MINUTES OF EVIDENCE TAKEN BEFORE THE SCIENCE AND TECHNOLOGY COMMITTEE

MONDAY 8 MARCH 1999

Members present:

Dr Michael Clark, in the Chair

Mr Nigel Beard	Mr Nigel Jones
Mrs Claire Curtis-Thomas	Dr Ashok Kumar
Dr Ian Gibson	Dr Desmond Turner
Dr Lynne Jones	Dr Alan W Williams

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INTRODUCTION AND BACKGROUND

http://www.publications.parliament.uk/pa/cm199899/cmselect/cmsctech/286/9030802.htm

In recognition that research on the effects of genetically modified (GM) crop plant on the environment is of fundamental importance and particularly that their dietary use and possible impact on the mammalian gastrointestinal tract has had scant attention without a single peer-reviewed paper by 1995 (only one since; J. Nutr. 1996), SOAEFD commissioned a 3-year multicentre project (FF 818); *Genetic engineering of crop plants for resistance to insect and nematode pests: effects of transgene expression on animal nutrition and the environment.* The main objective was: "To identify genes encoding antinutritional factors which will be suitable for transfer into plants to enhance their resistance towards insect and nematode pests, but will have minimum impact on non-target, beneficial organisms, the environment, livestock fed on these plants, and which will present no health risks for humans either directly or indirectly through the food chain". Our proposal describing the genes and plants, the experimental designs and protocols, the tasks of each participant and research milestones was peer-reviewed by BBSRC and approved by leading scientists. In recognition, SOAEFD selected our proposal against other competing tenders. The genes considered for transfer were those coding for plant antinutrients including lectins. With our unique previous experience of feeding rats using diets rich in insecticidal antinutrients, it was decided that the programme of work on the effects of GM-plants on the environment, target pests, beneficial insects and soil bacteria at University of Durham (UD) and the Scottish Crop Research Institute (SCRI) should be coordinated from the Rowett Research Institute (RRI). Our most important work task was to devise novel methods for the safety testing of GM-potatoes which could be incorporated by the regulatory authorities into the testing and risk assessment of GM-foodstuffs. Our work has concentrated on tubers from GM-potato lines expressing the gene of snowdrop (*Galanthus nivalis*) bulb lectin, GNA, and our task was to carry out chemical analyses to establish whether the parent and transgene lines were compositionally equivalent or not and to determine in 10-day and 3-month rat feeding trials whether the effect of GNA-GM lines on the mammalian gut and metabolism was similar to that of parent lines or not. The selection of GNA was not arbitrary. This gene has already been incorporated into several crops (rice, cabbages, oilseed-rape, etc) and indeed GNA-GM-potatoes have been grown in field-trials for several years in the UK. Moreover, our RRI group has done 6 years of previous work with GNA in which we demonstrated that GNA, even at much higher levels of dietary inclusion (up to 42 mg GNA/rat/d) than the expected expression levels in GM-plants, had apparently no deleterious effect on the growth and health of young rats.

RESULTS—CONCLUSIONS OF GM-POTATO WORK CARRIED OUT AT RRI

After GNA gene insertion changes in protein, starch, sugar, lectin and trypsin/chymotrypsin inhibitor levels were observed in the tubers of two generations of *two GNA-GM lines* suggesting *"possible gene silencing, suppression and/or somaclonal variation"* in the potato genome. *The GNA-GM-potato lines investigated in FF 818 programme were therefore* not "substantially equivalent" to the appropriate parent tubers or to each other.

In all three 10 day rat feeding trials with GNA-GM-potatoes significant changes in the weights of some of their vital organs were observed even when lactalbumin supplied two-third of the protein in the diet (D249). Multivariant statistical analyses indicated that although the treatment effects were small, the number of significant differences in organ weights was more than would be expected from Type I error rate, suggesting that, similar to the lack of compositional equivalence, the metabolic consequences of feeding GM-and parent potatoes were also substantially different even though "potato GNA" in GNA-GM-potato diets appeared to be functionally similar to "snowdrop GNA" in GNA-spiked diets.

The growth rate of rats fed potato diets was slightly but significantly less than that of rats fed lactalbumin diet but the presence of GNA had no significant effect of weight gain. However, as the protein content of GNA-GM-line 74/2T was significantly less than of the parent line, feed conversion efficiency of the rats with this GM-line diet was also less. Moreover, when GNA-GM-potatoes supplied most of the dietary protein (D227 & D242), digestion and absorption of nutrients was retarded and the effect became significant in D242.

Feeding rats with GNA-GM-potatoes for 10 days significantly reduced their lymphocyte responses to mitogenic stimuli compared to parents and these differences could not have occurred by chance. However, as on 110 day feeding the proliferative responses of rats given potato diets were strongly suppressed, possibly due to the cumulative effects of potato toxins, no differences between parent and GM-potatoes could be found. Accordingly, the existing data support our original suggestion that the consumption by rats of transgenic potatoes expressing GNA has significant effects on organ development, body metabolism and immune function that is fully in line with the significant compositional differences between transgenic and corresponding parent lines of potatoes.

THE ROWETT'S ROLE IN THE EVENTS BEFORE AND AFTER AUG 10

I am including this section in response to the Committee's request in respect of the Rowett's role in the handling of our results and the circumstances of my departure.

As the last worker of FF 818 left the programme by June 98, RRI work on GM-potatoes was at an end. With "Increased Flexibility Programmes" SOAEFD funding ends after the three-year period of the contract and it is up to the Institute to incorporate them into core-funded research. This is the normal course when the work produced good results and fits into the Institute's research profile. However, the Directors of RRI were not willing to allocate core funds or allow us to use some of the moneys our group has earned from external contracts to continue with GM research. We would have been willing to carry on at a minimum level of input with a PhD student till we were able to attract more external money for scaling up the work. As we have been running four programmes on external funds, our prospects were good. However, as the report of the Visiting Group early in 1998 criticised the Institute's work and its scientific management, there was no willingness to allocate funds to a new programme till the direction of the Institute's research will have been settled. All the same, the Director was happy for the continuation of our work but only if commercial funding could be attracted. For this, with the enthusiastic encouragement of the Directors of RRI & RRS (Rowett Research Services), the help of the PR officers of the Institute and based on our experimental results, we started to organize a major conference at RRI on the effects of GM-foodstuffs on consumers to which scientists from FF 818 and others and representatives of EU, industry, grant-providing and regulatory bodies were to be invited. The programme and even the date was agreed. To draw the attention of possible sponsors to the merit of our case and attract funds for the continuation of our GM work, the main speakers were to be the senior members of our RRI group to highlight our achievements and give details of our (hitherto unpublished) results. First it was to be 2 October because the Director was free. Later because of an "open day" at RRI on 23 October, we agreed that the conference be hosted in as part of this. Far from being against publicising our results, the Directors were keen to promote it. It was only after 12 August that the open day and the conference were cancelled.

My appearance on the "World in Action" TV programme was a part of the publicity for the conference and recorded in late June with Professor James's blessings and in the presence of the RRI's PR. Professor James phoned my wife after the broadcast to congratulate me on how well I handled the interview. If the Rowett had any qualms about the content of the programme they had seven weeks to stop it but they did not as I only talked about the necessity of finding new methods for testing with animals of GM-foodstuffs before they are released which was clearly based on our short- and long-term nutritional and immunological work with our two distinct lines of GNA-GM-potatoes. No experimental details or even the identity of the gene used were given (transcript; Appendix 1[1]). I reaffirmed my belief in GM technology but only if we got it right and handled it transparently. The Rowett was happy with the publicity as shown by the RRI Press Releases on 10 and 11 August and another by the Governing Body Chairman to M Jacques Santer and Frank Dobson (Appendix 2[2]) which were full of praise for our work "of strategic importance to our country and European Union consumers". "A range of carefully controlled studies underlie the basis of Dr Pusztai's concerns". "The testing of modified products with implanted genes needs to be thoroughly carried in the gut of animals and humans if unknown disasters are to be avoided".

Unfortunately, and in my view as a consequence of the Rowett's mishandling of the media by not consulting the scientists of our group early enough about the accuracy of the data which were released by the Rowett on 10 and 11 August, major mistakes were made. Statements in the 10 August Press Release such as that "*the potent insecticidal lectin concanavalin A obtained from the South American Jack Bean if inserted into potatoes will . . .* " was never discussed with us. Indeed, we never saw the contents of this Press Release till 14 August but by that time the media was full of our work on ConA-GM-potatoes or indeed, that we have never done any GM-potato feeding experiment. It appears that Professor James realized his error late in the afternoon of 11

August. Apparently he thought the best way to extricate himself from the responsibility for having mislead the public by giving out details of a work with ConA which has in fact never been done was to tell the world that I got "muddled" or even that I "took" data from a colleague who was absent at the time. He then also suspended me on 12 August and set up an Audit. As it now transpires he had no right to have an audit because I was never accused of scientific fraud by the Rowett and this could have been the only legitimate scientific reason for the audit. Even if I had drawn erroneous conclusions from our GM-potato-work (which I had not), it is not a serious enough offence to warrant the setting up of an audit. Moreover, against BBSRC rules I have never been given the reasons for my suspension and the audit in writing. All our data were confiscated. Professor James had written to me a series of letters (copies of these are available if needed[3]) in which he explicitly threatened me with legal action if I spoke to anyone in or outside the Rowett about our work. He also warned all Rowett staff of the dire consequences if anyone spoke to me. Indeed, I was sent to Coventry; only Professor James communicated with me by occasional warning letters. Although I was ostensibly only suspended from GM work, all our results, people in our group, my three PhD students and all of our funding, even the commercial, were summarily taken by the Rowett. I was left to my own devices in my office to fill out the remainder of my contract. I was arbitrarily removed from all EU programmes and conferences. Because of the confidentiality issue in my contract which was emphasized by Professor James, I was denied any right to clarify scientific or other points and issues which in my opinion were not right. So all information in the media originated from the Rowett after 10 August and none from me.

The composition of the Audit Committee in my view was inappropriate. Despite having many nutritionist staff members, a chemist (Chairman) and a microbiologist were appointed from RRI plus a potato biologist from SCRI. There was only one outside expert who had work experience with animals. The whole audit was over in less than 10 hours. Practically none of the data in the Audit Report was primary and no independent statistical analyses were carried out to validate the analyses which were done by the Committee or other staff at the time. This has come to light in the last two months as we managed to recover some of the laboratory and animal house books and data sheets to be passed on to Dr Horgan for independent statistical analysis. Had this been done at the time or had the Committee consulted me, the serious flaws in the Audit Report could have been avoided.

According to BBSRC rules some, but not all, of my data were returned to me on 19 October that I could comment on the Audit Report. For example, the immunology data were only recovered on 26 February 1999! The deadline set by Professor James was 7 pm on 22 October. This I did using the data available at the time by writing an alternative (Co-ordinator's) report. The two reports were complementary, to be read together and were not papers or meant to be published as public disclosure of data usually jeopardize their publication as papers. Despite this the Rowett published the Audit Report to coincide with Professor James' and Dr Chesson's appearance in the House of Lords' Select Committee on GM-related matters on 28 October. However, neither of them gave any indication that the data in the Audit Report were contested by me or that there was an alternative report. The secrecy went so far that even the scientists who participated in FF 818 were not given a copy of my report. However, after the publication of the Audit Report scientists who knew me and took a keen interest in our work started to ask for my side of the story. As the BBSRC staff code does not prohibit exchange of views and data between scientists, I sent my report (plus the Audit Report for comparison) in confidence to about 30 UK, European and American scientists but only those requesting it and only if they promised to send back their evaluation. The results are well known. At the end, 24 of them published a Memorandum (without giving away confidential data) and asked for my re-instatement to carry out further work.

