HOUSE OF LORDS

Revised transcript of evidence taken before

The Select Committee on Science and Technology

Inquiry on

GENETICALLY MODIFIED INSECTS

Evidence Session No. 3 *Heard in Public* *Questions 26 - 38*

TUESDAY 20 OCTOBER 2015

10.40 am

Witnesses: Professor Rosemary Hails, Dr Jeremy Sweet and Ms Camilla Beech

USE OF THE TRANSCRIPT

This is a corrected transcript of evidence taken in public and webcast on www.parliamentlive.tv.

Members present

Earl of Selborne (Chairman)
Lord Hunt of Chesterton
Lord Kakkar
Baroness Manningham-Buller
Lord Maxton
Duke of Montrose
Baroness Morgan of Huyton
Baroness Neville-Jones
Lord Patel (co-opted)
Lord Peston
Viscount Ridley
Lord Vallance of Tummel

Examination of Witnesses

Professor Rosemary Hails, Chair, Advisory Committee on Releases to the Environment (ACRE); **Dr Jeremy Sweet**, Environmental Consultant, Sweet Environmental Consultants; and **Ms Camilla Beech**, Head of Regulatory Affairs, Oxitec Limited

Q26 The Chairman: Good morning. We are most grateful to the three of you for giving evidence to this session in our inquiry into GM insects. We are being broadcast on the web. First, would you introduce yourselves for the record? If any of you would like to make an introductory statement, do feel free to do so.

Ms Camilla Beech: Good morning. Thank you for having me at the inquiry. I am Camilla Beech. I am head of regulatory affairs for Oxitec in the UK. We are the only company in the UK and probably the world dealing with GM insects and consequently we have quite a lot of knowledge. We can hopefully help your inquiry today.

Dr Jeremy Sweet: Good morning. My name is Jeremy Sweet. I am an environmental consultant. I am a member of the EFSA GMO panel, which is relevant to this discussion. I see in the questions for today there is a lot of discussion about regulation and I am not a regulator; I am a risk assessor. I was also involved with a group in EFSA in developing the EFSA guidance documentation for the environmental risk assessment of GM insects, together with a number of other independent scientists.

Professor Rosemary Hails: Good morning. I am Rosemary Hails. My day job is science director for biodiversity and ecosystem science at the Centre for Ecology & Hydrology. I am here because I have been a member of ACRE, the scientific advisory committee for the UK on releases into the environment of GM organisms. I have been a member since 2006 and the Chair since 2013. I was also an ad hoc expert for the Environment Working Group of EFSA from 2006 to 2010.

Q27 The Chairman: As Dr Sweet said, we hope to concentrate on the regulatory framework. Here we have represented, of course, those who are being regulated, those who assess the regulation and those who help set it, so I think that gives a good balance from which to discuss the regulatory framework. Can I ask a general question to start with? We are familiar from the written evidence with the role of ACRE within the United Kingdom and EFSA within the European Union. Can you give us your thoughts on the current regulatory environment in the UK and indeed in Europe? How do such regulations differ for non-EU countries that are members of the European Economic Area?

Professor Rosemary Hails: I shall summarise the legislation briefly. There are two EU directives on contained use and deliberate release and then there are three sets of national regulations to implement them on contained use, deliberate release and the Environmental Protection Act. ACRE is a statutory advisory committee set up under the Environmental Protection Act and it advises Ministers in the UK and the devolved Administrations. EFSA is the scientific advisory body at EU level that advises the EU Commission. We implement the deliberate release regulations through two parts. Part B is for research trials, which are assessed nationally, so ACRE would assess those for the UK. Part C is for commercial release and that is assessed at the EU level. EFSA leads on that with input from the member states. Also, ACRE advises the UK Government on the position to take from a scientific perspective at an EU level. The most notable thing from non-EU countries in the EEA relates to Norway. Norway has some additional legislation—the Gene Technology Act 1993—where it considers the benefits also of a particular element to the community and the contribution to sustainable development, but that is in addition to the other regulations.

The Chairman: On that subject, I note that in the written evidence from ACRE you refer to the benefits issue and how it is not taken into sufficient consideration perhaps. Are we inhibited in the UK from taking this approach that Norway has because of our membership of the EU or would we be free to take a view also?

Professor Rosemary Hails: Certainly we would be free to take a view. ACRE does have a view on this. Also we have some thoughts on how benefits could be taken more into account even within the existing framework. For example, in the whole risk assessment process, the very last question is to characterise the overall risk of a GM organism. Additional information could be provided on context under that question and that context could include benefits also. The reason why that does not happen routinely is the questions leading up to that final question do not put in the building blocks for benefits in the same way as they do for risks. There is scope within the existing framework.

