

Mid Term Review

LS & Biotechnology Strategy: 2002-2006-2010



- Excellent, visionary & pragmatic
- 100% EU-focused
- Concrete actions: what, who, when
- Respecting society values
- Respecting regulatory oversight
- Seeking coherence
- Across policies, sectors and actors

Endorsed by the Commission,
Parliament and heads of
Member States



EuropaBio

The European Association for Bioindustries

- Overall mission to promote and support a dynamic and globally competitive European life science industry
- Representing life science industry:
 - Across all sectors (health, agri-food, industrial biotech)
 - Start-ups, established biotechs and multinationals
- 70 corporate members, 25 national associations
- Providing advocacy for priority issues with European authorities (Commission, Parliament, etc.)



Mid Term Review

General policy recommendations from EuropaBio

- **Policy coherence.** Build policy consistency and predictable rules for all biotech sectors
- **Harmonised legislation.** Encourage and stimulate national implementation of EU legislation
- **Awareness and acceptance.** Bridging the gap and building public awareness of the benefits of biotech
- **Leverage research.** Support research and innovation centres



Mid Term Review

Working Group (WG) policy recommendations

- **WG Plant Science & Knowledge-Based Bio-Economy**

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- **WG Access to Finance**

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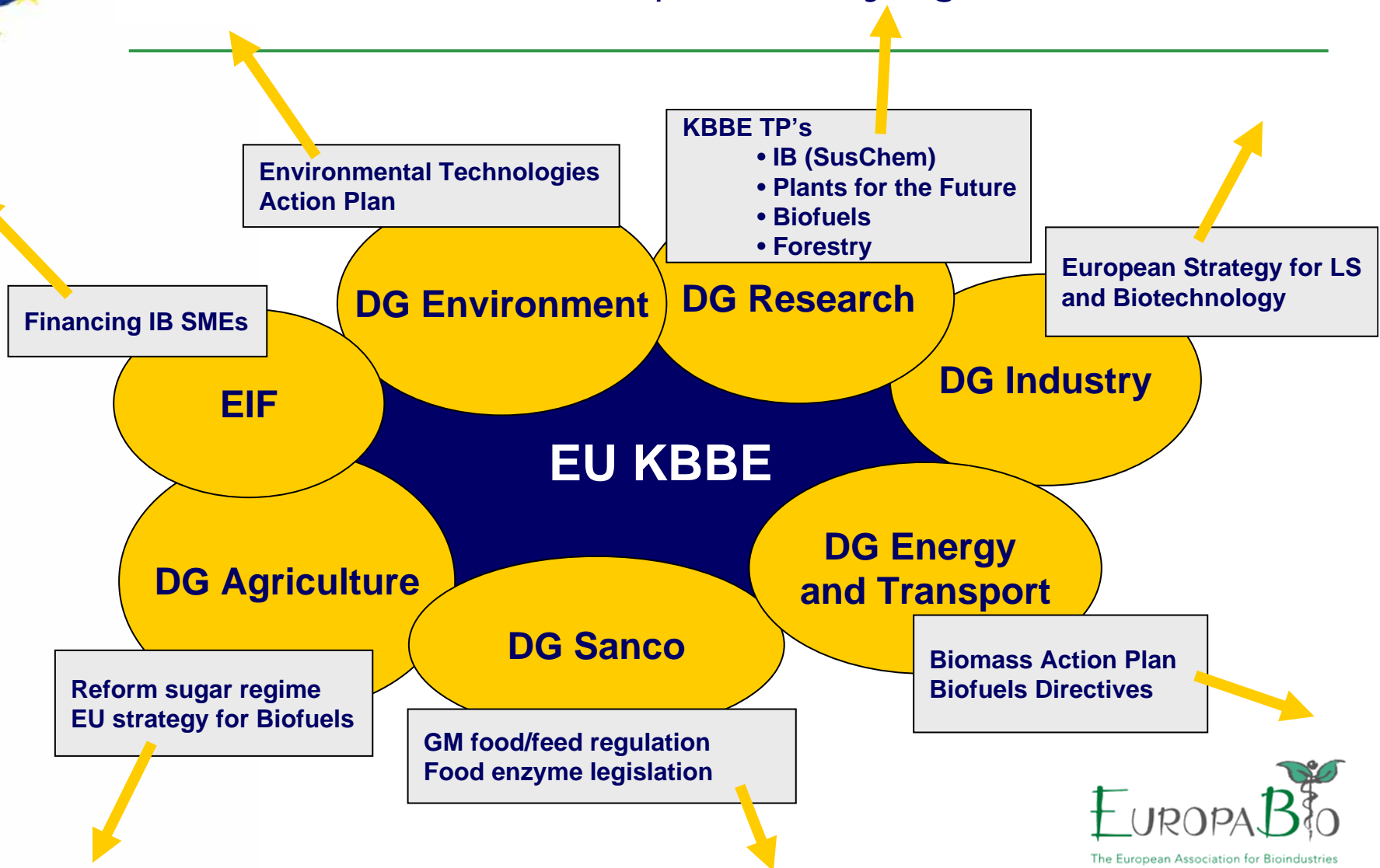
WG: Plant Science and KBBE

