HEALTH AND COMMUNITY CARE COMMITTEE

Wednesday 27 November 2002
(*Morning*)

Session 1

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HEALTH AND COMMUNITY CARE COMMITTEE
31st 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

Dr Mac Armstrong (Scottish Executive Health Department)
Dr Martin Donaghy (Scottish Executive Health Department)
Dr Vyvyan Howard (University of Liverpool)
Elspeth MacDonald (Food Standards Agency Scotland)
Mrs Mary Mulligan (Deputy Minister for Health and Community Care)
Dr David Robinson (Scottish Crop Research Institute)
Dr Paul Rylott (Bayer CropScience)
Dr Geoffrey Squire (Scottish Crop Research Institute)
Lydia Wilkie (Food Standards Agency Scotland)

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SENIOR ASSISTANT CLERK

Peter McGrath

ASSISTANT CLERK

Graeme Eliot

LOCATION

Committee Room 1

Scottish Parliament

Health and Community Care Committee

Wednesday 27 November 2002

(*Morning*)

[THE CONVENER *opened the meeting at 09:36*]

Item in Private

The Convener (Mrs Margaret Smith): Good morning. I welcome everyone to this meeting of the Health and Community Care Committee.

I ask the committee to decide whether it should take in private item 4, which concerns our draft report on the Mental Health (Scotland) Bill. Our usual practice is to take such items in private. Are members agreed?

Members *indicated agreement*.

Subordinate Legislation

Plastic Materials and Articles in Contact with Food (Amendment) (Scotland) Regulations 2002 (SSI 2002/498)

The Convener: The second item on the agenda is consideration of a negative instrument. No committee members have made any comments on the regulations and no motion to annul has been lodged. Moreover, the Subordinate Legislation Committee has made no comment. As a result, it is recommended that the committee has no recommendation to make on the regulations. Are members agreed?

Members *indicated agreement*.

GM Crops Inquiry

The Convener: The next item on the agenda is our final day of evidence taking for our inquiry into the public health aspects of genetically modified crops. I welcome to the meeting our first witness, Dr Vyvyan Howard from the University of Liverpool. I invite Dr Howard to introduce himself and to make a short, perhaps two or three-minute, statement. My colleagues and I will then ask some questions.

Unfortunately, as we have only just received your submission, it is more likely that you will be asked general rather than specific questions about your paper. When we have had the chance to consider the paper in more detail, we might well want to send you some written questions. Would that be acceptable?

Dr Vyvyan Howard (University of Liverpool): Absolutely. I apologise for the late submission; I have just come back from the US.

I thank the committee for the opportunity to attend today's meeting. I am a pathologist, specialising in toxicology. My group is particularly interested in matters that affect the developing child, the foetus and the infant.

This morning, I want to address the issue of risk assessment, what it tells us and, more important, what it does not tell us. We all espouse the precautionary principle, but it is rarely invoked, mainly because evidence in the form of a risk assessment is usually produced to show that something is safe.

The precautionary principle has been criticised in connection with stifling progress; that is covered on page 3 of the paper that I sent round. That comment appeared in *Nature*, and the next page of my paper features a letter that Professor Peter Saunders and I wrote to *Nature*. We pointed out that the precautionary principle was not about that. It is a tool for the use of, and for assistance to, decision makers in deciding whether the next step along a path ought to be taken. In the taking of that decision, consideration needs to be given to what the benefits are and what the costs are. That relates partly to the speed at which progress is made. Most of the things that I want to say this morning are essentially covered in our letter to *Nature*.

Risk assessment is a process that considers various sorts of information and comes to some sort of probabilistic conclusion. We should realise that risk and hazard are not the same thing. If someone crosses the road, they might be hit by a bus; that is a hazard. The risk is the likelihood of them being hit each time that they cross the road. On page 6 of my paper, I present a summary of a risk assessment that was produced by Monsanto a

few years ago. The bottom line says:

"The overall risk of damage is assessed as low to effectively zero."

That really means that the risk is non-zero. Everybody accepts that. Various things are missing from that statement, however. How long is it good for? Is it good for 10 minutes? Is it good for the duration of a growing season? Is it good for several generations? That is never explicitly stated.

Page 7 deals with the four phases of risk assessment. First, people have to be able to identify hazards, because it is not possible to test for hazards that have not been thought about. That is usually the most difficult phase. Secondly, hazard assessment is required for those hazards that are identified. That is hard science, which requires experimentation. If that comes up with negative results, those have to be addressed. Thirdly, for food, we need exposure assessment. We need to ask who is eating what and how much of it. It is only when all those are in place that—fourthly—a risk assessment may be attempted. Without the first three steps, however, it is very difficult.

Risk assessment was first devised by engineers to assess the structure of buildings, an area in which the problems are finite. However, the principle is now being applied to very complex systems, such as ecosystems, which contain many unknowns. When there are unknowns, people tend to replace data with models. At one extreme, it is possible to have risk assessments that are based totally on models, with no data. As well as the other extreme, we can have all the places in between.

Page 9 covers hazard identification. Areas of potential hazard include genetic instability, horizontal gene transfer and pleiotropic, unpredictable effects, such as allergy and toxicity.

For hazard assessment, we are presented with substantial equivalence as the test. However, that is a chemical test and we are really interested to know about the biological effects. That requires a biological hazard assessment, which is rather like the way in which a drug is tested. At the minute, however, the standard test is a simple one of chemical composition. If the product passes that test, it is then licensed—that is certainly the case in the United States.

Page 12 of my paper deals with exposure assessment. No exposure assessment has been done, as far as we know. In the States, where the GM plants have been introduced, no one really knows who is eating what. Without that information, we have to ask what the risk assessment is based on.

If subtle changes were being caused to people's health by GM plants, we would not know. What is worse, we would not have any way of detecting those changes, because we do not know where we are starting from and we do not know what the exposure level is. If GM products were acutely toxic, we would obviously know, but we accept that they are not acutely toxic. If, however, they were causing subtle changes at the level of allergy and so on—common things—we would not know. If thalidomide had caused cleft palate instead of a rather obvious malformation, the likelihood is that we still would not know about it, because cleft palate is a common condition. If one starts changing the rate of instance of common conditions, and one does not know the starting point and there is no exposure data, one cannot know whether something is causing a problem.

09:45

I turn to the last slide, on page 18 of my paper. The toxicological aspect of novel foods is a tractable problem. We could develop the methods to test them adequately, but we are not doing so at the minute. Such testing is done in the pharmaceutical industry; it costs about $400 million to produce a new pharmaceutical. We take pharmaceutical products voluntarily—usually for a good indication, usually for a limited time and usually in thousandths or millionths of a gram, so the lifetime exposure is probably a few grams. With food, we do not have any choice. The dose is kilograms in a day or tonnes in a lifetime. There are very strong arguments for being rather cautious about this technology; we are not doing enough to test those things, and that needs to change.

Nicola Sturgeon (Glasgow) (SNP): We will return to some of the issues that you raised about the risk assessment process. As a toxicologist, can you outline some of your concerns about the potential health implications of GM trials, especially the farm-scale trial of GM oil-seed rape?

Dr Howard: I am particularly concerned that if we cause subtle changes to principal components of the food chain, the most likely place in which they will have an impact is development. Subtle changes to the composition would not be picked up by a test of substantial equivalence—biological activities would have to be looked for. We know that, at particular times in development, the body's hormones are controlling development in low parts per trillion, which is an incredibly low concentration. For instance, we know that some chemical pollutants, which each of us has in our bodies, are able to be bioactive and cause problems at low parts per trillion. Those things are being measured now.

My first concern is that we need to test novel foods for biological activity in a developmental situation, which is the most critical time of life for being pushed off course. Currently, there are proposals to introduce vaccines and drugs into genetically modified plants to produce them for the pharmaceutical industry. If those genes get into the general gene population, there is a very definite prospect of them affecting development. My principal area of concern is at that level. Once a person is fully formed as an adult, it is rather more difficult to produce a toxicological effect.

Dorothy-Grace Elder (Glasgow) (Ind): Can you enlarge on your interpretation of the precautionary principle? You have explained substantial equivalence very well, in which a biological test is needed more than a chemical test.

Dr Howard: It is always easier to do something than to do nothing. That is a basic statement. The precautionary principle states that the weight of evidence should be examined and that one should be prepared to act without knowing that something is absolutely, scientifically proven to be the case. It means being prepared to act on the balance of probabilities. When a new technology is started, there is very little or no evidence.

In general, we have some working examples from the past. For instance, the green revolution, which involved the widespread use of chemicals in agriculture, had the net result that everyone sitting round this table has residues of several thousand chemicals that could not have been around when our grandparents were in their mothers' wombs.

Now, people say, "Gosh, that is a problem. We should reduce that amount." That result could have been predicted, because we knew the chemical nature of those compounds. They were fat soluble and persistent, but if somebody had said at the beginning, "We should not develop the technology because this, this and that might happen," a storm of protest would have arisen, and the chance of precaution being used would probably have been low. We are at the beginning of a new technology. If we embrace it, we must accept that the genes will spread. That is a given.

Dorothy-Grace Elder: That is the case once the genes are released. Your evidence says that the situation is different from the introduction of a new drug. If we are wrong about a new drug, it can eventually be withdrawn, as thalidomide was in the long term. However, once genes have left the laboratory, they cannot be recalled. That suggests that you are thinking of possible long-term damage to human beings—you referred to subtle changes that could occur in the body. Do you think that nothing might show up for many years?

Dr Howard: We are not collecting the information to find that out. If changes are caused, the link will be difficult to demonstrate. The technology is powerful and potentially useful in medicine, but we must treat it with much respect. I understand that any changes that we make will be in perpetuity, because they will self-replicate.

We have seen horizontal gene transfer. That is common sense. Any risk assessments that address the matter should assume that once genes are released into the environment, they will travel, although it is implied that that is not the case. Much more work must be done in the laboratory before general use is adopted and we use the planet as a test tube. Not enough homework has been done.

Mary Scanlon (Highlands and Islands) (SNP): Will you comment on the toxicological evidence base on which farm-scale GM crop evaluations are conducted?

We just received your paper this morning.

Dr Howard: I am sorry. I sent it yesterday and I realise that it was late.

Mary Scanlon: Will you expand on the points on pages 12 and 17 of your submission? Page 12 says:

"Exposure Assessment

There is none!

- GM crops were introduced into the US without any monitoring of consumption
- There were no baseline studies and nobody knows who is eating what
- There is no chance of finding out if GM foods are having an effect on common conditions such as allergy without this information".

As a member of a committee that deals with health, that seriously concerns me.

Dr Howard: You quoted a statement of fact. If people do not know where they are starting from and do not monitor exposure to the substance in which they are interested, they cannot relate that to any changes that might happen in the pattern of disease. It is important to realise that the risk assessments that are being presented are, by and large, opinions. They are not based on adequate hard evidence for conclusions.

We should undertake large-scale voluntary human feeding trials with such foods. That is what we do with pharmaceuticals—we test them in clinical trials. That is an option for considering human response. To look for allergies, we would be talking about big studies that involved several thousand people, but that could be done. However, at the moment, GM products are being released on to the market without any notion of who is eating what and what that is likely to cause.

As I said, if a change is caused to something that is common anyway, the chance of finding a causal link is as near to zero as we would care to consider.

Mary Scanlon: That is the problem. If there is an increase in asthma, there is no way of tracing it back to the increase in GMOs, or whatever. There is no trail.

Dr Howard: Not with the current database, no.

Mary Scanlon: The chief medical officer states in his submission:

"The available scientific evidence indicates that the potential adverse health effects arising from biotechnology … are already familiar to toxicologists."

