HEALTH AND COMMUNITY CARE COMMITTEE

Wednesday 20 November 2002
(*Morning*)

Session 1

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HEALTH AND COMMUNITY CARE COMMITTEE
30th Meeting 2002, Session 1

CONVENER

*Mrs Margaret Smith (Edinburgh West) (LD)

DEPUTY CONVENER

*Margaret Jamieson (Kilmarnock and Loudoun) (Lab)

COMMITTEE MEMBERS

*Bill Butler (Glasgow Anniesland) (Lab)
*Dorothy-Grace Elder (Glasgow) (Ind)
*Janis Hughes (Glasgow Rutherglen) (Lab)
*Mr John McAllion (Dundee East) (Lab)
*Shona Robison (North-East Scotland) (SNP)
*Mary Scanlon (Highlands and Islands) (Con)
*Nicola Sturgeon (Glasgow) (SNP)

COMMITTEE SUBSTITUTES

Brian Adam (North-East Scotland) (SNP)
Ian Jenkins (Tweeddale, Ettrick and Lauderdale) (LD)
Mr Tom McCabe (Hamilton South) (Lab)
Ben Wallace (North-East Scotland) (Con)

*attended

WITNESSES

Professor Janet Bainbridge (Advisory Committee on Releases to the Environment)
Derek Bearhop (Scottish Executive Environment and Rural Affairs Department)
Ross Finnie (Minister for Environment and Rural Development)
Professor Alan Gray (Advisory Committee on Releases to the Environment)
Dr Steven Hill (Advisory Committee on Releases to the Environment)
Professor Chris Lamb (Royal Society of Edinburgh)
Dr Charles Saunders (British Medical Association)
Professor Tony Trewavas (Royal Society of Edinburgh)

CLERK TO THE COMMITTEE

Jennifer Smart

SENIOR ASSISTANT CLERK

Peter McGrath

ASSISTANT CLERK

Graeme Eliot

LOCATION

The Hub

Scottish Parliament

Health and Community Care Committee

Wednesday 20 November 2002

(*Morning*)

[THE CONVENER *opened the meeting at 10:01*]

The Convener (Mrs Margaret Smith): Good morning and welcome to this meeting of the Health and Community Care Committee, which is in a slightly unusual setting. We have a late start this morning.

Mary Scanlon (Highlands and Islands) (Con): On a point of order, convener, although perhaps you will call it a point of clarification. The committee is carrying out an investigation into hepatitis C and has not finished its consideration of the matter. Given that, and given that the Minister for Health and Community Care will appear before the committee on 11 December, when we will question him about finance, is it competent or courteous to the committee for one of our members to go to the Finance Committee to ask for additional sums of money in relation to that issue? Will you give a ruling on that, convener?

The Convener: My view is that the point of order is not relevant to today's meeting because we do not have an agenda item on hepatitis C, although one is scheduled for the meeting on 11 December. It would be relevant to make the point of order then.

I do not want to go into too much detail, but it is perfectly competent for any member of the Scottish Parliament to go to the Finance Committee with a suggestion on the budget. I intend to write to Nicola Sturgeon to say that, as we considered the budget last week, that might have been a good time to raise the subject of hepatitis C. However, standing orders are clear that it is competent for any member to go to the Finance Committee. Therefore, the action was not incompetent.

Mary Scanlon: Given that we have not finished the investigation into hepatitis C, is it your ruling that it is competent for members of the committee to go out on a limb on matters that relate to committee investigations?

The Convener: My first ruling is that the point of order is not relevant today. I am happy to discuss the point on 11 December, when hepatitis C is on the agenda. I suggest that if you have matters to raise with me, you should write to me and we will consider the issue at that meeting. As I said, it is perfectly competent for any member to raise issues at the Finance Committee.

After 11 December, having heard from the minister, the expert group on hepatitis C and the Haemophilia Society, we will, as a committee, draw up a set of recommendations that will cover the details and the financing of any scheme. It is probably better for us to reserve judgment on the issue until we have heard from the minister and other witnesses on 11 December. You should write to me if you wish to discuss the matter further.

Mary Scanlon: I will, as I do not want to take up time at today's meeting. However, I have put my view on the record that it is discourteous to this committee for a committee member to have raised the issue at a meeting of the Finance Committee.

Items in Private

The Convener: It has been suggested that we take two items on the agenda for this morning's meeting in private. Item 3 is a request for witness expenses. Item 4 is the draft stage 1 report on the Mental Health (Scotland) Bill. Do members agree to take those two items in private?

Members *indicated agreement.*

GM Crops Inquiry

The Convener: Item 2 on the agenda is our continuing inquiry into genetically modified crops. Our first witness this morning is Dr Charles Saunders from the British Medical Association. Good morning, Dr Saunders. We are seated some way away from you—we do not normally meet in this room and the seating arrangement is perhaps not the best. However, we hope that we will hear what you have to say. Thank you for your written submission. Would you like to make a short statement before we question you on your evidence?

Dr Charles Saunders (British Medical Association): Certainly, although I will try to be brief. I thank the committee for giving us the opportunity to give evidence on the health impact of GM crop trials. It may be worth my clarifying that the evidence that the BMA in Scotland has submitted to the committee is based on the report of the BMA's board of science on the impact of genetic modification on agriculture, food and health, which was published in 1999.

The BMA's evidence is set out in our written submission. The key points are that there should be a moratorium on farm-scale trials and commercial planting of GM crops until smaller trials have assessed adequately the environmental and ecological impacts of such crops; that there should be effective health surveillance of people living around genetically modified organism trial areas; and that there should be an immediate ban on antibiotic resistance markers in GMOs. The submission highlights the judgment of the European Court of First Instance that was publicised in September this year. I would be happy to answer any questions.

Bill Butler (Glasgow Anniesland) (Lab): You have said:

"Releasing genetically modified organisms is effectively irreversible … we simply do not have enough reliable scientific evidence on their safety to be able to make a valid decision as to whether there are potential health effects or not."

Can you expand on those concerns? What impact might the transfer of genes from GM crops to non-GM crops have on health?

Dr Saunders: You have asked several questions. If I forget to deal with any of them, please remind me.

It is clear that once we release GMOs into the environment we cannot get them back out. At the moment we do not have enough evidence to show whether the release of GMOs into the environment is harmful to human health. Because we do not have such evidence, we should adopt the precautionary principle in relation to GMOs. The BMA proposes that additional work be done so that we can make a reasonable assessment of whether there are likely to be significant risks. If we wait until the risks are apparent, it may be too late to do anything about them. For that reason, we suggest that we proceed cautiously and keep as close an eye as possible on the potential side effects that may arise.

Because of the novel nature of the product and the technology, it is not yet possible to be certain what the potential adverse effects might be. For that reason, it is difficult to monitor the health of people who consume GM crops or live around GMO sites.

Nicola Sturgeon (Glasgow) (SNP): Those who seek to justify GM crops say that there is no evidence that they have caused any harm. The BMA's written submission argues that the fact that there is no evidence of adverse effects is not the same as knowledge that GM crops are safe. Given that it is difficult to prove conclusively that anything is safe, at what point in the scale would the precautionary principle allow us to say that it was safe to go ahead with GM crops?

Dr Saunders: Part of the difficulty is that, if one does not look for any adverse effects, one is pretty unlikely to find them. We do not know whether there are adverse effects on people who live near the trial sites. Adverse effects may be unlikely, but we do not have enough evidence to say that. The surveillance mechanisms that are in place across Scotland would not pick up any adverse effects unless they were extremely lethal and affected a significant number of people. That is why consideration must be given to devising adequate surveillance, which lasts long enough and follows through in sufficient detail, so that any potential side effects could be picked up. Without that, people could quite happily say that they are not aware of any adverse health effects, because they have not looked for them properly.

Let me give an analogy. In the past, smoking tobacco was not thought to be harmful. Indeed, many doctors recommended tobacco to patients for their health. Tobacco used to be recommended to people with chronic bronchitis because it was thought that it helped them to clear their chests in the morning. Only as a result of painstaking, detailed and long-term research have the adverse effects of smoking tobacco, which can be terminal, been discovered. Tobacco was around for some considerable time before that was shown.

The Convener: You said that, if one does not look for adverse effects on the population living near a trial site, one is unlikely to find any. What would you say to those who argue that potential adverse effects have already been tested for before we get to that kind of trial?

Dr Saunders: I do not believe that there have been sufficiently robust and thorough investigations into the potential adverse effects of these materials. In the United States, GMOs are not segregated in any way and their produce is mixed with many other things. Most Americans have no idea whether they are eating GMOs because no GM foods are labelled as such.

The idea that the health of people who have worked with GM materials in restricted environments can be extrapolated to the general population is unsound. We do not know what the potential long-term effects may be to people's health from the use of these novel technologies. Particular reactions in individuals may be extremely rare or may not have been picked up because not enough people were exposed during the pre-release process.

Another analogy is with allergies. Some allergies are rare and some are common. Someone with a relatively rare allergy may not have been exposed to the allergen so that the reaction has not been picked up. If that person is exposed later on, they could think that the reaction had come from something else. Another comparison might be with new variant CJD. We know that a fairly large proportion of the United Kingdom population has eaten food containing potentially infected material but only a small proportion has so far developed any infection from that.

Without looking at such things over a long period and in adequate detail, it is not possible to tell precisely what proportion of people may or may not be vulnerable. My point is that the numbers of people exposed in controlled situations is so small and so selective that it is not possible to generalise.

The Convener: I do not wish to hog the questioning, but it has been said to me that there is already GM in certain pharmaceuticals. I presume that the BMA does not want to stand in the way of progress and the development of better drugs and that your organisation has more involvement in and knowledge of that than it did in the past. How does the testing of GM crops compare with the testing of pharmaceuticals before they are used on the population at large?

10:15

Dr Saunders: The testing and surveillance process for new pharmaceutical products is extremely thorough and detailed. I cannot offhand think of an adequate analogy, but that process is several orders of magnitude more thorough than the one for GMOs and GMOs used in foodstuffs. If the same sort of surveillance applied for GMOs, that would probably answer a lot of people's concerns.

The Convener: In a way, I was hoping that that would be the answer.

Nicola Sturgeon: Do you have any comments to make on the risk assessment procedure that precedes the granting of a licence for GM crops? Is it robust enough?

Dr Saunders: The short answer is no. Quite a number of assumptions are made in that process and the BMA is not convinced that all those assumptions are valid—[*Interruption.*]

Dorothy-Grace Elder (Glasgow) (Ind): I beg your pardon for coughing.

Nicola Sturgeon: Your services may be required, Dr Saunders.

Dorothy-Grace Elder: An undertaker might be more appropriate.

Dr Saunders: It is that time of year.

The Convener: Dorothy-Grace Elder must be one of those people on that smoking treatment that we have heard about. Please continue, Dr Saunders.

Dr Saunders: I am not clear what area Nicola Sturgeon wants me to expand on.

Nicola Sturgeon: I was just giving you the opportunity to comment if you had not already done so.

Janis Hughes (Glasgow Rutherglen) (Lab): Dr Saunders, you say in your written evidence that BSE has contributed to a culture of distrust in relation to the scientific community and today you mentioned CJD. It could be argued that the parallel with GM crops is questionable, as BSE and CJD had nothing to do with genetic manipulation and the controls that transgenic foods have been subjected to seem much more stringent than those that were formerly applied to animal feed.

Dr Saunders: The difficulty is that there is general public disenchantment with science and an increasing lack of belief in what experts say. We have heard this morning about the use of genetic modification in producing potentially valuable new pharmaceutical products. There is some concern that, if the general public view with total distrust the entire process of producing GMOs, there may be difficulty in incorporating some of the pharmaceutical products from GMOs and using them on the public for their benefit.

