

17 December 2004

Dr Matthew Freeman
AEBC Secretariat
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1 Victoria Street
London SW1H 0ET

Dear Dr Freeman

AEBC Consultation on research agendas in agricultural biotechnology

Thank you for your letter of 1 November 2004 drawing our attention to your consultation document on research agendas in agricultural biotechnology.

As you know, the Nuffield Council on Bioethics examines ethical issues raised by new developments in biology and medicine. Established by the Nuffield Foundation in 1991, the Council is an independent body, funded jointly by the Foundation, the Medical Research Council and the Wellcome Trust. We have considered questions related to research agendas in agricultural biotechnology in a recent Discussion Paper on *The Use of GM crops in Developing Countries*. I hope that you will find the conclusions and recommendations which are copied at **Annex A** of use in your deliberations. A full copy of the Discussion Paper is also attached, and an electronic version can be downloaded at http://www.nuffieldbioethics.org/go/ourwork/gmcrops/page_218.html **Annex B** presents our discussion of related matters in the 1999 Report *Genetically Modified Crops: the ethical and social issues*, which can also be downloaded at http://www.nuffieldbioethics.org/go/ourwork/gmcrops/publication_301.html

You note in your letter that the consultation ‘...is focused primarily on UK-based and publicly funded research, while recognising that international and private sector influences cannot be ignored.’ We address these influences and focus on the global context in which agricultural biotechnological research takes place in Annex A and Annex B. We note in particular that decisions about research agendas in the UK and Europe can have very significant implications for many people in developing countries whose lives depend to a far greater degree on effective agriculture.

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In making recommendations on potential improvements and in seeking to influence policy that will help shape research agendas, I should therefore be grateful if AEBC would emphasise the UK's responsibilities in the global and not merely the national context. Agricultural biotechnologies such as GM crops clearly will not 'feed the world', but they can make a substantial contribution in specific contexts. Future research agendas in the UK should be tailored accordingly.

Your sincerely

A handwritten signature in blue ink that reads "Sandy Thomas". The signature is written in a cursive, slightly slanted style.

Dr Sandy Thomas
Director

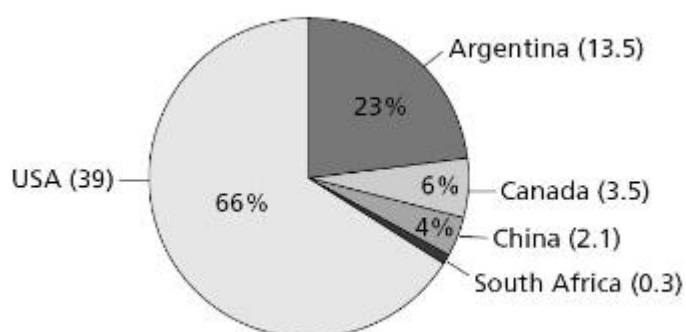
Please note: our comments relate mainly to Question 1 and 4 of the consultation Document and we offer our observations accordingly. The text below is taken from the Discussion Paper on The Use of GM crops in Developing Countries. Further detail is available in the full Report.

1. Factors influencing the research agenda of crops with relevance for developing countries

Global commercial use of GM crops

3.21 Three-quarters of GM crops which are grown worldwide are cultivated in developed countries, predominantly on large-scale industrial farms in the US, Argentina and Canada. Traits which have been successfully introduced by means of genetic modification relate primarily to the needs of these farmers. However, of the approximately six million farmers who grew GM crops legally in 2002 worldwide, more than three-quarters were resource-poor, small-scale cotton farmers in developing countries, mainly in China and South Africa.²¹ While the number of farmers using GM crops is the highest in developing countries, they only account for 27% of the total area. The five countries which grew 99% of the global GM crop are shown in Figure 3.1.

