GOVERNMENT RESPONSE TO THE REPORT ON GENETICALLY MODIFIED INSECTS BY THE HOUSE OF LORDS SCIENCE AND TECHNOLOGY SELECT COMMITTEE

Introduction

1. The Government is grateful to the Committee for conducting an inquiry into GM insect technologies. It has been a valuable process, bringing a focused consideration to bear on an emerging and potentially significant new area of science and technology, and providing a vital challenge to Government in terms of the appropriate policies that it should pursue.

Response to the specific conclusions and recommendations relevant to the Government:

We conclude that the excellence of the science base, investment in infrastructure and the skills pipeline must at least be preserved, and preferably enhanced, in order to maintain the UK's position as a world-leader in GM insect technology development. In this regard, we welcome the Chancellor's announcement in the recent Spending Review that the resource budget for science will be protected in real terms for this Parliament.

2. The Government recognises the importance of our thriving and world-class research base, and the continuing investment in this will help us achieve our ambition to make the UK the best place in the world to do science and research.

On account of the potential that GM insects offer, both economically and in terms of public health, we conclude that there is a strong case for Innovate UK to invest further in this area to promote commercialisation of UK-based GM insect research. We therefore recommend that Innovate UK, in partnership with the Research Councils, considers providing targeted funding in order to develop the commercial deployment of GM insect technologies.

3. As cited in their Written Evidence, the Research Councils and Innovate UK have a good track record of investment in GM insect research through individual grants. These have been awarded on the basis of scientific excellence, with independent peer view and expert assessment determining which projects should be funded. Strategic importance is also a relevant consideration, and in this respect any potential targeted initiative in relation to GM insects would need to be considered alongside other competing strategic priorities[1].

4. The Research Councils invest in research to achieve wider strategic aims, rather than to support a specific technology as an end in itself, and in the case of GM insects such aims could include alternative control mechanisms for disease vectors or agricultural pests. At present it is judged that funding for R&D involving GM insects should be responsive rather than targeted, with this approach to date putting the UK in a good position to develop and move forward in this emerging area. If it becomes apparent that there is a compelling case for greater strategic investment in GM insect technologies, the Research Councils will look into more directed investment approaches, including in partnership with Innovate UK.

[1] For example, BBSRC's strategic research priorities cover a range of scientific and societal challenges, as set out in its Strategic Plan (http://www.bbsrc.ac.uk/documents/strategic-plan-pdf/).

We are concerned that the application of GM insect technologies in the countries whose need is greatest may be affected by a lack of international guidance and leadership on the governance and regulation of these technologies. We recommend that the Government, in light of its strong commitment to international development, works through international organisations to help to address challenges of international guidance and leadership.

5. The Government agrees that it is important to provide international leadership and guidance on the governance and regulation of GM insect technologies. The Cartagena Protocol on Biosafety provides an international framework for addressing issues relating to the handling, use and transboundary movement of GMOs, including GM insects. The Protocol encourages countries to establish regulatory systems and the other capabilities needed to manage the handling and release of GMOs, and in support of that pursues capacity-building measures specifically for the benefit of developing countries, most of whom are parties to the Protocol. To facilitate prior informed decisions, the Protocol also requires countries to be notified of proposed exports to them of GMOs intended for release into the environment. The Government will continue to play an active role in the Cartagena Protocol forum to help developing countries put in place appropriate national governance frameworks.

We accept that there is some practical merit in the Government's decision to work to ensure that the existing regulatory regime for GMOs at least functions as written. We ask the Government to set out clearly how it intends to do so and to publish annual updates on progress made in improving the operation of the system, starting in the summer of 2016. However, we do not accept that this is sufficient and we advocate a more radical review of the regulatory framework later in this Chapter.

6. The Government has played a leading role in arguing for the GMO regime at EU level to function effectively, so that it offers applicants a predictable route to market for safe products, without the unjustified delays that have been experienced in relation to decisions on GM crops. This objective has been pursued by taking appropriate opportunities to raise the matter with the Commission, at both Ministerial and official level, and in EU meetings. We have also sought to influence other Member States through bilateral and other contacts.

7. We will continue to engage with the Commission and other Member States on GM issues. We understand that the Commission's current GM-related priorities are issuing a paper on the regulatory status of organisms produced using new genetic breeding techniques (e.g. gene-editing), and the fate of the legislative proposal which it published last year to allow more national subsidiarity in relation to EU decisions on the import and use of GM food and feed products. The Commission is also committed to updating the annexes to the GMO Directive 2001/18 which detail the requirements for the environmental risk assessment process.

8. The Commission should now also be taking steps to enable EU decisions to be reached without further delay on the outstanding applications to approve the commercial

cultivation of several GM crops, which goes directly to the issue of following the agreed EU rules. The Government has called for action on this on a number of occasions.