He also quotes the World Health Organization:

"GM foods currently available … have passed risk assessments and are not likely to present risks for human health."

The chief medical officer seems to be satisfied with the risk assessments that GMOs have undergone. Are you saying that those risk assessments were inadequate or merely opinions?

Dr Howard: The British Medical Association is less sanguine than the chief medical officer. There is, therefore, diversity of opinion among the medical profession on that issue. The chief medical officer might well be right, and I hope that he is, but we do not know. I do not think that the way that we have approached the issue will tell us. The only way to find out about human allergy, for example, is to test the crops on humans. The surrogates that are used in sequence homologies of amino acids and peptides do not really test for that. Testing has to be done properly, and I do not think that we have done that yet.

Mary Scanlon: The BMA paper seems to sum things up. The BMA says that, although GM foodstuffs have yet to be shown to be directly harmful to human health, they have equally not been shown to be not harmful in the long term. Does that sum up where you are coming from?

Dr Howard: Yes; that is a reasonable summary. The difficulty is not that we do not have the tools to approach the problem and to try to find out properly; the difficulty is that doing so will mean treating GM foodstuffs a bit more like pharmaceuticals, on a one-off basis, and that will be expensive. Of course, the developers do not like that idea. That is where the debate rests at the minute.

Mr John McAllion (Dundee East) (Lab): One of the arguments that is used by the chief medical officer and others who defend the current farm-scale evaluations is that, as they are not food safety trials and the material that is harvested is not used in the food chains, there is no need to test them for human allergies. Is that a reasonable argument?

Dr Howard: That is an example of something that we should be interested in finding out. The trials are a step along the way to full-scale introduction. If we have the trials without knowing the answer to the allergy question, we have taken more steps than we should have.

Clearly it is more complex to test a food—which is a mixture of many thousands of different compounds—than it is to test a single drug. However, it should be possible to develop such techniques. That is what Dr Pusztai was charged with doing. He got £1.6 million of Scottish Office grant, in competition with other laboratories, to develop techniques of hazard assessment for novel foods. That work does not seem to be continuing, although it should be. We should be developing methods of assessing the toxicological nature of novel foods, but such work is not being funded further.

The Convener: You said in passing that there were potential benefits from genetic manipulation, especially from its use in the technology of medicine. Can you say a bit more about that? The House of Lords Select Committee on the European Communities said in 1999 that it felt that the benefits of genetically manipulated crops outweighed their potential risks. What is your view on the potential benefits from either the crops or the technology in general?

Dr Howard: I have been prescribing insulin that has been produced by genetic modification techniques for decades, as have most other medics. That is an example of the use of recombinant DNA technology to produce medicines.

Recombinant DNA technology as we know it now is a hit-and-miss technology. New technologies that are emerging will be much more precise and controllable. I briefly address that important issue on page 14 of my paper. The classical paradigm on which recombinant DNA technology is based is that DNA produces ribonucleic acid, which then codes for a protein—it is a simple mechanistic flow in that direction—but if you turn the page you will see that we have learned all sorts of things over the years that make that idea just too simplistic. There are overlapping genes; there are interrupted genes; there are genes that delocalise; there are multigenes that are on different chromosomes; and there are multigene families. Our understanding of how a genome is destabilised when a new piece of genetic information from another species is fired randomly into it is in its infancy.

10:00

People are now trying to be much more selective about the way in which they put genes in. When they do that, many of the problems that have been associated with gene instability and unpredictable effects will diminish. My feeling is that there is still a lot more homework to do. We have to expect the unexpected. At the minute, that is standard, which is why issues have to be treated one at a time.

The benefits that have been claimed for GM plants are that they will grow in saline conditions and so on, and that may well be the case, but as far as health safety goes, I do not think that we are doing the right testing. Substantial equivalence is a scam. People say that a potato has vaguely the same amount of protein and starch and stuff as all other potatoes, and therefore that it is substantially equivalent, but that is not a test of anything biological. We have to examine and test, which costs money, but I do not think that we can afford to play fast and loose with this technology. We need to take great care.

The Convener: One of the questions that we asked was whether it should be incumbent upon the Scottish Executive to monitor the health of people who live around farm-scale GM evaluation sites. In the answers that you have given, you said that that would be possible, but difficult and expensive. We have heard from other witnesses, for example from the Advisory Committee on Releases to the Environment, about the Executive position, which is that, having done the laboratory tests, it does not see what the risk would be to human health, so how would it go about identifying the hazard and testing it? Your line is that the people who are most susceptible to allergies and toxins are more likely to be children, so what would the practicalities be of saying, "Okay, let's monitor the health of people living around one of these sites"?

To pick up on Dorothy-Grace Elder's point, presumably you are talking about something that is unlikely to be able to be identified and observed in a short time frame; it is more likely to take a long period of time. Would it show up in a time frame that would allow us to say, "Let's do further testing of human health around some evaluation sites before we move on"? What would be the practicalities in doing something like that?

Dr Howard: It depends what you are looking at. One could start to examine allergies in such areas, but the sites are small. I do not know what the population density is around them. It comes back to the point that if something is common, an enormous sample is needed to pick up a significant change. It may well be that such a sample would be unavailable. In developmental toxicology, we have animal-testing methods to examine such matters; for example we have developmental toxicity testing. That would be a first step.

The Convener: On that point, I think that it was the Bayer CropScience submission that said that there had been some testing on rats and that, on the basis of that, it did not feel that there was any threat to health.

Dr Howard: It would be very helpful if such information were in the public domain. I do not know whether it is in the public domain, but any testing that is to be used for licensing a product that will become part of the food chain should be open to scrutiny. There is no reason why that should be commercially sensitive. I can understand that the method of introducing the transgene into the plant is commercially sensitive, but toxicological testing should be in the public domain so that it can be inspected and commented on.

The Convener: If the research shows that there is no health risk, it would be to a company's commercial benefit to have that in the public domain and peer reviewed. However, your understanding is that that information is not in the public domain and is not peer reviewed.

Dr Howard: Some information is in the public domain, including Pusztai's work, which was an example of testing for developmental toxicity. I know of one other paper that has been published, but much of the material is kept commercially confidential. If it is being presented for the purpose of licensing a new crop that could become part of the food chain, it should be in the public domain for scrutiny.

The Convener: Can I get one point of clarification, bearing in the mind the difficulties with density that you mentioned? I cannot say what the population density of Munlochy is—I am sure that someone will tell us before the end of the meeting—but I am sure that it is not very large. Is it right that such large-scale testing would prove incredibly difficult to do based on the trial locations that we are talking about?

Dr Howard: You would have to know where you start.

The Convener: If we were to introduce another set of field tests at this stage and start by asking the question of where we are and then monitor where we go, it would still be difficult to get a result. You seem to be saying that thousands of people would have to be monitored.

Dr Howard: You have to look at the power of the experiment and to know that, you need to know the incidence of what you are interested in and the background population. If what you are interested in is normally rare, you might not need

that many people to detect a change. However, if it is common, you will need a large sample to get the statistical power into the experiment. Statisticians could advise you on that.

The Convener: Your other point was that a better way to find out was through feeding testing.

Dr Howard: Yes, through volunteer feeding trials.

Dorothy-Grace Elder: You mentioned commercial confidentiality and the fact that a large amount of information is not released to the public for that reason. Many people have asked us whether there is a comparison to the early days of the animal feed situation that led to the BSE tragedy. Commercial confidentiality was given as the reason for not revealing, even to farmers at first, what was in the animal feed. Is there a comparison in the levels of uncertainty and the lack of transparency and openness?

Dr Howard: There are large areas of uncertainty and ignorance. We do not know what has been tested and what the likely effects could be of X, Y and Z. There is a need for transparency.

Dorothy-Grace Elder: Should we not have learnt that from the BSE crisis?

Dr Howard: Yes. The case for keeping commercial confidentiality on toxicological testing is weak. I can understand that there are sensitivities about the mechanism for producing the transgenic organism, but I do not see why the testing should be commercially confidential.

The Convener: There are no further points now, so thank you very much, Dr Howard. If we have any further points, having read through your paper, and you are happy to accept them in written form, we may come back to you again. Thank you for your evidence this morning.

I will suspend the meeting for a quick break before the minister comes in.

10:09

Meeting suspended.

10:13

On resuming—

The Convener: Good morning minister. I see that you have one of your teams with you. You will know the form. You may introduce the people who are with you and make a short introductory statement. The committee will then come back at you with questions.

The Deputy Minister for Health and Community Care (Mrs Mary Mulligan): I will start by introducing those who are sitting alongside me. On my left are the chief medical officer, Dr Mac Armstrong and Martin Donaghy from the Scottish Executive public health department. On my right are Lydia Wilkie and Elspeth MacDonald, both from the Food Standards Agency Scotland.

As you would expect, the Executive's submission is set out in the paper that Dr Armstrong submitted to the committee. Members should have received that. I will highlight four particularly important points and then I will hand over to the CMO to allow him to speak briefly to his paper.

First, the precautionary principle underpins the regulatory process and is at the root of the purpose, design and safety of the farm-scale evaluation programme. Secondly, farm trials in the United Kingdom and in Scotland do not produce GM foodstuffs because all the products are destroyed. It is important to stress that point.

Thirdly, the field trials in Scotland are part of the Executive's precautionary approach to the development of GM technology in agriculture. Field trials are collecting valuable ecological information to better inform decision taking. They are not testing crop safety. The Executive wishes to base its decisions on facts and not supposition.

Finally, I stress that we are acutely aware of the need to maintain vigilance with regard to new and emerging hazards. As such, we stand ready to consider any specific proportionate and evidence-based proposal to build on existing health monitoring arrangements in order to address an identified risk factor. At present, however, there are no grounds to suggest that farm trials in Scotland pose any greater health risks for local populations than conventional crops.

I will hand over to the CMO.

10:15

Dr Mac Armstrong (Scottish Executive Health Department): Good morning. As CMO, my concern is to ensure that the Executive is appropriately advised on all matters affecting health and health care in Scotland. I am thus concerned about any potential health effects of GM crops and their production. I welcome the committee's investigation into the issue and the opportunity to address the committee today.

My role and concerns are shared by other United Kingdom CMOs with whom I work closely. My submission notes the findings of an investigation that was published in 1999 by the chief medical officer for England, Sir Liam Donaldson, and the UK Government's chief scientific advisor, Sir Robert May, that there was no evidence to suggest that GM food technologies were harmful to human health. I have seen no subsequent evidence to the contrary.

The trials that are the subject of the committee's concern are not food trials. I emphasise and endorse what the minister has just said. No GM food enters the food chain of either humans or domestic animals as a result of the trials. The sole exception to that is the possibility of the introduction of pollen from the GM crop to honey. That has been specifically considered and covered in the submission that the committee received from the Advisory Committee on Releases to the Environment.

I shall briefly summarise the responses that we have submitted to your four questions. The first question was whether the Executive should prevent GM crop trials from continuing on the ground that that is against the precautionary principle. Scottish ministers are advised on that by ACRE. That committee will not advise that trials should proceed where there is any reasonable concern over an effect on human health.

The farm-scale evaluations are proceeding on the basis of the operation of the precautionary principles as follows: ACRE has concluded that there is sufficient evidence to conclude that growing those crops does not pose a threat to human health. However, the impact of herbicide-tolerant crops on farmland biological diversity is less clear. The carefully controlled studies are designed to address that uncertainty before any further decisions are made.

We are now in the final growing phase of a three-year trial, which is an additional hurdle outwith the present regulations. The producers have voluntarily agreed that that phase should be undertaken in order to produce further information on that area of uncertainty.

