HOUSE OF LORDS

Revised transcript of evidence taken before

The Select Committee on Science and Technology

Inquiry on

GENETICALLY MODIFIED INSECTS

Evidence Session No. 9 *Heard in Public* *Questions 87 - 99*

TUESDAY 10 NOVEMBER 2015

10.40 am

Witness: Dr Ladislav Miko

USE OF THE TRANSCRIPT

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Members present

Earl of Selborne (Chairman)
Lord Fox
Lord Hennessy of Nympsfield
Lord Hunt of Chesterton
Lord Krebs (co-opted)
Baroness Manningham-Buller
Lord Maxton
Duke of Montrose
Baroness Morgan of Huyton
Lord Patel (co-opted)
Lord Peston
Lord Vallance of Tummel

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Examination of Witness

Dr Ladislav Miko, Deputy Director-General of DG SANTE, European Commission

Q87 The Chairman: Good morning, Dr Miko. Thank you very much, to you and your colleague, for joining us today on this link. I should just explain that this is being broadcast on our broadband network, so I am going to ask you to introduce yourself, for the record. If you would like to make any opening statement to us, do please feel free to do so.

Dr Ladislav Miko: Good morning. My name is Ladislav Miko. I have worked as a deputy director-general in the DG for health and food safety of the European Commission since 2011. One of my responsibilities is also in the area of biotech and genetic modifications. I would like to thank you for giving both me and the European Commission the opportunity to participate in this inquiry on GM insects. I understand that this issue has already led to interesting discussions in the Committee, and I am pleased to provide you today with an insight into the regulatory approach on the GM animals issue at our level in the EU.

I would like to start by stressing that the Commission is in favour of innovation, which is a core driver towards growth, jobs and competitiveness in Europe. Obviously, the innovation has to be in tune with the broad values of society and match the demands of the European citizens. This is why the European authorisation system for biotech products is based on sound science and strict case-by-case risk assessment. I would like to highlight that, as of today, there is no pending application for GM animals in the European Union. However, in order to be prepared for expected and possible future applications in this field, in 2007 the Commission requested that the European Food Safety Authority develop guidelines for the safety assessment of genetically modified animals for food and feed and release into the environment. EFSA published in 2012 and 2013 two guidance documents: one on the environmental risk assessment of genetically modified animals and the other on the risk assessment of food and feed from genetically modified food animals and on animal health and welfare aspects. Should an application for genetically modified animals be submitted into the European Union for field trials for placing on the market, the existing European Union legislation on GMOs and the EFSA guidance documents would be appropriate. GMO

labelling requirements would apply to any GM animal and its derived products in line with the GMO legislation.

I would like to underline that the Commission closely follows the development of genetically modified animals. We are aware of citizens' concerns that might be raised in the future, as described in a recent research project funded by the Commission. I am looking forward to the discussion we will have this morning, and I hope that I will be able to help you probe some of the areas raised in the previous sessions, and establish a clearer picture for the scientific community, regulators as well as the public, as it will be needed.

The Chairman: Thank you, Dr Miko, that is very helpful. Would your colleague like to introduce herself?

Dr Ladislav Miko: I can introduce her. She is Dorothée André, who is the head of Biotechnology Unit. You cannot see another colleague from the same unit, who is here if I need any assistance in terms of documents or papers.

Q88 The Chairman: Welcome to our meeting from a distance. Thank you very much. Let me start the questioning. We note that the deliberate release of GMOs directive is, effectively, the regulation which determines the release of any GMO, whether crop or insect. In practice, do you think it is fit for purpose for GM insect technologies, recognising that when the directive was drafted insect technologies probably were not as well understood as they might be now? Do you think that the regulatory environment could be improved in respect of insects?

Dr Ladislav Miko: Yes. In short, I would say, I think the existing legal framework is sufficient and fit for purpose. Until now we have never had any applications, so we do not have practical experience; but, as we have theoretically tested the system, it should be working and applicable also for the case of GM insects.

The Chairman: In the light of that, do you think that there would be a willingness by member states to reform the regime in respect of GM insects?

