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Dear Göran

EGE Opinion on the ethical aspects of modern developments in agricultural technologies

Thank you for the opportunity to join the EGE's Roundtable on ethical aspects of modern developments in agricultural technologies, held in Brussels on 18 June 2008. As requested at that meeting, I am enclosing here written comments for the EGE's ongoing deliberations.

The comments at Annex A are based on the Council's 2003 Discussion Paper The Use of GM crops in Developing Countries. They provide some general context to the debates around using GM crops in developing countries and focus on those conclusions and recommendations that are particularly relevant for the European Commission.

A full copy of the Discussion Paper is also enclosed, and an electronic version can be downloaded at http://www.nuffieldbioethics.org/go/ourwork/gmcrops/page_218.html The Council's earlier Report of Genetically Modified Crops: the ethical and social issues, can be downloaded at http://www.nuffieldbioethics.org/go/ourwork/gmcrops/publication_301.html and a hard copy is also enclosed.

Yours sincerely

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Chairman
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Annex A

General context

Modern developments in agricultural technologies encompass a very wide field. First, there are different purposes of agriculture, with food and feed production the most common. The use of crops for the production of biofuels has also become more prominent in recent years, and research is taking pace on the use of crops for the production of biopharmaceuticals. Secondly, there is a wide range of different approaches to doing agriculture. Opinions and practices differ as to how best to maximise yields, while reducing damage to the environment and minimising losses from biotic and abiotic stressors (eg diseases, pests, drought or saline soil conditions). Many regard organic farming as a promising approach in this respect. Advances such as integrated crop and pest management, fertilizer microdosing, and the use of improved crop varieties and hybrids are also important, whether genetically modified or not. Thirdly, agriculture plays very different roles in developed and developing countries, and, in the latter case, has a far more direct impact on the physical, economic and cultural livelihood of significant proportions of the population. The focus of our submission is on issues arising from current and future use of GM crops in developing countries.

A range of new methodologies could improve agricultural output in the developing world. There are generally no one-size-fits-all approaches because the natural conditions such as quality of soil and prevalence of biotic and abiotic stressors differ between countries, as do the political, social and economic environments. Successful solutions are therefore likely to be as varied as the conditions obtaining in different countries. GM crops may play an important role in the mix of technologies, and their potential needs to be assessed in equal depth as that of other technologies, in order to identify the safest, most efficient and most sustainable means of agricultural technologies that can promote livelihood and reduce poverty. This is not to suggest that GM crops constitute the only, or, in all cases, the best way of maximising yields in an environmentally sustainable way. However, we wish to emphasise that they can make a difference in specific cases.

However, as, for example, the discussion among participants of the EGE's Roundtable meeting on 18 June 2008 illustrated, the current context of the food (price) crisis has, in many ways, exacerbated the tensions that characterise the general debate on GM crops. The EGE is in a unique situation to contribute to an urgently needed de-polarisation of this debate. While the group's remit is on developments in agricultural technologies more generally, GM crops are clearly one part of the picture. Demonstrating the scope and limitations of using GM crops will help the Commission and others who draw on the EGE's opinions for advice to see past exaggerated claims that are occasionally made by proponents of the technology. Equally it should help readers to understand that those who suggest GM crops should play no role at all in modern agriculture need to propose effective and feasible alternatives, if their views are to be considered as constructive contributions to the debate.

Main findings

In the 2003 Discussion Paper *The Use of GM crops in Developing Countries* we explored the potential of GM crops to improve agriculture in developing countries by means of eight case studies. While the science has advanced since then, and use has increased three-fold in developing countries, with 10 million farmers using GM crops in 2007 as opposed to four million in 2003, the general conclusions and recommendations remain valid.

