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COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

on the mid term review of the Strategy on Life Sciences and Biotechnology

{SEC(2007) 441}

1. PREPARING THE EU FOR 2010

Life sciences and biotechnology[1] is a fast-evolving area with direct or potential significance for European businesses and European policymakers. It plays an increasing and accepted role in the health sector, with the development of new techniques for treatments and disease prevention. The industrial landscape in Europe is steadily being transformed by the use of life sciences and biotechnology by a large number of industries, resulting in a wide range of products already on the market[2].

The "bio-economy" therefore has the potential to contribute to key EU policy goals and help address new challenges in relation to health, energy supplies, global warming or an ageing population. The knowledge and skills available in Europe leaves it well placed to exploit this potential both within Europe and on a global scale, including in its relations with developing countries.

Biotechnology is an important means to promote growth, jobs and competitiveness in the EU. The use of biotechnology is however not without controversy and the enhanced use of biotechnology needs to be accompanied by a broad societal debate about the potential risks and benefits of biotechnology including its ethical dimension.

The European Council and the European Parliament have recognised the importance of life sciences and biotechnology, and the Commission has put forward an action plan to address the challenges and opportunities involved. This Strategy on Life Sciences and Biotechnology[3], adopted by the Commission in 2002, proposed a 30 point action plan involving the Commission, the other European Institutions and other stakeholders. It runs until 2010.

The scope of the Strategy – the first of its kind at EU level – was originally very broad, to cover all possible relevant policy issues and facilitate the uptake of the technology in a wide range of different sectors. Action was proposed under four headings: *harvesting the potential* (research, access to capital etc), *promoting governance* (social dialogue, ethical scrutiny etc), *answering global challenges* (encourage scientific cooperation with developing countries etc) and *ensuring coherence between the full range of policies concerned*.

The implementation of the Strategy is now at its mid point. It is time to evaluate the progress achieved since 2002 and update the Strategy, to reflect new analysis of how

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1 According to the latest OECD definition, biotechnology is defined as "the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services". http://stats.oecd.org/glossary/index.htm

2 Such as, for example, vaccines against Hepatitis B, fruit juice concentrates or car bumpers made out of bioplastic

3 COM(2002)27 of 23/01/2002

this fast-moving sector could contribute to EU policies[4]. This is the purpose of this Communication and the annexed Staff Working Paper.

The original design of the Strategy followed a holistic approach still relevant today. Life sciences and biotechnology cannot be seen in a vacuum. Other policies have a direct impact on their development, such as the innovation policy recently set out by the Commission and given political support at the informal meeting of Heads of State and Government at Lahti in October 2006[5].

The mid term review puts life sciences and biotechnology in this broader context, but also refocuses the Action Plan on sector specific issues and prioritises actions in those areas where the potential benefits of biotechnology can be maximised.

2. MODERN LIFE SCIENCES AND BIOTECHNOLOGY APPLICATIONS AND THEIR CONTRIBUTION TO EU POLICIES

2.1. The contribution to EU policies

Life sciences and biotechnology have grown to be central to certain sectors of the EU economy: in healthcare and pharmaceuticals, but also in the fields of industrial processing and primary production/agro-food. Overall, modern biotechnology relates to the generation of about 1.56% EU gross value added (GVA, 2002 values), to which could be added positive impacts of biotechnology such as a healthier population. The recent adoption of an ambitious energy policy for Europe is likely to stimulate the contribution of biotechnology to another sector, alternative energy.

In March 2007, the European Council agreed a binding minimum level for biofuels of 10% of vehicle fuel by 2020. Biofuels are seen as beneficial in that they are renewable, reducing greenhouse gas emissions and boosting the EU's energy security.

The production process of bioethanol relies largely on biotechnology (through the use of enzyme or micro-organisms, to make ethanol out of biomass, whether crops, wood or biowastes). It is estimated that the development of biofuels could create a significant number of new jobs throughout the EU and open new markets for agricultural products.

Secondly, life sciences and biotechnology make a significant contribution to core EU policy goals such as health, economic growth, job creation, the ageing society and sustainable development. Again, there are differences between the three main sectors (health, industrial production and processes, primary production/agro-food), which justify separate analysis.