Dr Ladislav Miko I am not sure that I understand the question. I believe that the existing framework will not need to be reformed. Basically, we can proceed within the existing legal framework in the case of GM insects. I do not see any obstacle or problem with the process, so basically it will start flowing as it is regulated now. As much as we can assess, there is no need to change anything in the legal framework.

The Chairman: No, I understand.

Dr Ladislav Miko: If you are asking about the positions of member states towards this issue, that is very difficult to predict from my point of view. I can only refer to existing experience with crops. As you know, the system which is set up is based on the scientific assessment by our scientific body, which is EFSA, based on the application, and then proceeding—which includes the positions of member states and their vote. Obviously, the European Commission is obliged to follow this procedure. We have had very different views of individual member states to genetic modifications in general. For me, it is very difficult to prejudge what would be the situation with GM insects. If the patterns that we have witnessed in the crops are followed, we can expect that some member states will support, some will not, and some will abstain. In the final result, what we have had in the crops as a general rule, basically from the beginning, is that the respective committee will reach no

opinion on any of the genetic modifications. The legislation covers that situation. It requires another try, and so forth, through the appeal committee. Following the appeal committee, if there is still no result, the Commission will be obliged to decide on the issue, which is the case. That is how we basically approve the GM.

The Chairman: One of the issues is that when the directive was originally drafted, some of the concepts we have on the horizon now, on gene drive and gene editing, were probably not as well developed. We therefore wonder whether the directive needs to take account of advances in the technology. From your response, I understand you think the directive is still fit for purpose for GM insects.

Dr Ladislav Miko: I have lost the picture—I can hear you but I cannot see you. I hope you can see me.

The Chairman: Yes, we can see you.

Dr Ladislav Miko: We believe the development of new techniques is not influencing, at least for now, what we have been looking at as far as the existing regulations being able to address these issues. The question will potentially be whether this or that technique will fall under the scope of this regulation. That needs to be carefully assessed but, per se, the regulation can work and deliver.

Q89 Baroness Morgan of Huyton: Dr Miko, we have had a fair amount of evidence that has effectively said that the current regulation is fit for purpose in theory, but not in reality in the way that it works. In a sense, the regulation functions at the scientific level, but as soon as it leaves the science committees, it is overruled and changed by politicians, and consequently very little is moving forward in the EU with, obviously, potentially detrimental effects both economically and scientifically within the EU. I wonder whether you would like to comment on that perception. We have had a range of people giving us that impression. When you say "fit for purpose", they sort of agree but then it does not function.

Dr Ladislav Miko: As I said, the problem is not in the legal framework. The problem is in how it is implemented, as you indicated; but on the other hand, there are procedural steps that we have to follow. Obviously, we have to reflect the scientific opinion, and this is what we have as the basis for the proposed decision, but then we are obliged to follow the voting of the member states and they have a right to represent their views. The reality is that in the history of this legislation we have never had a clear opinion either for or against any proposal. So, every time we have ended up with what is called a "no opinion" situation where the Commission has to decide. Then it follows the process and sometimes, because of the difficulties in the past in the political discussion, when they came to the level of a Commission decision, some decisions took a longer period. But since we started with the last Commission, President Juncker's Commission, the issues have been reviewed from our side, and we came up with solutions which we believed would help. One of the blocking elements in the political discourse was the issue of cultivation and we came up with a proposal on opting out for those countries which have other legitimate reasons for opting out of cultivation. Despite a very complex and lengthy discussion on this proposal, at the end we can say, after adoption, it really works. You may know that out of 28 member states, 19 actually used this legislation, including some parts of the UK, which indicates that for those who are willing to correctly follow on a scientific basis the approved safe products for cultivation, they can do so. We were also considering and proposing the same approach for

food and feed uses. Nevertheless, this is the proposal which is now in discussion, and we have a rather negative attitude in Parliament and we will see what the final position will be in the Council to this proposal. This is a little strange for us because we genuinely thought, as with cultivation, this could ease the procedure. I cannot say now about the result because the discussion in Council is not yet concluded.