Overview policy recommendations

1. Need for a coherent European Policy Agenda for IB and the KBBE
2. Stimulate and support innovation in plant science and industrial biotechnology
3. Stimulate use of bio-based products and processes
4. Create awareness amongst stakeholders
5. Improve investment in IB SME's

WG: Plant Science and KBBE

Need for a coherent European Policy Agenda for IB/KBBE





WG: Plant Science and KBBE

Need for a coherent European Policy Agenda for IB/KBBE

- To develop a competitive KBBE, there is need for a coherent European policy Agenda for IB:
 - At EC level, enhance the cooperation among competences involved in implementing KBBE (Research, Agriculture, Environment, Energy, etc.)
 - At Presidency and MS level, set up KBBE task force
 - Need for data (e.g. feasibility study on feedstock availability in the EU)
- Link EU policies and strategies: KBBE, Biofuels, Climate change, Sustainable development, Eco-innovation/ETAP, GHG-emission trading, etc.



WG: Plant Science and KBBE

Stimulate and support innovation in plant science and IB

- Implementation of the KBBE SRA's (IB, Plants for the Future, Forestry, Biofuels, etc.) at EC (FP7) and MS (ERA-Net)
 - Long-term planning and continuity of research funding
 - Increase industry participation and stimulate public-private partnership
 - Promote inter-disciplinary cooperation and overcome fragmentation
- Set up EU-wide demonstration project(s) → Integrated diversified biorefinery



WG: Plant Science and KBBE

Stimulate use of bio-based products and processes

- Help convert conventional industrial processes into bio-based ones:
 - Approval system: develop faster regulatory procedure and preferential treatment (like “fast track” regulatory process at EPA in the USA).
 - Make the link with EU’s “GHG emission trading” project
- Provide market incentives to stimulate the commercialisation of bio-based products:
 - By public procurement standards
 - Temporary pricing measures
 - Labeling (e.g. “biobased”, “biodegradable” , etc.)



WG: Plant Science and KBBE

Create awareness amongst stakeholders

- Develop action plan to raise awareness of IB and KBBE potential
 - Industry
 - Policy makers
 - Consumers
 - Investors
 - etc.

→ link with “Communication WG”



WG: Plant Science and KBBE

Improve investment in IB SME's

- Attract new and private investors:
 - Increase availability of seed funding for IB start-ups by reassuring investors through involvement of public funding bodies (EIF, EIB, etc.) or tax reductions to private individuals investing in “green” investment funds (cfr. Kok report)
 - Different “industrial” partners should be brought together to invest in an IB SME because of the multidisciplinary character of it
 - Create awareness among investors community and publish track record
→ link with “Financing WG”
- Better target the available funding at new technology projects (using a refined economic tool to assess the projects’ market efficiency and the potential for the Lisbon strategy)