9. The Government does not believe that this is an appropriate area for annual progress reports. It considers that the most appropriate and helpful course would be to provide the Committee with updates on the EU situation as and when there are significant developments to report.

We urge the Government to monitor the development of new genetic technologies, including GM insects, in order to ensure that the regulatory regime is fit-for-purpose. We recognise that a move to a trait-based system may not currently be appropriate. We see the risk that a move to a trait-based system may be counter-productive in the short term. We acknowledge, however, that trait-based regulation may be a valid long-term aim in order to develop a more scientifically robust, overarching regime once current regulatory barriers within 2001/18/EC have been addressed.

10. The Government accepts that it should continue to keep developments in new genetic technologies and the fitness of the EU regime under review, and to keep open the possibility of seeking changes in the regulatory environment when this is judged to be desirable and achievable.

The ecological impact of GMOs designed to persist in the environment presents a new regulatory challenge. In light of the advances in gene-drive research, we conclude that underpinning research is required in order to allow effective monitoring and tracking of this new generation of genetic modifications. The regulatory framework should take persistence into account and stipulate appropriate monitoring requirements.

11. EU Directive 2001/18 includes a standard risk assessment framework to determine whether the release of a GMO would pose a greater risk to human health or the environment than its unmodified counterpart. It is a framework that can be used to assess different organisms with a range of traits, although expertise will need to be developed in applying the framework to GM insects, particularly those containing gene-drive mechanisms. The Directive already specifies that the ability of a GMO to persist in the environment is a factor to be considered as part of the risk assessment process. This issue is also addressed in the guidance that EFSA published in 2013 on the risk assessment of GM animals, which includes a specific section on evaluating the persistence and invasiveness of GM insects.

12. The Directive also requires monitoring plans to be established for GMOs authorised for commercial release, and for monitoring to be considered on a case-by-case basis in relation to GMO trials. EFSA has published detailed guidance on the post-market monitoring of GM plants and it is expected that equivalent guidance will be developed for GM insects, with a specific focus on those having gene-drives. The UK will contribute to the development of EU guidance, with Defra taking independent scientific advice on this matter from the Advisory Committee on Releases to the Environment (ACRE).

13. With gene-drive technology still at a relatively early stage of development, it is likely to be some years before any proposal may be forthcoming for a field release of a gene-drive insect. In the meantime, scientific advisors and regulators in Defra will keep abreast of developments to ensure that risk assessment and regulatory processes are fit-for-purpose.

We consider the argument for including the benefits of a technology within the regulatory process to be entirely valid. Furthermore, we do not agree with the stance of the Government and the European Commission that there would be little to gain in modifying the current framework to include consideration of benefits. We recommend that consideration of benefits and dis-benefits be incorporated into the regulatory regime once the scientific risk assessment has taken place, during the risk management stage.

14. The Government recognises the force of the Committee's argument, as it would seem to be logical and helpful to consider non-safety impacts in addition to the risk assessment process. However by making the EU regime more complex, burdensome and subjective, it could in fact make it function less rather than more effectively. The Government believes that regulatory decisions on GMOs should be science-based, and we will continue to focus on trying to improve the operation of the EU regime as it stands.

15. As a general point, it should be recognised that it is not the terms of the EU legislation which have made it a barrier to innovation. Rather, it is the way that the operation of the regime has become overtly politicised due to negative attitudes towards GM technology, and the resulting failure to follow the principle (enshrined in the legislation) of science-based decision-making. Therefore, the reality is that changing the terms of the legislation will not of itself necessarily result in a better regime, if a significant number of Member States maintain a negative outlook on the release of GMOs.

Furthermore it is inappropriate that new GMO technologies are considered in relation to an unrealistic, risk-free alternative. We recommend that the regulatory process should acknowledge control methods currently in use, such as insecticides, which a new technology may replace.

16. The Government also acknowledges the Committee's argument on this point. However, extending the GMO regime so that they are assessed in relation to existing control methods like pesticides would not be straightforward, and there is a danger that seeking to change the EU regime could have undesirable consequences, with no assurance that the end result would be better than the status quo. As confirmed at paragraph 10, the Government will keep the EU regime under review and consider if and when it may be appropriate to seek positive changes.

The fact that the current EU regulatory regime remains untested for GM insect technologies is a major barrier to progress. Only when a field trial application has been approved will we be able to move forward. We therefore conclude that action must be taken to instigate a field trial which should also be used to drive public engagement.

We therefore recommend that the Government actively pursues and invests in a GM insect field trial to test fully the science of GM insects, regulatory processes and policies. This

trial could be considered as a GM insect counterpart to the Farm Scale Evaluations of new GM crop technologies undertaken from 1999 to 2006. Such a trial should be dual-approach in nature and investigate both an agricultural pest and a species of mosquito.