Q90 Lord Fox: Thank you for coming today, Dr Miko. You mentioned food and feed being in difficulty in terms of the opt-out. Insects are clearly not in food or feed, as I would regard them. Do you think they are potential candidates for this opt-out process? Do you think that would have a positive effect in moving towards some sort of implementation in disease control?

Dr Ladislav Miko: Yes. I repeat that, as the Commission, we do not have any experience, so what I can give you is my personal assessment of the situation. For us, I think that the sensitivity of the GM process has a clear link to the food or the feed. When we speak about the particular case of insects—if we do not speak about insects as a source of food or feed, but about their other uses—I expect that we would have fewer problems in the procedure, but we do not need to change or modify the existing legislative framework. I think we can go through, and I would not expect as many problems as we had with the food or feed-related applications.

Lord Fox: In your introduction you used the word "animals" throughout, and you seem to have bundled everything into one classification of creature. Is there some merit for unbundling that? Where you have insects, which are clearly not part of the food and feed play or objective, is it beneficial to pull them out and have a separate classification rather than as animals—as insects?

Dr Ladislav Miko: Sorry, I am not sure if I understood your question.

Lord Fox: You seem to have bundled everything that was not plants into animals. So you spoke of animals as a single classification rather than perhaps breaking that up into different uses and different objectives.

Dr Ladislav Miko: Not really; sorry if I was not clear. We are analysing all non-plant issues, and what we can expect in the near future, and looking at how to deal with the potential applications which come from the non-plant side. Basically, it is looking at fish, insects and potentially other animals that could be genetically modified. According to these tests, we are convinced that the existing procedures and framework could work. We do not need to adapt any specifically for the animals. We wanted to be prepared in case we concluded there was a need to change something, we needed to have some time to do so, but the conclusion was that we do not need to change the legal framework.

Lord Fox: To be clear, if the insects are not regarded as food or feed, then there is more chance of the opt-out working in their favour?

Dr Ladislav Miko: I would not say the opt-out, I would say the smooth application process. We do not need to opt out. Theoretically, when there is an application for insects not intended for food, I expect we will get the application filed with all the necessary information following the guidelines from EFSA. We will ask EFSA to assess all the existing risks, we will get EFSA's opinion, go to the committee and vote on the approval process. I do not see, in any element of that, any particular problem or obstacle. My judgment—of course, because we do not have the experience—is that this process would be smoother and

faster than the other processes because there is no link to food, which creates the sensitivities in some member states' positions.

Duke of Montrose: Dr Miko, on this question about the need for an application, does this need to be made at a national level, or are you asking for researchers or companies to submit applications?

Dr Ladislav Miko: It depends what you are speaking about. If we are in the phase of the scientific trials, then the application should be submitted to the national authority in the country where the trials are going to happen. If you are speaking about the approval of the genetic modification for use in the European Union, then the application should be submitted to the European Union and assessed by EFSA.

Q91 Lord Hunt of Chesterton: There are a number of different models for the regulation of GMOs internationally. Canada regulates the products rather than the process, and therefore uses a different word. The G word, or the GMO word, makes life difficult, as you have explained. In fact, the House of Commons suggested using some other words, particularly for GMO insects. Do you have a view on that? Perhaps I may follow that up with another question. What research is the Commission sponsoring to clarify these issues? Research, presumably funded by you, will have some European acceptance. Is that in fact an important part of your strategy? The EU has its own laboratory at Ispra. Is it involved in helping to establish the best way forward for regulation?

Dr Ladislav Miko: Yes. First, on the potential different types of approach to regulation, we do not think that changing the model from the European one would deliver a better result. We believe that the existing one is appropriate. We could discuss trait-based regulation, for example, as a model, or the model in Canada and other countries which includes the socio-economic benefits as part of the assessment. Personally, I would expect that it will not change the pattern, because it is linked to the GM as such. Secondly, we will only extend a potential amount of the products which need to go into the approval process because we check now—I am being very simplistic—only if the GM application is as safe as its non-GM counterpart. When we vote for the trait-based regulation we will have to assess any result of the breeding which brings a new trait—be it GM or not—so it will extend rather than limit the approval process, and we do not believe this will be helpful for the process.

