

REPORT OF THE EUROPEAN ROUND TABLE ON EU REGULATIONS FOR LIFE SCIENCES AND BIOTECHNOLOGY

BIONale, 2 November 2004

Rapporteur: Piet Schenkelaars

After a short introduction of the discussion paper by the rapporteur the chair gave the participants the opportunity for an exchange of views.

1. Horizontal actions

Discussion:

The participants first discussed the intricate interactions between European and national policy makers, politicians, pressure groups and the general public. This led to complicated regulatory frameworks for life sciences and biotechnology, particularly in the area of agro-food applications.

While the European life sciences and biotechnology strategy was appreciated as such, some participants pointed out that the real problem concerned its implementation. It was thereby noted that at the EU and national levels governmental institutions, ministries and directorate-generals were not always undivided in their views.

Several participants deplored that Europe lacked strong political, industrial and scientific leadership, while others further argued that it was urgent to inform the public about the need for applying life sciences and biotechnology with a view to wealth creation, employment opportunities and the quality of life. Some participants also noted that policy makers generally lacked a sense of urgency despite that Europe is lagging behind to its main competitors, in particularly the USA.

Subsequently, the participants discussed the actions proposed by the discussion paper for an integrated impact assessment, when formulating new EU legislation on life sciences and biotechnology and reviewing the workability, controllability and enforceability of existing EU directives and regulations. It was argued that the European Commission already more or less used this approach. However, the ensuing political negotiation process between the European Commission, the European Parliament and the European Council often resulted in 'last minute compromises'.

The chair established that the participants widely shared the view that an integrated impact assessment and benchmarking of regulatory implementation practices of EU member states and non-EU countries could contribute to better lawmaking in the area of life sciences and biotechnology.

Conclusions:

There was wide support for Actions 1.1, 1.2 and 1.3 to apply integrated impact assessments and benchmarking of regulatory practices of EU member states and non-EU countries, when formulating new EU legislation on life sciences and biotechnology and reviewing existing EU directives and regulations.

Implicitly, this also meant that there was support for Action 3.5 to apply such an approach to the review of the GM food and feed Regulation, on which the European Commission must report in November 2005.

2. Harmonisation actions

Discussion:

The participants generally agreed that it was crucial to harmonise the implementation of EU regulatory frameworks for healthcare biotechnology, agro-food biotechnology and industrial biotechnology at national level, so as to create a level playing field within the EU. Some participants argued that harmonisation might not always be that easy, particularly in the case of healthcare biotechnology applications, where EU member states might adhere to considerably different ethical values.

Other participants explained that differences in interpretation of definitions between EU member states, like the definition of 'genetically modified micro-organism' (GMM/GMO) in the case of so-called 'self-cloned' micro-organisms, led to unfair competition practices in the area of industrial biotechnology. It was also pointed out that the continuous development of new techniques to alter the genetic make-up of organisms, including micro-organisms and plants, also required to revisit these definitions regularly.

Moreover, for fermentation products from GMMs, it was urgent to clarify the scope of the GM food and feed Regulation. Notably, the chair pointed out that both issues of how to regulate 'self-cloned (GM) micro-organisms' and the scope of the GM food and feed regulation as to fermentation products of GMMs would probably not be well understood by most politicians, because of their technical nature.

Several participants reiterated that it was urgent for the European Commission and national governments to implement and improve the EU regulatory framework, as well as to raise public awareness and support for life sciences and biotechnology. As biotechnology applications for healthcare and environmental management were less prone to public debate than agro-food applications, some participants believed these applications could be used as starting point for public communication.

Other participants argued not only to approve the import and processing of GM crops but also to lift fully the so-called de facto moratorium by approving their cultivation in

Europe. Otherwise, European farmers would loose competition against non-EU farmers, who were allowed to export GM crops to the EU.

Conclusions:

There was wide consensus that EU regulatory frameworks for healthcare biotechnology, agro-food biotechnology and industrial biotechnology should be implemented in a harmonised way at national level. This implied that Actions 2.1, 2.2 and 2.3 for a further harmonisation of regulatory approaches to healthcare biotechnology, in particular gene therapy clinical trials were implicitly supported.

Action 3.1 to establish minimum thresholds for GM seeds in lots of non-GM seeds was explicitly supported especially by participants representing (biotechnology) industry. Action 3.2 for further biosafety research and Action 3.3 for support to the EU Task Force on co-existence were not explicitly addressed.

Finally, there was wide support for Action 4.1 to adopt a common position on the scope of the GM food and feed Regulation as to fermentation products from GMMs, as well as for Action 4.2 to adopt common guidance as to whether a self-cloned micro-organisms should be considered a GMM.