector partnerships including international collaborations.

Transfer of knowledge into practice

- The need for professionalism in technology transfer, intellectual property rights and management was emphasised. It is important to have well-trained top people for technology transfer and there is still much variation in quality between Member States institutes.

- The importance of private/public sector collaborations was highlighted (provided this does not compromise academic independence). As part of the follow-up to the Lisbon summit the European Investment Bank (EIB) is now providing loans for R&D in collaboration with DG RTD. The European Investment Fund (EIF) is the venture capital arm seeking to support start-up companies.

- There is a continuing need to develop and harmonise standards and regulations relating to risks, benefits and value assessments to ensure effective technology transfer. A European Patent scheme would be a great help and some considered that a grace period should be introduced in the EU as exists in the US.

The way ahead for European Research

- Research capacity needs strengthening. University/industry collaboration may substantially gear-up the funds available for research. Infrastructure support may be shared and compatible networking enhanced. Centres of expertise should be established on specific topics such as biocatalysis or industrial sustainability.

- Skill resources must be increased and a "brain-drain" reversed to become a "brain-gain".

- Schemes to promote risk-taking attitudes and the entrepreneurial approach should be established. Best practice should be encouraged to spread across Europe.

- Ethical concerns must be addressed at an early stage in R&D. Access to medical records and genetic data banks are examples of where ethical guidelines/standards are needed.

- Awareness of commercialisation potential should be raised among academics particularly relating to intellectual property rights and technology transfer.

- Advanced training courses for large-scale, multidisciplinary project managers should be established.

- Public understanding of science and technology developments should be promoted.

Report on Workshop 2: Innovation and Competitiveness

Rapporteur: Christian Siebert, Dept. Head of Unit, DG ENTR

Session 1 – Where we are

- **Relevance for Europe's competitiveness and innovation**

  Biotechnology is perceived by many as another technological wave, following and interacting with the IT-wave. Biotechnology is considered an enabling technology with cross-sector impact on areas like healthcare, environmental protection, agriculture, and many service industries. Technology convergence already takes place (e.g. with IT in Bioinformatics).

- **Europe's biotechnology industry**

  Industry recently grew in number to over 1500 dedicated biotechnology companies in Europe (SMEs, stronger growth in the pharmaceuticals sector than in agriculture). Member States with the highest number of firms (UK, D, F, S) show a strong regional concentration (regional clusters). These clusters are rather limited in scope, often having national boundaries (contrary to the US where clusters are broader in coverage). In addition, large US universities act as integrators in a way that European universities do not. European research is more in the domain of specialised centres (like Pasteur in France, Max Planck in Germany), and not so tightly linked with business.

  By comparison, the USA has achieved an advance with an already more established industry (bigger company size, higher revenues, higher capitalisation, more marketable products in pipeline). The ratios in favour of the US seem, depending on the question, to range between 3 and 10 to 1.

- **Is Europe lagging behind?**

  There are signs for a positive evolution:

  Industry is developing new business models for the co-operation (e.g. through licensing) between biotechnology SMEs and big pharmaceutical corporations. Finance sector increasingly perceives biotechnology as a distinct asset class and provides more capital; however, capital supply may not yet be sufficient at all company development stages.

  There remains, however, a sense of "Fragmentation":

  In what is called the "European paradox", Europe's strength "upstream" (its science base) is not sufficiently arriving "downstream" (marketable products). Links between the university and industry spheres as well as interregional research co-operation remain weak (empirical evidence shows low degree of co-research, co-patenting, technology transfer between member states).

- **Conclusion**

  The summary seems to be that Europe's activity is starting to substantially lack behind the US. The structure of research & development activity is quite different in Europe. The other form of the European "paradox" seems to be that there is plenty of diversity (which should be good for innovation and research), but that because it is so firmly divided and fragmented, Europe's network does not benefit from the "network" effects that the US activity benefits from. This needs to be addressed quite forcefully.

Session 2 - Where do we go?

Need for a European agenda

The Lisbon European Council (in 2000) took the commitment for Europe to become the world's most competitive and dynamic knowledge-based economy within the next 10 years.
The Stockholm European Council (in 2001) recognised biotechnology as a contributor to this objective and requested to examine appropriate action.

Discussion in the workshop revealed that the growing lag with the US and the fragmentation of Europe's activities seem to make a critical case for a European initiative in this area. The good news of the day is that there seems to be almost no one countering this conclusion. The direction of such an initiative would be to induce greater collaboration between existing centres, in academia and business, and across these domains. In addition, there is a need for additional focused investments in this domain, on a competitive basis.

