THE ROYAL SOCIETY

Submission to the House of Commons Science and Technology Committee's inquiry on *GM foods and application of the precautionary principle in Europe*

Summary

- The safety of GM techniques should be considered as part of a broader evidence-based assessment of what constitutes a sustainable and resilient agricultural system.
- A more effective regulatory system would result from a shift in emphasis from the method by which a crop is produced toward a focus on the trait that has been introduced.
- The development of regulations should include an assessment of potential *benefits* alongside potential risks and take into account the uncertainties associated with both.
- In its conventional application, the precautionary principle assesses the risks associated with taking a certain course of action' but fails to assess the risk of *not* doing something.
- The implementation of the precautionary principle should include the reassessment of the need for any restrictions when new evidence becomes available after a reasonable period of time.
- Safety assessments would be improved if they focused on testing clearly defined hypotheses of how a trait of a novel crop or its use could represent an environmental or health hazard.

Introduction

1. The Royal Society welcomes the opportunity to respond to the House of Commons Science and Technology Committee's inquiry on *'GM foods and application of the precautionary principle in Europe'.*

2. The Society is the national Academy of science in the UK. It is a self-governing Fellowship of many of the world's most distinguished scientists. The Society draws on the expertise of the Fellowship to provide independent and authoritative scientific advice to UK, European and international decision makers. This response is based on advice from some of the Society's Fellows and other experts in the field.

Context

3. In its 2009 report *Reaping the Benefits*[1] the Royal Society highlighted the pressing need for a 'sustainable intensification' of global agriculture, in which yields are increased without adverse environmental impact and without the cultivation of more land[2].

4. The report concluded that the sustainable intensification of agriculture requires technologies and approaches that are underpinned by good science including, but not limited to, GM techniques. These diverse approaches need to be implemented with due consideration for their contextual social, economic

[1] Royal Society (2009), *Reaping the Benefits.*
[2] See also Royal Society (2012), *People and the Planet.* The report draws attention to the finite availability of natural resources and environmental services essential for the provisioning of all economies, and notes the need to develop and use all kinds of available technologies to improve both productivity and sustainability.

and political dimensions. The science of crop management and agricultural practice were identified as vital in meeting the challenge of food security.

5. The report recommended that governance of agricultural innovation should maximise the opportunities for increased production while protecting against unintended negative side effects. Assessments of benefits, risks and uncertainties should be broad and should include the wider impacts of new technologies and practices on economies and societies, as well as the risks and benefits of not taking any action. Public and stakeholder dialogue should be a part of all such governance frameworks.

6. The Society considers that the emphasis of the debate should not be limited to the safety of one specific technology, but rather extend to the evidence-based assessment of what constitutes a sustainable and resilient agricultural system. Agricultural innovations, however produced, should be assessed on a case-by-case basis rather than judged according to the method by which they were produced.

7. The Society also considers that transparency is needed whenever scientifically based policy decisions are made. Such decisions need to take into account moral and political values alongside scientific evidence, the rationale behind each decision should be clear, and scientific evidence should be clearly distinguished from political considerations.

8. Many of the scientific challenges we face today have an international dimension, and the Society works closely with the other European Academies to address them. In 2013, the European Academies Science Advisory Council (EASAC), of which the Society is member, published the report *Planting the future: opportunities and challenges for using genetic improvement technologies for sustainable agriculture*[3] looking at the regulation and use of GM technologies in Europe in comparison with others internationally. Our responses to the Committee's questions cite evidence presented in that report.

9. The Society's response covers regulations concerning the cultivation of GM plants for human consumption, and regulations concerning products derived from GM organisms in the food chain. However, GM crops are also important for other processes such as the production of feed for animals and as feedstock for bioprocessing, for example as biofuels, and our comments are also relevant to these broader applications.

Responses to the Committee's questions

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

10. The current framework regulates the use of organisms in agriculture depending on how they have been developed (eg using recombinant DNA technology) rather than by their novelty (eg novel phenotypic traits). However, the introduction of new traits into crops can be achieved through several approaches, including, but not limited to, conventional selective breeding and genetic modification. Some of these approaches are more heavily regulated than others, although no evidence exists that GM methods, as defined in current legislation, are intrinsically more dangerous than other less regulated approaches[4].