The analogy is reasonable to the extent that the public were repeatedly told through the BSE—I suppose that the word "crisis" is too strong—episode that there was no risk, yet, lo and behold, that view was discredited and the public are now fully aware that there was a risk. The issue is if the public are told one thing by official bodies and the

Government and then discover that what they have been told is not true. The more that happens, the more difficult it is to get the public to understand and to accept scientific argument. Taking risks when it does not appear to be necessary to do so does not help that process.

Janis Hughes: That is true. However, do you agree that more stringent controls are applied to transgenic modification of foodstuffs than were applied in the situation from which BSE and CJD emerged?

Dr Saunders: The process is different. In the BSE situation, ground-up cows were being fed to other cows. No one is suggesting that that sort of process is going on with GMOs. In simple terms, the controls on grinding up cows, processing the material and feeding the result to other cows were relatively crude. The controls on the release of GMOs into the environment are more sophisticated, but they are not nearly as sophisticated as the controls and safeguards that apply to the release and production of new pharmaceutical agents.

Shona Robison (North-East Scotland) (SNP): In your evidence, you say that it should be incumbent on the Scottish Executive to monitor the health of populations that live around GM farm-scale evaluation sites. In response to an earlier question, you said that it is difficult to monitor the health of people living in such places. Can you suggest what kind of effective monitoring systems could be put in place?

Dr Saunders: To work out precisely what one would need to do and how one would need to do it would be a project in itself. It would be better to do that on a national basis. That would allow one to be more effective in picking up unusual complications or symptoms. It is beyond my competence to devise such a system this morning, as that would require a separate research project.

Having said that, I emphasise that the surveillance mechanisms for human health that are in place in the national health service are relatively crude. They depend on the picking up of known organisms, infections and conditions, at which they are not terribly good. Although they are quite good at picking up things that kill people, they are relatively poor at picking up things that do not. I would have no confidence in their ability to pick up unusual or unexpected symptoms in people who were living near GMO trial areas.

Shona Robison: You have alluded to the argument that monitoring should have taken place right at the beginning. Given that the crop trials have started, do you believe that it is too late to undertake monitoring?

Dr Saunders: I do not think that it is too late, even though it is less than ideal that the opportunity to begin monitoring before anything happened has been lost. It is not too late to claw back some of that lost ground by setting up adequate surveillance of human health around those areas, particularly as I imagine that the number of trial areas is likely to continue to increase across Scotland and other parts of the UK. It should not be too difficult to produce protocols for setting up such studies and putting those studies in place. Although I accept that some early opportunities have been lost, that does not mean that the whole process would have no value.

Shona Robison: In your view, would public health consultants in the NHS have a key role in that monitoring process?

Dr Saunders: That would depend on the protocol that was adopted. The process is likely to be relatively complicated and time consuming. Such a study would differ from most studies in that one would not have worked out what one was looking for. Therefore, one would be unable to set up specific picking-up mechanisms. One would have to try to work out whether unexpected things were happening, which is more difficult.

Mr John McAllion (Dundee East) (Lab): You said that GMOs are not segregated in the United States and that GM products are not labelled—in effect, they are out there in the general population. In your last answer, you suggested that some kind of national protocol was needed to examine a system for monitoring the health effects of GMOs. Has anything of that kind been done in the United States?

Dr Saunders: To the best of my knowledge, the belief in the United States is that genetically modified organisms and non-genetically modified organisms are to all extents and purposes identical. Because of the belief that no adverse results are expected, people say that there is no point in segregating GMOs or looking for adverse health effects as a result of the population consuming GMOs.

Mr McAllion: So when people say that the American experience suggests that there are no harmful health effects from GM crops, they are not talking scientifically. Basically, the situation in America is that no one has looked for the health effects that might arise from GM crops.

Dr Saunders: The issue is not only that. If an outbreak of food poisoning is being investigated, officials try to identify what foods people have consumed. They examine how many people who ate the pork on a menu became ill compared to the number of people who ate something else and became ill. In order to do that, people have to know what they have eaten, which is relatively straightforward—people know whether they ate a piece of pork or a Brussels sprout.

In food systems in which GMOs and non-GMOs are mixed together, no one can tell whether people have eaten GMOs. It becomes extremely difficult to try to identify whether a problem results from eating GMOs or eating something that lived near GMOs. A large noise factor is involved, which makes the issue extremely difficult.

We are not yet in that situation in the United Kingdom, which means that it should be feasible to do reasonable, thorough and robust research to examine whether there is a difference between the effects of GMOs and those of non-GMOs. We have no idea whether there will be a difference. However, I can guarantee that if we do not look for a difference, we will not find one.

Nicola Sturgeon: Perhaps I could play devil's advocate. Your position is that there should be a moratorium on GM crop trials until we have stronger evidence that GMOs do not result in adverse effects. You have just repeated that we will not find the evidence unless we look for it. How do you respond to someone saying that, without trials, we cannot look for the evidence and therefore we cannot find it? Are not the crop trials a necessary part of the process and an expression of the precautionary principle?

Dr Saunders: I think that we are saying that, at present, farm-scale trials and the commercial plantings would be a breach of the precautionary principle. We accept the need for further small-scale trials with adequate surveillance of human health around them in order to try to identify whether there is evidence of harmful effects on human health.

One could argue that, if the stuff were not grown at all, it would not be necessary to undertake surveillance—if GMOs are not grown, there is no issue. I am not sure that that position takes us much further forward. I fully accept that some trials have to be undertaken if we are to try to assess the health hazards. However, it seems sensible for the trials to be undertaken on a relatively small scale and for them to be monitored closely. At the moment, we are not in that situation.

Mary Scanlon: Page 3 of your submission sets out:

"There is a significant risk that antibiotic resistance markers may progress through the food chain, possibly into pathogenic organisms causing human disease."

It also sets out:

"GM foods would potentially have very serious adverse effects on human health."

Throughout the paper, you raise serious concerns about the potential effects of GM foods on human health. Will you repeat the argument stated in your paper that plants should not be produced with genes that confer resistance to antibiotics?

Dr Saunders: There is clear evidence and widespread knowledge that resistance to antibiotics is an increasing problem, mainly for human health but also for animal health. Increasingly, antibiotics that were previously highly effective against certain organisms are becoming less so. Organisms are developing that are resistant to a multitude of antibiotics, and some pathogenic organisms—in other words, organisms that are harmful to humans—have developed that are resistant to all the antibiotics that could have been used against them before.

The potential for the spread of antibiotic resistance through the food chain, from markers that have been deliberately introduced to food, is high. That will result, in animals and in humans, in infective organisms that are resistant to antibiotics. Antibiotic resistance has been inserted gratuitously, and making an existing problem worse seems irresponsible to the BMA—we cannot see the need for that. Given the potential adverse effects on human health, there should be an immediate ban on the use of markers.

10:30

Mary Scanlon: Is that a matter of concern now? Does the BMA have evidence that antibiotic resistance is emanating from GM crops?

Dr Saunders: No, it does not. It is a potential problem, but the BMA does not have sufficient evidence to state that it cannot happen. Given that, it seems to be taking an unnecessary risk to create a situation in which it might happen.

Mary Scanlon: It is not only the antibiotic resistance markers that worry me; I am very concerned about your submission, which states that the markers can create organisms that cause diseases in humans. The Royal Society of Edinburgh appears to have an opposing view. It has concluded that GM crops, when compared with conventional crops, pose no additional risks to humans. Which organisms cause human diseases? Which organisation is right—the Royal Society of Edinburgh or the BMA?

Dr Saunders: In answer to the second question, the BMA is right.

Mary Scanlon: Good for you.

Dr Saunders: To answer the first question, it is possible that several organisms that exist in animals and, to some extent, in the human gut could create problems that are difficult to treat as a result of the transfer of antibiotic resistance markers. For example, most healthy people have a large number of bacteria on their skin and in their noses and bowels. For most people, that presents no problem. However, people whose immune systems have stopped working well,

people who have other problems, and, indeed, people who have cuts on their skin can find themselves in a situation in which previously harmless bacteria can cause serious illness and even death.

If, as a result of using antibiotic resistance markers and genetically modified organisms, bacteria that exist in the body harmlessly become resistant to antibiotics, that would be a significant problem. If those bacteria started to cause problems for people, it would not be possible to treat them with the usual antibiotics.

Mary Scanlon: Therefore, the organisms cause human disease because they cannot be treated.

Dr Saunders: Organisms are harmful to people because we are unable to treat them properly.

Mary Scanlon: I understand.

Margaret Jamieson (Kilmarnock and Loudoun) (Lab): Will you explain to me how the point that you make about GM foods that are resistant to pesticide containing more pesticides fits in with the recommendation from the 1960s that the genetic engineering of disease-resistant plants is preferable to the use of chemicals?

Dr Saunders: There are certainly two sides to the argument about whether producing pesticide-resistant plants reduces the use of pesticides. Although the people who manufacture the plants and the pesticides say clearly that pesticide use is reduced when GMOs are grown that are developed specifically for that purpose, another lobby says that that is not the case and that, because it is feasible to use greater quantities of the stuff without damaging the crops that are being grown, it is easier to use more pesticides than would otherwise be used. I am not sure that there is adequate evidence to show who is right. Both sides call on quite convincing evidence to show that they are correct, and I do not know that there is clear evidence to show whether one opinion or the other is 100 per cent right. I do not know whether that answers your question.

Margaret Jamieson: It gives rise to other questions. Like everyone else, we look to those who are qualified in such areas to advise us, and it is of concern that you are saying that there is an equal amount of evidence on both sides. That evidence has been researched and provided by very knowledgeable individuals. The difficulty that we are experiencing in this inquiry is that there is evidence of equal weight on each side. As you have come out quite strongly and said, "We do not accept the way this is going," your opposition seems to be strong. However, at the moment you are saying that it is eeksie-peeksie.

The Convener: That is a technical term.

Dr Saunders: It is important to understand that there are differences between techniques and processes that are developed under controlled conditions and the way in which those techniques and processes are applied when they are in general use. Where there are tight and direct controls on the way in which pesticides are used as part of specific trials, it may be possible to show that there has been a reduction in pesticide use. However, when those processes enter general use by people who have not necessarily had the same training or who do not have the same interest in the outcome of the trials, that reduction in pesticide usage may not be maintained. Because people are individuals and tend to do things individually without direct supervision, the amount of pesticides that they use may vary enormously, from the lower levels, which may be termed the best-practice levels, to very high levels. We have already seen that happen in a variety of situations, not just in this country.

Nicola Sturgeon: This is not so much a question as a plea for clarification. It is important that we are clear about the evidence that we are given. Is it fair to say that you and others have concerns about certain risks that may be intrinsic to the process of genetic modification? Would those concerns lead you to call for a moratorium at this stage? By-products of that process, such as the increased use of pesticides, may not be intrinsic to the genetic modification process but may occur as a result of it. Should we keep the potential risks quite separate in our minds?

Dr Saunders: That is absolutely right. Put simply, the process involves taking a bit of DNA from one organism and sticking it into the DNA of another organism. The effects depend on how much is taken, where it is taken from and so on. People who do that are undoubtedly clear in their own minds that they are achieving a specific effect by using a specific protein and that the outcome is clear. We are saying that, because the process is relatively novel, it is by no means clear that moving DNA from one species to another will produce only one effect. Our knowledge of the effects of moving proteins in that way is imperfect, and no one can give a 100 per cent guarantee that it will achieve only the desired effect.

Dorothy-Grace Elder: The committee has asked the Advisory Committee on Releases to the Environment whether it should become incumbent on the Scottish Executive to monitor the health of people living around the GM farm-scale evaluation sites. Its view, which has already been published elsewhere, is that there is no requirement to monitor the health of people living near GM releases because

"It is extremely unlikely that ACRE would support the release of any GMO that warranted such monitoring."