Our main conclusion is that possible costs, benefits and risks associated with particular GM crops can be assessed only on a case by case basis. Any such assessment needs to take into account a variety of factors, such as the gene, or combination of genes, being inserted, and the nature of the target crop. Local agricultural practices, agro-ecological conditions and trade policies of the developing country in which GM crops might be grown are also important. **We therefore recommend that in considering whether GM crops should be used or not, it is essential to focus on the specific situation in a particular country, asking the question: 'How does the use of a GM crop compare to other alternatives?' All possible paths of action must be compared, including inaction, in respect of improving, in a cost-effective and environmentally sustainable way, human health, nutrition, and the ability to afford an adequate diet** (paragraph 4.49 – all paragraph numbers refer to the text of the Discussion Paper).

The improvement of agriculture and food security depends on several factors. These include stable political environments, appropriate infrastructures, fair international and national agricultural policies, access to land and water, and improved crop varieties which are suited to local conditions. In focusing on current and potential uses of GM crops we therefore consider only part, albeit an important one, of a large and complex picture. However, we are clear that **in particular cases, GM crops can contribute to substantial progress in improving agriculture, in parallel to the (usually slow) changes at the socio-political level. GM crops have demonstrated the potential to reduce environmental degradation and to address specific health, ecological and agricultural problems which have proved less responsive to the standard tools of plant breeding and organic or conventional agricultural practices. Thus, we affirm the conclusion of our 1999 Report that there is an ethical obligation to explore these potential benefits responsibly, in order to contribute to the reduction of poverty, and to improve food security and profitable agriculture in developing countries** (paragraph 4.48).

Specific conclusions and recommendations

Current and future research

For a variety of reasons, many of the crops such as rice, wheat, white maize, millet, sorghum, yams, cocoyams and others, which provide food and employment income for the poor in developing countries, have been ignored by the private sector. Much of the current privately funded research on GM crops serves the interest of large-scale farmers in developed countries. Consequently there is a serious risk that the needs of small-scale farmers in developing countries will be neglected. It appears that research on these crops will have to be supported primarily by the public sector.

We therefore affirm the recommendation made in our 1999 Report that genuinely additional resources be committed by the UK Department for International Development (DFID), the European Commission, national governments and others, to fund a major expansion of public GM-related research into tropical and sub-tropical staple foods, suitable for the needs of small-scale farmers in developing countries. In determining which traits and crops should be developed, funding bodies should be proactive in consulting with national and regional bodies in developing countries to identify relevant priorities (paragraphs 6.16-6.17).

There is not enough evidence of actual or potential harm to justify a blanket moratorium on either research, field trials, or the controlled release of GM crops into the environment at this stage. **We recommend that research on the use of GM crops in developing countries be sustained, governed by a reasonable application of the precautionary approach. Accumulating evidence from new scientific developments must be used to inform discussions about the current or future use of GM crops. The views of farmers and other relevant stakeholders must also be taken into account (paragraph 4.50).**

Liability

It has been suggested by some that the use of GM crops by farmers in developing countries might be exploited by the multinational seed industry in such a way that seed of questionable quality were provided. We are not aware of any such instances. However, it is clear that the same standards of liability need to apply to both developing countries and developed countries. **Where there is clear evidence of damage attributable to the seed producer, compensation will need to be provided, regardless of whether the seed is GM or non-GM (paragraph 5.36).** We note that in previous instances of crop failures in developed countries, compensation has been negotiated successfully.

We recommend that possible scenarios, which include the principle of compensation, be considered by policymakers and the seed industry. Agreed standards should be published widely, taking into account in particular the situation of small-scale farmers in developing countries. Illiteracy and lack of adequate infrastructure for effective communication can present additional obstacles that need to be considered. Wherever possible, agreements should be established, to facilitate compensation of small-scale farmers who, in the event of loss or damage, are unlikely to be able to afford appropriate legal action (paragraphs 5.36 and 5.45-5.46).

The impact of European regulations on GM crops

The freedom of choice of farmers in developing countries is being severely challenged by the agricultural policy of the European Union (EU). Developing countries might well be reluctant to approve GM crop varieties because of fears of jeopardising their current and future export markets. They may also not be able to provide the necessary infrastructure to enable compliance with EU requirements for traceability and labelling (paragraphs 5.20-5.21).

