

GM foods and application of the precautionary principle in Europe

A contribution from the Society of Biology to the
House of Commons Science and Technology Select Committee

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Summary

- A catalogue of improvements is needed throughout the food chain to address the challenge of food security. Genetic modification can accelerate the development of improved crops through a number of techniques.
- Regulation of GM foods within the EU resides within a framework of risk analysis; including both scientific and independent risk evaluation carried out by European Food Safety Authority (EFSA), and risk management, carried out by the European Commission and member states. Major delays are present at this latter stage, acting as a barrier to innovation.
- The UK and EU are less involved in the economic activities associated with GM crops despite a history of early innovation in this area. If EU legislation continues to be a limiting factor to developing and marketing food from GM crops, the UK is likely to suffer competitive losses.
- Regulation of novel foods is important. The regulatory trigger should not necessarily be the method by which the novel product is generated. GM is a type of production technology, the resulting product and its characteristics should be what is considered.
- The manner in which the precautionary principle has been applied to GM does not consider the potential benefits to agriculture, human health and environment function, nor offer a comparison with the hazards and risks of non GM foods.
- The use of the precautionary principle in this case also does not consider the risk of *not* using GM technology both for food security and the environmental impact of existing agricultural practices, including valuable ecosystem function.
- Inbuilt review mechanisms should take into account new evidence, and secondary benefits and costs of precautionary activity to allow for greater flexibility and appropriate decision making, and should be an integral part of the application of the precautionary principle.

Charles Darwin House, 12 Roger Street, London WC1N 2JU +44 (0)20 7685 2550 info@societyofbiology.org
www.societyofbiology.org

Strategies for Food Security

1. In the face of increasing global population and with the reality of current inequality and need, it is essential that we work towards improved health and wellbeing for all. This presents a very significant challenge that requires the use of the best strategies.
2. We welcome and agree with the Council for Science and Technology (CST) report¹ which stresses that a catalogue of improvements is needed throughout the food chain. Science has a key role to play in bringing about beneficial changes to agricultural practices and land management, as well as in the production of new crop varieties. The UK has a world-leading position in the field of livestock improvement, and both the CST report and the recent UK Plant Sciences Federation report² pointed out that although the UK has great strengths in plant science, there is an urgent need to improve resources available to this science in order to address current and future demands for food. A well-regulated system of public funding such as that of the UK, alongside scrutiny and engagement necessary for public support can bring great advantages for science and society.
3. GM technologies include new strategies that can accelerate the development of improved crops; however, the necessary safety testing and field trials also require time, and it would not be wise to delay beginning to address whether and how we can best benefit from GM solutions. Thus controlled research and testing of promising crops should be undertaken as a priority.
4. In the last decade, the science of genetic modification has made real progress towards arming the fight against diseases and environmental stresses that can devastate agricultural yields, and in potentially providing benefits to the consumer and environment by introducing novel desirable characteristics. Despite the commercial cultivation of only one GM crop in the EU, GM derived foods have been widely consumed since the mid 1990's, and the EU also imports more than 70% of animal protein feed requirements as GM crop products³. Worldwide, over 175 million hectares are dedicated to GM crop cultivation, accounting for 12 percent of arable land⁴, and no inherent risks have so far been identified to human or animal health from this consumption or to the environment from their cultivation¹.
5. There are reasons other than safety which affect public attitudes to GM foods, including consumer choice, who controls the global seed market and food chain and effects on small farmers. Such concerns are outside the scope of the precautionary principle, but affect the uptake of the technology and should be understood, considered and acknowledged during dialogue about the acceptability of GM products and the development of policy.
6. There are some European countries that have a firm anti-GM position (e.g. France⁵, Austria), however British public opinion on GM is more complex, for example a 2012 survey commissioned by *The Independent* newspaper showed that 64% of those surveyed agreed that experiments to develop GM crops should be encouraged by government so that farmers can reduce the amount of pesticides they use⁶. Scientists and companies developing GM foods are responding to the increasing demand for public knowledge as the debate moves on and therefore the potential benefits and risks of GM foods are becoming better understood, and are better communicated⁷.

¹ [GM Science Update](#). A report to the Council for Science and Technology, March 2014.

² [UK Plant Science: Current status and future challenges](#). A report by the UK Plant Science Federation, January 2014.

³ [Planting the future: opportunities and challenges for using crop genetic improvement technologies for sustainable agriculture](#), European Academies Science Advisory Council, June 2013.