Will you comment on that stance?

Dr Saunders: There is a certain degree of circularity in that argument. In essence, the advisory committee is saying that it would not release anything that was not safe and that because it would release only stuff that it knew was safe and for which it had no evidence of side effects, there is no need to look for any evidence. However, because ACRE does not look for any evidence of problems, it will not find any, and so the circle goes round. I do not find that entirely reassuring.

Dorothy-Grace Elder: Do you find that a robust scientific approach or otherwise?

Dr Saunders: Otherwise.

Dorothy-Grace Elder: Lastly, ACRE and others use the term "precautionary approach". Do you agree that that is different from the precautionary principle, which is enshrined in law?

Dr Saunders: Yes, I do. Put at its simplest, the precautionary principle means that if we cannot cope with the consequences of doing something and we do not have enough information to be sure of those consequences, we should not do it. My understanding of the precautionary approach is that we release things in tiny quantities and see what happens, and continue doing that until something happens or does not happen. The BMA's concern with that approach is that we may well find that something has happened far too late for us to do anything about it.

The Convener: Thank you very much, Dr Saunders.

Our next set of witnesses are from the Royal Society of Edinburgh. Good morning. We thank you for giving us your written submission in advance. I invite you to introduce yourselves and to make a short statement before we move to questioning.

Professor Tony Trewavas (Royal Society of Edinburgh): I am a professor at the University of Edinburgh and a fellow of both the Royal Society of Edinburgh and the Royal Society, so I stand as a witness for both organisations.

The evidence that I have read and understood about GM crops is very different from that which members have just heard. In fact, from a direct reading of the extensive evidence in the scientific literature, I am unable to understand how the BMA's conclusion could have been reached. I listened carefully to see whether Dr Saunders would bring forward direct evidence, but I was unable to hear any that satisfied me.

10:45

Professor Chris Lamb (Royal Society of Edinburgh): I am director of the John Innes Centre in Norwich, which is a charity that undertakes fundamental and strategic research in plant and microbial science. It is a company limited by guarantee, with grant in aid from the Biotechnology and Biological Sciences Research Council, which is a non-departmental public body. The John Innes Centre is not for profit, and 8 per cent of our total funding comes from industry; the Government target is 15 per cent. I am director of a technology transfer company that is owned in part by the John Innes Centre. I waive directors fees and have no other personal remuneration from industry or stockholdings in biotech companies.

I endorse Professor Trewavas's comments and the submission by the Royal Society of Edinburgh, which correctly notes that science never generates absolute certainty but can give only a balance of probability in the light of current knowledge. In attempting to understand those probabilities and the relative risks, costs and benefits of a new technology, we need to refer to those embodied in existing practices—in this case, non-GM-assisted breeding—and current agricultural practices. We must weigh the risks and unknowns in those practices against the impact of the new technology.

With respect to the specific remit of the discussion, I should also say that the field trials are supervised such that the crop does not enter the food chain and is destroyed at harvest.

Mary Scanlon: I was going to ask for your view on the BMA's assertion that, due to the lack of scientific certainty, the GM crop trials should not continue. Perhaps you could comment on that before I ask about your paper.

Professor Trewavas: The implication of what Dr Saunders was saying, in so far as I can interpret what he said, is that novel food should be tested on human beings—that is the only certainty that he would accept. I do not know whether it is ethical to do that. If you test novel food on human beings and find that there are deleterious effects, you would be under severe constraints and would probably be subject to litigation over what had been done. As I am sure the committee will hear later on, most novel foods are tested using animals. No GM crop that I know of has ever been released for agricultural use unless it has undergone the most vigorous and detailed scrutiny of its safety, using animals as the recipients of the treatment.

I mentioned in the Royal Society of Edinburgh's submission that there are three aspects to testing the safety of any novel food, which have been evolving slowly since the early 1990s and were first suggested by the Organisation for Economic Co-operation and Development. Because of the difficulties of testing food in its entirety, the OECD suggested using a process called substantial

equivalence. As I understand the way in which that process is currently used, it involves a detailed analysis of the new food against a comparative non-GM food. That detailed compositional analysis examines vitamin, mineral, protein and carbohydrate levels, lipids and phytoestrogens. It also includes secondary products, such as, in the potato, solanin and chaconin, which are known to be poisonous. All those are monitored and, if the composition looks identical, we then move on to the next stage.

The next stage involves examining the novel part of the GM crop, which is the new gene that has been inserted, and its product. It is expressed as a protein, which is then assessed by normal toxicological procedures. That involves rodent tests. A rodent is either fed or injected with a novel protein, and all aspects of it—its growth, reproduction, organ weight, histology, anatomy, blood chemistry and enzymology—are assessed. In fact, you name it, people examine it.

Finally, feeding experiments will be carried out on the animals. In other words, the animals will be fed on a GM food. In the scientific literature, well over 100 papers describe the result of feeding trials for all the GM crops that are currently in use in this country. Those papers are not published in medical literature; instead, they can be found in toxicological literature and rather obscure journals, because to date no one has found feeding an animal with a GM food rather than its non-GM comparator to have an influence.

To satisfy the Food and Drugs Administration in America, information must be presented on the crop that has been produced. Using a non-GM crop comparator, the crop's basic physiology, growth, branching, flowering and so on must be reported on. All those details are taken into account and are brought into the issue of food safety. If any of those are interrupted and differences are found in the process, people must return to a much earlier stage in the testing procedure and investigate matters further.

I do not know whether that is too much to take in. I am trying to give evidence of the detail that is examined.

Mary Scanlon: It probably is quite a lot to take in. You did not mention rodents' resistance to antibiotics.

Professor Trewavas: Quite a few papers have investigated whether antibiotic resistance is possible and whether there is transfer from GM crops that contain antibiotic resistance to bacteria. The Food Standards Agency commissioned several investigations into the issue and published its results earlier this year. I have read those papers, in which the FSA dismisses the issue as insignificant. I agree. The main reason for antibiotic resistance in the human population is the overprescription of antibiotics to the general public. That fact is well recognised.

Three years ago, the advice was that antibiotics should be phased out as marker genes in most plants and no further GM crops should be produced using antibiotic-resistant markers. The main antibiotic that is used is kanamycin, which is not commonly used for the treatment of disease because of its severe side effects. Ten per cent of soil bacteria are kanamycin resistant anyway, because that is where the gene came from in the first place. As a result, young children who play in the garden and lick their fingers are acquiring kanamycin-resistant bacteria through their intestinal system.

Professor Lamb: I believe that one in five humans have antibiotic-resistant bacteria in their guts anyway. In addition to the literature that Professor Trewavas cited, I draw the committee's attention to a study in which a cow's stomach was reconstructed in the laboratory and fed plant food that contained an antibiotic-resistant gene in the plant DNA together with the appropriate bacterial flora. Although the experiment was conducted under conditions that were very favourable to horizontal gene transfer from the degrading plant material to the bacteria, no such transfer was found to have occurred.

Mary Scanlon: As we are carrying out rigorous and detailed scrutiny, I want to refer again to your paper. In paragraph 4, you say:

"There is no scientifically proven evidence of any 'threats of serious or irreversible damage' to public health."

In paragraph 13, you say:

"The recent Royal Society of London report (Royal Society 2002) has noted that there was no formal assessment of the allergenic risks posed by inhalation of pollen and dusts."

Your paper also says that there is

"uncertainty about … long-term exposure"

and notes:

"The route of exposure of the local population … will be different from that"

of the whole population.

Professor Trewavas: Which point do you want me to start off with?

Mary Scanlon: I am just saying that, although I appreciate your comments, your paper also highlights several uncertainties and concerns about formal assessment for allergenic risks and local populations. We feel that you should address those points.

Professor Trewavas: On the point about there being no evidence of any threats of serious or irreversible damage to public health, that is certainly the case from the evidence that we have at present. Despite what Dr Saunders said about the USA, the Centers for Disease Control and Prevention office in Atlanta monitors the health of US citizens extremely carefully. It picks up isolated cases of disease easily as there is a requirement on all American doctors continually to convey information to the agency, so that it can monitor changes in the disease status of the US population.

In addition, the Royal Society of Edinburgh has an archive of about 180 papers that deal with the safety considerations of genetically modified food, based on the tests on animals that I described. When we say that there is no serious threat, I am sure that that is the case for the present crops.

On the issue of pollen allergies, I was not on the committee of the Royal Society of Edinburgh that produced that report. However, it refers to further developments that should be included in any risk assessment process for future GM crops. The crops that we have at present do not express their protein product in pollen, which means that there can be no difference between the allergic response in people who live near a trial site and in those who do not. The allergy symptoms will be the same because the composition of the pollen is identical. That is a technical point that is not well known, but which I hope answers your question. Having said that, I think that the possibility that pollen or dust might cause different allergic responses should be considered for GM crops that are produced in future. That will be introduced to one of the decision trees that toxicologists have for GM food.

Nicola Sturgeon: The Royal Society of London paper in 2002 referred to differences in the application of the principle of substantial equivalence, for example in the various member states of the European Union, and said that those needed to be resolved. Will you say more about that?

Professor Trewavas: The OECD introduced the principle and has tried to have a coherent statement of everything that is required to enable people to say that a GM crop is substantially equivalent. In the literature, one finds that one company has measured its crops' phytoestrogen but that another company has not measured that in its crop. The OECD wants to establish a set of measurements that must be taken from every GM crop. That is what is behind the principle of substantial equivalence.

Shona Robison: Earlier, you said that 8 per cent of your funding is from industry. Does any of that come from companies that are connected with the GM industry?

Professor Trewavas: It was Professor Lamb who said that. I have no commercial support at all. My last contact with a commercial company was 17 years ago.

Professor Lamb: The John Innes Centre takes industrial funding from small and medium-sized breeding companies and also from major companies such as DuPont and Syngenta.

Shona Robison: Is most of that 8 per cent from companies that are in some way connected to the GM industry?

Professor Lamb: No, but a significant proportion of it is. We receive a lot of grants from conventional breeding companies as well.

Shona Robison: I will play the devil's advocate. Do you think that it could be argued that the fact that the John Innes Centre receives a significant amount of funding from companies with links to the GM industry might compromise your statement that you are wholly independent and a neutral forum?

Professor Lamb: As I mentioned, we operate with grant in aid from a non-departmental public body that has set us a target of achieving 15 per cent industrial funding. One motivation for that is to meet EU targets for the development of the research and development budget. The second is to increase industry's use of the knowledge of excellent British science.

We propose specific pieces of research that we want to do. That is not contract research; it is just an alternative funding source. It is not involved in testing GM products; it is for basic research.

11:00

Shona Robison: So you would say that you do not feel in any way compromised.

Professor Lamb: We do not, and the process and our funding are entirely transparent.

Shona Robison: Okay.

Will you answer the anxiety that some have expressed about the transfer of genes from GM crops to non-GM crops carrying with it unknown hazards?

Professor Lamb: In my opening remarks, I pointed out that understanding the relative risks of a new technology inevitably refers to those practices and risks inherent in the existing technology. There is substantial knowledge of the processes of gene flow, pollen movement and tolerances for the admixture of seeds with different

genetic properties. That knowledge is well-established and understood from conventional breeding.

Any GM variety that is put into commercial use or a field trial will have undergone a detailed and thorough risk assessment of the kind that Professor Trewavas outlined. The framework for understanding the issues is to consider GM as another variety and refer to conventional agricultural practices.

For example, some varieties of oil-seed rape are specially bred to make edible oils and other varieties are bred to produce industrial chemicals such as lubricants. Those chemicals would be unpalatable and even damaging to one's health. The breeding and agricultural industry have operated to maintain segregation of such crops within respected tolerances.