The Chairman: Would the other two witnesses like to add anything at this stage on the regulatory framework?

Ms Camilla Beech: I would like to broaden it out. We have heard how the GM aspect is regulated but we are regulated also under the quarantine regulations because we work with insect pests, either for human health or agriculture. There are quarantine regulations that apply. Also, as insects are animals, there is an intersection with the animal feed and animal by-products regulations. There is a potential here that these regulations may be misapplied for insects because these regulations were intended for animal feed and food-producing animals. I would like to broaden the overall scope regarding the regulatory environment. The

other regulation with which we have to comply is the Cartagena Protocol transboundary movement regulation, as we are the only exporter of GM materials outside of Europe.

The Chairman: That is the international legal framework for cross-border movement of GMOs.

Ms Camilla Beech: Correct.

The Chairman: You have practised that, have you not, and moved GMOs across boundaries.

Ms Camilla Beech: We have already undertaken several movements of that, yes.

The Chairman: The directive from Europe that would affect you most, were you to release genetically modified insects into the environment in Europe, which I do not think you have done yet, would be Directive 2001/18/EC, which covers the deliberate release of GMOs.

Ms Camilla Beech: That is correct, 2001/18/EC on deliberate release, as Rosie says, either Part B for a field trial at national level or a Part C application which is for "commercial". Commercial also meaning placing on the market or giving to third parties.

The Chairman: I think that helps us explain the regulatory framework in which we are operating.

Q28 Lord Maxton: Is the European regulation very different from the international and, if so, why?

Ms Camilla Beech: There is no international regulation as such for GM insects.

Lord Maxton: For other countries then.

Ms Camilla Beech: Yes, in Europe the regulation specifies field trials and then commercial release. It is difficult to generalise, but for other countries it is a bit more seamless.

Dr Jeremy Sweet: There are regulations in different countries based largely on the principles of the Cartagena Protocol but with lots of different interpretations. Starting at what I would call the desirable end, there are the Canadian regulations, which are based on novelty, novel organisms or novel traits, so they do not discriminate GMOs from other types of engineering or manipulation or technologies. They look at the novelty of a product and say, "Are we concerned about this and do we need to look at it and regulate it?" It is very much a science-based approach of looking at whether a new organism could have an impact on human health and the environment, through to the much more rigid systems that apply in Europe and many countries elsewhere, which is very much based on the technology approach. I think you had some discussions about this last week.

This is a big problem because now there are tremendous debates about what the technology is and what GM is and what GM is not. We have new technologies coming through such as synthetic biology and various others which people are unable to put into a neat box and say, Yes, it is GM", or, "No, it isn't GM". We are getting into a bigger and bigger mess by basing the regulation around the technology. Many people, particularly scientists, feel that moving towards a trait-based approach, the Canadian approach, would be much more desirable.

The Chairman: We will come back to the trait-based approach in a later question.

Lord Kakkar: Just listening to the conversation so far, I would like to be clear on your views about the current European and UK regulatory environments and whether they are really fit for purpose, as that is fundamental to this issue.

Professor Rosemary Hails: I would like to separate this into about three parts. The first is that, if you were designing the regulatory system from scratch, you would design it differently. Jeremy has talked already about what actually triggers regulation. The second element is the scope, and we have already talked a little bit about the extent to which benefits are not explicitly included and perhaps we could make a little bit more of that. Thirdly, ACRE feels we could take the current regulations and interpret and implement them more effectively. Other countries have very similar frameworks and they have functioning systems. In the EU we do not have a functioning system for GM crops. In fact, the last mandatory evaluation of GMO cultivation for crops concluded that the EU legislative framework is not meeting its own objectives as it is operated today.

If we turn to medicinal and veterinary products, it is working somewhat better. For example, there have been 10 applications for commercial release of veterinary products. Nine of them have been authorised and one is still pending in the system. The picture for medicinal products is better than it is for crops. I think there have been about 10 commercial applications: two have been authorised, four have been withdrawn and four are still in the system.

Viscount Ridley: Can you clarify what you are talking about there? Are you talking about bacteria?

Professor Rosemary Hails: Largely I am talking about vaccines.

Viscount Ridley: But not in plants.