⁴ 2013 figures. James, Clive. Global Status of Commercialized Biotech/GM Crops: 2013. *ISAAA Brief* No. 46. ISAAA: Ithaca, NY.

⁵ [French parliament bans cultivation of GM maize](#), April 2014.

⁶ [ComRes Opinion Poll](#), June 2012.

⁷ [Growing Voices.EU](#) established in January 2014 as an experience sharing platform for stakeholders.

Are current EU and UK regulations intended to assess the safety of genetically modified (GM) foods fit for purpose? If not, why not?

7. Regulation of GM foods within the EU is stringent and resides within a framework of risk analysis; including both scientific and independent risk evaluation carried out by European Food Safety Authority (EFSA), and risk management, carried out by the European Commission and member states. It is the latter decision-making process that causes a high degree of commercial uncertainty about the likelihood of bringing GM varieties to market. Major delays are present at the EC once the risk assessment has been completed. The unpredictable nature of the approval process is cited as a barrier to innovation.
8. This has had repercussions. Since early 2013 two major agricultural biotechnology companies, BASF and Monsanto, have withdrawn their requests for permission to cultivate new GM crops in Europe. Both companies cited the impact of regulation and the lack of commercial prospects for GM varieties in the EU as reasons. BASF has also moved its plant science R&D headquarters from Germany to the US where it said it would focus on developing varieties for "attractive markets" in the Americas and Asia.
9. We agree with the Council for Science and Technology recommendation that it should be possible for regulation of the commercial cultivation of GM foods to act at a national, rather than EU, level, similar to the regulation of GM field trials. In this scenario, EFSA would still have an advisory role on risk and safety, but the regulation of EFSA-approved GM foods would be considered at a national level. This could take into consideration the geographical range of crops, soil types, climate and weather conditions, and government positions, which vary across the EU.
10. Field trials are regulated at the national level. In the UK there has been a reduction in the number of field trials from 37 in 1995, to only one in 2012¹, although the reasons for this are unclear. However, a contributing factor is very likely the additional expense of security costs for field trials. An additional £180,000 was provided by the BBSRC for security measures during the Rothamsted GM wheat field trial in 2013⁸.
11. We agree with the European Academies Science Advisory Council (EASAC) call for reform of GM regulation to include risk-benefit analysis, and to switch from technology to product properties regulation; the latter approach has been adopted by the Canadian government where the trigger for regulation is novelty³.
12. The regulatory framework for GM foods does not include consideration of potential benefits or a comparison with the hazards and risks of non GM foods (as a trade-off). GM foods can offer a range of benefits including decreased environmental degradation; better use of land, water and fertilizer; reduced pollution and greenhouse gas emissions; reduced need for pesticides and diesel for farm machinery; and the nutritional enhancement of foods⁹. These benefits should not be ignored given the significant need to improve food security and prepare for the potential impacts of climate change, especially in developing nations.
13. The regulation of GM foods is both a public and a scientific issue, and scientists and policy makers have a duty to inform and engage with the public on risks, benefits and ultimately on judgements of

⁸ <http://www.rothamsted.ac.uk/our-science/rothamsted-gm-wheat-trial>

⁹ See "Key environmental impacts of global genetically modified (GM) crop use 1996-2011." *GM crops & food* 4, no. 2 (2013) and Carpenter, Janet E. "Impact of GM crops on biodiversity." *GM crops* 2.1 (2011): 7-23.

acceptability. Following the European Commission's evaluation of the GMO legislation between 2009 and 2011, they highlighted the need for upgraded communication activities on GM technologies¹⁰.

How have EU and UK regulations on GM foods affected the UK's international competitiveness?

14. The UK has pioneered a number of crop transformation technologies over the past 30 years, the impact of which can be seen on a global scale¹¹. However there have not been opportunities for commercial gain from these technologies.
15. The UK and EU are much less involved in the economic activities associated with GM crops despite a history of early innovation in this area. If EU legislation continues to be a limiting factor to developing and marketing food from GM crops, the UK is likely to lose some competitiveness in this area.
16. A domestic and EU market for GM food is by no means assured, although other global markets and the animal feed market have developed in the US and other nations including Brazil, Canada and Australia.
17. The development of GM agricultural animals with beneficial traits is also ongoing both within and beyond the EU¹².