My answer then is that the origin of a new cultivar—if we set aside the red flag of its being GM—can be adequately dealt with through that kind of well-established and well-respected process in the industry.

Another example would be avoiding the admixture of wheat varieties for bread and for forage, which are entirely different.

Mr McAllion: In answer to the question of whether the health of people living around GM farm-scale evaluation sites should be monitored, your submission said

"no practical monitoring programme will have the power to show health effects within a reasonable time scale".

However, your earlier answer to Mary Scanlon's questioning seemed to suggest that the future monitoring of the health of people who might inhale or ingest GM pollen will be added to the tree to which you referred. Is there a practical way of monitoring the health of such people or not?

Professor Trewavas: It would be difficult without human trials. I said that you have a difficult ethical consideration on that particular point. What will be done is that we will use animals to see whether there is any possibility of allergic responses developing, particularly from pollen and dust from the preparation of GM wheat, which was a major concern of the Royal Society report.

We know that there are certain conditions that are quite common in Scotland. Farmer's lung was mentioned in one of the earlier documents. That is an allergic response to spores in mouldy wheat. There used to be a unit that did research in that area at the University of Edinburgh. It used mice to analyse the condition and was able to demonstrate an allergic response in mice that was very similar to the symptoms that the farmers experienced.

Mr McAllion: So you would rule out on ethical grounds monitoring the health of people living in the vicinity of GM crops?

Professor Trewavas: We cannot expose human beings deliberately to tests of this sort without others suggesting that we are pursuing concentration camp tactics. I would have to draw the line at the type of monitoring that the member describes. It is precisely to avoid that approach that we use animals for all toxicological investigation. After a drug has been developed, we monitor what happens when we use it on a human population. However, before doing so we try to ensure that it is safe by testing it on animals.

Mr McAllion: We must be clear on this issue. People who live at Munlochy, near the farm-scale evaluations, may be inhaling GM pollen or dust—they are already being exposed. We are asking why we cannot monitor the impact of exposure on those people's health.

Professor Trewavas: Charles Saunders asked for smaller trials, but I am not sure how much smaller they could be. Trials are taking place on one field at a time. The member asks why we cannot monitor the health impact of the trials on people who live at Munlochy. I have already explained that the GM gene in this case is not present in pollen, so I am not sure what we would look for. Rape is an insect-pollinated plant, rather than a wind-pollinated plant. The amount of pollen that enters the atmosphere from rape plants is extremely small.

Mr McAllion: Professor Lamb said that science could not be exact and that issues must be judged on the balance of probabilities, in the light of available knowledge. You are saying that the people at Munlochy, who are living next to farm-scale evaluations, must take their chances. You do not know for certain whether the trials will have health implications, but you are not prepared to say that they should be monitored for their impact on health.

Professor Lamb: I refer the member to my opening remarks. John McAllion is asking about relative risks. To understand those, we must refer to an existing baseline. In this case, the baseline is the risk from oil-seed rape that is non-GM—rape that has been changed genetically by non-GM techniques and conventional breeding.

Dr Saunders mentioned that one or a small number of genes are inserted into a GM crop by what I term a cut-and-paste approach, to create a desired outcome for the breeder and farmer. The nature of the genes that have been inserted is known and their properties have been studied for safety prior to release.

At the moment breeders use wide crossing between different varieties and with wild relatives

of a species. That involves transferring not one or a small number of genes—perhaps half a dozen—but 50,000 to 100,000 genes. Conventional breeding is about scrambling and sorting, or scrambling and recombining. Modern gene research is making it clear that the genetic make-ups of closely related species and even of distantly related varieties of the same species differ hugely. From that, we conclude that wide crossing involves mixing between 50,000 and 100,000 genes. We have no idea about the function of the majority of those genes.

The genetic information in the genotypes of the two varieties that are crossed—which we now know to be substantially different—is scrambled. Over 10 to 15 back-crossings, the breeder tries to sieve out the desired genes and to remove the undesired genes, leaving one or two genes that have been transferred. The aim is to achieve the same end product that the GM approach would achieve by cutting and pasting genes. To answer the question, one must look at the potential risks that are inherent in that process. One must also set that against the scrutiny that the non-GM crops have received, which is substantially less than that of GM crops.

Mr McAllion: You are losing me. Are you saying with absolute certainty that those who have inhaled GM pollen and dust at Munlochy, or at any of the other farm-scale evaluation sites, are at no risk whatsoever?

Professor Lamb: No. I am saying that the relative risk to which they are exposed is no greater, and may even be less, than that which would come from being next to a field of conventionally bred crops.

Mr McAllion: You say that the risk is no greater and may even be less. Do you mean that you do not know?

Professor Lamb: No. I have just told you what I know.

Mr McAllion: But it cannot be said with certainty that there is no risk.

Nicola Sturgeon: I know that, in such a complex area, it can be difficult to avoid baffling with science, but I ask for an answer to this question in ordinary language. Professor Trewavas said that it is not ethical to use human beings as guinea pigs and I understand that. However, that seems to ignore the fact that the people who live around the crop trial sites are in exactly that position. The Royal Society of Edinburgh's written submission states:

"There could, in theory, be long-term effects on human health that have not yet been detected",

but it has been said today that the risks from GM crop trials are no greater than, and may be less than, the risks from conventional crops. However, that cannot be said with certainty.

I am not sure—perhaps this can be clarified—whether the argument that is being proposed is that there is no need to monitor the health impact or that such monitoring cannot practically be done? That does not sound to me like a responsible argument.

Professor Trewavas: I am not sure what it is that we are being asked to monitor. I noticed that Dr Saunders was asked what exactly he would have us look for. There are situations in which we must accept that we do not know with certainty everything about something, yet life must continue. We try to assess the likelihood of a real risk against what is, in this case, the likelihood of a very low risk. We must try to balance out the benefits and risks accordingly, in this case as in all cases that we deal with.

The precautionary principle that says, "Do nothing until you know everything about something" is a recipe for total stagnation. We would never have developed electricity, gas, aeroplanes, trains or anything if people had ever taken that principle to heart. We have always tried to look ahead to see what risks we think we can see. The risks must be taken account of and if, after investigating and assessing them, they are thought to be slight or are unknown, we must move forward with caution.

Nicola Sturgeon: No monitoring of GM crop trials is being done after the fact. Charles Saunders asked how we will find the risks if we do not look for them. Professor Trewavas asks which risks we should monitor, yet his own submission states that there are potential long-term effects on human health.

Professor Trewavas: The risks that are mentioned in our submission would come from consumption, not from around particular trial sites. I have already explained that there is no difference between the pollen from a non-GM rape in Scotland and the pollen from a GM rape. I am not sure what health effects people would expect to find around trial sites.

There may be a different situation regarding consumption of food. Good monitoring is already carried out by the European Community and by the Centers for Disease Control and Prevention in the USA on the potential risk to humans from the consumption of GM food.

Although people say that there might be some risk round about the trial site, I must admit that I am unable to see where the risk would come from. It would not come from the pollen. As the committee has heard, the crops are always destroyed after the trial. Where would the health risk come from? As far as I can see there is no risk, but if it exists it can be only extremely tiny.

The Convener: I want to bring in another question because I am conscious that we are over-running our time. We have a number of other questions that we want to get in.

Margaret Jamieson: You mentioned the experience in the USA. In paragraph 13 of your submission you suggest that

"if there are any health effects, they will be very small and long term."

Could you elaborate on the US studies that you referred to, and what they show? Were they studies of GM crop trials?

11:15

Professor Trewavas: When you are monitoring the health of a whole population, you look at the incidence of disease or any striking change that seems to be coincident with the introduction of GM food. Thus, if I was at the Centers for Disease Control and Prevention, I would monitor many characteristics of the health of the US population before the introduction of GM—which in general terms started in 1995, but actually began with Flavr Savr in 1991-92—and use that for comparison. I would ask if I could see real things appearing, then I would go back and investigate further.

No one can guarantee the long-term safety of any food, including organic food. We cannot guarantee it because we know, for example, that 110,000 people in the UK die every year from a poor diet which, in a sense, is poisoning by the food that they eat; they either die from a heart attack or premature cancer. That is why we cannot guarantee real safety. If you do not eat, you die from it. If you do eat, you die from it anyway. Whether we die prematurely, and whether in future we may find ways of removing things from food that may truncate our lives, we do not know, but we cannot guarantee anything like that over the long term. There is no guarantee, I am afraid.

Professor Lamb: Neither can the long-term safety of conventionally bred crops be guaranteed. Up to 50 per cent of those have undergone genetic change by irradiation to increase the genetic variability that is available to breeders, or elaborate processes in the laboratory to transfer genes from one species to another, which would not happen in the wild. The science point is that if you compare the relative risks that are inherent in those processes, with those risks potentially in GM processes, it leads to the conclusion that I gave to Mr McAllion, which is that the risk to people around the site of a GM oil-seed rape trial is not greater, and may even be less, than that around a conventional field of oil-seed rape.

Dorothy-Grace Elder: I have a point of clarification, which is similar to that made by Shona Robison. Professor Trewavas stated that he had had no personal involvement with commercial concerns for many years, but the Royal Society of Edinburgh states that part of its funding comes

"from a range of public, private and charitable sources."

First, is any of those connected in any way with GM experimental companies or the biotech industry? Secondly, you state that a third of your funding comes from the Scottish Executive. As the Executive allows GM crop trials to go ahead, do you think that that compromises your opinion and evidence in any way?

Professor Trewavas: If I can answer for the Royal Society of Edinburgh, I do not know the details of its funding sources, and I receive no support directly from it. It has nice buildings on George Street; perhaps you have even been inside them. The only one of the society's sources of money that I noticed this morning when I walked in was the Royal Bank of Scotland. I am not aware—except indirectly—that that has anything to do with GM crop trials, but I am sure that the Royal Bank of Scotland funds quite a large number of farmers. Indirectly, it may be funding a farmer who is carrying out a GM crop trial, but it is not clear to me that that would in any way change my assessment of the evidence that I find in the scientific literature. As a scientist, I have to try to view it in a totally neutral way, examine the balance of evidence for and the balance of evidence against, and then come to a decision as a consequence of what I have read.

Dorothy-Grace Elder: What about a possible compromise given that the Scottish Executive gives the Royal Society of Edinburgh one-third of its funding? Does that compromise the society in any way?

Professor Trewavas: I do not think that it can possibly be compromised in that regard, because most of the money either goes towards the maintenance of the building or—most important—towards fellowships that are given to young scientists to continue research for three or four years. Most of the money goes in that particular direction rather than on anything else. Certainly, none of it comes to the fellows. In fact, I have to support the Royal Society of Edinburgh by donating money every year. It is the other way round.

Dorothy-Grace Elder: You are not clearly unlinked from GM is some situations.

Professor Trewavas: I know of nothing that would compromise the situation. Indeed, the report is very balanced.

Nicola Sturgeon: Much reliance appears to be placed on the risk assessment process that

precedes a licence for a GM crop trial being granted. Some concerns have been raised about how robust that process is. For example, it has been suggested that risk assessments do not follow a standard format, that they are about proving the safety of the GM organism rather than genuinely assessing potential hazard, that they do not identify areas of uncertainty and that they are overly reliant on modelling rather than on hard scientific assessment.

Professor Trewavas: It is not an over-reliance on modelling; it is a reliance on standard toxicological procedures and the substantial equivalence criterion for assessing the safety of food for consumption. I am not talking about the risk assessment of the transfer of genes to other organisms. I do not regard myself as properly competent to do that. I am a plant biologist. I have used GM technology for 20 years for fundamental research. However, I am not an ecologist. Later today you will hear from ecologists from ACRE, who can better inform you about that.