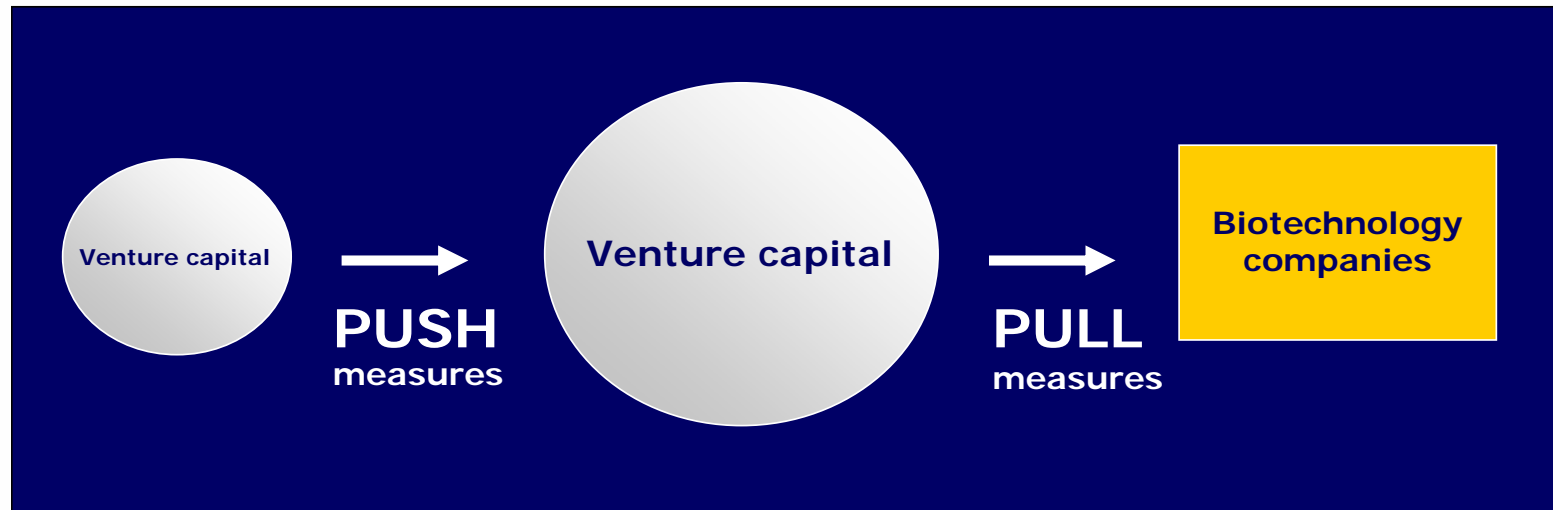
WG: Access to Finance

Overview policy recommendations

1. Implement EU-wide YIC-status
2. Install SME-initiative at the EPO
3. Reduce and harmonize restrictions faced by institutional investors to invest in high-risk equity
4. Re-enforce open dialogue with EIF
5. Create a European Pre-Incubation Capital Fund

WG: Access to Finance

General: push-pull strategies



- **PUSH:** aimed at increasing overall availability of capital for European biotechnology companies
- **PULL:** aimed at making European biotechnology companies more attractive for investors to invest in



WG: Access to Finance

Implement EU-wide YIC-status

- Young Innovative Company status
 - <15 years
 - >15% R&D
- Fiscal regime based on social cost and tax exemptions
 - 100% social cost exemption
 - 100% revenue tax exemption (sliding scale)
 - 100% capital gain tax exemptions on shares and options (3yrs)
- Allowing companies to invest savings in R&D
- Higher investment in R&D will reduce time-to-market of internal programs and increase productivity
- European definition: to serve as a reference (MS have no obligation) and legal framework



WG: Access to Finance

Install SME-initiative at EPO

- *“As an alternative to the Community Patent...”*
- Patent costs are often early stage investments, long before revenues are generated to recuperate these investments
- Patent costs in EU significantly higher than in US or Japan
- In 2005, Commission and EMEA installed new provisions for “SMEs” including fee reductions, payment deferrals, translation support, administrative support, etc.
- Industry asks for a similar initiative at EPO to reduce overall patent costs, allowing companies to re-invest savings in R&D such to reduce time-to-market of internal programs and increase productivity



WG: Access to Finance

Reduce/harmonize restrictions for institutional investors

- Clear correlation between status of institutional sector, and overall availability of (late stage) venture capital and of equity based trading activities in listed companies with high-risk profiles
- US sector far more developed than most part of Europe
- Fragmented regulation across Europe (“quantitative regulation” versus “prudent man”)
- Industry asks for measures to increase investments in high-risk equity to at least similar levels as in US, and for harmonization of regulatory frameworks across Europe



WG: Access to Finance

Reinforce open dialogue with European Investment Fund

- EIF is fund-to-fund directly investing in venture capital firms, thereby indirectly supporting biotech industry
- EIF also operates through mandates from Commission (e.g. CIP/MAP)
- Given the instrumental role of the EIF, the industry asks for a continuous dialogue to increase the understanding of the objectives, strategy, practices, interests and needs of each of all parties involved (i.e. EIF, VC-firms, Commission, etc.)



WG: Access to Finance

Create European Pre-Incubation Capital Fund

- Average seed financing in EU is €500K (US: €2,000K)
- Result of research projects spinning out too rapidly from the academic environment, lacking critical mass, which in turn results in inferior company valuations and smaller investment rounds
- Focus early-stage EU financial resources on supporting the incubation of start-up projects in market-oriented academic environments, rather than spreading it too thinly on too many small start-ups



WG: Regulation

Overview policy recommendations

1. Agree upon and implement a competitive patent system
2. Harmonize EU-wide patient access to biotherapeutics
3. Implement EU-legislation on agricultural biotech to ensure freedom of choice
4. Foster development of industrial biotechnology



WG: Regulation

Agree upon and implement a competitive patent system

- Develop and implement a single affordable Community Patent
- Take necessary action against un-harmonized implementation of Directive 98/44/EC on Biotech Patents