The risk assessment procedures for farm-scale evaluations build on knowledge found in previous phases of development in laboratory conditions and small-scale environmental releases. For this crop, you will know that the releases have been going on for about 14 years.There is a case-by-case assessment of both hazard and environment. The hazards to be assessed specifically include hazards to human health. I believe that the risk assessment by ACRE is robust and comprehensive and is consistent with EU guidance on the application of the precautionary principle. All of that is set out in detail in ACRE's submission to the committee.

There is no evidence of any specific health effect that we should be monitoring. There is no evidence of any health effect in the workers or researchers who were involved in the previous phases of the trials. Neither is there evidence of any health effect in the populations around sites of commercial production of the crops in other countries. Those are the kind of conclusions that have led ACRE to believe that there is sufficient certainty that the crops do not pose a threat to human health.

Local public health departments throughout Scotland consistently monitor the health status of their populations and are on the lookout for any new or emerging health hazards. I am sure that the committee is aware that that is important, particularly in the environment and context surrounding the consequences of 11 September last year.

We have contacted all departments of public health in areas where farm-scale evaluations are being carried out and I can tell the committee that they report no unusual patterns of disease or of new or unexplained illness in their populations.

The Convener: I welcome the fact that you have inquired into the health effects of the crops in areas abroad where the crops have been commercially grown. Although you said that there was no evidence that anyone's health had been affected, our previous witness told us that the people who are most likely to be affected are children and that, although he accepts that there is no acute toxicological issue involved, the likelihood is that we will see minor changes in people's health over a long term. It was suggested that those changes might be to do with conditions such as allergies, which are quite common. Thousands of people would have to be monitored if we were to be able to say whether there had been a change. To ask the local general practitioner whether they had a lot of patients coming to them with obvious complaints after the crops were planted is not as helpful or informative as implementing a robust monitoring system, over many years, that takes as its baseline the situation that pertained before the field was ploughed.

Dr Armstrong: I acknowledge that, but there are certain key principles of health monitoring that have been well articulated by the World Health Organisation. The monitoring programme has to be specific, which means that we have to have an accurate definition of what we are monitoring and it has to be measurable, which means that we have to have systems that are capable of counting what we are trying to find. Further, the system has to be action-oriented, which means that the data that we collect must help to guide some action, as well as being realistic and timely.

I heard the previous witness say that, had Thalidomide caused cleft palate, rather than phocomelia, no one would have noticed. I want the committee to know that we have excellent background monitoring systems in Scotland, particularly in relation to developing children and development in utero, and that we monitor congenital abnormalities. I have every confidence that any alteration of background patterns would be spotted. Perhaps Martin Donaghy would like to give the committee more information about that.

Dr Martin Donaghy (Scottish Executive Health Department): Yes. To pick up on what the CMO said, we have two levels of health monitoring. One level is general health monitoring, during which we try to pick up differences or different patterns of illness in the community. Every child who is born in a Scottish hospital has a return sent to the information and statistics division in Edinburgh and there is follow-up to find out about the child's development through our child health monitoring and surveillance programme. Therefore, we pick up problems with congenital abnormalities, clusters and increasing trends.

The second type of monitoring happens when we look for something specific that has been emerging, such as a new illness. Recently, there has been concern about a new type of viral illness associated with birds, which was first seen in New York. We call such illnesses emerging illnesses. We target certain areas and collect evidence to monitor.

In respect of genetic modification and the latter type of monitoring, if we wanted to institute a programme, we would need something specific to look for, as the CMO said, otherwise we could not do a count. Genetic modification is a technological process. Part of the regulatory framework includes ACRE's going through the specifics of which genes have been modified. If there was any concern that a specific gene could lead or relate to a potential health hazard, a trial should not go ahead. If we scanned the literature and found a potential health hazard, we could institute a programme as we do for other problems and new illnesses, but we have seen no evidence or indications at all of such hazards that would lead us to institute such a programme.

Allergenicity gives rise to a range of health problems that we call atopic, such as asthma, eczema and rhinitis, or runny nose. In the past 10 to 15 years, there has been a large increase in such illnesses in the general population. Asthma in particular has been the subject of much intensive research. Some increases in asthma levels have been associated with exposure to plant allergens—that is, plants without any genetic modification. However, we have no specific evidence that links the genetic modification that is employed in the crop trials with specific increases in allergens.

Members probably know that many of the crop trials involve oil-seed rape. Given the extent of the cultivation of conventional oil-seed rape, particularly in Scotland, it has been the focus of study over the past few years. There is some evidence that there has been a slight increase in rhinitis in particular as a result of oil-seed rape. From the evidence, it is thought that that might not be due specifically to the pollen or the allergen, but to the fact that those oil-bearing products can release volatile organic compounds into the air, which may cause rhinitis. That happens in only a very small minority of the population who are sensitive.

We have no specific evidence on which we could develop a programme. There has been background monitoring. As the CMO said, we monitor every child in Scotland. We would pick up on increases in abnormalities to do with cleft palate, which a previous witness mentioned.

Margaret Jamieson (Kilmarnock and Loudoun) (Lab): You said that no specific evidence is available to develop a monitoring process. I have concerns about such situations even when evidence becomes available. Although it does not relate to genetic modification, for many years a community in my constituency perceived a link between electricity pylons and the incidence of cancer. Public health teams in Ayrshire said continually that the pylons were not a cause of cancer and that they should not be taken into consideration, but research has developed and there is now evidence.

Can you reassure me that the department is continually reassessing its evidence to ensure that with GM we will not be in a similar situation to that in which my constituents in Shortlees were in relation to cancer?

10:30

Dr Armstrong: I will ask Martin Donaghy to comment. Margaret Jamieson flagged up a good example of the way in which public concern about a potential new hazard can develop over a long period. The best that we can say about the potential hazard from radio communications equipment is that a potential biological effect that we can now monitor has been postulated. The jury is still out on the case and activity continues on the matter.

Margaret Jamieson mentioned a good example of how long-term concerns can develop, but I emphasise that what is going on in GM trials is of a different order: the trials are localised and farm-scale evaluations are designed and controlled to answer specific questions. Those questions are asked largely to enable us to get to the next stage of decision making. At that next stage of decision making—about the potential commercial development of the crops, which my colleagues will talk about—a different set of questions must be answered.

Dr Donaghy: I will reiterate what Dr Armstrong said. The main difference between electricity pylons and GM crops is that the pylons are up. On GM crops, we are at the stage of going through a regulatory process, which involves assessment of

scientific literature by ACRE. If there had been any potential hazards, the next stage—the crop trials—would not have been reached. We now have crop trials and the product of those trials is not going into the food chain, so people are not being exposed to it. The results of the trials will be evaluated and will be considered by ACRE. If there are negative results, the process will not move forward. The next stage will be to go through the next regulatory hurdle.

We are at a different stage in relation to GM crops than we are with electrical pylons. A tight precautionary approach is being taken, which is designed to sift out problems before we make decisions on whether the products of the new GM technologies should be made available to the general population.

Bill Butler (Glasgow Anniesland) (Lab): Are you saying that you are completely satisfied that there is sufficient evidence that GMOs pose no risk to human health and that the risk assessment is sufficiently robust from a public health perspective?

Dr Armstrong: I am satisfied that ACRE has asked the right questions and that it has properly considered the appropriate evidence. I cannot say that there is no risk; of course there is a risk and it would be foolish of me to say that there is none. I remind members of the statement that was made by the previous witness—which I endorse—who said that we are not in a situation in which there is certainty, but in which we are ensuring that there is a proper balance of risks, benefits and costs.

Bill Butler: Is there any monitoring of possible health effects on people who live around the GM evaluation sites? Perhaps you could clarify something that puzzles me. Paragraph 13 on page 3 of your evidence states that

"currently there are insufficient grounds to suggest that farm trials in Scotland pose any health risks for local populations".

Paragraph 14 states:

"we maintain a watching brief in this area … should emerging scientific evidence support a change to this position".

How can you find out whether there are sufficient grounds for concern or that evidence is becoming available if you are not monitoring the health effects at the trial sites, especially when—as the previous witness said—there could be "subtle changes" in terms of allergies?

Dr Armstrong: People who suffer from allergies would not regard such changes as subtle—either one has an allergy or one does not have it.

Bill Butler: I did not mean that. I was quoting the exact words of the previous witness, who said that the changes might be so subtle that one could not possibly tell that there was no evidence of such effects.

Dr Armstrong: I draw your attention to ACRE's evidence and that from the Royal Society, which make it crystal clear that it is not scientifically possible to prove a negative.

Bill Butler: How can one prove anything if one is not looking for it? Perhaps you could address that question.

Dr Armstrong: I certainly will. It is not the case that we are not looking for anything. As Martin Donaghy explained in detail, at least two levels of monitoring go on—background monitoring and specific monitoring. I have explained that if a specific effect were identified, we could monitor an area for that effect. For example, if it was identified that certain GM crops posed a threat of increased allergenicity that was likely to translate into higher levels of allergic reactions such as asthma, rhinitis and dermatitis through the simple mechanism of living near the crops—we are not talking about ingesting the crops—we would be able to monitor the area for those effects.

Bill Butler: Why not carry out specific monitoring anyway? Surely that would be a third way in which to ensure that there were no ill-health effects.

Dr Armstrong: As I said, we must have a balance between risks, benefits and costs.

Bill Butler: Are costs the determining factor?

Dr Armstrong: The precautionary principle refers to the need to take appropriate levels of action. I do not believe that such a level of action would be appropriate.

Bill Butler: Why do you believe that it would be inappropriate?

Dr Armstrong: The background monitoring in all the areas in which the trials are being carried out has not detected any specific effects. We have asked the local public health departments to look for such effects. Each of those departments produces an annual report on the health status of their populations.

Bill Butler: I accept that those two levels do not identify anything, but why not have the third level, which would be a localised attempt to identify any ill-health effects?

Dr Armstrong: The trials, which started three years ago, were set up under a regulatory framework that asked Scottish ministers to authorise them on the basis of specific advice. The advice that ministers are required to take is set out in the legislative framework. That advice comes from a variety of sources, including the Advisory Committee on Releases to the Environment, the Health and Safety Executive, the Food Standards

Agency and the Department of Health. All that advice indicated consistently that there was no discernible risk to human health that would require a specific health monitoring process. If there had been any evidence of such a risk, the trials would not have been authorised without the appropriate safeguards.

Bill Butler: How can you say that there was no evidence when you did not look for any? How can one discern a risk if one is not looking for it?

Dr Armstrong: I seem to be going round in circles.

Bill Butler: Yes, you do—that is the problem.

Martin Donaghy: Before the crop trials take place, considerable research is carried out, particularly on animal models, to pick up whether there are any effects on mammalian systems. We examine the research on the nearest available equivalents to humans. That is the first level at which we look for effects. If there are effects, the trials go no further.

Those research initiatives take place in laboratories; there is day-to-day contact with the workers who are involved in the initiatives and the Health and Safety Executive is involved. In some ways, those workers form what we call a sentinel population. If there were any demonstrable effects on the immediate population—that is, laboratory workers and researchers—such effects would be picked up and the trials would not go any further. By the time a crop trial is carried out and the evidence on the trial is submitted, work will have been done to identify potential effects. From our point of view, if there are potential effects on human health, there should not be a crop trial. ACRE is asked to screen out that possibility so that by the time of a crop trial there is no effect for testing to pick up.

We are being asked, as a safety net, to find out whether there is a health effect. The problem with that is in working out what we should look for, because the effects might be subtle. Many hundreds, if not thousands, of tests could be carried out to find out whether the trials have an effect on people. The ethical point is that a trial should not proceed if we believe that there will be an effect on human health. However, if we raise the alarm unnecessarily, people will ask what we are looking for and we will have to reply, "We don't know, but there might be something." The evidence, however, shows that there is nothing specific to look for. To go back to our preliminary statement, we depend on our on-going health monitoring of the population.

