

ROYAL COMMISSION ON ENVIRONMENTAL POLLUTION

PESTICIDES STUDY

held at

The Institute of Materials, Minerals and Mining
One Carlton House Terrace, London SW1

on

Thursday, 4th November 2004

Committee Members:

SIR TOM BLUNDELL: (CHAIRMAN)

Sir Brian Follett
Prof. Ekins
Prof. Plant
Prof. Rayner
Dr. Graham-Bryce
Mr. Speirs

Prof. Clift
Prof. Sprent
Prof. Jowell
Prof. Hoskins
Dr. Owens
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Mr. Guy Mawhinny (Secretariat)
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Mr. Tom Eddy (Secretariat)
Dr. Charlotte Grey (Secretariat)
Dr. Diana Wilkins (Secretariat)
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INTERVIEW WITH: PROF. DAVID COGGON

CHAIRMAN OF THE ADVISORY COMMITTEE ON PESTICIDES

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(The meeting commenced at 10.45 p.m.)

THE CHAIRMAN: Let me welcome Prof. Coggon. Thank you very much for coming along to see us for this session. The reason why our discussion has gone a little over a quarter-to-11 is because everybody recognises that this is a very important session for us to understand your views and how the ACP operates. A transcript is being made. Almost certainly we are going to be asked about this meeting -- there will almost certainly be a minute of this meeting -- so would you mind if the transcript is made public?

A. No; not at all. I do get a chance to correct my grammatical errors, do I not?

Q. Yes. We will certainly show you the transcript before it goes anywhere near a website. We will put it on the website. I think this is the most public of all the studies that we have done in recent years.

A. That is the nature of pesticides.

Q. Could you tell us a bit about your background? I am told that not only are you a mathematician from Cambridge but that you are also a medical doctor.

A. I am not a real mathematician because I only did two years, but I saw the light and changed to medicine, which I can assure you is considerably more lucrative. I trained initially in internal medicine but I knew I wanted to do research in epidemiology from the time that I was a medical student. Since 1980 I have worked at the MRC Environmental Epidemiology Unit in Southampton, initially with Donald Acheson and then leading a team myself. My research interest has been in the epidemiology of occupational and environmental causes of disease, principally. Within that field, my main interest has been the occupational causes of muscular disorders and the risks of adverse health effects from chemical exposure in the workplace and in the general environment.

My specialist clinical training is in occupational medicine. Until about four years ago I was still doing clinics in occupational medicine with an honorary contract from the Trust, although I was working at IBM most recently and doing things for them. They paid the Trust for my time. In addition to that, I have spent, as you will have gathered, a lot of time sitting on advisory committees. In addition to pesticides and the DH Working Group on organophosphates, I was also on the Stewart Committee on Mobile Phones and EPAQs air quality standards with Stephen Holgate, plus the Industrial Injuries Advisory Council. I have also chaired the Depleted Uranium Oversight Board at the MoD. So it is quite a wide range of environmental topics.

Q. We are only going to ask you about pesticides as simple bystanders. I don't know whether you have a few words you wanted to say before we got into a general discussion, because I know my colleagues have a number of questions to ask of you.

A. I have felt all along that the public interest in your Inquiry lies in its being independent from the ACP. We, like you, are an independent advisory committee and we form our views of things. We conduct our own inquiries. Like you, we are fiercely independent. Therefore, I think the appropriate thing is for me to respond to your questions rather than to try and lead you in any way.

Q. I understand that you are free up to about 12 o'clock.

A. I am free for as long as you want today.

Q. We are rather scoping the thing at the moment in terms of looking at models and then at plausibility questions, looking at some of the legal and regulatory side and then perhaps coming to the whole question of public concern. There are also a number of other issues, but maybe we can look at the discussion in those four areas to begin with to see how we get on. Let us start on the side of modelling where we have already had a discussion from your colleagues. Brian, you wanted to start on this.

PROF. HOSKINS: As someone who spent three years in mathematics, can I ask you about the modelling? How confident do you feel about the modelling of exposure, in particular for the bystander who is really the neighbour?

A. I think one can be quite confident that the exposures are less than those of operators, even where operators are using personal protective equipment. In general, they are going to be substantially lower. The highest exposures of bystanders are going to be on the day or, couple of days after, pesticides are applied very close to where they are, and over the longer term their exposures are much lower than those which operators experience on the day when they are applying pesticides.

Q. I suppose I was referring to the modelling itself. We have been told that it has to be simplified modelling in some way and it has parameters then which are input from certain field experiments, and it does not include lots of things. So let us concentrate on the modelling itself. What do you feel about this modelling?

A. It is a crude model, but the indications are, supported by empirical data, that the major determinant of exposure for a bystander for almost all pesticides is going to be if they are very close to a sprayer when it goes past. That exposure occurs from inhalation of droplets and from dermal deposition of droplets and skin absorption. There are other potential routes for exposure, so you may be exposed to vapour from volatile pesticides which you inhale. You may be exposed to skin contamination from the pick up of deposits on surfaces, and that is particularly a concern for children who are crawling around on the ground which is adjacent to land which is being sprayed. When you look at the evidence on the levels of exposure that can be incurred by those different routes, apart possibly from one or two relatively volatile pesticides, the major determinant of individual exposure -- the highest potential for exposure -- is if an individual is very close to a sprayer when it goes past. Actually, the exposure that somebody gets from that single, very close, pass in comparison with what they get when the sprayer goes past multiple times at a distance away from them, that is the dominant determinant of exposure. If you base your risk assessment on the exposure that could occur if somebody was next to a sprayer when it was going past, and particularly when you are assuming that that can occur on every day of the spraying season and not on just one day, then I think you have a very conservative method of assessing exposures for the risk assessment.

PROF. HOSKINS: If I could just go back to the model itself, many things have not been taken into account. For instance, the dispersal of the spray. In reality, there will be turbulent eddies and different topographical effects in different regions. Clearly, none of those are taken into account in this model.

A. There are things like wind speed, the clothing that people are wearing and the activities that they are undertaking. I am not an occupational hygienist, but from talking to hygienists, I really think it is extremely unlikely that somebody is going to incur substantially or importantly higher exposure than that which is assumed in the model on the basis of those sorts of effects.

Q. If I take the fact that the boundary is full of turbulent eddies, so a single wind speed and direction is not what you feel, so sometimes the spray will be carried in a one direction and sometimes it will not?

A. But I would have expected that to have shown up in the empirical monitoring that has been done and in the experiments which have been done to look at what level of deposition you get and what air levels you get close to a sprayer and at different distances. The experimental data do not really suggest that that is a major issue.

Q. Have there been many experiments, then?

A. There are experimental data that have been produced by the Health & Safety Laboratory. There are further experimental data which have been produced at our request more recently because of the concern about bystander exposure. There are also experimental data which are sometimes generated by approval holders in support of applications where the model for assessing operator exposure does not demonstrate acceptable exposure. They may go on to generate further data. There are also data which have been collected in relation to concerns about aquatic toxicity and looking at deposition on water courses and things. So there is quite a large data base on the deposition of pesticides.

Q. So there has been a definite trial of this model and the comparisons with experimental data has been found to be good, has it?

A. In terms of bystander exposure?

Q. Yes.

A. There have not been direct experiments in which people have done bio-monitoring of bystanders and looked at the doses which they receive. There have been in operators. The model for exposure of operators appears to be really rather conservative, and when you do bio-monitoring the internal exposure that you record is generally substantially lower than that which is estimated by the exposure model.

Q. It has been said to us that the bystander part is really a bolt-on to the model.

A. It has evolved out of it. We are ahead of, virtually, any country in the world in trying to get to grips more with this. Pesticide risk assessment is a continually evolving process, but I think that, bearing in mind when you do your risk assessment you are assessing the estimated potential exposure of a bystander against the same toxicological end-point as you would use for an operator, you can be extremely confident that the exposures of bystanders are going to be a lot lower than those of the operators. Again, the experimental data that we have, not so many from this country at the moment, although there is a study being commissioned, really support that quite strongly.

Q. So the meteorological conditions that go into this are wind speed and direction?

A. Yes.

Q. So we all know from bonfires or whatever that there are other things which affect how much something disperses such as the stability of the atmosphere. So nothing else is actually taken into account in terms of the dispersion?

A. Not in the model. We are looking at what happens very close to the source, because in the distance exposures tend to be much lower.

PROF. RAYNER: I want to ask a couple of questions of clarification. You said expect for one or two volatile pesticides that this was the most likely exposure. What about the exceptions and what attention has been paid to those?

A. Yes. The two in particular are chlorpyrifos, which is an organophosphate insecticide, the use of which has gone down quite a lot but it is still used in this country, and methyl bromide, which is a fumigant, which is disappearing under the Montreal Protocol, but is still used. We do have data on airborne levels of more volatile pesticides from a study that was carried out in California. The levels that occur there are likely to be higher than would occur in the UK as the temperatures are higher. We have asked PSD to do a risk assessment based on the data from the California study.

PROF. HOSKINS: This is Sharon Lees' work, is it?

A. I really cannot remember whose it is, but it is not just one paper. It is a monitoring exercise, so there are quite a lot of data available. I am sure PSD could give you chapter and verse on what they published. We did ask PSD to look at these data and to see what the implications were for our risk assessment for chlorpyrifos. When they did that, the risk assessment was acceptable.

