

**Royal Society Consultation
Biological Approaches to Enhance Food Crop Production**

Summary

Our research has shown that the current European system for developing and regulating biological approaches to food crop production is seriously flawed and is likely to lead to ever-increasing disadvantages for European agriculture, particularly if commodity food prices continue to rise and climate change increasingly disrupts crop production globally. These disadvantages are also already evident in many developing countries.

This response outlines the complexity of the background to the current systemic failure of the European regulatory system for GM crops, including particularly missed policy opportunities and a failure to build evidence-based approaches to risk governance. This is having a serious impact on today's innovation environment for biological approaches to enhance food crop production. A similar impact on future generations of biological approach will be inescapable if there is not a policy-led strategic approach to the development of a an effective governance system. This will require a more flexible and robust design in the face of 21st Century opportunities to benefit from biological discoveries and, on the negative side, to cope with global climate change and a changing financial environment.

Background and coverage

1. Innogen is the ESRC Centre for Social and Economic Research on Innovation in Genomics¹. Our focus is on the life sciences which have the potential to transform health care and food production systems in developed and developing countries and to provide one of the main platforms of economic growth and global competitiveness in the 21st century. Rapid developments in life sciences challenge our existing regulatory systems and raise new ethical and social issues and our research aims to provide a sound base for decision-making in science, industry, policy and public arenas related to innovation in life sciences.
2. Staff at the Innogen Centre have experience since the 1980s in areas relevant to the role of biological and related sciences in enhancing global food crop production, including research projects funded from a range of sources, published reports and journal articles, and advice to government and other bodies nationally and internationally. Recent relevant grants and publications are listed in Annex 1.
3. In this submission we have focussed primarily on **barriers to the effective introduction and use of biological approaches to enhancing food crop production, regulatory hurdles, knowledge and technology transfer**, primarily in the context of new discoveries in life sciences.
4. Our research on these questions has covered the following:
 - (i) knowledge generation in scientific communities and its translation to innovative products and processes;

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- (ii) governance, policy development and risk regulation²; and
- (iii) public and stakeholder engagement and related values and perceptions.

5. Interactions among these three constituencies determine: which products and processes are developed and applied; what are the overall benefits and costs and to whom do they accrue; whether they are developed in the public or private sector; if in the private sector which companies, and indeed which countries, are able to participate (refs 2-4, 6, 8, 18,19, 27).

6. The most prominent recent example of the adoption (or not) of biological approaches to enhance food crop production, in Europe and elsewhere, has been GM crops. This illustrates particularly well how the interactions between the three constituencies outlined above operate and how knowledge of these interactions can enable more accurate foresight on future development and uptake of technology and its impact on food crop production (refs 52, 53). Indeed a full understanding of these interactions and of how they have affected the current status of GM crops in Europe is essential if we are to deal in a more open and rational way with future biological technologies.

The legacy of the GM crop experience in Europe

7. As a result of difficulties and disagreements over how to regulate GM crops which began in the 1980s, but emerged in a virulent form around 1998, we now have a regulatory system in Europe which is more complex and demanding than that for any other technology anywhere in the world³. And yet there is no evidence of direct environmental damage or health risks from approved GM crops and considerable evidence of their benefits. Nevertheless, for political reasons, many governments in Europe, including the Scottish and Welsh Governments in the UK, refuse to countenance even GM crop trials in their region, usually quoting as a reason the risks to people and the environment.

8. As in other areas of life sciences (ref 38) this time consuming and costly set of regulatory requirements has resulted in the dominance of large multinational companies in setting the innovation strategies for the sector as a whole. Small companies that want to develop novel biological approaches to enhance food crop production are unable to raise the necessary funding on a long enough time frame, from commercial or public sources, and must work with and through multinational companies. Any novel approach that may challenge or compete with multinational company strategies is thus unlikely to be developed in the current regulatory climate (refs 4, 6, 16, 17).

9. As very many people have remarked, we need to learn the lessons from the GM crops experience. However, the lessons quoted are invariably too simplistic, focusing on failure to engage with the public at an early enough stage, untrammelled pursuit of profits by multinational companies and failure of regulators to exercise sufficient control over the technology.