THE ADEQUACY AND QUALITY OF SCIENTIFIC ADVICE AT PRESENT

As referred to above, I regard the scientific evidence on record of the possible biological and nutritional effects of GM-foodstuffs, a single paper in a peer-reviewed journal, as wholly inadequate. The results of "in house" work by Companies introducing new GM crops are unpublished as regards the public although they may have been submitted to the appropriate regulatory authorities for scrutiny. Clearly, even if they give excellent accounts of the work done, they fall down on the public's (and other scientists') desire of transparency.

THE ROLE AND FRAMEWORK OF ADVISORY COMMITTEES

With the predicted onrush of genetically modified crops in the next decade, the role and the framework of the advisory committees will be severely tested. As I understand, the scope of their ability to give advice can be restricted by their apparent limitation in commissioning GM-food testing of their own or basic work underpinning GM-research. Their judgement is therefore mainly based on information received from the

companies. Although they can ask for more work to be done when, in their opinion, this is needed, this may not be the best solution, nor is it conducive to the transparency demanded by the public. It also appears that the lines of communication between advisory committees and active scientists working in GM-related fields may not be adequate. The committees' advice is likely to be dependent to some extent on the personal knowledge of what is going on in the labs and fields and by whom. This in view of the members' high workload leaves too much to chance. In a European context the situation becomes even more acute, particularly considering the number of possibly relevant papers published each year. In fact, if nothing else was demonstrated by our case with the GM-potato work, it showed that once I was gagged, the results of our work could not reach the Advisory Committees. There is a clear need for a route through which, when needed, results could more directly be passed on to the Committees without permission from Institute Directors. Scientific secretarial help may also be needed for pre-assessment of relevant papers which need to be passed on to overworked Committee members. As the forte of most of the members is scientific administration, the Committees should not only be strengthened by the presence of consumer and environmental pressure groups but also by the appointment of active scientists.

THE ABILITY OF THE CURRENT SYSTEM TO RESPOND RAPID SCIENTIFIC DEVELOPMENTS

This more or less follows on from above. It is unlikely in my opinion that due to the slow publication of scientific papers, members of the Committees, without a network of contacts with workers at Institutes active on the field, will be able to keep up with scientific progress. Whether it is liked or not, they will have to be more proactive/interactive with scientists and get information about unpublished work in confidence as early as possible.

OVERARCHING BODY TO ADVISE ON AND OVERSEE GENETICALLY MODIFIED FOOD

I think above I have made a compelling case for just such a body. Perhaps as part of FSA it may be possible to set it up. However, it has to be able to fund research of its own, be independent and, most of all, its work must be fully transparent. I am confident that under such conditions the Government will be an "intelligent customer" for the advice.

My final sentiment as I expressed in the World in Action programme: "I actually believe that this (GM) technology can be made to work for us. And if genetically modified food will be shown to be safe, then we have really done a great service to all our fellow citizens".

NOTE

This Memorandum (with tentative recommendations for GM-food testing; Appendix 3[4]*) was compiled by Dr Pusztai, dated 1 March 1999. No contribution from the Rowett, SOAEFD or scientists who have participated in FF 818 Programme was received and none implied.*

1 March 1999

Supplementary memorandum submitted by Dr Arpad Pusztai

http://www.publications.parliament.uk/pa/cm199899/cmselect/cmsctech/286/9030803.htm

It is not my intention to use this forum as the means of airing the dispute between myself and RRI. For that reason I had previously limited my submission to the Committee so far as it related to that matter. What is at stake here, however, is the validity and freedom of the scientific process, as demonstrated by the treatment to which I have been subjected. It is to correct mis-statements made in regard to this process, that I am submitting this further paper.

1.Precise nature of RRI experiments

It was never part of the experimental process at RRI to involve feeding GM potatoes with the lectin PHA whether from red kidney beans or otherwise, nor the lectin ConA. The only lectin involved in our experiments was GNA.

2.The "ConA" muddle

There was never any misunderstanding by me as to the non-involvement of ConA in the experiments we were conducting. All my statements related specifically to GNA GM-potatoes. It is evident that Professor James thought otherwise, as appears from the Press Release of 10 August 1998 issued wholly without reference to me (Appendix 2 in my earlier Memorandum dated 1 March 1999)[5]. This was also apparent from changes he proposed to a letter he had requested I draft to Mr Wotherspoon of MAFF. I do not know if the letter was sent and in what form. It is clear that he subsequently recognised his mistake, shown by the Press Release of 12 August 1998. He represented that error, however, as one for which I was responsible. That emphatically is not the case.

3.Other misconceptions

> —The 110 day GNA immune studies with the parent and GM-potatoes were already completed and calculated when the "World in Action" programme was recorded (24 June 1998). See pages 46 and 47 of the Audit Report (copies annexed)[5];
>
> —The suggestion that "Dr Pusztai and his assistants agreed that the growth impairment" had not been found in the 110 day feeding studies; that is totally at variance with our findings. Although the growth rate of rats fed the parent and the GM-potatoes, was apparently the same in a particular study, it was one in which a 20 per cent increase in protein was deliberately provided to compensate for the growth impairment.

4."World in Action"

The programme was recorded in the presence of the PR to RRI some 7 weeks prior to the actual broadcast. The approved RRI approach to GM safety issues, was one of caution. It was proposed that I should participate in the programme because of the direct part I had in the relevant experimentation and study. In expressing the RRI cautionary approach, it followed that in the programme I stated that there were concerns. When pressed as to the concerns, I referred to the tests I had conducted, making the point that further evidence was needed.

As to the "Frontline Scotland" programme, I had no part in it.

5.Publication of Reports

The Audit Report was presented to the House of Lords by Professor James on 28 October 1998 at which time my Alternative Report was available, in which I contested many of the conclusions. For purposes of balance, one needed to be considered in conjunction with the other but that opportunity was not given.

6.Suspension and subsequent events

Professor James in his presentation to the House of Lords expressly stated that there was no questionof any malpractice on my part, making the kind observation that "we did not expect that remotely withDr Pusztai, of such prestige and known to be so scientifically rigorous". Nevertheless, he used an MRC procedure to effect my suspension which is only appropriate for use when there is malpractice. By doing so, RRI created the impression that I had in some fashion been guilty of such an act. That was highly damaging to my scientific reputation and put the credibility of my work in doubt.

It had always been the understanding that I would continue at RRI until the conclusion of my programmes, expected in mid 2000. I had never agreed to earlier retirement.

I have no arrangement with the RRI to continue as a consultant (none has been offered) and there are no measures to protect my financial interests as suggested by Professor James. All personnel and working facilities were withdrawn from me on 12 August and persisted until my forced retirement. Professor James' letters to me of 18 and 20 August 1998 (copies annexed)* set out in detailed form the legal and practical limitations which he stated applied to me with emphatic warnings as to the consequences if I failed to observe them. None of this was at all conducive to any continuing involvement in the programmes, with which I had been so actively connected throughout.

Since leaving RRI, I have had to manage on my own.

CONCLUSIONS

Our data are neither crude nor preliminary. They are the intitial results of carefully designed and conducted studies which have now been fully verified by independent statistical analysis which justify our claims that the expression of GNA gene in potatoes do affect the nutritional value of the potatoes and that the organ development and immune system's responsiveness of rat fed on diets containing these potatoes, suffer significant damage.

8 March 1999

Memorandum submitted by Dr Stanley William Barclay Ewen, Department of Pathology, University of Aberdeen

http://www.publications.parliament.uk/pa/cm199899/cmselect/cmsctech/286/9030804.htm

1.INTRODUCTION

In 1998 I was invited by Dr Pusztai to assist with the microscopic investigation of changes in gut structure following the oral ingestion of sugar binding plant proteins called lectins. The Department of Patholgy, University of Aberdeen has since processed in excess of 6,000 microscopic slides of gut tissue (usually from rat) supplied to me by Dr Pusztai for our collaborative projects. We established that gut weight increases following feeding of raw kidney bean, or jack bean, due to thickening of the lining of the gut whereas snowdrop lectin (GNA) has no effect (sometimes reduced thickness has been recorded microscopically). These studies were published in scientific journals after due process of peer review (1-3). My present involvement in the genetically modified potato project was simply a continuation of our extended collaboration and the microscopical techniques were identical to those developed for earlier experiments.

2.THE ADEQUACY AND QUALITY OF SCIENTIFIC ADVICE AT PRESENT

Genetically modified food suffers from a lack of peer reviewed information in the public domain. Only one paper has been published and that describes the feeding value of GM soybeans in rats, chickens, catfish and dairy cattle (4). This single paper refers to microscopy of rat pancreas but gut microscopy is not mentioned if performed. Scientific advice is not available for informed consideration and our studies were designed to establish the normality of the target organ after feeding GM potatoes. Present scientific advice can only be based on industrial information that has not been divulged in the public domain.

3.THE ROLE AND FRAMEWORK OF ADVISORY COMMITTEES

As a hospital pathologist, the role and framework of the present advisory committees seems satisfactory and are apparently able to respond to scientific developments. The perceived orientation of the various committees seems distinctly producer based paying little attention to the needs of consumers with the result that intelligent choice of food is precluded. In addition, special needs exist within the community, for example gluten sensitivity (coeliac disease), for whom the safety of genetically modified food cannot be presumed.

4.THE ABILITY OF THE CURRENT SYSTEM TO RESPOND TO RAPID SCIENTIFIC DEVELOPMENTS

The current system seemed to be very responsive to the present situation once the problem had been highlighted. The time from publicising our memorandum of the Rowett Audit Report on 12 February 1999 was very short. Dr Pusztai had been unmuzzled and his report was made public on 16 February 1999. I am impressed at the rapidity of initiating this Select Committee.

5.OVERARCHING BODY TO ADVISE ON AND OVERSEE GENETICALLY MODIFIED FOOD

I believe this proposal does have merit. Consumers will expect accurate information about all genetically modified food and expect complete testing to ensure substantial equivalence is, not only analytical equivalence, but also nutritional and metabolic equivalence. Many human food related problems are idiosyncratic and testing methods presently in use would not detect such a problem. Our results indicate that

animal testing may have to be relied upon as young animals laying down muscle tissue are a sensitive model. Measurements on carefully oriented microscopic sections will be important in the evaluation of crop genetically modified food. I believe that these sources of information would best be evaluated by an overarching body dedicated to this special branch of food safety so that genetically modified food is risk free for all normal consumers.

6.THE CAPACITY OF GOVERNMENT TO BE AN "INTELLIGENT CUSTOMER" FOR THE ADVICE IT RECEIVES

My perception of Government activity leads me to believe that advice will be acted upon expeditiously. Clearly Government must be responsive to public concern about genetically modified food and a sensitive "intelligent customer" would react by insisting on careful, understandable product labelling. Short term public anxiety would be minimised by explicit labelling so that avoiding action could, if desired, be taken.