PROF. RAYNER: Secondly, you said that there has been no bio-monitoring of bystanders.

A. There is some work being commissioned at the moment. It has been done in other countries. There are a number of studies in the United States which provide information. It is not quite so simple as it sounds. There are challenges in doing bio-monitoring studies. First of all, you have to have a pesticide for which there is an adequate bio-marker that is sufficiently specific. Secondly, you have to be able to convert the measured level of the biomarker into an estimated dose.

Q. Do you need to do that for exposure?

A. Yes. How else could you do it? If you do not have a biomarker, how could you assess how good is the model.

PROF. PLANT: Could you not measure body content?

A. That is a biomarker.

Q. Yes, but biomarkers are often used in a different sense.

A. You get biomarkers of exposure and biomarkers of early effect and biomarkers of late effect, but they are all called "biomarkers". But you have to have a suitable biomarker for the pesticide and it has to be specific. For example, there are some pesticides which produce metabolites and those same metabolites are also generated endogenously as well, so it makes interpretation more

difficult. You also need to be able to translate from your measurement of the biomarker into a dose, and that may not be straight forward. When you measure your biomarker, if it is a blood level, for example, at one point in time or if it is a spot sample of urine rather than a prolonged collection over a period of days -- you are measuring it at one point in time -- and translating from that to a dose that may be received either at a single instant or over a period of time is not straightforward. There are challenges in doing this. The other thing, really, is that we know from the bio-monitoring that has been done on samples on people, and also in this country on pesticide sprayers as part of studies done to validate exposure assessments for sprayers, (and studies have been done in which they have been investigating using bio-markers where you do a baseline measurement and then you do measurements at intervals over the course of the spraying operation), that exposure levels in general are going to be extremely low. So if you are going to try and test the scenario at its weakest point -- that is the most stringent test -- you have to try and do your bio-monitoring of bystanders at a time when they are most likely to have been exposed.

Q. Why do you use blood and urine when most of these things have a very high partition coefficient to fat? Stephen and I were looking at data yesterday which showed that for a number of these pesticides, if you look at blood and urine, you get a level that can be a thousand times lower than in body fat?

A. I am not sure that I agree with you entirely. I think there are some pesticides that partition strongly to fat, but many of them do not. Getting fat biopsies off people acutely is not an easy thing to do. There are plenty of studies which have looked at levels of organochlorine compounds, and their metabolites in fat. It has been a very widely used technique. I have been involved in studies where we have measured levels of dioxins. Usually, it is done in blood. It is done in lipids from blood samples rather than in fat biopsies. Dioxins are not pesticides but they do contaminate some pesticides which have been used in the past. In general, it is not really a feasible exercise in relation to the sort of studies that one would like to do for most pesticides. If you would like to propose a specific pesticide and design a study in which it could be used ----

Q. When these people are concerned about it, then they get a measurement in their blood and urine which is pretty meaningless, and then they go and get their own body fat measurement and it comes out very much higher, it looks as if the system is designed to come up with the answer "No, there is no problem".

A. It depends what pesticide you are assessing.

Q. Many of them are fat soluble.

A. In general, the sorts of things that people pick up when they do these fat measurements -- the environmental medicine specialists -- they are mostly organochlorines.

Q. We saw some yesterday which were organophosphates, too, and quite a few of those have a high partition co-efficient.

A. Yes. If organophosphate exposure were occurring at a level which would be of concern in relation to the risk assessment, then it would be detectable by the bio-markers which are used in urine and the bio-markers which are used in blood.

Q. The data we saw yesterday looked very different from that. I would like to ask about another aspect of this. Do you use in your model the whole cocktail of what is sprayed or do you just use

the so-called "active ingredient"? Information now suggests that some of the carriers may have to be looked at quite seriously under REACH.

A. Yes. Certainly we have been aware of the potential for enhanced toxicity from combinations (a) of one active substance with another active substance; (b) of one active substance with a safener or something else added to the formulation to make the pesticide work better and (c) of the active substance with other components of the formulation. Perhaps most importantly, and something which other people do not worry about so much, a pesticide active substance with a medicine which somebody is taking - which is probably a bigger concern because the doses of medicines that people get are much much higher than the doses of pesticides. For a long time, and certainly for all the time that I have been a member of the ACP, there has always been an element of toxicity testing on the formulation as well as on the active substance, so you do a few toxicity tests on the formulation. That is relatively crude but it can give an indication of whether there might be something going on there which is unexplained, where you get much higher toxicity from the formulation than you would predict from the active substance.

Q. But is this in your model?

A. The risk assessment is done principally for the active substance. What you then have to think about is whether there is a potential for interaction. If there is more than one active substance, then, again, that may need to be modelled. It is principally a concern for operators because, as I said earlier, the exposure of operators would tend to be the critical thing, not the exposure of members of the public.

PROF. RAYNER: Do you mean it is modelled or it may need to be modelled?

A. First, you have to do an assessment.

Q. You are talking prescriptively. I am interested in knowing the difference. Is it actually being done, or are you talking about prescriptively what one needs to do?

A. No. It is done in some circumstances.

Q. Can you help us to understand in which circumstances you do and in which circumstances you do not?

A. What you have to do is to consider the toxicity profile of the component active substances and you are looking to see whether there is a potential for anything other than simple additivity of effect. In general the default assumption -- I do not know if you have read the WiGRAMP report on Interactions and Mixtures Pesticides -- would be that you get additivity of effect, but there are some circumstances where you would be concerned about something beyond that. The most common one is likely to be where you have two pesticides that act by the same toxicological mechanism. In that situation, you are really looking at an additivity of dose. How that translates into an effect will depend on where you are on the exposure-response curve because, generally, exposure-response curves are a sigmoid shape. so you may end up with something less than an additivity of effect, and you may end up with a lot more than an additivity of effect. But you do need to be careful in that situation. Also you may be in a situation where you have got two pesticides, two active substances, that act on the same end tissue and organ but, perhaps, by different mechanisms. In that situation, you need to consider whether there is a potential for interaction. Another situation where we have looked at the potential for interaction in more detail is where one pesticide induces a liver enzyme

which is involved in the metabolism of another and, therefore, you have to consider whether that might have implications for its toxicity. So wherever we have two active substances in the formulation, we will always look quite carefully at whether we need to do a further and more detailed risk assessment to take account of that. There are several examples in the work which we have been doing in the past year.

DR. GRAHAM-BRYCE: I would like to make a quick observation first. I think it is a relatively small proportion of the whole spectrum of pesticides that partition more favourably into an aqueous system from a lipophilic one. They are mostly on the lipophilic side. You were talking about chemicals such as bipyridiliums or phenoxy acetic acids.

A. That is why dermal absorption is important. I do not think it is so gross that you cannot get useful information from measuring metabolites in urine or measuring blood levels.

Q. I do not want to labour the points which Prof. Hoskins made but, in a sense, we may be often concerned with incidents which occur at relatively low frequency rather than an average situation. That is where something like the eddy situation might become important if there was a particular case of that kind. Moving from that, the impression given is that the models look for the worst case or most conservative situations. In respect of worst cases, they assume good practice. How far do they allow for bad practice?

A. There is some allowance made for poor practice. For example, the wind speed assumptions in the exposure model are in excess of those that are permitted for the application of pesticides. There is a limit as to how far you can go. We also recognise that you cannot expect people to comply completely with the prescribed conditions of approval, particularly in relation to non-professional use. For that reason, it has been our policy where, in order to have an acceptable level of exposure, you need to use personal protective equipment, we will not allow that pesticide for use by amateurs, by non-professionals, just because you cannot be sure that people will do that.

Q. But there might be other ways than the assumption in the model in terms of conditions? A. There are certainly episodes of poor practice. We know about those. They come to light occasionally. For example, you can measure pesticide residues in food. Then you investigate and you find that somebody has not used pesticides according to the conditions of approval. There are a few episodes that occur where people get their gardens over-sprayed with a herbicide and they get plants dying as a consequence. So things are not always done in the prescribed way, in the same way that people do not stick to speed limits when they drive cars. It is a question of getting the right sort of balance. How much allowance do you make for the fact that people do not always comply with the rules? Our feeling has been, and we have thought about this quite carefully, that based on the surveillance that is done and the frequency with which we identify adverse incidents, although this does occur from time to time, it is really quite rare. At the moment it does not justify stricter regulation. But that is a judgement, I recognise that. It is not a matter of science.

Q. You are confident that you have a good enough evidence base to make that judgement, because the impression that we have been given sometimes is that the monitoring is not that comprehensive.

A. For adverse health effects?

Q. Yes; for adverse health effects and for exposure, adverse exposure?

A. As to adverse exposure, it is adverse health effects with

which we are concerned, principally. Q. At the end of the day, adverse exposure may be linked to that, give that some people's health effects are quite different.

