

**EUROPEAN BUSINESS SUPPORTS EU-STRATEGY  
FOR BIOTECHNOLOGY**

**UNICE POSITION**

The European Commission Communication "Life sciences and biotechnology – a strategy for Europe" from January 2002, contains an action plan for the responsible development of biotechnology in Europe. It is a follow-up to the Lisbon and Stockholm summits, where biotechnology was acknowledged as a key component of a knowledge-based economy and a vital driver of Europe's competitiveness. In March 2002, it was endorsed by the European Council meeting in Barcelona.

The action plan contains 30 closely inter-related actions that cover all areas of importance: legislation, public perception, financing, research, workforce education, and international aspects. Endorsement and rapid implementation of the action plan are crucial for meeting the Lisbon objectives for innovation. Modern biotechnology is a key technology, with applications, job creation and development opportunities in many business areas such as health, sustainable chemistry, agriculture and food. The plan is particularly welcome as European biotech keeps lagging behind the US in terms of turnover, employment, patents and R&D, while a brain drain takes place out of Europe.

To achieve the Lisbon goals, UNICE believes that, above all, an attractive climate for investors, entrepreneurs and researchers is needed. Yet we perceive a European "schizophrenia": despite resounding statements about the potential of biotech made by Prime Ministers and Presidents, regulatory obstacles and uncertainty are discouraging investments in biotechnology. As a result, the opportunities are less attractive than elsewhere, and biotech business activities and researchers are leaving Europe. This threatens the knowledge base and prevents Europe from reaping the fruits of biotechnology. While all aspects covered in the action plan are essential, UNICE considers clear decisions on the issue of legislation of utmost importance to restore confidence in EU biotechnology. Without this, even the best R&D funding or venture capital support policies will be insufficient.

**UNICE's message to the Competitiveness Council is:**

- **Endorse the EU-strategy for biotechnology.** The Council should adopt and work towards the full implementation of the overall EU-strategy for biotechnology (COM (2002) 27). All member states must adopt and implement similar national strategies. The responsibilities and participation of all stakeholders, working together with the proposed Competitiveness Advisory Group, should be identified for each action item in the strategy.

- **Provide improved market authorisation for new biotechnological products.** An enabling, proportionate, non-discriminatory, consistently applied science based product authorisation procedure is crucial for investors. This is true for all biotechnological products. In particular, with regards to genetically modified organisms (GMO's), UNICE calls the establishment of a centralised approval procedure, the implementation of the EU legislation set in place to assess and approve GMO's, the lifting of the *de facto* moratorium and the development of a Regulation for labelling and traceability of GMO products based on the detectability of GMO material.
- **Ensure and improve the legal protection of biotechnological inventions.** Full and swift transposition of directive 98/44/EC on the legal protection of biotechnological inventions, based on the information in the recent Commission annual report, is required for all remaining member States. While certain progress has been made, the EU should maintain the pressure, including the initiation of infraction procedures at an earlier stage. In addition, consensus on the Community Patent is urgently needed.
- **Improve public debate.** At the same time, Europe needs to achieve a common understanding among all stakeholders and policy makers, and strive to find consensus where views diverge. Biotechnological products must be developed and commercialised in a responsible, safe and acceptable manner. Decisions on the development of biotechnology must include dialogue, to secure a democratic process dealing with ethical dilemmas in a balanced, operational and systemic way. Public debate therefore remains of central importance. Industry is committed to participate actively in dialogue,.

These messages were recently underlined at the EU-Presidency Conference on Biotechnology in Copenhagen. Only by taking the above measures will the EU improve the investment climate in Europe and strengthen the competitiveness of European business.

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