Risk assessment is a very complex area of work. I have lectured on risk assessment and read some of the basic classics on it. The available knowledge must be used to try to assess what is likely to occur if some particular action is carried out. If, from all the knowledge available, there is no reason why that course of action should not be followed, then one can proceed. However, if it is a new area of work, one proceeds with caution simply because we cannot know everything about something. We cannot give a guarantee of 100 per cent certainty of safety—no scientist will ever do that.

Janis Hughes: The BMA's evidence cited uncertainty as the reason for invoking the precautionary principle, but from my reading of it, the Royal Society of Edinburgh's submission appears to conclude that it would be wrong to do so. What is the society's position on invoking the precautionary principle?

Professor Trewavas: The precautionary principle has several different interpretations. I have seen at least 50 different statements defining the precautionary principle. The statement chosen depends on individual character and personality.

If the extreme version of the precautionary principle is taken—that is, do nothing until everything is known about the future—no progress will be made and there will be complete stagnation. Some people interpret it like that. A more logical statement from the European Commission, which has a website, gives a much more detailed consideration of courses of action and associated risks, and the risks associated with not taking a course of action. The commission statement also asserts that the action taken should be proportionate to the assessed risk. That is a much more reasoned approach to the precautionary principle.

We must recognise how we arrived at society's current mindset, which, in a sense, is that there is no gain without risk. We have always taken risks in the past in developing new technologies and we have all benefited from it. When penicillin was developed, there was a risk that, if it was injected into people or used for treatment, it would kill them. The risk was taken and penicillin proved to be extremely beneficial.

A good example is the polio vaccine, developed by Sabin about 30 to 40 years ago. We all carry that vaccine inside us. It is an attenuated, or live, virus. When the vaccine was first produced, we knew nothing about it, other than the fact that it would prevent polio. In the past decade, the number of polio cases in the world has reduced from about 400,000 to 40,000. Using the Sabin vaccine, the World Health Organization aims to eliminate polio by 2004.

When it was finally investigated, the Sabin vaccine was found to be so close to the real virus that in one in 1 million cases, it could revert to the real virus and induce polio. Fortunately for most of us, when the virus starts to replicate in our gut, we rapidly form antibodies against it and prevent the virus from gaining effect. If we had known that statistic when the vaccine was developed, we would never have used it and many people who have a normal, full life today would be dead or paralysed. Applying the precautionary principle in its extreme form is not an acceptable way for most of us to go through life.

Janis Hughes: You said that you support the European Commission's view of the precautionary principle and you mentioned assessed risk. Do you differentiate that from perceived risk?

Professor Trewavas: People assess risk from their knowledge of the process at the moment. If I walk over Princes Street when a bus is coming down it, the risk that I will be run over is extremely high. We learn about that risk. Some children do not; unfortunately, they die in the process.

When we cross a road, we all take the risk that a car might suddenly start off. As a child, I was knocked down. I had learned to deal with the risk by looking around, but I had not looked carefully enough. When I cross a road now, I am much more careful. I know the risks, so I take precautionary action to deal with them.

As a scientist, I have examined the risks of GM crops. As Professor Lamb has said, I do not find the risks greater than those of any of the conventionally bred crops that we grow routinely and which are beneficial to our economy, health and nutrition. I might be wrong—I must accept as a scientist that literature might appear that shows

that I am wrong—but I cannot deduce that from the existing literature.

Bill Butler: Good morning, gentlemen.

Are the distances that are being set for crop trials adequate to prevent bees from pollinating non-GM crops with GM pollen?

Professor Trewavas: That is a difficult question. To produce honey that is altogether free of GM pollen, enormous separation distances will be required, according to my understanding of the distances that bees can fly. The only way that I suggest of dealing with that—the matter will have to be dealt with if we grow GM crops in this country—is accepting some levels of contamination as effectively GM free. That is not a solution that I can produce for you. I can suggest distances, but it is up to people such as you to set down those distances in law, after hearing the available evidence.

It is clear that the nearer a hive is to a GM crop, the greater the likely contamination. However, people such as you will have to set the level of contamination for beekeepers, farmers and those who wish to use GM crops. I cannot advise the committee on that directly. All that I can say is that contamination is likely.

Bill Butler: Whom do you suggest that we ask for advice?

Professor Lamb: I will refer to a previous point. The farming and breeding communities have a wealth of experience and there are respected tolerances, for example for varieties of wheat and oil-seed rape that it would be undesirable to mix, whether in the grain hopper or by cross-pollination. Professor Trewavas can correct me if I am wrong, but I think that those tolerances are between 0.5 per cent and 2 per cent. Consuming the non-edible version of oil-seed rape, which contains industrial chemicals, would cause harm.

Experience and tradition in tolerances for such mixtures of seeds and for cross-pollination are robust. It is for society to decide whether it wishes to attach a red flag to a GM-bred variety and whether it wishes to set different tolerance levels.

11:30

Bill Butler: You cannot help with distances.

Professor Trewavas: A detailed Australian investigation was conducted that involved measuring millions of seeds between adjacent raked fields. Advantage was taken of a rather unusual situation. The paper was published earlier this year in the leading scientific magazine, *Science*, and it said that the maximum contamination of seeds between adjacent fields was 0.07 per cent of GM material moving into a non-GM field.

That investigation found no contamination in many fields, but the maximum of 0.07 per cent is much lower than the 0.5 per cent that Margaret Beckett suggested for the level of GM product in a non-GM food, below which the non-GM food could be labelled non-GM. On that basis, I do not expect bees with a hive to produce honey with a higher level than 0.07 per cent of GM pollen compared with non-GM pollen. That is a tiny amount. I do not know whether society will accept such products as GM free. That is not my decision.

The Convener: I thank the witnesses for their evidence. We will take a short comfort break before moving on to the next set of witnesses.

11:31

Meeting suspended.

11:36

On resuming—

The Convener: Our next set of witnesses is from the Advisory Committee on Releases to the Environment—ACRE for short. You may begin by introducing yourselves and making a short statement. We will then move on to questions. The issue is complex, but I ask that members and witnesses keep their questions and answers tight, so that we can catch up some of the time.

Professor Alan Gray (Advisory Committee on Releases to the Environment): Thank you for asking us to come and speak and for donating me an extra L in my name, as it appears on my name-plate.

The Convener: Just for the L of it.

Professor Gray: I am the chairman of ACRE. I have with me Professor Janet Bainbridge, who is an ex officio member of ACRE and who chairs a committee that is important in the context of what we are talking about today—the Advisory Committee on Novel Foods and Processes. I am also accompanied by Dr Steven Hill from the secretariat of the Department for Environment, Food and Rural Affairs, which serves ACRE with joint regulatory authority.

Dr Steven Hill (Advisory Committee on Releases to the Environment): I add my thanks for having the opportunity to talk to you today. I lead the ACRE secretariat. I am responsible for supporting the work of ACRE and for implementing the regulations regarding the deliberate release of GMOs in the UK. I shall briefly outline the framework within which GMOs are regulated.

The release of GMOs into the environment is regulated at European Community level. Since 17 October, the relevant legislation is directive

2001/18/EC; prior to that, it was directive 90/220/EEC. In the UK, that legislation is enacted by the Environmental Protection Act 1990 and the Genetically Modified Organisms (Deliberate Release) Regulations 2002, which add detail to that act.

GMOs are carefully defined in the legislation as being produced essentially through the use of recombinant DNA technologies. That is, they contain genetic material that has been added using methods other than conventional breeding processes. Members have heard some of the detail of that from Professor Trewavas and Professor Lamb. Organisms that have genetic material through the use of DNA methods are also included in the legislation.

The legislation does not cover organisms with novel traits that have been produced by conventional breeding. For example, herbicide-tolerant crops that have been produced through conventional breeding programmes are not covered and can be used in agriculture without prior approval. However, the herbicide concerned might need approval under pesticides legislation.

The premise underlying the regulations is that GMOs may be released into the environment only if they have been shown to pose no greater risk to human health and the environment than their non-GM counterparts. That must be determined through a science-based risk assessment that considers direct and indirect effects, immediate effects and delayed effects. The risk assessment must also take into account the size of the release and its purpose—whether it is to be used for research, marketing, food or feed. That is a key point. Risk assessment is a step-by-step process whereby outcomes of smaller scale releases are considered as part of the assessment of an increase in scale.

The legislation also provides that an expert scientific committee is required to carry out the science-based risk assessment. That role in Scotland and the rest of the UK is fulfilled by ACRE, which is made up of independent scientists. ACRE is not a Government committee, but a committee of independent scientists that advises the Government. All the scientists concerned are leaders in their fields and cover a range of academic disciplines that are relevant to the questions that the committee must address. The scientists advise ministers on the risks posed by GMOs and that advice informs the decision that ministers take on whether to allow the release of the GMOs.

I will now hand back to Professor Gray, who will introduce some of ACRE's work.

Professor Gray: I will not make a long formal statement. In fact, Dr Hill has covered much of what I wanted to say. However, I want to underline, particularly in view of the evidence that I heard earlier, that the committee which I chair is an independent committee and not a Government one. Therefore, ACRE sits in the middle on GMOs. We work within a strict regulatory framework. We must look for risks and identify hazards and harms. We must also assess whether people and the environment are exposed to those harms and, if so, we must assess the degree of exposure and whether that constitutes a risk in any sense. The 2001/18/EC regulatory framework within which we work also charges us to look at other aspects of GM technology, which will probably be discussed later.

The current 13 members of ACRE include ecologists, agronomists, microbial ecologists, geneticists, a medical virologist, an expert on sustainable agriculture and an entomologist. It is clear that it is not possible to cover the entire spectrum of expertise that might be needed to assess a particular crop. To help us to do that we are, and statutorily must be, strongly linked with a set of other committees. When anyone applies to release a crop or a GMO into the environment, they are obliged to send all their information not only to ACRE, but to statutory consultees such as the Advisory Committee on Novel Foods and Processes, the Advisory Committee on Animal Feedingstuffs and, if pesticides are involved, to the Advisory Committee on Pesticides.

Therefore, a set of scientists examines the issue. If we feel that we are falling short in our knowledge of an area, we freely seek information from those who are involved in that area. We regard it as important not only to take all the best scientific evidence and weigh it, but to continually review the evidence that we receive. Therefore, the process is iterative. For example, information from smaller scale trials might eventually cause us to identify a harm.

My feeling from the earlier evidence is that much confusion about GM is generated by our tendency to talk in a generic way about GM. For example, we ask whether GM will do something, whether GM could be harmful, and whether GM crops are different. We have to consider such things on a case-by-case basis. GM is a tool or a technology in the same way as microscopy or vaccination is. To ask whether vaccination is good or bad is not legitimate. It depends on the vaccine, the receiving population, the history of susceptibility and so on. We look at every GM.

GM is different because it enables scientists to introduce genes into plants and other organisms such as bacteria and vaccines in which they would not occur in nature. In some ways, as you have heard, that is a very precise process. That is why we regulate it, but we have to look at every case

because every case is different. In this case, we are dealing with a well-characterised gene and we can go on to talk about that later.

11:45

Professor Janet Bainbridge (Advisory Committee on Releases to the Environment): I will introduce myself and the committee that I chair, the Advisory Committee on Novel Foods and Processes. I have worked in the food industry as a research microbiologist and I have also worked in the national health service. I have also had a long academic career as a biochemical engineer.

I have chaired the Advisory Committee on Novel Foods and Processes since September 1997. That committee is another independent committee of experts. Its remit is to advise the central authorities in England, Scotland, Northern Ireland and Wales on matters relating to novel foods—and in the context of today's discussion, all GM foods are novel—and novel food processes. In the same way as ACRE, the ACNFP has due regard to the relative expertise of a range of other committees. I am delighted to be here to support ACRE in its efforts.