Professor Rosemary Hails: No. I am making the distinction that in that case it is working. They are also governed by 2001/18/EC for the environmental risk assessment part and it is working somewhat better than it is for GM crops, which is where the problem really is. The big issue for GM crops is that so many applications have been stuck in the system for so long that in many cases they are being withdrawn by companies because they are no longer commercially relevant.

Lord Kakkar: Just to be clear, the regulations around GM insects are an extension of those for crops.

Professor Rosemary Hails: Yes.

Lord Kakkar: For crops they are working very badly; for insects there may be capacity for them to work better.

Professor Rosemary Hails: Yes.

Lord Kakkar: Overall, how bad is it that there is this link between crops and insects, in perception and in regulation? To pick up on a point to which you have already alluded, when you talk about regulations working better in other countries, is that other European countries that have decided to interpret the European regulations in a different way or is it countries outside Europe? What genuine capacity in UK regulation do we have to look at the application of what the European directives and regulations tell us?

Professor Rosemary Hails: I was talking about countries outside Europe. Within Europe we are all part of the same system for GM crops that is not currently working. If you look at other countries such as the United States and Australia, I would say that their risk assessments follow very broadly a similar process and they have more effective systems.

Lord Kakkar: You mentioned in the previous answer the question of incorporating benefits into the equation. To be clear about it, are you saying that the current EU regulation will prevent that, whether it is crops or insects?

Professor Rosemary Hail: There is no explicit consideration of benefits but in the structured risk assessment process the last question is to characterise the overall risk and in doing that applicants could be encouraged to provide more information on context that would also include benefits.

Lord Kakkar: That would not be open to challenge at a European level.

Professor Rosemary Hails: Surely more information for decision-makers must be a better thing.

Ms Camilla Beech: As an applicant we believe that the European system does not work because it is just not predictable. You put an application in and you can never predict when you are going to receive a response. That is bad for innovation and it is bad for companies.

Lord Kakkar: Why is it not predictable? Is there not clear guidance to the regulators on the time they have to look at an application and respond to the applicant?

Ms Camilla Beech: There is some guidance, but it is routinely ignored.

The Chairman: Honoured in the breach.

Lord Patel: Can I be clear? From what you said, the European regulation relating to GM insects performs on the same basis as the regulation relating to GM crops. If that is the case, what discussions took place at the time when the regulation for GM insects was being considered, or was it just rubber-stamping that this was the same GM?

Dr Jeremy Sweet: To come back to the original discussion, the framework covers all GMOs. It was initiated originally because of microbes and because people were genetically engineering bacteria for various reasons. The original regulations were established around microbes and then developed for plants and now have been developed for animals. All GMOs in Europe come under the same regulatory framework and, as you have heard, the problem with that is not so much at the scientific level, the risk assessment process and so on; it is what happens after that. For example, in EFSA we produce scientific opinions which go to the Commission and to the member states, and that is where they are lost. They disappear into a black hole. There is never a qualified majority vote and so nobody will make a decision on whether or not to commercialise a GM crop. There are several GM crops on which we have given favourable opinions for cultivation in Europe that have been sitting there for up to eight years purely because the political process is not allowing decision-making to take place.

Baroness Morgan of Huyton: In essence, are you saying that the process is significantly more difficult than the regulation itself?

Dr Jeremy Sweet: As Rosie said earlier, the regulation in principle is workable.

Baroness Morgan of Huyton: Is it doable?

Dr Jeremy Sweet: There are problems with the definition of GMOs and so on with the new technologies. In principle it should work, because similar ones are working in other countries, but in practice its application is the big problem. This is why in Europe there has been this discussion to have opt-outs so that countries that want to cultivate GM crops can do so and other countries can say they will not. This was to try and get through this logjam to allow some countries to proceed and not be blocked by other countries which said that they were not going to have any GMOs.

Q29 Viscount Ridley: Can I probe further on the question of stifling innovation, which has already been mentioned? A surprising number of the written submissions we have had have mentioned this point. Oxitec Limited said, "If we over-regulate we alienate entrepreneurial innovations and value creation". Even ACRE said, more guardedly perhaps, that these issues could conceivably affect innovation, which is a serious concern given the threat to humans and other animals from insect-borne diseases. Is this really happening? Can you give real examples? Of course it is hard to give an example of somebody who did not start a company because they could not, but could you flesh this out?

Ms Camilla Beech: Maybe I can help you with an example. We have a product for olive fly which is a very destructive pest in Europe. We would like to field-test it in a cage to start with, not in the open environment, and we applied to Spain under the deliberate release directive 2001/18/EC for a caged trial with a security fence in a research environment at a research station. The Spanish authorities felt they could not authorise that trial without additional significant containment measures in place. We said, therefore, we would withdraw the dossier because we have other strains coming along on which we can better spend our money. We cannot even get to the first hurdle of getting a genetically modified insect in a field cage.

