



## Science and Technology Committee

### Oral evidence: [GM foods and application of the precautionary principle in Europe](#), HC 328

Monday 1 December 2014

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Written evidence from witnesses:

- [Professor Joe Perry](#)
- [Professor Joe Perry \(supplementary\)](#)

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Members present: Mr Andrew Miller (Chair); Jim Dowd; Mr David Heath; Stephen Metcalfe; Stephen Mosley; Graham Stringer

Questions 304-405

Witnesses: **Dr Elisabeth Waigmann**, Head of Genetically Modified Organisms Unit, European Food Safety Authority, and **Professor Joe Perry**, Chair, Genetically Modified Organisms Panel, European Food Safety Authority, gave evidence.

**Q304 Chair:** I welcome our two witnesses. Thank you for travelling to the UK today for this session. Quite a lot is happening in Parliament today, so one or two of my colleagues are popping in and out. Do not regard that as any slight on your evidence; it is just the way things work in this place. Can I formally welcome you and ask the two of you to introduce yourselves?

**Dr Waigmann:** My name is Elisabeth Waigmann. I am the head of the GMO unit in the European Food Safety Authority. By training, I am a molecular biologist and plant biochemist. Before I came to EFSA I worked in research for quite a long time.

**Professor Perry:** My name is Joe Perry. I worked at Rothamsted for about 30 years, where I studied quantitative ecology. I worked on the Farm Scale Evaluations of GMHT crops. I retired from Rothamsted in 2006 and joined the expert GMO Panel of EFSA, which I now chair.

**Q305 Chair:** For clarity, can I ask you about the respective roles of the European Food Safety Authority's GMO unit and the GMO Panel? What are the differences between those two bodies?

**Dr Waigmann:** In most cases the GMO Panel is the group that will adopt a scientific opinion. Generally, they are opinions on GM market applications, guidance development and also ad hoc requests from the European Commission or self-initiatives. The GMO unit, to quite a large extent, is a bit like a mirror cabinet. We have similar expertise in the scientific staff in the unit and we support the Panel, both scientifically and administratively. Scientifically, that means that we prepare the analysis of applications. We read all the studies and support a first draft to bring it to the working group. We also have some outputs of our own, which are covered by the founding regulation; for example, we do explanatory notes for guidance, or we have emergency requests from the European Commission. Typically, this is done from the staff side because we are faster and do not need to go through the procedures that are linked to the Panel opinions.

**Professor Perry:** I agree with all of that. The experts on the Panel are independent academics and have a recognised track record of publication in journals. Our declarations of interest and CVs are on the EFSA website for everybody to look at. When they first join the Panel, the experts might have experience of GMOs, but it is not essential. They may have experience of regulation and risk assessment, but again that is not essential when they join. We serve for a maximum of three three-year terms and we develop expertise in risk assessment while we are serving. Typical disciplines for us would be molecular biology, toxicology and ecology. The unit has expertise in GMOs and in risk assessment. Since EFSA started in 2002, it is fair to say that the unit has gradually assumed more responsibility for initiating text. Although the Panel is responsible for adopting the documents, and ultimately responsible for the safety of the half billion European consumers, the unit does a lot of the text initiation these days, and the Panel often acts as referees, in addition to acting as authors.

**Q306 Chair:** If an application comes forward for the cultivation of a GMO, how long does it typically spend inside the regulatory system?

**Dr Waigmann:** I heard that this question might be coming, so I did a bit of work on numbers. For a cultivation application, you need to understand that for the first part the environmental risk assessment is done by a member state. The application will then move completely to the member state, which will also send questions to the applicant, if necessary, and then draft a report. When we get the report, EFSA's risk assessment starts, so there is a two-step procedure. On average, from validity—meaning that we deem the dossier complete—to adoption takes nearly four years. For about half that, or 2.09 years on average, it is on the side of the member state. You could say that overall it is a shared time frame. However, the legal deadline is six months and, typically, in most cases, we are within the legal deadline. How is that possible? It is possible because whenever we send a question to the applicant, we stop the clock that ticks throughout the six months. We wait for data to come back to us, and when we are satisfied with the data we start the clock again, and the time keeps running.

**Q307 Chair:** Any time frame that is beyond six months in practice is because of questions you pose to the applicant and, presumably, delays in the first part of the process at member state level.

*Dr Waigmann:* They also pose questions to the applicants, and then we stop the clock in the same way.

**Q308 Chair:** Are there any other factors that influence the time frame?

*Dr Waigmann:* That is the most important one. On the member state side, sometimes they cannot submit the report immediately it is finalised, for various internal reasons, but from our side we pose the questions and then we wait for the answers from the applicant before we open the clock again.

**Q309 Chair:** I want to explore the status of opinions given by EFSA under current legislation. If EFSA were to say that a particular crop could be developed, is any other authorisation needed under the current legislation?

*Dr Waigmann:* Yes. EFSA is only on the side of the risk assessment, so our opinion is not at all an authorisation. The following procedure is on the side of the member states, and the European Commission starts out with a public consultation on our opinion. That is done under the auspices of the European Commission. We receive comments from the public, look at them and provide feedback to the European Commission. The whole procedure will be better explained by other colleagues, but there is a whole comitology procedure before it comes to an authorisation. Our part is only the beginning.

**Q310 Chair:** Under the current legislation, is it legally possible for an EFSA opinion to be regarded as sufficient, or are you saying that under the framework of legislation it has to go through other procedures?

*Dr Waigmann:* To my knowledge, yes. When we have an opinion under 1829/2003, which is our main legal framework for food and feed, it by no means indicates that it is going to be authorised. A whole procedure has to be followed afterwards.

**Q311 Chair:** This is a procedure other than the Commission, so your report does not go just to the Commission.

*Dr Waigmann:* It goes to the Commission, but it is published on the website.

**Q312 Chair:** What I do not understand is why that report is not sufficient for the Commission to make a decision.

*Dr Waigmann:* Under the procedure the first step is that the member states vote. This is done in standing committee and, depending on whether or not a qualified majority arises from the vote, that would be the end of the procedure, but typically in the GMO area no qualified majority is reached. That is why it goes through several further steps in the comitology procedure.

**Q313 Stephen Metcalfe:** What sort of influence does the European Commission have over EFSA's scientific guidance and assessment? What is the relationship when it comes to the science?

**Professor Perry:** The European Commission does not develop the guidance; the Panel develops the guidance and publishes it. Sometimes the Commission might take the guidance and translate it into a legal implementing regulation; I will come back to that in a minute. I think the problems would come because the Panel focuses entirely on the science—that is really all we are interested in—and ignores the politics, whereas obviously for the Commission the politics is a key driver. This can create some tensions. I will give you maybe three examples. The Panel feels an increasing need to be transparent about uncertainty, which is also an EFSA policy, but the Commission as risk manager may find it easier if our final text is clear and unambiguous, so there might be difficulties in reconciling those two aims.

To give another example, we have a clear duty to assess all the environmental effects, including the indirect effects on biodiversity of herbicide-tolerant GM systems. Recent Commission draft proposals say that our opinions in future should not consider that risk but that it should be assessed instead under the pesticide regulations. We do not think that is currently adequate; we do not think it is done adequately under the pesticide regulations, and some members of the panel may refuse to comply with that request. It is an area on which the UK Government spent €10 million in the Farm Scale Evaluations. I think it may be of concern to member states and to conservation organisations.

Another example, possibly a more major one, was the way the Commission used political considerations when it translated our EFSA food and feed guidance document into Implementing Regulation 503/2013 and ignored the advice of the panel, which was that the 90-day feeding studies should not be mandatory; but they are now mandatory, legally.

**Q314 Stephen Metcalfe:** It is pretty clear that a tension exists between the panel and the European Commission. Do you feel that too much political influence is being exerted upon you, certainly in the framing of regulation 503/2013?

**Professor Perry:** The fact that the 90-day feeding studies are now mandatory has created a problem for us, when we stated very clearly that there was no need for that on scientific grounds. I could go through the reasons. We have to think how, if we get these studies, we are going to assess them. Of course, we have to assess all data that come in, but how will we assess those studies? That has created quite a scientific challenge.