We work to a European framework—the novel food regulation 258/97. The ACNFP has 16 scientific members, roughly half of whom are medically qualified and half of whom are scientifically qualified. The committee also has consumer representation and an ethicist.

I am clear that the focus of the committee's inquiry is not on GM for food use, and the ACNFP has not submitted evidence, but I am happy to pick up on any questions that the committee might have that are directly related to food. As Professor Gray has said, it is crucial to take on board the breadth of expertise that is available.

In the same way as ACRE, the ACNFP's role is risk assessment. We give rigorous consideration to peer-reviewed scientific data. We also give advice. The ACNFP's role is not risk management. Risk management is carried out by our competent authority, which is the Food Standards Agency.

I have a personal comment to add that draws on what I have heard. I agree about the importance of not confusing the specific and generic. It is sad that, in relation to GM technology, the argument is polarised and we hear and read references to the two sides—pro and anti. As the chair of an advisory committee, I feel very strongly that our job is not to take sides but to consider the evidence, to interrogate it, to raise issues, to explain clearly to the public where there are concerns and where we do not have the knowledge, and to make recommendations for further research. In short, we should be totally independent of all aspects of the argument so that we can give a clear, focused and evidence-based view.

The Convener: I have a quick point. It would be helpful if the panel decides who is going to answer a question—frankly, we do not have time for all three witnesses to answer.

Are there any public health professionals on ACRE or any of the other advisory committees?

Professor Gray: We currently have an expert in human virology. We consult public health officials. Our work is observed by assessors from the Health and Safety Executive and from the Department of Health. Interestingly, at the time that the construct in question was being considered, there was a specialist in allergenicity—Dr Kate Venables—on the committee. If we did not have that expertise, we would look for it.

Bill Butler: In your opening remarks, you all emphasised that you are representing independent committees not Government committees. However, I note from the register of interests that some of your members have links with commercial companies such as Syngenta. Does that cause any conflict of interest or any impairment to the committee's independence?

Professor Gray: No. Those individuals declare their interests and, if anything in which they might have an interest is discussed in committee, they ensure that they are not there to influence opinion. In a modern, post-Thatcherite Britain, most good scientists receive funding from industry. That is the way that we have been taught to work. I have received funding from SEPA and Scottish National Heritage. Scientists receive funding from people and organisations with interests in the environment. My work involves genetics and conservation. It is certain that scientists are able to separate their interests when making decisions. I vigorously defend the probity and professionalism of the scientists who serve on ACRE.

Bill Butler: Do the criteria in ACRE's register of non-commercial interests include non-pecuniary interests?

Professor Gray: Yes.

Mr McAllion: How good is the research that has been done on the health impact of GMOs? The committee took evidence earlier from representatives of the Royal Society of Edinburgh. They praised the Centers for Disease Control and Prevention in Atlanta for the way in which it closely monitors the health of the American population and detects any changes that occur. The committee also heard from Dr Charles Saunders that, as the food system in the United States does not make any distinction between GMOs and non-

GMOs, changes in health cannot be attributed to them.

There seems to be a question about the poor quality of the research into the health impact of GMOs. Is there sufficient evidence to make sound judgments about whether GMOs are a danger to human health in Scotland?

Professor Bainbridge: The ACNFP has considered fully the health impact of the consumption of GM foods. The committee decided that it would be a good idea to persuade the Food Standards Agency to commission some research. However, when the committee came to define the objectives that it hoped that the research would demonstrate, it found that that was technically difficult. Therefore, the committee commissioned a feasibility study, which is being carried out at Imperial College by one of the UK's leading groups of epidemiologists. The group is working to determine whether it is practical to monitor GM food consumption using a combination of data that are already available, such as medical records.

That work is almost complete, and the group will report in early spring. The Food Standards Agency plans to hold an open meeting to discuss the findings, which are out for peer review. I have not seen the results of the feasibility study. It has been a three-year project, and when it started, it was possible to buy GM foods, most notably tomato puree, which were clearly labelled. As a result of public pressure, those items are not available in supermarkets and it will be difficult to monitor something that is not being consumed.

It is not possible to correlate data on consumption in America and translate that to the human population. Therefore, it is difficult to monitor food consumption, but the committee is looking to see whether there is anything that the group can recommend to advance its knowledge.

Mr McAllion: Are you telling the committee that the quality of research available is poor, which is why the ACNFP has had to commission further research? There is no research that says that GM crops are safe and do not impact on human health.

Professor Bainbridge: I am not criticising the quality of the research and I am not saying—

Mr McAllion: That is what my—

Professor Bainbridge: I am saying that it is technically difficult to formulate an experimental protocol with rigorous controls to obtain results that are realistic and meaningful.

Mr McAllion: It is a simple question—is research available that says that GM organisms do not impact on human health?

Professor Gray: There is no evidence to show that they do.

Mr McAllion: That means that there is no evidence to show that they do not.

Professor Gray: We have to face the reality that GM has developed since 1983 and that more than 60 million hectares of GM foods are grown in North America and around the world. A whole set of people, including Americans, South Americans, Chinese and South Africans have been eating GM foods for a long time.

Mr McAllion: No one is looking for the health implications.

Professor Gray: No one has monitored them because there has not been a rational reason for doing so. If people who monitor health generally come across tummy upsets, for example, they ascribe them to pathogens. Bacteria cause health problems, not genes.

Mr McAllion: You are saying that there is no research on the issue. That is fine—we know that now.

Professor Bainbridge: It is necessary to monitor for an effect. Much work is done on the consumption of saturated fats. The concern about the number of deaths from cardiac disease is the reason for that research.

Mr McAllion: I am quite happy—you have said that there is no research. We accept that.

The Convener: Have you finished what you were saying? Mr McAllion jumped in on you.

Professor Bainbridge: I was saying—

Mr McAllion: I am sure that there is research on saturated fats, but that is not what I was asking about.

The Convener: We will move on, because we are way over time.

Nicola Sturgeon: In your written submission, you say that ACRE would not approve the release of

"crops modified to contain genes conferring resistance to antibiotics that are of clinical importance".

Will you give examples of other circumstances in which you would envisage not approving the release of a crop?

Professor Gray: I want to address the antibiotics issue, because it is important. I will try not to go into too much detail. It has been mentioned that antibiotics were used in the early development of GM foods. In particular, they were used as markers—the plants were grown on a medium containing the antiobiotic. Neomycin or kanamycin resistance has been referred to. As the Royal Society of Edinburgh witnesses said, that gene is widespread in the environment and is resistant to bacteria that are found in the soil and in the gut.

During my involvement with ACRE, both as a member and as chairman, there have been other applications in which different antibiotic resistance marker genes have been used. AAD is the gene that makes plants resistant to spectinomycin. Our advice was that that was an important antiobiotic in clinical terms, because it was used in an application for cotton in Spain and in a linseed that was to be introduced in the UK. Our advice to the minister was not to issue consent, because we had concerns. That is a good illustration of the fact that consideration is carried out on a case-by-case basis. Not all genes are the same and not all antibiotic resistance markers are the same.

I can think of other examples. A gene—an anti-feedant protein—was designed to target insects. There was evidence that the gene was non-specific in its effect and had a wide spectrum of effects on targets. I suspect that we would advise the minister that that should not be released.

Janis Hughes: In your written evidence, you claim:

"Risk assessments are continually up-dated in the light of new scientific information."

Does that support the criticism that current knowledge and evidence are insufficient and that, as some decisions might be irreversible, the precautionary principle should apply?

Professor Gray: I will say something about the precautionary principle. As I understand it, the precautionary principle tells us that, if we have a rational reason for supposing that there might be a risk or a harm, we should not act until we have eliminated that possibility. In other words, we should seek scientific evidence for such harm. We need some evidence of potential harm.

The trials are a good example of the precautionary principle. They are not about safety or danger or about harm to people. No one would release anything where there was any possibility of harm to people. The trials represent an attempt to understand whether using broad-spectrum herbicides—the substance in question happens to be a GM but, as Dr Hill said, it could be produced by conventional breeding—will impact on biodiversity in our farmlands. That series of trials is almost finished and the results will be available early next year. As you know, a period of public debate has been called for to decide whether the next step of full commercialisation—which happens on a very small scale in Europe, and not at all in the UK—should be taken. As a result, we feel that we have acted with precaution the whole way through the process.

12:00

We first saw the construct in the late 1980s. The dossier on importing oil and cake made from this herbicide-tolerant rape first came to ACRE in 1994 and to the French competence authority, which is a similar committee, in 1995. Furthermore, the European scientific committee and committees throughout the world have considered the evidence in order to assess safety. Where we have had worries—for example, with biodiversity—we have adopted a precautionary approach. The product was not released commercially. Instead we decided to find out whether it would impact on our countryside.

Margaret Jamieson: We have received written evidence that there is a lack of information about animal trials in the public domain. Why is that the case?

Dr Hill: As Professor Trewavas said earlier, a wealth of information is available in the literature. However, it is often not easily accessible, because the results of those animal feeding trials have shown that there are no adverse effects. It is not high-profile scientific information and is therefore published in relatively obscure toxicological journals.

Moreover, applications for deliberate release of GMOs are usually accompanied by detailed compositional and animal-feeding trial studies that the applicants have carried out. That information is all available to ACRE when it makes its assessment. However, some of the information in the applications is not in the public domain because of issues of commercial confidentiality. However, the principle is that as much information as possible is made public, while ensuring that we protect the applicants' rights with regard to commercial information.

Margaret Jamieson: Surely that causes concern? I expect that toxicologists know where to find the information; however, if a significant group of individuals involved in the health chain—if I can describe it that way—cannot access the information, how do you share it with them? It is unfortunate that people will think that applicants are simply hiding behind the claim of commercial confidentiality.

Professor Gray: I am sorry to bring members back to this point, but it is important to highlight it. All the information on feeding trials is available in the public domain in a massive 1,500-page dossier that details the various tests. Moreover, information on the insertion of a gene that codes with the same enzyme and confers herbicide tolerance in maize is also publicly available. ACRE has even held a public meeting at which people with contrary interpretations and different evidence have discussed the results of the feeding trials. In that case, the information is in the public domain.

However, Dr Hill is referring to the early stages of the so-called part B applications for research

and development trials. We are very rigorous about allowing companies to keep anything in commercial confidence.

Mary Scanlon: The Medical Research Council reported that substantial equivalence tests involve somewhat subjective judgment. How do you respond to that criticism?

Professor Bainbridge: I refute that statement. We at the ACNFP examine the dossier and make very strict comparisons between the GM and non-GM material that we are considering. We have never used substantial equivalence tests for any GM novel food product; we have always subjected the product to a full assessment.

The only time when we would use substantial equivalence is if we were considering a pure oil—a pressed, purified oil—perhaps a soya oil, which was derived from GM soya. Before we would go down the substantial equivalence route of our decision tree, we would be sure that there was no DNA of any type or protein in the soya oil. We would ensure that we were looking at 100 per cent pure oil. We would treat that as substantially equivalent to soya oil from a non-GM derivative. The assertion that the substantial equivalence route is a backdoor route or a shortcut is fallacious. It is true that we spend a vast amount of time looking at non-GM products that companies have submitted through the substantial equivalence route. We do not just accept the product through that route—we would look at it and verify it. We would often say, "No, we need to do a full assessment."

Mary Scanlon: You have talked mainly about the consumption of GM foods. Have you carried out an assessment of the allergenic risks that are posed by inhalation of the pollen and dusts?

Professor Bainbridge: The allergenic risk of the food is, again, a very complex issue. We have two people on the ACNFP who are experts in allergies—one has a scientific background and the other has a medical background—and we are always pushing the frontiers of what they know. We can look at protein sequences and compare them with huge databanks of protein sequences that are known to have caused allergy. We are constantly at the boundaries of the science and what we know. We have commissioned a large programme of research, with specific objectives, to help us to arrive at a more robust decision-making process. It is a fascinating area and we need to learn a vast amount. I stress that we are interested in the allergenic response following ingestion of food.

