The response reproduced below was submitted further to an invitation to comment on the draft Discussion Paper by the Nuffield Council on Bioethics: *The use of genetically modified crops in developing countries,* during June to August 2003. The views expressed are solely those of the respondent(s) and not those of the Council.

EuropaBio, Plant Technology Unit

The Plant Biotechnology Unit of EuropaBio welcomes the opportunity provided to comment on the Nuffield Council on Bioethics *draft report* "The use of genetically modified crops in developing countries."

We note, and agree, with a conclusion of the report that genetic modification used as one tool in plant variety development offers the opportunity to provide solutions, on a case-by-case basis, to numerous serious crop production problems associated with the different agricultures in developing countries.

We note also, and agree, that technologies applied to agriculture in developing countries so as to provide food security in a safe and sustainable manner can act as a cornerstone in developing systems that can break cycles of poverty. These same technologies, through alleviation of poverty, will also play a crucial role in preventing the destruction of biodiversity that is occurring through the continued transformation of natural environments into marginal agricultural lands – a fact that many have pointed out is the greatest destroyer of natural biodiversity today.

We consider that the linkage of secure and sustainable agricultural production to the reduction of poverty of subsistence farmers in developing countries and consequently to sustaining biodiversity must form a key part of the report.

We consider that biosafety and food and feed safety regulation do have an important role to play in ensuring the safe use of genetically modified crop plants. Our experience is that within the EU, over the past number of years, development of regulation for genetically modified crop plants, and its implementation (or failure to implement) has become restrictive and disproportionate to the potential risks they pose. We share the view stated in the report that there is not enough evidence of actual or potential harm to justify a moratorium on research, field trials, or the controlled release of GM crops into the environment at this time.

The Work of the Organisation for Economic Cooperation and Development:
The report makes numerous references to the concept of "case by case" evaluation, both in terms of use of specific GM crops to meet specific needs and in their safety assessment. We would point out that this concept is not new. It was clearly established when the OECD published "Recombinant DNA – Safety Considerations" in 1986, "Safety Considerations for Biotechnology: Scale-up of Crop Plants" in 1993 and in numerous subsequent *consensus* documents developed by the Member countries of the OECD (of which the EU Member States and the EU Commission make up approximately one half).

The OECD has also been active in the area of food and feed safety assessment of foods derived from GM crop plants. "Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles" was published in 1993 and included a substantive discussion on the concept of substantial equivalence as one tool in the safety assessment of GM foods and feeds.

The basic principles of safety assessment established in the OECD work form the basis of biosafety and food and feed safety assessment in legislation of OECD Member countries and in international legislation (the Cartagena Protocol on Biosafety being one example).

The Nuffield report stresses the importance of harmonizing regulatory activities (see for example paragraph 158), especially as a means to empower developing countries with limited resources to make choices concerning the safety assessment and use of GM crop plants to meet their own needs. We consider that the work of the OECD serves as a very useful model that through the consensus of the Member countries establishes harmonized approaches to the safety based regulation of GM crop plants. This past and ongoing work clearly needs to be considered in any development of capacity building projects so that unnecessary duplication of work and the development of conflicting procedures are avoided.

Harmonised regulatory approaches.

It is evident that there are various initiatives by individual countries, groups of countries (e.g., EU), and by international organisations to assist developing countries in the capacity building required for both the regulation of GM crop plant, and for research and development into crops plants that meet their own needs.

How is coordination of these various initiatives achieved? Is there a consistent approach, or are competing models and philosophies being promoted? We consider it crucial to aim for a high degree of conformity globally since without this trade in agricultural products will be jeopardized – as is already the case, for instance, because of the EU's lagging behind other countries in their GM approval procedures. It is important to stress that while it is essential to have harmonized regulatory approaches a positive outcome will only be attained if these are implemented in a consistent manner.

The "Precautionary Principle."

The Nuffield report makes a number of references to, and comments on, the concept and use of the "precautionary principle."

While the "principle" is clearly a component of EU law, it is interesting to note that neither the Convention on Biological Diversity (CBD), nor the Cartagena Protocol on Biosafety (CPB) refer to the "principle." As the report notes, in its preamble the CBD notes "*that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.*"

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It is important to note also that the CBD in a number of instances points to the importance of technologies to be used to sustain or improve biodiversity, and it clearly includes "biotechnology" within the term "technology" (Article 2, Uses and Terms). Clearly, achieving a secure safe food supply achieved without recourse to bringing more natural lands into cultivation is an important way of achieving this objective of the CBD.

Neither does the Cartagena Protocol on Biosafety refer to the "principle" but rather reaffirms "the *precautionary approach* contained in Principle15 of the Rio Declaration on Environment and Development…." "Article 1, Objective, In accordance with the *precautionary approach* contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol……."