**Q315 Stephen Metcalfe:** Have you expressed to the Commission your concerns about political influence being exerted on a scientific committee?

**Professor Perry:** I think the Panel expressed this clearly to the Commission at the time of the finalisation of the Implementing Regulation, and put forward at least four reasons why we felt sufficient data existed without those.

**Dr Waigmann:** The Implementing Regulation, as with other regulations, is owned by the member states; they are the legislators, so our frame has been set by two main regulatory

frameworks where areas are outlined in which we should do risk assessment which we observe. For example, the ERA guidance document very closely followed the general issues outlined in Directive 2001/18.

With the new implementing regulation that Professor Perry mentioned, the step was in the other direction. We developed a guidance document, and many elements of that document were taken and put into an implementing regulation, but the member states and the European Commission—the legislators—added elements, so we were in a chain of events. First, we had the regulation; then we developed guidance documents; and then it went into the implementing regulation, not one to one but with additional elements. That is the hierarchy of the process.

**Stephen Metcalfe:** That is very useful. Thank you.

**Q316 Stephen Mosley:** Professor Perry, I know you have been quite scathing about some of the evidence we have seen. ACRE said that “environmental harm” was “not defined in the EU GMO legislation”. Has it been? As far as EFSA is concerned, how do you define harm for the purpose of GMO risk assessment?

*Professor Perry:* We start with risk, which is hazard times likelihood of that hazard occurring; you cannot have one without the other. You do not assess just on the basis of hazard; you also have to assess also on the basis of likelihood, which is sometimes called exposure. And then change. Change is not equivalent to harm. How do we define harm? Let’s go back and look at the type of data we have. We look at differences between the GM plant being tested, if it is a plant we are assessing, and the conventional plant with which it is compared, so it is a comparative analysis. We would look for adverse effects on human or animal health or the environment, and they may be detected as differences between the plant and its conventional comparator.

But just because you detect a statistical difference—a sensitive statistical test may reveal such a difference—does not necessarily mean that the effect is large enough to be biologically relevant. The difference is regarded as harm if the magnitude of the difference exceeds a threshold recognised by experts as representing a biologically relevant effect. EFSA has published an Opinion on that, which contrasts statistical significance with biological relevance, and defines a relevant effect as being ‘large enough to alter the way decisions are taken on a particular problem’. That is not very helpful, and it depends on the biological field we are talking about. In toxicology, any type of histopathological change might be regarded as relevant, whereas in ecology you might have an effect where, say, 10% mortality in the life stage of a lepidoptera—an insect—may not be considered harmful if the population, through its population dynamics, could recover in a sufficiently short time. In some areas, small effects will be regarded as harm; in other areas they may not be. To decide exactly what size of effects is harmful is probably the responsibility of the risk manager. We are risk assessors in EFSA, not risk managers.

In practice, the panel gets no guidance on this and has to try to make its own decisions. I do not want to make it more complicated, but it is, because quite often we are considering hundreds of end points; it is a multivariate problem. If I were to say that I had found a difference in one end point, that might or might not be a concern, but if I said that I had found five differences in five end points and they were all related to liver function, it

would begin to be a bit more of a concern. You can see that we are often looking for patterns rather than specific differences, because we know that one in 20 statistically significant differences will occur by chance anyway.

I have made it a bit complicated, and I admit that it is a difficult area. When I ask biologists, as I often do, “What size of effect do you consider demonstrates harm?” it is probably the one question they hate to answer, and in general try not to, or take a long time to answer. It is clearly critical in effects on human health. We get environmental effects, and there we have protection goals that we know member states are interested in—things they want to protect—and those should be translated by risk managers into specific measures of harm, but they rarely are. In EFSA we have a Protection Goal Working Group which is trying to harmonise across various disciplines to answer this question: ‘what is harm?’

**Q317 Stephen Mosley:** You say you are the risk assessors rather than the risk managers. Who should those risk managers be? Who should be the people giving this definition?

*Professor Perry:* The risk managers are the European Commission and the member states, but in practice there might be a lack of resources, and possibly a lack of will, in tackling the difficult problem of translating protection goals, such as “We want to protect biodiversity.” What do we mean by that in essence? Do we mean we want to protect all butterflies from all mortalities, or are we okay if 2% of them are killed? What exactly does it mean? Answering that would be very helpful to us, and that is the kind of feedback we are not getting or that we haven’t had over the years.

**Q318 Stephen Mosley:** Are you assessing those risks on a European-wide basis, or do you look at individual local specifics as well?

*Professor Perry:* We recognise that environments within the EU vary, so our environmental risk assessment guidance has a whole section on receiving environments. It is not just that those environments differ. The difficulty is that member states have different ways of interpreting protection goals and they need harmonisation across the EU, because there are anomalies. There are also anomalies, as has been pointed out in previous evidence to you, because the legislation differs between pesticides and GMOs, for example, and you are legislating the same type of system.

**Q319 Jim Dowd:** On transparency and the acquisition of data, we heard in an earlier session that between 95% and 99% of the information EFSA receives is available publicly. Can you confirm that, and what is not disclosed from the data submitted to you?

*Professor Perry:* Yes. As I said, we take transparency very seriously. The reason I take it seriously is that GM is a rather controversial area and we get criticised from all directions. The only way to meet that criticism is to show, first of all, that we are independent, but also to demonstrate that we have reached our opinion on the basis of evidence and show the public how we reached that decision. It is not enough just to publish an opinion. Early opinions of EFSA might have been 15 pages; now, this one is 85 pages. They are much longer opinions than they used to be.

Transparency leads to public confidence. To quote Elisabeth's predecessor, Per Bergman, if a company applies to market a product to be fed to our children, is it not reasonable for the data to be available to all the public? In general, it is. The only things that typically are withheld are the exact molecular sequences at DNA level. They are withheld for confidential business information purposes.

**Q320 Jim Dowd:** Would applicants request that of you when they submit the information and the data?

*Professor Perry:* Yes.

*Dr Waigmann:* Applicants will typically submit two versions of the dossier: one contains the complete information and one is the public access version. Accessibility to the data is based upon a very informal procedure. One sends an e-mail to EFSA that says, "I would like to see the data in the dossier." You give your list and we give access. The applicant in the first place establishes the public access version, as Joe said. You referred to a percentage. I did not quite hear the numbers.

**Q321 Jim Dowd:** It was said to us that it was between 95% and 99%.

*Dr Waigmann:* The vast majority of the data are publicly accessible already in the applicant's public access version. Later on, there is a step where the European Commission also confirms that, so the final decision on the remaining confidentiality claim is made between the applicant and European Commission. Applicants have learned that very few data can be withheld from public access, and sequences are quite frequently among those. Then there is data protection in terms of names, study authors and so on, which will be kept confidential.

**Q322 Jim Dowd:** Are you reasonably satisfied that the applicants submit all the information they have and are not withholding elements that may be to their disadvantage?

*Professor Perry:* It is difficult to be reasonably confident of that when you as a Panel ask a question. A lot of the questions we ask will be along the lines of, "We don't think this study is of sufficiently good quality. We need more data to be able to reach a conclusion." A lot of the questions mean that the applicant has to generate data. It is not just asking them a question; they have to go away and do some work, which is one of the reasons why it can take so long for an applicant to come back with an answer before the clock starts ticking again. But on quite a number of occasions we ask an applicant a question about a study, and they immediately come back to say, "We've got one, and here it is." Since they clearly had that on their shelves, they had not given us all the information. Having said that, it would not be helpful for us to have every single trial that the applicant has done in other parts of the world, such as Asia, because quite often the guidance under which those regulatory authorities are working may be different from ours, so those data may not be useful to us.

My impression is that it is not the case, as has happened in some pharmaceutical applications, that safety considerations have been swept under the carpet. It is not that they

are withholding data because it shows their product is unsafe; it is just that they do not give us all the information we ask for.

**Q323 Jim Dowd:** It is your secondary interrogative process that reveals that, is it?

*Professor Perry:* Yes.