Regarding the research in the Commission, I have to say that we have very limited capacity ourselves to do the research. Obviously we have our Joint Research Centre, which also looks at the GM issues, but it is rather more about the needs of regulation. For example, methods of assessment or methods of detection of GMs help us to select the ones which could be broadly used in the European context in a harmonised way. They do not do the GM research per se. We finance the GM research within the rather large amounts of moneys that are distributed to the European researchers via DG Research and Innovation. I am aware that there are some projects which allow for researching genetic modifications, but this is support to science in general. It is usually not a concrete question to be answered, but rather support for the new trends in genetic modification to support the innovation process. I do not have with me an overview of the projects, but if you would be interested in that, I would recommend either to go to DG Research colleagues or, alternatively, we can provide you with a written overview of the projects relevant to GM in the last five years.

Q92 The Chairman: That would be useful. Thank you. Could I follow up your reference to the Joint Research Centre? We understand that the JRC's Institute for Prospective Technological Studies in Seville hosts the European GMO Socio-Economics Bureau. Has this group considered GM insect technologies?

Dr Ladislav Miko: I do not think that we had a particular assessment of any GM insects in socio-economic terms because basically it was always about the crops.

The Chairman: What is the role of the European GMO Socio-Economics Bureau? How does it connect with the regulatory process, whether for crops or insects, or any other GM? What are its functions or benefits within the regulatory framework?

Dr Ladislav Miko: If we are speaking directly about the approval procedure as such, there is no direct work by this bureau, but we have plenty of discussions with member states related to the potential benefits as, let us say, a counterweight to the potential risks. For that, we need to establish a capacity which will be able to analyse and provide us with quantified potential positive effects. In this sense, the bureau is delivering the information which is then used in our role as the risk manager, so when we then decide, and substantiate our decision, on the application before the final approval, we can use the results of their work. I would say that the bureau is not directly responsible for a better or worse result of the approval, but it is rather our tool to provide arguments on the positive socio-economic effects in particular decisions.

The Chairman: One of the issues that has come up time and time again, as we have taken both written and oral evidence, is the need for an exchange of technical and scientific information regarding the socio-economic implications of GMOs, whether insects, crops, or anything else. We would be very interested to know whether you feel that this bureau could play an enhanced role. We know very little about it ourselves.

Dr Ladislav Miko: It is quite difficult for me to judge, to be honest. In my view, all the experience we have shows that the position of member states which are not supporting the GMs will not be dramatically changed by any socio-economic analysis. I may be wrong, but this is my opinion. It is rather useful for us because we need to communicate broadly with the public, and with the scientific community, and we need to provide information because, as I said, every decision in the end is a decision by the Commission, because there is no opinion. We need to show the reasons for that because the issue of the socio-economic impact is often raised in the vote as one of the reasons why member states abstain and do not provide an opinion, and we feel obliged to have this information in our communications. So, for that reason, it is helpful. I do not believe that making it an obligatory part of the procedure or the decision-making will dramatically change the patterns of the vote, because I do not think this is the major reason for it. I think that the data on the benefits are more or less highlighted quite well in the applications. The companies which come with applications try to show why they do it. We try to extend it and, with the help of the bureau, to analyse it in the European context, so we are able to answer some of the questions, but I do not believe the approval procedure would benefit if we add the socio-economic analysis as an additional step. It is rather the argumentaire for the final decision where we can use this information.

The Chairman: That is helpful. Lord Fox, do you want to follow up or have you covered the point?

Lord Fox: No, I think I have covered it. Thank you very much.

Q93 Lord Patel: Dr Miko, I would like to explore with you the level of awareness in both the Government and the public of GM insect technology. What do you think shapes that view? Are the attitudes of the Governments of different EU countries being shaped by the attitude to GM crops? What do you think is the level of awareness of the different EU member states?

