HOUSE OF LORDS

Revised transcript of evidence taken before

The Select Committee on Science and Technology

Inquiry on

GENETICALLY MODIFIED INSECTS

Evidence Session No. 4 *Heard in Public* *Questions 39 - 47*

TUESDAY 20 OCTOBER 2015

11.40 am

Witnesses: Professor Paulo Paes de Andrade, Professor John Mumford and Dr Jack Stilgoe

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

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Examination of Witnesses

Professor Paulo Paes de Andrade, Department of Genetics, Federal University of Pernambuco, Brazil, **Professor John Mumford**, Professor of Natural Resource Management, Centre for Environmental Policy, Imperial College London, and **Dr Jack Stilgoe**, Senior Lecturer, Department of Science and Technology Studies, University College London

Q39 The Chairman: I thank our three witnesses who have come to help us in the second session. We are being broadcast on the web, so could I ask you to introduce yourselves for the record? If any of you would like to make an introductory statement, do feel free to do so.

Professor John Mumford: I am John Mumford, I am a Professor in the Centre for Environmental Policy at Imperial College London. I have been a contributor to both the EFSA and the WHO guidelines on GM animals and GM mosquitoes. I manage the risk analysis part of a project called Target Malaria, which is funded by the Foundation for the National Institutes of Health in the US. A little more broadly, I have worked extensively with the International Atomic Energy Agency on the design and evaluation of sterile insect technique programmes around the world, so I have a lot of experience with radiation sterility; and I chair the Great Britain Non-native Species Risk Analysis Panel, which advises the three Governments in Great Britain on invasive species. In the course of that, we have overseen over 130 risk assessments of invasive species, so I have very practical experience of the risk assessment process.

The Chairman: Thank you. Dr Stilgoe?

Dr Jack Stilgoe: I am Jack Stilgoe, Senior Lecturer in Science and Technology Policy at University College London, where my particular interests are in the governance of emerging technologies rather than GM insects in particular. Relevant to this inquiry, I have been working with the research councils developing frameworks for what we and they call responsible innovation. Also relevant to declare, given your previous witnesses, I am on the steering committee of Sciencewise, the Government's public engagement with science arm.

The Chairman: Thank you very much. Professor Andrade?

Professor Paulo Paes de Andrade: I am Paulo Andrade, Professor of Genetics at the University of Pernambuco in Brazil. I am a former member of the Brazilian National Biosafety Council, from 2006 to 2012, and I was engaged in the risk assessment of the transgenic mosquito that we are dealing with here, and many other organisms, including plants, vaccines, yeasts, algae and other relevant organisms such as trees. I have a lot of experience in risk assessment as a risk assessor, but I do not have much experience as a risk analyst. I am not used to discussing political questions related to biosafety, but I am glad to be invited for a second time here. I was here in February; Lord Patel was the chair of the meeting and it was very pleasant.

Q40 The Chairman: We are particularly grateful to you because you have come from Brazil via Lisbon, and that is well beyond the call of duty. Thank you very much indeed for having joined us today. I must start with an apology: I am afraid that I have a medical appointment which I was not able to change, so for the last quarter of an hour or so of this session Baroness Manningham-Buller will take my place and take the Chair. I do apologise for having to leave early. Perhaps I may start by asking a rather general question, in order to set the scene. Do not feel you all have to answer this question. Is the current regulatory environment in the European Union and the United Kingdom, in your view, fit for purpose for GM insect technologies? In other words, has the right balance been struck between innovation and regulation?

Professor John Mumford: The answer, almost certainly, is that it varies, because there are many purposes; it may be fit for some and less fit for others. You are also asking about a balance between innovation and regulation. I am not sure one of its purposes is to promote innovation. The main purpose of the regulations, as I understand them, is to protect the environment and human health. We have to keep in context what those purposes are. But getting to the point that you are trying to make, it is certainly restrictive; it works against the introduction of innovation, as we have heard in the previous session. It is certainly very burdensome on the applicants—some would say rightly so; they should show that things are safe—but, on the other hand, we want the innovation, so you have to get the balance. It is very process focused. I would like to see a much more flexible system rather than one which is highly prescribed. In that sense, I think it is not quite fit.

The Chairman: Would you like to describe what would be the alternative to something which is process oriented? Would you prefer something that was product oriented?