7.THE RESULTS OF DR PUSZTAI'S RESEARCH ON GENETICALLY MODIFIED FOOD

I have worked closely with Dr Pusztai for more than a decade and have found him to be an exacting, fastidious scientist. He always paid great attention to experimental design and the genetically modified potato experiments were no exception. The recent experiments involved feeding raw or cooked genetically modified potatoes to young rats and very adequate control groups were fed synchronously. Despite the complexity of the experiments I always felt that Dr Pusztai was in complete control and there was no evidence of muddle when I visited to take samples for microscopy. His experimental results were available soon after the experiment had been performed whereas, due to pressure of patient commitments, my results were not available until October and were then prepared for oral presentation at a meeting in Lund, Sweden on 27.11.98. I was never uneasy about the quality of the experiments designed and overseen by him and I admired the team approach that ensured maximum collection of data from several physiological systems from any one rat. The experiments were limited to six rats per goup but the complete experiment with various countrols would involve 50-55 rats. The small size of each group means that the experimental results can only be regarded as an initial step and hence we recommend further similar experiments.

8.MICROSCOPICAL RESULTS, ASSESSED BY DR S EWEN, ON YOUNG RATS FED GENETICALLY MODIFIED POTATOES FOR 10 DAYS

The mircroscopical features, derived from approximately 300 microscope slides, measured and assessed by myself are exactly analogous to the work I perform as a Hospital Pathologist. My results are objective and less judgmental than usual in human pathology and my observations are supported by the attached photomicrographs. The typical procedure for any hospital pathologist is to receive tissue samples that are processed into sections. The sections are examined by microscopy and an opinion formed followed by the issue of a report. In the present case I was given samples from young rats fed genetically modified potatoes for 10 days. These samples from gastrointestinal tract were carefully oriented to facilitate objective measurements. (I must stress that the changes identified will not be apparent unless photographs of test and control are compared side by side or a series of measurements made and statistically analysed). The lining of the small bowel has two major components consisting of finger like villi that are supplied with immature cells from the subjacent crypt. It is the crypt region that I have measured in my observations and significant elongation of the crypt in the rats fed raw genetically modified food is the main finding. In addition I have counted the chronic inflammatory cells within the lining cells and found increased numbers of these cells in the rats fed raw genetically modified potatoes. The results of these observations are found in appendix 1[6] and the photomicrographs are to be found in appendix 2[7]. My report would be: after comparison of sections from rats fed genetically modified potatoes with sections from control rats, there are significant differences in crypt length that cannot be explained by the insertion of the *Galanthus nivalis* gene. This work has been submitted for publication in a peer reviewed journal.

9.HANDLING OF DR PUSZTAI'S RESULTS BY THE ROWETT RESEARCH INSTITUTE

With the benefit of hindsight, I believe that every major institute should have a policy concerning the type of programme in which the staff of that institute may participate. A purely documentary approach may be permissible and even laudable but a potentially politically oriented presentation placing science against pressure groups could have been predictably assessed as unacceptable by any percipient institute. It was into such an apparent policy vacuum that Dr Pusztai fell. The World in Action programme was made with the support and co-operation of Rowett staff, I believe, in the presence of the press officer. The actual broadcast of the final programme occurred approximately five weeks after the initial "take" but no attempt was made to

check the programme content or Dr Pusztai's final wording although such a check would have been acceptable to Granada. The initial response was moderate praise for those concerned but plaudits were soon to be replaced by a complete "U turn". The broadcast view was that "an old man had muddled the results". The results seemed to be treated as fraudulent enabling the Audit mechanism to be commenced under Biotechnology and Biology Science Research Council rules. Four eminent persons were selected without recourse to Dr Pusztai and he was left defenceless. He was immediately gagged and his great reputation nullified at a stroke. The Audit report was put into the public domain several months later but that report demonstrated that the Audit Committee did not believe a significant difference existed between genetically modified potatoes and the parent potato. Unfortunately, the Audit Report did not contain any statement regarding the lack of "muddle" and Dr Pusztai was not demonstrably exonerated and he remained gagged. Dr Pusztai was urged to write up his experimental results despite the fact that four other scientists, comprising the Audit Report Committee, had placed his work in the public domain in minute detail. His friends and colleagues felt a real sense of outrage that Dr Pusztai, a Hungarian refugee from KGB dominated Hungary in 1956, had been treated in this heavy handed manner. The response of his European and International friends was to indicate apparent shortcomings in the Audit Report and to publish a memorandum that was made public on 12.02.99. The outcome of this memorandum was to "unmuzzle" Dr Pusztai, and enable his response to the Audit report to be made public, within three days. The scientists who signed the memorandum continue to believe that the mechanism employed was excessive considering the relatively minor initial misdemeanour and that justice has not been seen to be done.

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26 February 1999

Examination of witnesses (Questions 126 - 139)

MONDAY 8 MARCH 1999

DR ARPAD PUSZTAI and DR STANLEY EWEN

http://www.publications.parliament.uk/pa/cm199899/cmselect/cmsctech/286/9030805.htm

Chairman

126. Dr Pusztai, thank you very much indeed for coming along this evening to give evidence to our Select Committee. You will know, I think, that we are doing an inquiry into Scientific Advice to Government, and, in doing that inquiry, we thought it would be a good idea if we took a certain number of case studies, to see what is happening in the scientific world and, where there are controversial bits of science, how government is coping with advice it is receiving, in the face of that scientific controversy. And, because of the circumstances around your experimentation and your results, we thought it would be a good idea if we started off with you and your case study, in the first instance. So we are most grateful to you for coming along this evening and helping us with our evidence. We shall, of course, be focusing quite a lot on the World In Action TV programme, and that will not surprise you. Dr Ewen, we will approach you for answers from time to time, but, I

think, when we do so we shall direct our questions specifically at you, otherwise our questions will be to Dr Pusztai. Dr Pusztai, the World In Action programme, that you pre-recorded, I wonder if you could tell me how long before the transmission you pre-recorded it?

(*Dr Pusztai*) It was exactly seven weeks.

127. And in that programme you discussed your results and you discussed in general terms the possibility of the general public being used as guinea-pigs. Can you just confirm that your comments about the possibility of the general public being used as guinea-pigs was a general expression and was a general concern, and was not necessarily relating to your experiments or the potatoes you used in your experiments?

(*Dr Pusztai*) It was a general comment. Having come across what is submitted to the various Novel Foods and other committees, knowing exactly the extent of what is required, and compared it with our own experience, I thought that it was perhaps a fair comment; maybe it was not a very wise comment but it was a very fair comment, at the time.

128. I am sure, Dr Pusztai, it was a very fair comment; it only had some difficulty when it was linked in some people's minds with other things that were said in the programme. But it was a free-standing comment. I am sure it was a very fair one. But could I just ask you, did you think it was appropriate to discuss on television the results that you had, before those results had been subject to peer review?

(*Dr Pusztai*) This is a debatable point, that what I disclosed were results; they were certainly not data. It was a long-standing policy of the Institute to have a sort of cautious approach to GM-related matters, and we all felt, including Professor James, that the route we had to take should be a very, very gradual and well-researched route. So, in a sense, what I expressed there was nothing surprising, considering the background of the Institute's work in that direction. What I eventually actually said was that I feel concerned that some of the testing techniques are not up to what we thought it was necessary to do, and therefore we should have more testing. We said that we felt concerned, so they asked: "Why do you feel concerned?", and, obviously, the reason for it was because we had done some experiments which made us feel concerned; and that was the background to it.

129. If some experiments had not been done, do you think it is appropriate that an eminent scientist such as yourself should go on television and discuss sophisticated experiments when the work was not complete, knowing perhaps, as you did, the programme was going to be a controversial programme and was going to take a hard stance against genetically modified foods?

(*Dr Pusztai*) I was not sure at all in my own mind, when I did do it; I did not know what would be the final outcome of the programme; the programme had changed quite a bit, and I had exactly 150 seconds in it.

130. And you did not know, at the time you were asked to go on the programme, it was likely to be a hostile programme?

(*Dr Pusztai*) No; no, not at all.

131. My final question. The GNA 110-day trials, at what stage were they when you filmed this episode for the World In Action programme in June of last year?

(*Dr Pusztai*) I think that, without being very technical, 99 per cent of it was complete.

132. The experimentation and the results?

(*Dr Pusztai*) Yes, and it is also dated. It is dated, even in the audit report; there is in the submission, the actual date of the calculations, and the completion dates are there, and you have a copy of it.

Chairman: Thank you very much indeed.

Dr Turner

133. There was confusion, as you recall, at the time, Dr Pusztai, because it was published in the press as being experiments using ConA-spiked potatoes; can you account for the confusion which arose, because there seemed to be reasonable doubt that the experiments had been done with GNA?

(*Dr Pusztai*) Yes. I know exactly where the confusion came in. The confusion came in because, if you remember, I said there were two lines of genetically modified potatoes, but because I was not to disclose any experimental details, I did not say what these were; as it so happens, they were both GNA lines. We have never done any ConA-GM experiments, genetically modified potato experiments, and I think that a lot of people actually jumped to the wrong conclusion about them. There were two lines, both of them were genetically modified and had the GNA gene, and the reason why we say that there were two lines and two kinds is because they were not substantially equivalent, they were not substantially equivalent to the parent, but they were not substantially equivalent in composition to each other, so they had to be regarded as two different types of potatoes.

Mrs Curtis-Thomas

134. Dr Pusztai, the Rowett press release of 10 August last year, on GM foods, states that the preliminary results of studies with Jack bean ConA genes in GM potatoes suggested that these potatoes caused stunted growth and reduced immune response in rats. As a matter of interest, were you or your team consulted on the contents of this document before it was released?

(*Dr Pusztai*) I am afraid not; that is the other bit of the confusion. As I say, a lot of people jumped to conclusions about things, and, for some reason or other, which I do not fully understand, that press release went out, and I only had a copy of it on the14th, to be precise, from my secretary; and I could not understand, when people had originally `phoned me on the 11th, asking: "Why is it that they are talking about ConA, we have not done ConA genetically modified potato experiments?" So if you ask the question and the question is the wrong question, it is very difficult to give a coherent answer, because I wanted to talk about GNA-GM potatoes and people were starting to ask me: "Have you done any ConA-GM experiments?" and I had to say: "No."

135. I presume then that you would agree that you have never discussed ConA-GM feeding experiments with the press; is that right?

(*Dr Pusztai*) No.

136. You have not; right; thank you.

(*Dr Pusztai*) They asked me, over the `phone, but from the 11th onwards I never spoke.

137. So you have not spoken to the press about ConA-GM experiments?

(*Dr Pusztai*) No.

Mr Jones

138. Dr Pusztai, Professor Philip James, the Director of the Rowett Research Institute, tells us that the weekend before the World In Action programme was broadcast you were "bombarded at home by enquiries, praise and criticisms from all over the world." What do you think triggered that interest?

(*Dr Pusztai*) There was, of course, a press release by the World In Action programme. Again, they seemed to have missed me, with these press releases, I only received that press release about a week later, so I did not know what it was that people were `phoning me for, on Sunday afternoon. And there were actually three major contacts; one was with a BBC programme, which was broadcast next morning, on BBC Radio Four (the Today programme), and there was a very extensive discussion, in which they played some of the things I said into the `phone. But Dan Verakis, who represented Monsanto, was actually present in the studio, and I listened to it time and time again, because I just wanted to find out whether I did say anything about ConA; I did not, there was no ConA in that discussion. Now whether you regarded this as a blitz, having three major telephone—in fact, the BBC kept me up till about 1 o'clock in the morning, which was not very welcome, because at 6 o'clock I had to go into the GMTV studio, where I could hardly keep my eyes open.

139. Can you remember—Professor James says that there were criticisms as well—who did the criticisms come from?

(*Dr Pusztai*) I do not know; what criticisms? I am sorry, I do not know, you will probably have to ask Professor James, because I do not recollect any criticisms.