10. Our research has shown a much more complex picture. Over the past 20 years, there have been several 'tipping points' where a different decision could have changed the direction of the debate, radically changing the acceptance of, and innovation opportunities for, GM crops. In many cases the key to an alternative future was in the hands of policy makers, but the implied actions would not fit easily with the traditional policy making role. Also, at one or two key points, independent actions by various bodies operated synergistically, but probably accidentally, to move the GM crops innovation system further away from public acceptance (ref 13).

² We use the term 'governance' to apply to the whole process of promoting basic science, setting the conditions for its development to useful products and processes, influencing market conditions for new technology and regulating the risks to people and the environment (ref 25).

³ Although we have focused our attention here on the European regulatory system, this does not imply that regulations in other parts of the world are beyond criticism.

11. The following points give a brief summary of the most important opportunities and interactions.
- i. Regulatory discussions in the 1980s focused on pesticide regulatory systems as the preferred precedent for GM crop regulation (ref 15). This had the long term effect, largely through setting regulatory barriers to entry for small firms, of ensuring that the innovation strategies of large multinational agro-biotechnology firms dominated the development of the technology (refs 16, 17). If instead regulators had chosen to modify existing regulatory systems for seeds and plant varieties, this would have enabled a continuing role for independent seed companies and food processors in developing the technology, and may have significantly influenced the public towards a more positive attitude to the technology.
 - ii. Research in the late 1980s showed that public attitudes to GM crops were ambivalent, that the public would have responded favourably to information on expected public benefits from the technology, and that reduction in pesticide use was one of the benefits they would have found attractive (refs 33, 49-51). Those working on GM crops in agro-biotechnology companies were aware of this and were also aware that that this would indeed be one of the impacts of GM crops. However they were unable to state publicly that a reduction in pesticide use would be a good thing, given their previous reassurances about the safety of pesticides and also given that they had to raise funding for GM crop developments within their companies in competition with pesticides (refs 46-48). Nevertheless, policy makers or independent farming advisers could have taken a lead in publicising these benefits.
 - iii. GM crop technology was path-breaking for agro-biotechnology companies but would have been path-dependent for seed companies or food processors (ref 2). Thus, the dilemma described for agro-biotechnology companies would not have existed for the latter had they still been involved in GM crop development (refs 16, 17). We may then have seen a wider range of useful GM crop traits than are available today. For agro-biotechnology companies the dilemma reinforced the attractiveness of herbicide resistance as a priority GM trait, leading to products whose environmental benefits (although real in many cases) were difficult to sell to the public (ref 46).
 - iv. This reticence about the potential benefits of GM crops passed the initiative, in negatively framing GM crop technology in the minds of the general public, to a range of pressure groups including many with ideological objections to the technology. The resulting advocacy coalition, bringing together environmental, consumer and third world activist groups, had a powerful impact on the public debate and was supported by most of the UK press who successfully framed the technology as dangerous to people and the environment, offering no benefits to the public, but contributing solely to the profits of greedy multinational companies. This ideological, in-principle opposition to GM crop technology is as unrelenting today as it was ten years ago and will not easily be influenced by scientific evidence or rational argument (refs 12, 13, 26).
 - v. Public engagement around issues of GM crop development began in the 1980s, led by staff in the European Commission and by multinational companies. In the early stages inputs to these discussions were fairly evenly balanced between policy makers, industry and advocacy groups. However, as the debate became more polarised and more heated the balance of influence shifted strongly towards anti-GM advocacy groups (ref 13). The dominance of these groups in framing public attitudes and in driving revisions to the European regulatory system was facilitated by the precautionary principle which enabled them to invoke 'risk' as an issue to attain leverage in policy debates which were at heart ideological and unrelated to evidence of harm to people or the environment. Notably, being precautionary about sustainability of the world food supply was never part of this debate (ref 26). The voice of farmers was largely unheard throughout the consultation process, although it is clear that, where farmers are given the opportunity to grow and sell GM crops, they are usually enthusiastic about the technology, in both developed and developing countries (refs 21, 34-36, 39, 40, 43, 44).