Professor John Mumford: The emphasis on the problem-formulation stage that is part of the European regulation was touched on in the earlier session. If that problem-formulation stage was more open, more fluid, involving more discussion between the applicants, the regulators and indeed the interested public at that early stage—this is prior to actually doing risk assessments—I suspect that quite a few of the issues could be designed out prior to an application going in. It would be much easier to do risk assessments on relatively safe products that have good design features already put into them. That is the kind of thing I mean regarding a bit more fluidity. We are starting to see that already in applicants being encouraged to talk to regulators at an early stage. We could formalise that fluid process to get them talking about what the public is concerned about and what the regulators are concerned about and what are the several options, because most applicants will have several pathways that they could follow in the development of their products.

The Chairman: Would either of the others like to add anything to that, or shall we move on?

Professor Paulo Paes de Andrade: I would like to emphasise that risk assessment is the core of the regulation in Europe, and should also be here in the UK, since the UK follows what the European Union decides in terms of risk of GMO regulation. I frequently see people putting issues of benefit together with issues of risk. Risk assessment is usually done by scientists—scientists are not risk assessors; they are not trained for it, but they learn with time. The language is different and the process is different, but it is scientifically driven. So, after a while, scientists learn how to do it. But scientists do not know how to evaluate the benefits, because that is an economic issue. The best element to use in deciding whether or not a product is useful is the market. If we leave that decision to any member or any group of people, we are putting the state in front of the economy and that is bad; that is socialism. I am not against socialist countries, but I am against socialism now, as it is. It is completely outdated. We have to think of the market as a decision element and not put benefits in front of risks; risk assessment is just biological and should be completely separated from benefits. I have heard this suggestion many times, and I know you may think it is useful, but it is very bad for risk assessors to discuss economic issues, because they are not prepared for that. Europe is mixing things, and although the main framework is good, doing it is not good in Europe; they are not experienced in evaluating and agreeing the economic use of some products. In the end, everything comes to a dead end and we cannot approve anything in Europe. One of the reasons is that Europeans try to balance benefits and risks. Just try to keep doing risk assessment; nothing else.

Dr Jack Stilgoe: May I quickly follow up on that? Though not specific to the matter of GM insects, there are important regulatory considerations to be taken on board that recognise that markets are rather bad at decision making under the conditions of uncertainty that emerging technologies tend to generate. Regulators, it strikes me, should rightly represent the public interest in ways beyond just questions of scientific risk. Those are the reasons why the European regulatory system has emerged to that end.

Viscount Ridley: I was a little puzzled by what you have just said, Professor Andrade. I can see what you are getting at—that state regulators are not best placed to measure benefits—but our problem in Europe is that nobody is measuring benefits; nobody is allowing benefits into the equation at all, it seems to me. We are discussing risks with the right hand and nothing with the left hand. Is that not the case?

Professor Paulo Paes de Andrade: It is really a burden for the risk assessor because he or she cannot argue in terms of benefits. The technology is nice, there are no risks or low risks and the advantages are clear, but risk assessors should not talk about advantages—just say whether or not it is safe. If the product is accepted later on, that is a question of a political decision sometimes or just a market decision. In my country, it is just a market decision.

Viscount Ridley: Before anything gets near the market somebody has to speak up for the potential benefits.

Professor Paulo Paes de Andrade: No, not at all. Not in Brazil.

Viscount Ridley: How do we ever capture these benefits? How do we ever have a sensible conversation?

Professor Paulo Paes de Andrade: The company—the developer—captures the benefits.

Viscount Ridley: But if the company cannot come to market because of the regulators, we do not get the chance to do that.

Professor Paulo Paes de Andrade: No chances.

Lord Peston: I am a little bit lost. I start from the fact there is a problem: people are dying of malaria. That is the problem. They are dying of it. It is possible that science will develop and we can do something on the GM side so that they do not die of malaria. That is why we are in this field to start with. We are not there outside of the world; we are there because there is an actual problem. I do not understand your position, Professor Andrade. Are you telling all these people: "You have to die"? Is that your position? I cannot believe it is for one minute.

Professor Paulo Paes de Andrade: No, it is not my position.