Chairman

140. You do not recollect any—we are told, you see, here, a quotation from Professor James—that you were "bombarded at home by enquiries, praise and criticisms from all over the world", but you do not remember any criticisms?

(*Dr Pusztai*) As I said, there were three, I know who the three people were. One, I already said, is the BBC, and that is on record, you can actually listen to it, and I listened to it many times. There was a Daily Express reporter who `phoned me; and there was another one, whom I cannot remember.[8] But they were mainly trying to find out what was happening. I do not know whether that was, as I say, a blitz, that is not really my recollection; I was certainly given a number.

Mr Jones

141. What aspect of your work were they particularly interested in; the fact that these rats became ill?

(*Dr Pusztai*) You have to understand that when I started off I spent a lot of time, something like over six years, on selecting GNA out, as a gene product which, in my opinion, was extremely safe; in fact, it had quite a few beneficial properties. So it was mainly on my advice that GNA was inserted into potatoes, and all sorts of other things, not just potatoes, but we only dealt with potatoes. So we had this background in it. And when the experiments which we did started to sort of indicate that everything was not alright, then we tried to do more experiments, designing them in such a way that we perhaps could more precisely pinpoint what would be the trouble. And the trouble which we found was, first, that there were, compositionally, major differences—I say "major" quite deliberately—major difference; if you have a potato line which is grown side by side in the same tunnel and has got 20 per cent less protein, that I would regard as a major difference. But there were other compositional differences; now we tried to correct for these, but, of course, you cannot correct for all compositional differences. So we tried to do experiments in which we looked at not just the growth rate—we knew already that the growth would be affected, if you have 20 per cent less protein, by definition, the growth rate will be affected—but we tried to compensate for it, just to see if any other functions of the body, or any other part of the gastrointestinal tract, or whatever other organ, would be affected. And this was when we started to get really very seriously worried about the outcome of the experiments.

142. Can I ask you: why do you think the Rowett press release of 10 August talked of ConA-GM studies when you were using an entirely different gene, let us call it the snowdrop gene?

(*Dr Pusztai*) I think that it was certainly a breakdown in communications, that is what it was. I do not want to say another word for it, but it was a breakdown.

Chairman

143. Do you think that breakdown in communications could have been rectified had you been shown the press release before it was issued?

(*Dr Pusztai*) Yes.

Dr Kumar

144. Dr Pusztai, you say that you were suspended and then, and I quote you, from your submission to this Committee, "denied any right to clarify scientific or other points and issues." In what way were you denied this right?

(*Dr Pusztai*) Very explicitly, I am afraid, in letters, which I received from my Director. Remember that I am an active scientist. The BBSRC staff code, which applied to us, is about 800 pages, I do not think that any scientist has ever read that, but then the relevant sections of that which refer to disciplinary matters were very precisely and extremely explicitly described to me by Professor James in this letter. He said what I can do and what I cannot do; mostly what I cannot do, perhaps, as has been said, what I must not do. And remember that I was in a bit of a shock myself. It is not a situation which you—well, certainly, I never expected to be in that situation, and it is also a real shock to me, and perhaps I kept quiet for a long time; for remember that all our experimental data had been taken away, so I could not say, even if I wanted to say, something about a point

coming up, in some press release or whatever, I could not precisely answer it because I had to rely on my memory. I had no data, not till 19 October, well over two months later, when the data started to come back. So it was, on one hand, an explicit command not to speak; on the other, it was that I did not even have the data, so how could I actually explain things in such a way that I would not do anybody, least of all myself, any injustice.

145. Was it one letter or was it several letters that he wrote to you?

(*Dr Pusztai*) Several letters.

146. Could you provide to us those letters?

(*Dr Pusztai*) In confidence, they were confidential, and, of course, I do not know what—I do have them, actually, so we can provide them, if necessary.

Chairman

147. If the Committee thinks it appropriate to ask for them, you would—in fact, I am advised by my adviser that we do already have them, sealed and in a safe, and they are received in confidence.

(*Dr Pusztai*) As I say, they are confidential, and I certainly do not want to—I am very anxious to avoid any sort of ...

Chairman: Yes, I understand.

Dr Kumar

148. Is Professor James correct to state that, and I quote from his submission, "the challenge that we `gagged' Dr Pusztai related to our insistence that he only discuss published work when speaking to the media"; is he correct in saying that?

(*Dr Pusztai*) I do not know when he did say this; he certainly did say it later, after the event, but, at the beginning, before we started off with all this, remember, this was, how shall I put it, I was, in fact, saying something which was Institute policy, it is this cautionary approach to the whole business of genetic modification, or any other novel food, for that matter. So it is very important that we should remember that this business of me going on the programme was very much a part of the normal publicity, sort of what you get nowadays, because you have to raise money—you have to raise money—and most of the reason why, eight years after I retired, I was there was because I raised a lot of money, it is as simple as that, so if you can get some more money then that is a good thing.

Dr Jones

149. In the seven weeks between the recording of the programme and it being transmitted, did you discuss with any of your colleagues, particularly those working with you that had done the actual experiments, but also other people in the Institute, what had happened on the programme?

(*Dr Pusztai*) The programme was recorded in the presence of the Institute's PR person. Of course, our group was intimately involved; in fact, some of them were televised as they were doing the work. And then there was also a period when we were away; remember, July is the month when people normally take holidays, and I was away, too. We came back well before 10 August, because we did not even know which day the programme would be shown. But within the group we had discussed it extensively, yes.

150. Discussed what you said?

(*Dr Pusztai*) Yes.

Dr Williams

151. Two very brief ones. Have you heard of any other scientist gagged and sacked in this way?

(*Dr Pusztai*) I do not know any other. I do know some, but it is only by hearsay.

152. And, at that time, or over the next few weeks, why do you think it happened?

(*Dr Pusztai*) I would have to speculate, and that, I am afraid, is a very difficult thing.

153. What went through your mind; what were the reasons?

(*Dr Pusztai*) Look, I am a bit naive—I may not look naive now, but I was at the time very naive; I thought that I was going to do something which was, in a sense, an Institute approach to something, and something important, but I did not, in fact, realise, neither did the Institute realise, the huge commercial and other political significance of what I said. It was a bit of dynamite. Now I do realise it, but at the time I did not realise it. You see, on 13 January, I said almost exactly the same thing, on the BBC Newsnight programme. As I say, there is nothing unusual about it.

Dr Kumar

154. In your submission, you said that the audit of your work was carried out incorrectly and came to incorrect conclusions; how convinced are you?

(*Dr Pusztai*) It is a strange business that in a nutrition institute there was no nutritionist on the committee, that is a strange business; and most of the work was nutrition, with all sorts of other associations, but there was no animal expertise, so I thought that it was rather inappropriate to have people on it who had very little animal work experience; in fact, three of the people had practically none.

155. Can I just check that it took less than ten hours, this audit?

(*Dr Pusztai*) I think so, because Professor Bourne, whom I knew quite well, previously, arrived on Thursday afternoon, very late in the afternoon, and probably could have had some sort of coming together with the Rowett members, but the audit actually started at 9 o'clock on Friday morning, and I know that it was finished by half-past three, because one of the members of the committee, with some technical help, was carrying back all the papers, for safekeeping.

Chairman

156. Could I just clarify one particular point of Dr Kumar's, before I go to Dr Jones? I am sure you are saying that a ten-hour audit on all the work you did was inappropriate, and you have every reason to think it may well have been inappropriate, but inappropriateness does not necessarily result in incorrect conclusions. So, although we might agree that it was inappropriate, are you certain that the conclusions reached were incorrect?

(*Dr Pusztai*) The point is that we had done experimental work, altogether something like 170 rats, dissecting them into 20 different tissues, wet and dry, so we are talking about something like 6,000, 7,000, 8,000 bits of information. Now they should have been put into the appropriate statistical analysis, and you can judge it from the fact that the independent statistical analysis has only been done before this week. And, therefore, I would say that it was not really well done.

Dr Jones

157. You refer to an independent statistical analysis; is that the analysis that has been done by Dr Graham Horgan, which you sent to us? Can I just quote from what Dr Horgan said, it is here, I have not read the whole report, it is just his summary, and he says: "However, no consistent pattern of changes in organ weights was discernible over the four experiments. Diet differences were also found in the immune responses of the rats, but concerns about the experimental design meant that these results are open to other interpretations." Do you agree with Dr Horgan's conclusion?

(*Dr Pusztai*) I think that you have to consider it in this light, that we had two different lines, which were substantially not equivalent, and, therefore, you cannot compare four experiments which were done with two different, substantially non-equivalent potatoes; and also there were other differences, not just in time but protein concentration. This was an initial piece of work which was to probe into the whole problem, and the only experiment which you can compare is, for example, the D227—I do not want to—forget about the numbers—

Chairman

158. Can I also say, Dr Pusztai, thank you very much for that, because we are here really to inquire into procedures and treatment—

(*Dr Pusztai*) I am sorry about it.

159. No, not at all, not at all; we asked the question and you were answering it, so it is not your fault in any way. But we do want to try to keep the details on the science to a minimum, otherwise we will never get through the principle of the matter.

(*Dr Pusztai*) Yes.

Dr Jones

160. Perhaps you could give us a note about your views of Dr Horgan because it was one that you sent to us as being independent?

(*Dr Pusztai*) Yes, it was independent.

161. In the World In Action programme, you refer to 110-day experiments, the effect of slight growth retardation. In your submission to the Committee, you say that on 110-day feeding actually no differences between parents and GM potatoes could be found; that is what you have told us?

(*Dr Pusztai*) The reason for it is because there was 20 per cent less protein, so we had to put in more protein to compensate for it; there is no point in doing a stupid experiment; if you were putting in less protein you would get a retardation, so we wanted to—

162. But can you confirm that there were no differences at 110 days?

(*Dr Pusztai*) No, because the design of the experiment prevented it.

Mr Beard

163. Taking the quotation that Dr Jones just made to you, if, indeed, it is true that the experiment was not properly statistically designed, given the variability there is in so many factors, is it not the case that it is not possible to draw any scientifically-based conclusions from the results?

(*Dr Pusztai*) You see, this whole programme was not about testing GM potatoes, it was to come up with testing procedures which might have relevance to other GM matter. So, therefore, because substantial equivalence has such an importance in the matter, if you find that there is no substantial equivalence, there is no point in doing an experiment.

164. But the evidence that Dr Jones quoted is that the design was not adequate to draw conclusions, but you had been drawing conclusions, in the World In Action programme?

(*Dr Pusztai*) No, I do not actually agree with that, I do not agree with that. We had done four totally different experiments, with two different lines of potatoes, and it came to an end at a time when it was really starting to become extremely interesting.

Dr Turner

165. Is it fair to say, Dr Pusztai, that the controversy surrounding yourself is a slightly phoney one, in the sense that you were never setting out to test a potentially commercially-viable product?

(*Dr Pusztai*) Precisely.

166. That you were, in fact, simply using it as a means to establish a technical basis for assessment of products?

(*Dr Pusztai*) Precisely.

167. So the fact that there may or may not be statistically-significant results has no bearing on whether, in principle, genetic modification is a risk?

(*Dr Pusztai*) But there are; even in that statistical analysis, there are. And if you are comparing two different lines and you try to make a statistical point then it is wrong; but if you are comparing lines which were the same, for example, in those experiments, where the only difference was in the total protein content that how much you supplemented with, there are very significant differences and there are very consistent differences, and I would be very pleased to actually show them to you, if it—

Chairman: Thank you. There is a promise.