A. The only way you can monitor for adverse exposure is by going out and doing lots of unannounced exposure measurements, because as soon as you do exposure measurements, then people change the way in which they work so you do not necessarily pick up bad practice. That applies across the board in occupational health. In terms of looking for adverse health effects, it is impossible to have a perfect system, but it is, again, something which we have thought about very carefully and repeatedly. It is not something you just think about and it goes away. You have to come back and re-visit it. Let me tell you the approach we adopt. Firstly, you have to make a distinction between acute health effects and long-term health effects, because the approach to the two is really rather different.

Q. Let me interrupt you for a second because I am sure that others will want to pursue these epidemiological and other effects I just want to move to one other aspect in the modelling, if I may, Chairman ----

THE CHAIRMAN: We will have to move on quite quickly, though.

DR. GRAHAM-BRYCE: One more area, and that is the safety factors which are built into the no-effects levels and so on. The safety factor of 100 is a commonly used one. There is a feeling that that is 10 for a species difference and ten for vulnerable ----

A. It originated in a rather arbitrary fashion. This breakdown has really emerged since it was originally put in.

Q. It seemed reasonable at the time. The other 10 is for vulnerable groups.

A. The differences within species; yes. So 10 for the differences within species and then people have attempted to split within that between pharmacokinetics and pharmacodynamics. Then the other element of conservatism in setting the reference value is, of course, the dose spacing that is used in the toxicological studies which are used to set that because, often you have an order of magnitude in the dose spacing but you base it on a no observed adverse effect level.

Q. So, inevitably, it depends on the methodology used to determine it, which is what you are saying. If you have used those and each of those two 10's could be subject to a lot of debate and challenge, you have then used them up, if you see what I mean. People sometimes appear to be using this safety factor to say, "Well, okay, if the model is a bit rosy, it does not matter because we have a safety factor".

A. No, I do not think that. The conservatism in the model in terms of assessing exposure comes from elsewhere, does it not? When you do a study, exposures in practice tend to be much lower than those predicted by the models. In the case of bystanders, you are making the assumption that somebody is right next to a pesticide sprayer as it goes past, exercising hard, wearing virtually no clothes on a day when the wind is blowing hard, every day for a whole growing season. That just does not happen in practice, but that is the assumption that is made, so there is a big element of conservatism in the exposure assessment as well as in the assessment and setting of the toxicological end points.

PROF. EKINS: I would like to refer to two things. Firstly, you talked about standing right next to the sprayer. My reading in this field is very limited because I am an economist, not a natural scientist. I understand that 8 metres is the standard. Then you have done one study that looked at a one metre level only as part of the consultation process, but actually the model is calibrated to 8 metres?

A. Yes; but what you find is that when you go up one metre you do not increase the exposure by that much. You do get an increase. It is less than tenfold. It is about two or three fold. Again, you are assuming that people get that dose. They do not generally do that. They do not go within 1 metre of a sprayer when it is going past. Because you are assuming that they are getting a level of exposure which goes repeatedly on every day of the spraying season, it seemed to us that it is really highly conservative.

Q. The real question I want to put is to run to ground this issue of mixtures, because the issue of mixtures is surfaces again and again and causes concern. We repeatedly hear from those people who have concerns that no account is taken of mixtures and the modelling concerns single substances, etc. I would like to be absolutely categorical that where the science considers that there is the possibility of more than additive effects from mixtures, that the modelling has been done -- it will be very helpful if it has been published because then we can see it -- with the supposed enhanced effects in order to ensure that we remain below the necessary levels. That is a very important point that we will need to run to earth when we come to report.

A. I think the best thing is if I ask the secretariat to give you some of the relevant discussions from meetings and evaluations of pesticides where that has been done.

THE CHAIRMAN: We will note that and come back to you. I want to come back to Brian and then I will go on to health. The point is that we are half-an-hour into the meeting.

PROF. HOSKINS: I will try and keep it short. Is any account taken of the actual technology of spraying; first, the boom height is important and then we hear there are some very advanced spray nozzles which really determine the droplet size spectrum, and then the velocity of the trajectory of the droplets? There are others which are very old.

A. We assume the worst case.

Q. You assume the oldest technology with a boom height of what?

A. It would depend on what is being applied to what. For example, if you are spraying an orchard, it is going to be different to spraying an agricultural crop, but the assumptions are the worst case. The debate has been whether one can go beyond that these days, but we have resisted that at the moment.

Q. Some people have raised with us the fact that the dust at harvesting is something that should be modelled.

A. That was raised quite early on when we got into this, and we therefore asked PSD to do an evaluation, a risk assessment, in relation to that. On the basis of that, we were comfortable that that was not the critical determinant of the risk assessment. It was the exposures during application which were going to be critical to bystanders, not the exposure to dust.

Q. Is that information available to us?

A. Yes.

PROF. RAYNER: What is the criteria for criticality, then?

A. It is the scenario, the situation, at which you can get the maximum potential exposure.

Q. You said at the beginning that you were confident that neighbours' exposure would be less than that of operators. Presumably, we are not talking about women and children operators? Do you make any differences in the differentiation of the model for exposures to different persons?

A. Not in terms of exposure, but you would, where necessary, in terms of the acceptability of the exposure.

PROF. EKINS: I thought that that would be wrapped up in one of the factors of 10?

A. It goes beyond that because there are some toxic effects which are specific.

PROF. RAYNER: For example, babies spend a lot more time on the ground than grown-ups.

A. That has been looked at. You do exposure assessments. In relation to bystander exposure, we have considered the scenario of a toddler who is crawling around on a lawn next to a field which has been sprayed with pesticides. Again, it is there in one of the papers that we have looked at and you are welcome to see it.

THE CHAIRMAN: I now want to move on to the health issues. Stephen, would you like to lead on this.

PROF. HOLGATE: We have already received some, but no means a comprehensive view yet, on the health aspects of bystander exposure. What we are beginning to appreciate is that the public concern, both through pressure groups and at a wider level, relate more to the chronic effects of pesticides rather than the acute effects. That is what we are hearing at the moment.

A. It has changed a bit, in the last couple of years. Initially, it was very much about acute effects. Now we have moved on to chronic effects.

Q. That is the sort of information we are getting back. Of course, a lot of these people are talking about multi-system disorders which go under a variety of names, which we do not necessarily need to go into now. I would like your view on what you think these multi-system complaints relate to and whether they have been systematically investigated to a point where you are absolutely confident that the multi-system complaint is not associated with either an acute or repeated exposure?

A. When you say "multi-system", you mean chronic fatigue, do you?

Q. These are patients who complain of aches and pains, loss of weight, appetite problems and depression. We can put labels on them, but I prefer not to use labels, but rather to call them "multi-system disorders".

A. This sort of illness is not uncommon. If you go out and do surveys in the general population and ask about the sort of symptoms of which people complain, then you find that these symptoms do get reported very frequently. Quite a lot about the research that I am involved in is collecting information about these sorts of symptoms. Some people believe that they are related to exposures to pesticides. Of course, there are other things that people attribute them to, such as mobile phone masts and the use of mobile phones, and exposures in the Persian Gulf. Sometimes it is just chemicals in general. Trying to understand what gives rise to this illness and by what mechanism is not straight forward. Clearly, one has always to be alert to the possibility that at least some of the illness might be due to a toxic mechanism. I do not think that anybody can say with 100% confidence that none of these illnesses are ever caused by pesticides. That is not the nature of science, is it. You can never be absolutely certain of anything. It is a question of how confident can you be about it, and are you sufficiently concerned that you feel you need to take some action on the basis of that concern. The action could either be research or regulatory.

Q. Let me turn this on its head put to you the idea that there is a definite set of diseases or illnesses out there, which may be linked to this multi-system symptoms. So I am not a definite pesticide-associated illness, we are making the assumption that there is. So we say there is a group of conditions out there, linked to pesticide exposure, the underlying mechanisms of which we do not understand at the moment. What do you think

A. You have used the words "diseases", "illnesses" and "conditions". I use those in slightly different ways.

Q. Let me give you an example. If someone was involved in the Clapham rail disaster, for example, but were not injured. When they removed themselves from the accident they were severely shaken up and their lives for the next ten years were severely affected. You could call this an anxiety disorder or you could give it a name such as "post traumatic stress disorder". The individual's life is severely disturbed by that particular event. Someone, like a psychiatrist, might call that a "disease state", whereas others might call it a "psychological state".

A. It would be an illness. I would lump it under the heading of "disorder". I would not call it a disease.

Q. Let us assume that there is an organic basis for these things at the moment.

A. When you say "organic basis", do you mean you distinguish between a clear organic pathogenesis and organic processes which are going on in the body? By that, I mean if you put me in a field with a bull and it is stamping its feet, I am going to get physiological changes as a consequence, so there are organic changes going on but it does not mean to say that there has been organic injury to my body.

Q. I want to turn the burden of proof in the other direction and make the assumption, for the moment, that there is something definite that causes the disorder. I am not trying to argue that there is, but let us make the assumption, at the moment, that maybe these people are right and there is a pesticide-related problem, and that it is linked to chemical exposures. What I want to know is what do you think we should do, either through regulatory activity or through health monitoring, as pertinent to those people, (as opposed to the population in general), to try and track down whether there is an association between chemical exposure and their symptoms?