In order to undertake this trial, Government departments, including DEFRA, BIS and DFID, should work together to develop a proposal to be put out for tender to the UK science community. Funding should be drawn from these Government departments as well as Innovate UK.

Alternative regulatory approaches should be considered in the light of this trial, including those highlighted in this report, such as: consideration of benefits, evaluation against real-world alternatives and trait-based regulatory triggers.

17. The Government's policy is to support the development and use of beneficial new technologies, and to create the best conditions possible for investment, R&D and economic growth in the UK. We therefore share the Committee's concern that difficulties with the EU regime could hinder progress being made with GM insect technology.

18. The EU situation is clearly less than ideal, and the Government is firmly committed to seeking a better way forward. At the same time, however, experience shows that there is no easy or obvious solution, given the lack of a political consensus on the appropriate treatment of GM technology, especially in relation to its use in agriculture. The issue is what can usefully and realistically be done in this challenging context to improve the prospects for GM insect technology, with a more effective regulatory framework for the release of GMOs.

19. The Committee's idea of commissioning a GM insect trial is an interesting one. The Government has given this careful consideration and believes the following points need to be taken into account:

- the key difficulty with the regulatory regime is the unpredictability and burden of securing EU approval for the commercial release of a GMO. Decisions on research trials are taken at national level, and in principle it is open to those developing GM insects in the UK, such as Oxitec, to gain approval for trials in England from Defra, when they need to do so and providing there are no safety concerns. Defra has authorised many GM trials, and in broad terms this aspect of the regulatory process can be said to be well-practised and effective.

- similarly, it is open to researchers and developers to seek public funding for research that may involve field trials of GM insects as part of the project (as they do currently for GM crops[2]). Of relevance here is the recently published high level strategy for animal and plant health research[3]. This includes a specific thematic element to encourage new technologies to combat current and emerging pest and disease threats.

[2] For example, the BBSRC-funded research on GM wheat, potato and camelina.
[3] 'A Vision and high-level Strategy for UK Animal and Plant Health Research To 2020 and Beyond', available at http://www.bbsrc.ac.uk/documents/1601-animal-and-plant-health-report-3/.

- the Committee suggests that a GM insect trial could be taken forward as a counterpart to the previous Government-sponsored Farm Scale Evaluation (FSE) trials of GM crops. However, the FSEs were designed to investigate a specific regulatory question which arose in relation to the possible use of GM herbicide-tolerant crops (the environmental impact of the new herbicide management practices that the GM crops implied). There is no comparable issue at the present time in relation to GM insects that would point to the need for a Government-funded trial.

- Oxitec is understood to be the only UK company or institute which has types of GM insect in development which are at the stage where field trials are an active consideration. Of the insects that fall within this category, most are designed for use in other countries to tackle issues that do not arise here (Mediterranean fruit fly, olive fly, Pink bollworm and the Aedes aegypti mosquito). Oxitec has conducted or is seeking to conduct trials of these insects in relevant countries, and there would be no practical or scientific rationale for pursuing such trials in the UK.

- it is doubtful that undertaking one or more GM insect trials here would have a significant influence which helps to improve the problematic situation at EU level, so that would not be a compelling reason in itself for the Government to instigate a trial programme.

20. In the light of these considerations, the Government does not think it is necessary or would be appropriate to commission a GM insect trial at the present time. The Government will keep this under review, and does not rule out the possibility of actively supporting GM insect trials in the future if there is a strong case to do so.

21. The Government's views in relation to the consideration of benefits and evaluating GM insects against the alternatives are given in paragraphs 14-16 above.

Alongside this trial, with the aim of ensuring that regulation remains relevant and up to date, we recommend that the Government monitors the suitability of the regulatory environment for emerging technologies, such as GM insects, to ensure that the potential benefits they could bring are not stifled at inception due to anachronistic regulation. This includes the development of new mechanisms to allow for effective post-release monitoring and tracking of new genetic material promoted via gene drives. We recommend that the Government issues an annual statement which provides their assessment of the suitability of the regulatory environment for emerging technologies.

22. As confirmed at paragraphs 9 and 10, the Government will keep the fitness of the EU regime under review and update the Committee when significant developments take place. The issue concerning the monitoring of insects with gene drives is addressed at paragraphs 12 and 13.

We envisage that appropriate public engagement strategies will have a critical role to play in the development and progression of GM insect technologies. Engagement with the

public, both in the UK and overseas, particularly in countries where insect-borne disease is rife, will be required. It is vital that the evolution of an inflamed debate like that which has enveloped GM crop technologies in the UK and across the EU is avoided.

