

BIONale 2004, Maastricht, 2 November 2004

**EUROPEAN ROUND TABLE ON REGULATIONS
FOR LIFE SCIENCES AND BIOTECHNOLOGY**

DISCUSSION PAPER

final version

26 October, 2004

Prepared by Schenkelaars Biotechnology Consultancy
In commission of the Netherlands Ministry of Economic Affairs

BACKGROUND

This discussion paper summarises a review of the present state of affairs as regards the EU regulatory frameworks for healthcare biotechnology and agro-food biotechnology. Its aim is to facilitate an exchange of views at the European Round Table on the needs for further action in this area. The following four documents were key to the review that can be found in the Annex to this discussion paper:

- The EU Life Sciences and Biotechnology Strategy of 2002.
- The Competitiveness in Biotechnology Advisory Group (CBAG) report of 2003.
- The 2nd progress report on the EU Life Sciences and Biotechnology strategy of 2004.
- The Competitiveness Council of May 2004 on approaches to better regulation.

1. COHERENCE AND IMPACT OF EU LEGISLATION

In 2002 the Commission recognised in its strategy for life sciences and biotechnology that Europe does not have a single policy for life sciences and biotechnology but a patchwork of specific regulations, overlaid by many sectoral and horizontal policies at international, Community, national and local levels. Therefore it was proposed to monitor progress in biotechnology policy development, to anticipate emerging issues, and to review the coherence across Community legislation and policies, with particular attention for achieving international objectives and facilitating innovation and competitiveness. The Commission services would be enhanced for early identification of newly emerging issues, as well as its monitoring and review function of the coherence and socio-economic impacts of EU legislation and policy measures. Member States were called upon to also provide enhanced foresight/review functions and a co-ordinated interface for policy dialogue.

In 2003 the CBAG noted that new or improved EU legislation must be as good or better than that of Europe's main competitors, in order to truly raise competitiveness. Requirements for industry to comply with legislation should be proportionate and should strike the right balance between the enabling and controlling objectives. In addition, legislation should particularly take due account of Small and Medium Enterprises (SMEs), which are a vital parts of the biotechnology community. For them, requirements and procedures, which are manageable by larger companies, might represent a major obstacle or even a dissuasion to engage in certain activities. Notably, in its second progress report of 2004 the Commission indicated that more active co-operation from all Member States was needed as regards the newly adopted legislation governing genetically modified organisms (GMOs).

The implementation of both EU regulatory frameworks for healthcare biotechnology products and for agro-food biotechnology products requires an efficient and effective functioning of the interfaces between 'vertical' product legislation and 'horizontal' GMO legislation. Notably, at these interfaces the Commission, the European Medicines Evaluation Agency (EMA), the European Food Safety Authority (EFSA) and Member States sometimes experience difficulties in co-ordinating and fine-tuning data or protocol

requirements in the context of centralised assessment and authorisation procedures, given specific national or regional circumstances.

While in May 2004 the Competitiveness Council recognised life sciences and biotechnology as key enabling technologies for a knowledge-based economy, the Council also adopted a series of conclusions as regards Better Lawmaking (in general). The Competitiveness Council further suggested a series of actions to the Commission and Member States, aiming at simplifying EU legislation through reviews, based on an integrated assessment of socio-economic impacts, administrative burden to business and regulatory quality, with an emphasis on the competitiveness dimension.

Recommended actions:

1.1: Base monitoring and reviewing of both EU regulatory frameworks for healthcare biotechnology and agro-food biotechnology on an integrated assessment of socio-economic impacts, administrative burden to business and regulatory quality, with attention for the functioning of the interface between product legislation and GMO legislation.

1.2: Benchmark regulatory approaches and implementation practices of Member States and non-EU countries for life sciences and biotechnology at regular intervals and improve further the exchange of best practices on better regulation between the Commission and Member States.

1.3: Make information relevant to an assessment of socio-economic impacts, the administrative burden, the regulatory quality and benchmarking publicly available, in order to maximise the benefits of consultation procedures.

2. HEALTHCARE BIOTECHNOLOGY

The revision of the Community pharmaceutical legislation, which was adopted in March 2004, essentially corresponds with most of the CBAG recommendations. It includes a centralised assessment and authorisation procedure for a large majority of current healthcare biotechnology products, while it reinforces the strengths of the EMEA and the centralised authorisation procedure. For the implementation of the assessment of biotechnology-derived medicinal proteins the EMEA has in the mean time issued two technical guidelines and an action plan for the maintenance, revision and development of a series of other technical guidelines for several types of healthcare biotechnology products.

Since many of the gene therapy products currently under development are GM viruses, these products are classified as GMOs, which are either regulated under the contained use Directive or the deliberate release Directive at national level. The EMEA agreed to develop the scientific Environmental Risk Assessment (ERA) requirements, also because market authorisation of gene therapy products requires an ERA to be made for the GMO. Yet, there is still a need for harmonisation of regulatory approaches to the ERA of gene therapy clinical trials throughout the EU. Meanwhile, for gene therapy trials in multiple centres in different Member States, an approach could be that one of the Member States

takes the lead in co-ordinating and fine-tuning the set of the protocol requirements that are to be met by the applicant in to obtain from all involved Member States.