Viscount Ridley: That is you as an existing company with a track record.

Ms Camilla Beech: Correct.

Viscount Ridley: What would the effect be if there was a research group in a university where one of the professors was thinking of spinning out a company and starting this because he could see an opportunity? What would it be like for him to do that today?

Ms Camilla Beech: The bottom line is probably they would not start, certainly in Europe. To take an example, we have just had a release in the USA of a diamondback moth, because at the very least they could see the benefits of testing it. That is the next step forward. We have had people saying, "We cannot use your technology because Europe will say no".

Viscount Ridley: To be clear, if I was to start a company tomorrow to suppress the Scottish midge, for example, using the old-fashioned sterile insect technique—ie irradiating midges—that would be no bother, I could do that straight away.

Ms Camilla Beech: Correct. It would be no bother at all.

Viscount Ridley: But that is (a) less effective and (b) possibly a more risky technology than if I was to do it with a specific GM version.

Ms Camilla Beech: You are introducing mutations into the whole genome in that midge by irradiation whereas we are specifically putting one or two genes into our insect.

The Chairman: Is it not evident within Europe that there is a great suspicion about the concept of genetically modified organisms and as such the public expect a different regulatory regime?

Ms Camilla Beech: I think it is an appetite and an attitude and the attitude is precautionary. It is based on the precautionary principle that you do not know enough about it. The regulators do a thorough assessment of the product.

Lord Maxton: You may have answered my question already. You mentioned Spain. Was it a Spanish authority regulation that they were applying or was it a European one?

Ms Camilla Beech: It was the same directive, 2001/18/EC, the deliberate release directive. It is the same in the UK and it has been implemented into Spanish law. It is exactly the same set of questions.

Lord Patel: Could I have some clarification on what you said about the European law regarding germline mutations? Does that arise out of the regulations relating to human genome manipulation and is it directly applied therefore to any insects or animals?

Ms Camilla Beech: I do not believe so. I am not very familiar with that law. I apologise but I do not think I know the answer to your question.

Q30 Baroness Neville-Jones: My question follows from the current conversation. One has rather a strong sense that there is an impasse here, from what Ms Beech was saying about not being able to start a field trial. Is it possible then to start thinking ahead to try and get proposals on the table which get ahead of the current situation—in other words, instead of waiting on and on for a field trial that may never happen, because you cannot get to that post, actually start initiating a dialogue on a new regime? If you did that, what would you like to see as its salient characteristics?

Professor Rosemary Hails: I think we should be proactive in trying to solve these problems on two fronts. As you say, we should look to the long game about designing a system that my committee would feel is more scientifically defensible. A key feature of that system and the trigger for regulation would be around novelty rather than around a particular method that has been used to produce the organism, as Jeremy has already alluded to, because that is more scientifically rational now.

Baroness Neville-Jones: The trait?

Professor Rosemary Hails: Yes, that is right. When the regulations were first produced, recombinant DNA technology was very new and they could see the potential to produce very different sorts of organisms. This is why we have our current regulatory system now. Yes, we should play that longer game and seek to set up a new system that is more defensible and more future-proof. We have this bizarre debate now where new techniques are being developed to manipulate genomes and you have people scrutinising the legislation to try to decide whether technically it is captured by it or not. That is a bit of a nonsense.

In designing that new system, we would like to see one where benefits are very explicitly included. However, I think we ought to be proactive on another front as well, because that is

a very long game. We ought to be proactive on trying to make the current system work more effectively. In essence, we have the evidence that it works more effectively in other countries. We have this big issue to which we have alluded where politics is being conflated with the scientific process. It is really embodied in the position of GM crops where we have these applications in a suspended state. I have pointed to the fact already that for medicinal and veterinary vaccines we have had more success.

The cultivation proposal is where countries can opt out of growing GM crops and that is an attempt to separate the science from the politics to some extent. It is early days yet. It remains to be seen whether that will be effective. Also there are other issues of detail about how the risk assessment is conducted in the EU. ACRE is one of several voices across Europe which promote the problem-formulation approach. Risk assessment should test plausible, clearly defined hypotheses. There is some pressure within the EU to focus on harmonising data requirements and standardising methodologies and we feel that that acts a little bit in opposition to the case-by-case approach to risk assessment. There are some issues of detail that we can work on with EFSA to improve the efficiency of the environmental risk assessment. Whether this will solve the big issue is quite another matter.