*Dr Waigmann:* In the new implementing regulation, which has been in force since the end of last year, one of the elements is that applicants need to provide a list of all the studies that have been done on the product in question—not the studies themselves—so that at least we know. As Professor Perry mentioned, it would not be useful to get all the studies that had been done in different regulatory frameworks when some were done in a way that we would not accept anyhow.

**Q324 Jim Dowd:** Professor Perry, you said earlier that you were keen to establish your credentials as an independent organisation. There are those who would claim that there has been insufficient independent research into the impact of GMOs on human health.

*Professor Perry:* You have had evidence of that from GM Freeze, which I thought was ill informed. I take this document as an example; it is an opinion on MON810 which we published in 2009, and it is available on our website. If you go to the back, there are about 180 references to the scientific literature. The vast majority of those references will be to independent academic research in refereed, peer-reviewed international journals, so clearly we do not just use the evidence that the applicant delivers. We keep abreast of the scientific literature and use all the evidence we can.

There are two things. First, in my written evidence I pointed out that the precautionary principle, which you are inquiring into, states that it is the applicant who is responsible for gathering the data. The second thing is that it is obviously true that the dossier of information presented by the applicants, which is about that tall—about a metre of paper—contains very detailed information that is just about the application itself. In the scientific literature there may be more general information which does not necessarily always relate—sometimes it does—to exactly the event or application we are looking at, but we always look at the literature, because if there is anything in it that raises a safety concern, it is our duty to pursue it, look at it and use it in our assessments.

**Chair:** We are going to explore the precautionary principle a little further now.

**Q325 Stephen Mosley:** As I understand it, the European Commission said that the precautionary principle should be used when there is not enough data to conduct a full risk assessment. Is that fair?

*Professor Perry:* I am not sure whether or not it is fair. You will have to ask the experts in the Commission. I looked at what the European Commission says about the precautionary principle, which is quite sensible, and has been given in previous evidence to your Committee. It is on EU websites in about three different places. In broad terms, there is nothing much wrong with the way it is framed. However, we on the Panel hardly ever talk about, refer to or discuss the precautionary principle; it just does not come up. Obviously,



NGOs raise it, although I do not think they follow the exact definition that the EU uses. The only major area that is not being taken care of is benefit. The risk managers—the Commission and the member states—are meant to do a detailed analysis of benefit. We cannot do that. All we can do is analyse risk. We are not allowed legally to look at benefits at all; so we do not - but they are meant to. Whether or not it is lack of resources or expertise—I do not know what it is—quite clearly this is not being done. The sort of work done at the University of Reading on life-cycle analysis, looking at energy flows, carbon sinks and so on, is not, as far as I am aware, done in any depth.

**Q326 Stephen Mosley:** In terms of the work that you do and the items before you, do you see the full scientific data?

*Professor Perry:* We see the data concerning risk, so we see the hazard and exposure data. We do not see anything about benefits, because the applicant does not submit anything about them.

**Q327 Stephen Mosley:** In terms of the risk posed by the process, do you believe that the evidence you see is incomplete, imprecise or inconclusive, or would you say the opposite?

*Professor Perry:* I would say the opposite. We have given an opinion on maybe between 40 and 60 applications on food and feed, import processing and also cultivation. Certainly, on the food and feed safety side, we are very confident in our opinions. Very occasionally they are partially inconclusive, where we do not have the data, but that is rare. For the ones that are fully conclusive, I would have no hesitation in being confident that they show that the crops we have assessed in the past are as safe as their conventional counterparts.

**Q328 Stephen Metcalfe:** To go back to the issue of taking account of potential benefits as well as potential risks, how could the system be changed so that benefit was included as part of the assessment? What would your recommendations be?

*Dr Waigmann:* I would like to underline that it is out of our remit at the moment. We are only asked to look at safety, not at benefits at all, and not at efficacy. In other areas of EFSA those are included, but not for us. We also need to define the type of benefits. If you are talking about the socio-economic sector, given the way we are set up at EFSA, in the GMO area at the moment we would not have the expertise in-house, because we are really focusing on risks. We have natural scientists, but we have nobody who would do economics. If it was more to do with whether a conventional pesticide spray was ecologically more or less damaging along scientific lines, possibly you could consider having experts from two different panels, who are used to working in their respective areas, sitting together on a committee to make that comparison, but once you get into socio-economics EFSA is not set up for that at all. You would need to establish competence, maybe in another body.

**Q329 Stephen Metcalfe:** If you were to look at the overarching regulatory framework, should that include taking account of benefits?

**Dr Waigmann:** Whether or not the framework we have at the moment should do that?

**Stephen Metcalfe:** Yes.

**Dr Waigmann:** There is some interesting information to be gained, in particular for the risk manager, because at the end of the day, you might be in a position of needing to choose between different possibilities. If there is something like a benefit assessment, you might be in a better position to choose, but the decision on whether it is realistic to set it up—I do not think it is easy to come up with a benefit analysis on a socio-economic scale—really lies with the Commission and the member states. To go into that is not a triviality.

**Q330 Stephen Metcalfe:** One other suggestion or idea we have had is to move away from a regulatory system looking at process to a traits-based system. What would be the challenges in assessing traits rather than the process, and how might we overcome those challenges?

**Dr Waigmann:** To my knowledge, there is a system in Canada which is more trait-based and not technology-based. One question that comes to my mind is how one would set the frame and delimit it. You say that you are going to a trait-based system, but what will be considered a trait that would fall under that trait-based assessment and what would still be outside? At the moment, in the technology-based area we have an ongoing discussion on what to do with new techniques that do not clearly fall under the GMO regulation and also are not clearly outside it. I think that in a trait-based system you would have a similar discussion, because somehow you would need to set limits. I am not sure that at the end of such a process there would not be more in the regulatory frame than at the moment, so in the end the challenge could be a qualitative one but maybe also a quantitative one.

**Professor Perry:** I agree with that. We should not assume that it is going to be less work; nor should we confuse, as I said in my supplementary written evidence, the idea of a trait versus process-based regulation with a search for unintended effects, because the two are completely separate issues. Health Canada, which has been mentioned by Elisabeth as the only regulatory authority that regulates on the basis of trait rather than process, still looks for unintended effects. Even if one accepts the argument, which I have heard put forward in evidence, that the technology is not inherently risky, the Health Canada guidelines say, “the wide variety of manipulations possible through genetic modification, and the potential for the introduction of toxic compounds, unexpected secondary effects and changes in the nutritional and toxic characteristics of the food product may give rise to safety concerns.” And that is just plants. So I do not accept the argument put forward that we have assessed plants for 15 years and not found any problems; therefore there aren’t going to be any in the future and we should not do any more assessment. As Elisabeth said, techniques are changing all the time. We have recently developed guidance for GM animals, and I am sure there is a need to continue to assess and regulate those. I just hope that we are not going to throw the baby out with the regulatory bathwater.

**Q331 Jim Dowd:** I want to look at the proposed amendment to the deliberate release directive. I would appreciate your assessment of what you feel the impact of that could be on the cultivation of crops.

**Dr Waigmann:** We looked through the amendments. What one notes is that in the latest version there are several spots where one of the grounds on which member states could choose to opt out of cultivation is risk assessment. A number of items are listed in the amendment and several of them clearly address risk assessment, and it is not obvious why there needs to be a local component. You could argue that for some of them EFSA makes a general risk assessment and the member state would then look in a lot of detail at their regional specialities, but for several of them I do not see where the local component is. To me, a large part of that is covered by the EFSA risk assessment, so it would be a repetition but maybe with different outcomes. I do not know how that would work in practice, but I would say that such a move would result in a bit of duplication.

**Professor Perry:** I completely agree with that. The panel is very conscious of the difference between need to know for the risk assessment and what it would be nice to know as a scientists, but it costs money to provide data. We realise that and we try to be proportionate in what we ask for. That is difficult, but that is what we try to do. We ask for data proportionate to the risk we are assessing. In our view, there is no need to weaken or strengthen the current guidelines for the information we ask for.