- **Basis for success**

  Necessary condition for this knowledge-based industry clearly is identified as people, in a broad sense. This includes both focused scientific excellence as well as entrepreneurial excellence. Centres of scientific excellence in specific technology areas, spread over regional clusters in Europe, already exist and should thrive further. An "intelligent management of diversity" would seek to exploit the "network" benefits of this regional specialisation. Increasing the entrepreneurial resource bases should equally be stimulated, including through the initiation of new teaching programmes dedicated to this cause.

  But, beyond selected investments in the "people and training" areas, many of the suggestions for improved performance in this area were generic to other economic sectors as well. These include: stable and relatively predictable regulatory framework, increased economic incentives, greater risk taking and entrepreneurship, … which, if implemented, would strengthen entire sectors of the economy, not just biotechnology.

- **Change of mindset**

  A common theme of discussion was the need for a "change of mindset" into a more entrepreneurial spirit that facilitates different forms of "networking/linking-up" to overcome Europe's current "fragmentation".

Examples:

- Clusters: they combine private/public research, biotechnology SMEs/big pharmaceutical companies, possibly in interregional co-operation
- Incubators: public/private organisations that host and support start-up companies in their early phase
- Technology transfer: should there be a European-wide mechanism?
- Skills: Successful operation of biotechnology SMEs requires the combination of scientific knowledge with entrepreneurial management skill.
- Concept of innovation as a "chain" of co-operation rather than a one-off event: large companies adapt their organisation and set up small business units to detect co-operation possibilities with innovative SMEs.

- **Regulatory framework**

The subjects of all other workshops (research, public attitudes, regulation) have a clear impact on competitiveness. As regards the regulatory framework:

- Improvement of Intellectual Property protection appears essential (Community patent, implementation of biotechnological inventions Directive)

- Functioning of the regulatory framework that specifically applies to the biotechnology industry can improve through early dialogue with member states (to facilitate application) and internationally (to reduce trade friction).

- **A multi-level responsibility**

Action will imply private operators as well as public authorities at all (regional, national, European) levels, according to responsibility, but with a common focus on excellence and effectiveness of the measures envisaged.

Report on Workshop 3: Regulation and Governance

Rapporteur: Paola Testori Coggi,
Director, DG Health and Consumer Protection

The Workshop unanimously welcomed the public consultation launched by the Commission and the opportunity to participate in a broad and forward-looking public debate on a wide range of issues surrounding biotechnology, including ethical preoccupations, public perception, innovation and competitiveness.

The regulatory framework

There was general agreement that regulatory oversight was needed to ensure the safe and socially acceptable development and application of biotechnology.

In this respect the enactment of Directive 2001/18/EC earlier this year and the recent proposals of the European Commission on genetically modified food and feed and on the traceability of GMOs were perceived as heading in the right direction.

There was hardly any disagreement:

- that **GM seeds, food and feed should only be authorised if they have been found to be safe for human and animal health and for the environment**,

- that **decisions should be based on the outcome of a full and complete science-based risk assessment** (and the Commission's proposal to abandon the notification procedure for "substantially equivalent products" was welcomed in this respect),

- that **it was essential that scientists participating in this risk assessment would both be independent and appear to be independent** (some participants went as far as suggesting that too many scientists were seen to be serving the interests of industry and not the public at large; more publicly funded research was therefore needed to inform the risk assessment of GM products; and a good deal was expected from the future European Food Authority and its envisaged role in the assessment of GM food and feed),

- that **a high degree of transparency and public information was therefore essential, throughout the assessment and the decision-making process** (some participants specifically underlined the need for the public to have access to summaries of applications and to be allowed to make comments on these before conclusions were reached and decisions were taken).

Controversy developped about **the new labelling rules** proposed by the Commission. Labelling all food and feed produced from a GMO, irrespective of the presence of DNA or protein resulting from the genetic modification, was welcomed by consumers, environmentalists and retailers. This was necessary to allow consumer choice, said Commissioner Byrne. But some participants felt

that this would be too costly, unenforceable; some even argued that it would reduce, not increase consumer choice, as retailers were likely not to stock GM products at all. Other participants felt, on the contrary, that the Commission proposal was not going far enough: everything had to be labelled, they said, whenever a biotechnology process had been used at some stage in the production of the food concerned (e.g. meat from animals fed on GM feed). This again prompted questions as to whether consumer choice would not be reduced, rather than increased, by the operation of such a wide-encompassing labelling provision.

Also controversial was the suggestion that science alone is no longer sufficient and that values should play a greater role. Should the **benefits of GM foods** for society be taken into account when reaching decisions on their authorisation? Commissioner Byrne stated that this was no matter for risk assessors or risk managers, and that this should be left for the public and the market to decide. There would be little response from the market, said the Commissioner, unless there were clear consumer benefits associated with GM food, if only in terms of reduced prices.