Figure 3.1: Global area of legally planted GM crops in 2002 by country (million hectares)

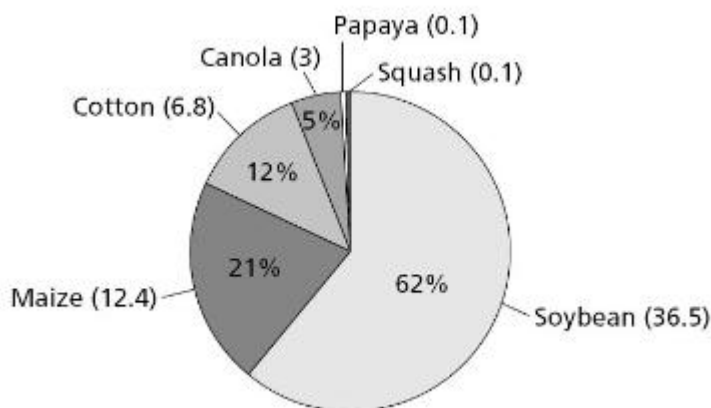


James C (2002) *Preview, Global Status of Commercialized Transgenic Crops: 2002 ISAAA Brief No. 27* (Ithaca, NY: ISAAA).

²¹ James C (2002) *Preview, Global Status of Commercialized Transgenic Crops: 2002 ISAAA Brief No. 27* (Ithaca, NY: ISAAA). This figure excludes those farmers who grew GM crops illegally, for which there is anecdotal evidence in Brazil, Pakistan and India during 2002.

3.22 Between 1999-2002, the principal GM crops grown have been non-staple crops, grown by commercial farmers in developed countries. The most commonly used traits were herbicide tolerance (75%) and pest resistance (15%). Varieties carrying two or more transgenes which conferred both pest resistance and herbicide tolerance accounted for 8% of all crops. Herbicide tolerant soybean was the most widely grown GM crop in 2002 (see Figure 3.2).

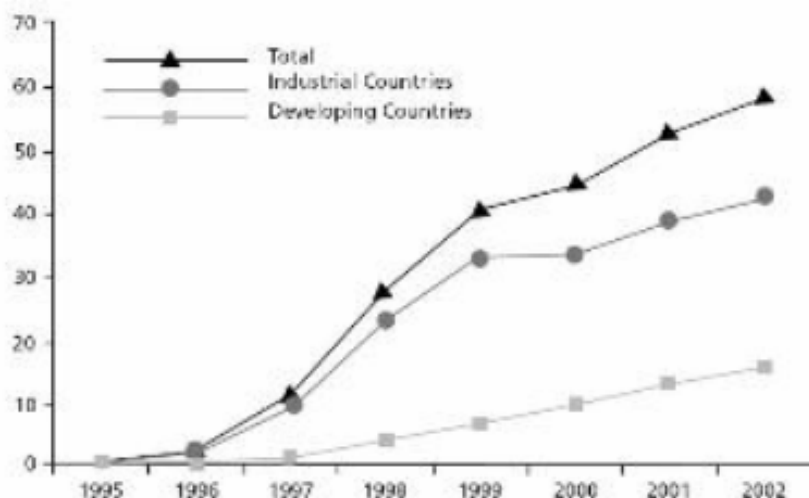
Figure 3.2: Global area of legally planted GM crops in 2002 by crop (million hectares)



James C (2002) *Preview, Global Status of Commercialized Transgenic Crops: 2002 ISAAA Brief No. 27* (Ithaca, NY: ISAAA).

3.23 In 2002, nearly one-quarter of the total area of GM crops worldwide was grown in Argentina. Soybean and maize for export as animal feed were planted predominantly on large-scale farms. Since our 1999 Report was published, the area of GM crops in developing countries has doubled. The growth in cultivation of GM non-staple crops in developing countries is expected to continue over the coming years (see Figure 3.3).

Figure 3.3: Global area of legally planted GM crops, 1996-2002 (million hectares)



James C (2002) *Preview, Global Status of Commercialized Transgenic Crops: 2002 ISAAA Brief No. 27* (Ithaca, NY: ISAAA).

- 3.24 In China, GM varieties were grown on 51%, or two million hectares, of the land used for growing cotton. In India, GM cotton received regulatory approval in April 2002 and 45,000 hectares were subsequently planted. Indonesia has also recently introduced GM crops, which means that the three most populous countries in Asia have adopted the technology.²²
- 3.25 While the rapidly increasing spread of GM crops is noteworthy, most GM food and feed crops, such as soybean or rice, have not yet been approved for commercial planting in Africa, Asia, or the Middle East. The exceptions are South Africa and the Philippines, where GM maize has been approved, and Argentina, where GM maize and soybean are grown. One of the main reasons for this pattern is that regulators in developing countries often opt for a highly conservative precautionary approach when deciding about the use of a new GM crop. Unresolved concerns about the safety of GM crops for human consumption and for the environment (see paragraphs 4.28-4.47), together with possible restrictions arising from international trade policies (see paragraphs 5.43-5.50) have been influential in this respect.