11. This process-based approach to regulation results in inconsistencies because the same phenotypic trait, for example resistance to a particular herbicide, may fall in or out of the scope of the

[3] EASAC (2013), *Planting the Future*
[4] EASAC (2013), *Planting the Future,* par. 4.1 (p.25)

regulations (ie it may be judged to represent a different risk) simply because of the way it was introduced. Moreover, technological progress quickly outpaces regulations and process-based regulations fail to capture these new emerging technologies, resulting in a distinction between regulated and unregulated technologies that is difficult to justify from a risk assessment perspective.

12. The Society considers that a more effective regulatory system would result from a shift in emphasis from the method by which a crop is produced toward a focus on the trait that has been introduced,[5] similar, for example, to that in operation in Canada[6]. This system would be more resilient to the introduction of new technologies and more likely to deliver environmental protection and food safety. It would apply to all crops with a novel trait and should be less onerous than the one currently in place for GM crops.

13. Furthermore, current regulations focus exclusively on the hazards and risks associated with certain technologies. However, they do not take into account the potential benefits of implementing such technologies, and the hazards and risks of *not* doing so. Adequate regulations should include an assessment of potential *benefits* alongside potential risks and take into account the uncertainties associated with both.[7]

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

14. The effect of existing regulations on the competitiveness of the UK can be observed at three levels:

15. **Economic competitiveness**

The increasingly restrictive regulations have driven companies and investments away from the UK and Europe in favour of other countries, mostly notably in north America[8]. The 2013 report from EASAC offers a detailed analysis of the declining European competitiveness in GM[9], highlighting the added costs and burdens of conducting research on the application of GM technologies in Europe.

16. **Agricultural competitiveness**

A competitive agricultural system needs to be adaptable and sustainable, and GM is one of a set of techniques that can be employed to address these issues. In the short term GM techniques could provide new developments, which may be similar to the advances that can be gained with traditional plant breeding techniques, although often achievable more quickly and precisely. Traits that are being introduced include for example: disease resistance, drought tolerance and resistance to biotic stress. In the medium to long term there are opportunities to introduce radical and highly significant improvements to crops, including for example increasing photosynthetic efficiency and remodelling some crops to make them perennial, allowing for year-round cultivation[10]. A recent example of a new crop variety that, if approved, could improve the competiveness and resilience of UK agriculture is the development through genetic modifications of a blight resistant variety of potato by the Sainsbury Laboratory in Norwich[11].

[5] See recommendation 2 of EASAC (2013), *Planting the Future*, p. 37
[6] EASAC (2013), *Planting the Future,* par. 2.3.5 (pp. 16-18)
[7] Royal Society (2009), *Reaping the Benefits* , p. 51
[8] Council for Science and Technology (2014), *GM Science Update*, p. 34
[9] EASAC (2013), *Planting the Future,* p. 26 Box 5: *Is innovation in the EU falling behind?*
[10] For more details see Royal Society (2009), *Reaping the Benefits*, Chapter 3
[11] See Jones et al. (2014), *Elevating crop disease resistance with cloned genes*,

17. **Scientific competiveness**

The existing barriers to translational research (see Question 4 below) mean that the UK is not developing adequate capacity in the field, and is losing the fruits of its basic research to countries such as Canada, USA and emerging economies such as China and Brazil[12]. This could also lead to problems in the talent pipeline for the bioeconomy in general[13]. The Society considers that, for the UK to become a world leader in agricultural technology, the country needs a robust research and training base in all disciplines relevant to a sustainable intensification of food crop production, such as agronomy, plant physiology, pathology and general botany, soil science, environmental microbiology, weed science and entomology[14].

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

18. The UK has a strong science base in the different fields that contribute to the development of GM applications in food production. However, barriers exist to prevent this research being effectively translated into useful agricultural solutions.