A. I think there is certainly an association between the circumstances linked to chemical exposure and symptoms. I do not think there is any doubt about that. There is an excess of illness associated with exposure to chemicals, including pesticides. We know, for example, in the first Gulf War that there is an excess of illness in Gulf War veterans. The question then is what is the mechanism giving rise to that illness? Is it a toxic effect or is it psychologically mediated? It is quite

plausible that it is psychologically mediated, because we know there is good scientific evidence that one can get these sorts of symptoms, this sort of illness, caused by psychological mechanisms. There are well-documented cases where people have been exposed to perceived environmental hazards, they have got ill and it has turned out that there was no exposure at all. There are experimental studies on people ----

Q. I understand that. You need not go through that. Let us assume that there is an illness and that it is associated with a series of events which are linked to spraying pesticides on crops. Coming back to you again, in that population and in those people who are complaining so vociferously, but not in the population as a whole, what do you think should be done to try and monitor and find out whether or not their justifications for the illnesses that they are complaining of are linked to the exposure or linked to other factors related to the crop spraying?

A. Clearly, you need to assess what the nature of the illness is that they are complaining of, whether there is any objective evidence of pathology. You need to look at what exposure they have.

Q. Have we got such an assessment system in place in Britain at the moment which is actually studying these people?

A. In our group, we are trying to do research on it. We are identifying people who get symptoms or have symptoms in relation to pesticide exposure and looking at their characteristics. What we have found is that you are much more likely to report these symptoms in relation to pesticide exposure if you suffer from or exhibit what we call "somatising" tendencies; that is a tendency to report a whole lot of problems with a whole lot of physical symptoms.

Q. We have received evidence from several individuals, including some people who are bedridden, to indicate that circumstances linked to pesticide exposure has a very major impact on people's lives. What studies are being done on these severely affected individuals?

A. In relation to organophosphates, a study is in progress which is being done by Tony Fletcher at the London School of Hygiene.

Q. So there is no data at the moment? Has anything been published on this that you are aware of in the United Kingdom?

A. Of detailed investigations of case studies?

Q. At the severe end of the disease spectrum where people are housebound and not able to perform properly?

A. There is in relation to the Gulf War veterans. A report on organophosphates is coming. That was a recommendation of the Organophosphates Working Group that I was a member of, which

is almost complete, I think.

PROF. PLANT: Does it include body fat samples because these people have often obtained them for themselves, so it is clear that your statement that this would be a difficult sample to collect is not the case from those people?

A. Not unless you did an epidemiological study in which you showed that their exposure ----

Q. Surely, it has been done?

A. ---- was very different to that of controls.

THE CHAIRMAN: Just before you go there. Let me ask one question. Recent data has come out of the Gulf War when they did a genetic analysis, which was blind originally, which showed a strong correlation with genetics which would imply susceptibility. Are experiments like that in hand?

A. Yes. That work has been done in relation to organophosphates.

PROF. HOLGATE: In relation to other metabolizing enzymes in these people who say their lives have been affected to a major degree, has any genetic study been done, or any attempt been made to study the influence of genetic variants on the detoxification enzymes thought to be involved in pesticide breakdown?

A. As I said, it has been done in relation to organophosphates. Are you talking about in relation to other pesticides?

Q. Yes.

A. Not that I am aware of, although there is probably a little in the literature but not very much.

Q. My second question relates to the impact of odour or smell, which we have not talked about much. This does not relate to the highly toxic pesticide materials which may be mixed together, but to the solvents which may be used to disperse them. We have heard quite a bit of evidence already that this has had quite a major impact in the places where spraying is put down and often can be detected quite long distances from the places where they are sprayed.

A. I did a study in the past at a pesticides factory and every time I received one of their letters it was perfumed.

Q. I wondered whether, from your own experience of looking at the exposure to different occupational chemicals, a smell, under the detection of odour, and encountered more frequently, has a reinforcing effect in any way?

A. I would certainly expect that.

Q. Do you know if there is any data to support that?

A. I do not know of data specifically on the smell, but there is evidence where people perceive that they have been exposed to hazardous situations. I think there are some instances where the

detection was by smell, but there are others where it comes to light in other ways. It may be an irritant effect or it may just be that it is in the press or something like that. Then people can get quite severely ill as a consequence.

Q. That is helpful. A third point relates to the safety factor used by application to animal toxicology studies using a factor of 10 when extrapolating toxic effects from animal to human. If we had relied on this to detect lead poisoning in relation to impaired intelligence in human beings, we would never have detected it. The question which is often put to us when we try to talk to people who are worried about the relevance of the -- is that they say, "What is

your confidence that the animal testing system can reflect the symptomatology that patients are complaining of, even at the extreme end?" Assume there is a situation in small animals, such as rodents which are adapted to chemicals by being able to survive in places such as sewers and other places where they are exposed to high levels of chemicals. The relevance of the specific -- of toxic -- relating to impedimentation of complex higher functions in different forms, such as loss of memory which I was referring to in the multi-symptom disorders, also needs to be commended. Because this has been put to us, what is the confidence that the toxic screening mechanism, both acute and chronic, is able to detect the end points, the toxicological end points, which people have which they are actually complaining of?

A. It is very difficult to grade confidence in that way. Certainly you cannot be completely confident in animal toxicity. Asbestos would be another example, as would arsenic, where you might miss a carcinogenic effect. You need to do the best that you can with the animal toxicity. Then you need to back that up by epidemiological studies and health surveillance to check that you do not find evidence of unexpected adverse effects. In relation to the neurological outcomes that you are talking about the most extensive work has been done on cholinesterase inhibitors. On the Organophosphate Working Group, when we reported on that, we did look in very great depth at evidence from detailed human studies to see whether there was an indication of problems of the sort you get from lead. We looked at the seen evidence, and the indications were that if was not a major problem. But you cannot be completely certain of that, any more than on EPAQs we could be confident that there were not other adverse health effects that we did not know about. You are always going to have an element of uncertainty. You have to make a judgement as to how concerned you are about that uncertainty. My personal feeling is that, in relation to pesticides, and given everything we know, I am not unduly concerned about that uncertainty.

Q. On what basis?

A. On the basis that, first of all, there are other plausible mechanisms for what is actually quite a common phenomenon. Secondly, the nature of the problem. It is a rather non-specific thing. In general it is not related to a specific type of pesticide. In our studies, when people report symptoms in relation to pesticides, they tend often to report them in relation to a whole lot. They say that herbicides, insecticides and sheep dip all give the same sort of symptoms, but that is not really what you would expect. You get problems in children from lead, but it does not mean that you are going to get it from iron or other metals. If these things are causing disease, they tend to be by ore specific mechanisms. Where we have done further research to look in humans to see where there might be a problem, we have not found evidence of a big problem. You still have to go on looking. You still have to do further research in humans, but at the moment I do not see evidence of a big problem.

PROF. RAYNER: I am sorry, but that particular argument does not apply to somatic effects; correct?

A. So?

Q. So if somebody is having a somatic effect from exposure to this range of sheep dips, herbicides and pesticides, the argument that the chemical composition and therefore the toxicological routing is different does not actually break that chain of relationship between the stimulus and the somatising effect?

A. No. These people are really ill. I think it is caused by exposure to pesticides in that if they were not exposed to pesticides they would not get the illness like that. I think it is probably, but I cannot be certain, in most cases, due to non-toxic mechanisms. Then the question is what do you do about it? The point is, if you say, "Right, we must protect people from this because it is a problem, you may end up, perversely, increasing the public's perception that a risk exists and causing more illness in society than you had before. It is a real problem with these sorts of illnesses.

Q. To what extent do you see that as your explicit responsibility as a committee, not personally?

A. We have discussed this a little bit. I think we are principally required to advise on the toxicological safety of pesticides, but we make clear that there may be other reasons why there is a problem. In relation to the bystander issue, I do not think that there are people getting a lot of toxicological problems from exposure, but I recognise that people do not like it. In some cases, they get ill in association with it, in the same way that they might in relation to somebody having a smelly bonfire next door - they do not like that - and there may, therefore, be good grounds for limiting exposure to bystanders for those social reasons, rather than to protect them from toxicity. We gave that advice to ministers.

PROF. HOLGATE: It goes beyond social if somebody is bedridden.

A. The bedridden scenario is extremely rare.

Q. How uncommon is it? What surveys have been done to establish the figures?

We have done surveys of the general population. We have not found ----

Q. I mean around farming?

A. This is in rural areas where we have looked. We have asked specifically about pesticides and we do not find people bedridden. In a survey which we conducted where 4,500 people had used pesticides occupationally, I think there were only eight who left their jobs because of perceived health problems from pesticides, so that is quite rare. When you go out to campaigning groups, like the organophosphate people, they do not come up with very many who are bedridden. You certainly get people who are severely disabled, but to the extent of being bedridden is, I think, quite unusual. But, then, people will get bedridden for all sorts of reasons. They will attribute it to whatever they feel might be responsible and often on rather weak grounds.

THE CHAIRMAN: They cannot have any strong grounds really, because, as you pointed out, the evidence does not really exist. We just do not know.

A. I do not like saying, "We just don't know", because there are levels of "Just don't know". You can be much more confident about some things than about others. So there are some major areas of uncertainty. There are other areas of uncertainty which I think are rather smaller and less of a priority.

