



## EUROPEAN FEDERATION OF BIOTECHNOLOGY

### **Annex 1 CONSIDERATIONS for the Orientation Debate**

In the opinion of the European Federation of Biotechnology – the voice of life scientists in Europe – the following considerations for the Orientation Discussion of the College of Commissioners would appear pertinent:

#### **The GM crop approval process:**

Plant biotechnology – and more specifically its use in the production of genetically modified (GM) crops – like all frontiers of innovation, needs appropriate biosafety legislation for its real societal, environmental and economic benefits to be harnessed, applied and governed.

Much has been said about the use of a precautionary approach in managing possible risks associated with modern biotechnology. Indeed, the first – and best – example of this was an action initiated by scientists in 1973 who voiced their concerns about conjectural risks associated with the new organisms being created. Their conclusions and recommendations were reported very publicly, in the journals *Science* and *Nature* in July 1974, and the whole matter was conducted with the utmost transparency. The debate was also conducted internationally, notably through the OECD, and their 1986 Council Recommendation – or “Blue Book” - remains a widely quoted reference document in the context of discussions on biosafety and modern biotechnology<sup>1</sup>.

Today’s public biosafety policy environment in Europe has nothing at all to do with a rational definition of precaution – *a dynamic and practical method of managing the uncertainties of innovation and of striking a balance between unknown risks, and the risks of stifling valuable innovations*. As stated, the problem is that an otherwise acceptable approvals process is not allowed to function as it was intended.

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<sup>1</sup> “Recombinant DNA Safety Considerations: Safety considerations for industrial, agricultural and environmental applications of organisms derived by recombinant DNA techniques”, OECD, Paris, 1986.

Indeed, the implementation of present European legislature for the approval of GM crop varieties is a departure from the “Precautionary Principle” as defined in Principle 15 of the Rio Declaration<sup>2</sup> and in the Sanitary and Phyto-Sanitary agreement of the World Trade Organisation (paragraphs 6 & 7 of Article 5)<sup>3</sup> and as communicated by the Commission<sup>4</sup>. This communication of the Commission states that:

“Where action is deemed necessary, measures based on the precautionary principle should be, *inter alia*:

- *proportional* to the chosen level of protection,
- *non-discriminatory* in their application,
- *consistent* with similar measures already taken,
- *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
- *subject to review*, in light of new scientific data, and
- *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment.”

Taken together, the Rio Declaration, the WTO agreement, and the Commission communication should in theory be sufficient to address economic, societal and environmental values adequately. In practice, mechanisms for implementation in Europe ignore international, OECD and Commission positions and the substantial body of peer reviewed scientific evidence that attests to the safety and benefits accrued from the deployment of GM crops by 100 million farmers in 23 countries. In contrast, the US, which has embraced the OECD recommendation that there was no need for a regulatory framework specific to the products of recombinant DNA technology, or other countries that adopted *appropriate* biosafety legislature – such as Argentina, have advanced, to the benefit of their research, innovation and commercial position.

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<sup>2</sup> “In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”

<sup>3</sup> Paragraph 6: ...”when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility”

Paragraph 7: ...”In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time”.

<sup>4</sup> [http://ec.europa.eu/dgs/health\\_consumer/library/pub/pub07\\_en.pdf](http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf)

Such countries – and the list is growing – have transformed the face of modern agriculture with year on year, double digit growth in the adoption of this technology around the world, and a whole catalogue of environmental, societal and economic benefits continues to unfold.