Baroness Neville-Jones: As a practical matter, how do you think you could start a debate on changing the approach?

Professor Rosemary Hails: That is a very good question. EFSA would be the place where the dialogue would need to start, as leaders of the process in Europe.

Q31 Lord Hunt of Chesterton: I was going to ask whether you can model this. You have risk assessment and then you have regulations, but the question is whether there are models both of the biological and the physical process of the effect of different kinds of regulation. You do experiments and you examine those in the laboratory and conceptually, but then how do you study the effects of different kinds of regulation, to put the question another way?

Professor Rosemary Hails: I guess the evidence is in whether or not the regulation is effective, in that applications that have been deemed to be safe or even beneficial for human health and the environment are then allowed to reach the market. I would say that would be the hallmark of success for a regulatory system.

Lord Hunt of Chesterton: I am thinking of the example of this box in Spain in which you were going to do the experiment. The way the question was answered was whether it does or does not fit within the regulation, rather than a scientific study of what would be the consequences if something went wrong and all the possibilities and how that would affect the decision. The decision would be made with a rich knowledge of all the possibilities that might emerge from a particular trial or experiment or whatever.

Ms Camilla Beech: That is included in the risk assessment process that the authorities undergo. When you apply you have to envisage all the potential scenarios that are both direct, indirect, short term and long term that could be a consequence of an organism being in the environment.

Lord Hunt of Chesterton: Do you think the risk assessors do that job very completely? It sounds as if in your olive fly experiment you did all your calculations but, before the decision

was made, did the Government or European side look at your science and your calculations and did they test them?

Ms Camilla Beech: I agree very much with Rosemary and Jeremy that the risk assessment process itself works scientifically. The problem that we face in Europe is a political overlay of the implementation of the regulations.

Dr Jeremy Sweet: Can I come back to your previous issue? One of the things that has been looked at in Europe, particularly by EFSA, which is taking a lead on this, is to try and switch the focus of risk assessment away from looking at whatever is regulated, whether it is a pesticide or a GMO, towards what we are really concerned about, which is the environment. We want to protect the environment, so whatever we put in it is a stressor on that environment and we need to look at it and see what the impact is. There are now discussions in EFSA and at other levels to try to harmonise the approach to risk assessment taken by the pesticide people, by the invasive species people—and maybe John can say something about this later—and by those dealing with GMOs. We are all trying to address the same concern that you are putting something new into the environment and, therefore, what is the environmental impact, how do you assess it and how do you come to a conclusion? There is a move to try and harmonise this approach and to move the focus away from looking at all the different technologies and saying the issue is environmental protection and let us build a framework that is focused on environmental protection. This is the way we are trying to move things in Europe at the moment, but it is very difficult because there are very strong political forces who say immediately, "You're trying to hide the fact that it is GM by wrapping everything up into an umbrella framework". I would like to see a one-stop shop, so that you produce something new and you say, "Let's do an environmental risk assessment", and everybody is following the same, agreed process. This would be the ideal solution, but that is too simple for regulators.

Baroness Neville-Jones: In your view, that would improve the risk assessment process. Would it actually deal with the issue of benefits or would that still lie outside?

Dr Jeremy Sweet: The risk assessments are always comparative. You are asking what the situation is now and how it will change when you put the GM organism or pesticide out there. In the case of GMOs, therefore, the baseline is the current situation. If what you are dealing with is a pest or a mosquito or whatever, then the baseline is pretty horrendous. What you are saying is that you have this really bad baseline and what happens when you put the GM mosquito or the GM olive fly out there, where does it move from the baseline? Of course it moves upwards and you can then assess across a whole range of environmental areas and see in most areas that it is moving up from that baseline. There may be one or two particular ecological issues that need to be ironed out but, on the whole, if you are comparing with the appropriate baseline, then to a certain extent you are looking at the benefit of what you are putting out there.

Baroness Neville-Jones: You are saying it would emerge from the process.

Dr Jeremy Sweet: This is what we do in the risk assessment.

Q32 Lord Kakkar: We have heard a lot about the regulatory framework and we have just heard that it could be improved, but also that it is reasonably good in comparison to those in

other nations in the world. There is a political overlay beyond that where, once the scientific advice is provided based upon the regulatory framework, it goes into some system and is lost there. First, I would like to understand a bit more about the stage beyond the scientific assessment and the approval for a particular approach. Where does it go after that? Secondly, how would you propose dealing with that political roadblock beyond the independent scientific opinion to ensure that things move?