People with an agenda are either pro or anti. The panel are not acting as advocates pro or anti; we are just independent and we do not really have a view either way. We are passionate about the science, but not about whether we are pro or anti. People with an agenda always try to say, “You need more evidence. You need more data”, if they are the Greens who dominate the European Parliament, and the plant scientists you have already heard from will say “You need fewer data and less regulation”.

The document from the European Parliament that I have seen is highly political; I do not see the need to strengthen the risk assessment procedures for environments. I think there is no good evidence for that, because the procedures have not yet been tested. A new guidance document for environmental risk assessment was published in 2010 in response to a request from the Environment Ministers of Europe to look at things like long-term effects and receiving environments. We did that; we now have a lot of material in the guidance. That guidance has not yet been tested, in the sense that we have not received any new applications for cultivation since it came out in 2010, because—as you know—applicants feel that the atmosphere for cultivation in the EU is not conducive for them, so we have not had an opportunity to go through the assessment process under the new guidance. In my view, there is no need at all to start to change it.

**Q332 Jim Dowd:** What you have said, Professor, covers the other supplementaries I had on this subject. I am grateful for that. If I have understood you, what you are saying is that there is no scientific basis, of which you are aware, for what the amendment suggests, and basically it is just a political fix.

**Professor Perry:** Yes.

**Jim Dowd:** That has the virtue of both brevity and clarity.

**Professor Perry:** Thank you.

**Q333 Mr Heath:** There are new biotechnologies coming along, like genome editing. Is it your expectation that the Commission will see the current GMO legislation as sufficient to deal with them?

*Professor Perry:* The Commission has already realised that there are problems with legislation framed in 2001 and 2003, with new techniques coming along all the time. They have already asked us to look at techniques such as cisgenics, where one takes a gene from a plant of the same species and places it in another plant, and zinc finger nuclease techniques. We have delivered an opinion as to whether our guidance would be sufficient, and also whether or not it would be fit for purpose to assess those techniques, and whether further or less information might be needed. New techniques such as RNAi are coming out, and I think the Commission has a real problem in legislating according to what is quite old legislation. We will do our best to give an opinion on whether or not our guidance would be fit, and in most cases it would because it is relatively stringent; for cisgenics, for example, we said that we would not always see the same need for as much data as is submitted at the moment.

**Q334 Mr Heath:** It is certainly stringent, but is it still proportionate?

*Professor Perry:* It could be that fewer data might be needed, which is the conclusion in that opinion, but it is case by case.

**Q335 Mr Heath:** The risk assessment process might be different for those technologies than it is currently, or would it be largely the same process but perhaps with differing degrees of data required?

*Professor Perry:* I imagine it would be similar in the sense that it would look at molecular characterisation, toxicology, allergenicity, nutrition and environmental effects, but we cannot say exactly what it would look like. I think it would take a long time for the European Union to pass new legislation.

**Q336 Mr Heath:** I think so too.

*Dr Waigmann:* A case-by-case approach is embedded in the current system. If, for example, there is a history of the use of a protein newly introgressed in a plant by transgenesis, we have some things that do not need to be done. That flexibility is part of the system we have now.

**Q337 Mr Heath:** Can I take you back, Professor Perry, to something you said a little earlier? You were talking about risk management being a role for either the Commission or the individual member state, having received your opinion. Do you give guidance as to what might be the appropriate risk management?

*Professor Perry:* We give recommendations when we are asked to. For example, MON810 is a maize that is insect resistant, so it expresses a Bt toxin which can have an effect on non-target butterflies and moths. Part of my personal research is to look at the ways in which those risks can be both quantified and also mitigated. Previously, we have

worked on requests from the European Commission. When we look at mitigation and those effects, we are moving into risk management. EFSA is set up officially only for risk assessment, but we try to help. At the moment there is someone very good at the Commission with whom we work very well on that particular problem.

**Q338 Mr Heath:** Is it published when you give that advice?

*Professor Perry:* Yes. We have published in the *Journal of Applied Ecology* and the *Proceedings of the Royal Society* as scientific papers, and also within our Opinions. I remember that Professor Sir David Baulcombe mentioned in his evidence the 1507 maize and said that it had been around for a long time. EFSA first gave an opinion on it in 2005 and we gave a supplementary opinion in 2009. As a result of the potential risks to non-target lepidoptera, the European Commission came back to us in 2010 and said, “Will you give us further evidence?” We gave them further evidence as urgent requests in 2011 and 2012, and yet 1507 is still waiting for approval.

**Q339 Mr Heath:** Would you be confident that when member states adopt safeguard clauses they do so on the basis of robust evidence, or does it again become a political issue?

*Professor Perry:* In my view, it is too often a merely political ploy which has in the past wasted the time of the panel. In their safeguard clause they are meant to supply new scientific information, and too often it does not. I remember one from France, which was little more than a cut and paste of our previous output. Clearly, that did not contain any new scientific information, yet the panel had to spend a lot of time on it, which is precious time, because we only meet in plenary eight times a year. We have a lot of more important opinions to try to adopt. Fortunately, the unit now helps us with those safeguard clauses, but I am sad to say that sometimes their time is wasted too.

**Q340 Mr Heath:** Would it be reasonable to say that you feel slightly frustrated by the process?

*Professor Perry:* Yes—frustrated.

**Q341 Jim Dowd:** Can I look briefly at some of the post-market environmental monitoring? Are the current requirements based purely on science, or do they also take into account social concerns about GM crops?

*Dr Waigmann:* The current requirements are based on two elements: general surveillance and case-specific monitoring. General surveillance is mandatory at any rate, so it is not dependent on the outcome of the risk assessment. Case-specific monitoring is linked directly to the outcome of the risk assessment, so we would say yes. If the risk assessment has a remaining concern or uncertainty, that needs to be addressed, and if the panel recommends case-specific monitoring, which would then be taken further up than in an authorisation decision, clearly that is rational and should be based on science, and in my view it is based on science—on what we have been doing.

General surveillance by its nature is a generic hypothesis, so you are not targeting a specific issue. Apparently, it is based on literature surveys and overviews, which I think is very reasonable, and there are farmer questionnaires filled in by the cultivators. There is a pending issue about using existing environmental monitoring networks in different member states. This does not function to a very high degree yet, because there is no harmonisation in data collection between the networks. Also, they are not always happy to donate their data, so this element is not really in place. By and large, I think it is quite reasonable.

**Q342 Jim Dowd:** General surveillance seems to imply almost indefinite engagement. Is that a proportionate response to the risks posed by GM?

*Dr Waigmann:* I think that at least one should be following the literature. You need to know what is going on in science and keep your eye on developments. The basis of a scientific risk assessment is that you keep monitoring the literature, and not only in the frame of general surveillance. We do it all the time anyhow, and also the applicants do it.

**Q343 Jim Dowd:** For all agricultural products—pesticides and so on.

*Dr Waigmann:* For GMOs, we do that.

**Q344 Jim Dowd:** What about other agricultural products? Is this a normal scientific approach for pesticides?

*Dr Waigmann:* I thought you were asking me about how it is related in the frame of monitoring for GMOs.

**Q345 Jim Dowd:** Yes. What I am trying to uncover is why the approach for GMOs is different, if it is, from that for other agricultural products.

*Dr Waigmann:* I would say that in other areas of EFSA the literature is there too. This is not unique to us.

*Professor Perry:* It is certainly the case, as I said before, that we were asked to address long-term effects in our environmental risk assessment guidance update, which we did in 2011. Scientifically, it is difficult to assess long-term effects. It is certainly difficult to imagine how one could gather data on long-term effects without doing some general surveillance. I cannot say whether or not I think it is proportionate, but I can give you an idea. In the farmer questionnaires that go out, I think about 250 farmers are questioned every year. It will be about 10 years before there is sufficient statistical power to detect a reasonable-sized effect. You will probably only detect quite large effects with farmer questionnaires. It is difficult to imagine how you would look at long-term effects without somehow going back to the people who are growing it. They are the guys who really know and are the first to be able to look around and say, “That’s happening; that’s unusual.”