- vi. Our research in the 1990s showed that European multinational companies were much more attuned to the environmental concerns of the European public than American-based companies and were incorporating these concerns within their product development strategies (ref 46). However, given the onerous nature of the current EU regulatory system compared to that of the USA, and delays and disruptions to their introduction, it is unlikely that any GM crops will be tailored to the needs of European farming systems. European companies will either stop developing GM crops or move headquarters to the US where they will eventually begin to conform to US, rather than European, cultural norms (ref 46). Thus the counter-intuitive outcome of European environmentally motivated pressures on multinational companies is likely to be that the global GM crop industry will be dominated by US companies with a less nuanced approach to environmental questions.
- vii. In the late 1990s, genetic use restriction technologies (GURTs) were being developed, largely with the aim of protecting commercial investments and intellectual property rights in GM crops. This technology was presented by the anti-GM advocacy coalition as a violation of the rights of farmers to grow crops from their own saved seed, a view that was supported by several influential scientists, with the result that companies agreed to halt such developments. However, GURTs could have been framed more positively as a means to prevent the environmental dissemination of GM plants by pollen or seeds or cross-pollination of wild plants with GM relatives (ref 26). Policy makers could have required this technique to be incorporated into any GM crop that was capable of environmental spread through pollen or seeds, as part of the regulatory approval system, thus giving public reassurance. Unfortunately, the approach has become so stigmatised, again by the anti-GM advocacy coalition, that scientists, policy makers and industry are unwilling even to discuss this question.
- viii. In developing countries, the legacy of simplistic interpretations of benefits and risks of GM crops has developed into ideological debates through which little real engagement can take place. Debates hinge around the ways in which developing countries and their citizens are unable to make their own decisions about GM technologies, so that decision-making happens for or on behalf of them. In this policy vacuum meaningful, contextualised debates do not develop. Issues such as the risks of alienating European export markets, the different R&D capacities of different developing countries, the appropriateness of different crops or even agricultural systems, and the maturity and strength of different countries' regulatory systems are often by-passed in favour of disconnected, macro-debates about whether GM is 'right' or not (refs 5, 23, 24). This inability to contextualise decision-making and policy has not helped to alleviate uncertainty, or to build knowledge bases or develop the capacity for more nuanced, appropriate decision-making regarding GMOs.

12. The above instances constitute a serious failure of evidence-based governance in Europe (ref), what systems analysts refer to as a 'mess' – a complex system of interacting problems (ref). However, given the tendency of regulators to seek the closest available precedent when faced with the need to regulate a new area of scientific endeavour, it is possible that this will be seen as an appropriate precedent for the governance of future biological approaches to enhanced food production, e.g. from future generations of GM developments or, for example, from synthetic biology. If biological science is to contribute fully to future European farming systems, if it is to attract the necessary commercial, as well as public, investment and if European agriculture is to remain globally competitive, there is an urgent need to begin to reform the overall governance of biological science and crop production.

Paving the way for future generations of biological technologies

13. The shadow of this GM crop experience, in Europe and in many other parts of the world, hangs over future developments in biological science for food production. Scientists, company managers, regulators and policy makers working in frontier areas such as nanotechnology and synthetic biology are already tailoring their research and development so as “... not to attract the attention of the regulators or the public”, in a manner reminiscent of the impact of politically powerful, ideologically motivated advocacy groups on earlier generations of scientists. Advocacy groups

themselves are seeking opportunities to build on their past success, so that future innovative biologically-based approaches to enhance food crop production are also negatively framed in the minds of members of the public (ref 1 and also a recent web-based contribution to this consultation (<http://www.gmfreeze.org/page.asp?id=351&iType=>)).

14. Attempts to ignore this past experience, to side-step the shadow of GM and to progress unhindered to new generations of biological innovation are unlikely to be successful. New biological approaches would benefit from a move to governance systems (including regulatory approaches) that are better attuned to the opportunities presented by 21st Century science, and that are robust and flexible and democratic in the face of current societal pressures while continuing to ensure safety for people and the environment. As noted above, policy makers and regulators (given political backing) will be best positioned to guide the change process.

15. Regulation and governance of new biological approaches should be based on an understanding of the deficiencies of the current European system, the complexity of the interactions that led to this system and the counter-intuitive negative impacts it is having on European agriculture. Based on this more in-depth and complex understanding, there should indeed be a desire to make sure that we do not repeat the mistakes of the past (ref 26).