Baroness Morgan of Huyton: Can I ask a supplementary on exactly the same issue? To what extent do you think that Defra and probably BIS as well are sufficiently proactive in trying to move this forward at the EU level?

Dr Jeremy Sweet: You are the closest one to Defra!

Ms Camilla Beech: That is the second question. Do you want to start with the first question?

Dr Jeremy Sweet: I am not an expert on what happens in the political environment in Europe, but I have observed it for a long time. There are big political constraints in different European countries which are holding them back. The other thing that is not helpful is many European countries do not even have independent scientific committees. We are fortunate in the UK that we have ACRE and other committees and of course Europe has EFSA. There are a number of countries that have pseudo-scientific committees where all the scientists are directly employed by the Government or there are committees which will produce an opinion but then it is entirely overruled by Ministers, as happens just across the Channel from here. You have a very tricky situation where either the scientists are not able to express themselves or, if they do express themselves, they get overruled by politicians. That works its way up to the political decision-making process in Europe by the majority of states. There are a large number of states, such as the UK, which give scientifically based opinions, but unfortunately they do not carry a lot of political weight across Europe as a whole.

Ms Camilla Beech: A lot of countries take the opinions of some of the NGO groups and regard them with the same scientific weight that the opinions of EFSA and Defra are given, without the rigorous scientific evaluation of those comments. If you wanted to change the system in some way, it would be useful to level that playing field so that the scientific weight is equal on both parties.

Q33 Lord Peston: Most of the questions I was going to ask have already been asked by colleagues, which makes me quite fed up, but could I ask a more general question? To take an example, we regulate the financial sector because financial institutions have done enormous damage in our economy. Are there any examples at all of anybody in this field—GM or specifically insect GM—doing any damage at all up until now? Can you cite me an example of someone who has done some damage and therefore needs regulation?

Professor Rosemary Hails: If the regulatory system is working, that would not be the case. I would turn that question round and say that in the past agriculture has had an impact on the environment and some of those impacts have been very undesirable. GM crops are a part of that agricultural picture, so I think we should regulate them, but we should regulate them robustly and proportionately. One of the reasons why I feel we should move to a different trigger for regulation is that there may well be new farming practices in the future that are

not captured by regulation which could further damage the environment. We need robust but proportionate regulation to protect the environment and human health.

Lord Peston: I must say, wearing my economics hat, that that sounds like regulation for the sake of regulating. You have not made any case to me as to why we need to regulate. It is always, "It might be and therefore we had better regulate". If I could add to that, if you construct some regulations and you get some regulators, what are they going to do to earn their income? They are going to regulate. How will they interpret regulation? They will interpret it as stopping things. That seems to me to be a way of destroying an economy, not a way of giving us the world we want.

Professor Rosemary Hails: We are an independent scientific committee.

Lord Peston: You are independent, yes.

Professor Rosemary Hails: We are not actually regulators. I would contest that what I was stating was regulation for the sake of it. I am also a member of the Natural Capital Committee, which has just finished and produced three reports that illustrate that the natural capital—the state of the environment—is in decline because of pressures on the environment. This is just one of the potential environmental drivers. We need to be better stewards of the environment.

Dr Jeremy Sweet: Just to add to that, one of the few good things about the European system is that, as well as looking at the impact of GMOs, we also look at the impact of the management of GMOs. That distinguishes Europe from other countries such as the United States of America. For example, within EFSA we have been looking very carefully at herbicide-tolerant crops because here you have two stressors, the GM crop itself and the fact that the herbicide regimes are changed by the management. You therefore have to look holistically at the impact of these and come to a conclusion. We have seen already in some areas of North and South America where there has been an extensive move to some of these herbicide-tolerant crops that there have been consequences for agricultural systems which we would not want to see in Europe. To a certain extent this came out experimentally in the farm-scale evaluation studies with which I think some of you are familiar, which showed that certain herbicide regimes could reduce botanical diversity and therefore biodiversity in farmland. If we introduce those systems, they have to be managed appropriately and not make the situation in farmland worse. These are the sorts of issues that need to be looked at very carefully. I come back to my original comment that regulation is there to protect the environment and therefore I think that it is justifiable. That would be my response to saying that we are overregulating, because we need to protect our environment.