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4 The current mid term review exercise has had the chance to benefit from a so far unique source of information on biotechnology in the EU, the "Bio4EU" study, which presents an exhaustive picture of possible applications, with concrete examples, and assesses their impact on an economical, social and environmental point of view, including comparative data on the situation in third countries. This study has been finalised in April 2007. All figures are from BIO4EU, otherwise specified - http://bio4eu.jrc.es/index.html

5 Commission Communication "Putting knowledge into practice: A broad based innovation strategy for the EU", COM(2006) 502 final, 13.9.2006

The European dedicated biotechnology industry directly employs 96.500 people, mostly in SMEs, but employment in industries using biotechnology products is many times higher. The industry is highly research-intensive with 44% of employees (42.500) involved in research and development functions[6].

Biotechnology products and processes are used in numerous other industries (e.g. chemicals, textile, paper etc) both in terms of novel products and improved production methods.

Thirdly, whilst current statistics show relatively modest figures for the biotechnology industry in the European Union, it also appears that those may be underestimated since they mainly count as "biotech companies" only those which are exclusively dedicated to this activity, thus excluding large industrial groups which use biotechnology to bring added value to their core business (such as chemicals or pharmaceuticals).

According to the latest statistics, in 2004, Europe had 2163 dedicated biotech companies, which spent in total €7.6 billion in R&D. The typical European company might be 6-10 years of age and rather small, averaging around 28 employees, and spending an average of €3.3 million on R&D activities[7]*. The share of the European Union in biotechnology patents filed at the EPO in 2002-2004 was 34,8%, as compared to 41,1% for the USA. Despite many successful European start-ups, it is not yet a sizeable and sustainable industry.*

2.2. Healthcare biotechnology

This is the main area of activity of the dedicated biotech industry and includes many applications with considerable economic and public health significance. Modern biotechnology applications in human health represent some 5% of the pharmaceutical sector GVA (2002 values) and about 0.04% of the EU25 GVA, but indirect effects would add to these figures. Biotech-based products are mainly for therapeutic use (i.e. biopharmaceutical[8]), but also diagnostics and preventives (i.e. vaccines[9]).

Biotechnology is also a processing technology used when the end product is not biological but chemical, and as a result is widely used in the pharmaceutical sector. In the context of current challenges such as the consequences of an ageing population or the fight against possible pandemics (e.g. avian flu), life sciences and biotechnology appear to be of key importance. This includes the responsible and effective use of genomics (including genetic testing) for the benefit of human health.

Many promising applications are in the pipeline, including so-called "advanced therapies", involving tissue engineering, gene and cell-based therapies, and "nanomedicine"[10]. Some raise high expectations and at the same time significant controversy, such as the use of embryonic stem cells.

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6 Biotechnology in Europe: 2006 Comparative study, Critical I, 2006.

7 Critical I, 2006.

8 Biopharmaceuticals represented 9% of the EU pharmaceutical market per value (€ 11 billion) in 2005.

9 Recombinant vaccines represent about 20% of all available vaccines.

10 Application of nanotechnology in treatment and disease diagnosis and monitoring

Human insulin was the first true biotechnology based product and gradually replaced the insulin extracted from cattle and pigs. It is currently the most available form of insulin worldwide, accounting for 70% of the worldwide insulin market. Aside from drugs, biotechnology has also enabled the development of tests for diagnosis of acute cardiovascular disease in emergency clinics, for the detection of hereditary diseases (genetic testing) or infectious diseases such as HIV/AIDS.

Actions which could support the development of the health biotechnology industry, in particular helping SMEs and increasing research should be considered to be a particular priority for the European Union. This would take account of the full range of economic, ethical and other considerations.

2.3. Industrial biotechnology

Industrial biotechnology is already used for a broad range of products and processes, often unknown to the general public. Industrial biotechnology is gaining momentum due to increasing environmental and energy supply concerns, since it represents an alternative to chemical processes and fossil fuels and promises economic and environmental benefits. Industrial biotechnology contributes to about 0.46% of the GVA of the manufacturing sector and about 0.08% of the EU GVA (without food processing and chemicals), reflecting its limited use so far.

The change from the chemical to the biotechnological method for the production of a widespread category of antibiotics[11] *showed a reduction of the use of electricity of 37%, of solvents of almost 100% and a reduction in wastewater by 90%. There are other industrial applications, such as biodegradable plastics and packaging, which could bring similar benefits.*

The development of biotechnology processes and their uptake by the industry are not optimal. Aside from underfunding, which is regularly highlighted by the industry, technology transfer appears to be insufficient. In combination with EU policies on innovation, this should be as a priority for the Strategy, with support actions for research and the uptake of new technologies.