Q. It seems to me that if you have got the Gulf War veterans, and you can do a symptomatic study on a large cohort and do some significant genetic or other studies, then you can know, but it seems to me, in this particular area of bystander pesticide exposure, that it might be quite difficult to do that sort of study.

A. Actually, a study was proposed of sheep-dip workers. I was on the committee of the MRC when it came up. I said it should be done, but in their wisdom the non-epidemiologists said, "Oh, you cannot do it. It is a biased sample. They all think they have been poisoned".

PROF. SPRENT: I want to follow up this point on public perception because this is something we have to face one way or the other. As I understand it, your farmers and so forth know exactly what they are dealing with. They have been given training and they are told how to use the stuff.

A. I do not think they all perceive it that way. Some of them do.

Q. They know to some extent. Whether they follow the advice is another matter, but as far as I can tell, the public cannot say, "Look, I have just been sprayed with something. What is in it?" They cannot get that information. Is that true and if so why?

A. We have said to the Government that this is something they should consider. It is not really a scientific matter. It is a policy matter. It is about social values and balancing the benefits for people being able to access the information against the potential inconvenience to farmers and others.

Q. It is rather patronising in a sense, but the general public do not see it in that way, do they?

A. I am not being patronising. I am not saying one way or the other. I am saying it is for the Government to decide where the balance lies.

PROF. HOLGATE: So it is the Government who creates the values?

A. Yes; and the Government are the elected representatives of the people.

Q. You make the scientific judgement but who makes the value judgement?

A. The Government do.

Q. Do you think the public is satisfied with that?

A. In some respects, the public certainly are not. Do you think the public is satisfied with the Government value judgement on fox hunting? Clearly, in managing risks, and this is about managing risks and access to information, that policy involves weighing up benefits and adverse effects for different sectors of society and deciding where the balance lies. That, I think, is a function of Government as the elected representatives of the people. If the people do not like the

way in which the Government are doing things, then they can raise objections to it and they can throw the Government out if they feel that strongly about it. We can point out to Government what we feel the situation is, whether we think it is causing a lot of anxiety in members of the public. In this case, we have raised it. It is an issue, and the Government have conducted a public consultation about it and they have come to their conclusions.

Q. The conclusions were based on?

A. In relation to information on pesticides? They based it on the consultation that they carried out.

Q. But there are many, many comments in this consultation here which expressed huge public concern, and it seems that the conclusions which were drawn dropped back to the scientific toxicological assessment of the individual?

A. No. That was the Government's decision. That was not the ACP's which decided that. We gave our advice to ministers some time ago. Actually, we framed that advice very carefully. We gave ministers a clear option to take action on the basis of the social concerns. It is a big cause of public concern. However, if I were taking action I would want to do it in a way which did not say "This is being done because of concerns about toxicity". I would want to do it in a way which said, "This is being done because people do not like it".

PROF. SPRENT: People want to know what is in their food, so they want to know what is in the sprayer.

PROF. EKINS: I want to go back to health from which we have strayed, because we have public concern coming up later as a series of topics. Again, I want to be really clear about this issue of trying to understand the nature of the disorders that these people are complaining of and the extent to which we actually have an evidence base. I have read a certain amount now about bodies like the Pesticides Incidents Appraisal Panel and the kind of evidence that is put to that body. I gather that that is at the moment the principal body that would be generating such an evidence base. We have also heard from numbers of people that when they go to their GPs, which is inevitably their first port of all when they experience symptoms which they attribute to pesticides, the GPs do not normally understand very much about the subject because they do not have a great deal of toxicological training. The people who go to the GPs are unable to tell them what they have been sprayed with and they are not able to find out that information within a meaningful period of time. There is no system whereby the GP can either find out that information or can log the fact that somebody has come in and complained of symptoms of that kind. If that person is extremely persistent, they may find that their incident does get through to the HSE and the various avenues that might result in it being logged, but one can imagine that in a very great number of cases this does not happen. You have obviously thought about this, because your committee will have thought about this. Firstly, is this situation adequate, and if it is not adequate -- as you will have gathered, it currently seems to me that it is not -- how might it be improved?

A. Have you read the discussions we have had on this that were sent to the committee?

Q. I have read some of the papers that we have been sent. I cannot say, hand on heart, that I have read all of them.

A. It is something, again, that we have looked at repeatedly and at some length. First of all, PIAP is not the only system. There is a range of different potential sources of information about adverse effects of pesticides. They vary in their quality and the level of health effect that they can detect. So at the very hard end, you have mortality data, you have data on hospital admissions for accidental pesticide poisoning and for deliberate pesticide poisoning. We know that the frequency of admission to hospital in this country for accidental pesticide poisoning is really very low. In adults it is about 40 - 50 per year, something like that. Just to put that into context, there are about 30,000 hospital attendances per year for non-occupational accidents with ladders. It is a pretty small number. It is tiny in comparison with other chemical poisoning in general. That is pretty hard data. Generally speaking, you expect an iceberg effect. So if there are a very large number of people being mildly poisoned by pesticides, you would expect to see significant numbers getting into hospital because they have been poisoned rather worse. You then have the PIAP system. The PIAP system has all sorts of limitations, some of which I think there is rather little we can do about, and some of which I think there are things we can do about. The one that concerns me most, about which we have made a recommendation, is that at the moment, within HSE, once somebody in HSE or in a local authority which is notified, once that gets through it takes yonks before somebody goes and investigates properly. By that time, everything is unclear in people's memories, and it is difficult to get accurate evidence. You can do something about that. What I have suggested is that there should be a separate office in HSE and as soon as an inspector gets a notification of a problem with a pesticide, the contact details of the complainant should go immediately to the central office, which could then despatch, or telephone with, a short questionnaire, to get the detail of what the circumstances were, what the illness is, if there is an illness, etc. That would give us much better quality information. It would also make people feel that somebody was taking an interest. I have put that to HSE very strongly. If you could put that to them as well, then maybe we could get somewhere because we have been trying. There are other problems. There is the problem that the local authorities do not notify the HSE very often. Whether that is because they are not getting many notifications or because they do not do it when they receive notification, I am not clear, but we have asked HSE to make sure that the local authorities are aware. The big problem, as you have said, is that incidents occur but do not get notified to HSE. Trying to assess something like that is actually quite difficult. Even where you have a statutory system with a requirement for notification, as they do in some countries, and as we do in this country for occupational injuries and diseases, it does not work that well, even when there is a law which says you have to report. So I think there are limitations to what we are going to achieve in trying to get more complete reporting. We just have to recognise that.

Q. Even through the GP system, for example? If GPs had an obligation to call a specific number ---

A. I do not think it would work that well. Actually, we did for a time trial a green card system in two regions of the country, rather like the yellow card system for reporting adverse effects of drugs. That was actually abandoned because there were so few reports. GPs had been contacted, they had been given the system of notifying to a certain office, but the problem was that they just did not do it in practice. Another problem is that people come to GPs and they say, "I have this problem and I think it is caused by X or Y". If the GP does not really think it is very likely that it is caused by X or Y, do they report it or not? So PIAP is not going to pick up everything but it could do better than it does at the moment. It does provide useful information and that information has impacted on what we have done. In particular it has highlighted the fact that there has been a problem with the use of sulphuric acid on potatoes. There have been a disproportionate number of complaints in relation to that, as compared with other types of pesticides, even with the relatively small data set, and that has led to stricter controls on the way in which sulphuric acid is used. I think the fact that

it is capable of picking that up is an indication that it can do useful things. It can pick up even rather minor acute effects. The other thing that we have been exploring as a source of information is to try and use better the notifications of queries to the Poisons Information Service - to see whether we could follow up selected queries with a questionnaire to GPs saying, "Can you give us more information?" It is not always easy because they make an inquiry about Warfarin, and is it Warfarin used as a drug or Warfarin used as a rat poison? It will be a drug much more often. We are exploring what can be done there.

THE CHAIRMAN: Sir Brian Follett.

SIR BRIAN FOLLETT: What you have said, Professor, during the past five minutes has been very important. I think it bears on the scale of the problem in one way or the other as to how or whether, as a society, we should try to understand more about the scale of the problem. My questions are really related to it. The first one is this. You opened your statement with something with which, intrinsically, I agree, that it is likely to be the operator who is the one who is

most highly exposed to these pesticides. I wondered whether there had been a sufficient analysis of these operators to show whether any of them were showing the kinds of symptoms that are being claimed by people who have been in contact with us. That is question one. Question two is quite a tricky one. I am very struck by the fact that the clinical evidence for these complainants who have been in contact with us and are often on the radio and/or television is really so weak. It is reduced to the GP. This is not adequate. If we are dealing with a really serious problem, then you have to ask a separate question, which is at what point has society the right to say, "Right, you need to move in and really find out what is going on with this individual", because the alternative for society is to overturn a major commitment or policy on the basis of one person's perceived complaint, plus some rather weak clinical evidence. There are two questions there.