Mary Scanlon: Would I be right in saying that you have not carried out an assessment of the risks that are posed by inhalation of GM dusts and pollen?

Professor Bainbridge: We have not carried out a formal assessment of inhalation. However, we look very closely at honey, for example, to examine the likelihood of the presence in it of GM pollen and the effect that that may have in provoking an allergenic response.

Professor Gray: We took advice on the pollen in question. The committee heard from Professor Trewavas that the particular protein is not expressed in the pollen. We asked the questions that would be asked in a risk assessment: what if that is wrong? If it is wrong, what would be the impact of inhaling that pollen? What is the conceivable risk from so doing? The conclusion was that the risk was no greater than the risk from inhaling rape-seed pollen. Rape-seed pollen—I think that this is contrary to what Tony Trewavas said—releases large volumes of pollen into the air, whether or not it is insect pollinated. I know that that has an impact on people with asthma and respiratory problems who live near oil-seed rape fields. We asked that question and we could find no reason why having that particular gene would make a difference.

Mary Scanlon: Are the distances that are being set in the crop trials adequate to prevent bees from pollinating non-GM crops with GM pollen?

Professor Gray: We heard something of an answer to that earlier. We face some real problems on this matter. The distances for the farm-scale evaluations were set to ensure that the threshold levels of cross-pollination between the GM and non-GM would not at any time exceed 1 per cent. The amount of cross-pollination falls off rapidly with distance. Depending on the size, source and position of the site and whether it is downwind, there is enormous variability.

The Scottish Crop Research Institute has done a lot of elegant work to show that it would be difficult in a commercial world—that is something that we will have to debate—to separate GM and non-GM oil-seed rape. It would be different with other sorts of plants. Professor Lamb alluded to a scheme that is used to separate industrial oil seed with high erucic acid levels from oil-seed rape for food. The scheme is used in Essex for zoning, and it is constantly monitored to ensure that the levels in the food do not exceed EU standards. Again, the public's desire for GM-free food will constrain the ability to grow the two crops side by side. That is a different debate, but for the trials, the distances are adequate.

Mary Scanlon: Sorry, could you repeat that last point?

Professor Gray: For the trials, the distances are adequate to ensure that the presence of any GM protein in the non-GM site does not exceed 1 per cent. As you heard, the material is destroyed at the end of the trial in any case.

Shona Robison: Do you take into account the decisions of other EU member states? For example, if other member states decided against proceeding with oil-seed rape trials, would that affect your conclusion? Do you reconsider your advice in the light of the decisions of other EU member states?

Dr Hill: Perhaps I can answer that by explaining a little about how the EU process works. The process distinguishes between two types of release depending on their purpose. They are releases for marketing and releases for purposes other than marketing, which are primarily for research. In the case of releases for research purposes, the decision about whether to grant consent for release is a matter for the member state. Indeed, within the UK, it is for the devolved Administrations to decide whether consent is given. The marketing process involves wider consultation in the EU, and the decision is EU wide.

You asked whether a decision by another member state would influence a research release in the UK. It would if that decision was based on new scientific evidence that had not been considered by the committee in its initial assessment or on a new interpretation of existing scientific evidence. Therefore, the answer to your question is yes. If a decision were taken elsewhere in the EU on a part B research release, we would re-examine the decision in the UK. However, that does not mean that we would necessarily agree with the other decision.

Professor Gray: I want to add something that I meant to say when we were talking about antibiotic resistance. Dr Hill's mention of the EU has reminded me that the new regulations say that antibiotic resistance marker genes must be phased out in crops that are cultivated by 2004 and in the smaller so-called part B trials by 2008. The new regulatory system has said, in effect, that antibiotic resistance markers can no longer be used in the development of crops.

Shona Robison: It just strikes me that some other countries have made decisions—presumably on scientific advice—and come to a different conclusion. Are you saying that that is a different interpretation of the same scientific advice?

Professor Gray: I do not remember a different decision.

Shona Robison: There were some on the oil-seed rape trials.

Professor Gray: On the oil-seed rape case, there were differences based on agronomic experience. When the idea of herbicide-tolerant oil-seed rape first came out, one question was whether transferring the gene to a weed in the field—either another oil-seed rape that was a volunteer weed, or a relative—would create a weed problem. It happens widely. There are 125 species in the world that are herbicide tolerant because we have been putting herbicides on to fields. According to our agronomy advisers, that was not an issue in the UK, as we do not have a big problem with a related plant called wild turnip—brassica rapa—as a weed, but Denmark does. Therefore, part of the assessment in Denmark would have been based on whether it was sensible, not just safe, to create a weed problem.

Those are differences in interpretation in respect of how to grow the plants, but I do not remember any major differences on safety grounds between scientists in different countries. In fact, we get together regularly with our opposite numbers in Europe to discuss issues. We have to tell ministers that we think that research should be done if there is uncertainty in an area. The trials are about uncertainty.

12:15

Shona Robison: I have a final question on public perception, which John McAllion asked about. The answer that he was finally given seemed to be that there was no evidence one way or the other on harm, or no harm, being caused to people living in the locality of a crop trial. Given that answer, could it be argued that it would do no harm to have on-going monitoring of the health of local populations, even if only to allay the fears of cynical MSPs or cynical members of the public? Would that be a positive approach?

Dr Hill: It is worth pointing out that ACRE's remit is to advise the Government on the risks that are posed by releases of GMOs. Having received that advice, the Government must decide whether a release should continue and whether it should be monitored. ACRE's advice on the particular line of GM oil-seed rape that we are discussing is that there is no risk to human health or the environment, as the protein that is concerned has been well characterised and its properties are well known. There have been animal feeding studies, for example, and there is a battery of evidence behind that statement. If the Government receives such advice and thinks that there should still be monitoring, that is a perfectly valid—

Shona Robison: You advise whether there should be monitoring. There is advice in your evidence, so giving advice is in your remit.

Professor Gray: Of course we do and we accept responsibility for it. Nobody has advised us and we can see no reason why, if there was such monitoring, there should not logically also be monitoring of every new variety that is produced by cross-breeding and every new crop of lupins,

for example. If one is to have a rational and reasonable basis for advice, it must be based on the science.

I fully understand people's concerns. People have become frightened of genetic modification and the blame for that can be laid in many directions. I am a grandfather and do not want to think that I would be responsible for doing anything that might harm future generations. There is simply no rational basis for those concerns. We searched rigorously for any evidence that there could be a human health issue.

The Convener: We will leave the discussion there. I thank the witnesses for their written and oral evidence.

Our final witness is the Minister for Environment and Rural Development, Ross Finnie, who has been waiting for a long time.

Good afternoon, minister. I apologise for the fact that the meeting is running substantially later than anticipated—that reflects the fact that we are finding the topic not only challenging, but increasingly interesting, as we get into it. From memory, I think that you are the first minister without responsibility for health that the committee has questioned; I am not sure whether you should feel honoured or victimised. Do you wish to make a statement or are you happy to take questions?

The Minister for Environment and Rural Development (Ross Finnie): Thank you, convener. I have one or two brief introductory remarks to make.

As the convener rightly points out, I am not the minister with responsibility for health and these introductory remarks allow me to put my own position into context. The issue of my acting principally on behalf of my colleagues in the spirit of collective responsibility arose because genetically modified crops could be seen as a branch of agriculture. It therefore fell to me to act as the principal minister, although I am always acting on behalf of the Scottish ministers.

Having assumed that role, it is fair to say that, in common with the committee, I had to absorb an enormous amount of briefing to try to understand the process and regulatory framework within which I was to operate. One becomes more familiar than one would wish with directive 90/220/EEC—the committee will also have done so. It was also necessary to see the directive transposed into domestic legislation in respect of part VI of the Environmental Protection Act 1990, from which a number of statutory instruments have flowed that control the release of genetically modified organisms.

That may be all very interesting if rather dry, but it is also rather important. Two things struck me forcibly as a result of the directive. First, ministers were required to come to decisions on the basis of objective scientific advice. It became obvious that the body from which the committee has just taken evidence—the Advisory Committee on Releases to the Environment—was established to give ministers access to objective scientific advice.

Secondly, a priority of the regulatory framework was that, in granting permission for release, ministers had to be satisfied on an objective basis that such a release would not pose an unreasonable threat to the environment or, in the case of the remit of the Health and Community Care Committee, to human health. Decisions were taken on that basis and on a garnering of an understanding of that basis.

The trials are unusual in the sense that, technically, they do not form part of the regulatory process. The new Labour Government, which was elected in 1997, added that step in recognition of the real concerns that no adequate work had been done to test the effect of growing such crops on biodiversity. My query in that respect was to ask what was the step that preceded that decision.

As I am sure the committee has heard from ACRE and others, one had to have at least some understanding that the seeds that were to be the subject of such applications could not be approved by ACRE unless there had been prior testing either in a laboratory or in confined areas or small plot-scale trials. The seeds did not suddenly come for ministerial approval for use for the very first time; they had to have been subjected to a previous testing regime. To use the technical term, they had to have part B approval.

That was the context in which I referred the first and all subsequent applications to the Advisory Committee on Releases to the Environment. My simple standpoint was that I required to receive from the advisory committee unequivocal assurances, based on independent scientific objective analysis, that the proposed trial posed no material threat to the environment or human health —in terms of the seed and variety to be used, its location and all the other factors that were involved. Only on receiving those assurances have I granted the applications that have been made to date.

Bill Butler: Many opponents of GM crops claim that the potential risks that they pose to human health and the environment far outweigh the benefits that they offer. What do you see as the benefits of allowing GM crop trials? Are you concerned about the potential disbenefits of allowing such trials?

Ross Finnie: There are two elements to Bill Butler's question. The trials precede the process of assessing whether GM crops should be allowed

to enter the food chain. We are assembling information for the process of determining whether we are satisfied that the crops should be grown and that a part B consent should be issued.

The benefits of GM crops must be proven in the round. One potential benefit is a radical reduction in the amount of pesticides and other chemicals that are used. We may also be able to reduce soil erosion and to provide targeted means for growing crops by focusing on issues such as exposure to sunshine, dearth of water or excess moisture. There are a number of potential benefits associated with GM crops. Genetic modification could lead to a better quality and yield of crop. However, that must be proved. The process in which we are engaged is aimed at establishing whether such benefits exist, within a strict regulatory framework.

Nicola Sturgeon: I would like to comment on something that you said in your opening statement. How meaningful is your instruction to ACRE that it should make an unequivocal recommendation to you? This morning we have been told that science cannot be unequivocal or provide guarantees. Do you want to comment further on that?

When you are deciding whether to give consent to a trial, what evidence or information do you take into account in relation to that trial's implications for public health? Are your decisions based entirely on advice from ACRE or do you consider information in addition to ACRE recommendations?

Ross Finnie: Clearly, we are in the business of managing risk. Much of life is about that. We must reach a view on whether ACRE comprises people of sufficient skill, expertise, probity and integrity for us to be able to rely on that body. I accept wholly that in the case of GM crops we are dealing with the balance of probabilities, rather than absolutes. That is true of any scientific issue. It is important that ACRE is able to reach a balanced view, having taken account of all the factors and accepting that it cannot speak with absolute certainty on this matter. ACRE should be able to say, with all the caveats that I have mentioned, that it is advising ministers that release to the environment as part of the regulatory process should not cause material harm either to health or to the environment.

Nicola Sturgeon: That is hardly unequivocal.