Dr Ladislav Miko: First, I think you are right that the main debate, and the main source of the positions of the member states to GMs, is linked to food and feed, or the food chain, if you wish. I think this is the reason why the crops are treated as they are. Personally, I do not think there is a broad awareness about the non-food/feed insect GM technology within Europe. I think most of the public have no clue that something like that exists. If we are to get any application we will have to invest, and I assume the companies developing these methodologies will also have to invest, in communication of this tool. I am reluctantly more optimistic—I do not want to wait because it is difficult to predict with that technology—because we have very clearly seen that the other GMs which are not related to food do not have particular problems going through the system. If we are speaking about the medicines based on GM technology, for example, they go through quickly. There is support. We do not have any problems with that. If it is not food, there is a broad acceptance. If it is well presented and communicated—and here we are speaking, and are very well informed, about the plant protection use of GM insects—I would be rather optimistic about the result.

Lord Patel: Is there not a risk—and you had a good example with GM medicines where GM medicine applications are controlled and regulated by the Medicines Regulatory Authority—that in this case any applications related to GM insects will go to the GM authority, which mainly concerns itself with the crops, and they would not understand the distinction, especially as there is, as you say, no awareness of the benefits of GM insect technology?

Dr Ladislav Miko: I disagree slightly. Of course, there are different authorities deciding, and the problem is not in the authority but in the substance. When the issue is linked to food and feed, the member states and the public remain sensitive. Even if you consider distinguishing between pure food and feed uses and cultivation, there is a much more dramatic negative reaction when it is about cultivation, which means releasing GMs into the environment, compared with their use. GM feed in particular is so broadly used in Europe that, even if we have no opinion by the member states in the process, the usage of GM feed is accepted. Maybe there are one or two countries which do not use it broadly, but all the others use GM feed for their animals. As you can see, there is acceptance if there is a clear and beneficial use. If we are able to communicate, together with the applicants and the scientists, that this is a tool for caring for plant health and is nothing to do with the food chain per se, the result should be easier to achieve.

Lord Patel: Do you think that your evidence today and our inquiry are going to help raise awareness about GM-insect technologies?

Dr Ladislav Miko: There is already quite a lot of information that we could use, but there is a question about the extent to which it is advisable to start this communication campaign before we have practical examples of applications. As I said at the beginning, this is very much a case-by-case issue, so we need to know the details of the application in order to communicate properly. What I see as a big risk is if we, let us say, communicate something in

general and then the application is divergent in certain details from what we communicated before, it is highly sensitive and will be used against this communication. I think it is better to communicate on a concrete case, where we know all the details, and then we can cover all the questions related to this particular case.

Q94 Lord Peston: Some of us regard the antipathy to GM crops as entirely irrational and not based on any evidence whatsoever. Is there any danger that this irrationality will spill over into the question of GM-modified insects, so that a life-saving strategy—admittedly long term—will be denied to those who need it most, namely those in the poorest countries in the world? Do you see this as a danger, or are you confident that it will not happen?

Dr Ladislav Miko: To be very direct, I cannot exclude that because we have witnessed all kinds of abuse coming from Europe. I cannot say a priori that nobody will hijack GM insects within this discussion, but the probability for that is much lower than the issues related to food and feed.

I also want to say that, yes, on one side it is clearly without scientific assessment, so we can say it is completely irrational, but we also have to admit that the legislation recognises what are called "other legitimate factors", so we should admit that there are issues other than science which should be taken into account, because this is required by the legal framework. We cannot blankly deny it if someone is raising these issues. We have to assess carefully each of them and address them. Obviously, if you have reasons like culture, tradition or religion, et cetera, these are areas which are very difficult to assess by scientific methods. As the legislation recognises that such reasons could exist, we cannot avoid discussing these issues.

Q95 Baroness Manningham-Buller: Dr Miko, thank you for helping us on these issues. Perhaps I may recap some of the things you said. I think you said that you thought there would be less of a problem in this area than in the crop area, and that if the benefits were clear, you have some optimism. But you then went on to say that it was up to the companies which might wish to use this technology to communicate that. At the same time, you felt you could only communicate if you had a specific application to deal with. In our recommendations, which we are going to discuss later, we want to think about how we can resolve these slightly conflicting problems. Could the European Academies' Science Advisory Council be of value in beginning to facilitate these conversations with member states to improve public understanding of the benefits of this technology? What do you think about that?