Dr Jones: Basically, the GM potatoes were knackered in terms of a food, were they not; they were not very good food value?

Chairman: No, we must move on now. I am sure there is scope for a private meeting hereafter.

Dr Gibson

168. Dr Ewen, to turn to you, if I may. In your submission to us, you talk about your work over a decade, ten years, with Dr Pusztai, and you have seen him as an exacting, fastidious scientist, and you record some of your work. But in the last line of your report you talk about a "relatively minor initial misdemeanour"; could you explain what you meant by that, in the original work?

(*Dr Ewen*) Yes. I think the difficulty is a slight difference in meaning between Scottish parlance and English, Englishness.

169. I do not know about it; tell me?

(*Dr Ewen*) What I was actually meaning was that there was an infringement of convention, shall we say, and "misdemeanour", I think, in that respect, was too strong a term.

170. And what was that, do you think, the infringement?

(*Dr Ewen*) I think we have heard explained that on the programme perhaps the lack of published evidence is the main criticism.

171. Right; let me turn to you then, Dr Pusztai, about results. Do you think it is justified for scientists to go public, as it were, with preliminary results or unfinished results? You are not the first to have done it, incidentally; Richard Gallo did it with the Aids virus, I seem to remember, he had a presidential conference; so it happens. What do you think about doing that though?

(*Dr Pusztai*) I think that what we have to put over, and I think that I probably did it too well, looking at it now, is that, based on our experience, there ought to be a concern. Now when you are saying that there is concern they will probe into it, that what is this concern. I am not sufficiently famous to say that I feel concerned and then everybody will take notice of it; what they will say is: "Okay, you feel concerned, so what gives you a basis for that concern?"; then I said that because we had done some experiments. Now I still regard that, if I say that on the basis of our studies, I am not giving any details away, what I am saying is that on the basis of those experiments, when we did see some effects on growth, maybe not directly but indirectly, but we did see some effect, and we also see some effects on immune responsiveness, or organ weights, or organ metabolism, then you have to somehow say something, otherwise the whole thing will be totally useless, nobody will believe you, so that concern had to be expressed.

172. Do you want to add to that?

(*Dr Pusztai*) I said, right at the beginning, that, because I do happen to know all that has been submitted to the Novel Foods Committee, all the arguments and all the science which has been submitted, and also taking into consideration there is only one peer reviewed paper on record, this technology has been introduced on the back of a single paper in Journal of Nutrition, in 1996, when it all comes together then your results and your concerns are becoming a bit stronger, and you feel frustrated, you have to do something about it.

173. So why did you not just publish a short note and get it peer reviewed, which is a conventional way for scientists to do this; what was your thinking at that point? You have obviously done something since, I see your thinking of doing it, but why not at the time?

(*Dr Pusztai*) Even that will take some time, as we found out, quite some time, particularly if it is hostile, if it can be construed to be hostile to a very important technology; then even papers which were, in a sense, good, from the point of view of GM, had very rough treatment, people just did not want to get involved.

174. Looking back down the track, would you do it all again; would you go through the same procedure again?

(*Dr Pusztai*) Yes; yes, definitely.

175. You would not change a thing?

(*Dr Pusztai*) I have never changed my mind about it. I do realise that, some of the data, I actually would contest anyone, any scientist, I would sit down and contest it, that what I found and what could be the restrictions or the limitations on it; but, essentially, it certainly gave me a concern, and, in fact, it was very much shared by the Institute, this concern.

Chairman

176. Just so that we are absolutely clear, when Dr Gibson says, with hindsight and looking back, would you do the same again, I do not think we are talking about would you do your scientific work again; I am sure the answer to that is an emphatic "yes", but would you, with hindsight, handle the situation again; would you expose yourself to media coverage, World In Action, a hostile programme and sceptical scientists; would you do that again?

(*Dr Pusztai*) It is a very difficult question to answer, because sometimes you do not get these opportunities, sometimes you do get them, sometimes they come along and sometimes they do not come along, you cannot really say that it would be—but I do not really try to get out of it.

177. No, but you do not have strong regret; from your answer you are giving, you do not have strong regret about it?

(*Dr Pusztai*) No, because, in one sense, what I achieved is that we are all sitting here and talking about it.

Chairman: We have got three or four questions now on genetically modified food, and we are running out of time, because we have another set of witnesses. So could I please ask the Committee members to put their questions as briefly as possible, and, Dr Pusztai, we would be very grateful if you could respond as quickly as possible, consistent with the truth and fairness.

Mr Beard

178. Could I just go back to your answer, when Dr Jones was quoting the statistical question-marks over the design of the experiment, and your answer was that you were not really looking for results, you were looking for a methodology for testing genetically modified plants, and that, therefore, the fact that there was no statistically significant difference in the result did not really matter; is that what your response was?

(*Dr Pusztai*) No, I would not agree with that. There were statistically significant differences. And if you look through the whole business you will see that if you make predictions on the basis of random error you would expect something like six statistically significant differences, you got 50; now there is a huge difference between 50 and six, and, therefore, I would say that they are statistically significant. So I do not accept that.

179. Could we go to the World In Action broadcast, Dr Pusztai? In it, you said that you "find that it's very, very unfair to use our fellow citizens as guinea-pigs"; that is taken from the World In Action programme transcript. What evidence had you got for saying that?

(*Dr Pusztai*) The only evidence is that there is only one paper published; that is good enough evidence for me, that it has been given out a new technology has been introduced and it is based on a single paper.

Examination of witnesses (Questions 180 - 199)

MONDAY 8 MARCH 1999

DR ARPAD PUSZTAI and DR STANLEY EWEN

180. The force of your statement was that genetically modified foods are being released onto the market without control and without people knowing whether they are toxic or not, or whether they have other damaging effects; that is the force of that statement. And I find it puzzling that the answer to that, as a justification, is that there was only one paper ever published. I say, again, what is the evidence that damaging, genetically modified food is being released into the public, so that they are, effectively, guinea-pigs?

(*Dr Pusztai*) No, I did not say that.

181. That is the transcript from the World In Action programme?

(*Dr Pusztai*) What I said was that you are going to find it out by releasing it; that is the guinea-pig, to me.

182. The transcript is that "it is very, very unfair to use our fellow citizens as guinea-pigs". Now I am asking you what the evidence is, and your response is there was only ever one paper published; now that is not evidence?

(*Dr Pusztai*) No, but you use guinea-pigs in the laboratory to find out something; that is the point.

Chairman

183. We could say it is unfair to starve human beings; it does not mean to say we are starving human beings; you can make a statement that it is unfair to do something. Are you saying it is unfair to use our citizens as guinea-pigs because they are being used as guinea-pigs, or are you making a moral statement that it is unfair to use our citizens as guinea-pigs?

(*Dr Pusztai*) I think that it is a perfectly good way of finding out, using guinea-pigs in the lab., that is a perfectly good way of going about it.

Mr Beard

184. But that was not what you said. You said the general public, effectively, are being used as guinea-pigs, and I am asking what evidence there was for it?

(*Dr Pusztai*) But if you have no guinea-pigs and it is you who is the guinea-pig then I do not really see why it is not logical; logically, it is quite alright, to me.

Dr Williams

185. Could I ask, how should genetically modified food be tested?

(*Dr Pusztai*) I think that is what all this business is about. We tried to come up with new ways of testing. Remember that I do know what the companies did, I looked at that, and with that knowledge behind me I could see which way we could stretch this, to come up with new things, and we used genetically modified potatoes as a sort of testing model. That was it.

186. Yes. Could I ask Dr Ewen, you have looked at Dr Pusztai's, or did a lot of the pathology on the samples, and—

(*Dr Ewen*) One experiment.

187. And I have read, as well as your submission to us, an article in The Guardian, on 13 February, which was quite disturbing, in terms of the stomach wall, the enlarging—I am not a biologist so I do not follow in detail—but is there something very disturbing in that effect that it had on the lining of the rat's stomach?

(*Dr Ewen*) I have not actually read the piece that you mention.

188. It is similar to what is in your brief?

(*Dr Ewen*) But, yes, the thickening of the mucosa, I think, is a difference, and, therefore, if there is a thickening, it causes me concern, as a pathologist.

189. Does it mean that carcinogenic materials could pass into these elongated structures?

(*Dr Ewen*) I would not like to speculate by using the word "carcinogenic"; this is a simple growth, like a hyperplasia, it just means that cells are added.

190. Why was there that difference? Again, in this article, rather than the brief, there is speculation that it may have been due to the cauliflower mosaic virus, used as a promoter.

(*Dr Ewen*) Those words are not mine. I have not read the article in The Guardian.

191. But is it possible that it is that, that it is the promoter that is causing the problem?

(*Dr Ewen*) I would like to widen it to the construct rather than, necessarily, singling out one part of it.

Dr Jones

192. Could I just say: you have not done any experiments that demonstrate that cauliflower mosaic virus is expressed in any of your tissue samples?

(*Dr Ewen*) No, indeed, I have not. I would love to.

Dr Turner

193. You are very critical of the advisory committees, because they cannot commission their own research, or they cannot test GM foods themselves, and the only data that they have available to them is what the companies themselves produce?

(*Dr Pusztai*) Precisely.

194. On the other hand, that is exactly what happens in testing a new pharmaceutical product, it is the basis of the pharmaceutical regulation; why do you think GM foods should be treated differently?

(*Dr Pusztai*) I do not know what they do with pharmaceuticals, but I know that they are tested much more extensively; that is for a start. The other is, of course, that pharmaceuticals are not staples; we only take them from time to time, we do not eat them all the time.

195. That is true. And do you feel that the members of the advisory committees, as presently constituted, are competent to assess data, from the scientific point of view?

(*Dr Pusztai*) I think they are doing a job under very difficult conditions. Obviously, if they are coming together once or twice a month, or two months, and they will have to go through a very extensive, scientific input, without means of actually checking some of the perhaps potentially controversial issues, then that is a difficult job, and it is up to them how they do it, how best they do it, but you notice that there are not many new things coming on.

196. So you would be happier, I take it, with some strengthened system; can you give any indication of what you would like to see?

(*Dr Pusztai*) I think, as I say, I would certainly like to have more input by actual practising scientists, rather than, let us say, those who are perhaps doing more administrative science. It is now almost a European business, and I do not even know myself that which other scientists are working on, in related fields, I do not know how the committees know that. So there seems to be, again, a sort of communication gap, they may not get the most up-to-date and best scientific advice, and it would certainly be strengthened if you had a few more actively working scientists on, at least relating to, the committees.

Dr Jones

197. Both of you have expressed concerns about the current regulatory system, and, obviously, you have called into question the expertise of the Advisory Committee on Novel Foods and Processes. Do you know what the composition of those committees are?

(*Dr Pusztai*) I used to know, for example, Professor James was on it, Professor Burke on it, some of them I knew reasonably well. I did not say that they are doing a bad job. What I am saying is that they are doing a very

difficult job under difficult circumstances, with not many possibilities that perhaps asked those questions, like we asked; they may not have the answers to them.

198. You have named two scientists, but do you know any of the others, because you have just said that there are not any who are close to the science? What gives you that impression?