Ross Finnie: Let me illustrate what I mean. Clearly, ACRE cannot be absolute about the risk assessment process and its evaluation. However, I did not want ACRE simply to list concerns and uncertainties. I really wanted an opinion that, in all the circumstances, was as clear as it could be. Had ACRE confronted me with a list of concerns and uncertainties, I would have asked whether some of those concerns that were subject to something else could have been purified before I received the advice.

12:30

Derek Bearhop (Scottish Executive Environment and Rural Affairs Department): Although the advice from ACRE is paramount in ministers' consideration, the minister also receives advice from the Health and Safety Executive and the Food Standards Agency prior to every decision that he takes in relation to release. Those agencies focus much more on health than environmental issues, which are a large part of the ACRE remit.

Nicola Sturgeon: The second part of my question concerned what information about public health implications is considered when a final decision is being made.

Ross Finnie: One was concerned to know what aspects of the potential risks were being assessed. We are dealing with the crop growing, not the entry of the crop into the food chain. Therefore, one was concerned to know that some assessment was being made of the risk of the content of matter that was presumably airborne, which is recognised as carrying the greatest potential risk to humans coming into contact with the material. Therefore, one wanted to know that the agencies were concerned about that, and that information was being assessed to enable those agencies to form a view about the risk of inhaling airborne material from pollen from the particular crop.

Janis Hughes: When the minister gave evidence to the Transport and the Environment Committee in May, he was asked why the Belgian minister had refused to give consent to certain releases. At the time, he said that he was unsure whether those decisions were based on scientific evidence or some other ground. Can the minister shed some further light on that?

Ross Finnie: My understanding of the situation is that, like me, the Belgian minister had received advice from the near equivalent of ACRE in Belgium. I hate to go back to the term, but it is my understanding that the Belgian minister formed the view that there was some equivocation in that advice. She did not refuse that advice, but sought further clarification from the equivalent body.

Janis Hughes: What was her subsequent decision when she got further information?

Ross Finnie: I am not clear. We certainly know that she has not pronounced a decision. All we know is that we are still in the position where she remitted it back to the committee for further advice.

Shona Robison: On a similar theme, the minister's correspondence with the Transport and the Environment Committee of April 2002 states that a refusal to grant deliberate release consent would be illegal unless it was based on sound scientific evidence of potential harm. Therefore, why was the application for MS8RF3, the oil-seed rape trials, refused by eight other EU countries but approved in Scotland?

Ross Finnie: With all due respect, one would have to ask those EU countries that refused. Directive 90/220/EEC and its replacement, 2001/18/EC, are both quite clear that those decisions should be based on objective scientific advice. I have explained the process, and it is my decision. However, to satisfy those criteria, I receive advice principally from ACRE, but also from the FSA and the HSE. If one follows the logic of how the regulations are written, one must grant on the basis of objective scientific advice. If one intercedes, it must be on the same basis. I had no such basis for not granting or for interceding.

Shona Robison: You have told us of the similar format and evidence that ministers and other EU countries will be presented with. Given the fact that different conclusions were reached from similar scientific evidence, is it the ministers' conclusions based on that evidence that are different or is it their assessment of risk? What do you think the differing opinion is?

Ross Finnie: With respect, I think that you are asking me to enter the minds of fellow ministers. I am capable of doing a number of things, but I am not capable of entering the minds of other ministers. I can only state clearly, honestly and openly the basis upon which I have sought to discharge the heavy responsibilities that are laid out in statute and prescribed in those terms. I have explained that, in relation to the particular seed to be used, the particular site and all the other circumstances that were taken into account, I received advice that did not suggest that either of the advisory bodies had any concerns about the statutory requirement of the process. In those circumstances, no other objective scientific factor was presented to me.

Shona Robison: Do you have regular contact with the other ministers?

Ross Finnie: Not on this issue.

Mary Scanlon: Given the fact that the substantial equivalence tests have been criticised as being subjective and unscientific, are you satisfied that the risk assessment process is robust enough from the public health perspective?

Ross Finnie: That question would be more properly answered by the Minister for Health and Community Care. If you examine that issue, you will find that there is perhaps more criticism of equivalence tests in relation to products that are entering the food chain. I have looked carefully at the evidence that has been presented. When material is entering the food chain, there are issues about the standard and level of testing that is required. I have considered the matter carefully, as it is a very difficult duty to discharge.

Mary Scanlon: The impression that I have received from this morning's evidence is that there is more testing on consumption. The Royal Society of Edinburgh's submission states that it

"has noted that there was no formal assessment of the allergenic risks posed by inhalation of pollen and dusts."

You have stated unequivocally that there is no threat to human health. However, do you feel that insufficient assessment has been made of the potential allergenic effects of pollens and dusts?

Derek Bearhop: We heard from ACRE that it actively considers the allergenic consequences of airborne pollutants, if we can call them that. The Royal Society of Edinburgh concluded that it was satisfied that the risks posed by the products that had already been through the approvals process remained under control. It referred to future food products on which it wanted further allergenicity tests to be conducted.

Mary Scanlon: So it is an area of uncertainty. More robust evidence has been taken on the input to the food chain than on the inhalation risks. That is where we are on this one.

Ross Finnie: It is partly, but it is also a question of the assessment of risk by those bodies. They have stated that, in their opinion, the risk is less from a crop than from a foodstuff. That is why different tests have to be applied before permission can be granted for a product to go beyond part B into part C of the process.

Mary Scanlon: You stated at the outset, minister, that, according to advice given to you, there was no harm to human health, yet we have received a paper from the RSE citing various concerns. The BMA, which represents 80 per cent of doctors, has expressed very serious concerns. Its written evidence states:

"GM crop trials present us with profound uncertainties."

If the minister could put himself in our shoes for the time being, he would appreciate that we have to come to a decision on the matter. We cannot ignore an organisation representing 80 per cent of British doctors. Does the matter concern you?

Ross Finnie: Yes, but I have not had much time to study the BMA's submission in detail. The initial process whereby seeds are assessed involves a range of tests, going from laboratory testing to plot testing to field-scale trials. There is a clearly stated reservation on the part of the BMA, but—and this

may be because I have not had the same time as committee members in which to study the BMA's document—I have not been able to discern which part of the process, which is being undertaken according to the applicable regulation and which has been assessed by ACRE, the BMA finds wanting. I would be very interested to know that—it is at the heart of the matter.

One can have views and opinions based on anecdotal evidence—and I will read the BMA's submission with considerable interest—but I would be interested to establish at what point in the regulatory process the BMA has adduced evidence that undermines or seriously questions that process. I regret, convener, that, in the time that is available to me, I am not able to read that. From having briefly read the BMA's report, I am not sure that we are aware that—

Mary Scanlon: I do not wish to start representing the BMA—

Ross Finnie: Let me make it clear that I take very seriously an opinion expressed by that body, but we are dealing with a process that is laid down by regulation. I hope that ACRE will have made clear in its evidence to the committee the criteria that it applies when determining risk, and that it commented on the processes that it goes through in order to assess that risk. I am open for someone to present evidence that demonstrates that the process and criteria that ACRE uses to gauge harm when it gives advice on the risks are in some way flawed.

Mary Scanlon: To me, that is the crux of the matter. I looked through ACRE's nine-page impacts matrix for risk assessment. It looks very impressive, but my problem is that ACRE's risk assessment has not been sufficient to satisfy the concerns of an organisation that represents 80 per cent of our doctors. As a member of the Health—

Ross Finnie: I want to find out whether the BMA has actually considered ACRE's risk assessment.

Mary Scanlon: So do I.

Ross Finnie: It may well be that it has done so, but I am slightly surprised that the BMA's submission does not say that it has reviewed the ACRE assessment of harm and then detailed the areas where it finds the assessment wanting. I would put myself exactly in Mary Scanlon's position in that regard but, with all due respect, I do not think that she has reflected quite what is being said. I share your view, Ms Scanlon: it is a material consideration whether the BMA is saying that, following an objective, critical analysis of the criteria for assessing harm, it finds that analysis wanting.

Margaret Jamieson: Do you believe that the companies that are involved in GM crop trials should be forced to take out insurance to provide compensation for any harm arising from any as-yet-unknown effects of GMOs?

Ross Finnie: I have considered the matter, as have the relevant bodies in the European Union that oversaw the formulation of European directive 2001/18/EC. There is a bit of a puzzle here. The European approach, which is in marked contrast to the North American approach, states that we will not let companies release GMOs into the environment unless we have assessed the risk. It also states that we will control and regulate the process.

It would be a little odd to have insisted that the applications go through and to have approved the seed variety on the basis of an opinion that it causes no harm to the environment, but then to say that we want to force the company to have some level of minimum insurance. There would be a dichotomy. Would the regulatory authority then be perceived to be saying that the process is not robust and sound?

12:45

Margaret Jamieson: The issue for us is that we have heard evidence that suggests that the problems would not present themselves in the first five years and that they might involve long-term health issues. Obviously, we are concerned about the impact that that will have on the public purse. Do you believe that you have an obligation to ensure that you protect the public purse when making an authorisation?

Ross Finnie: With respect, that illustrates the dilemma. If there is substantive evidence that there would be a long-term problem, I cannot see how the seed would get through the first part of the process. If that is the conclusion of objective advice, we should not be granting the approval.

There are other issues, which I will not go into because I have not had to deal with them, that relate to the commercial growing of crops and the entry of those crops into the food chain.

Margaret Jamieson: I draw a comparison between the process that GMOs go through and the process that the pharmaceutical products go through before they are marketed in the UK. Pharmaceutical companies are required to have in place assurances that protect those who dispense the trial drugs and those who monitor the effects of them to ensure that no accidents occur in that process. The two situations are quite similar, but your view of how GMOs should be dealt with is quite different from your view of the way in which medicines should be dealt with.

Ross Finnie: That issue has generated a considerable amount of debate.

Derek Bearhop: I take the point that you make. The Environmental Protection Act 1990 offers some form of penalties should there be infringements of the conditions that apply to every release. Obviously, the companies are still bound by product liability legislation and, indeed, if any harm is caused by nuisance or negligence, that is a matter for the courts. The real issue is one of economic loss in relation to GM crops and that is not covered by legislation at present. Whether that situation changes would be a political decision.

Ross Finnie: It is still a matter for debate.

Nicola Sturgeon: This morning we have been talking about risk assessment and scientific evidence. I do not for a minute underestimate the importance of all that, but what role, if any, should the general public and public opinion have in the decisions about whether to allow a trial to go ahead?

Ross Finnie: I have stated publicly that I am in no doubt that the process that was prescribed under EU directive 90/220 and was transposed into part VI of the Environmental Protection Act 1990 was deficient in relation to public engagement.

It is instructive that the Agricultural and Environmental Biotechnology Commission—AEBC—which was invited by the UK Government to assess the progress of the trials, came to the conclusion to which I rather suspect everyone in this room will have come, which is that the very appearance of the trials has generated a debate about genetic modification that ought to have taken place 10, 12 or 14 years ago when the varieties of seeds were being granted part B approvals. That is why AEBC recommended to the UK Government that there ought to be a much wider debate in which information that had not been adequately discussed in public could be scrutinised properly. It was felt that everybody would benefit from a much wider dissemination of information about the process so that they could arrive at a more informed view.

The critical point is that we have drawn a line after the end of a trial process before moving forward to the commercial growing stage at which the organism would enter the food chain. It is appropriate, therefore, that there should be a wider debate that will, we hope, raise the level of information available so that everyone can make an assessment on the basis of better information.

The Convener: I am aware of the fact that at least two members still want to ask questions, but we have gone way over our time and we have to consider our draft report on the Mental Health (Scotland) Bill while we still have our adviser with us. Therefore, with your agreement, minister, I suggest that Dorothy-Grace Elder and John McAllion write to you, through the clerks, with the questions that they were unable to ask orally.

That completes the public part of this morning's business.

12:51

Meeting continued in private until 13:12.

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