16. There will, as before, be varying interpretations of the nature of these mistakes and of the desirability of specific outcomes, pointing to the continuing need for public engagement. However, future engagement should take account of the following important aspects of biological technologies:

- i. Where there is a very long lead time, first in the conduct of scientific research and then in its development as a safe and effective new approach, it is impossible to know in advance the outcome of the research or its costs, risks and benefits. Any attempt to apply a precautionary approach will therefore be very speculative indeed.
- ii. Public attitudes are labile and can change rapidly in response to new political, environmental or financial circumstances. It is therefore unwise to make judgements today about future responses to a biological approach which may not be put into practice for 10-15 years.
- iii. Future engagement on biological approaches should take equitable account of the views of all stakeholders including (although this is difficult) those who currently do not know or do not care about these approaches.
- iv. Good standards of scientific validity should be applied to evidence quoted in support of discussion points. Failing this, equitable scepticism should be applied to evidence brought forward by, for example, industry and environmental groups(ref 13).
- v. Good standards of engagement practice should be agreed to by all taking part in an engagement exercise, e.g. willingness to listen to, and be influenced by, the views of others.
- vi. Policy makers could usefully adopt guidelines which make it difficult for a vocal sub-section of society to decide for others what they should eat and how they should conduct their business, in the absence of evidence of risks to health or the environment.

17. A joint strategic approach could usefully be developed to modifying the current European governance system to make it more flexible and robust in the face of global climate change and a changing financial environment, and at the same time to deliver products that are in tune with the needs and values of the European public (but as noted above, without allowing the values of one factional interest to dominate decision making). This would then facilitate the governance of future biological approaches.

18. The initiative for developing this strategic approach should be taken by policy makers, but it should include all key stakeholders. Components of such a strategy that could effect rapid and far-reaching change would be: developing regulatory 'fast tracks' for biological approaches that could provide public benefits compared to existing crop production methods (e.g. insect or disease resistance, nitrogen capture); requirement for GURTs to be incorporated in any GM plant that is capable of environmental spread by pollen or seed. Both could contribute positively to an information

campaign that could rapidly change the general public perception of GM crops and also have knock-on benefits for new biological approaches.

19. This new strategic approach should be supported by research designed to generate independent evidence of the costs and benefits of life science-based approaches to enhance food crop production. As research evaluators, we have personal experience of the unwillingness of research funders in Europe and the UK to support such research, in practice although not overtly.

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ANNEX 1**GRANTS AND PUBLICATIONS RELEVANT TO BIOLOGICAL APPROACHES TO ENHANCE FOOD PRODUCTION****Research and Consultancy**

Research contributing to the programme of the ESRC-funded Innogen Centre (Centre for Social and Economic Research on Innovation in Genomics) (www.genomicsnetwork.ac.uk/innogen)

Tait, J., Wield, D. and Williams, R. (Oct. 2007-Sept. 2012), £5.2 million.

Tait, J., Wield, D. and Williams, R. (Oct. 2002-Sept. 2007), £2,1 million

Lane, A., Oreszczyn, S and Carr, S. (2004-7) *Farmers' Understandings of Genetically Modified Crops within Local Communities*, ESRC Science and Society Programme, £131,000.

Tait, J (April-Dec. 2006) European Techno-Economic Policy Support Network (ETEPS) *Lead, Work Package 2, Consequences, Opportunities and Challenges of Modern Biotechnology for Europe – Primary Production, Agro-food*. 80,000 Euros.

Wield, D. *Precautionary Expertise for GM Crops (PEG)*, EC 5th Framework Programme, Open University.

Chataway (with Ayele and Wield) (2003-2007) *Institutional impacts of north-south partnerships in agricultural biotechnology and Regulatory practices and challenges of the African crop biotechnology sector*, ESRC Science and Society Programme, £100,000

Tait, J. and Wield, D. (Jan. 1998-Dec. 2001) *Policy Influences on Technology for Agriculture (PITA)*, EC 4th Framework Programme, Targeted Socio-Economic Research (TSER), 838,000 Euros; Open University.

Publications**Journal Articles**

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(see <http://www.genomicsnetwork.ac.uk/innogen/publications/policypapers/> for 18-21)

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