(*Dr Pusztai*) I think that, judging from all the people whom I knew, and I cannot give you more examples because, at the moment, I cannot remember their names, but, for example, there was—again, I cannot remember, I am sorry. But I did know personally quite a few of them, and I know that they keep a very strong connection with science, but they are not active scientists, let us say, they are having so many overworked committees and all sorts of commitments—for example, Professor James must have been on at least on half a dozen different committees, and he also has a responsibility for running an Institute, he also has all sorts of external commitments. The day is only 24 hours, so he may not have all the time to spend, let us say, to go into the lab to see the sort of work going on.

199. I wonder if I could ask Dr Ewen the same question? What changes would you make, either in the composition of the committee or its remit?

(*Dr Ewen*) Of course, I am not a nutritionist, I am just a hospital pathologist, but it does seem to me that we must always keep the consumer firmly in view, and, to that extent, sometimes, I feel that there may be undue bias against the consumer.

Examination of witnesses (Questions 200 - 206)

MONDAY 8 MARCH 1999

DR ARPAD PUSZTAI and DR STANLEY EWEN

200. You are not aware that there is a consumer representative on the advisory committee?

(*Dr Ewen*) I am not sure what the proportion is.

201. There is both a consumer representative and an ethical representative. Does that reassure you at all?

(*Dr Ewen*) I am not sure—the construction of the committee—perhaps one is not enough, I just would not like to say. I think there ought to be a proper balance.

Chairman

202. Can I just put one final question to Dr Pusztai? The research results you have obtained, Dr Pusztai, with a transgenic potato diet in rats, do these results suggest any specific new concerns regarding genetically modified foods, or the safety of those foods, or the need for better regulation of those foods?

(*Dr Pusztai*) I think that what you need is certainly more testing, this is a new technology, we must have new technology testing techniques.

203. I am talking about concerns, I am not talking about things that are proved; do you feel that what you have done has suggested new concerns with regard to genetically modified foods?

(*Dr Pusztai*) Yes. I think so, yes.

204. Thank you very much. And have you raised these concerns with the Advisory Committee on Novel Foods and Processes?

(*Dr Pusztai*) No, because I had no way of getting to them.

205. But I have little doubt they have noticed what has gone on since the World In Action programme?

(*Dr Pusztai*) Since then, yes.

206. Dr Pusztai and Dr Ewen, but especially to you, Dr Pusztai, who have spent an hour in the hot seat, may I thank you very much indeed for the help you have given us this afternoon, for the evidence that you have

allowed the Committee to share, and may I say that I hope that your experience of Parliament in action has been more amenable to you than the World In Action. Thank you very much indeed.

(*Dr Pusztai*) Thank you very much for your kind attention.

Chairman: Thank you.

Memorandum submitted by the Rowett Research Institute, Aberdeen

1. Introduction

2. The adequacy and quality of scientific advice at present

3. The role and framework of Advisory Committees

3.1The speed of change and the time involved in safety scrutiny

3.2EU: UK relationship

3.3The major role for Codex Alimentarius in the WTO mechanism for safety evaluation

4. The ability of the current system to respond to rapid scientific developments

5. The value of an overarching body for GMOs

6. The Government as an "intelligent customer" for advice received

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9. Events relating to Dr Pusztai

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10. Annex

1. INTRODUCTION

The Rowett Research Institute undertakes research in the field of nutritional science with emphasis on the role of diet in health. This has led us to assess how to improve the safety evaluation of novel foods and feeds including those that involve genetic modification. We also have or have had extensive involvement in both the UK and EU systems of scientific advice (see 10. Annex). Dr Chesson is a member of the EU's GMO and Animal Nutrition Committees and Professor James is currently developing for the EU a new approach to meet the broader concerns of the public and European Parliament about GMOs. In this submission we do not deal with environmental issues relating to GMOs but concentrate only on food safety. We consider that more stringent testing systems are needed than those which appear to be acceptable in the US. We are currently proposing new measures for Europe to improve further the assessment of GMOs by using recently developed screening techniques. We consider first the questions listed by the Clerk of the Committee, then provide more details of the safety issues and finally deal with recent events relating to Dr Pusztai.

2. THE ADEQUACY AND QUALITY OF SCIENTIFIC ADVICE AT PRESENT

Our personal experience of the merit based selection process for membership of the new EU expert committee structure established in late 1997 revealed that the UK has the most numerous and impressive high quality range of scientific expertise of any country in Europe. In order to maintain a reasonable geographical balance of experts, the Commission properly had to limit the UK input to EU committees. Our current analyses also show that the UK Scientific Committee system tends to be better supported in terms of scientifically trained administrators and secretarial assistance than many EU countries and the current, albeit expanding, DGXXIV system in Brussels. Nevertheless the decision about five years ago to reduce the numbers of senior Whitehall civil servants seemed to have a selective effect in removing outstanding scientific expertise from UK committees dealing with food safety. The effectiveness of the UK committee system depends on maintaining very high quality scientists in the Civil Service.

3. THE ROLE AND FRAMEWORK OF ADVISORY COMMITTEES

The UK and EU committees tend traditionally to be in responsive mode, ie they answer the specific questions put to them by Ministries. Effective and pro-active committee Chairmen have, however, always had the ability to initiate changes in committee processes and to push for new areas to be considered. The system could, however, benefit from the clear acceptance that Committees should be able to propose areas for further analyses. This could be particularly useful and relevant to GMOs (see below). In the EU's Scientific Steering Committee, there is an explicit requirement by the Commission that we should evaluate issues broadly and initiate new approaches to problem solving. This is a valuable innovation.

3.1 The Speed of Change and the Time Involved in Safety Scrutiny

The time demands on UK scientists who serve on GMO scrutiny groups is likely to escalate markedly. At present the university or institute funding and assessment mechanisms make no allowance for this contribution so UK scientists are, in effect, doing the work in their spare time. Our current experience of serving on EU committees also shows that to play an effective and very active part requires allocating up to two days per week with additional help from scientific assistants. Yet no formal support is currently available from either the EU or UK for this work.

New UK arrangements have recently been developed to help with the checking of other EU country analyses of GMOs. These clearances will be checked by some of a large group of experts who will now be expected to work individually by post and e-mail. Our experience suggests, however, that there is no substitute for conjoint deliberations in committee and that the somewhat mechanical scrutiny of increasing numbers of GMO dossiers will fail to deal with broader issues of concern. That is why we propose below a new initiative to upgrade the guidelines for screening new GMOs.

3.2 EU: UK Relationship

The relationship between EU and UK committees is still too complex. As noted above, UK committees now have to respond extremely rapidly to the clearance of new foods by other member states. We know that some EU countries do not have the same range of expertise on their committees as the UK so it is theoretically possible for a company to seek clearance for a food in a less rigorous system than in the UK. When there is disagreement within the EU the Commission plans that its DGXXIV committee system provides the Commission

with independent advice. It is therefore seen as potentially acting as an arbiter between two opposing national views.

Sweden now presents an anomaly within the EU. It has the most long-standing Food Authority within the EU and a justified reputation for rigorous analysis of issues. This is expected of an exceptionally talented scientific nation. It has been claimed that Sweden has decided that the FDA system of clearance is, in principle, very effective and that therefore the US clearance of a product should be acceptable in Sweden. If this is ture, now that Sweden is an EU member this would, by implication sanction the new food within the EU unless the UK expert group responds promptly with an objection. We, however, set out below some scientific proposals which go beyond the FDA's current approach to GMOs. These proposals imply that the EU should take a distinctive position on GMOs which will enhance the safeguards and might go some way towards allaying the very different and greater concerns in Europe about the safety of GMOs.

Given the very large surge in GMOs coming up for approval in the next ten years, we believe it is important that the UK's system of scrutiny is enhanced, preferably with an even greater involvement in the EU system of evaluation. We believe the Commission might welcome proposals from the UK for a greater interaction with our national bodies. Experience with handling BSE issues in Brussels suggests that a new interactive process could work well at a civil service level without the repeated need for Commissioner/Ministerial clearance of new analyses and information from the UK. The UK has certaintly benefited in BSE terms by providing the EU with extensive expertise and background information. Whilst doing this it is essential to recognise that the Commission, and especially DGXXIV, must be seen to be completely impartial.

3.3 The major role for Codex Alimentarius in the WTO mechanism for safety evaluation

If the EU concludes that a biotechnological innovation is unacceptable on safety or other, eg environmental grounds, this may clash with current US, Japanese or Chinese assessments. The US government, for example, may then claim inappropriate trade discrimination and appeal to the WTO. The agreed mechanism then is for the Codex Alimentarius Commission (a joint WHO/FAO responsibility) to bedesignated the final arbitrator if the trade barriers depend on a health issue. Codex has already arbitrated against the EU ban on the use of hormones in beef production and the EU is currently required to provide positive evidence that hormone residues in meat are a risk to health. The same issue may arise if the EU follows the new decision by Canada to ban the use of bovine somatotrophin (BST) currently used throughout the US dairy industry. The decision may turn predominantly on animal rather than human health so how this is handled by the WTO remains unclear to us.

Public Health has traditionally been of little import in WTO terms when there is a trade dispute. Thus when India tried to ban US cigarette imports, the WTO forced India to give access to US tobacco companies and use equivalent measures against cigarette use for both US and Indian products. Despite the huge financial muscle of US tobacco firms, the only measures available to India were to ban all cigarette advertising and discourage cigarette use through a variety of classic measures such as health education and smoking restriction in some public places.

The reputation of Codex is disputed. It has evolved over decades as a useful system for specifying standards for pesticide residues and other safety measures as well as crude technical issues such as the methods needed to measure the nutrient content of foods for special dietary uses. It operates, however, through a series of committees with very heavy industrial involvement (particularly from the US) and very few representatives of the public interest. Only half of all member states ever become involved through their health ministries. When there is a health issue and Third World countries are very poorly represented. Modern and well accepted principles of public health, eg the concept that modest individual but universal risks cumulatively impose substantial health burdens on societies or that health education involving the labelling of foods to enable individual choice has limited application in many population groups, are also poorly understood.

These public health concepts are also often disputed by those from other disciplines so it seems unlikely that important new public health concerns will have much impact in Codex let alone in the WTO. Therefore how GMOs will be handled given the startlingly different attitudes in Europe and the US to the risk/benefit ratios of new GMOs is very uncertain.

4. THE ABILITY OF THE CURRENT SYSTEM TO RESPOND TO RAPID SCIENTIFIC DEVELOPMENTS

The very few GMOs currently cleared in the UK have not presented any major problems in relation to public health during their evaluation. Thus neither of us is concerned with the current GM foods available for sale within the UK. However, given the extremely large number of GMOs currently under trial, we consider that there is a need to develop new screening strategies which take account of current scientific knowledge and the need, clearly expressed within Europe, to have greater assurances on the safety of GMOs.

The system does not at present respond well to rapid scientific developments for the following reasons:—

(a)Most companies understandably and properly have followed guidelines for submitting data on safety. These guidelines, however, were established many years ago. Since almost all scrutinised data on a GMO are company derived, they inevitably conform with these older guidelines. Only when objections come from a country's expert evaluation will further work be undertaken.

(b)The types of safety evaluation are, as expected, those traditionally used in toxicological analyses.

(c)The response to novel developments is usually to base the assessment on screening methods which have evolved after decades of experience with hundreds of environmental contaminants/pesticides etc. An assessment is then made of whether a chemical compound is "substantially equivalent". If so, then it is expected to behave similarly to older compounds.

We believe that both on a UK and EU basis there is a need to upgrade and extend the safety evaluation processes so that clear guidelines can be generated based on modern scientific analyses and understanding. This therefore requires a new proactive role in developing more extensive and sophisticated guidelines which should be regularly updated.