Lord Peston: Therefore, the fact is that the benefits are very clear and cannot be avoided. You have to deal with the other problem which puzzles me. Are you going to tell all these people dying of malaria: "I am afraid you have to die, but you are dying in a rather nicer environment than you would have done"? Is that your position?

Professor Paulo Paes de Andrade: I must apologise for my bad English. Maybe I was not clear enough. Risk assessors should not consider benefits. The first point is that, for public health products, it is obvious that the Government should encourage the adoption of something which has low risks and also shows benefits. The Government should support that. The first point is low risks. We can imagine a product that can combat or control malaria, or the dengue virus in my country, but if it is dangerous for the environment it should not be released, or should be balanced against the benefits. However, if the risks are very, very low then anyone would support it. It is not a question of arguing, because the risks are so low. The first thing is to do the risk assessment. I am not really saying that people should die of malaria—not at all.

Professor John Mumford: Perhaps I could outline the process of risk analysis which might help to put Professor Andrade's point in some context. It is a multi-stage process: you start with risk concern, you move on to risk assessment, you move on to risk management, and there are iterations and repeats as you go along. My understanding of what he is saying is that the risk assessment stage should be independent of values such as benefits. Those may enter at a later stage, at the risk management stage, where a decision is made, but not at the assessment stage. Assessment should be objective and management should focus on performance and benefits. The point made in the previous session by some of their Lordships is that that last stage is not happening adequately. There is plenty of emphasis on the concerns and plenty of emphasis on the risk assessments. The two could be tied together better, so that we were doing risk assessments related to real concerns—that would come out, as I was saying earlier, in the problem formulation stage—then decisions at the risk management stage would more actively consider benefits.

Q41 Baroness Manningham-Buller: Professor Andrade, we know you had a very successful programme against malaria in Brazil. Who in your system did the benefits bit? The risk assessment showed this was low risk. Who articulated, for the public and more widely, the benefits?

Professor Paulo Paes de Andrade: If it is not a GMO it is the registration agency; in Brazil it is called ANVISA, the national health authority. It evaluates if the product is good and effective

and registers the product to be sold or used somehow in my country. If it is a GMO, it is first analysed for biosafety concerns by the National Biosafety Authority. Later, if there is any special question, it can be reassessed by the National Biosafety Council, which is composed of 11 state ministers. It has never met because the crops are just crops, and even for the insect the benefits are so large it was not necessary to put the 11 ministers together to discuss that.

Baroness Manningham-Buller: So public opinion was behind the health one. Also, for the other things you mentioned, such as vaccines and yeasts, you have not had any opposition to it?

Professor Paulo Paes de Andrade: No. The public has opportunities because we have public audiences—public hearings—where the public can put their concerns about the technology or the product before CTNBio makes a decision on the biosafety. Moreover, the ministers also represent the public, so there is a second opportunity to directly put the public opinion in the final decision.

Lord Ridley: On a point of fact, we have slightly taken as read that there were huge benefits here. Can you enumerate the impact on malaria, dengue or on mosquito numbers, or whatever, from the Oxitec experiments in Brazil?

Professor Paulo Paes de Andrade: The negative impacts are known. We had trials in Brazil, in two different cities, and they were very well conducted by the company and observed by CTNBio, and the negative impacts are known to be null. We have still to see the positive impacts because we are now adopting the technology at a pre-commercial level[1]. We have seen that the insect population has drastically reduced in a few months. But I do not know if it will impact dengue virus transmission. That will be seen in the future. We have to have large-scale experiments.

Lord Ridley: The mosquito impact is known, but we are still waiting to know the dengue effect.

Professor Paulo Paes de Andrade: That is it.

Q42 Baroness Neville-Jones: In the light of this general discussion, perhaps there are some differing views, but there are other disruptive technologies. My question is: do you think it is possible to learn the way in which some of those are being managed—any improvements in the system for GM—and what kind of alternative regulatory regime would you really like to see, if you could design it?