**Q346 Jim Dowd:** You are saying that you need at least 10 years' experience either to detect trends or to identify developments.

*Professor Perry:* Yes.

**Q347 Jim Dowd:** How far into that are you now?

*Professor Perry:* We have been assessing the reports on MON810 for about four or five years.

**Q348 Jim Dowd:** It is far too early to say, by your requirement, whether any unexpected effects have emerged compared with the risk assessment.

*Professor Perry:* Yes, but there are no signs of any such effects yet. Also, we did our best to cover long-term effects in our original assessment. We would find it difficult to detect any small effects in the run of data that we have so far, but we still feel fairly confident about our opinion on the long-term effects of MON810.

**Q349 Jim Dowd:** You see nothing to indicate that the risk assessment may have been significantly in error.

*Professor Perry:* There is nothing to indicate that either in the reports or from the scientific literature.

**Chair:** I thank the two of you for coming this afternoon. It has been extremely helpful. Thank you very much.

### **Examination of Witnesses**

Witnesses: **Eric Pondelet**, Director, Safety of the Food Chain, Directorate General for Health and Consumers, European Commission, and **Dorothee André**, Head of Unit, Biotechnology, Directorate General for Health and Consumers, European Commission, gave evidence.

**Q350 Chair:** Can I welcome the two of you here this afternoon? Thank you very much for coming to see us. For the record, would you kindly introduce yourselves?

*Dorothee André:* My name is Dorothee André. I work in DG SANCO—health and consumers—and I am head of the biotechnology unit. My background is that I am an agronomist.

*Eric Pondelet:* I am Eric Pondelet, director of the safety of the food chain, and among the six units dealing with pesticides, food labelling and so on I have responsibility for the GMO unit.

**Q351 Chair:** I understand that an independent evaluation was commissioned by the Commission on the cultivation of GMOs which concluded that the current legislative

framework was “not meeting needs or expectations, or its own objectives”. Is that a fair conclusion?

**Eric Pondelet:** I do not know whether or not it is fair, but it is the conclusion. That was the reason President Barroso instructed us to propose a new system, in particular for member states to be able to opt out. As you probably know, today the current legislative framework for the cultivation of GMOs is for all member states; there is total harmonisation on cultivation. Due to the number of safeguard clauses that a certain number of member states have adopted, we have seen that it is not an appropriate framework. We proposed a new system for the opt-out of cultivation, which is currently being discussed, and we hope it can be adopted by the Council and the European Parliament quite soon, in the coming weeks. That is for cultivation. For feed, there is no major problem. Member states are not always in favour, but we have adopted 58 GMOs to be used in feed and food, mainly feed. It is authorised for food, as you know, but there is a labelling system; food for human beings is labelled. Due to the obligation for labelling, very little or quasi-zero food is produced from GM.

**Q352 Chair:** Apart from the one aspect you have very clearly described, are there any other weaknesses in the current framework, or is that the substantive issue that needs changing in your view?

**Eric Pondelet:** There is no problem in the legislative framework. The problems come more or less from the process of adoption, where member states have to vote with the qualified majority system. We have never had a qualified majority either in favour or against. That means that responsibility for approval always comes back to the Commission, but the problem is the decision-making process, not the legislation on the assessment or approval of GMOs.

**Q353 Chair:** All of this sounds a fairly complicated process. What are the annual costs to the Commission and to EFSA of processing cultivation dossiers and developing associated guidance?

**Eric Pondelet:** The annual cost? In terms of money?

**Chair:** Yes.

**Eric Pondelet:** I do not know. At EFSA we have a scientific process, as described by our predecessor, and a unit of 15 staff. You can calculate the salaries of the staff. I can tell you about the research. The Commission invests quite a lot of money—about €200 million over some years—to try to develop independent research, because as was mentioned by Professor Perry, most of the research is done by the applicants. We want to stimulate independent research by independent laboratories and for that reason we invest, if that is a response to your question about the costs.

**Q354 Stephen Metcalfe:** When I was talking to the earlier panel it appeared that some tension existed between the European Commission and EFSA. Would you like to comment



on the remarks made by Professor Perry in particular? Do you see that perhaps there is too much political influence upon the scientific evidence?

**Eric Pondelet:** I would say there is no tension. Since the BSE crisis, which you were familiar with in the UK, the Commission has established complete independence between risk assessment and risk management. It is now inscribed in general food law. Before the BSE crisis I am sure there was some influence by the risk manager on the risk assessor. Now it is strictly independent. We ask a question, with terms of reference, of EFSA, and EFSA is completely free to deliver an opinion, but we are free to take that opinion into account, or not. We do not have any obligation to follow EFSA's opinion; we are totally free to take a completely opposite decision. That means there is no tension. We ask a question; they answer. They take the time, or they interview, and we adopt. Usually, we follow EFSA. Sometimes we are more severe than EFSA. You call that politics. Obviously, as a risk manager we have to get a vote from member states, but we also have to take into account other legitimate factors, which EFSA does not. In particular, you mentioned the benefits. EFSA has absolutely no role in benefits. The Commission might have a role. We have reflected on that and, if you want, I can develop that in more detail.

We might take a decision different from that recommended by EFSA. May I give you some examples? Bisphenol A, which is a substance used in plastics, has been recognised as an endocrine disruptor by some scientists. Canada adopted national rules to ban bisphenol A in plastic baby bottles. We asked EFSA to deliver an opinion on this. Their opinion was grey, not black and white, but in 2011 the Commission adopted a decision to ban bisphenol A in plastic for baby bottles. EFSA did not recommend this; they said we could mitigate the risk.

Another example is neonicotinoid pesticides and bees. In 2013 we suspended the use of neonicotinoids in some cultivation for sunflowers or rapeseed oil because there was some evidence, which was very clear, that bees lost their way back to their beehives. Based on different information, in particular other than the science, the Commission decided to suspend the use of neonicotinoids on certain bee-attracting plants. That means we are not bound by EFSA's opinion. There is no tension for us. We have a good relationship. I am sorry. We have no tension.

**Q355 Stephen Metcalfe:** I hear what you say. Therefore, you are free to put into regulation 503 whatever you wish to put in, and you feel that all the requirements that have been detailed are justified.

**Eric Pondelet:** Yes.

**Q356 Stephen Metcalfe:** Including the 90-day rodent feeding studies.

**Eric Pondelet:** Yes.

**Q357 Stephen Metcalfe:** But EFSA does not.

**Eric Pondelet:** No.

**Q358 Stephen Metcalfe:** Could you explain? If that is not a tension, what is?

*Eric Pondelet:* It is not a tension. The guidelines have to be adopted by the Commission, not by EFSA. EFSA propose. We follow the rules.

**Q359 Stephen Metcalfe:** Help me understand why you think it is necessary and EFSA does not?

*Eric Pondelet:* In certain cases, the applicants voluntarily submitted the 90-day studies, sometimes not. Sometimes EFSA requests it. Most of the time EFSA considers that it is not useful. To restore the confidence of citizens through their representatives at the European Parliament, there was a request that the 90-day study be more systematic. It was also requested that the two-year studies for GMO were systematic, because it is compulsory for pesticides. When there is an application dossier for a pesticide the applicant has to submit those studies. Some people consider that it should be similar for pesticides and toxicity, and the same thing could be asked. We requested that the 90-day study should now be compulsory. It was accepted by the member states when they voted. We are now reflecting on two-year studies, despite the fact that many scientists consider that they are not wholly necessary.

Some studies have been criticised by the scientific community, in particular the Séralini study which demonstrates that GMO NK603 can cause tumours in rats. This study has been severely criticised by the scientific community not only in the EU but all over the world, but that creates questions for us. We wanted to verify whether or not a two-year study is necessary. We invested money in research, and there is now a research programme to restart the study to verify whether the Séralini study was done in a proper way. When the result of the study is available, probably in 2016 or 2017, we will decide, because we want to have evidence about whether a two-year toxicity study is useful or whether a 90-day study is enough. If the 90-day study demonstrates some evidence, we might use the two-year study but not systematically.