The nature of an engagement initiative and its framing is vitally important. Setting GM insect technologies in the context of the issues and problems they are designed to address is crucial. We envisage that a public dialogue approach would be most appropriate.

While we recognise the value in early-stage intervention, we are concerned that undertaking a large scale public dialogue in the UK when an application for a GM insect trial is not in train—either at a national or EU level—may prevent the full impact of such an exercise being achieved.

We therefore recommend that a concomitant public dialogue exercise be a component of the UK-based GM insect trial we advocate in Chapter 4. This exercise should be framed around the context of the technologies and separate the public health uses of GM insects from agricultural applications. It should also allow for public input into the process of the trial and regulatory exploration. The Government should draw on the expertise of a suitably qualified organisation in order to develop this initiative.

Furthermore, as a long-term aim, we recommend that the Government, via a suitably qualified organisation, monitors the development of GM insect technologies and acts to initiate a broad programme of public dialogue when these technologies are deemed to be nearer to commercialisation.

23. The Government recognises the desirability of there being appropriate public engagement in the UK on the subject of GM insect technology. At this relatively early stage in the development of GM insects, there is a role for the scientific community and others involved to engage with the public, not least to explain the science and the R&D taking place. In this respect the Government would note the helpful engagement event organised last year by the Pirbright Institute, which brought together a range of interested participants to discuss GM insects and disease control[4]. Consideration is being given to holding similar events in future, which the Government would encourage.

24. In relation to the Research Councils, they recognise the need to ensure that broader science-in-society aspects are properly considered alongside the funding of GM insects research, particularly any targeted future initiatives. The Research Councils operate within the principles of a Responsible Innovation Framework, a process that seeks to promote creativity and opportunities for science and innovation that are socially desirable and undertaken in the public interest. With public dialogue recognised as one possible tool to engage stakeholders, the Research Councils consider that engagement should aim to inform research so that it advances in a way that takes account of the public view and values. This is likely to lead to outcomes aligned with social needs and increased confidence and trust in science.

[4] http://www.pirbright.ac.uk/Pub_Engage/docs/GM%20insects%20event%20report.pdf

25. In terms of the Government's role, if an application is made for permission to undertake a GM insect trial in England, Defra will publish it and invite the public to make representations concerning potential risks to human health and the environment. Any such representations would then be considered by the independent Advisory Committee on Releases to the Environment, before it delivers its scientific advice to Ministers on the safety of the proposed release. In that way public views can be taken into account and inform decisions on GMO trials. This process is in line with the underlying principle of EU Directive 2001/18, which requires regulatory decisions on the environmental release of GMOs to be grounded on a science-based risk assessment. The Government believes that this is the right approach for the regulatory framework, and therefore would not propose to open up the existing regime for public debate. Further points to note in relation to Directive 2001/18 are that:

(i) the European Commission is required to make relevant information available to the public on applications for EU approval to place GMOs on the market, and to invite public comments which are shared with all the Member State authorities before an EU decision is taken; and

(ii) deadlines are specified within which regulatory decisions on GMO trial or marketing applications should be taken, and these do not allow for an extensive public dialogue process to take place before decisions are reached

(iii) provision is made for the Commission, on its own initiative or at the request of the European Parliament, Council or a Member State, to consult the European Group on Ethics, should it be judged that there are ethical issues arising from GM technologies that should be considered. Such consultation should be conducted in a way that is open and publicly accessible, and with the outcome accessible to the public.

26. Alongside the formal decision-making process for a GM insect trial, the Government would expect the proponent of the trial to implement an engagement strategy, to explain the purpose of the work and respond to public comments as appropriate. In this respect, the excellent work undertaken by the Rothamsted Institute for their GM wheat trial could provide a suitable model.

27. The Government agrees with the Committee that it should monitor developments in GM insect technologies. Defra will undertake this in conjunction with the Health and Safety Executive (given its role in relation to the contained-use of GM organisms), taking independent advice as necessary from ACRE and the Scientific Advisory Committee on Genetic Modification.

28. The Government will keep under review the recommendation that a public dialogue should be undertaken when GM insect technologies are near to potential commercialisation in the UK. A decision on whether or how to proceed will need to take account of the circumstances arising at that time, which is expected to be several years away at best. Based on current knowledge, it is likely that the first applications of the technology that might come forward would be for agricultural use rather than for public health purposes. As the Committee has noted based on the evidence it received, the public may have more

concerns or be less favourably disposed towards agricultural applications of GM insects, and this would need to be taken into account when considering a possible engagement strategy. The Government also agrees with the Committee's point that engagement would best be framed in the context of the real-world problem to be addressed, acknowledging that GM technology may only be one option alongside others that could have a role to play. Broad engagement processes already in place, such as those under the Global Food Security Programme, could provide opportunities to discuss the potential use of GM insects.