Dr Jack Stilgoe: My strong sense is that past experiences with emerging technologies, both good and bad, can be extremely helpful in this regard, given that when it comes to assessing the risks and benefits of any new technology, necessarily there is vast uncertainty surrounding those assessments. Lessons of previous examples, good and bad, would include, for me, the European experience with GM crops and comparisons in other countries. The good news story I would draw upon would be the British experience with fertilisation and embryology and the way in which a solid governance regime has emerged alongside a hugely innovative research and clinical community there. However, the lesson from those, taken together, is that governance needs to improve. I do not like the presumption that we are

[1] The positive impacts on the reduction of vector population is already very clear – what is still missing is the impact on disease transmission.

dealing with balancing innovation and regulation, because what we would all ideally like is something like responsible innovation that is steered towards particular problems, whether those are problems of disease control or something else, and away from the risks and hazards that we might be able to identify. Numerous efforts have been made over the last couple of decades. The Royal Commission on Environmental Pollution—much missed—outlined in its final report some important lessons for what it called "adaptive governance", where we presume that we do not know all the risks and the benefits that we face when we are running experiments and rolling out technologies, and so we put in place requirements to better monitor and understand the impacts of those experiments, whether those are field trials or the actual rollout of technology. So governance can improve in all sorts of different directions. I would finish by saying that, in my own work, the research councils have been looking very far upstream, so the issue is how scientists can get better involved in anticipating some of these concerns, engaging with members of the public and reflecting on those concerns.

Baroness Neville-Jones: Perhaps I may pursue that a tiny bit. I entirely agree with you about responsible innovation and that it is not so much about balancing as about the manner in which you actually combine those two considerations.

Dr Jack Stilgoe: Indeed.

Baroness Neville-Jones: How, specifically, to turn to GM, would you like to apply what you have just said as general principles to the situation we are in to get some forward movement? We are actually at something of an impasse.

Dr Jack Stilgoe: Indeed. GM is one of those situations where, if your concern is with upstream questions, as mine is, I am afraid it is one of those situations where you could say 'you wouldn't start from here'.

Baroness Neville-Jones: But we are here.

Dr Jack Stilgoe: We are indeed. Considering all the other interests involved in the current state of GM regulation and the European dimension of it, it is hard to know where one might go. It strikes me that that is a straightforward political fight that the UK needs to have with Europe as much as it is one about good governance.

Baroness Neville-Jones: Does anybody else have any thoughts on this?

Professor John Mumford: I am thinking of a completely different example, but one where the upshot at the end was that governance was changed. Thirty years ago, in Australia, there was objection to the introduction of biological control agents. Some people argued that they were going to lose out as a result of the introduction of biological control agents which might do harm to some interests they had. As they had a harm-based regulatory system at the time, if anybody said they were going to suffer some harm the whole thing stopped. This was clearly untenable, in the end; it did not represent what society wanted. The system was changed and the Biological Control Act was introduced in Australia. It set up a system of public inquiries to determine who benefits, who loses, how much the losers will lose and how they should be compensated. That system has been in place and has been much more effective. I think it covers one of the points that Jack Stilgoe is making—that you need to introduce a governance system that actually meets the purpose. That is an example of where they did it. They simply changed it.

Baroness Neville-Jones: Would a trait-based system serve the purpose, in your view?

Professor John Mumford: Yes, I would much prefer to see a trait-based system. That is different from having a governance system, but we need trait-based systems with good governance, so I would like to see both.

Dr Jack Stilgoe: The only qualification I would add to the discussion about trait-based regulation—sometimes called product-based versus process-based regulation—is that there are reasons why one might want to put in place a process-based regulatory scheme. They are to do with the uncertainties that we might be unable to predict in terms of the products, whether those are the products themselves or the products of that particular innovation in terms of the consequences and ramifications of those traits, and actually paying attention to the processes might better take you into a precautionary approach to governing those uncertainties.

Q43 Lord Hunt of Chesterton: I sat on a Lords Committee on animals in scientific procedures. It was very interesting that the Home Office's view, as is broadly accepted in the United Kingdom, is that essentially you must be very, very careful about animal experiments, whereas in the United States they do many more experiments on animals. My wife is asthmatic; all her drugs are tested on primates in America. That could never be done in the United Kingdom. Similarly, perhaps you can also see this in America with GMOs; they have used them very widely and have not worried about the loss of biodiversity in hedgerows and other things—they have a view about looking at food for people. What you feel about the European aspect of this is that we are extremely conscious of perhaps the biodiversity element. That is why it is such a strong political driver. The question really is that the public debate, it seems to me, is very limited. We did not have a strong public debate, really, about animals in scientific procedures. We have not had a strong, meaningful public debate on these issues here, certainly not on the continent of Europe. We had a meeting last week and put to our panel: how should there be a more intelligent public debate on this? They said: this is an area for experts; experts should talk about it. I was not completely happy with that answer. What is your answer to that question?