5. THE VALUE OF AN OVERARCHING BODY FOR GMOS

We understand that the health issues relating to GMOs will be dealt with by the new Food Standards Agency (FSA) if, as seems likely, it is established during this Parliamentary session. In the original proposal for establishing the FSA it was assumed that when there were issues relating to other problems, eg environmental concerns, there would be a need for a conjoint group to link the two areas of concern. Such a mechanism still seems to be appropriate.

6. THE GOVERNMENT AS AN "INTELLIGENT CUSTOMER" FOR ADVICE RECEIVED

The role of scientists within the senior Civil Service has been much debated for several decades. With the recent cuts in senior Civil Service posts, the support structures for departmental senior scientists seem to have been markedly reduced. Nevertheless, the welcome new emphasis on the industrial significance of scientific innovation, the Foresight exercises and the prominent roles of the Chief Scientists and Director of Research Councils are evidence of the Government's ability to act as an "intelligent customer". The recognition of the need for sophisticated scientific interpretation for policy making when coping with the BSE crises has amplified the importance of high quality science at a senior level. Whether the UK has the "capacity" to cope with the welter of new scientific issues might need, however, spearate analysis.

7. CONCLUSIONS RELATING TO THE COMMITTEE'S SPECIFIC QUESTIONS

The UK has an exceptionally good reputation for the quality and range of scientific advise available to it for policy-making purposes. The effectiveness of the advice depends, however, on maintaining very high quality senior Civil Servants with scientific expertise. Given the very substantial increase in the number of GM crops for scrutiny in the next five to 10 years, the UK needs to be sure that it can cope with the demand for rapid assessments. We consider, as set out in more detail below, that there is a need to develop more effective guidelines for the scrutiny of GM crops. We assume that the Food Standards Agency will be proactive in enhancing the quality of scientific data required and in ensuring that Non Governmental Organisations and other public interest groups recognise and contribute to the assurance of safety. The development of more effective guidelines should also take advantage of the continuing Royal Society scrutinty of these issues and regular updating of the guidelines will be required.

The complexity of UK/EU and World Trade Organisation relationships needs to be recognised. It is suggested that a proactive UK role in developing better guidelines which go well beyond current US FDA requirements could contribute to improving the interaction of UK and EU scientific analyses. Trade disputes might well arise and the UK would then need to have in place a substantial body of scientific research and opinion to provide to the Codex Alimentarius Commission which is not currently tuned to exert its designated role in global arbitration on these complex scientific issues.

8. A MORE DETAILED SCIENTIFIC ANALYSIS OF GM ISSUES

Dr Chesson's experience of scrutinising GMOs on a European basis has led to a more detailed analysis of the issues and the development of proposals as set out below.

In the EU the assessment of risk to humans, animals and the environment centres on Directive 90/220/ECC and any hazard following "accidental" consumption or exposure. In addition, the requirements of the Novel Foods and Novel Food Ingredients Regulation (EC 258/97) must be satisfied before a GM crop (or any product derived from it) can be used for food purposes. In the UK, Ministers are advised on these issues by the Advisory Committee on Releases to the Environment (ACRE) and the Advisory Committee Novel Foods and Processes (ACNFP). In the future, the feed use of GM crops may be separated from the present system and dealt with by new regulations and/or advisory bodies in both the UK and EU.

The current principal issues considered by advisory bodies in relation to the release of GMOs are:

—the potential for transfer of the introduced gene(s) to other species;

—the safety of the introduced gene product(s) and

—the question of "substantial equivalence".

The third issue is a commonly applied concept used to suggest that inadvertent changes, ie other than those deliberately introduced by recombinant technology, can be expected to be of no significance in the transformed plant. This approach has proved adequate for the few crops than have been formally assessed for safety to date at a National or European level, but it is based only on the experience gained from the consideration of a handful of structural and regulatory genes (Table 1).

Table 1

THE STRUCTURAL GENES INTRODUCED INTO CROPS WHICH HAVE SOUGHT UK OR EU APPROVAL FOR RELEASE

Introduced gene	*Description/phenotype*	*Number of products*
	Insect resistance	
cry1(A)b and *cry 1(A)c*	truncated Btk endotoxin	4
	Herbicide tolerance	
pat and *bar*	glufosinate ammonium (Basta) tolerance	5
cp4 epsps and *gox*	glyphosate (Roundup) tolerance	3
	Antibiotic resistance markers	
nptll (*syn.aph(3)-ll*)	kanomycin/neomycin resistance	5
nptlll (*syn aph(3)-llla*)	amikacin tolerance	1
aadA (*syn. ant(3)-1a*)	streptomycin/spectinomycin resistance	2
bla	ampicillin resistance	1

	Male sterility/fertility	
barnase and *barstar*	ribonuclease and ribonuclease inhibitor	2
	Sense/antisense gene silencing	
pg (partial sense)	delay in fruit softening	1
gbss (antisense)	starch with reduced amylose content	2

Consideration of any hazards posed by transgenics involving the genes listed in Table 1 has been protracted and drew on historical data such as the absence of detectable toxic effects of the *Btk* toxin after 30 years use as an insecticide. Thus the FDA and various other national advisory bodies have had nearly 10 years to consider and investigate these product types. Since these GM crops were also the first commercial products, they have been the subject of investigation by many other interested parties and, as a result, a considerable body of data exists on which to base a safety assessment.

It is unlikely that this slow rate of introduction of new GMOs for assessment will continue. A scan of the data bases produced by the competent authorities in most OECD countries shows that a very large range of traits have been successfully incorporated into crops which are now undergoing field trials. These triats range from protection against various forms of pests to the production of industrial feedstock. Field trials involving 56 different plant species have been completed in the USA alone (compared with 12 in the UK). Trials may involve a single modification to one plant species or, in the case of the more important crops, many different types of transgenic plants. The 450 trials in the USA between 1989 and 1997 made with GM potatoes, for example, encompassed at least 32 different traits. As a consequence, the range of genetic modifications in crops and numbers of new products likely to be seeking regulatory approval in the future will be far greater than those already considered and will inevitably challenge the existing safety assessment and risk management procedures.

Although Companies seeking to introduce a GM product are required to demonstrate its safety, it is very unlikely that any Company will provide more information than is indicated as necessary in the guidelines which accompany the regulations. Thus the value of information provided to government and to its advisory bodies is dependent on the nature of the information sought. Guidelines based on our limited experience to date need amplifying to deal with all the issues raised by the far greater diversity of genetic traits likely to seek release in the near future. This will be most apparent in the consideration of human safety and three areas now need additional safeguards to provide the level of assurance necessary to allow a transgenic plant to enter the food chain.

8.1 Quality and rigor of existing criteria

Most companies seeking approval for the release of GM crops in Europe have first sought approval in the USA. Therefore the dossiers being submitted reflect the procedures of the FDA. We conclude that practices currently considered acceptable and promoted by the FDA are not rigorous enough for future use. One of the key issues in establishing safety is the ability of the digestive tract to digest the protein encoded by the transgene. The FDA approved tests of gastric and intestinal survival represent a "best case" situation and do not reflect the digestive capacity of the very young, the elderly and that segment of the population unable to produce stomach acid. Secondly, the difficulty in extracting sufficient protein from a transgenic plant for testing, has led to an "accepted" practice of making tests on the protein from the same gene expressed in a different host, usually a bacterium. It is well known that a protein expressed in a different host will undergo different post-translational modification and will not possess the same biological and physical properties. Extrapolating from the tested behaviour of an isolated protein produced in a bacterium to predicting the behaviour of the same protein when it is an integral part of the transgenic plant is unsound and could lead to premature conclusions about safety.

8.2 Substantial equivalence

The concept of substantial equivalence is a useful framework in which to consider effects which do not directly relate to the transgene or its product, but which may have been caused by the process of introducing the foreign genetic material. Conventionally, substantial equivalence is established by comparing data on the

composition of the transgenic plant grown at several locations over two or more seasons with the same data from the unmodified parent line grown alongside the transgenic line. However, establishing substantial equivalence, depends on correctly specifying and then measuring those elements of concern. Much of the data produced is simply a measure of gross composition which is difficult to interpret. At what levels do changes to protein, carbohydrate or fat concentrations pose an additional risk to human health and why? There is obvious value in measuring the concentrations of known natural toxicants such as glycoalkaloids in potato or glucosinolates in brassicas, since safe levels for these compounds have been established. The routine analytical procedures currently used, however, would be unlikely to detect, toxic metabolites which accumulated because the introduction of transgenic material silenced an existing plant gene and disrupted a metabolic pathway.

The concept of substantial equivalence would be better served by the use of techniques which make no assumptions but which attempt to measure the construct as a whole. We propose that three relatively new technical approaches would allow a more discerning analysis than at present.

—Differential display methods can detect differences in mRNA induced by other genes as well as the transcribed gene.

—Proteomics to detect differences in total protein expression would allay concern about the whether the transcribed gene has led to different protein structures because of additional post-transcriptional changes, eg. by the addition of carbohydrate units by virtue of these processes occurring in a new plant host.

—Metabolic profiling techniques they could lead to a clear documentation of amplified or suppressed metabolic pathways which would not even be considered in current testing systems. Analyses of metabolic pathways should be mandatory when an introduced gene is known to code for an enzyme involved in the production of plant secondary metabolites (the *epsps* gene for example).

8.3 Immune and hormonal status

Existing assessment methods require tests for chronic and acute toxicity. However these are invariably made with the isolated protein produced by the transgene and not with transgenic plant itself. This is because of the difficulty of achieving the higher test concentration required in the diets of test animals. While such tests do provide a measure of security, they offer a poor screen for more subtle effects or those which may have a relatively long gestation. One such issue is that of allergenicity. Existing assessments rely heavily on comparing the similarity of the transgenic protein with known allergens (ie whether the sequence homology is or is not the same as the known allergens). This assumes, however, that the allergy depends only on an epitope with a continuous sequence and, secondly, that all allergens are known. Neither is a comfortable assumption. However there are no widely accepted methods for assessing allergenic potential. We understand that the Royal Socieity is considering the issue of allergies in relation to GMOs so there may well be new proposals for screening or research strategies emerging from their review.

A second set of issues relate to intestinal secretions and hormonal changes, ie endocrine and exocrine functions which are not addressed in the current guidelines for GMO assessment. Although not particularly relevant to those crops already approved for release, these issues are likely to become of far greater concern in the future. Many of the genes now being considered for introduction to provide insect resistance depend for their action on disrupting the digestive function of the pest (Table 2). Some of the enzyme inhibitors and lectins being considered may produce similar effects in mammals. In addition, they are known to be highly resistant to degradation in the digestive tract when produced in their natural host and, if absorbed, may have effects on many aspects of metabolism, including the immune and hormonal systems. This was the issue being addressed by Dr Pusztai in his research.

Unless the development of assessment tools parallel and keep pace with developments in plant genetic engineering, it will not be possible for advisory bodies to provide secure advice on the safety to humans of future GM plants seeking release in the UK and Europe. Industry claims that over stringent requirementsfor evidence of safety will stifle development of a vital technology has limited validity and then only in the short-term. It is better to start with rigorous requirements for safety evaluation and then relax the specifications in the light of experience rather than having to tighten regulations once evidence of damage to human health has occured.