Nicola Sturgeon: I want to move on from monitoring to ask about the process of granting or not granting consents for part B releases. Last week, the Minister for Environment and Rural Development said that he acts on ACRE's advice. What role, if any, does the health department have at that stage?

Mrs Mulligan: Members will accept that the trials started some time ago and that the initial decisions were taken by the then Scottish Office. At that time, those who were involved with food and rural issues reported to one of the health ministers. Since the Scottish Parliament began in 1999, the Executive has had responsibility for those issues. The Minister for Environment and Rural Development, who spoke to the committee last week, was involved with the decision to proceed with the trials, but the health department was aware of the implications at all times. As we have just heard, the department was aware of the research and of what, if any, need there was for health monitoring.

Nicola Sturgeon: Witnesses on both sides of the debate have talked about the principle of substantial equivalence and its use in the regulatory framework. What do you understand by that test? Are you satisfied that it is robust enough for such decisions?

Mrs Mulligan: As has been explained with regard to monitoring, we have reached the stage that we are at through a step process that relied on our gaining significant robust evidence before moving to the next stage. On equivalence, we are considering the trials alongside the development of GM crops. As the CMO said, the on-going farm-scale evaluations are part of a process of testing the effects on the environment. Should those evaluations be successful, we will consider further tests before introducing GM crops into the food chain. At that stage, further tests would be carried out and the FSA would become involved.

Nicola Sturgeon: You mentioned entry into the food chain. I appreciate that the farm-scale trials do not produce foodstuffs, but is it fair to say that you cannot guarantee that there will be no GM entry to the food chain? For example, Mac Armstrong mentioned the pollen and honey incident. What steps are you taking to deal with the risk of GM organisms entering the food chain before we reach the next stage of the process?

The Convener: Let me add to Nicola Sturgeon's question before the minister answers it. In addition to the oral evidence that we have taken, we have received many written submissions. One of those comes from Karin Kremer, another person from Munlochy who has submitted evidence. Martin Donaghy, the CMO and the minister have all said today that the GM crops do not enter the food chain. I think that Mr Donaghy said that a tight precautionary approach was being taken. However, Karin Kremer writes:

"As we live in Munlochy, we frequently have witnessed the GM crop trials on top of a hill and drainage"

that is

"insufficient, cascades of brown, earthy water running down the hill, from the crop trial, down to the main Tore-Cromarty Road and beyond, down to Munlochy Bay and where the potentially polluted water runs into the Moray Firth to be consumed by fish, to be consumed by us. I cannot imagine that this has no long-term implications on humans."

In addition to the monitoring of whether GM pollen goes into honey, which Nicola Sturgeon asked about, what other monitoring is being done? I would not describe what I have just read out as an example of a tight precautionary approach.

10:45

Mrs Mulligan: Let me deal with the questions in the order in which they came.

The event concerning the honey has been well researched. It was unfortunate that the seeds were used, but the situation has been examined and the seeds have been removed from the trial. On cross-contamination, we are aware that there could be either wind-blown or insect-carried contamination within the area, but those risks are assessed and dealt with in such a way as to minimise risks to the environment. Any resulting risks would be further monitored. Obviously, both those types of contamination were tested further in the tests that the Food Standards Agency carried out on the honey. Perhaps the Food Standards Agency can provide the committee with more information on that.

In response to the point that the convener made, as part of the overall analysis, monitoring needs to be carried out around the sites that are involved in the trials. I am sure that, if it did not do so last week, the Scottish Executive environment and rural affairs department will be able to provide further information on that.

Nicola Sturgeon: I have a supplementary question on the honey case. I do not want to go back over the Executive's position on monitoring of public health, which the minister has explained quite well. I understand that the honey situation was picked up not by research that was commissioned by the Scottish Executive, but by *The Sunday Times*. Does the Executive undertake any monitoring or research work that might have picked up that situation had it not been picked up by a newspaper?

Mrs Mulligan: I believe that there is sufficient monitoring and that the situation would have been picked up as the trial went on.

Nicola Sturgeon: At what point would it have been picked up?

Mrs Mulligan: It is possible that it would have been picked up at the same time. We continue to monitor those things.

Nicola Sturgeon: What research and monitoring mechanisms are in place that make the minister confident that the problem would have been picked up?

Mrs Mulligan: I ask Lydia Wilkie to explain the process.

Lydia Wilkie (Food Standards Agency Scotland): It is important to say that the possibility of GM pollen's being in honey is not new; it was first considered by the Advisory Committee on Novel Foods and Processes—ACNFP—as long ago as 1991. That possibility has always existed. After specific concerns were expressed, the position was reassessed in 1999. That pre-dates the Food Standards Agency Scotland, so I am merely providing information from records that are in the public domain.

Having been reassessed in 1999, the situation was brought to the agency's attention after we were set up in 2000. The ACNFP was last asked to examine the matter in 1991. The ACNFP is a very broad committee that contains toxicology experts and allergy experts as well as consumer experts and ethicists. That committee's view was that, although there could be GM pollen in honey, the levels would be so low that they would not present a meaningful risk to consumers.

It might help if I put that in context. Research that was funded by the Ministry of Agriculture, Fisheries and Food a number of years ago tried to assess what amount of GM pollen might get into honey. We are trying to get people to understand that the amount—unless members want to talk in terms of nanograms, which I find quite difficult—is equivalent to one crystal of sugar in 28,000 1kg bags of sugar. The possibility is so tiny that, although it could exist through transfer from bees, it is not deemed to be a risk. As recently as last year, we asked the ACNFP to re-examine the matter.

Nicola Sturgeon: What about the more general point that the convener raised? The thrust of a lot of what you are saying is that there is a step-by-step process, that we are not dealing with foodstuffs or the food chain at the moment and that, when we come to that point, there will be rigorous testing. What happens if that is not the case? What do we do if material is entering the food chain but, because it is not being tested for rigorously at the moment, we are going into the unknown before the process has formally reached that point?

Dr Armstrong: On the question that the convener asked, let us leave pollen aside and consider that material—

The Convener: Nicola Sturgeon covered pollen.

Dr Armstrong: The lady who wrote to you was specifically concerned that GM material could be entering the food chain through watercourses—

The Convener: And through fish.

Dr Armstrong: As I am sure members are aware, the expert advisory committee that was set up to advise ministers—the Advisory Committee on Releases to the Environment—is under the Office of Science and Technology's general guidance on the operation of such committees and is drawn from a very wide constituency. With specific reference to Nicola Sturgeon's question, I am sure that you are aware that the chairman of that committee, Professor Alan Gray, has considerable expertise in hydrology. He is director of the Natural Environment Research Council centre for ecology and hydrology. The Advisory Committee on Releases to the Environment is in the process of making a further appointment in Banchory from the NERC centre for ecology and hydrology. I want merely to underscore the point that, through those advisory committees, we make strenuous efforts to ensure that all possible threats to the environment, through all possible routes, are covered. Although they cannot give any guarantee that the environment is risk free, those committees exist to address those points.

The Convener: I know that those who are on the advisory committees are highly specialised experts; there is no doubt about that. However, mistakes can happen in real life and the practicalities of that have been witnessed by a resident of Munlochy. I would like a practical answer. Have the concerns that were raised been taken into account and are the fish around the site monitored? Is anything being done that would answer that lady's concerns?

Mrs Mulligan: I shall ask Elspeth MacDonald to answer that, because her experience is relevant.

Elspeth MacDonald (Food Standards Agency Scotland): I would like to return to the issue of pollen in general, regardless—

The Convener: I would really rather that you answered my question on fish.

Elspeth MacDonald: I hope that my answer will address your question.

The Convener: Well, let us not go off the fish. Let us deal with both matters.

Elspeth MacDonald: The lady's question was about pollen going into the water and possibly into fish.

The Convener: With respect, I asked a supplementary to Nicola Sturgeon's question because I wanted to say that the issue is actually about whether or not pollen is entering the food chain. All the witnesses have told us today that pollen has not entered the food chain, but we know that it has entered the food chain through pollen. I mentioned fish because people have said that they are concerned that GM material has entered the food chain in other ways. We are concerned with the general issue of GM material's entering the food chain, rather than just with pollen or fish.

Nicola Sturgeon: We are considering whether the risk assessment process is at all stages robust enough to protect public health. You are saying that at this stage of the process you are not interested in food safety, because we are not dealing with foodstuffs. If there is evidence that material is entering the food chain, it becomes more difficult to accept that argument.

Dorothy-Grace Elder: As Mr Finnie admitted in the chamber in 2000, an unauthorised GM harvest entered the food chain in 1999. In 2000, crops had to be pulled up because yet another wrong batch of seeds had been sent to Scotland—you might recall that a warning from Westminster came three weeks too late. Wrong batches of seeds were sent on two occasions, and there are concerns about serious accidents on a large scale. As Mr Finnie acknowledged, the crops in question are now in the food chain.

Elspeth MacDonald: I will try to address all the points that have been made.

Crop trials are not about food safety—Mac Armstrong has outlined the purpose and background of the trials. However, it is important to bear it in mind that ACRE's assessment process takes into consideration the possible implications of inhalation of pollen, accidental ingestion of material from crops and people's coming into contact with crops. At the forefront of our minds is the fact that the trials are being carried out for environmental reasons, but the implications of material getting into the food chain, being inhaled or coming into direct contact with people are addressed in the safety assessment that ACRE carries out. It is important to bear it in mind that we have not yet reached the stage of examining the crops from the point of view of food safety; however, that issue is not ignored in the safety assessment.

Margaret Jamieson: How does the minister respond to the argument that the precautionary principle should apply because unknown hazards are associated with the crop trials? People cannot choose whether or not to be exposed to those hazards. On other occasions the committee has talked for many hours about the lack of public consultation on measures that the health department is attempting to implement in local areas. Could it be argued that keeping the general population in the dark will make people distrustful

and ensure that the Executive's view of the precautionary principle is ignored?

Mrs Mulligan: The precautionary principle has been followed in this case. Before arriving at this stage of trials, we have followed a number of robust testing procedures. Scientific evidence has shown that there is no risk, so we have moved forward to the next stage. The trials are the next part of the testing process.

As Elspeth MacDonald indicated, there will be further testing of the impact of the trials. Those tests will examine not the risks of what is planned, but what might happen by accident. The precautionary principle has been followed and we have moved to this stage gradually. We will review what happens in the crop trials and their impact before we proceed to the next stage. In order to ensure that we maintain people's safety, it is important that everything that we do is supported by testing, by evidence and by contributions from the scientific population. We continually review the risk of each stage of the process and of having the trials in place.

Margaret Jamieson: That is fine, but how do you engage with the local population who raised the petition with the Parliament? The committee has considered other issues in which a lack of consultation with the public was involved.

Mrs Mulligan: Obviously, the decision about where to conduct trials is taken by SEERAD. In my experience, we need to continue to speak to people. I am very aware of people's fears on the subject. Given the food scares that we have had in recent years, people need to have confidence that we are taking all possible precautionary measures to ensure that health is not put at risk. People also need to have confidence that we will continue our monitoring during the trial process and that we will respond quickly to any indication that there might be a risk to health. We need to make information available to people to ensure that they know what we are doing.

11:00

Margaret Jamieson: The reason why petition PE470 was submitted to the Parliament is that the fears of the local population were never channelled appropriately. Local people felt that they had no option other than to come to the Parliament with their concerns. It is clear to me from the evidence that no Government agency has undertaken any dialogue with local people and yet the Executive has a corporate responsibility to do so. It should not come down to whether the health department, the Food Standards Agency or someone else does it, as the Government has a corporate responsibility to ensure that officials engage with the local population.