Dr Ladislav Miko: Obviously, we believe that this is one of the ways. It is nevertheless another issue which we have tried. We have already organised several events—workshops, conferences—of broad or narrow audiences with the member states, relevant industries and relevant NGOs, to discuss these issues. I have to say that it has had some effect, but it is a very lengthy process, very burdensome and also capacity consuming. Nevertheless, in my view, the opt-out as regards cultivation would not have been finally accepted and adopted without that process, where we pushed people around the table and we brought all the evidence together. We had a discussion and we were trying to answer all the questions related to that—on the one side, scientific, and on the other, procedural. After that, I would say that there was a better feeling by the participating bodies that things can move forward. In my view, it makes sense to invest in discussion, awareness-raising and communication. It

should be very well structured—and this will look a little controversial from what I said before—and when you have a discussion, it is better to have a discussion about the general elements which are questioned rather than a concrete application, because in a concrete application you have pre-set positions of the players and they usually have very little space to debate. When you discuss the issue per se, there is more willingness and acceptance of the arguments.

When we come to a new area, for example GM insects for plant health, we need to explain what it is in general, and that could be done also in the way you describe, but we need to use a concrete proposal as an example to answer more detailed questions if they come. Yes, in principle, it is beneficial, but we only have a certain capacity to do it.

Last years, at the request of our Commissioner, who was very keen to go for the discussions, we organised three events. To organise three events, from our point of view, is an overload, and we were overworked and at the limits of what we could do. That is why I say it is also for member states, industry and business operators to contribute to that.

Baroness Manningham-Buller: Can I make one observation, Dr Miko, and ask you one final question? I think you have touched on my observation. There is an argument that you prepare people to think about these issues before there is a specific application, so that there is plenty of time to think through the principles. You seem to be saying that you cannot have these debates very easily without a specific application. Is that really what you are saying?

Dr Ladislav Miko: Sorry, the point is what we want to communicate. It is relatively easy to communicate the general principles. We could have a GM application that is not food or feed related, which falls, nevertheless, within the framework of our legislation, and we can communicate why it is good, and whether or not there are potential risks. We can do that. If we do not know enough about a concrete application, we will not be able to have the discussion, or to answer concrete questions.

My judgment is that it will not be helpful because in such a discussion people will say, "In general it's fine but the devil is in the detail. So unless we know exactly what you are proposing, we cannot actually tell you our view". In that sense, we need to have a concrete application in order to be more detailed in the answers. If a campaign is needed to introduce the technology per se, that could be done in general, but I do not think that it will be helpful if it is us who starts with that. I think we need to be able to answer the questions and that is not possible without an application.

Baroness Manningham-Buller: You said that in the last years you have had some of these debates and meetings, which had been quite resource intensive, so you saw some value in them without having a specific application. Do you plan to have any more next year?

Dr Ladislav Miko: These discussions were only about crops and the problems which were repeatedly raised where we had divergent rules, so it was about how the risk assessment is done, how it is communicated and how the risk management is done. We had a very clear scope for the discussion and experience from the concrete cases, so we could answer the questions from experience.

Q96 Lord Hunt of Chesterton: I want to ask you a question about Europe and the rest of the world, because of the frustration felt by some groups that there is no research involving GMOs in other countries, for example in Brazil. What is the policy of the European Union?

The EU is a major international player in diplomacy. In some senses, will you be encouraging the application of EU research in other parts of the world where there is not this problem of regulation? In particular, how is the EU working on this with the main United Nations agencies—the Food and Agriculture Organization and the World Health Organization—because I believe they respect very much the EU's work. Finally, it seems to me that if we can get international projects working, then that may be one of the ways of educating or explaining to European politicians and groups the value of this approach.