WG: Regulation

Harmonize EU-wide patient access to biotherapeutics (1)

- Ensure involvement of stakeholder in regulatory process
 - Appeal procedures
 - Develop guidance and criteria on biomarkers
 - Patients involvement at key stages
- Review Clinical Trials Directive
 - Review current directive with a view of moving towards a regulation to ensure harmonized trial requirements at MS level
 - Amend to recognize advent and effects of genetics and pharmacogenetics



WG: Regulation

Harmonize EU-wide patient access to biotherapeutics (2)

- Implement the support for Orphan Medicinal Products
 - Ensure OMPs can be registered throughout EU quickly
 - Ensure harmonized approach to compassionate use across MS
 - Review MS incentives for the development of OMP at MS level
- Advanced Therapies
 - Give high priority to the approval of the proposed regulation on Advanced Therapies
- Biosimilars
 - Clarity regarding the naming and labelling of biosimilars will be key
- Access to markets in Member States
 - Systems should be put in place at MS level to ensure innovation brought by biotech-derived products is recognised
 - Pricing and reimbursement setting should avoid generating a situation where not all European patients have access to products that address unmet medical needs such as innovative products



WG: Regulation

Implement EU-legislation on agricultural biotech

To ensure freedom of choice:

- Implement **predictable approval process with respect to timing** (also to avoid issues related to IP loss)
 - Provide for **Supplementary Protection Certificates** (SPC) for those patented GM plants that have reduced commercial lives because of delay in the approval process
- **Expand the scope of Art 47** in Reg (EC) No 1829/2003 to establish acceptable AP thresholds of third country approved GM events
- Ensure action is taken against **illegal bans of field trials** on a national/regional level, and when **field trials are vandalized**
- Ensure Commission acts to impose EU law when Member States impose **illegal bans of EU approved GM products**



WG: Regulation

Implement EU-legislation on agricultural biotech

To ensure freedom of choice:

- Support the development of detailed **EU guidelines on coexistence on a crop by crop basis**
- Ensure action is taken against **legislated GM-free zones and regions**
- Agree and implement an **EU threshold for adventitious presence of GM seeds in non-GM seeds**
- Apply **0,9% labelling threshold** to all food ingredients, inc. organic



WG: Regulation

Foster development of the knowledge-based bio-economy

- **Implement the full SRAs** as developed by the TPs (Industrial Biotechnology, Plants for the Future, Forestry, Biofuels, etc.) **at EU and MS level**
- Ensure link between '**Industrial Biotech**' and the '**Biomass Action Plan**' and '**ETAP**'
- **Create incentives to promote use of biological processes and bioproducts** (e.g. green sourcing/public procurement, environmental impact standards, specific labelling, etc.)

→ *Link to « Plant science and KBBE »*



WG: Communications

Overview policy recommendations

1. Support initiatives aimed at increasing the public's understanding of biotechnology and how it contributes to society
2. Support initiatives aimed at increasing the policymakers' understanding of the biotechnology and how it contributes to society
3. Tailor communication language to the target group
4. Increase biotech industry coverage by financial institutions



WG: Communications

Increase the public's understanding and awareness

- Examples of initiatives that can be further developed:
 - Biotech TV Channel (in addition to investors, companies,...)
 - Clearinghouse for science media
 - BioImpact study
 - Database with bio-product examples
 - Biopicture Festival
 - EU authorities to “lead by example” (i.e. bioplastic cups)
 - Famous people endorsement
 - GMO Compass (information portal on GMOs and food)



WG: Communications

Increase policymakers' understanding and awareness

- Examples of initiatives that can be further developed:
 - BioClass event for policymakers (and journalists)
 - Major socio-economic study to underline the contribution of the biotech industry to society, environment and competitiveness (incl. annual benchmarking study on the state of the biotech industry)
 - Tool to track implementation of EU biotech strategy across Europe and to share “best practice”
 - Annual survey of citizens' attitude towards biotech



WG: Communications

Tailor communication language to the target group

- Communication should provide true and scientifically sound information based on facts
- However, if information is targeted to the general public, communication language should also be very clear and easy to understand
- How can this be achieved? Some suggestions:
 - Use simple words; avoid EU-language
 - Use glossaries in communication explaining scientific terms
 - Use of explanatory drawings in communication
 - Use of hyperlinks to relevant websites offering further information



WG: Communications

Increase biotech industry coverage by financial institutions

- Financial institutions play important role in communicating listed biotech company's activities and performance thereby increasing the investment community's awareness and understanding of, and interest in the biotech industry
- On the Continent, however, equity research reports on biotech companies not as developed (both, in quantity and quality) compared to the US
- Create incentives for financial institutions to increase and improve biotech industry coverage