Ms Camilla Beech: Perhaps I could add a little to that. When we are talking about genetically modified insects specifically, not GM crops necessarily, a lot of these species are invasive. They have come into our environments and they should not really be there. When you are considering—Jeremy was saying what the baseline is—regulating these, you have to decide what you want to protect in the environment and that is where we have political goals, because we do not really know what we want to protect. You say, "Protect the environment", but what is it in the environment that we want to protect? Is it naturalness?

Is it farmland? What are the end points that we want to protect? I would ask you to consider that point strongly when you are considering this inquiry.

Lord Peston: Do you not want to protect all the people dying of malaria in the poorest countries in the world? Should that not be the thing you focus on first and foremost?

Ms Camilla Beech: Absolutely and that is exactly what we are doing in Brazil where we have had very high success in reducing the amount of vectors in the environment with our technologies.

The Chairman: We are coming back to the benefits and disadvantages equation.

Viscount Ridley: To follow on from that, we are not necessarily talking about protecting the environment but improving it in many cases. We have a damaged environment in all sorts of ways and we want to bring it back to something better. Surely we are not after the status quo in many of these cases.

Professor Rosemary Hails: Absolutely I would agree.

Viscount Ridley: I hope I am not treading on someone else's toes but, on the point about how we want to bring benefits into the regulation as well as risks, is this a general problem with the way the precautionary principle has been adopted in the European Union, that it essentially compares any new technology to Utopia rather than comparing it with the existing system?

Professor Rosemary Hails: I would say that the precautionary principle properly applied would also take into account the risks of not developing a particular technology and the benefits forgone. It is a misuse of the precautionary principle that has led us to this place.

Viscount Ridley: The way it has been specifically defined in the European Union does not include that.

Professor Rosemary Hails: No, that is right.

Q34 Baroness Morgan of Huyton: We are clear that you all think that, were we starting from scratch, a trait-based approach would be a better way of effective regulation. If we take that as a given, can you give us a little bit more explanation of why that works and where it works? You mentioned Canada. Why does it work better? If we did that, could GM insect technologies be separated from GM crops? Would that be helpful in your view or would that not be necessary if we had a different form of regulation?

Professor Rosemary Hails: The reason why I think it would work better is partly because it is more scientifically defensible. I can give you a crop and an insect example. We can produce herbicide-tolerant crops by different methods and some are captured by the regulations and some are not. It is the same with insects. We are producing sterile insects by different methods. Some are captured by the regulations and some are not. Moving to a trait-based system would not separate insects from crops; it would separate some insects from other insects and some crops from other crops. That is the first point. Also it would be more future-proof because the technology is developing rapidly and it would be very hard to word legislation in a way that would capture all potential new techniques. We might try and do it for now and we might be back here in five or 10 years' time with us having the same

discussion. It would be more future-proof. That is why I think it would work. Of course, the Canadian system does appear to work well.

Q35 Lord Patel: My question is more general but I am also asking you to do a bit of crystal-ball gazing. It sounds from the evidence we have heard so far as if the current regulation is restrictive or even prohibitive, to the extent that it might prohibit development in science, let alone the application of that science. If this continues with the science now, where do you think the UK would be placed in 10 years' time? On the other hand, if the regulation was not so prohibitive and allowed for science and its application to flourish, where do you think we might be in 10 years' time?

Ms Camilla Beech: With our existing frameworks and the existing politicisation of the process, the EU and the UK are unlikely to benefit from GM insect technologies. We have tried in Europe already and have been knocked back in trying to achieve that. It is not that it is not going to happen, but it is going to be very difficult for a company to put forward applications in the current environment. If you change the environment and move to maybe a trait-based one, then it is untested of course, but we may have more opportunity for success. It is like reviewing a book as to whether it has been written on a typewriter or a computer and not on its content.

Baroness Neville-Jones: You paint a very powerful picture of interference with the system and none of you gives us any hope that that is going to change in short order, for all sorts of institutional reasons which you have set out. Can the opt-out system get us anywhere?

Professor Rosemary Hails: That remains to be seen.

Baroness Neville-Jones: What would be the nature of the opt-out that is likely to be developed and how far would it provide a basis, at least for field trials, in the UK?

Professor Rosemary Hails: Currently the opt-out system is just for the cultivation of GM crops.

Baroness Neville-Jones: If the legislation is for all varieties of genome, why could the principle not be extended?

Professor Rosemary Hails: The opt-out is to opt out of a decision made at the EU level. If a decision was made at EU level that a crop could be commercialised, a country could then opt out. That is my understanding.