19. The two main factors hindering translational research are the practical difficulties of running field trials, and the high costs of getting regulatory approval for a new GM crop in Europe. Running field trials in the UK involves high security costs as they are frequently vandalised by protesters. Furthermore, the length and cost of the development and approval process means that in practice smaller players, such as university spin offs and other SMEs, are prevented from entering the market. This limits support to large multinational firms that are increasingly moving their research efforts to other countries. This results in a lack of commercial partners willing to invest resources and know-how into the development of GM products.

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?

The application of the precautionary principle

20. The EU adopted legislation to control the use of GM organisms in 1990, when the development of crops using recombinant DNA technology was in its infancy. The precautionary principle was applied at the time due to an absence of evidence of whether GMOs posed different or greater risks to human health and/or the environment than organisms developed using existing methods.

21. Our understanding of genomes and experience of using GM crops has expanded considerably since 1990, and the consensus of scientific bodies is that the scientific evidence no longer justifies the precaution of controlling organisms *specifically* because they were generated using recombinant DNA technology[15]. Where risks have been identified, for example in the case of herbicide tolerance, they relate to the trait that has been introduced rather than the method by which it was introduced. It is important that any risk/benefit analysis is commensurate with the impact of identified potential risks, and this should not be restricted to one type of genetic improvement technique.

22. In its conventional application, the precautionary principle assesses the risks associated with taking a certain course of action but fails to assess the risk of *not* doing something. The system is

[12] See UK Plant Science Federation (2014), *UK Plant Science: Current status & Future Challenges*
[13] For more details see paragraph 4.3 of EASAC (2013), *Planting the Future*, p. 28
[14] See recommendation 5, Royal Society (2009), *Reaping the Benefits*, p. 50
[15] Council for Science and Technology (2014), *GM Science Update*,

currently biased towards maintaining the status quo, while a properly balanced assessment should consider all the possible scenarios and the full costs and benefits for each[16].

23. The implementation of the precautionary principle should include the reassessment of the need for any restrictions when new evidence becomes available after a reasonable period of time. This would help ensure that any restrictions that are no longer scientifically justifiable are removed, so that the evaluation of valuable technologies is not unduly delayed.

The concepts of hazard and risk

24. The precautionary principle relates to the possibility that actions can lead to hazards, i.e. possible sources of harm. An assessment of risk considers not only possible hazards, but the likelihood that they will occur. A plane at 30,000 feet altitude constitutes a hazard, as there is huge potential for harm, but people fly because regulation has rendered the risks to be acceptably low. It is important to focus on risk of harm rather than discussing the application of the precautionary principle in the abstract.

25. While it is possible to test rigorously a specific hypothesis about whether a crop with a particular new trait causes a particular harm, no process of risk assessment can possibly examine every possible unintended effect, with no plausible hypothesis linking a characteristic of the new technology to harm. However, although it is impossible to prove absolute safety, experience can make us increasingly confident that any potential harms, even if currently unknown, are likely to be very small.

26. A high quality safety assessment system should involve consideration of the likelihood of identified harms (risks of action), the likelihood of identified harms from the status quo (risks of inaction), and the likelihood of benefits. It is reasonable to include some element of precaution, given the possibility of unknown or unexpected risks, but this aspect should be subject to updating as more information becomes available.

27. The current European regulatory framework for GM does not define environmental harm, and thus prevents the appropriate identification and management of risks. Safety assessments would be improved if they focused on testing clearly defined hypotheses of how a trait of a novel crop or its use could represent an environmental or health hazard. This requires a more coherent understanding of what constitutes unacceptable harm from the outset and a plausible pathway linking the novel trait to a harmful effect. Without this foundation, it is inevitable that assessments will become data-gathering exercises rather than focusing on answering risk-based questions that are necessary to inform decision-making.

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[16] *'An adequate interpretation of the precautionary approach would require comparison of the risks of the status quo with those posed by other possible paths of action'* Nuffield Council on Bioethics (2003), *The use of genetically modified crops in developing countries.*