Recommended actions:

2.1: Continue and further improve consultation by the Commission and the EMEA of interested parties with a view to maintain, revise, update and/or develop common guidelines for the centralised assessment and authorisation of healthcare biotechnology products.

2.2: Harmonise national differences in regulatory approaches to gene therapy clinical trials.

2.3: Co-ordinate and fine-tune protocol requirements for gene therapy trials in multiple centres in different Member States.

3. AGRO-FOOD BIOTECHNOLOGY

Basically, the EU regulatory framework for the development and use of GMOs from farm to fork has now been adopted at Community level. It comprises 1) the 'new' deliberate release Directive; 2) the GM food and feed Regulation; 3) the traceability and labelling Regulation; 4) the transboundary movement Regulation, and; 5) the environmental liability Directive. While the 'new' deliberate release Directive has been applicable since October 2002, both the GM food and feed and the traceability and labelling Regulations came into force in April 2004. As such, this corresponds with the CBAG recommendations to complete and adopt the EU regulatory framework for agro-food biotechnology. Also the authorisation procedures related to GM crops have been re-started under either the deliberate release Directive or the GM food and feed Regulation. Yet, in all cases of approval so far, Member States had difficulties finding a common position on the risk assessment (data) in spite of a positive opinion by the European Food Safety Authority (EFSA), thereby leaving it to the Commission to make the final decision.

In the Commission report of 2004 on the deliberate release Directive a steep decline was noted in annual numbers of field trials with GM crops from 1997 to 2002. This might be due to the fact that the new regulatory framework was still under development, or due to fears of malicious damage of field trials, while it could also indicate a weakening of the European research base in this area. In addition, stricter ERA requirements were considered by the plant biotechnology industry a substantial regulatory burden, which would disadvantage SMEs and public research institutions to bring products to the market. The Commission further noted that the EU regulatory framework might have an adverse impact on producers in developing countries. It might also have the possibility of a brain-drain from Europe, a decrease in scientific activity and interest by students to train in this publicly controversial research field, and finally the related possibility of a loss of competitiveness.

In October 2004 a majority of the Agriculture Council of October 2004 supported to set up a European task force to ensure the co-existence of GM crops and other crops, agreeing on the need to collect and disseminate information on successful approaches and

best practices. The majority also agreed to identify research requirements at the EU-level, also because there is still a need to set values for the minimum labelling thresholds levels of EU-authorized GM seeds in lots of non-GM seeds under the horizontal deliberate releases Directive and, subsequently, under the vertical Seeds Directives.

Recommended actions:

3.1: Establish minimum thresholds for EU-authorized GM seeds in lots of non-GM seeds.

3.2: Support further research on: 1) rates of gene flow in relation to the adventitious presence of GMOs in other seeds, food and feed; 2) the efficacy of measures to limit pollen flow, and; 3) the environmental impact of different methods of conventional farming ('baselines') against which to compare the findings from GM crop growing.

3.3: Provide support to the EU Task Force on co-existence of GM crops and other crops.

Since both the GM food and feed and traceability and labelling Regulations only came into force in April 2004, the experience acquired is rather limited. Moreover, there are still concerns among Member States about the implementation of the 0.9 % labelling-threshold, as a common technical guidance for sampling and testing has not yet been published. Nonetheless, within one year from now, that is no later than 7 November 2005, the Commission must also report on the implementation, accompanied, where appropriate, by any suitable proposal.

Recommended actions:

3.4: Publish a common technical guidance on sampling and testing to implement the 0.9 % labelling-threshold of GM material in non-GM food.

3.5: Apply an integrated impact assessment (see 2) for the review of both the GM food and feed and traceability and labelling Regulations. Consider the outcome, when drafting proposals for improvement in the report of November 2005.

4. INDUSTRIAL BIOTECHNOLOGY

According to the CBAG, Europe is still a frontrunner in industrial biotechnology research and innovation. But its global competitive position is eroding quickly, due to long-term strategic investments by the USA and East Asia, and to Europe's structural weaknesses, including regulatory uncertainty. Concerning the food enzyme legislation under preparation, industry expected a clear and simple approval system. The CBAG further recommended clarification of the scope of the GM food and feed Regulation as to fermentation products derived of GM micro-organisms (GMMs). Also Commission guidance was needed on whether so-called 'self-cloned' micro-organisms are GMOs in the meaning of EU legislation.

Recommended actions:

4.1: Adopt a common position on the scope of the GM food and feed Regulation as to fermentation products from GMMs.

4.2: Adopt guidance as to whether a self-cloned micro-organisms should be considered a GMO in the meaning of EU legislation on GMOs.