And yet, Europe – to where much of the early innovation in GM crop technology can be traced – continues to oppose the cultivation of these crops, to the detriment of humanity and to the detriment of both research and industry in Europe. The EU's Environmental Council has repeatedly ignored the advice of the EU's expert advisory bodies, such as the European Food Safety Agency (EFSA), on the proven safety of GM crops. The European Union's explicit policy is that "no form of Agriculture should be excluded from the Union, and yet, repeatedly, the EU's Environmental Council is failing to respect the rights of Member State's farmers to choose to plant GM crops. The Council repeatedly fails to implement its own laws, favouring state censorship rather than offering choice. This departure from rational decision-making is damaging the credibility of the regulatory system on which much of Europe's innovative and industrial capacity relies and is an attack on freedom of choice and a strong disincentive to every innovator in every industrial sector that is dependent upon EU regulation. According to the databases of the European Commission's Joint Research Centre, 2121 field trials have been conducted since 1991 in accordance with Article 9 of Directive 90/220/EEC and Directive 2001/18/EEC<sup>5</sup>. To date, the impact of this major effort has been to no avail. *In addition, according to the Life Sciences and Biotechnology Strategy Progress Report of the EU (5th March 2003)*<sup>6</sup>, *GMO field trial applications had dropped by 76% since 1998, 39% of GMO research projects had been cancelled between 1999-2003, VC investments had dropped, and small companies stopped participating in innovative plant biotechnology research. Further effects were seen in the relocation of research, field trials and commercialisation of new GM crops outside the EU.*

Interpretations of the present European biosafety policy environment in those parts of the world that would most benefit from the advancement of GM crop research, impede its effective use to address local problems in agriculture. Political interest groups – mostly having their origins in Europe - that advocate against the design and implementation of GM crop biosafety policies and regulations around the world would like to see the development, commercialisation and application of the technology stopped. This is, quite simply, unethical and irresponsible.

The result of this long and ill-informed debate is that the economic and political disincentives Europe imposes on the use of more modern and precise technologies and more environmentally friendly agricultural production erodes the position of EU farmers, and makes it impossible for the developing world to develop new improved crops. This cannot be justified rationally.

### **Empower public sector scientists**

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<sup>5</sup> <http://biotech.jrc.it/deliberate/gmo.asp>

<sup>6</sup> COM (2003) 96

The current content and governance of regulatory policy are damaging the prospects of public sector biotech to the point where most of its significant contributions are stalled. If the current trend in Europe continues unchallenged in its current inconsistencies on the regulation of GM crops, the efforts of public research to create sustainable solutions for the food security and health problems of the developing world are under serious threat. Critics of GM crops can no longer base their campaigns of disinformation on arguments that biotechnology is simply a tool with which multinational corporations will subjugate unwitting farmers. Nor can they assert that their opposition to GM crops is based on concern over the environment or human health. Rather they should acknowledge that most, if not all innovative research in agricultural biotechnology in the developing countries is done in public research institutions working towards public goods outputs. The fact that it is only a small number of multinationals that control the commercialisation of GM crops – to which critics of GM technology continuously allude – is in reality a sad reflection of the price of over regulation, and the fact that until recently, the exclusion of the public sector scientists from the international regulatory decision-making platforms that shape the future of their work.

Continued investment in agricultural biotechnology in the developing world will depend ultimately on the development and commercialisation of products that serve the needs of farmers and consumers. In so doing, it is critical that developing countries are free to make balanced and scientifically sound choices that reflect their food security, environmental and economic interests. If it is the intention of the European Commission to act as a global standard setter in regulatory affairs, it should take steps to considerably improve the consistency in its governance of these matters.

What is critical is to design appropriate institutional arrangements and supporting funding mechanisms that bring knowledge to bear on development. In a major gesture of self-regulation, it was public sector scientists that first raised the concept of the “*precautionary principle*” in 1973. 30 years on, and in the same enduring spirit of scientific accountability and transparency, the EFB and sister organisations have been advocating the need for science-based decision making in the regulatory supervision of biotech.

The lack of input from the public sector research and the undue attention paid to interest groups with a record of distorting scientific evidence to advance their agenda has resulted in an inefficient system which Europe has been forced to pay for heavily in terms of lost research capacity and industry. Now it is taking on global dimensions, and further inaction, or even worse, delay or moratorium would simply be unthinkable.

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European Federation of Biotechnology