2.4. Primary production and agro-food biotechnology

There are many modern biotechnology applications in primary production and agro-food, which are less visible, but have sizable economic, environmental and public health significance. Modern biotechnology is mainly used in the input sectors, i.e. breeding, diagnostics, fine chemicals (feed additives) and enzyme production. Overall, modern biotechnology is used for 1.31-1.57 % of GVA generated by the primary production and agro-food sector.

Biotech-based diagnostics and veterinary products, mainly vaccines, play a role in controlling and monitoring some of the most important animal diseases, zoonoses and food safety concerns.

The development of biotechnological methods for surveillance of Bovine spongiform encephalopathy in the EU have allowed for many more samples to be tested, enabling the

11 Cephalosporin

level of surveillance required by Community legislation to be met and contributing to the protection of consumers and the resumption of trade. Biotech-based diagnostics are also used for the early detection of salmonella.

Aside from these applications, biotechnology is also used to select, or improve, specific traits of an organism. The best known examples are genetically modified plants. About a dozen products have been recently approved under the EU legal framework, which requires stringent risk assessment procedures, and some forty are in the pipeline, including some for cultivation. GM technology is likely to have in the future more application in the field of industrial processes. For example, sectors such as the production of biofuels or paper will have an interest in higher yielding plants.

There is a strong need for an assessment of the benefits and risks of the use of genetically modified organisms (GMOs) in all sectors, taking into account their environmental and health effects as well as their acceptance in EU society. However, the approval of GMOs should continue to be based on a case by case risk analysis. In certain cases, risk management measures to prevent contamination of the food/feed chain by products which are specifically designed for industrial uses (e.g. when crops are used for example for the production of pharmaceutical substances) should be further developed.

3. THE DIVERSIFIED SCOPE OF MODERN BIOTECHNOLOGY AND PUBLIC PERCEPTIONS

Governance was a key issue in the original design of the Strategy. Recent experience with the implementation of sectoral legislation has confirmed that the uptake of biotechnology depends on the development of specific applications as well as relying on public support. Overall all fields of biotechnology generally enjoy a high level of public support with the exception of GM food, where public opinion is more ambivalent, and the implementation of the legislation in this field has proved to be difficult.

Eurobarometer 2005[12] *shows that optimism about biotechnology has increased since 1999, after a period of decline (52% say it will improve their life) and an overall support for many biotech applications (such as gene therapy, biofuel or, bioplastics). It also shows that knowledge about biotechnology and genetics, although improving, remains limited.*

However, 58% of the respondents oppose GM food while 42% do not. The Eurobarometer confirmed also that there were major differences in acceptance levels between Member States. It should be noted that 50% or more say they would buy GM food if it were healthier, if it were to contain less pesticide residues, or if were to be more environmentally friendly.

Despite the fact that the EU has an entirely new science-based legal framework, one of the most stringent in the world, negative public perceptions of GM food has an influence on the positions taken by Member States when faced with case-by-case decisions about whether to place a product on the market. In all recent cases there

[12] http://www.ec.europa.eu/research/press/2006/pdf/pr1906_eb_64_3_final_report-may2006_en.pdf

has been no consensus. The issue of EU decision taking on GMOs was also the subject of a report by a World Trade Organisation Panel at the end of 2006[13].

The implementation and enforcement problems which have been encountered are partly due to the fact that the applicable legal framework is recent: the implementation of transition provisions between the "old" and the "new" legislation has led to reluctance by some Member States. Although GMOs represent only a small part of biotechnology, public perception often sees this as the main application. The gap between public perception and the agreed legal framework on GMOs has to be addressed.

4. THE IMPLEMENTATION OF THE STRATEGY FOR THE 2002-2006 PERIOD

The annexed Commission Staff Working Paper contains a detailed report on the implementation of the Action Plan. It has been elaborated on the basis of contributions from Commission services, Member State authorities and stakeholders. It is complemented by a summary chart of the main achievements in the implementation of the 30 actions.

