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ESA POSITION PAPER on COMMISSION BIOTECH STRATEGY

Introduction

On 23 January 2002, the European Commission issued its communication “Life Sciences and biotechnology – A strategy for Europe.” as result of public debates and the official consultation held in September 2001.

The Commission’s strategy points to the strategic challenges facing the development of biotech in Europe up to 2010 and highlights the social and economic potential of the industry.

The paper focuses on practical issues such as skill shortages, boosting European research and the importance of predictable regulation and enforcement of community law as well as the importance for industry to contribute to societal debate and be prepared for ethical scrutiny.

Specifically, the Commission sets out a 30 point Action Plan in a number of policy areas and most importantly in view of agricultural applications in the following:

- **Generating and exploiting knowledge** – increase European research in biotech applications, aim to bring more products to market; and especially facilitate access for SMEs to research results and funds
- **Exploitation of intellectual property** – respect for IPR rights must be established
- **Proactive role for public authorities** - reinforce the role of public authorities in contributing to the development of a strong biotech industry and promoting transparency and access to information
- **Societal scrutiny and ethics** – promoting dialogue among stakeholders and organising public debates to accompany the development of life sciences and biotechnology and ensure it is in harmony with societal values

- **Confidence in Science based regulatory oversight** – sets out regulatory plans and a wish list and firmly recognises the importance of implementing and enforcing the law across the Community
- **International commitments** – allowing biotech to meet its potential in developing countries both to meet short term as well as long term needs especially in combating hunger and disease

General comment

ESA European Seed Association welcomes the Commission's efforts in presenting a comprehensive strategy and detailed action plan clearly setting out strategic political and economic objectives and what needs to be done, by whom and to what end. However, although the strategy paper is an accurate summary of the current situation of biotechnology in general and of the situation of and current challenges for this technology in the European Union in particular, the much needed and repeatedly announced practical and coordinated political and legislative action plan is still missing. But resources and energies must now be mobilized now and coordinated at all levels – national, regional and local – if Europe is to profit from the benefits of this important technology that many believe to be the single most important determining factor for economic growth, sustainable development and societal change in the 21st century.

⇒ **Recommendation:**

ESA supports a broad based approach to the future of biotechnology in Europe.

At the same time, we believe that due to the long-term standstill of developments in view of biotechnology in agriculture, the Commission in particular as well as the European Union in general must concentrate efforts to those areas where they have clear responsibilities and legislative competence and/or where considerable and effective financial resources may be mobilised to promote defined political objectives.

To do so, existing legislation, standards, policies, and procedures in countries currently more advanced in this area should be assessed in view of possibilities for taking over or taking similar approaches in the EU and negotiating mutual notification, recognition etc. arrangements.

To implement this approach, the European Commission should launch a 'B-Europe' or 'Bio-Europe' policy containing its concrete policy agenda for the coming years. Practically, this should be done as soon as possible and at the beginning of the next Commission's term of office with possible updates by the Commission's yearly legislative work plan.

In addition, within the European Commission, prime responsibility for implementing and coordinating this approach must be awarded to one Commissioner and one respective Directorate General.

General comment on Biotechnology and Agriculture

The practical use of modern biotechnology in agriculture and related industries in Europe is lagging even further behind than applications of biotechnology in other areas like e.g. in the medical or pharmaceutical area. This situation must be changed as soon as possible in order to

- maintain a European science and research base in this important area
- to allow an EU based agro-biotech industry to produce products and services including and in particular such which are specifically designed and developed for the EU situation and to do so under a clear, consistent, scientifically sound and predictable legislative framework
- to allow European plant breeders, farmers and other related industries to compete at a level playing field with their competitors in the world

The Commission paper defines a number of pressing issues but fails to relate this correct analysis to shortcomings in the EU's concrete current policies and clear cut political messages for the future that would enable the 'green' biotech industry like e.g. plant breeders, farmers, retailers and food and feed industry to relate their respective concrete policy and production choices to a roadmap of future EU policy and legislation.

Specific comments on Biotechnology and Agriculture

a) Generating and exploiting knowledge / exploitation of intellectual property

The EU's 6th Research Framework Programme already in the Commission's own proposal did fail to put research in the area of Biotechnology and Agriculture at the top of its priorities. Quite contrary, it constituted a step back in relation to the 5th Framework Programme both in terms of funding envisaged and research goals and areas covered. This not only sent a counterproductive message to researchers but also to industry in general in this area. The European Parliament has successfully amended the Commission's proposal to give this specific research a greater weight.