**Q360 Stephen Metcalfe:** Is what motivates or drives you based entirely on the science, or do you feel that you have to put some politics into this to bring member states along with you? If that is the case, what is the proportion of science to politics?

*Eric Pondelet:* It seems to me that your word “politics” gives some negative input. For me, politics are not negative; they are the way politicians—you are politicians—drive the rules and lives of our citizens. We do not see politics as a negative input. We see politics as a way that the regulation of particular innovative products like GMOs could be accepted by our citizens. Today, in most member states—maybe not the UK—GMOs are not really accepted for food. Few people know they are used to feed dairy cows, pigs, laying hens and so on, but for food many citizens consider that they are not appropriate. We would like to try to convince the citizen that GMOs could be a benefit—you were talking about benefits. Unfortunately, today biotech companies have not really demonstrated that they could put on the market GMOs that are really beneficial for humanity—for citizens—not for themselves in terms of money. Through such actions we would like to restore confidence in GMOs; the GMO technique should not be banned as a

technique. Some GMOs could be accepted or not accepted, but the technique is certainly an innovative one that can bring benefits.

**Q361 Stephen Mosley:** A number of witnesses have highlighted the delays between genetically modified crops getting an opinion from EFSA and the Commission producing a draft decision. Are there delays?

*Eric Pondelet:* Yes. We are guilty.

**Q362 Stephen Mosley:** What are you going to do about it?

*Eric Pondelet:* If you ask me this question, you know the rule. The rule is that the Commission should adopt three months after an EFSA opinion. We have never respected the three months—never—because we need to get approval from member states under that famous qualified majority. When we present to the standing committee where member states have to vote, despite the fact that EFSA has published very substantial opinions, member states have a lot of questions. We stop the clock. We ask the company to deliver new information, not scientific information, which might be on risk management, monitoring and so on. Our authorised rule is to find a solution that commands the widest possible support from member states. We might present a proposal three months after the EFSA opinion, but we have never had a qualified majority. If we present it and force a vote after three months, we are sure that we will have a worse result than if we try to inform and convince member states. As of today, we have never had a qualified majority.

Despite that, we have some rules where the Commission may adopt. We have adopted 58 GMOs for feed and food. We had three for cultivation but only one is left. The European Court of Justice repealed one decision on the cultivation of the Amflora potato, which was not used for food but to produce paper—technical use. But despite the fact that member states do not give a qualified majority and despite the fact that it is a long process, we adopt. It is not as quick as a biotech company would appreciate. In other countries in the world—Canada, USA, Argentina, Brazil—assessment is very quick; the scientific and management decisions are very quick, but we are proud to have probably the best scientific and risk assessment in the world. It is much better than in other countries in the world, but we have to pay the price.

**Q363 Stephen Mosley:** The European Parliament in February 2014 passed a resolution which basically asked the Commission not to propose authorisation of any more GMOs until, as they said, risk assessment methods had been improved. Does that not completely fly in the face of existing legislation?

*Eric Pondelet:* It is true that we have a backlog of decisions. We are waiting for a political decision by the College of Commissioners. The previous Commission, which ended on 1 November, and the new one wanted to give the cultivation proposal a chance, and member states the freedom to cultivate. The previous College of Commissioners and the present one want to be sure that the cultivation proposal is adopted by the Council and the Parliament before calling for a new proposal to approve food and feed GMOs, or GMOs for cultivation. Due to that resolution of Parliament we have a backlog. On political

grounds, it is difficult for the College of Commissioners not to take into account a resolution voted by the European Parliament.

**Q364 Chair:** Following on from that, you started your response to Mr Mosley with the very straight answer that the delays are not good. Do you not regret the fact that consequent on this very slow process we have now lost from Europe two research-based companies? Syngenta and BASF have transferred to the United States. Is that not a bad reflection on the machinery of Europe?

*Eric Pondelet:* I have no personal feeling about that. There is a legal instrument that companies can use if they are not happy with the delay, and they have used it. In particular, the Commission has been condemned for carence in the cultivation of maize 1507—the Court of Justice in Luxembourg condemned the Commission for taking an extremely long time on approving that maize. There can also be a request to the ombudsman. The ombudsman has to verify whether we have, in the jargon, been guilty of maladministration and delay. That is ongoing. We will see what the ombudsman, which like EFSA is also independent, says to the Commission. There is an instrument. My personal feeling has nothing to do with it.

**Q365 Chair:** You pointed out that we are politicians, and we are entitled to express opinions like that. I personally regret the fact that two major companies withdrew from Europe.

*Eric Pondelet:* Of particular companies, BASF has withdrawn some applications relating to cultivation, not based on the length of the approval process but on mainly the difficulties of getting acceptance by citizens and also because some green activists destroyed experimental fields and so on. That is their choice—the choice of the company.

**Q366 Jim Dowd:** We are politicians, but there are those of us who believe that the Commission and all those who work in it are no less political than formal politicians. I want to test the precautionary principle and the way the Commission seems to view it and yet applies it to GM regulation. Let's start with common ground. According to the Commission's website, the principle is relevant where there are reasonable grounds to believe that a product may pose an unacceptable risk to society, or there are insufficient data to make a comprehensive risk assessment. Could we accept that that is common ground and that is the view the Commission holds?

*Eric Pondelet:* We are officials, not politicians. The College of Commissioners are politicians, not us. We are officials. We obey. We are slaves and we obey our political masters. You made a second point.

**Q367 Jim Dowd:** I have a number of other questions which should avail themselves of a yes/no answer, provided we can agree on the proposition I just put to you. Is my understanding of the Commission's view of the precautionary principle accurate?

*Eric Pondelet:* It is accurate, but it has never been used for GMO authorisation.

**Q368 Jim Dowd:** Indeed not, and that is the apparent contradiction that I want to examine. Do you consider that positive safety opinions delivered by EFSA are based either on insufficient data or incomplete risk assessment?

*Eric Pondelet:* Not really. EFSA is working on the valuable science of today. Science today is probably more limited than science will be in 20 years, but EFSA has to work with the best science when it issues an opinion. We do not have the feeling that it is incomplete science or unsafe science. It is the role of EFSA to verify, as explained by the professor, that the company is not hiding negative research, or something like that. It is the role of EFSA to verify that all the scientific evidence has been delivered by the applicants, or by other independent laboratories, to feed EFSA's assessment.

**Q369 Jim Dowd:** I appreciate that, but what you said is simply that we will know more tomorrow than we do today. That is a recipe for doing nothing.

*Eric Pondelet:* No, because we approve GMOs. We have approved. We do not stick to—

**Q370 Jim Dowd:** But you said that is for animal feed.

*Eric Pondelet:* They are approved for food and feed. For food, as for feed, it should be labelled.

**Q371 Jim Dowd:** You do not believe there is a universal threat from GMOs to public health.

*Eric Pondelet:* There is scientific evidence, and then you have the perception of consumers.

**Q372 Jim Dowd:** But that is not science.

*Eric Pondelet:* No. Absolutely. You are right. The perception of consumers has nothing to do with science. I cannot explain the perception of consumers, but it has nothing to do with science. Science is clear: GMOs when grown under certain conditions have no real harmful effect on animals, plants, insects, biodiversity, human beings and so on. The science is clear, but consumers and citizens do not believe the science. That is probably the paradox in the divorce between the science and the citizen's opinion.

**Q373 Jim Dowd:** That is why you need politicians to regulate it.

*Eric Pondelet:* You cannot regulate this.

**Q374 Jim Dowd:** To decide what to do in the light of it? Yes.

*Eric Pondelet:* No. That is the reason we approve it despite the fact that member states do not accept it by qualified majority. The Commission approve because we believe in science; we believe in EFSA.

**Q375 Jim Dowd:** Mme André, you were about to say something. As you have not said anything so far, I thought you might like to come in.