The main conclusions of this review exercise are that:

– The Strategy has been successful and is still relevant. The list of achievements, such as research activities and regional integration of clusters, clearly highlights the role that the Strategy has played in terms of integrating the "biotech dimension" in other policy areas, as well as inspiring national biotech plans. The strong support enjoyed by the Strategy from stakeholders is evidence of its success;

– A small number of actions have already been completed. This mainly relates to the adoption of the new legal framework on GMOs, which has been very significantly revised since 2002;

– A few other actions have become obsolete, mainly because of lack of interest by the audience they targeted (e.g. Action aiming at creating networks of biotechnology company managers);

– There is a strong case to continue a majority of the actions, ensuring coherence with other horizontal initiatives (e.g. education, IPR…) and in accordance with the EU's international commitments (e.g. contribution to Multilateral Environmental Agreements);

– Some actions need to be refocused and given a special priority, given their importance and biotechnology-specific character.

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[13] European Communities — Measures Affecting the Approval and Marketing of Biotech Products - http://www.wto.org/english/tratop_e/dispu_e/meet_21nov06_e.htm

5. WAY FORWARD FOR THE CONTINUATION OF THE STRATEGY

The original design of the Strategy was consciously wide in scope, to give an initial mapping of the situation and to identify the full range of linked policy areas. With this phase complete, the mid term review offers an opportunity to refocus in order to maximise the impact of the Strategy. This implies pursuing actions which are still relevant according to their original design, reinforcing synergies with other horizontal policies and reviewing priorities which are specific to the sector of biotechnologies. The result will be to improve the output of the Strategy to 2010.

These biotech-specific priorities can be regrouped under five main interdependent themes:

(1) *Promote research and market development for life sciences and biotechnology applications and the Knowledge Based Bio-Economy (KBBE).* Research remains a precondition for the development of biotechnology and the Action Plan needs to be adapted to the new FP7. Europe's basic biotech research is advanced but Europe does not excel in turning research into commercial applications. The Action Plan should be refocused in order to foster market development for bio-based products and improve the uptake of new technologies;

(2) *Foster competitiveness, knowledge transfer and innovation from the science base to industry*. Europe's dedicated biotech companies are mostly SMEs with limited resources whose growth and economic sustainability are held back by three main constraints: Europe's fragmented patent system, the insufficient supply of risk capital and shortcomings in the cooperation between science and business. The Commission has identified the lack of a clear and coherent legal framework for IPR protection as an obstacle to innovation in Europe[14], and will propose concrete steps toward a modern and affordable framework. In addition to this, refocusing the Action Plan can contribute to addressing some framework conditions relating to competitiveness specific to the biotech sector.

(3) *Encourage informed societal debates on the benefits and risk of life sciences and biotechnology*. The uptake of biotechnology is also conditional on its societal and market acceptance. Ethical concerns are also more prevalent than in other forefront technologies. There is a clear prerequisite for actions aiming at associating the public and stakeholders as closely as possible to the decision making process, taking into account the benefits and risks of life sciences and biotechnology, on the basis of harmonised data and statistics, as well as ethical considerations.

(4) *Ensure a sustainable contribution of modern biotechnology to agriculture*. Biotechnology in the field of primary production and agro/food has a huge potential for development, in particular the replacement of chemical processes and fossil fuels. Nonetheless, some of the technologies involved

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[14] Commission Communication ""An innovation-friendly modern Europe", COM(2006) 589 final, 12.10.2006

need close scrutiny. The legal framework on GMOs takes into account possible long-term effects on the environment and health, the safety of the food chain and respects other modes of agricultural production. Nonetheless, in certain cases risk management measures for products which are specifically designed for industrial uses should be further developed.

(5) *Improve the implementation of the legislation and its impact on competitiveness*. The EU has probably the most developed, and sometimes most stringent, legal framework on life sciences and biotechnology. Nonetheless, stringent rules should not hinder competitiveness and innovation.

The way the Commission intends to refocus its implementation of the Strategy in light of the above five priority themes is detailed in the attached "Refocused Life Sciences and Biotechnology Action Plan".

6. CONCLUSIONS

The potential of biotechnology to support EU policies is real and has been proven by numerous practical examples. Consequently, there is a strong need to continue promoting the development of life sciences and biotechnology in the EU, in particular by increasing research and promoting competitiveness. The main EU instrument for this is the Strategy.

Whilst the technology is promising, there is also a call for a reasoned use of some of its applications, in particular in the agro-food area, as well as for closer public scrutiny and forward looking regulatory control.