Intellectual property rights

- 6.12 We observed in the 1999 Report that the agrochemical and seed industries were tightly consolidated around a small number of multinational companies. We noted that further consolidation might not be in the public interest and we recommended that the relevant competition authorities keep the sector under close review. Since then, AstraZeneca and Novartis have merged to form Syngenta and Aventis CropScience has merged with Bayer to form Bayer CropScience. With regard to markets in developing countries, Monsanto has, for example, increased its share of the Brazilian maize market from zero to 60% in just two years. Only one Brazilian company remains, which has a 5% share of the market.¹² In anticipation of such developments, we emphasised in our 1999 Report that farmers in developing countries should retain the capacity to choose between growing either new improved seed from the companies or improved seed from national breeding programmes or the CGIAR centres.
- 6.13 It has been argued that the growth of patent claims in both the public and private sectors could have an inhibiting effect on research. The challenge for the public sector, especially where research is directed at agriculture in developing countries, is how to access GM technologies without infringing IPRs. In addition, they must decide on the way in which their own technologies will be made available.

²² James C (2002) Preview, Global Status of Commercialized Transgenic Crops: 2002 ISAAA Brief No. 27 (Ithaca, NY: ISAAA).

¹² Commission on Intellectual Property Rights (2002) *Integrating Intellectual Property Rights and Development Policy* (London: CIPR).

- 6.14 New initiatives which recognise the potential of these constraints to inhibit research into crops relevant to developing countries are therefore particularly welcome. Several US universities are now finding that the exclusive licensing of their technologies has deprived them of access to their own inventions. The Public Intellectual Property Resource for Agriculture (PIPRA) is a recent initiative which aims to promote licensing strategies in US universities that encourage retention of rights to their own technologies.¹³ These rights can be exercised for non-profit purposes or for the development of crops especially suited to the needs of developing countries.
- 6.15 The recent establishment of the African Agricultural Technology Foundation (AATF) also seeks to address IP issues in agriculture, relevant to the needs of developing countries.¹⁴ Together with similar activities organised by the ISAAA, the AATF will create partnerships with existing organisations. It will transfer materials and knowledge associated with advanced agricultural technologies that are privately owned by companies and other research institutions, on a royalty-free basis.¹⁵ The AATF will focus on improvements that can be achieved by genetic modification of crops relevant to small-scale African farmers. These include cowpeas, chickpeas, cassava, sweet potatoes, bananas and maize. It has secured support from four of the leading multinational agrochemical companies which have agreed to share patent rights, seed varieties and expertise with African researchers.¹⁶ The AATF also intends to negotiate with other companies for support as well as for licences to important patents.¹⁷
- 6.16 As we have noted, the majority of successful applications of GM crops have been developed by industry for commercial agriculture in developed countries (see paragraphs 3.21-3.25 and 3.27). In contrast, most research on GM crops that may have potential for developing countries continues to be undertaken by publicly-funded organisations. A major concern which we expressed in our 1999 Report was the neglect of a serious issue: the risk that gains from GM crops will not be brought to bear on the needs of poor people in developing countries. We also concluded that GM crop technology was unduly concentrated on the crops and farm systems of industrialised countries. The role of the CGIAR in research on GM crops is strategically important. But funding for the CGIAR has fallen in real terms since 1990. Although it spends about US\$360 million per year, less than 10% is directed to research on the genetic modification of crops. **We therefore affirm the recommendation**

¹³ See <http://www.pipra.org/>.

¹⁴ See <http://www.aftechfound.org/index.php>.

¹⁵ Conway G (2003) *From the Green Revolution to the Biotechnology Revolution: Food for Poor People in the 21st Century*. Speech at the Woodrow Wilson International Center for Scholars Director's Forum. 12 March 2003. Available:

<http://www.rockfound.org/documents/566/Conway.pdf>. Accessed on: 10 Oct 2003; see also: ISAAA The Papaya Biotechnology Network of Southeast Asia, <http://www.isaaa.org/Projects/SEAsia/transfer.htm>. Accessed on: 31 Oct 2003.