One strategy which developing countries might choose could be to adopt GM crops for domestic use only. However, problems could arise if separation of GM crops and non-GM crops for export cannot be readily achieved. For example, small amounts of GM produce might become mixed with non-GM produce during storage.

If current attitudes among EU policy makers and consumers prevail, countries which depend on exports to the European market might then be at considerable disadvantage (paragraphs 5.43-5.48).

A number of recent authoritative reviews have concluded that, based on current evidence, neither GM crops, nor food produced from GM crops, pose a significant risk to humans who consume them. However, complications could arise where risks for human health or the environment are exaggerated by the scepticism of some commentators from developed countries. Policy makers in developing countries would then be faced with very difficult choices. If a national policy that allowed the responsible domestic use of GM crops were adopted, it might well be perceived as promoting unsafe foods, and could lead to the loss of EU export markets. It is therefore important that policy makers in developing countries seek a range of advice about these issues.

There is 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. Current provisions of the revised *Directive 2001/18/EC*, *Regulation 1830/2003/EC on Traceability and Labelling* and of *Regulation 1829/2003/EC on Food and Feed* have not given sufficient consideration to the effects that these policies are likely to have on developing countries. **We recommend that the European Commission (EC), the UK Department for International Development (DFID) and appropriate non-governmental organisations which monitor the agricultural policies of developing countries examine the consequences of EU regulatory policies for the use of GM crops in developing countries. We recommend that the European Commission establish a procedure to report on the impact of its regulations accordingly** (paragraph 5.50).

Intellectual property rights (IPRs)

In 1999 we noted that the agrochemical and seed industry was tightly consolidated around a small number of multinational companies. There has been continuing concentration in the number of companies that control between them the provision of seeds and important research technologies. There are concerns that growth of patents in both the private and public sectors could have an inhibiting effect on publicly funded 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. New initiatives which recognise the potential of these constraints to inhibit research into crops relevant to developing countries are therefore very timely. However, we also note that the recent example of Golden Rice shows that patented technologies need not necessarily be a barrier

Control of and access to genetic modification technologies

Access to plant genetic resources is critically important for the development of GM crops which are suited to the needs of developing countries. Usually, access to such resources is governed by Material Transfer Agreements (MTAs). The perception that the recent proliferation of MTAs is not necessarily in the public interest is widespread.

We welcome the decision by the UK Government to ratify the *International Treaty on Plant Genetic Resources for Food and Agriculture*. Access to resources falling under the Treaty is of crucial importance in the development of crops suited to

developing countries. We recommend that in the negotiations regarding the standard Material Transfer Agreement (MTA), the UK Government aims for provisions that exempt users in developing countries from payments, where commercial applications arise from material covered by the MTA. Where exemptions are not appropriate, differentiation of payments should take into account the level of development of the country in question (paragraph 5.15).

Under patent law in the UK, it appears that a plant breeder does not have the clear right to use a patented GM plant variety for breeding purposes. To avoid possible litigation, he can either refrain from using the variety or apply for a licence from the patent owner. Such requests may be refused or granted on less than favourable terms and the provision of compulsory licensing is often not straightforward. As we noted in our 1999 Report, this potential locking up of genetic variation would be contrary to the spirit and intent of plant variety rights (PVRs). We consider that there is a strong case for the principle of the breeders' research exemption, established for PVRs, to be applied to patented varieties. **We reaffirm our recommendation from that Report that the World Intellectual Property Organization (WIPO), the European Commission (EC), the Union for the Protection of the New Varieties of Plants (UPOV), the Consultative Group on International Agricultural Research (CGIAR) and the International Plant Genetic Resources Institute (IPGRI) together closely monitor the impact of patents on the availability of germplasm to plant breeders (paragraph 6.11 and paragraph 3.61 of the 1999 Report).**