Local people do not want to hear the views of this or that professor being quoted; they want to hear what measures the Executive is going to put in place to protect them and how the Executive is going to report on those measures. That is the one thing that is missing from the exercise.

Mrs Mulligan: I totally agree that it is essential for us to ensure that people are given confidence that we are not using them as guinea pigs. We also need to ensure that people know that the trials are not being conducted without the kind of robust risk assessment that is necessary in such trials, just as we would do if we were developing new medicines, for example. We have to ensure that we protect people who may feel that they are vulnerable in some way. We have to ensure that information is made available to people so that they can see what is happening and what the risks might be.

Margaret Jamieson: Will you undertake to speak to the other Scottish Executive departments to ensure that consultation starts on a regular basis with the community, albeit that it will be a bit late?

Mrs Mulligan: I am happy to speak to my colleagues on the matter. It has always been a principle that we should make available to people as much information as possible so that they are given confidence in what is happening.

Margaret Jamieson: Okay.

Nicola Sturgeon: This might be a minor point, but it was put to me early in the process in relation to some of the work that was undertaken, including by Scottish Executive officials, that although European Union legislation enshrines the precautionary principle, the Scottish Executive adheres to the precautionary approach. What is the difference between the two?

Mrs Mulligan: I suspect that that is an allegation rather than the truth. I believe that we are following the precautionary principle, which is one that guarantees that we act on the basis of sound evidence. I also believe that we continue to monitor our actions so as to ensure that there are no disbenefits to the population.

Mr McAllion: Before I move on to my question, I want to pick up on evidence that was given by the Food Standards Agency. I think that the Food Standards Agency witnesses said that they were happy for ACRE to address the health implications from ingesting or inhaling GMOs as part of its risk assessment procedure. However, we heard earlier from Dr Howard that at the heart of ACRE's risk assessment procedure is the test of substantial equivalence. He said that, as that was a chemical and not a biological test, it could not detect health changes. He seemed to suggest that what the FSA witnesses said is not true. What is their response to that?

Elspeth MacDonald: I can talk to you about substantial equivalence as it is used to asses GM foods, rather than—

Mr McAllion: This is about the health implications. You specifically said that ACRE would address the health implications; yet we were specifically told earlier that ACRE is not addressing the health implications or carrying out any kind of biological testing.

Elspeth MacDonald: The membership of ACRE includes Professor Janet Bainbridge, who is the chairperson of the Advisory Committee on Novel Foods and Processes and who gave evidence to the committee recently. The ACNFP is an expert scientific committee that advises the Food Standards Agency on novel foods, including GM foods. There is obviously cross-representation between ACRE and the ACNFP.

Substantial equivalence is not in itself a safety assessment for a novel food or a GM food; it is a concept around which a safety assessment might be built. At the heart of substantial equivalence is the principle of taking a novel food—which would include a GM food—and comparing it with its conventional counterpart. That is the absolute starting point.

Throughout the process of using substantial equivalence as a framework of safety assessment, we look at the similarities and differences—I stress the differences—between the new food and its conventional counterpart, which has a history of safe food use. Substantial equivalence looks at the differences; it does not just look at the similarities, and—

Mr McAllion: Chemical differences?

Elspeth MacDonald: It covers various differences. Those might include the composition of the food, its nutritional value, its metabolism and so on. The safety assessment that then goes forward focuses on the health implications of the differences. It is important that members keep in their minds the fact that substantial equivalence does not just say, "Yes, they are broadly similar." It tries to identify the differences that might exist and to assess the potential—

Mr McAllion: But it does not involve carrying out any kind of biological test.

Elspeth MacDonald: Substantial equivalence is used widely in the world. It is—

Mr McAllion: Is it a biological test? Yes or no?

Elspeth MacDonald: It is not a test in itself. Substantial equivalence is a concept around which safety assessment—

Mr McAllion: Dr Armstrong said that it is not a food safety trial. ACRE is not conducting a food safety trial. That is correct, is it not?

Dr Armstrong: The farm-scale evaluations are not food safety trials. They are environmental—

Mr McAllion: So we do not really know what the health implications are.

Dr Armstrong: No, that is not true. Any environmental release, at whatever part of the regulatory process it takes place—I have said that the farm-scale evaluations are an additional hurdle that the Scottish Executive has introduced into the regulatory process—can be advised only on the basis of a risk assessment. The risk assessment has to go through the framework that is being described, which includes an assessment of health hazards.

Mr McAllion: And that is done by ACRE.

Dr Armstrong: Yes. The trials are not designed to test food safety; nonetheless, they are advised only on the basis that there is no hazard to human health.

Mr McAllion: We have heard from various witnesses that GM technology is in its infancy, and that there is widespread ignorance about what its implications might be in the long term. It might well be that harmful effects will emerge in years to come, although there is no current evidence that they exist. When, or if, that happens, the people who are affected will be very upset and will, no doubt, be looking for compensation from those who allowed the farm-scale evaluations to go ahead. Who should pay that compensation? Should it be the Scottish Executive health department, which has sanctioned the farm-scale evaluations, or should it be the companies that produce the GM crops? Should the companies be taking out insurance to cover the likely cost of such compensation claims in the future?

Dr Armstrong: I will not get drawn into that. It is not my role to say what commercial companies should or should not do. I will say, however, that your question perfectly illustrates the answer to a previous one, on the difference between the precautionary principle and the precautionary approach. The precautionary principle is not a principle about human health. It was stated in the Rio declaration on the protection of the environment. As a principle, it has been translated into a wide variety of contexts, and it is now used in relation to health—quite rightly so, in my view.

However, the precautionary principle does not say that, until we have certainty, we must do nothing. This is illustrated at paragraph 8 of my written evidence, which states of the Royal Society of Edinburgh:

"The RSE also referenced the European Commission communication on the use of the precautionary principle"—

that is to say, the precautionary approach—

"in the EU and internationally … which stated:

> 'Where action is deemed necessary, measures based on the precautionary principle should be, inter alia:
>
> - proportional to the chosen level of protection
> - non-discriminatory in their application
> - consistent with similar measures already taken'".

That is the reason why the substantial equivalence idea—

Mr McAllion: You mentioned the laboratory tests that were carried out prior to the farm-scale evaluations, which would look for health implications from GMOs. Who carried out those tests? Was it the health department, the Food Standards Agency or the companies that are promoting GMOs? If it was the companies, are all their toxicological tests in the public domain?

Dr Donaghy: Testing is mainly carried out by companies, university departments or research institutes that are commissioned to do that work.

Mr McAllion: Are all the data published?

Dr Donaghy: The data go to ACRE. That does not apply only to GM foods; it is how all expert scientific advisory committees work. There are protocols about commercial companies submitting data to expert scientific committees, which often see data not just from commercial companies, but from universities, before publication. Therefore, those expert committees are privy to those details. Sometimes the commercial companies will publish data, sometimes they will not. Obviously, we try to promote openness in publication, but the only way—

Mr McAllion: Are there any toxicological tests that are not published?

Dr Donaghy: Just to conclude, the only way in which the scientific committees can do their job—to properly assess the evidence—is by entering into agreements with commercial companies to obtain those data. Otherwise, they cannot properly assess the risk to the public.

Mr McAllion: Are there any toxicological tests that have not been published?

Dr Donaghy: There are toxicological tests on mammalian models. There are obvious ethical issues about using human beings as guinea pigs, so humans are not involved in those trials. There are toxicological tests on mammalian models, mainly mice, which are applied to the organisms that have been fed GM.

Mr McAllion: And those test results are not published.

Dr Donaghy: Some are and some are not.

Mr McAllion: We heard this morning that there is no reason not to publish toxicological test results. What possible commercially confidential reason can there be for not publishing those tests, which have implications for human health?

Dr Donaghy: With all due respect, I do not work for a commercial company. However, the usual reason is that companies will retain that information for competitive advantage. The Government's stance is to promote the publication of such data by companies, but those data are shared with the Government. If they were not shared, the expert committees could not do the job of assessing risk.

Mr McAllion: Is the Executive quite happy that private companies pursuing GM technology keep toxicological tests out of the public domain?

Mrs Mulligan: As I said in my response to Margaret Jamieson, I always seek to make as much information as possible available. I understand that, on occasion, companies will keep things for commercial reasons. It is always a balance as to whether we accept that that is done for a commercial reason. However, if we err on the side of caution, it will always be the case that unless the scientific body involved was confident that its information proved the point on which it was seeking information, it would not move on to the next stage. I encourage such information to be made available, but I accept that, at times, some of it may not be.

Mr McAllion: Therefore, ministers have accepted that GM companies have kept certain toxicological tests out of the public domain.

Mrs Mulligan: It is important that we ensure that as much information as possible is available and that the information that we need to make decisions on whether to move to the next stage is available. If companies keep commercial information to themselves, I suspect that we must accept that.

Mr McAllion: I think that that was a yes.

The Convener: To clarify a point, does the Scottish Executive have the power to compel commercial organisations to make available to your department any toxicological evidence relating to human health?

11:15

Dr Armstrong: That type of approach is the same as that which is taken to the evaluation, and subsequent licensing, of new drugs. It is interesting that some of the companies involved develop both drugs and GM foods. The technology is the same; in fact, GMOs are used in pharmaceutical products already. This is a world in which commercial considerations apply, and the

licensing procedures allow companies to disclose fully all the information that is necessary to satisfy the licensing authorities but not put it in the public domain at that instant.

The Convener: With respect, there are similarities between this process and the steps that pharmaceutical companies take when developing new medicines. However, there are also some glaringly obvious differences. For example, new drugs are subjected to clinical trials, for which people volunteer, usually because it is put to them that the drugs will be of benefit to, for example, the treatment of cancer. We are discussing a substance that could enter the human food chain and be ingested by people who have not been consulted and who have in effect been used as guinea pigs because the Government has not had access to all the relevant information about toxicology.

Dr Donaghy: The original question was about placing information in the public domain through means such as the media. The convener's point was about the access the Government has to that information. The Government has complete access. The differences between drug licensing and clinical trials were compared. To get permission to carry out clinical trials, drug companies submit research data on a commercially sensitive area, based on mammalian models, to the relevant committee. Once a drug trial takes place, everyone knows about it because it is in the public domain. The processes that are used in that area are the same as those that are used in many other areas, including the introduction of new food products to the market. The Executive is given access to data, but there are agreements about the release of commercially sensitive data to the public.

The Convener: John McAllion asked whether the health department has access to all the data. Can the health department compel a company to give it all the data, even if they are commercially sensitive, on the understanding that those data will not be passed on and that the health department, as a regulatory body for human health and the environment, must look at the data to ensure that it is happy to progress in a precautionary manner to the next stage? Can the department compel companies to give it any data that it wants to see?

Dr Donaghy: Yes, partly because the companies must be licensed to do the original experiments.

The Convener: Can commercial companies say what they will and will not let the health department see? Can the department compel companies to let it see all the evidence of their work? If companies can say, "You can see this, but you cannot see that," the power remains with the companies, not with the Executive.

Dr Armstrong: The answer to those questions is yes.

Mary Scanlon: The measles, mumps and rubella vaccine report stated that some GPs were very conscientious about reporting adverse health reactions. However, fewer than 7 per cent of GPs in Scotland reported any adverse health reactions. Therefore, I got very excited when the minister spoke about the health monitoring arrangements—it was the first time that I had heard of them. Has the health department at least asked the GPs in the Black Isle to report any potential health reaction? Has it asked GPs in the areas where the trials took place to report back on any problems in a conscientious way?