¹⁶ Monsanto, DuPont, Syngenta and Dow AgroSciences.

¹⁷ Gillis J (2003) To feed hungry Africans, firms plant seeds of science, *Washington Post* 11 March 2003.

made in our 1999 Report that genuinely additional resources be committed by governments, the European Commission and others, to fund a major expansion of GM-related research into tropical and sub-tropical staple foods.

6.17 Furthermore, as one respondent to our Consultation observed:

‘The priorities for the development of GM crops seem to be set by institution and/or organisations outside of Africa that may not necessarily address on-farm constraints of major importance. And currently very few countries outside of South Africa have the capacity to develop GM crops. Africa at least needs to develop an inventory of intractable constraints of major food and commercial crops that need urgent attention. Regional bodies such as FARA, CORAF, ASARECA and SADC/FANR¹⁸ might best draw up a list of such constraints and seek funding to develop the capacity necessary for the evaluation of GM crops in Africa.’

Dr Kanayo F Nwanze, Director General, WARDA - The Africa Rice Centre

We endorse this suggestion and recommend that those sponsoring research, in determining which traits in which crops should be developed, be proactive in consulting with national and regional bodies in developing countries to determine priorities for research.

¹⁸ FARA – Forum for Agricultural Research in Africa, CORAF – West and Central African Council for Agricultural Research and Development, ASARECA – Association for Strengthening Agricultural Research in Eastern and Central Africa, SADC – South African Development Community and FANR – Food, Agriculture and Natural Resources Development Unit in Harare, Zimbabwe.

2. Stakeholder consultations on research priorities and crop management

5.33 Local communities should be included as far as possible in decision making processes, for example by means of consultations with stakeholders. In this context, formal and non-formal programmes that promote the dissemination of balanced information, communication, education and training of those involved are essential. In particular, farmers need to be informed about the technological potential and management requirements of GM crops. Expectations are sometimes inappropriately high, and knowledge about specialised farm management practices may be absent. **We recommend that companies marketing GM crops in developing countries share, with governments, the costs of:**

- **locally appropriate schemes to elicit small-scale farmers' preferences regarding traits sought by GM-based breeding;**
- **their participation, where appropriate, in plant breeding; and**
- **subsequent mechanisms to improve dissemination of balanced information, education and training about the use of GM crops.**

3. Interdependence: the impact of European and international trade policy on the choices of people in developing countries

- 5.48 Unless European consumers become far less sceptical towards GM crops, few developing countries will wish to grow them. We have observed that a rapid spread of GM crops has already occurred in several parts of the world (paragraph 3.21). However, scarcely any GM food and feed crops have been approved for commercial planting in the developing countries of Asia, Africa or the Middle East. This situation appears to derive in part from fears that a highly restrictive interpretation of the precautionary approach in Europe and Japan will close off export sales.
- 5.49 The freedom of choice that farmers in developing countries can exercise is severely restricted by the agricultural policy of the EU. This policy has been developed primarily to protect European consumers and the environment from potential dangers. But after almost a decade of use of GM crops, there is no robust scientific evidence that their consumption has adverse effects on human health.³⁴ There have been reports of gene flow from GM crops to other cultivars or wild relatives. However, as we have said (see paragraphs 4.28- 4.34) this phenomenon is not specific to GM crops. It also occurs frequently in the case of organic and conventionally bred crops, and from improved crops, which have been changed in their genetic structure by exposure to radiation or chemical substances. In our view, the possibility of gene flow as such cannot justify the prohibition of the planting of a crop; only specific adverse consequences which result from it should provide the basis for such a decision (see paragraphs 4.28-4.34).
- 5.50 There is thus a considerable imbalance between the hypothetical benefits afforded by the EU policy for its own citizens, and the probable and substantial benefits that could be afforded to developing countries (see also paragraphs 4.1-4.2 of the 1999 Report). We conclude that the current provisions of the revised Directive 2001/18/EC, Regulation 1830/2003/EC on Traceability and Labelling and Regulation 1829/2003/EC on Food and Feed have not taken sufficiently into account the negative effect that these policy instruments are likely to have on those working in the agricultural sector in developing countries. It seems unlikely that the current and proposed European regulations will be substantially revised in the near future to prevent the raising of artificial trade barriers for GM products from developing countries. **However, we recommend that the European Union (EU), the UK Department for International Development (DFID) and appropriate non-governmental organisations which monitor the agricultural policy of developing countries examine the consequences of EU regulatory policies for the use of GM**