A. Yes. In relation to the first one, as to studies on operators, first of all, there are epidemiological studies looking at long-term outcomes in operators, which was not your major theme. In relation to short-term effects, I think our group has taken the lead nationally in trying to progress this, although there is also work being done by the University of Manchester as well. We are just in the process of analysing a large cross-sectional survey of men of working age who are resident in rural populations, in which there is a high prevalence of work in farming. We went to the general population rather than to farmers because we wanted those who had left farming as well as those who were still working as farmers. In that study we have data from over 10,000 subjects, of whom over 4,000 had worked occupationally with pesticides. We have asked about the occurrence of symptoms within 48 hours of using a pesticide. We have asked about different categories of pesticides, not specific products, because people cannot remember that. We have also looked at the frequency of symptoms in relation to individual characteristics and possible risk factors, and also at regional differences. We deliberately went to Devon where there has been a lot of public concern and publicity about sheep dip, but also to Lincolnshire, where there has been much less concern about sheep dip and rather a lot of concern about organophosphates used in growing brassicas. We are just in the process of analysing the data, but the findings are beginning to emerge. They certainly do not rule out the possibility that some people have been poisoned. You cannot do that from that sort of crude study, but they do suggest that there are likely to be important cultural and psychological influences on the reporting of symptoms in relation to pesticide usage, and also that such symptoms are very common. Overall, about 30% of the people who had used sheep dip said that they had experienced one or more of 12 specified acute symptoms within 48 hours of using sheep dip. There were far more individuals reporting multiple symptoms than you would expect if each symptom were independent. There are far more individuals reporting symptoms in relation

to multiple categories of pesticides than you would expect if each one was independent. Also there were regional differences. Whilst I said that 30% of sheep dip users reported symptoms that was true in Devon and in the Welsh borders, but it was much lower in Lincolnshire. The type of pesticide most commonly associated with symptoms in Lincolnshire was insecticides, while herbicides and wood preservatives came lower down the list that is a start. It is not the most rigorous of studies. It had a response rate of only 35%, and that was because ethical committees will not let us have names and addresses. There are tremendous obstacles to doing this type of research these days. That is something which could be an extremely helpful outcome of your report. Just to get anonymised data on hospital admissions -- we are doing a study and trying to find out more about people admitted to hospital with accidental pesticide poisoning, to find out what the circumstances were (were they using it, was somebody else using it, was it badly stored?) we had to go through a three or four month process, an informal appeal and then a formal appeal to a second ethics committee because they said it was not ethical to be given anonymised data without the person having the opportunity to opt out. Our study is about acute symptoms. The next step would be to try and look in more detail at the people who are complaining of multiple symptoms, identified in that way (rather than people who have come forward spontaneously), to see if we can find more about the characteristics of their illness.

THE CHAIRMAN: Let us move on. Professor Coggon, are you happy to go on?

A. I am happy to go on. It is an enormous subject.

Q. I realise that spending an hour on this subject is a bit optimistic. Perhaps we could go on for another half-hour at least, if that is all right with you?

A. Yes.

Q. I want to ask you a question about your response to the Ontario Report, which we have had a look at, and particularly to your paper on 10th May of this year.

A. I do not have a copy with me. I will try and remember.

Q. You were pretty critical and dismissive ----

A. I don't usually do that, but this was poor science.

Q. I have a number of questions. It may be poor science, but I wonder if you could give us some examples. You instance, for example, the search procedures they use and missing out data. I think you are implying that it was a methodological shortcoming rather than implying that they cherry pick the data to make the case. Could you let us know, or send in afterwards, a few examples of where, if they had done the analysis properly, then the conclusions would really have been different. I can easily see that one could dismiss an argument for methodological reasons, and you give a number of them, but it does not mean, necessarily, that the conclusions are wrong?

A. No, it does not. Actually, this was on a gross scale. For example, if you look at the results of cohort studies in relation to lung cancer, there were some positive studies reported with an excess of lung cancer in relation to pesticide exposure, but there were a whole lot of other cohort studies which they identified and which they quoted in relation to lymphoma or breast cancer or other tumours, but which also provided information on lung cancer. It is just that there was not an excess of lung cancer in those studies. They did not include the data from those studies when looking at

lung cancer. There are also some major epidemiological studies, including a large international collaborative study co-ordinated by the International Agency for Research on Cancer (IARC) -----

Q. Is that the Kogenivas paper?

A. Yes. ---- which do not get a mention at all.

Q. I was a little confused, because in brackets in your analysis you have some extra data. I am referring to page 2 of annex C at the top. You say: "The analysis included 1,127 cancer deaths in workers exposed to phenoxy herbicides and chlorophenols, among which 380 were from lung cancer." Then you go on to say: "In the subset of subjects with no exposure to TCDD or other higher dioxins, mortality from lung cancer was close to expectation." I am not quite sure what you are saying about the first set?

A. There was a small excess of lung cancer. Dioxins are classified as human carcinogens. So it is not surprising that you get an excess of lung cancer in people exposed to dioxins. It is rather small. It is 15% or something of that order.

Q. So are you saying that the 1,127 cancer deaths was expected there?

A. I have not given the expectation of cancer overall. I have given it for lung cancer specifically.

Q. What was the significance of that large study?

A. What it showed was that there was an excess of cancer in the subset who were exposed also to dioxins but not in those who were not exposed. Really, it was used to illustrate that they were quoting positive results from small studies of lung cancer, yet here was a very much larger study with a lot of lung cancer deaths that was non-positive and they had not taken it into account.

Q. Do you have an analysis anywhere of other places where similarly wrong conclusions are?

A. I think the example I mentioned of the organophosphates is a good one. If you compare the review that they have done on neurotoxicity in relation to organophosphates with the one which was done by the Department of Health Working Group, it

just does not compare in terms of its thoroughness and the extent to which the issues are covered. The conclusions were, therefore, rather different.

Q. I think it would be quite helpful because your paper is really a methodological criticism. We really do need to know. The Ontario Report, as you know, is quoted by many, many people and it has caused quite a good deal of concern.

A. I know. You have seen the first set of my correspondence with Don Cole. Don Cole was a friend of mine in Canada. It is embarrassing for me to have had to do this to him. If you look at his response, there were two epidemiologists involved and all the rest was done by non-epidemiologists.

Q. I take that point. I just wanted to know whether you got the wrong conclusions as a result.

I think we had better move on. If you have any detailed examples to show us that the conclusions should have been different, rather than ----

A. It would entail me going out and doing the work because I would have to go back to all of the original papers to get the data out.

Q. But it is a rather serious question because it leaves us in a position of, perhaps, understanding that the Ontario Study may not be based on a proper methodology. It is a matter of not knowing really what to conclude. Do we need to have another study?

A. If you want me to make a good job of what they were trying to do, it is a major, major commitment. They had a limited budget and that is why they did a bad job.

PROF. EKINS: I think it would be unreasonable to even think of asking you to do what they have not done, but if you were able, as you have been able in that one case, for example, to say "This cohort study is wrong. They have not taken into account this thing at all". You could point to two or three different points as an illustrative basis.

PROF. HOLGATE: This is very interesting. There is very little on chronic effects. Is this the report you were referring to?

A. No. I was returning to a report from the Department of Health. It has a blue cover, and is on organophosphates and sheep dip.

PROF. EKINS: Just three or four examples, without trawling back and being comprehensive, saying, "I know there is this, this, this and this which, had they been taken into account, should have changed the conclusion substantially". That will then give us something to follow-up in a secretariat way.

DR. GRAHAM-BRYCE: Surely, to be fair, that is stated that there are other studies and they are cited?

A. I can give you a list. That was the thrust of it. I recognised that mine was a personal view, which is why I said that we must go out independently to five other epidemiologists to make sure that it was not just me being idiosyncratic.

THE CHAIRMAN: We had a little bit of worry about this. Let me put to you the counterview that they are all people involved in Government committees and things, are they not?

A. But not on pesticides.

PROF. HOLGATE: But people outside who are perceived ----

A. But you are all on Government committees as well, are you not? This is a Government committee.

THE CHAIRMAN: This is not a Government committee. The general view that we have shown is that we are always concerned that experts can criticise lay opinions. I think we need to have

substance and not just methodological criticisms. If the conclusions of our report is going to carry with the people out there, I think we really need to know.

A. It is a little difficult because the conclusions in the report are largely in relation to pesticides in general. To do a thorough review of pesticides in general, even in relation to a single cancer, is a major, major undertaking. There are lots of good reviews available in the literature which look at cancer in relation to specific pesticides. The reason why I picked out organophosphates as a particular example is because in that area there is more overlap in what they have done with what has been done before. You can see the difference in the conclusions which have been drawn and the methods used.

Q. I think I have to move on. We would like to have a little session on legal and policy issues.

PROF. EKINS: You have made a very strong case, which is based on your long experience in this area. Broadly, people can feel assured about the kinds of processes which are in place to protect them from pesticides in the way that we are investigating. We will come in a minute to the way in which this assurance has been conveyed when we think about public concern, but I would like to ask, first of all, about the Green Code. An argument which has been put to us is, "If everything is fine in the basic legislation and we can feel assured about the basic legislation, why is it that this Green Code exists at all? Why is there any need for this Green Code?" Why, when it is promoted, do people say that it will increase assurance and make things safer when, at the beginning, the statutory position is supposed to be fine? Then, of course, the fact that it is a voluntary code, and there is no legal recourse against those who choose not to abide by its recommendations, means that for those people who feel they have been hard done by, it is clear that the legal situation is not as cut and dried as they were being told because otherwise there would not be this thing called a Green Code, that does not give them any statutory protection. What is the purpose of this thing if it is not necessary?