Mrs Mulligan: As was said, we have been in contact with the four health boards that cover the areas in which the trials have been carried out. None of those boards has reported unusual patterns of ill health. I expect that the boards made contact with GPs in their areas in order to provide us with that information.

Mary Scanlon: That is a scatter-gun, ad hoc approach. The health boards might not have spoken to local GPs.

Mrs Mulligan: I do not know how the health boards could have given us the information if they had not spoken to GPs.

Mary Scanlon: The boards might not have got certain information if they were not looking for anything out of the ordinary.

Mrs Mulligan: I suspect that if anything out of the ordinary arose, it would be noticed through the normal procedures.

The Convener: Could you give us written confirmation of the fact that those questions were asked of GPs?

Mrs Mulligan: Yes. I am happy to look into the matter further.

Mary Scanlon: I know that responses on MMR were received from fewer than 7 per cent of GPs in Scotland.

My final question is for Mac Armstrong, who previously held a position with the BMA. We are faced with his evidence and with the BMA's evidence, which states that

"GM crop trials present us with profound uncertainties",

that

"insufficient care has been taken with regards to public health"

and that there are

"unquantified public health implications."

The BMA represents 80 per cent of doctors in this country. Who is right—you or the BMA?

Dr Armstrong: I make it absolutely clear that I no longer work for the BMA, although I was its secretary when the submission was written. The question is rather unfair. I do not need to explain to a parliamentary committee the democratic basis on which such organisations are run and the dispassionate role that the management of such an organisation is required to take when faced with a decision at an annual meeting that such a report should be written.

I say for the record that I was profoundly disturbed by the line that the BMA report took and that I regard it as one of the poorest reports that the BMA has produced. The evidence is confused and the report consistently mixes up the precautionary principle's application to the proper process of evaluation of GMOs through the regulatory framework and the principle's application to the release of GMOs in commercially developed food. I have no hesitation in saying that I disagree profoundly with a number of points in the BMA's submission. If you wish, I will give the committee a point-by-point rebuttal of the BMA's evidence. I hope that you will not confuse my role as, in effect, the chief executive of the BMA when that report was written with a personal involvement with or endorsement of its conclusions.

Mary Scanlon: As you said, the BMA is a democratic organisation and I presume that it consulted all its members in writing the report, whereas your monitoring and consultation with GPs has been fairly sparse. As a health committee, we cannot ignore the evidence of the BMA, which represents public health directors and others. I am shocked that you disagree totally with the BMA's evidence, which contains profound concerns. The committee would be irresponsible if it ignored that evidence.

Dr Armstrong: From my experience, the BMA does not routinely consult all its members before it publishes such reports.

Nicola Sturgeon: I understand entirely what you have said about your relationship with the BMA. However, can you give us a guarantee that, in five or 10 years, when you might be in another job, you will not be sitting in front of a committee and distancing yourself from the Scottish Executive and its research, as you have just done with the BMA?

Dr Armstrong: There is a difference. If I were to be brought to account for my stewardship of my role at the BMA, as I might be—I could, for example, be called to answer before an industrial tribunal or to answer on a health and safety or legal matter that related to my time there—I could not distance myself from my role in the process. That role is different from my professional opinion on the outcome of the process. I do my job as CMO as independently and professionally as I can and will defend the decisions that I make as CMO; I will remain accountable for them for the rest of my life.

Nicola Sturgeon: The point that I am making is, how do we know that you are not sticking to the Government line in the way that you stuck to the BMA line when you were with the BMA? Are we getting a dispassionate and independent view from the CMO?

Dr Armstrong: I have explained that, in my position at the BMA, I was never required to endorse the line that was promoted in the report. Saying that sketchily states the relationship between the BMA's senior management and the process from which the report resulted. There is an overview of the process—that is the secretariat's role—but it is not possible to interfere with the content of the report. That is how the BMA is set up. My role was to ensure that the process was correct and that the report was produced; it was not to endorse the report, which I do not.

Mary Scanlon: Is it the case that you are a Government employee and adviser, so you must toe the Government line rather than be an independent-minded member of the BMA?

Dr Armstrong: That is wrong: I deny that I must do so. That is not my role.

Dorothy-Grace Elder: May I just add—

The Convener: No. We are way over time. One of the points that Dr Armstrong made was that he would be happy to give us a line-by-line rebuttal of the BMA's case. We would be interested in receiving that at some point in the future.

I thank all the witnesses for their verbal and written evidence to us. We shall take a short break before we hear from our next set of witnesses, who are from the Scottish Crop Research Institute.

11:28

Meeting suspended.

11:34

On resuming—

The Convener: Our next witnesses are from the Scottish Crop Research Institute. Good morning, gentlemen. Thank you for your written submission and for your attendance today. I ask you to introduce yourselves and to make a short statement before we ask questions.

Dr Geoffrey Squire (Scottish Crop Research Institute): I co-ordinate the environment theme, which is one of the three main research themes at the SCRI.

Dr David Robinson (Scottish Crop Research Institute): I am a virologist by profession and have

been a member of the Advisory Committee on Releases to the Environment and a biological safety officer.

Dr Squire: In our written submission, we attempted to clarify our role. Our experience is not medical, but we have worked on issues of medical and clinical safety, particularly that of non-GM oil-seed rape as an allergen. We have been involved for many years in plant selection and breeding to reduce the chemicals that occur in the brassica, or cabbage, family that are potentially harmful to livestock and humans. We have interests in and contacts with health issues through our involvement in plant breeding and pollen movement and our study of chemicals emitted by oil-seed rape and other brassicas, but we have no direct clinical involvement or expertise.

Our perception of the issue is coloured by our stance, which is outlined at the bottom of the first page of our submission. We give weight to reports and papers that are reviewed properly and which are open in their results and findings so that they can be reproduced. We apply a rigorous set of criteria, which we expect others to apply when they give opinions on matters of ecological or environmental health.

I confirm that our role in the present farm-scale evaluations of GM, herbicide-tolerant crops is that of an impartial observer of their effects. We are not involved in the making or marketing of those crops, which in the Scottish context are oil-seed rape crops that are tolerant to a broad-spectrum herbicide, but we are involved heavily in the ecological field testing of them.

Janis Hughes (Glasgow Rutherglen) (Lab): The minister and her team emphasised the fact that the current farm-scale trials do not involve crops that are used for food, because the crops are destroyed. In that context, food safety is not so much of an issue, as we heard in evidence earlier. However, are you confident that genetically modified material from the current trials cannot enter the food chain?

Dr Squire: Our role has been to examine the rate and distance of cross-pollination between fields and other sources, such as the feral oil-seed rape plants that are seen commonly on road sides and field margins. Our view, which is based on considerable field research that has been conducted in several countries, including our own research, is that cross-pollination over distance is likely to occur. I cite some of the likely values that are based on the expected values from evidence that has been accrued so far. We might expect around one in 10,000 seeds in surrounding fields to be cross-pollinated hybrids.

The Executive is funding us to obtain accurate measurements of cross-pollination in the fields surrounding the farm-scale evaluation GM sites. That work will be published next year. It will take time and we will have to go through the peer-review process. I cannot comment on that work in progress, but the likelihood is that genes will find their way, in low frequencies, from any field to other fields in the vicinity.

Janis Hughes: Therefore, there is a possibility that the food chain will be reached eventually.

Dr Squire: That is correct.

Mary Scanlon: Given your interest in the possible health effects of GM crops, are you satisfied that there has been sufficient research to put your mind at ease?

Dr Squire: Yes. Our view is that we have to be case-specific on issues concerning GM crops. They are like other kinds of crops, in that they differ in species and in the type of modification—the bit of DNA that goes into them and its effect. We are against blanket statements and recommendations.

On the basis of published evidence and the evidence of various learned bodies, including the committees that have examined the crops, the SCRI is satisfied that the main farm-scale evaluations of GM crops that are going on in the UK are safe for our staff who work directly with the crops—including me—and people who live in the neighbourhood. However, we cannot extend that statement to all eventualities that might occur in future.

Mary Scanlon: I draw your attention to the paper that you submitted and to your answer to question 2 in which you state:

> "We believe these specialists have made the correct judgement, though we are aware that this judgement is based on negative results, i.e. that no harmful effects have been discovered."

Saying that nothing harmful has been discovered is not exactly a positive endorsement of the safety of GMOs. Do you agree that, although they have not been shown to be directly harmful to human health, GMOs have equally not been shown to be not harmful in the long term?

Dr Robinson: As previous witnesses have pointed out, we can never prove that something is safe.

Mary Scanlon: Never?

Dr Robinson: I do not believe so. We can never eliminate all possibilities. It is in the nature of things that evidence of safety is negative evidence—evidence of no risk. We can never eliminate the possibility of a risk that we have not thought of. That is the point that we are trying to make.

Mary Scanlon: Do you think that more should be done to assess the risk? Earlier this morning, Dr Howard said that there is no chance of finding out whether GM foods have any effects on common conditions without exposure assessment. Do you think that researchers should undertake more risk assessment, rather than waiting five, 10 or 20 years for a cluster of cases of a certain condition to appear? Should we be doing more now?

Dr Robinson: All hazards that can be identified should be considered and tested. I believe that that has happened with all the hazards that have been identified so far. It is difficult to say what more could be done. If someone identified another hazard—another problem that might arise—that could and should be considered and tested.

Mary Scanlon: Do you think that sufficient research is being undertaken into antibiotic resistance markers, allergenicity and the inhalation of pollen?

Dr Robinson: First, I think that antibiotic resistance markers have been thoroughly tested. Secondly, they are being phased out. Thirdly, they do not apply in this case—the materials do not have antibiotic resistance markers in them. As far as I am aware, all the tests on allergenicity that are possible have been done.

11:45

Mary Scanlon: What tests have been done?

Dr Robinson: I believe that animal model tests have been done with the pollens.

Mary Scanlon: Who carried out those tests?

Dr Robinson: You would probably have to ask ACRE about that.

Mary Scanlon: Are you satisfied that the tests are robust enough?

Dr Robinson: I have confidence that the people who are conducting the assessments are doing them properly.

Nicola Sturgeon: You say in your evidence that the risks of GM crops

"are negligible compared with the routine hazards and risks that our staff face daily going about their business."

Implied in that statement is an acknowledgement that there are risks associated with GM crops. Will you say a bit more about what you think those risks are?

Dr Squire: The statement was made to put things in perspective. In the case of the main GM crops that are being grown in the UK and Scotland, I would say that the risks are so small as to be negligible, especially compared with the risk of driving to the field sites, for example. That puts it in context.

We are not against rocking the boat if we think that there is an issue. On the allergy aspects of oil-seed rape, we made considerable noise in the early 1990s about the risks of general oil-seed rape to human health. We, and colleagues in other organisations, did a lot to point to the risks of the old kinds of oil-seed rape that were originally used for industrial purposes but that were grown in the 1970s for cattle or food. As I have said, plant breeding did much to remove those risks by changing the oil qualities and the types of chemicals in the leaves and oil.

We do not sit back complacently in the hope that there will be no problems. We monitor such matters and, if we think that there is an issue from our biological and plant chemical standpoint, we say so and investigate it. In the present instance, our viewing of the evidence makes our opinion clear: even given the normal allergenic risks of oil-seed rape, any risk to our staff of working in the field sites is negligible compared with what else they do in their daily business.

Shona Robison (North-East Scotland) (SNP): Whether or not you agree that people should be anxious, how do you respond to the clear anxiety that exists that the transfer of genes from GM crops to non-GM crops carries with it unknown hazards? You have been up front in your evidence in saying that there is no doubt that such a transfer takes place, so what do you say to people who are anxious about that?