³⁴ FAO and WHO (2002) Safety Aspects of Genetically Modified Foods of Plant Origin Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, WHO, Geneva, Switzerland, 29 May – 2 June 2000 (Geneva: WHO); Royal Society (2002) *Genetically Modified Plants for Food Use and Human Health – an update* (London: Royal Society).

crops in developing countries. We recommend that the European Commission (EC) establish a procedure to report on the impact of its regulations accordingly.

4. *UK research agendas in agricultural biotechnology and the needs of developing countries - Discussion from the 1999 Report Genetically Modified Crops: the ethical and social issues*

- 8.48 The most serious of the dangers for the developing world may arise from not developing the capacity to screen, breed and safety-test GM crops, and to manage their release and use. If no such capacities are developed, the best scientists in the developing countries and the CGIAR system will be tempted to migrate to commercial organisations in industrialised countries. The danger is then that yield increases and employment income from food staples will remain sluggish.
- 8.49 So far, GM crops have had little effect, good or bad, on food-poor consumers in developing countries, or the farmers and farmworkers who mainly supply them. 'The market' has not directed any major private-sector scientific resources at breakthroughs into conventional Green Revolution-type plant breeding or into GM crops or main food staples (or tropical export crops) for employment-intensive production in poor countries. Serious prospects for such shifts will require new market incentives and/or new public resources for non-commercial research. To forego such efforts would not protect the poor from any unregulated risks of genetic modification and other agricultural innovations, but would sacrifice the prospects of major GM crop-based advances in food and agricultural output and employment for the food-poor.
- 8.50 At present the balance of agricultural research between the developed and developing world could well limit the use of increasing numbers of desirable plant types. This would occur because desirable GM plants could be subject to patents on GM technology or other controls, perhaps including GURT (gene use restriction technology or 'Terminator' technology). In addition, in the private sector, there may be a failure to develop or even attempts to actively prevent development of apomixis genes. This could be inefficient as well as inequitable. **The UK should use its position in the World Bank, EU, CGIAR, WTO and other bodies to reverse this trend through improving the infrastructures and remedying the underfunding and biases of public-sector research in developing countries.**
- 8.51 8.51 Multinational companies are likely to operate increasingly in developing countries, particularly in Asia and South America. These companies will probably wish to deploy intellectual property measures which have been successful in developed countries. While farmers may well benefit from these new technologies, it is most important that they retain the choice to grow either the new improved seed from the companies or the new improved seed from national breeding programmes or the CGIAR Centres. We consider that it is vital, therefore, that these centres maintain proficiency in the latest technologies and continue to deploy the best technology available in the public sector. **We strongly**

recommend that the UK continue to support the CGIAR system to this end. At the same time we recommend that the CGIAR seeks to protect proactively its own technology through patenting and use it to access other protected technology on behalf of their clients, the developing world (paragraph 4.78).

- 8.52 The TRIPS agreement has 'no requirement on patent applicants to involve or consult with local communities or governments about patenting a compound based on a natural product from that country, or sharing the benefits or including the prior contributions of indigenous peoples'. The Convention on Biological Diversity (CBD), on the other hand, requires host government consent and 'approval and involvement' of traditional communities. There have been attempts to amend patent law so that the CBD objectives would be better supported by taking into account the access legislation.
- 8.53 The UK, occupying an intermediate position on GM crops between the liberal regulatory position of the US Government and the hostile view of some European governments and non-governmental organisations, is well placed to broker progress on this matter via the WTO and the CGIAR. **The Working Party recommends that the UK, in consultation with like-minded developing countries and other member states of the EU, propose that the WTO explore and report on the extent to which the international and national legal framework currently frustrates the objectives of the CBD on providing fair and equitable access to genetic resources and how this conflict might be addressed.** (paragraph 4.73). There is an overriding need to respect the property rights of developing country researchers, public agencies and indigenous communities regarding plant materials developed by them.
- 8.54 **The Working Party recommends that the UK Government and EC, preferably working through the CGIAR, invite those developing countries willing and able to commit genuinely additional resources, to enter a joint initiative. In view of the proven high returns to and impact on poverty of appropriate agricultural research, and the new salience of fundamental and applied GM research, there should be a funded major expansion of research:**
- (i) into higher, more stable and sustainable production of tropical and sub-tropical food staples;**
 - (ii) seeking gains for poor farmworkers, food consumers and smallholders;**
 - (iii) by mainly CGIAR institutes and developing-country national agricultural research systems (NARS) working with private sector researchers in the developing and developed world where desirable;**