Q36 Lord Patel: My question also had the science development component to it, because even if we were developing insect modification in mosquitoes to prevent the spread of malaria, we could not do it under the current regulation because the science would fall foul of the genome modification regulation. Am I correct?

Ms Camilla Beech: The genetic modification regulations work very well in the UK for contained use—for example, science in laboratories. A lot of laboratories in the UK are doing that and I believe we are a world leader in that area. That process is not subject to the same political constraints as releasing into the environment and therefore I do not think the UK would suffer if we continued to use GM insects in the laboratories. The concern is when we want to go to a wider scale in the environment.

Lord Patel: That takes me to a comment that Professor Hails made earlier about vaccine development. If you go to using reverse vaccinology to develop vaccines, which involves genome sequencing and then manipulating the genome side of that to produce vaccines, we can do the science but we cannot do the application of the development of vaccines by that process in the United Kingdom. Is that correct?

Professor Rosemary Hails: I do not see why we could not do it, because the regulatory system seems to have worked more effectively particularly for veterinary vaccines.

Lord Patel: But not for human vaccines.

The Chairman: I am concerned that we have the opportunity for Lord Vallance to ask his question.

Q37 Lord Vallance of Tummel: Turning to the commercial side of this—and perhaps this is one for Ms Beech—Oxitec Limited, a UK company, is the world leader in this technology and it was acquired by Intrexon, which is a larger American company. What are the implications of that for the UK, if any? It would help us to understand it if we knew a little bit about how the acquisition developed. Who approached whom? The assumption might be that the Americans approached a smaller UK company, but there would be good reasons for a smaller UK company to approach the Americans.

Ms Camilla Beech: When you work in this space, you know the other people who work in this space. We knew about each other for a long time—two or three years—and it became obvious there would be some synergies if we got together. That is how the acquisition arose.

Lord Vallance of Tummel: A spontaneous transatlantic meeting of minds and no commercial side.

Ms Camilla Beech: No. You meet in scientific conferences. They are a leader in synthetic biology and we are a leader in the genetic modification of insects, so the minds meet—hopefully not mid-Atlantic. They are looking at a whole range of sectors as well—food, consumer, environment applications—and, knowing each other, it became obvious to share our common goals. It is securing funding for inward investment into the UK as well. We will remain in the UK and, while previously we had lots of small shareholders as a private company, we now have just one large shareholder. We will remain in the UK and we are increasing our footprint in the UK, so there will be inward investment into the UK as a result of this acquisition.

Lord Vallance of Tummel: In effect, you are saying that this is a benefit to the UK rather than having an independent UK company.

Ms Camilla Beech: It is a little early to tell because it is very fresh—the deal was only completed in September—but we believe that that will be the approach.

Lord Vallance of Tummel: Did the differential regulatory regimes in the UK, Europe and the United States play any part in the acquisition?

Ms Camilla Beech: No, not at all.

Lord Vallance of Tummel: You were not looking for reach beyond Europe.

Ms Camilla Beech: No. We have an application for mosquitoes in the US at the moment. That is one of the regulatory regimes that works well, but even then it has taken them quite a long time—five years—to work out what to do with mosquitoes.

Q38 Lord Hunt of Chesterton: Lord Patel asked about what the position might be 10 years from now. I am afraid to say that a lot of my European continental colleagues always look at the downside, but the fact is that there are dangers; we have lost elm and chestnut trees. Therefore it seems to me that the danger over the 10 years concerns what aspects of our biodiversity we will lose. Nobody seems to be playing this card as a way of preserving European biodiversity through this kind of technique. Nobody in Europe on the political green side addresses the dangers of just carrying on as we are. Is that something that you are pushing in your own discussions and presentations?

Professor Rosemary Hails: That is a very interesting point and for any one application that would be an element that would be brought in, both in the wider context and in the consideration of benefits. These potential benefits also extend to GM crops. If you use GM crops that are insect-resistant, how does that compare with the spraying of insecticides? It might greatly reduce the non-target effects.

Lord Kakkar: Let me just come back to the opt-out system. If I understand it correctly, if some poor application manages to get itself all the way through European political bureaucracy and gets a positive opinion, the scheme will be for member states to opt out of that particular GM organism technology or whatever. Is there a way of a negative decision coming from Europe and a country such as ours opting in to use it nevertheless?

Professor Rosemary Hails: I am not aware of any such mechanism.

The Chairman: That brings us to the end of this session. We could have continued much longer. Thank you very much, particularly for the help in exploring the regulatory framework and the developments you would like to see us propose in the report. You have given us many leads. Thank you all very much.