With biotechnology evolving at a rapid pace, there is an absolute necessity for policy makers to maintain a flexible forward looking approach in order to anticipate developments and adapt to new challenges. Recent examples include the potential use of cloned animals or of their offspring in the agro/food sector, or the use of genetically modified chicken for the production of pharmaceutical substances in their eggs.

The original broad scope of the Strategy has offered a full picture; now a refocusing would ensure effective implementation, with more precise goals and enhanced coherence with other policies.

For these reasons, the Commission will:

– Continue the implementation of the action plan up to 2010, while putting a specific emphasis on a focused set of biotech specific priority actions;

– Include biotechnology in the implementation of innovation strategies;

– In cooperation with Member States and stakeholders, improve the implementation of the Strategy.

Refocused Life Sciences and Biotechnology Action Plan

(1) Promote research and market development for life sciences and biotechnology applications and the KBBE. – Refocused action 3[15]:

- Generate new knowledge under FP7.
- In cooperation with industry, Member States and other funding bodies, mobilise public and private research funding and reinforce the coordination of research.
- Through a public-private partnership between European Commission and the European Federation of Pharmaceutical Industries Associations (EFPIA), implement the Joint Technology Initiative on Innovative Medicine under FP7.
- In cooperation with industry, Member States and other funding bodies, engage schemes to finance/promote the establishment of multi-functional pilot plants to demonstrate the potential of bio-based applications and facilitate their market penetration, subject to a proportionate impact assessment and in accordance with EC rules in the field of competition and internal market.
- Explore in cooperation with stakeholders lead market initiatives in the areas of eco-efficient bio-based products, subject to a proportionate impact assessment and in accordance with EC rules in the field of competition and internal market.

(2) Foster competitiveness, knowledge transfer and innovation from the science base to industry. Refocused actions 5, 6 and 9:

- In cooperation with Member States, develop best practices in the responsible licensing of genetic inventions.
- In cooperation with Member States, promote knowledge transfer by improving links between research organisations and industry and incentives to innovation.
- Monitor the implementation of Directive 98/44/EC on the legal protection of biotechnological inventions and explore ways of facilitating the patenting system for SMEs.
- Encourage Member States to consider specific rules and/or incentives for Young Innovative Companies.
- Promote the use of EIF/EIB instruments and the Competitiveness and Innovation Framework Programme to facilitate access to finance for biotechnology companies.
- In cooperation with the EIB, implement Risk–Sharing Finance Facilities co-funded by FP7 and the EIB.
- Support for the development and the integration of clusters and of regional networks.

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15 Action numbers in brackets refer to the original Action Plan

(3) Encourage societal debates on the benefits and risk of life sciences and biotechnology. Refocused actions 13, 14 and 16:

- Stimulate the possible establishment of an institutionalised interface with different stakeholders on benefits and risk of life sciences and biotechnology.
- Set up proposals on how to improve the cooperation with all relevant stakeholders to ensure input in the Commission's activities.
- In cooperation with Eurostat, Industry, Member States and OECD, set up a proposal for the establishment of international quantitative impact indicators (including social and economic) and structured collection of data.
- Adapt the action to the new FP7, and produce guidance for EC funded activities to address ethical issues.
- Anticipate the possible ethical and socio-economic impact of emerging scientific issues.

(4) Ensure a sustainable contribution of modern biotechnology to agriculture. Refocused actions 17 and 23:

- Assess notified national and regional measures on co-existence and study applicable national civil liability systems.
- Re-evaluate by 2008 the possible need for further guidance on co-existence at EU level.
- In cooperation with Member States, support research and develop guidelines for crop-specific co-existence measures and exchange information on best practices among Member States.
- Adopt crop-specific labelling thresholds for seeds.
- Conduct studies and support related research activities on potential positive and negative long term effects of commercially available GMOs.
- Explore benefits and risks of GM crops used for industrial transformation or molecular farming.

(5) Improve the implementation of the legislation and its impact on competitiveness. Refocused action 29:

- Reinforce the existing networks with Member States to monitor the implementation of the Strategy and address regulatory obstacles to competitiveness.
- Pursue foresight activities and the evaluation of the regulatory coverage on emerging issues.
- Improve policy coordination, including on cross cutting issues, with a particular focus on newly emerging issues.