devising alongside *locally appropriate*:

- (i) research planning;
- (ii) regulatory/implementation mechanisms for environmental review of GM crop experiments (paragraph 4.62);
- (iii) food-safety clearance of GM releases to farmers.

The Working Party further recommends that the Department For International Development (DFID) and the Ministry of Agriculture, Fisheries and Food (MAFF) should jointly help UK researchers to contribute to developing this initiative (paragraph 4.42). We endorse the recommendation by the House of Commons Environmental Audit Committee that a Minister from DFID be appointed to the Cabinet Ministerial Group on Biotechnology and Genetic Modification.

8.55 The Working Party welcomes the aim of the March 1998 White Paper on overseas aid to underpin the agreed Organisation for Economic Co-operation and Development (OECD) effort to construct 'aid partnerships' with developing countries to halve world poverty by 2015. **To help to achieve this we recommend that alongside consultations with the developing countries concerned about their own agricultural research priorities, the UK Government should pre-commit a substantial amount of the rise in UK aid announced in July 1998 to additional spending on the research and development of GM food staples grown in developing countries** (paragraph 4.48). A part of this sum should be for consultative work with those countries on the design of appropriate regulatory regimes (see paragraph 4.62). **We further recommend that this contribution should be used to leverage extra funds from other donors (including the EU) for developing country NARS and for the CGIAR institutes** (paragraph 4.48). The funds should be focused on those developing countries eager to support the initiative with extra domestic financing for public-sector agricultural research.

8.56 Of the various traits under consideration in GM crops, it should be noted that herbicide-tolerance may be associated with special socio-economic effects when utilised in varieties for use in developing country agricultures. For example, the use of herbicides replaces hand weeding. Notwithstanding the fact that some of the most striking applications of herbicide-tolerance are in developing countries (such as the introduction of direct seeding rice in the Philippines), the same use of herbicide-tolerant varieties may work against poverty reduction programmes which requires raising, not lowering, the demand for labour. **We recommend that the CGIAR should carefully assess both socio-economic and agricultural needs before introducing crop varieties with novel traits into developing country agricultures and should co-ordinate careful assessment of the potential risks of hybridisation of GM crop plants with weed relatives** (paragraph 4.57).

8.57 It is important to ask how risks to environmental and human health can be minimised, given the limited regulatory capacity of many developing countries. The costs and risks can almost certainly be much reduced by ensuring appropriate public awareness and by insisting on transparent arrangements for overview and enforcement. However, this will have to depend far more on incentives, and co-operation with scientists and companies, and less on command-and-control, than is feasible or necessary in the developed world. Nevertheless, we conclude that transfer of experience and know-how from advisory and regulatory bodies in developed countries to the developing world, with suitable adaptation to its socio-political as well as physical environments, is urgently needed. **The Working Party recommends that part of new UK aid funds recommended to be earmarked for GM research and development in and for developing countries (see paragraph 4.48) should be used to help such countries in devising appropriate incentive and regulatory regimes against possible environmental and biosafety hazards (paragraph 4.62).** While consultation with regulatory bodies in the US, EU and elsewhere is essential, developing countries have different (and varied) farming systems, food chains, and environments, and so need different biosafety and environmental procedures. **We therefore recommend that this part of the new GM funding be guided by leading researchers via appropriate international bodies with strong developing-country representation such as the Food and Agriculture Organisation, the International Food Policy Research Institute, and/or the Institute for the Support of National Agricultural Research (paragraph 4.62).**