Serious concern was further expressed about **enforcement of the regulatory framework**. Good regulations were not enough, said Mr de Greef, speaking on behalf of the biotechnology industry, if there is little political will to enforce them. Others stressed the importance of validated analytical methods for proper and effective enforcement. Too little had been done in this respect and the Commission should draw the necessary conclusions.

Mr Consoli, from Greenpeace, had strong words about the proposed 1% threshold for **adventitious** contamination from unauthorised varieties proposed by the Commission, about the lack of an adequate **liability regime** and about the **patentability of genes, living beings or parts of them**.

Governance in the international perspective

There was general agreement that **public information and public debate** are essential not just in connection with the authorisation process for GM products, but more generally about the development and application of life sciences and biotechnology. The Commission should take more initiatives like this Conference, said many participants.

Mrs Corbey, MEP called for wide **public involvement in all decisions about biotechnology**, not least those about research and investment, whether public or private. “What is needed, said Mrs Corbey, is a democratisation of knowledge”.

The Chairman of the Workshop, Mr Brinkhorst, insisted that the **public debate should be based on sound scientific data and clear and correct facts**. NGOs and industry should engage in an open dialogue and overcome the current excessive polarisation of the debate surrounding biotechnology. To this effect, suggested Mr Brinkhorst, they should be made accountable to the public for the information they provide.

There was broad consensus on the need to preserve a **multifunctional agriculture** in Europe. Several participants noted the need to safeguard the co-existence of conventional and organic agriculture alongside GM crops. Unfortunately, there was not much time to discuss how this could be achieved, except to underline that leadership was expected from the European institutions.

Public dialogue was also important at the **international level**, not only between Europe and the industrialised World, but also, crucially, with **developing countries**. Mr Liégeois, speaking on behalf of the Belgian Presidency, stressed the need to orient research towards application in developing countries and the need to ensure that these countries are capable of exploiting the new technologies

The European Union should continue to **favour negotiated international solutions**. The Biosafety Protocol was seen by the Workshop as providing a good framework for international harmonisation, although there were concerns about its wider ratification. Multilateral processes, such as the *Codex Alimentarius*, were agreed to be important although they are often very slow, and not immune from political influence.

Conclusion

The Workshop did not reach formal conclusions.

What clearly emerged, however, from a remarkably educated and well conducted debate, is the general willingness from all quarters to engage in a constructive dialogue on how to establish, in Europe and at the international level, a stable, predictable and trustworthy regulatory framework which is capable of:

- guaranteeing that the development and application of life sciences and biotechnology are safe for humans and animals,

- safeguarding the biodiversity of our environment and the multifunctionality of our agriculture,

- allowing consumers to choose as they wish between the produce of genetically modified, conventional and organic agriculture, and

- enabling our farmers and our industry to seize the opportunity that these new sciences and technologies offer, for the ultimate benefit of Society at large.

Report on Workshop 4: Public Perception, Ethical Implications

Rapporteur: Bernhard Zepter, Deputy Secretary General

The discussion in Workshop 4 was particularly rich and lively. It's almost impossible to deliver a complete summary. Given the particular nature of the issues, rather than to try to present a systematic overview, I would like to refer to some key points and arguments of our debate and in particular to **such ideas and suggestions** that **could help the Commission** to **identify important elements for the strategy** we wish to present to the Council and the European Parliament by the end of this year.

The discussion centred on two main clusters which were **public perception** and **ethical implications**. But of course there was a substantial amount of **overlapping** and **interaction** between these two clusters.

The need for clear distinction between pure **science** and **application** of science through **production** and **marketing** of life sciences and biotechnology products was stressed from the outset, despite the fact that **public perception** did not necessarily make this distinction**.**

Public Perception

The presentation of panellists and the following discussion revolved around the **definition of public opinion** and the **specific nature of** the **public debate** on life sciences and biotechnology.

There was a predominant view that in public perception there was a distinct difference between so-called **"red" biotechnology** (medicines and pharmaceuticals) and **"green" biotechnology** which refers to plant biotechnology. Whereas red biotechnology is generally accepted, consumers appear to see no or little benefit in GMO's for food, feed and seeds.

One participant in the discussion took, however, the view, that the pharmaceutical industry takes hostage its clients to pressure for the protection and promotion of biotechnology pharmaceuticals. Others did not share this view and underlined the obvious contradiction between the acceptance of red and the apparent rejection of green biotechnology.