Dr Squire: The furore about that a few years ago took us by surprise, because we are not habitually in the limelight. We have to accept that some science has had a hard time and a bad press, and part of the problem is that science does not reach people as much as it should do. In our small way, we try to do something about that by holding public lectures and meetings to explain our position and be open about our knowledge. It will not be easy, and I cannot say to people that everything is fine, because that would be wrong.

All we can say is, "These are the facts as we know them; this is our interpretation of the facts; and this is how our organisation is going to behave in the light of those facts." I hope that, over the years in Scotland, responsible organisations such as ours can start to have a far better rapport with the public to ensure that such concerns arise less frequently. However, there is no immediate solution to the problem.

Shona Robison: I presume that you heard the earlier evidence about consultation with communities where the trial sites are located. Should communities have been consulted before any such trials were carried out and should that happen in future?

Dr Squire: Yes, that should happen in the future. A number of sides made errors in the current case, although I do not want to apportion any blame. The SCRI entered the trials and bid for the contract with our consortium partners in England because we wanted to be involved. Because of the need to gain knowledge, we would rather be involved than not. We soon found that in some instances local communities were very concerned about the issues. We can look only to the future; and, as far as future developments in biotechnology are concerned, we must be more sensitive and take into account the views of a wider range of people. We are part of a system; when we bid for and win a contract and begin to carry out the work, we become part of the process. In future and in the light of our experience, we will change our stance on the issue.

Dr Robinson: In principle, the new deliberate release regulations expand the requirements for public consultation, but we will have to wait and see whether the new arrangements are sufficient.

Dorothy-Grace Elder: In your evidence, you use the term "precautionary approach". Do you accept that that term is very different from the "precautionary principle", which is enshrined in the treaty of Rome, and that it carries no official validity at all?

Dr Squire: We debated the wording extensively. My view—and that of many of my colleagues in the SCRI and elsewhere—is that it is not really a principle in the sense that we can use it to guide our operations. Indeed, most human endeavour does not seem to operate according to a fixed precautionary principle.

Dorothy-Grace Elder: Yes, but the precautionary principle is a legal entity; as I said, it is enshrined in the treaty of Rome. You use the term "precautionary approach" in your submission, which seems to latch on to the word precautionary, but it is not what you mean at all. After all, the term "precautionary principle" is quite strict as far as safeguarding people is concerned.

Dr Robinson: The term "precautionary approach" means what one does in the light of the precautionary principle. As you have said, the precautionary principle is quite clear, but one cannot use it as an excuse for paralysis; one has to do something. The response is to proceed very cautiously and to take a step-by-step approach.

Dorothy-Grace Elder: However, you are not operating under the precautionary principle itself. You are operating under the term "precautionary approach".

Dr Robinson: We contend that what we are doing is consistent with the precautionary principle.

Dr Squire: From memory, the documents that were sent around, I presume by the committee, use the phrase "precautionary principle (approach)". Is that correct?

Dorothy-Grace Elder: Well, the term "precautionary approach" is used quite a lot in your submission, not "precautionary principle". You will accept that the term is rather different.

Dr Squire: An approach is a way of applying a principle. I refer to the statement at the back of the documents, where the word "approach" is in brackets.

The Convener: I am aware that we are running out of time. Perhaps John McAllion would be happy to put his question on the record and ask for a written answer from Dr Squire and Dr Robinson.

Mr McAllion: Yes. Earlier, Dr Squire and Dr Robinson said that they were happy with the tests that are being carried out on the farm-scale evaluations by the regulatory bodies. However, we have had evidence that the lab tests that are being carried out by the commercial companies that are promoting genetically modified organisms are inadequate and that the risk assessment procedure adopted by ACRE is irrelevant to the health implications as it is based on substantial equivalence. We have also heard evidence suggesting that there needs to be a moratorium on farm-scale evaluations and a further five years of lab testing for health effects. What is the SCRI's position on those views? I would also like to know whether any GM companies fund research through the SCRI.

The Convener: Would you be able to answer that in writing, gentlemen?

Dr Robinson: We would be happy to do so, but it would be helpful if the question could also be sent to us in writing.

The Convener: Thanks for your attendance and for agreeing to answer that question in writing.

Our final witness is Dr Paul Rylott, from Bayer CropScience, who is here on his own, as his colleague is a victim of the air traffic controllers strike in France.

Dr Paul Rylott (Bayer CropScience): Thanks for inviting me here to speak to the committee. I apologise for the fact that, due to illness, I was unable to attend the meeting on 13 November.

I would like to add a few things to the information that is contained in the submission that was given to the committee in time for the meeting on 13 November. I will give some context by telling members about the history of the genetically modified oil-seed rape crop and the food safety work that has gone on, as there seemed to be a

little bit of confusion this morning about what sort of testing has gone on.

The original genetic modification of the oil-seed rape crop took place in laboratories in Ghent in Belgium in the early 1980s. Because of the rules of the regulatory authorities in Europe and around the world—I draw members' attention to the part in our submission about the precautionary principle—open-air trials for GM crops are not allowed unless there is good evidence that there is no detrimental effect to human health or the environment. Because we are a responsible company, we followed those rules. From the early 1980s until the 1990s, we quite rightly went through a period of laboratory and greenhouse testing of the crops to ensure that there was no detrimental effect on human health and the environment before we were allowed to plant the crops in the open air.

We were given approval to plant the oil-seed rape crop in the UK in 1989 and the first trials started in Scotland in the early 1990s. The crop has been growing in the United Kingdom for 14 years. It is a fallacy that the farm-scale evaluations are the first tests of GM crops in the UK, because they have been going on since 1989. The crop was commercialised in Canada in 1995. Since then, the growing of many millions of acres of the crop in Canada has brought no detrimental effects to human health or the environment and has produced plenty of beneficial effects.

12:00

On the testing of GM crops, much has been said about substantial equivalence. It is a myth that substantial equivalence is the only form of testing of GM crops that goes on—that is not the case. Substantial equivalence is the starting point. One genetically modifies a non-GM oil-seed rape plant. In this instance, the oil-seed rape plant has been modified to make it tolerant to a herbicide. We have done that by placing inside the original plant cell—one cannot modify the plant—a gene that expresses the phosphinothricin acetyl transferase, or PAT, protein, which confers tolerance to the herbicide. As a matter of interest, the PAT protein is part of the natural ecosystem—that is where we found it. There are plenty of bacteria in the UK that produce the PAT protein naturally in soil. Anyone who has ever eaten a dirty carrot has probably eaten a PAT protein along with it. Members who are old enough have probably been eating the PAT protein for many hundreds of years. [*Laughter.*]

The Convener: It just feels like that sometimes.

Dr Rylott: Substantial equivalence was introduced by the Organisation for Economic Co-operation and Development in 1993. As the Food Standards Agency said, it is a concept for identifying what risk assessments it is necessary to carry out on a particular crop or a novel food. Substantial equivalence allows one to compare the GM plant with the non-GM plant. One can say that the GM plant is, in effect, substantially equivalent; in other words, there have been no changes at all. One can say that the GM plant is substantially equivalent, apart from the introduced trait—which, in this instance, is herbicide tolerance and the production of the PAT protein. One can also say that the GM plant is not equivalent at all. An example of that would be a modified starch crop whose use is completely different from that of the non-GM crop.

Let us return to oil-seed rape, because that is what we are discussing. During the substantial equivalence testing that was carried out, a compositional chemical analysis found that the GM crop could be categorised as being substantially equivalent to the non-GM crop, apart from the introduced trait. Non-GM herbicide-tolerant crops are obviously not tolerant to the herbicide glufosinate. That is the difference.

The next question is what that means. One crop produces the PAT protein, which a non-GM crop does not produce. Is the PAT protein safe? In order to find that out, one has to carry out clinical tests—one has to do feeding tests on mammalian species. The standard OECD guideline stipulates that the first feeding tests should be done on rats. We fed the PAT protein to rats. Remember that the production of the PAT protein is the only difference between the GM crop and the non-GM crop. We fed it at levels of 100 and 1,000 times the levels of a normal diet. As members will see from our submission, we examined a number of analyses, such as body weight, food consumption, blood and urine analyses and microscopic pathology. The feeding study produced no evidence of toxicology.

Such feeding studies allow one to establish a level of feeding that gives no observable toxic effect. For a human to ingest the level of the PAT protein that was fed to rats, they would have to eat 24,000 tonnes of oil-seed rape every day before there was any toxicological effect attributable to the PAT protein. Someone would have to eat a heap of oil-seed rape 10 times the size of this room, every day, before any toxicological effect from the PAT protein would be observed. By then, I think that there would be a toxicological effect from something else, or the person would at least feel rather full.

The Convener: How long did that study go on for?

Dr Rylott: It was a standard clinical feeding study on rats, which is conducted over 14 days.

The Convener: You monitor the rats over 14 days, but not six months or a year later?

Dr Rylott: That is standard practice in all clinical trials. Will I continue? I have more to say.

The Convener: May I ask you to shorten your statement? If you have anything that is different from what is in your written submission, will you focus on that? We will then ask questions.

Dr Rylott: There is a little bit more.

That test identified the safety of the PAT protein, which is the novel protein produced in a GM crop. One must also examine whether there may be other effects on the whole crop, which is again done through feeding studies. That answers one of the earlier questions from the lady who was concerned about possibly eating the crop by other methods. We have done studies on feeding target species, including chickens, which have a 15-fold increase in body weight in the first 18 days of their lives. We go through the full life cycle of chickens, feeding them oil-seed rape, to see whether there are any differences in live weight gain, nutritional value, mortality and so on. Again, there were no differences.

We have done studies on rabbits and birds as well, to find out whether there is any effect if a bird flies across a GM crop, feeds on it and a farmer or poacher then shoots and eats it. Again, there were no effects on birds or rabbits. All those studies have been done and, I hasten to stress, are in the public domain and always have been. Some are available through the Department for Environment, Food and Rural Affairs website and, as far as I am aware, both the Scottish Executive environment and rural affairs department and DEFRA make printed copies available if anyone wants them.

Finally, on the food safety of the crop, the committee may want to note that the UK granted food safety to the crop in 1995.

Bill Butler: There has been a great deal of discussion about the precautionary principle and what it means. Some witnesses have said that the precautionary principle justifies halting the trials due to the lack of scientific evidence of either health benefits or health disbenefits. Obviously, that is not your interpretation. For the record, will you tell the committee your interpretation of the precautionary principle?

Dr Rylott: There are two versions of the precautionary principle. One is the 1992 United Nations Rio Declaration on Environment and Development, which says that GM crops in open air should be permitted only if there is good evidence that there is no detrimental effect on human or animal health or on the environment. That is what the studies in the laboratory phase of the development prove before we are allowed to conduct open-air trials. In addition, the EU regulations state:

> "recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified".

That was not the case in this instance. Moreover, in 1998, the EU Scientific Committee on Plants concluded about the crop:

> "there is no evidence to indicate that the placing on the market … with the purpose to be used as any other oilseed rape is likely to cause adverse effects on human health and on the environment."

Bill Butler: What do you make of the lack of monitoring of human health around the trial sites? If you are not looking for something, how can you identify it?

Dr Rylott: Studies have been conducted, both at laboratory level and elsewhere, on that particular crop. Those studies, together with evidence accrued from the rest of the world, show that there is no evidence, be it food safety or allergenicity, to suggest that this crop is any more likely to have an allergenic effect on the local population or to have any effect on food safety.

If that clinical, step-by-step process is followed, it is not incumbent to have any further studies on local populations. In addition, it is important that all our scientists who are in daily contact with those crops, inhaling pollen, go through health screens once a year. There is no indication whatever of any changes.

Bill Butler: So you are absolutely content?

Dr Rylott: I am personally content—

Bill Butler: I take it that there are no children among your scientists.