*Dorothee André:* I can confirm that the Commission proposes and then member states dispose, in a way. Even if we propose something based on EFSA we do not have a qualified majority in favour. In the end, the Commission adopts, but when member states vote—this is not the UK’s position in the committee—some believe EFSA is not doing the job appropriately, which the Commission disagrees with because we propose the decision. Others say, “My citizens don’t want it.” In the end, you have to count, because the rule is that the Commission proposes to the committee of 28 member states and then member states vote. The UK has a big vote. France and Germany have a big vote, but you have others. A lot abstain or vote against. We do not have a lot who vote in favour. What Eric says is absolutely true. At the end, we hear a lot of member states saying, “My citizens do not want it. The science is not good. I don’t need this. There is no benefit.” That is the reality.

**Q376 Jim Dowd:** We understand that there is no qualified majority. That has been stated half a dozen times this afternoon. We are trying to establish why. You say the science is not good. That is the first time I have heard that mentioned. I have heard it said that certain citizens across the Union do not like it. I accept that, but science is not a democracy, is it?

*Eric Pondelet:* Please, we do not respond to these questions. Science is nothing to do with democracy; science should be science.

**Jim Dowd:** Indeed.

*Eric Pondelet:* As any scientist will say—the professor will confirm it—there is always doubt in science. It is not mathematics. There is some doubt. Some groups of citizens use those doubts to elaborate a position against GMOs, as is their right. A lot of NGOs and associations criticise the process, saying that EFSA is not independent and so on, and they stimulate lack of confidence in EFSA. We are agreed, but we consider it is up to the biotech companies to promote their products. It is not for the Commission to campaign to promote GM consumption; absolutely not. It is up to the biotech companies to say their GMOs have positive elements, such as less pesticide or anything they can demonstrate, but probably they are failing to convince citizens. They succeed in north and south America but they fail completely in Europe, or at least in most of the countries of the European Union.

**Jim Dowd:** I think I have gone as far as I can go.

**Q377 Graham Stringer:** You mentioned positive benefits that different companies might claim for genetically modified organisms. As I understand it, the benefits—the positive elements—are not considered under the current regulatory system. Is that true, and, if so, why?

*Eric Pondelet:* No. EFSA certainly has no mandate to assess the cost benefit of GMOs. We and the Commission as risk manager can introduce what we call other legitimate

factors—cost benefit. We have established an organisation to treat that problem and to have independent assessment relating to the cost of the benefit of GMOs, but it is completely independent from the scientific assessment. It involves economists and agronomists; it is completely independent. We do not want to give that to EFSA. EFSA has a role. Full stop.

The cost benefit risk should be assessed by another body; we call it the joint research centre. It has established a bureau of cost benefit where 18 member states have been asked to deliver expertise. They will issue a report, probably next year, about the cost of cultivation in particular, and whether the cultivation of GM in Europe brings some benefit for the farmer, the environment and citizens. We already have some information that in Spain, for example, where there are 130,000 of the 150,000 hectares of GM cultivation in the whole EU, the benefit for the farmer is between €0 and €12 per hectare. There is divergent information. We want independent information to see if there is a benefit for different groups of the population, in particular for farmers who grow GM as feed for animals; for the food industry, if they want to produce food; or for citizens. We will have more information on that. We reflected on asking the company, parallel to the scientific application dossier, to present a dossier to explain the benefit to society. We discussed it a lot but it was not introduced in the legislation, so for the moment it is not compulsory; it is voluntary. If the company wants to do so, they can provide information to us, not EFSA. EFSA has nothing to do with the cost-benefit study.

**Q378 Graham Stringer:** Is it not strange to look just at the potential problems and not the benefits in a regulatory system?

*Eric Pondelet:* No. It is a tool for member states to vote and accept, and also for citizens.

**Q379 Graham Stringer:** But you can scientifically evaluate the benefits just as clearly as you can evaluate disbenefits, surely.

*Eric Pondelet:* No. EFSA's role is not to assess the benefit. EFSA's role is to assess adverse and harmful effects on the environment, plants, animals, human beings and so on. It has nothing to do with benefits.

**Q380 Chair:** But you yourself described circumstances where the balance might be some perceived adverse effect versus, for example, applications of pesticides. The balance is in favour of using the crop rather than spraying pesticides which may damage the environment and people. We have heard evidence about that in the context of GMO cotton in Africa, for example. Is it not odd that that balance is not within the remit of EFSA, because that is science?

*Eric Pondelet:* It is not scientific assessment of the risk as we conceive it. It is important for the risk manager to decide whether the benefit is more important than the risk. It is like medicinal drugs. Many drugs contain a small amount of poison, but the benefit is that they cure your disease. There is a balance. If it is too poisonous, it is not authorised as a medicinal product, or only with a lot of mitigation measures. Here, for the moment, according to the legislation, we do not ask officially what the benefit is. The company

explains and gives some information but there is no formal dossier for the application. I repeat that we are reflecting on whether to ask in the future, but it is not yet decided.

**Q381 Graham Stringer:** My colleague Mr Dowd asked you about the precautionary principle. The precautionary principle is always provisional and it needs re-evaluating in time, in the light of new knowledge. What new knowledge and information do you think would be required so that the universal precautionary principle could be put on one side as no longer necessary?

*Eric Pondelet:* We have never implemented the precautionary principle for the authorisation of GMOs. We have used it for bisphenol A in babies' bottles, but not for GM. For GM, it was decided to implement the 90-day study by the applicant. Certain persons might consider that there are not enough toxicological studies. The scientists—the panel—say, “We have enough for the moment.” We want to see whether those famous studies and the two-year toxicology studies, either on a compulsory basis or a request basis, could be useful.

The problem is that today GMOs are used in feed, and animals are usually slaughtered very quickly, except dairy cows which are slaughtered when they are four or five years old. They do not have time to develop cancer. For human beings it is different, but I repeat that in the European Union there is no—quasi no—GM food for human beings. In the USA or Canada, yes. Is it enough to consider that GMOs on the food market in north America for 15 or 20 years demonstrate that it is not harmful, or that there is a history of non-problematic use? I leave it to toxicologists to reply. Remember the BSE story: 30 years of incubation.

**Q382 Mr Heath:** I am still struggling to understand why the benefits are not properly taken into account. I can understand the difficulties of making a socio-economic assessment. I cannot understand what the difficulty is in dealing with the potential environmental benefits, particularly when we are talking about substitution of one product for another. Surely, that is a relevant regulatory issue. If you use one product, which happens to be engineered in this way and it removes the requirement for a highly toxic pesticide or herbicide, that is a relevant issue for the regulatory process, but you are telling me it is not; and that it is simply that the regulatory process is more of a beauty contest than a regulatory system.

*Eric Pondelet:* No. The regulation says that scientific assessment by EFSA shall deal with the risks posed. The regulation to date does not speak on the benefit.

**Q383 Mr Heath:** But why doesn't it? That is precisely the question. Is there any move to make it do so?

*Eric Pondelet:* We can change the legislation. That is true. But today the legislation does not speak about the benefit. To modify the legislation in terms of GMOs is quite difficult. We tried to modify it for the opt-out cultivation system. It took us four years to change half of article 26b. You probably understand from my comments that we are in favour, but completely to change the legislation is an enormous challenge for multiple reasons, in particular the tension between Parliament and the Council.



**Q384 Mr Heath:** I understand that. I think I am beginning to understand why one would ban neonicotinoids and increase the use of pyrethroids, but that is a different matter. Can I talk about another area of change in the regulatory system which has been suggested to us and which we touched on earlier? It is suggested that we should be looking at traits rather than technologies. Unless you take the view, which I hope most scientists would not, that genetic modification is inherently an evil process, it is the trait that should decide whether something is potentially harmful to the environment, to health or whatever. Do you think there is any possibility of ever moving to a system which looks at traits rather than technologies?

*Eric Pondelet:* Professor Perry gave you a very good answer, and we share it. We are not sure that changing the policy will bring a quicker response in terms of approval. If we have to go in your direction, we have to change the legislation, which is extremely difficult because it is a change of policy. We made a political choice not to change the whole system of legislation for cultivation in the old system but to change only half an article, because we were afraid that if we proposed a completely new system of authorisation—policy—it would take years and years and endless discussion with Parliament and member states. The bad science of politics could probably play a role.