⇒ **Recommendation:**

The Commission's proposal for the next Framework Programme for Research should put biotechnology in general and specifically biotechnology in agriculture as one of its top priorities with respectively increased financial means and where necessary with specific measures. Moreover, this part of the EU's research policy should form an integral part of the 'Bio-Europe' policy.

The Commission rightfully states the special importance in this respect of a workable science-based and consistent regulatory process and framework for the biotech industry across Member States. This currently is lacking in the EU, in particular with a view to the 1998 Directive on the patenting of Biotechnological inventions still not transposed in all Member States as well as by the lack of a real European wide Community Patent Regulation.

⇒ **Recommendation:**

The Commission must ensure proper transposition of existing EU law into national laws. Where necessary, the legal procedures must be launched and respective action must be taken. In view of the Community Patent, we urge the Commission and Member States to find a solution that will meet the needs of researchers and innovators in public research facilities as well as in industry and that will trigger and motivate an increased take-up of science and technology into products and services.

b) Proactive role for public authorities / confidence in a science based regulatory oversight

In highlighting the role of public authorities and the importance of science based Community law in the strategy, the Commission correctly identifies the source of many of today's problems in dealing with biotechnology in agriculture, e.g. in today's GMO problems. The refusal of a number of Member States to grant GMO authorisations under part C of Directive 90/220 (2001/18) is only one but prominent example where proper EU legislation is not enforced and where subsequently other related EU legislation practically becomes unenforceable and policies grind to a halt. Community law must be respected and implemented across Europe - the focus equally must be on how Member States meet their obligations under EU law.

⇒ **Recommendation:**

The regulatory framework on biotechnology in agriculture must not only be set up wherever respective Regulations and Directives are either missing or must be updated. It must also be continuously monitored in view of its correct implementation and its effects. This monitoring must be coordinated by a central political unit responsible for Biotechnology within the Commission's services.

Specific current regulatory issues:

In detail, ESA again stresses the need for an overall and consistent regulatory approach to the issue of adventitious presence of GMO in non-GM products. In view of the on-going discussions within the framework of the legislative proposals on traceability and labelling of GMOs and GM food and feed as well as within the deliberations on amending the seed marketing Directives to include adventitious presence of GMOs it must be stated, that the current Commission proposals lack this consistency. They are unsustainable in view of an increasing use and production of GM plant varieties in the world and do fail to address all relevant problems, i.e. possible sources of adventitious presence of GMOs in conventional products.

ESA again urges the Commission to draw up the necessary seed specific Regulations covering all relevant aspects of adventitious presence of GMOs in seeds not only regulating events authorised under part C of Directive 2001/18 and those having received a positive opinion of the relevant Scientific Committee (pipeline events), but especially also to include all possible sources of such adventitious presence, i.e.

- events authorised in third countries with comparable authorisation procedures and risk assessment standards (OECD countries) and
- events authorised for field trials within the European Union under part B of Directive 90/220 (2001/18)

c) International commitments

Biotechnology in agriculture is developing fast and with still impressive growth rates in all parts of the world – except the European Union. This situation means that the EU must set up proper legislation that takes account of this development and that is necessary in any case and regardless of the EU's own policy in view of authorisations of new products in order to assure and safeguard international research and trade in goods and services.

The Commission paper quotes a large number of international fora dealing with different aspects of biotechnology in general and biotechnology in agriculture in particular. The EU must be a constructive and reliable partner in such fora and negotiations. This requires a coordinated policy (political leadership within the

Commission) as well as the necessary expertise and practical experience (scientific research and applications).

Unrealistic positions will single out Europe and its approach to biotechnology, will surely weaken its impact on the further development and international agreements and in the long harm the EU's position in the world in the area of biotechnology.

⇒ **Recommendation:**

Existing legislation, standards, policies, and procedures in countries currently more advanced in this area should be assessed in view of possibilities for taking over or taking similar approaches in the EU and negotiating mutual notification, recognition etc. arrangements.

Agreements must be both practical and sustainable in view of the increased use of biotechnology in agriculture all around the world as well as in view of a re-launch of authorisations for GMOs and related crop production in the European Union.