Dr Ladislav Miko: First of all, we generally follow the line of supporting any pro-export activities. This is not excluding anything, including potential GM products produced in Europe. The difficulty is that we can export our science, but we can hardly export our produce, because there is no GM produce in Europe, except in the area of medicines. In general terms, my answer would be yes.

We also have very close contact and collaboration with international agencies and bodies. The discussion usually comes back to the situation in the European Union and how we can speed up our procedures, rather than about the limits of our export of science results or technologies outside. I do not see any problem. It was not raised as a problem and I do not think there is a difficulty there.

If you ask about the active promotion of concrete science results, we do not have a mechanism to do so. At the moment, when it comes to the application, and if it is part of the export—and obviously I can only speak for the food and feed area—we are prepared to do whatever we can for the promotion of European products.

I have one comment on countries such as Brazil, China, India and others. One of the elements of why GM is so broadly accepted is the dramatic change which has happened in the last two decades through the introduction of GM technology there. It was one of the tools which contributed dramatically to solving poverty issues, securing food for the poor people in these countries, and also providing job opportunities. It is connected with a very well-perceived, immediate, positive effect by many people. Therefore, the general atmosphere in the acceptance of GM is much broader because the people have witnessed themselves the positive effects.

One element of the European reality, and I am speaking about food and feed now because it is one food chain, is that people do not see the need—and now I am speaking in general—because they do not have the feeling that we have a problem with the production of the very broad variety of different foods, et cetera.

One of the ideas we have been developing in the last few years is to find the arguments which will show those European citizens who are, let us say, doubtful or do not want GM, the concrete benefits that they could bring to them. Generally speaking, you can imagine people going to the supermarket and having two products which are declared by the regulatory systems as the same. One is GM and one is non-GM. What is the reason for anyone to pay for the GM product if they hear from parts of society, "Who knows what the problem is? We don't believe there's a system"—blah, blah, blah—and the authorities say, "Actually, it is the same", so they say, "Okay, if it's the same, I'll take the one I know. I don't have a reason to go for the GM". I think this effect—which I have not described very well but I hope you understand what I mean—is here, and there is not a push from society for these technologies, which could indeed save many people in the developing world, could help

many businesses, and jobs, et cetera. There is no question about that, but the perception in the European public is not like that in many places, although not everywhere.

Q97 Lord Fox: You have talked about the need for a concrete example in order to start the process of communicating. There is credible evidence, from what we have received from other speakers here, that the scientific community is put off from going through the process of the member states giving no opinion, the Commission then punting it back, and it going round in circles, so you are almost in a catch-22 situation. What message do you think the current process sends to researchers in this area? Also, it has not been clear in anything you have said, and that is because we have not asked, whether you value this research? Is this something that you think we should lead on? How is the regulatory process helping the objective of delivering leadership?

Dr Ladislav Miko: Absolutely not, sorry. I was concentrating on explaining our regulatory role. As I said at the very beginning, we are very supportive of anything which can contribute to innovation efforts in the European periphery, and GM is clearly the road to that. Yes we do value, obviously, the new applications. If you ask me, I am a biologist and an entomologist by education, and I found this application to be a very smart and very good solution, which has very close to zero risks. If I may assess it—and I am not the one who has to assess it—it is very low risk and has very good benefits. It is a very smart and very good approach, which I really think should be supported. It will have another side effect because we will need to use fewer chemicals to address the same problems, et cetera. There is no question that this is a very positive idea.

You mentioned that sometimes we are in a kind of catch-22. It is difficult for me to judge because we have not had, I repeat, a single application for GM insects in our system. I do not think it will be the case here. I think it will be fairly simply processed and adopted once we get it, with of course the required information which is given in the guidance from the EFSA. You referred to the process in Spain with the trial. This is very difficult for me to comment on because I do not know the details. I know that there was a demand for additional scientific information and the company decided to gather this information throughout one or two seasons, so it was a reasonable load and timeline. There was additional information provided and then the conditions, which had been set up by the national body—and I do not know the details of why—were so difficult for the company that, instead of getting an inconclusive or negative opinion, they would rather withdraw. This is my information, but I do not know the details about that. So, it is difficult for me to comment.