**Mr Heath:** I think it plays a role at the moment. Thank you.

**Q385 Jim Dowd:** On the legislation, and what you are proposing, I note what you say about how long it takes to do things in the Commission and the EU generally, but is that not more a commentary on the way it operates than on any particular activity that it undertakes? It is a tower of Babel which would keep people talking for ever, if it could. I see you agree. The new Commissioner in DG SANCO said that it was his intention to review the GMO legislation within six months of taking office.

*Eric Pondelet:* No.

**Q386 Jim Dowd:** He did not.

*Eric Pondelet:* No. Excuse me. President Juncker said he wants to review the decision-making process, to avoid taking decisions that are against a clear majority of member states. It is not a review of EFSA; it is about the way, after the EFSA opinion has been delivered, we decide in the absence of a qualified majority. In the absence of a qualified majority, the Commission decides. President Juncker, in the light of the decision of the Council about the cultivation of maize 1507, where 19 member states were against but there was no qualified majority, has proposed in his programme for the new Commission to modify the decision-making process. The Commission will make a proposal within six months—before the end of April. We do not know yet what proposal it will be, but a proposal will be made to the Council and Parliament, to take into account that commitment by President Juncker, but that is nothing to do with the risk assessment.

**Q387 Jim Dowd:** I am not talking about anything the president said; I was talking about what Commissioner Vytenis Andriukaitis of DG SANCO, if I have the name right—it looks Greek to me—said.

*Eric Pondelet:* He is our commissioner.

**Q388 Jim Dowd:** I have him saying that he would “review the legislation applicable to the authorisation of genetically modified organisms” within “the first six months”.

*Eric Pondelet:* Yes.

**Q389 Jim Dowd:** You endorse that.

*Eric Pondelet:* Yes.

**Q390 Jim Dowd:** So the answer to my question, “Is it this?” when you said, “No,” is actually, “Yes.” That is the position the new commissioner has adopted: he wants to review the legislative framework.

*Eric Pondelet:* Relating to the decision-making process, yes.

**Q391 Jim Dowd:** What aspects of the legislation might be changed by such a review, in your estimation?

*Eric Pondelet:* The decision-making process does not mean the scientific assessment.

**Q392 Jim Dowd:** Taken together with the proposed amendment to the deliberate release directive, in your estimation as a very experienced eurocrat, do you think it will be adopted in its present form?

*Eric Pondelet:* You mean the cultivation proposal.

**Q393 Jim Dowd:** The amendment to the deliberate release directive.

*Eric Pondelet:* As you know, we have entered what we call the trialogue between the European Parliament and the Council, and the Commission has to play the role of honest broker. The two institutions—the European Parliament and the Council—have to agree. The next and hopefully final trialogue will be this Wednesday, when the Commission expect the Parliament and Council to arrive at a compromise agreement, but we do not know which agreement it will be; it is between the two institutions. The Commission has nothing to do with that. I repeat that its role is as honest broker. We have to run from the Parliament to the Council and from the Council to the Parliament to try to find a compromise, but they can decide over the top of the Commission. We made a proposal four years ago. What they are discussing today substantially modifies the proposal we made in 2011, but that is the democratic process in EU institutions. They could agree something that does not please us but we have to accept it. We expect that the Greek presidency, based in particular on the UK, France and Germany—the three important member states—changing their position in June 2014, will breathe new life into the proposal, because it was stuck with no qualified majority. Because the UK, France and

Germany changed their position with a new proposal made by the Greek presidency, that has given a new incentive. We expect that it could be accepted this Wednesday.

**Q394 Jim Dowd:** Were the amendment to the deliberate release directive to proceed, while it provides an obvious mechanism for those who are resolutely opposed to adopting any GMO regime, do you estimate that it will be equally open to those member states who wish to promote it to do so?

*Eric Pondelet:* When President Barroso made that proposal, he expected that the member states would not want to cultivate GMOs. Most do not want to cultivate them; only five member states cultivate GMOs today. But those who do not want to cultivate might give positive approval when we present the proposal in standing committee. They will know that there is no cultivation at home, so they are certain they will not authorise cultivation. We expect that they will not abstain or that they will give a favourable vote when we present the decision to be voted on. One of the basic elements in the proposal is to avoid a lot of abstentions by member states. Abstentions do not count as qualified majority and so on. Those who abstain do so for bad political reasons, but if they know they will not cultivate they might vote in favour or against, so a clear majority might be obtained in favour or against, but not “No opinion”.

**Q395 Jim Dowd:** What the whole process has demonstrated is that the EU/Commission is unfit to deal with this as an EU-wide competence, and it should never have been incorporated as such.

*Eric Pondelet:* I will not comment on this statement.

**Jim Dowd:** I did not think you would.

**Q396 Mr Heath:** When I was a Minister I had the chance to speak to Mr Borg about this.

*Eric Pondelet:* Commissioner Borg, the previous Commissioner?

**Q397 Mr Heath:** Yes. I just wondered whether Commissioner Andriukaitis has broadly the same view as Commissioner Borg. Is he in the same place?

*Eric Pondelet:* You should ask Mr Andriukaitis himself.

**Q398 Mr Heath:** I thought you might know.

*Eric Pondelet:* It is not a question of personal opinion. Mr Borg was not against. It is not a question of being against or in favour. We overcome personal opinion, because we have strict rules of procedure which we follow. Whatever you are personally against or in favour of, we have EFSA’s opinion which we propose to member states to adopt.

**Q399 Stephen Mosley:** With new plant-breeding techniques coming along, such as genome editing, would it be the Commission's intention that they would be caught by existing GMO legislation?

*Eric Pondelet:* It is a difficult process; you heard the statements from the professor. EFSA has delivered an opinion on the eight different techniques. The problem is to classify whether they are covered by GMO or not. If they are not, it is an easy process; seeds will be approved extremely rapidly. If they are covered by a similar GMO process, they will take three, four or five years to be approved. Obviously, the seed industry is in favour of excluding them; some NGOs want to include them within the scope of GM. There is great tension. We are stuck in this process. We have very divergent and strong positions in favour or against. Probably one or two could be non-GM; one or two that could be GM; and some could be in a grey zone in the middle where it would be difficult to classify them. Probably Commissioner Andriukaitis will relaunch the debate with scientists, seed producers, farmers and citizens to try to find a position that meets most of the concerns.

**Q400 Stephen Mosley:** When will that decision be made?

*Eric Pondelet:* It is difficult to tell you, probably in the coming month, but don't take that as an administrative promise. In terms of GMOs we have never respected the deadline, so please do not take that as a commitment.

**Q401 Graham Stringer:** When you are developing new areas of policy, where do you get your scientific advice, and how will that change now that Professor Anne Glover has not been reappointed?

*Eric Pondelet:* Mrs Glover has not really given a scientific assessment relating to GMOs. We get the risk assessment from EFSA. If there is new scientific evidence which has not been taken into account by EFSA—for example, when a member state decides to ban a GMO despite EFSA having given a favourable opinion—we immediately give EFSA the scientific evidence of that member state for it to be assessed by EFSA. All our scientific information comes from EFSA. Each time an article is published in the world, we give it to EFSA.

**Q402 Graham Stringer:** On these issues and the development of policy, you have not met Professor Glover. How many times have you met Greenpeace on these issues?

*Eric Pondelet:* Myself?

**Q403 Graham Stringer:** Or your section.

*Eric Pondelet:* We meet Greenpeace when they ask to meet us, as we meet the biotech industry each time they ask. We never refuse to give an appointment. Never. We have an open policy. Each time an NGO or association asks to meet us—it is a question of timing and agenda—we accept.

**Q404 Graham Stringer:** I understand that. How many times in the last year or six months—it does not really matter—have you met Greenpeace? Is it once a week, once a month, once a year?

*Eric Pondelet:* I do not know.

**Q405 Jim Dowd:** Perhaps when you get back you could drop us a line to let us know.

*Dorothee André:* Yes. It would be on request, maybe twice a year or something like that.

**Chair:** Thank you very much for your attendance this afternoon. Have a safe journey home.