A. It is necessary. It is rather like the Highway Code is necessary. We have traffic laws but we also have a Highway Code, do we not? We teach children how to cross the road? Why do we have to teach children to cross the road when we have traffic laws to protect them? You need these things as well. You can have regulations, but to make the regulations work, you have to understand what is required of them and there is a need for more detailed guidance. It seems to me absolutely sensible to have something like the Green Code. It sets out in more detail what would be regarded as good practice. You cannot stick it all onto the label of a pesticide. It is not big enough. You can put it in a leaflet inside the pesticide packaging, but people will not read that every time they start using the pesticide. We have done survey of farmers and they do not. So you have to have a system which creates a culture whereby people behave in a certain way and you have to give them the information that they need. I am not a lawyer. You really need to talk to somebody from HSE about what the exact legal status of the Green Code is, but it is not simply advisory. If a farmer practises in a bad way and it is outside the Green Code and clearly contrary to the Green Code, then I think they are in a more difficult position in defending themselves if the HSE take them to court. It is difficult to take people to court for bad practice. It is very difficult with pesticides because you only come along after the event. It is very difficult to pin down that somebody has done something wrong, but the Green Code does actually have some status.

Q. Let me come back on that. We have had this comparison with the Highway Code before, but I do not think it is helpful for several reasons. The first is that roads are, fundamentally, very dangerous places. They kill large numbers of people and everybody recognises that. At the same time, being on roads and driving on roads is an activity done by very large numbers of people,

which is very difficult to regulate through regulation of a governmental kind. One can imagine, therefore, given that we all value driving on roads very much but we also recognise that we kill very large numbers of people and maim very large numbers of people through that, and given that we cannot regulate it, then the Highway Code is the next best thing. That is a very different situation to the one which pertains for pesticides. This is a substance in relation to which, firstly, the statutory mechanisms are said to be of negligible risk, safe or whatever terminology one wants to use.

A. If people do things according to the rules ----

Q. If people do things in the approved manner, where a relatively small population is involved and they are required to be licensed and regulated in a whole heap of ways, therefore, the basic regulatory structure is in place to ensure that they do behave in an appropriate manner. It certainly would not be possible to prosecute a farmer or even a pedestrian who violated the Highway Code, and it is not possible to prosecute a farmer who violates the Green Code. If they are seen to have violated their licence conditions or something that is legal, the evidence that they have acted contrary to the Green Code may serve to make their case more damning, but I think the issue is that, given that this is a specialised industrial activity using dangerous substances, if the legal assurance is adequate that people are protected, why do we need a voluntary system as well?

A. No. The legal assurance is only adequate if people do things in the approved manner.

Q. But the approved manner as defined by the Green Code is not ----

THE CHAIRMAN: Let us bring our lawyer in.

PROF. JOWELL: The Highway Code has a status particularly in the licensing system, namely, the testing of new drivers. They are tested in accordance with the Highway Code. If they do not know the Highway Code, they do not get their licence in the first place. So there is a testing and licensing system which, as far as I know, does not apply to crop spraying; is that correct?

A. You either have to hold a certificate of competence now or you have to be working under the supervision of somebody who has a certificate of competence, so there is an accreditation scheme. It is different for different types of pesticide application.

Q. The accreditation system, the testing, is done ----

A. There is a National Pesticide Training Scheme.

Q. Can you spray if you do not have that certificate, if there is private spraying done by a farmer on his own land?

A. No. You cannot professionally spray pesticides unless you either hold a certificate under that scheme or you are working under the supervision of someone else. The slightly unsatisfactory thing is that there was a grandfather clause. They had to bring it in gradually. That is gradually working out of the system now. There are more than 50,000 people in this country who have been through the system. It is a large number. It is not a small number of people who do this.

PROF. HOSKINS: There are 220,000 farms in this country.

A. I do not know. I only know because of the size of the cohort that is being studied for health outcomes. There are more than 50,000 of them. Those the only the ones who have given permission for their names to be included in the study, but it is quite substantial numbers. The sort of people who are doing this are not all full-time pesticide contractors. A of them do other types of work. Some of them go in and out of agricultural work. They do not stay in it for that long a time. People need to be properly and adequately trained. We try to ensure that we have a system in place for training and they need guidance on the way in which they should do things. I think the Green Code is absolutely a good thing. I think that if we did not have the Green Code, then we would be liable to have more problems. I disagree with the view that just because you have the legal system in place and know what the rules specify, you will achieve your objectives.

PROF. EKINS: I suppose that the argument which is made is that all these people would say, "Yes, the Green Code is a good thing, but it needs to be made statutory"?

A. Yes. I think you need to talk to HSE about the pros and cons of making it statutory and whether it would really actually add very much to what they are able to do. Effectively, some elements of it have been reinforced in specific situations, where there are additional statutory requirements - for example, for the aerial spraying of pesticides, which has virtually disappeared. Actually, the real problem for HSE is that it is quite difficult to enforce against malpractice when you only find out about it after the event. You do not get bodies left behind, usually. If there has clearly been some over spraying and a lot of plants have been damaged in the next property, then you have some evidence that you can go on, but what you really need is to set up systems that require farmers to do things that are not unreasonably burdensome on them but which, nevertheless, enable you to enforce on them.

Q. It would open up the possibility to private litigation apart from anything else, and I am sure there would be quite a bit of that if the Green Code was a statutory provision.

A. Yes; but proving whether or not it had been followed could be difficult.

PROF. JOWELL: What about the purchase of pesticides and herbicides? In order to do that, do you have to show that you have a certificate?

A. I cannot recall. I think there is a suggestion that that provision should come in, but I am not sure that it is in place at the moment. You need to ask PSD about that.

Q. From my own personal knowledge, it is not.

A. Not in the home, it is not.

Q. But for small farmers and certain contractors can just pick up the stuff, can't they? Even if they have not got a licence, they can spray it.

THE CHAIRMAN: Are there any other aspects? I know that Brian wants to come back on the regulatory side.

SIR BRIAN FOLLETT: I wanted to broaden it out and ask for international comparisons. Here we are discovering the wheel in this small island. What is going on about the equivalent regulations over bystander exposure in North problem with multiple chemical sensitivity than we do. These things are culturally determined to quite a significant extent.

Q. I think what you have said there is quite important. I think that we, as a Commission, need to find out rather more about different cultures and sensitivities. If we have a group of people who have decided that it is pesticide bystander exposure, but if we were all in Stockholm it would be the local electric power cables which would come under pressure. I think we need to take that into account. Can we have any harder data to say that this problem is strangely unique to the UK?

A. I would not say that it is unique. I am sure there are concerns. You could do a literature search, but I have not seen one. I think you would have to go out and do a survey.

MR. DAN HAMZA GOODACRE: If I might interject, we have requested a document from the Pesticide Journal from the DEFRA library, so, yes, we have received confirmation on this, but in California they do have buffer zones, particularly around schools. They have even set up a compensation fund paid for by the industry to pay compensation to bystanders. I have seen the abstract but I am waiting for the actual article. I do not think that this is unique to the UK by any means.

A. It may well not be specific but it is much more of a problem in the UK.

SIR BRIAN FOLLETT: I find it very strange when, at this level, we are talking about a Royal Commission spending months and vast amounts of energy when actually our knowledge of what is going on in the rest of the world is a lot softer than the sort of statements which you have been able to make during the past couple of hours. You do not seem to know. "We have found an abstract". Oh, that is pretty impressive. It does suggest that it is not pretty cohesive and pulled together. You would think that there would be a book of words saying, "This is the international situation" ----

A. The only way you would find out is by doing surveys. Why would we embark on a massive survey in this country on electric hypersensitivity when it is not perceived as a problem?

Q. I think that says a lot about what the problem might be.

THE CHAIRMAN: I am going to give a warning to my colleagues sitting around this table that we ought to try and complete this session in the next five to ten minutes. You have been through a marathon session here. I offer you up to Steve for a penultimate question.

PROF. RAYNER: I know that Paul also wants to put some questions on the issue of public concern. With respect to what you have just said, of course, we also know that there are significance differences in cultural foci on different kinds of diseases around the world, and that is quite long-established. Surely, there is one respect in which there is a huge difference between the situation here and in the United States in these matters, and that is with respect to the right-to-know legislation. Whereas here the complaint is "We don't know what we are being exposed to", in fact that problem has been eliminated by Federal legislation.

A. I understand Defra are proposing to increase the information available to people. You need to talk to them.

Q. I would like to get back to the statement you made earlier which is when you were talking about how to protect people with somatic consequences of exposure when to do so might exacerbate public concerns unnecessarily. I would like to ask you to dilate a bit on the extent to

which your committee, the ACP, sees itself as having a role in providing or ensuring public confidence in pesticide safety. To what extent do you see that as part of your remit?