Does the current EU and UK regulatory framework allow for GM foods to effectively contribute to the delivery of the UK Agricultural Technologies Strategy? If not, why not?

18. The UK Agricultural Technologies Strategy¹³ states:

“The EU regulatory pipeline for genetically modified (GM) crops remains blocked. This is despite European Commission reports finding no scientific evidence associating GM organisms with higher risks for the environment or food and feed safety. The EU approach is in contrast to other countries: GM crops are now grown by 17 million farmers on over 12% of the world's arable land. There is a continuing challenge to ensure the balance is right between innovation and regulation.”

19. No applications for the commercial farming of GM livestock have been received in the EU so far; however EFSA have developed risk assessment guidelines to evaluate the possible risks for food and feed safety, the environment, as well as related animal health and welfare aspects in preparedness for future applications of GM animals or derived products¹⁴.
20. This regulatory process is important given the advances in GM animal research in the UK. Research using genetic engineering of chickens at The Roslin Institute has been successful at breeding GM

¹⁰ [Evaluation of the EU legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and Reg'n \(EC\) No 1829/2003, and the placing on the market of GMOs as or in products under Directive 2001/18/EC](#) Final Report, March 2011.

¹¹ UK research in the 1980s help to found the basic principles and technologies behind transgenic crops, now estimated to be worth a global value of US\$14.84bn. [UK Plant Science: Current status and future challenges](#). A report by the UK Plant Science Federation January 2014, p27.

¹² EnviropigTM was developed at the University of Guelph, Canada; see *J Anim Sci*. 2003 81:E68-E77.

¹³ [A UK Strategy for Agricultural Technologies](#) (July 2013)

¹⁴ [Guidance on the environmental risk assessment of genetically modified animals](#). EFSA Journal 2013;11(5):3200

chickens that do not transmit avian influenza virus to other chickens. Further research into breeding birds that are fully resistant to avian influenza infection is ongoing¹⁵.

What are the particular barriers to the conduct of research on GM foods in the UK?

21. Research on GM crops includes basic plant science research, the results of which could be applied through GM means. This research is still very strong in the UK, but will require sustained and stable funding to continue.
22. The development and evaluation of GM crops must have some chance of commercial viability for feasible public- private partnerships. This is not likely in the current regulatory environment.
23. The regulatory and security costs are a huge burden to SMEs, leaving only a small number of large corporate companies able to proceed using this technology. Without due communication this could reinforce a perception that there is an inherent link between GM and commercial exploitation which is misleading.
24. The development of GM approaches in livestock, to disease resistance and even more so to production traits, has been held back significantly. The Roslin Institute has received funding in this area but many more novel ideas could have been developed and tested if more researchers believed that their research had the potential to be taken to application.
25. The perception that GM technologies will never be applied has a negative impact on the evaluation of research proposals.

Is the EU's application of the precautionary principle in relation to GM foods appropriate? Does the EU recognise and handle properly the concepts of hazard and risk?

26. Action to prevent harm to people and the environment is a vital undertaking, and proper vigilance to guard against either recklessness or ignorance is a high priority. Assessment of risk, especially in the face of uncertainty is a serious undertaking and due care is essential. The difficulties of judgment are increased when the potential for risks and benefits accrue to different groups or areas of the environment. It is also important to ensure fair access to all in terms of representation. Precaution is therefore an appropriate basis from which to assess novel technologies and their products. Additionally there should be an onus of care resting on the creator of a GM product to ensure that there is not avoidable harm to a potentially valuable ecosystem function or piece of biodiversity.
27. In the EU the precautionary principle is applied across a broad spectrum and therefore although its consideration in relation to GM technology receives attention and comment, and is a legitimate interest, it is by no means a typical case for the Committee to consider.
28. Hazard, or the potential for harm, is used as the key arbiter in the precautionary principle in its application to GM foods in the EU. This simplification has some administrative advantages but can hinder the taking of a fully proportionate view. The consideration of risk is a more appropriate approach; the likelihood that the hazard will occur, and the impact which it may have under real-world circumstances, including range, extent and area (or group) impacted, would be beneficial.

¹⁵ [GM Chickens That Don't Transmit Bird Flu](#), Roslin, University of Edinburgh.