Dr Jack Stilgoe: I had a look back through last week's evidence and I did not get that message from it—maybe I was looking for different things. As I mentioned, I am on the steering group of Sciencewise, and last week you had Sir Roland Jackson, representing Sciencewise, talking about the sorts of public debates that are commissioned through that process. Clearly, not everything can be a topic of public debate, which is why I think it is important to learn from previous experiences in this regard. I would want to see experts, certainly, prompting that debate, but not presuming that their knowledge or wisdom is complete in that regard. That is why I think that the dialogue between experts and the public—whether that is the public in Britain or specifically the public in the local communities where trials are happening or problems are prevalent—is absolutely vital. There are all sorts of mechanisms through which one might take those forward.

Lord Maxton: What drives public opinion?

Dr Jack Stilgoe: There is a sociology degree in that.

Lord Hunt of Chesterton: Why is it different in different countries? That is the point. Why is it so different in Europe and the United States?

Dr Jack Stilgoe: My other response to that question is that public opinion may be a relatively small part of the experience there. If you take the GM crops comparison, perhaps a more

stark example would be French agriculture relative to US agriculture. Other committees have done countless inquiries on this. However, GM crops suit American agriculture in a way that they simply do not in France, and one could equally explain it in those terms. Actually, caricaturing the public as anti-science or anti-technology in Britain or Europe—this was discussed last week, I think—is an enormous mistake, because all the evidence suggests that they are simply not.

Lord Hunt of Chesterton: I did not say that; it is different aspects of the science—that is the point. People give the environment a different emphasis.

Dr Jack Stilgoe: There is no straightforward explanation, I think.

Lord Maxton: We have talked about GM crops and GM insects, but of course there is human genetic modification as well. Where does that fit into all this?

Professor Paulo Paes de Andrade: In my opinion, comparing Brazil and Britain, it is obvious that the debate in Britain is dependent now on the alternative media. There is a lot of debate on GMOs in alternative media, with no access or no influence of the Government or of scientists. Scientists do not have time for that, and I think people from the Government also do not, so the discussion goes on over the internet. It has enormous influence on the risk perception of the public in general. We have somehow to interact with this huge cloud of information, but I do not know how to do it. In Brazil the internet does not have that much influence, and the large media—the official media—can still have a lot of influence. We use journals, papers and television, and the discussion then is a bit more scientific than what runs in the underground, and this may be the difference. In the United States it is just the opposite, because they have such internet facilities; everybody has a mobile that can access the internet, and they have a lot of opposition to biotechnology, but the Government decided on a scientific basis, and they really separated risk assessment from the other decisions. That is the trick there.

Q44 Baroness Morgan of Huyton: Perhaps I can come in now rather than later, since we are talking about this issue. How have we managed to have, I would say, a pretty reasonable public debate about embryology and its wider aspects in the United Kingdom that has involved the scientific community, the medical community and the media? Somehow that has worked, and yet we fail in this area. Are there lessons from that which we should apply to this? One of my concerns about last week's evidence was about taking it issue by issue by issue, rather than saying: "Let's have a larger public debate about the risks and benefits of this new technology", which arguably we have done in the field of embryology.

Dr Jack Stilgoe: I think the issue-by-issue-by-issue thing is exactly what recent reports, such as the Royal Commission's and also the one from the Nuffield Council on Bioethics, have tried to get past, which is the idea that actually these things tend to raise similar questions over and over again, and we are slowly getting better at understanding how to come to terms with them. In the debate about embryology, I would say the reason that worked was that it asked a broad set of questions early, prompted by the first clinical use of IVF. It involved experts from a wide variety of disciplines: Mary Warnock and others led the discussion, as well as the scientists and clinicians involved. It was public and it was done before there had been an entrenchment of particular positions. With GM crops, the benefits were presumed from the start and the risks were presumed to be relatively negligible, which meant that those with interests in GM crops were taken by surprise by the additional set of

concerns presented by European citizens. Perhaps I may also remind the Committee of the large amount of work done by social science in precisely understanding the roots of public concerns on GM crops; there was a vast amount of evidence that the Commons Committee went over.

