## Information note on Life Sciences & Biotechnology- a Strategy for Europe 20 October 2005

Following a request from the European Council<sup>1</sup>, the Commission adopted in January 2002 "Life sciences and biotechnology – A strategy for Europe" (COM(2002)27 -23 January 2002). The strategy has been developed with the aim of bringing coherence to policy-making, which in Europe is characterised by diverse economic, social and environmental concerns. The strategy seeks to address these concerns comprehensively and coherently and sets out a strategic vision for this area up to 2010, to allow Europe to benefit from the positive potential of life sciences and biotechnology in healthcare, agriculture, food production and environmental protection, to ensure proper governance and to meet Europe's global responsibilities.

The strategy consisting of two parts – policy orientations and a 30-points action plan for concrete short, medium and long term measures, to be carried out by Commission, Member States, as well as recommendations for other public and private actors, respecting the subsidiarity principles.

The strategy has four pillars:

**Harvesting the potential -** Aiming at developing skills, support European research, providing a strong European intellectual property system, increasing access to capital, networking all the various actors working in biotechnology in Europe and increasing the proactive role of the public authorities.

Responsible policy at governing life sciences and biotechnology - Including dialogue among stakeholders, ethical and social implications, consumer's right to choose and the legislative framework.

Europe in the World – responding to global challenges - Highlighting Europe's role in developing international guidelines standards and recommendations based on international scientific consensus, and indicate the areas where Europe can support the developing world in its efforts. Europe has a particular responsibility to support developing countries in dealing with the risks, challenges and opportunities, and to facilitate the safe and orderly development of these new technologies at the global level, in accordance with the choice of individual countries.

**Implementation and coherence across policies, sectors and actors**Focussing on the role of the European Commission in evaluating and further developing the European biotechnology policy in the coming years.

The European Commission has set up an internal coordination body - the Biotechnology Steering Committee - in order to monitor progress in policy development and to anticipate emerging issues in this fast-developing area.

<sup>&</sup>lt;sup>1</sup> Presidency Conclusion, European Council 23-24 March 2001 in Stockholm

<sup>&</sup>quot;Highlights the importance of research, entrepreneurship... Identifies biotechnology as a frontier technology ... and requests the Commission, together with the Council, to examine measures required to utilise the full potential of biotechnology and strengthen the European biotechnology sector's competitiveness"

On 29 June 2005, the Commission presented its **third progress report and future orientations** on the Life Sciences and Biotechnology – A strategy for Europe (COM(2005) 286, SEC(2005)850), which highlighted the progress made but also pointed out delays and obstacles in some areas.

As depicted in the third progress report, several steps towards fulfilling the goals of the biotechnology strategy have been taken, e.g.: setting up networks and advisory groups with Member States and industry<sup>2</sup>, carrying out a benchmarking exercise on national biotechnology policies<sup>3</sup>, launching an ambitious cost-benefit analysis of the whole biotechnology sector, pushing for the implementation of the directive 98/44 on the legal protection of biotechnological inventions and proposing a Community Patent Regulation, encouraging a stronger networking of biotechnology clusters in Europe, supporting research under the 6th Framework Programme for research , putting forward the proposals for the 7<sup>th</sup> Framework Programme for Research and the Competitiveness and Innovation Programme, taking initiatives to increase investments into and access to capital for biotech companies, continuing the effort to draw together the innovation triangle: science, society and economy, the reviewing pharmaceutical legislation, implementing balanced European legislation on GMOs and pushing for coherent implementation in all Member States.

Some legislation is under preparation, such as the introduction of labelling thresholds on for the adventitious presence of authorised GM seeds in seeds of conventional and organic varieties, legislation on human tissue engineered products, and legislation on the protection of worker's personal data as regards genetic testing. Furthermore, the Commission has taken initiatives in collaboration with Member States to ensure the highest quality of genetic testing in the EU and beyond<sup>4</sup>.