29. Professor Anne Glover, Chief Scientific Advisor to the European Commission recently stated in an interview pertaining to the implementations of regulations around GM foods that “the precautionary principle is no longer relevant with GMO foods or crops.”¹⁶ Her answer was based on the substantial bank of evidence from more than 15 years of growing and consuming GM foods globally, which shows no substantiated case for any adverse impact on human or environmental health from those currently in cultivation and consumption.
30. This is in line with the view from the Council for Science and Technology (CST) that states; “We should have confidence in the consensus on the scientific evidence which concludes that, when properly controlled, GM products are as safe as their conventional counterparts”¹⁷.
31. The analysis should also consider potential benefits, either directly mitigating or closely associated. Article 191 of the Treaty on the Functioning of the European Union (2008)¹⁸ refers to the Union policy on the environmental protection, which, it states ‘shall be based on the precautionary principle’, and later states:
- ‘In preparing its policy on the environment, the Union shall take account of:
- available scientific and technical data,
 - environmental conditions in the various regions of the Union ,
 - the **potential benefits and costs of action or lack of action** [emphasis added],
 - the economic and social development of the Union as a whole and the balanced development of its regions’
- Without this consideration, and therefore inappropriately, a narrow interpretation of the precautionary principle could, in the case of an unlikely hazard, prevent progress towards a likely benefit.
32. The manner in which the precautionary principle has been applied to GM does not consider the potential benefits to agriculture, human health and environment function, (discussed in paragraph 13) nor offer a comparison with the hazards and risks of non GM foods.
33. Finally, the use of the precautionary principle in this case also does not consider the risk of *not* using GM technology both for food security and the environmental impact of existing agricultural practices, including valuable ecosystem function.

Are there other examples of EU regulation in which the precautionary principle has not been applied appropriately?

34. There are a number of definitions of the precautionary principle in use, with different formulations and variability in interpretation¹⁹. Furthermore the precautionary *approach* as defined at the Rio 1992 Earth Summit is a different regulatory framework, allowing for greater flexibility in terms of national capabilities and cost-effective measures²⁰, and which the US commonly uses because of the legal

¹⁶ [EU science advisor: 'Lots of policies are not based on evidence'](#), July 2012.

¹⁷ [Letter to the Prime Minister regarding GM Technologies, from the Council for Science and Technology](#), November 2013.

¹⁸ [Treaty on the Functioning of the European Union \(TFEU\)](#) as amended by the Treaty of Lisbon. Foundation for EU Democracy (2008).

¹⁹ Foster, Kenneth R., Paolo Vecchia, and Michael H. Repacholi. "Science and the precautionary principle." *Science* 288.5468 (2000): 979-981.

²⁰ “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.’ (Principle 15), [Rio Declaration on Environment and Development](#), 1992.

connotations of the term 'principle' in US law.

35. The precautionary principle is narrower than 'being cautious'²¹, and clarity on the terms of the precautionary principle are also complex at the policy level. For example, the EU adopted the REACH system of regulation²² in 2006; a largely successful chemicals policy based on the precautionary principle. However some have commented that the regulation lacks key elements of this framework, rather the issues REACH address are more in line with prevention rather than precaution²³. It can therefore be difficult to identify where the precautionary principle has been invoked and the terms and conditions that apply to it.
36. The precautionary principle is not always applied consistently or so that it's proper use can prevent harm. It is the governance of risk and innovation, and therefore the application of the principles rather than the precautionary principle itself where the focus of attention should lie for those seeking to improve regulation.
37. Inbuilt review mechanisms should take into account new evidence, and secondary benefits and costs of precautionary activity to allow for greater flexibility and appropriate decision making, and should be an integral part of the application of the precautionary principle. This along with greater clarity on the terms of the precautionary principle framework, and transparency of risk research, could help to ensure that precaution is applied appropriately.

The Society of Biology is pleased for this report to be publicly available. For any queries, please contact The Society of Biology Policy Team at Society of Biology, Charles Darwin House, 12 Roger Street, London, WC1N 2JU. Email: policy@societyofbiology.org

²¹[The Precautionary Principle: Policy and Application](#). United Kingdom Interdepartmental Liaison Group on Risk Assessment (UK-ILGRA)

²² REACH: Registration, Evaluation, Authorisation and Restrictions of Chemicals [European Parliament and Council Regulation \(EC\) No 1907/2006](#)

²³ Hansen, Steffen Foss, Lars Carlsen, and Joel A. Tickner. "Chemicals regulation and precaution: does REACH really incorporate the precautionary principle." *Environmental science & policy* 10.5 (2007): 395-404.

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