The Chairman: We will, in a later session, be hearing from the Nuffield Council on Bioethics, and we will have an opportunity to address those issues, as indeed we did last week.

Lord Vallance of Tummel: Tell me if I am wrong, but my instinct is that public concern is in two very different areas. One is to do with tail-end risks—low probability, high impact, although they may not put it that way—but the other is a moral dimension. I suspect that these have to be dealt with in two very different ways. Perhaps with embryology it was done properly, but I think if you do not address both upfront you are not going to get the right answer from the public. Am I wrong?

Dr Jack Stilgoe: I do not think one can easily, necessarily, separate those things because quite often people's perception of the risk is bound up with the extent to which they trust the morality of the person they feel is making the intervention. I think, absolutely, it is important to consider the ethical dimension as well as the calculable risk dimension of the construction of those concerns.

The Chairman: Lord Hunt, have we dealt with your question?

Lord Hunt of Chesterton: Yes, Lord Chairman.

The Chairman: Could we move on to Lord Ridley? Perhaps I may also ask Baroness Manningham-Buller if she will take over from me.

Baroness Manningham-Buller took the Chair.

Q45 Viscount Ridley: Just to comment on the last conversation before moving on to my question, I am very interested in what Professor Andrade says about social media, and so on, and I think we probably should try and follow up on that. Those of us who have experienced the anti-GM crowd on Twitter know what you are talking about. The WHO has come out with some guidelines on GM insects and so has the European Food Safety Agency. Given our written evidence, it seems the WHO guidelines are not particularly problematic but the EFSA ones are much more so. The Royal Entomological Society described them as "probably overbearing and inhibitory to innovation". Is that a view the panel shares?

Professor John Mumford: Having contributed to both of them, I know that they are certainly very different. They were for different purposes, and I think the outcome reflects that. For EFSA, they required a document that would explain to applicants and the public how the process worked, and it was very prescribed by the way that the deliberate release directive is written. All the sections within it address, section by section, point by point, what is in that regulation.

Viscount Ridley: That regulation was originally written for crops rather than insects.

Professor John Mumford: Exactly, yes. In fact, we spent a great deal of our time, in the insect section that I worked on, trying to interpret what was a crop-directed set of instructions to explain to insect applicants and the insect-interested public how this system would work,

and we tried to do that with quite a lot of examples. As we looked into it there was huge variation in the potential GM insect applications. There are some that are very similar to GM crops—a silkworm with higher productivity kept in captivity is not that dissimilar to growing wheat—whereas others are released entirely into—

Viscount Ridley: Except that we do not eat silk.

Professor John Mumford: Yes, that is true. We also looked at honeybees and, potentially, GM honeybees. We also looked at vectors, and in fact as vectors seemed to be the most likely applications in the short term we put a lot of effort into those. We found one of the key differences there was to think about populations, very long timescales and very large spatial scales. We put emphasis on the use of models. We tried to be instructive to applicants by saying what an applicant should provide and how they should provide it. It was very, very specific, with very highly detailed bits about the parts of the directive. In the WHO guidance it was, in some senses, much easier because we were focused entirely on GM mosquitoes. There were two basic strategies—and several different technologies within those two strategies—of replacement and suppression that we could address. As it was much more specific, that made it easier. We were also aiming at looking at the whole process from start to finish, not just at the risk assessment stage but thinking why would you start with this and how you would go step by step through to a decision to implement in the end. We were able to think about a continuum, from the early stages where you focus on biosafety through to a later stage where you are starting to think about the economic benefits and wider social benefits, and so you could take everything step by step. We could not do that in the EFSA guidance because we had to start and stop with the risk assessment stage, so it was after concerns and before decisions, so there was not much scope in the middle.

Viscount Ridley: Just to pin you down, do you think those EFSA guidelines are inhibitory to innovation?

Professor John Mumford: Not in themselves. I think the process that makes decisions subsequent to a risk assessment is inhibitory—the process after the risk assessment stage. The EFSA guidance is about the risk assessment stage for environmental and public health risks. It is not about decision-making. It is simply saying, "As expressed and articulated in the directive, here are a number of concerns that have been proposed; here are examples of why they are a problem, how we might assess them and factors to take into account", and then it stops. There is nothing in it about how a decision would be made, so there is no value judgment at all at the end.