The Sixth Framework Programme (2002-2006)<sup>5</sup> is continuing to give a strong impetus to Life Sciences and Biotech research in Europe, in particular in terms of critical mass of human and financial resources, sharing of knowledge and facilities, strengthening of scientific excellence, co-ordination of national activities and support to EU policies. The establishment of technology platforms<sup>6</sup>, an innovation in EU research policy, has fostered a new public-private partnership. Eight technology platforms in Life Sciences and Biotechnology have been launched respectively on Innovative Medicines, Industrial Biotechnology (part of the TP on sustainable chemistry), Global Animal Health, Nanomedicine, Food for Life, Forestry-based sector, Farm animal breading. It is expected that these industry driven platforms will play an important role in the research priority setting in FP7 in order to ensure that our efforts are focused on potential future markets. It is also expected that the research agendas and action plan developed by the platforms will have their impact at national and regional level. The implementation of **joint technology initiatives** is a way of going further in such public-private partnerships. One example in preparation is in the area of innovative medicines. Other initiatives may be launched in the biotech sector in the coming years.

Life Sciences and biotechnology research for medical applications will remain an important priority in the collaboration programme under the "Health" in the

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<sup>&</sup>lt;sup>2</sup> the full text of the Group's report is available at <a href="http://europa.eu.int/comm/dgs/enterprise/index\_en.htm">http://europa.eu.int/comm/dgs/enterprise/index\_en.htm</a>

<sup>&</sup>lt;sup>3</sup> http://europa.eu.int/comm/dgs/enterprise/index\_en.htm

<sup>&</sup>lt;sup>4</sup> http://europa.eu.int/comm/research/biosociety/pdf/bioethics-survey-test2106.pdf

<sup>&</sup>lt;sup>5</sup> http://europa.eu.int/comm/research/fp6/index\_en.cfm

<sup>6</sup> http://www.cordis.lu/technology-platforms/

Seventh Framework Programme<sup>7</sup>. But FP7 is also expected to give a major impetus to food, agriculture, marine, industrial and environmental biotechnology under the theme "Food, Agriculture and Biotechnology". It is the intention of the Commission to bring together the relevant technologies and sectors to develop a European Knowledge Based Bio-Economy (KBBE)<sup>8</sup>. A conference "Towards a knowledge based bio-economy in Europe" took place 15-16 September 2005<sup>9</sup>. As a follow-up of this conference the Commission intends to establish a network of officials from across Europe on the Knowledge Based Bio-economy in order to stimulate a coordinated effort in the development and implementation of a European research and innovation policy in this area. The European Research Council is expected to enhance the basic knowledge in life sciences and biotechnology and specific measures will be provided to encourage SME participation, international cooperation and mobility and training of researchers. Support for the establishment of infrastructures and region of knowledge will be provided.

Since 2002, the Commission has progressed with much of its own actions, but a more active cooperation from all Member States in the implementation is needed at the political level to secure the objectives of the biotechnology strategy.

The new Commission has re-launched the Lisbon strategy and aims at making Europe a competitive knowledge-based economy. To do this, biotechnology should play an important part. It is an economically and strategically important area and should be given priority in our efforts to fulfil the Lisbon objectives.

The strategy will undergo a thorough **mid-term review** in 2006-2007, based on the results of on-going studies (an ambitious **cost-benefit study** carried out by the JRC in Seville). The mid-term review will include a stocktaking of the achievements and the latest developments, the identification of obstacles, and the setting of new priorities for action together with Member States and the stakeholders.

The **time frame** for the mid-term review is to report back to the autumn Competitiveness Council in 2006 and the spring European Council in 2007.

Member States are encouraged to contribute actively to the mid-term review, notably by:

- identifying further action priorities together with the Commission,
- committing themselves to realise action priorities timely,
- providing national plans for the implementation of the strategy.

The Commission services will take up the collaboration with Member States for the review in the informal biotechnology contact network of Member State officials. The network with officials on the knowledge-based bio-economy (KBBE) is also expected to contribute to this exercise, in co-ordination with the Standing Committee on Agricultural Research.

Contact: Line Matthiessen-Guyader, MD, PhD

European Commission - DG Research

Directorate E "Biotechnology, Agriculture and Food"

SDME 8/39, B - 1049 Brussels

email: line-gertrud.matthiessen-guyader@cec.eu.int

<sup>&</sup>lt;sup>7</sup> http://europa.eu.int/comm/research/future/index\_en.cfm

<sup>&</sup>lt;sup>8</sup> We understand the term « bio-economy » as including all industries and economic sectors that produce, manage and otherwise exploit biological resources (such as agriculture, food, forestry, fisheries, health) and related services, supply or consumer industries.

<sup>9</sup> http://europa.eu.int/comm/research/conferences/2005/kbb/index\_en.html