Q98 Duke of Montrose: Dr Miko, your recommendations appear to be that you want specific applications either from companies or countries on particular issues. There is a whole European issue, and I do not know whether Europe has a body that looks into this whole question of the vectors of diseases, a great many of which are insects. We have had some fairly disastrous examples of diseases being carried across Europe. Will Europe be looking at overall research and control on that aspect?

Dr Ladislav Miko: Yes. This is broadening the scope of the discussion, but, yes, we should address it. In my view, we are now in the process of addressing the crisis preparedness of the European Union in relation to potential harmful organisms coming into both the animal and plant health areas, and here we are not speaking only about food. Indeed, we are now concluding that the risks, especially in plant protection, are growing, and we can expect

more and more dramatic impacts, which are also linked to climate change, globalisation of trade, more goods being moved, et cetera. In that sense, we started already with an information campaign that we need to increase our ability to deal with a potential crisis in that area. It is not specific to GM, but indeed you are right, the GM solution could be presented and promoted here as one of the elegant solutions for cases where insects are vectors. That is true and we can include it in this discussion. We are just at the start of this campaign, of this work, so there is no problem including this example as one of the modern tools on how to address the problem.

Q99 The Chairman: Could I put a last question to you? I think we have recognised that the burden of insect-borne diseases falls particularly on low and middle-income countries. That is the nature of dengue fever, malaria and much else. In answer to Baroness Manningham-Buller, you explained how you had the capacity to structure dialogues with participating bodies. Would this include the potential beneficiaries of these lower and middle-income countries? After all, it seems that there is a disparity. Much of the excellent research in this field comes from North America and Europe, and the beneficiaries will be in other countries, so there is a need to have continuity between research workers and potential beneficiaries, if there are to be any. Do you think, were you to be able to structure a dialogue, you will be able to involve such potential beneficiaries? Could I also ask, just to be quite clear—and I may have missed the point—when you set up these dialogues and the discussions, who owns the discussion in Europe? Which body are we talking about?

Dr Ladislav Miko: May I start from the end? The discussions were organised by the Commission at the initiative of our Commissioner. We invited all interested parties to these discussions: businesses, member states' administrations, member states' bodies and civic society, represented by NGOs or different organisations. We usually also have the international bodies present, by the way.

This brings me to the first part of your question. It is very difficult to structure this dialogue individually with all potential partners. We collaborate quite closely with international organisations such as the OECD, FAO or specialised expert bodies, such as the OIE or the Codex Alimentarius, where we are trying to present and promote solutions which have been found or born in Europe.

Within the activities at this international level, we communicate and propagate European solutions. I am not aware—which does not mean it does not happen—of particular meetings addressing the concrete beneficiaries in the different regions of the world. Apart from one thing, we have a system called Better Training for Safer Food—BTSF—where we invest quite a significant amount of money in addressing the problems at source. We send in our experts and we teach, train and pass information to the regions of the world where there is a problem, either a problem for the locals or the problem of the food which is later exported to the European Union, because that was the reason we established that. This is a mechanism by which we can pass the information and communicate with the potential beneficiaries, and we are using it to the extent we are able to. There is quite a comprehensive budget for that and, as I said, our inspectors and experts from the EU level, but also from the national level, are part of these BTSF activities throughout the world. In different parts of the world we have quite a comprehensive amount of these efforts.

The Chairman: We said that we hoped to have you available to help us for an hour and we have taken an hour of your time. We are most grateful. We have run out of questions on this

end. You have very kindly said that you will send us some further information on an overview of GM science, particularly the research over the last five years and, if you could send us that information, we would be enormously grateful for that. We will read the record in order to pick up any other points. You will get a copy of the transcript in case any minor corrections are required because our transcript is incorrect in any respect. On behalf of the Committee, thank you for being so forthcoming with us today. It has been most helpful to us.

Dr Ladislav Miko: Thank you very much. Obviously, we will provide you with the material as discussed. I hope I was able to help you and to elucidate some of the issues which are relevant to our work in the GM area. Thank you very much for the invitation.

The Chairman: Thank you.