Dr Rylott: Children do not tend to have PhDs.

I am as convinced of the safety of this crop as I possibly can be.

Dorothy-Grace Elder: When you talk of safety assessments, you note how things should be. You have told us that the trials on rats lasted for only 14 days, and we know that only 10 rats were involved. Do you think that that was a sufficient test? You said that the test identified the safety of the PAT protein. Do you think that that test was sufficient before the crop trials were situated next to 400 human beings in Scotland?

Dr Rylott: Yes, I do. That is not only my view. It is the view of the OECD committees, which set the protocols of those trials, and the view of regulatory authorities around the world that have assessed those studies, be it ACRE in the UK, the Food and Drug Administration in the US, the Japanese or the rest of Europe. All 15 EU member states have examined the case and all were convinced that those studies are enough.

Dorothy-Grace Elder: All those people say that it is quite safe to expose several hundred human beings who live next to those crop trials, when the trials have been tested on only 10 rats for just over a fortnight?

Dr Rylott: Of course, that is not the only study that has been done.

Dorothy-Grace Elder: Why were more rats not used?

Dr Rylott: There is a protocol that allows such studies, which is set up by eminent independent scientists.

Dorothy-Grace Elder: Quite. You mentioned tests on birds and rabbits. Approximately how many birds and rabbits were involved in those tests?

Dr Rylott: I have the data here, if you will bear with me.

Dorothy-Grace Elder: Are we talking about hundreds or 10?

Dr Rylott: No, we do not need hundreds. It is numbers in tens.

Dorothy-Grace Elder: Tens of birds and ten rabbits and the ten rats. What benefit do you think the people of Scotland, who must live next to those experimental fields, will get in the long term? What financial benefits will Bayer get, as a company, in the future?

Dr Rylott: I am not willing to share what our commercial benefit on that may be.

Dorothy-Grace Elder: Oh please, have a guess. [*Laughter.*] Some bioengineering companies have been quoted as expecting to get £10 billion in the long term. Would you expect hundreds of millions of pounds in the long term?

Dr Rylott: It potentially could be.

Dorothy-Grace Elder: Quite. But what benefit will the people of Scotland get from it?

Dr Rylott: There are several benefits for the people of Scotland. First, with this particular crop, as I have outlined in some parts of the paper, it offers the chance to grow a crop in much greater sympathy with the environment than many current farming practices. That will mean that, if we are looking for environmental benefits, there will be a wider biodiversity associated with the growing of those crops compared with current agricultural practices.

Also, the yield increases from those crops mean that we can produce a unit of oil on a smaller unit area of land. That either frees up land to enable other crops to be grown or frees up land for other environmental and recreational activities.

Dorothy-Grace Elder: Do you accept the fact that we do not need much land to be freed up, because a lot of land—thousands of acres—is under set-aside at the moment? In your submission, you state that the land could be used for recreational purposes. That has not happened with set-aside land, so why should it happen with other land?

12:15

Dr Rylott: That is a slightly different issue. Land can be freed up for other reasons. However, we still need to supply food. I assume that we all want to eat. There is a finite amount of land in the UK, and producing food on a smaller unit area of land gives us the opportunity to set aside land for environmental or recreational reasons. Importantly, the GM crop also allows us to grow more oil per unit area with significantly fewer inputs. That means that the crop can be utilised for biodiesel and the oil from oil-seed rape can be used as a sustainable green fuel. We are talking about yield increases of 15 to 20 per cent, which significantly changes the energy-balance ratio compared with current agricultural practices.

Finally, the Scottish consumer is getting a food source that is safer as well as more cost-effective. It is safer not purely because it has been tested and tested and tested. The product that leaves the farmer's field can be safer than the natural forms of oil-seed rape, which, as Dr Squire said, can be high in noxious substances that are anti-nutritional factors. One such substance is isothiocyanate, which is the precursor—

Dorothy-Grace Elder: But do you accept the fact that Scottish consumers do not want the trials to be next to their homes?

Dr Rylott: May I finish, please? So, one such substance is a precursor—

The Convener: Dr Rylott, I will tell her to shut up.

Dr Rylott: I beg your pardon. I apologise.

Plant breeding has continued over many years to reduce the naturally occurring levels of substances such as isothiocyanates, which are the precursor of mustard gas, in oil-seed rape. However, plant breeders have not been concentrating on reducing the occurrence of isothiocyanates in weeds. It is currently impossible to control those in an oil-seed rape crop, but it will be possible to control them through GM technology. Therefore, the final product will be essentially safer than what we currently have. I am not suggesting that what we currently have is not safe; I am saying that genetically modified oil-seed rape will be safer.

Nicola Sturgeon: Some of the benefits to which you refer are open to debate. For example, it has

been put to us that crops that are designed to reduce the use of herbicides may result in an increased use of herbicides. There is some debate about that.

I have two points to raise, the first of which concerns substantial equivalence. With respect, I do not think that any committee member thinks that substantial equivalence is the be-all and end-all: we know that it forms the basis for further tests. Whether something is designated as substantially equivalent, substantially equivalent apart from the introduced trait, or not substantially equivalent, determines the further tests that will take place. If something is substantially equivalent, those tests will be less rigorous than they might otherwise have been. That is the first point on which I would like clarification.

The second point is completely different. Some evidence that we have received during the inquiry has suggested that the regulations concerning the separation distances that are required between GM and non-GM crops and the regulations concerning the cleaning of equipment and the treatment of crop sites after the trials have taken place are not being adhered to. Perhaps you can respond to that suggestion.

Dr Rylott: You first question was whether substantial equivalence alters the way in which the studies are carried out. Substantial equivalence is the starting point in considering the risk assessments and hazard assessments that have to be carried out on any novel crop—in this instance, a GM crop. There are three options: the crop is exactly the same; the crop is exactly the same apart from the introduced trait; the crop is completely different. This crop fits into the second category, as it is exactly the same apart from the introduced trait. That determines the sort of testing that is necessary to clarify that the substantial equivalence testing was correct and that the hazards that were identified through that testing have been addressed to our satisfaction and the satisfaction of the regulatory authorities.

Does that answer your question?

Nicola Sturgeon: For the moment, yes.

Dr Rylott: The second question was about separation distances. When the crops were first grown some years ago, separation distances were not required. In many instances, the industry has volunteered to use separation distances to ensure consumer choice, so that people can choose GM or non-GM products. Those distances are based on levels of cross-pollination between GM and non-GM species. Pollen is clearly designed to travel and to cross-pollinate, but we can manage the amount of cross-pollination that occurs between one crop and another, otherwise we would not have a seeds industry.

The levels of cross-pollination from an oil-seed rape crop are very different to the levels of distance that the pollen can travel. That is always a difficult concept to come to terms with. For example, I could have in my pocket pollen that I had brought from Suffolk this morning, but we do not know whether it could cross-pollinate anything in this room. There is cross-pollination, but the levels of cross-pollination drop off dramatically. It requires only 1.5m between fields to make sure that field A is GM and field B is 99 per cent non-GM.

During the farm-scale evaluations, we agreed voluntarily to a minimum separation distance of 50m between GM and non-GM crops, to 200m between GM crops and seed crops, and to 200m between a GM crop and an organic oil-seed rape crop. For the record, there are fewer organic oil-seed rape crops in the UK than there are GM oil-seed rape crops. The system that has been set up minimises the amount of cross-pollination of other crops in the area. We have conducted 250 farm-scale evaluations throughout the UK over the past three or four years and there have been no breaches of those separation distances.

Nicola Sturgeon: That is fine just now.

Mary Scanlon: What is your view on ACRE's recommendation that plants should not be produced with genes that confer resistance to antibiotics that are used in human and veterinary medicine?

Dr Rylott: That is now enshrined in regulation and the industry has signed up to abide by it. The antibiotic resistance marker genes that were used in the early technologies were considered safe. If you consider UK approvals, our earlier version of oil-seed rape was in 1995 fully approved for food, feed and environmental safety. That version contained the antibiotic marker resistance gene. The crop that is currently being grown in Scotland does not contain that gene and although we believe that many of the stories about antibiotic resistance marker gene technologies are unfounded, we have developed the technology, but do not have to rely on it any more. It therefore makes sense for us to not use it.

Mary Scanlon: There are two points in that. One is that you disagree with ACRE. Secondly, I am concerned about the fact that the technology was previously considered to be safe, but is now causing enough concern for a government department to advise that we should not be producing genes conferring that marker. Given the evidence that we have heard about cross-pollination and GM material entering the food chain, is it possible that some damage has been done or that some resistance to antibiotics has been conferred?

Dr Rylott: As I understand it, ACRE's advice is that the use of antibiotic resistance marker genes should be phased out. ACRE has not said that it considers those genes to be unsafe, but that it would be sensible to phase them out, given that other technologies exist.

Mary Scanlon: Why does ACRE want those genes to be phased out if it thinks that they are safe?

Dr Rylott: I do not know—you would have to ask ACRE that question. I believe that the genes are safe and that many of the untruths surrounding them have been blown out of proportion. The genes continue to be used in other countries, but our company has decided to phase them out. However, we do not believe that they are unsafe.

Mary Scanlon: You have been told to phase them out.

Dr Rylott: Yes, but the company decided to phase them out before that announcement was made. The decision was made partly because of the regulatory work that is associated with GM crops. It is eminently sensible to have what is called one elite event to put through the regulatory processes throughout the world. If there are 10 events, the job becomes much more difficult. That is why we have phased out the others and are left with one elite event.

Mary Scanlon: Given cross-pollination and the fact that some GM material has entered the food chain, is not it possible that damage has been done and that some people have become resistant to antibiotics?

Dr Rylott: There is no evidence that the use of antibiotic resistance marker genes in GM technology transfers from GM plants to, for example, gut bacteria in humans. To be perfectly honest, it is likely that GM material has entered the food chain because we eat GM crops that are imported from the rest of the world all the time. The issue is not only about crops that are grown in the UK, but about imported crops. At some point, everybody has eaten food that contained the antibiotic resistance marker gene technology.

Mary Scanlon: If I go to the doctor tomorrow and it is discovered that I am resistant to antibiotics, is there a process that can trail my resistance back to contact with GM materials? Could the connection be proved?

Dr Rylott: As I said, there is no evidence that antibiotic resistance is transferred from GM plants to humans. The antibiotic resistance marker genes that are used in GM plants are different from those that are used in relation to human health.

Margaret Jamieson: Does your company have a view on whether and how it should consult members of the public and the communities in which GM crop trials are to be carried out?

Dr Rylott: Yes, we have a view on that. We have submitted evidence and views to the various consultation processes that surround the changes to the 2001/18/EC regulatory processes. The company's view—and my view—is that when a release to the environment is assessed and when ACRE considers the company's submissions, there should also be a period of consultation with the general public to discover their views on the safety of the release in relation to human and animal health and the environment. The consultation should be carried out at the beginning and ACRE should take due notice of the general populace's comments in deciding whether the release should be allowed. When ACRE has assessed fully the food safety implications and has taken into account public concerns and the effects on the environment, the decision should be made and the consultation process should end.

I do not believe that we should stop saying where trials will be carried out, although the damage that has been meted out to some trials as a consequence of our revealing their locations is not helpful. After everyone has been consulted effectively, the consultation process should end and the process of notifying people where the trials will be should begin. The company is open about what it does and we tell people about the trials.

The Convener: There are two or three more questions, but we have gone way over time and we have to complete a stage 1 legislative report. Are you happy for us to put those questions in writing?

Dr Rylott: No problem.

The Convener: I thank you for coming along and for your written submission.

That brings to an end the public part of the meeting. We will now take agenda item 4 in private.

12:29

Meeting continued in private until 13:12.

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