A. I think it is part of our role. We would like people to have confidence in what we are doing, if nothing else. If people are not confident in the way in which pesticide regulation is operating, then we should certainly be doing something about it. Yes, that is an objective which we would like to achieve. However, in practice it is not the easiest thing to do. There is an enormous amount of misinformation that goes out to the public about pesticides. There are a lot of pressure groups which are very active, We spend an enormous amount of time responding to issues that they have raised in the media. There is a difficult choice. I get lobbied by industry saying, "Why aren't you going out actively and promoting what the true situation is?" If you do that in the current climate, then you are perceived as trying to spin a story and people do not trust you. That seems to me to be a problem which the current Government have had. My approach has been to act more in a responsive way when we do put information out. We do put information out on our website. I go to meetings and talk to people. I tend to do it in a situation where somebody is asking me the question rather than going out pro-actively and spreading the message of "This is what we should do in this situation". It is not entirely satisfactory. If you feel that the ACP ought to be much more pro-active in this area, then that would be an interesting view.

Q. I had the opposite impression from what you said subsequently, that these judgements about safety were not scientific judgements but were in fact value judgements and judgements ----

A. What, about the acceptability of risk and uncertainty? They are value judgements. They require the application of value judgements. The way in which we approach that is different from single issue committees. The way in which EPAQs (Expert Panel on Air Quality Standards) works is that the committee says, "This is what the science tells us.. This is the level for an air pollutant which we think would protect adequately." Clearly there are uncertainties, but then the Government looks at what is practical and what should be the policy given that advice?" With pesticides we are looking at a lot of different risk assessments on a regular basis. At a meeting we may well have four different pesticides to look at. There are about eight or nine broad areas of the risk assessment and each of those has uncertainties attached to it. There is no way that you can communicate your assessment of risk, all the different risks and benefits with the attendant uncertainties to a lay Minister and say, "Here is all the information for these four pesticides for this meeting. You weigh it all up and decide what to do". So the way in which it operates for routine business is that the Government sets the overall tone of precaution that they would like to operate. We then try to ensure that we work within that framework and achieve a consistent approach to different pesticides so that we do not end up being much more precautionary for one than another, and we give our advice to Government in terms of a recommendation for policy. So we are actually making recommendations for risk management but we do that within a framework of value judgements that have been set by Government and which it is open to the Government to change at any stage.

On a few specialist issues, we will actually put the uncertainties to Government and say "These are the pros and cons. These are the uncertainties. You must decide what to do".

THE CHAIRMAN: We will go to John and then to Paul. Then we will finish.

MR. SPEIRS: The situation seems to be that the ACP is quite clear in that it has no scientific evidence that there is a problem. On the other hand, you have accepted that there is concern. Leaving that aside, one of the interesting things is that the problems you are having in dealing with all of these people who are complaining has been going on for a long time. You may say, "We

have explained to them that the science does not support it". On the other hand, they are not accepting that. The other thing is that when you read through it, they are really fussed that they feel they have not been consulted or not adequately have had things taken into account, that they do not have information and so on. I was interested in one of them here. It has been going for six years, particularly in the Isle of Wight. The HSE's reaction part of the way through that is appalling. What do you want? Unless something is done, this is going to go on bothering you for ever.

A. I have made enormous efforts to be open and available to people, much more than my predecessor, I think. In the time since I have become chair, which is five years now, first of all, we introduced an open meeting to which anybody can come. They raise issues. It is rather like the meeting you had. It is generally just as exciting, I think. We have had Georgina Downs running the show with videos. I invited her to come along. We do not just do it to pay lipservice way to the recommendations on openness. PSD sometimes worry that we are being too controversial, but we try to encourage people to come along and have a vigorous debate. Secondly, I have engaged with the pressure groups -- I have invited them to come to the open meeting and we have invited them to come to other closed meetings - not the main committee, but its panels, where a lot more detailed business is done -- and I have consulted them in writing about things. Regularly they, or members of the public, submit questions which they would like us to consider, and they are included in the agenda at main meetings and we respond. On top of that I get a lot of correspondence which does not require discussion at a meeting but which I deal with. I have had these people to visit me at my office. Georgina Downs is a regular phone caller and so are lots of the others. It is about a day a week that I spend doing all of this stuff.

Q. Do you feel that the problem is that the problem should not be coming to you but it is a political issue?

A. I am very happy for them to come to me and I think it is important that I should be open to them. They do not just come to me. They also go to ministers. They have been taken on a day trip round PSD to see how things are done and how things work. They will tell you that they do not get any communication, but I think that is grossly unfair. I also go to their meetings as well. I go to Pesticide Action Network meetings and contribute to those. In comparison with other areas of public risk assessment and risk management, we are much more open than the other committees that I sit on.

DR. GRAHAM-BRYCE: Let me clarify one question that was put to you. I think John said that you felt there was not a problem. My understanding was that you were saying that you could not identify a toxicological cause, but you accepted that these people were ill ----

A. Yes.

Q. ---- and that that was associated with pesticide spraying.

A. Yes.

Q. But in all the risk assessment and other work that you have done, you have not been able to identify a toxicological cause for that in the conventional sense that we use it?

A. Yes. On the basis of all the information that is available, and there is a lot of information, I think in most cases, at least -- I cannot be confident in every case -- it is not going to be through the toxic mechanism. It is going to be through non toxic mechanisms. However, there is uncertainty.

Of course there is uncertainty. It may be that there are some people out there who are unusually susceptible for reasons that we do not know. In general, if that were occurring, you would expect it to show first in operators unless it was a particular age group - for example tiny children. We have to be aware of the uncertainties.

Q. So you are not saying that there is not a problem?

A. No.

PROF. EKINS: I would like to talk about language. I language is really important. A number of us on this committee have tried to understand the communication/public science kind of interface. Obviously, in this case, that has broken down to a major extent. The fact that we are doing this report at all is simply because a group of people who have made enough noise do not believe it. They simply do not believe what they are being told by the people who think they are doing the best possible job in working these things out. I think language is partly something to do with that. I must say that I am glad that Ian clarified that business about a problem because, according to the transcript of various meetings which we have been sent, you have on a number of occasions admitted that there is a problem.

A. That has been clear all along.

Q. Absolutely. For example, and I quote: "There is certainly some ill health that is occurring in relation to pesticide spraying. Nobody is trying to deny that." That is a quote which you are said to have made.

A. I bet I know where that came from. She records every word I say.

Q. Absolutely. That is why we are very sensitive to this. If I look at what DEFRA has been telling people on the basis of the consultations and what they have got out of talking to you, we heard words like "safe". It has been said on a number of occasions that the use of these pesticides, under current circumstances is, and I quote, "safe". We now hear phrases like "acceptable risk", which of course is a complete red rag to a bull to the people who think they have been affected because no one asked them whether they accept the risk or not. This is a decision which has been taken on their behalf. We have heard the phrase "negligible risk". Then when those phrases are put next to what I believe to be a proper scientific comment, such as you have made, we clearly get a major problem of public confidence, because they say, "These guys are telling us that it is a safe and negligible risk, but Prof. Coggon says that there is a problem with ill health from pesticides". How can one express that issue in order to get across what it is ----

A. You try to be consistent all the way through. That statement is absolutely true and I stand by that. The statement about risk and safety relates to toxic effects. I try to make clear when I am talking about toxic effects and when I am talking about possible non-toxic effects. I would never say that anything is safe because you cannot say that. To say that is just a hostage to fortune. You, sooner or later, will be found out. You can only talk in terms of acceptability. I have tried to avoid talking about "acceptable risk" and talk about "acceptable exposure", because it is not just about risk, but about uncertainty as well. I make a very clear distinction between risk and uncertainty. Some risk assessors just lump them altogether as risk, but I think there is a big difference between risk, by which I mean that a proportion of people who have experienced an exposure will get ill as a result, but I do not know which ones, and uncertainty, where I do not know whether anyone is going to get ill at all. I make a distinction in my language. I try to be very

careful all the time when I deal with people to do it in that way, but there are a lot of people involved in the business and they are not all precise in their language.

PROF. RAYNER: Is that the sole explanation as to why DEFRA can come up and make statements such as "There is no scientific basis for concern"? The point is that you are saying that there is very little toxicological basis for the concern. That is a very different claim to make, is it not?

A. Yes.

Q. Then why is that not corrected?

A. I do not monitor everything. You try to make sure that people understand the nuances of language. I try to put this to people. I spend a long time -- I am very obsessional about it -- on the detail of our minutes of meetings. You cannot control everything. You have to try and gradually educate people to what you are trying to get across.

THE CHAIRMAN: I think I am going to have to close the discussion at this stage. You have been going for more than two hours. I know my Secretariat said that an hour was the likely time.

A. It is all right. I have budgeted the whole day. We have hardly touched on things. Another thing you might like to talk about is the publication of our detailed record of discussions. At the moment, we publish our minutes, which are a summary, on our website, but we do not publish the detailed record of discussion. This is because of concerns about commercial confidentiality. We have said to the Government that we think we should publish it. The Government have held back because they are concerned about legal action. If you can push them on that, that would be great. for a splendid session. As you can see, we are finding our way through it. We come to it from a different background, which is not having specialist expertise. That was very helpful. I am sure you will get some further questions from the Secretariat. We probably will not send as many e-mails as some of the activists. Thank you very much.

A. Thank you. We look forward to seeing your report when it comes out. Obviously, our committee will look at it very carefully and there will be a response from us.

(The meeting concluded at 12.48 p.m.)