The **choice of the consumer** was an important issue in this context. Everybody stressed the need to give the consumers the **relevant information** on biotechnology products. Was **labelling** the right answer - and what type of labelling? Some stressed the need for meaningful information, easy to understand. It was also questioned whether the European markets **offer a real choice** since GM products, in practice, are not offered on these markets - or not offered in transparent competition with non-GM products.

Another question was how much biotechnology **really mattered** in public perception. It was noted that according to EUROBAROMETER, only 50% of consumers have ever discussed biotechnology with someone else. But the

printed **press** has significantly **increased its coverage** over the last 30 years of scientific question.

There was reference to Portuguese and Danish efforts to ensure discussion on science through the **educational systems**, including the necessity to teach children how to cope with the issue.

Reference was made to **patenting legislation and practices**, criticising its imprecise terminology which raised fears and led to apprehensions**.**

Another key question was: how does and how should **different actors** respond to public opinion? There was unanimity on the need for a **public dialogue,** also to improve **knowledge**. Among industry there are different strategies and **experiences** ranging from TESCO (retailer company): "follow the consumer" to Novo Nordisk or other producers: "dialogue with and convince the consumer". The question was raised: "What are the ingredients of **trust** in public decision-making?" Several spoke of a **social contract** in this context. George Gaskell in particular suggested **public dialogue** and **public consultation,** but on condition that public authorities be genuinely ready to **listen** and **adapt** and that **decision-making** is **transparent** and **accountable**.

Public funding for **research** was mentioned as an important element to improve trust.

Questions were raised about **who represents** the civil society and the democratic legitimacy of NGO's. Questions were also raised concerning the role of **big money** in this context, also with respect to private research and the neutrality and independence of science in support of public policies.

Some expressed the view that the debate and policy making is hypocritical in neglecting some deep incoherences between expectations to agriculture/food production and actual consumer behaviour which is to buy cheaply. The important role of consumer organisations to improve quality and to respond to the real wishes of the consumers was underlined.

The Ethical Implications

The strongest message was the need to accept the value of human life and to preserve human dignity. There was a very strong plea from Xavier Mirabel not to link the **value of a human being** to normality of physical or mental characteristics but to accept deviances as such. Imperfection was part of human life and of our culture. Xavier Mirabel referred to the **rights of disabled** to live in dignity and to meet with understanding. Life sciences and biotechnology should not be the means to make artificial adjustments in favour of more uniform characteristics of life.

The issue of **non-discrimination** played an important role in this context in the discussion: the key question is to ensure quality of life, avoiding to judge or make decisions on behalf of others. Margot von Renesse referred to the ongoing discussion in Germany where economic success was sometimes judged as immoral. It was important to preserve human **dignity** as an **expression of human freedom** and **freedom of choice** according to Emanuel Kant's **moral principles.** At the same time it was important to take the difficult discussions on

ethical aspects and not to establish an **artificial hierarchy** among them (between more important and less important values). A **broad debate** was needed, not "**top-down**" decisions by experts and bureaucrats.

Margot Wallström gave a short insight into the present debate within the Commission in order to shape an appropriate strategy and to launch an ongoing process of **discussion with stakeholders**. She stressed the importance for the academic community to accept **self-limitations** on the basis of a sound ethical debate in order to regain public confidence, referring to the precedent of the 1975 Asilomar scientists' voluntary guidelines.

Octavi Quintana Trias explained the role of the **European Group of Ethics in Science and New Technologies** and expressed the important role which such groups can play in order to identify and clarify the constantly evolving issues and to bridge the gap between science and the society. Others felt that such committees could be more of an obstacle for direct debate among the public or their representatives.

In the discussion, the question was also raised whether societal limits should be set, and which instruments could be the more useful ones? Some favoured prohibition (e.g. on reproductive cloning). Others felt, as a matter of principle, that **prohibition** was too inflexible as an instrument in the face of rapidly evolving sciences and technologies and preferred more flexible solutions like moratoria. Some thought that setting **limits** was important and called for **societal rules**, others preferred that ethical matters should mainly remain a matter of **personal conscience.**

The **European dimension** was **generally present** in the debate. In that context, the following points should be highlighted:

(1) It was noted that ethical debate in Member States **varies** greatly. A European debate is therefore **useful** and welcome.

(2) Although limited, **Community law** gives some relevant basis (e.g. the Charter on fundamental rights).

(3) The Community has already integrated procedures and criteria for taking into account ethical implications into e.g. **research funding.** But there was encouragement for the Commission to do more in this respect.

(4) The need to respect the **principle of subsidiarity** was also stressed.

(5) In the context of the international dimension: some participants stressed the need to **avoid an EU-centric approach**.