Furthermore, with respect to the EU and the "precautionary principle" we would draw your attention to the European Council – Nice – 7 to 10 December 2000 and to the conclusions of the Presidency when Council noted the Council Resolution of the Precautionary Principle and whose annex included the following with respect to the precautionary principle:

> "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 the light of new scientific data, and
> - *capable of assigning responsibility for* producing *the scientific evidence* necessary for a more comprehensive risk assessment.

We are fully supportive of the Nuffield report's comments re the use/misuse of the "precautionary principle" in paragraphs 118 through to 121, especially the factoring into the risk assessment model the real cost of inaction. It would seem that at this time, and with respect to genetically modified crop plants, the EU's own criteria are not consistently applied.

EU regulation of GM crops – the setting of tolerance thresholds.

We note with interest paragraphs 171 – 177 in the report. As stated above, we are fully supportive of pragmatic safety based regulation that provides for a high level of protection for humans and for the environment.

The EU GM crop regulatory model can be broadly divided into two parts: regulation that requires pre-market authorisation following a positive safety based

risk assessment; and, regulation within the safety based legislation (GM Food and Feed Regulation, GM Traceability and Labelling Regulation – both recently finalised with publication anticipated in the autumn of 2003) that imposes special procedures (labelling and traceability) aimed at providing European consumers with the ability to choose GM or non-GM products. It is this second component of the regulation that, independent of safety issues, is likely to result in the greatest challenge to developing countries wishing to utilize GM crop plants to meet their specific needs.

EU legislation clearly recognizes that achieving 100% purity of both GM and non-GM products cannot be guaranteed and sets limits (0.9% for labelling) for the "adventitious or technically unavoidable presence" of GM in non-GM products. Specific "not yet approved" products may also be present if "adventitious or technically unavoidable" at levels up to 0.5%. These are in reality very rigorous standards for the highly efficient industrial agriculture and commodity industries of the developed world to meet – they are more stringent than the purity levels set in contracts for many commodities. Yet there are calls from certain groups with special interests, the "organic" or "bio" farming community for instance, who demand that thresholds be set at the level of detection, a level much lower than that set in the EU legislation. Lowering these already established thresholds would set standards impossible to meet in the developed world, let alone the developing countries.

The recognition in the GM Food and Feed Regulation of the possible adventitious presence of "not yet EU approved" GM events at up to 0.5% is a positive move, though the scope is restricted to certain events and a time limitation. Globally, synchronized approvals of GM event cannot be achieved. The EU already has experienced problems with GM events approved and grown over millions of hectares by third countries that are not yet approved there. This has serious implications for trade and could cause severe difficulties for developing countries that are exporters of agricultural products. A simple example would be the presence at very low adventitiously present levels of Bt cotton seeds in a shipment of non-GM rice from a south east Asian country. Since the Bt cotton is not approved in the EU (though the refined oil may be approved under the existing Novel Food Regulation), the shipment is in jeopardy as it contains an unapproved GM Bt cotton event.

We consider that in the long term it will be essential for the international community to establish a mechanism(s) whereby the "adventitious or technically unavoidable " presence of GM events approved for commercialisation by reputable regulatory authorities, for example, countries with safety based regulatory regimes based on the OECD principles, be "mutually recognized" as safe at if found at trace levels.

The case studies.

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We note with interest the discussion of benefits and potential risks associated with the seven case studies. We note also the categorization of benefits into three general types: agronomic; nutritional; and, specialty protein production, e.g., biopharmaceutical. We note also that in many cases these benefits are not scale dependent, though in many cases subsistence and small scale farmers may derive greater benefits form these than do their highly mechanized industrial farming counterparts in the developed world. We note also the referral to "traditional" plant breeding methodologies and the use of crop plant varieties developed in this way as a baseline for comparing the potential risks and benefits of GM derived counterparts.

Within the EU the perception amongst the general public, and perhaps the majority of policy makers and regulators, is that improving agronomic traits provides benefits only to farmers with no benefit to consumers. This is an unfortunate state of affairs since global society today depends for its secure and safe food supply on the past and present work of the plant breeding community, and maintaining and improving agronomic traits has been and will remain a key objective of this work.

In developing countries it is the development of crop varieties with beneficial agronomic characteristics providing food security in a sustainable way that will play the major role in breaking the cycle of poverty, improve the quality of life and offer a way to protect fragile biodiversity. As the report notes, in some countries 80% of citizens are farmers who will recognize immediately the benefits of agronomic qualities that provide them with food security and the potential to maintain and improve their agricultural environment and biodiversity.

EuropaBio, the European Association for Bioindustries, has 35 corporate members operating worldwide and 21 national biotechnology associations representing some 1200 small and medium sized enterprises involved in research and development, testing, manufacturing and distribution of biotechnology products.