Viscount Ridley: One further point: you mentioned the distinction in the WHO guidelines between population suppression and population replacement. Is that distinction sufficiently captured in the regulations that are coming forward generally? Does more work need to go into teasing apart the differences there?

Professor John Mumford: I would say it is not captured at all. In fact, it is a fundamental conflict within the regulation that there are seven large areas of technical concern within the deliberate release directive, and persistence is one of those seven. Obviously, with the self-sustaining mode of action for some of these methods, you are starting from an assumption that the whole mode of action is a concern. That is an inherent conflict within the regulation. I think it would be difficult in designing a regulation to allow for every possible strategy that

might develop in the future. I do not say it is a fault of the regulation, but it is a problem with it.

Viscount Ridley: It is not well future-proofed?

Professor John Mumford: No, and it is one of the things we tried to explain in the EFSA guidance.

Lord Maxton: I am not quite clear on this. You give scientific, technical advice, or that is given, but no decision. How many times has your advice been ignored by those who take the decisions?

Professor John Mumford: Nobody has made an application, other than on the olive fly in Spain, that is related to GM insects.

Lord Maxton: No one else has come to you so far?

Professor John Mumford: In Europe, yes. It has been different in other places. We have had releases and acceptance of releases in Brazil, trials in cages in the US and releases in the open for mosquitoes in a number of other countries.

Q46 Duke of Montrose: Much of the GM insect technology is focused on mosquitoes because of the various human diseases which come from mosquitoes. Have the difficulties encountered there led to work being put off work on other insect problems, such as tsetse fly and other tropical diseases? Is there much going on in GM technology?

Professor Paulo Paes de Andrade: At least in my country there is a lot going on in mosquito control based on GM technologies, but we are certainly behind England now. We do not expect to have a product in the near future, at least not for mosquitoes, but we may have for other animals, especially fish.

Viscount Ridley: What kind of fish?

Professor Paulo Paes de Andrade: It is freshwater fish, which is edible, not salmon but another fish. It is a Brazilian fish. It is more difficult for us. It would be better to have just salmon because it is not Brazilian—it is not even from the South Atlantic—so we can leave it free; it does not matter. The Brazilian fish is more complicated.

Viscount Ridley: You are not trying to suppress the population of fish; you are trying to encourage it?

Professor Paulo Paes de Andrade: Not at all. We want the opposite; we want to encourage the population.

Professor John Mumford: There are applications of GM fish, though, to control invasive fish. In Australia, for example, there has been interest in the use of GM carp to control wild, invasive carp.

Viscount Ridley: We will come to this later in the inquiry, but is the use of this technology for dealing with invasive species promising, distant or a big part of the story? It is obviously not a health issue but it is quite an important ecological issue.

Professor John Mumford: It certainly has some potential. The invasive species are, like everything else in the environment, very variable, and it depends on the timing of them. Some of the GM technologies that are being considered require concentrations of a population to control; it would depend whether the invasive species were widely spread or

focused. It may depend on whether they were intermittent. Many invasive species have very, very low stages in their population and then surge seasonally. Those kinds of populations may not be particularly well suited to a biologically based approach.

Q47 Lord Patel: My question is about the developing science and the regulatory framework that will be required for the benefits of this science to be harnessed. The US National Academy of Sciences has set up a committee to look at the state of the genomic science now—technology such as gene drive and gene editing, using technologies such as CRISPR, which is used to gene edit, which could actually end up applying to humans, but let us not go there just now. Do you think the UK, to inform those concerned with regulation and those who might be concerned with public involvement too, should set up such a committee to assess the state of the science and where it is likely to go?

Dr Jack Stilgoe: I am a former employee of the Royal Society's Science Policy Centre, which would be the obvious place to locate such an equivalent. The magic of such exercises tends to be in how they are framed. The National Academy has taken an approach of looking at this issue beyond just the immediate problem, or an immediate suggested solution, and looking more broadly at the issue of genome editing, particularly germline editing, and I can see the wisdom of that. The Royal Society's contribution in the last couple of decades has been to be a broader source of expertise than the National Academy's, and I think it does that job extremely well. The question would be whether one starts from a problem, and one might want to start with the problem of disease control, or whether one looks at a particular, suggested technological solution of concern and starts the inquiry from there. I do not think there is any easy answer to that question. Similarly, as I have said before, there are plenty of lessons that can be learned from similar inquiries and efforts that are going on elsewhere by the Nuffield Council and others.

Lord Patel: We are likely to end up in a situation where the science—let us focus on GM insects just now—is the same; the gene drive, gene editing, is the technology that is used for GM modification of insects. When it comes to public understanding of whether this science is harmful or not or whether it can be beneficial, both to crops and human health, the regulation will thwart any further development, as we heard in the last evidence session. Do we need to be ahead of that and, as the US National Academy of Science has done, inform them of what the science is likely to deliver?

Dr Jack Stilgoe: I think there is, as I say, value in doing those sorts of exercises. I think they work best when one does not presume in advance what the public understanding of the issue is or what the public fears are. Instead, you go out and ask people. That I think should be a part of any good inquiry, and that is something that the Royal Society and other organisations have been doing now for decades, and doing it very productively.

The Chairman: Professor Mumford, do you agree with that reply?

Professor Paulo Paes de Andrade: May I add some words on that?

The Chairman: Yes.

Professor Paulo Paes de Andrade: I think that the scientific discussion is very welcome but that scientists are not the right people to talk about risk communication; they are usually very bad communicators indeed. What happens is that they discuss among themselves, they come to conclusions and they put out nice words, but words that sometimes cannot be completely understood by the general population. Moreover, they are not risk assessors, so

if they meet to discuss risks they possibly will make bad mistakes. I really encourage scientific discussion but I do not agree that scientists should discuss risks by themselves. They should sit together with experienced regulators to learn from them how to do risk assessment before stating whether or not something is risky.

Lord Peston: I accept that, in a democracy, we have to have meaningful public involvement. I accept that as a Member of the House of Lords, which is totally undemocratic. My worry is that most members of the general public have no idea of the concepts of risk or uncertainty—the great Frank Knight distinction; uncertainty being the really hard one, because it essentially amounts to "the unpredictable always happens"—let alone that the general public believe that if you toss a coin, and it is a fair coin, and it comes up three heads in a row, the probability of it coming tails next time has gone up. What worries me enormously is, why do we have experts if we have to consult the public on matters where they simply do not understand what the problem is in the first place? Dr Stilgoe, I am addressing you because you know a lot about all this. I know we have to bring the public in somewhere but, wearing my professorial hat, I am very worried about what they can say other than: "We are worried".

Dr Jack Stilgoe: The quick answer—as I said, this runs the risk of being another degree course—would be that the reason why one needs to talk, and should talk, to people outside conventional experts is that people are experts in different things. As my former boss, Lord Rees, former member of this Committee, was fond of saying: "Experts are depressingly lay outside their own specialisms". Also, when it comes to matters of GM insects, they are not simple, technical problems. They are riven through with all sorts of political questions which are actually legitimate points of public discussion and should be rightfully informed by expertise. However, the idea that any single or even group of experts will be able to come up with a complete understanding, let alone a complete understanding that determines a decision, I think, is just a misunderstanding of science.

Lord Peston: I am not disagreeing with you. I get things wrong, and have done all my career to an enormous extent. In fact, mostly my wife will tell you if I say what is going to happen, bet against that if nothing else. If you take a different field, such as pharmaceuticals, where all these sorts of problems arise and we have very strict regulations, on the whole we do not seem to get the public involved. Why is this area different?

Dr Jack Stilgoe: I would say there are all sorts of channels of public involvement throughout all sorts of regulations.

The Chairman: Lord Patel, I think you wanted to finish off your area of questioning.

Lord Patel: It was not directly related but I wanted to ask Professor Andrade whether they have used GM insects to increase sugar cane crops in Brazil.

Professor Paulo Paes de Andrade: GM technology for sugar cane?

Lord Patel: Yes, insect modified.

Professor Paulo Paes de Andrade: Insect modified?

Lord Patel: Yes.

Professor Paulo Paes de Andrade: Not yet. I do not know of anyone working on that.

The Chairman: Thank you all very much for your evidence; we are very appreciative of it. We are particularly grateful to Professor Andrade for having come a long way to help us. I do not know if any of you have any final comments you want to make. If you think of something after the meeting you wish you had said, please send it in; otherwise, we will draw to a close. Thank you very much indeed.