Table 2
INSECT RESISTANCE GENES TRANSFERRED TO CROP SPECIES

alpha-Amylase inhibitors	*Lectins*
Bean	Snowdrop lectin—GNA
Cereal	Pea lectin
Protease inhibitors	Wheat germ agglutinin—WGA
Soybean (serine protease)	Jacalin
Barley (trypsin)	Rice lectin
Squash (trypsin)	*Others*
Cowpea (trypsin)	Bean chitinase
Mustard (serine protease)	Tobacco peroxidase
Rice (cysteine protease)	Tomato chitinase
Potato (protease inhibitors I and II)	Tryptophan decarboxylase
Soybean (Kunitz trypsin inhibitor)	*Animal genes*
Tomato (protease inhibitors I and II)	Various enzyme inhibitors

Taken from Schuler et al TIBTECH 16 168-175 (1998).

8.4 Industrial crops: managing the risk of chemical entry to the food chain

The focus of debate on GM crops has been safety in respect to food use and the consequences for the environment. Relatively little attention has been paid to broader questions of risk analysis and management. Programmes designed to detect gene transfer to non-transgenic crops and related species and the spread of resistance to the *Btk* toxin amongst target insects are underway. However we consider the impact of new GM crops grown for industrial rather than food/feed purposes is likely to become of great importance. Plants have long been used as bioreactors able to produce high value naturally-occurring chemicals, predominately for pharmaceutical or cosmetic use. Recombinant technology has greatly expanded the options for the production of high-value products, particularly peptide and protein based therapeutics. Transgenic constructs exist which are able to express antibodies, to produce proteins for vaccines and various signalling peptides. At the other end of the scale, low-cost bulk feedstock can also be produced economically and will be able to replace, in part, feedstock derived from non-renewable sources. Bulk production has focused on the use of oilseed rape in which the oil produced has been modified by changing the expression of key enzymes. One of the first GM plants to be approved for release in the USA (1993) was an oilseed rape modified to produce high concentrations of lauric acid for use in the detergent industry. Table 3 shows this and some other transgenic rape crops designed for industrial purposes which have reached the stage of field trials.

Table 3

TRANSGENIC RAPE CROPS PRODUCING OILS MODIFIED FOR INDUSTRIAL PURPOSES

Seeds modified to produce:	*Industrial products*
Stearic acid (40%)	Margarine, cocoa butter substitute
Lauric acid (40-60%)	Detergents
Oleic acid (80%)	Food, lubricants, ink
Petroselinic acid	Polymers, detergents
Jojoba wax	Cosmetics, lubricants
Myrisatic acid (40%)	Detergents, soap
Erucic acid (90%)	Polymers, cosmetics, ink
Ricinoleic acid	Lubricants, plasticisers, pharmaceuticals
Polyhydroxybutyrate	Biodegradable plastics

Taken from Murphy et al TIBTECH 14 206-213 (1996).

The only economically significant route for the disposal of the seedmeal remaining after the extraction of oil from oilseed plants is as animal feed. At present feed compounders or those farmers who mix feed on the farm treat all batches of oilseed meals as equivalent. This will no longer be possible if seedmeal derived from GM rape, or other commonly used by-products of the extraction industries (eg cottonseed meal) derived from other GM crops, become commonplace. Not only will there be appreciable issues for example if the lauric acid content of meat or milk rises, but there is clearly a demand that GM foods should be kept and labelled separately. Lauric acid is known to be a potent stimulator of blood cholesterol in man and erucic acid is also a well-known toxicant. Feed producers will need to accurately source their raw ingredients to ensure that residues of highly potent biological agents or toxic chemicals (eg erucic acid in modified rape) are absent. We doubt whether it will be possible to keep all GM foods completely separated in 10 years' time but if needed in the animal feed business a complete transformation of agricultural practice will be required. Risk management measures will have to be introduced in other countries even if such crops are not to be grown in Europe in the foreseeable future. The animal feed trade, like the food industry, is a global enterprise that sources its ingredients from all over the world. In the absence of any risk management strategy, traditional routes for the disposal of some crop by-products may have to be reconsidered.

8.5 Conclusions on some new proposals for better safety scrutiny

The current FDA approaches to the sanctioning of new GM crops will prove inadequate when assessing the large number of different genetic traits now being tested in a variety of new plant hosts. There is therefore a need to develop more effective and appropriate screening methods to alert companies and government agencies to the unexpected consequences of the often random insertion of genetic traits into plants. The proposed use of differential display techniques to monitor the induction of specific genes, the development of proteomics to assess the range and nature of new proteins and metabolic screening for unusual metabolite accumulation or loss are simply examples of how to assess the impact of genetic manipulations without making assumptions about the outcome. The issues of allergy, gastrointestinal and metabolic effects of lectins and other transcribed genes remain. The expansion of GM industrial crops presents major new challenges if consumers seek to ensure a complete separation of GM crops on a long term basis and ensure that disadvantageous by-products do not enter the food chain. There is a need to develop anad apply new scientific approaches in the safety evaluation of GMOs. This is not only appropriate scientifically but should go some way towards allaying public concern about the safety of these GMO developments.

9. EVENTS RELATING TO DR PUSZTAI

Dr Arpad Pusztai is a distinguished expert in lectins, ie plant proteins of complex and varied structure with a very broad range of actions. In plants, lectins seem to act by deterring pests: lectins are frequently found to damage the intestine of insects, nematodes etc. Therefore they have become popular with plant molecular biologists since the insertion of a lectin into a major crop may enhance its pest resistance and reduce the need for spraying with alternative pesticides. Dr Pusztai showed years ago, however, that some lectins, eg the phytohaemagglutinin lectin (PHA) obtained from red kidney beans can induce very marked intestinal damage to the mammalian gut. This is why traditionally red kidney beans are soaked and well cooked before consumption; severe diarrhoea may otherwise occur. Pusztai's major concern therefore has been that plant molecular biologists will introduce lectins which damage the mammalian gut as well as pests. He therefore rightly stresses the need for better discrimination techniques to evaluate the well recognised specific interaction of particular lectins with precise carbohydrate structures in the mammalian intestine. Lectins' subsequent effects on intestinal responses, turnover and immunological function are at present unpredictable. Some lectins are also absorbed and may have unusual metabolic effects. Others induce pancreatic swelling, excess replication and, when fed chronically, pancreatic tumour formation.

Some years ago we took Dr Pusztai's concerns to the DoH/MAFF Advisory Committee on Novel Foods and Processes at a time when it was evolving new schemes for evaluating new foods and novel food processes. An additional line of enquiry was therefore inserted to alert plant molecular biologists to the potential impact of new gene inserts on mammalian function. The modified scheme was then also taken by Philip James by virtue of his joint committee membership to a European level when the EU was evolving its own scheme. The EU scheme in practice is very heavily based on the UK approach.

Pusztai remains convinced (and we agree) that adequate *in vivo* tests need to be developed before a new GM crop with a lectin insert is released for either animal or human consumption. Pusztai's views have been published and are widely recognised. These views led the Scottish Office to establish in 1995 a new research programme involving Dr Gatehouse, a plant molecular biologist at the University of Durham, the Scottish Crop Research Institute (SCRI) and Dr Pusztai. The plan was for Dr Gatehouse to insert three different lectins; PHA from red kidney beans, ConA from the jack bean and GNA from the snowdrop bulb into potatoes. This crop was chosen because SCRI have exceptional experience of both potato genetics and how to grow new varieties and GMOs under highly controlled conditions. The potato was also chosen because it could be used with Dr Pusztai's nutritional expertise in substantial quantity in rat diets. The plan was to see how to develop new test schemes; both PHA and ConA are well-recognised lectins with both intestinal and immunostimulatory effects whereas Dr Pusztai's previous published analyses with purified GNA led him to conclude that GNA was harmless. This research was obviously of a strategic nature, ie to develop new screening methods and was not designed to specify whether these potato lines should enter the market.

9.1 The World in Action programme

Dr Pusztai had aired his views on a Newsnight programme in early 1998 and had been involved in a Scottish TV programme dominated by Rowett Institute research which took a cautious look at GM safety issues. When *World in Action* requested his involvement Dr Pusztai was given permission to take part provided he maintained his published cautionary approach to the use of lectins and did not release any unpublished material.

Given the recognised approach of *World in Action* particular care was taken to forewarn Dr Pusztai of expected problems but Dr Pusztai reassured the Institute Director, Philip James, both after filming and again on having the transcript read to him, that no unpublished material had been used and that no problems were expected. Yet the weekend before the programme was broadcast on 10 August, Dr Pusztai was bombarded at home by enquiries, praise and criticisms from all over the world. This intense media blitz stemmed from a pre-broadcast press release by *World in Action* with or without additional briefing.

9.2 10 August

On discovering extraordinary and intense governmental, industrial, NGO and media interest in data from unpublished Con A transgenic potato experiments, the Directors relieved Dr Pusztai of media involvement and tried to quell the release of further unpublished data by issuing a press release after briefing Dr Pusztai. Emphasis was laid on the experimental nature of the approach, the long-recognised actions of ConA and that

the transgenic ConA potato diet had unsurprisingly led to impaired growth and immune depression. We emphasised that no further unpublished data would be issued but all relevant information would be made available to policy makers. We then had to cope with intense scientific criticism about the release of unpublished data.

Dr Pusztai's collaborators from two major research programmes also dissociated themselves from his discussion of experiments and concepts which had not been agreed and sought new collaborative arrangements with the Institute. Finally the Directors were asked by Dr Pusztai to delay inspection of all the available data until the following day when Dr Pusztai's assistant returned to the Institute.

9.3 11 August

The media's intense interest in Dr Pusztai's revelations continued and featured as the main news story on many TV and radio channels throughout the world. By 5 p.m., however, after we had reviewed all the available new data, Dr Pusztai's assistants informed us that in fact no transgenic ConA studies had been conducted: it would seem, therefore, that Dr Pusztai was confused about which studies had actually been completed. Furthermore, Dr Pusztai and his assistants agreed that growth impairment had not been found in the long-term (110 day) feeding studies with GNA transgenic potatoes. Unfortunately the 110 day GNA immune studies were still incomplete at this time and therefore results of these experiments could not have been available when filming for *World in Action* took place in June. The Audit Committee has subsequently concluded that three errors were transmitted in the *World in Action* programme and these errors led, in conjunction with Dr Pusztai's media interviews over the weekend, to misleading claims being made about the health hazards of transgenic lectin use.

9.4 12 August

As a result of these developments, Philip James instigated an independent audit using Medical Research Council guidelines to protect Dr Pusztai from the charge that he had concocted data and to settle the apparent confusion about exactly what experiments had been done and what conclusions were appropriate. Dr Pusztai was temporarily suspended only from his lectin work and was encouraged to continue with his other work within the Institute. The Audit Report was produced on 22 August and concluded that the assistants' account of the experiments conducted was correct. Only GNA studies had been carried out with transgenic potatoes. There was no slowing of growth in the rats on the GNA potato diet. In addition, the results of the immune studies were far too variable to draw any reliable conclusions. Dr Pusztai was asked to comment on the Audit Report and to write up all the studies which had been completed in the proper scientific manner, ie with publication, after peer review, in appropriate scientific journals.

9.5 Dr Pusztai's contract

Dr Pusztai's post-retirement contract was very unusual. He should have retired aged 60 years on 8th September 1990, but we devised a scheme whereby we gave him annual Senior Research Fellowship contracts. His pension was supplemented to bring his total remuneration approximately up to his previous salary level. Annual reviews were made until Dr Pusztai was 65 years when he was still working intensely hard with major international collaborators and EU, Scottish Office and industrial projects. At that stage he wondered whether he could maintain his work rate for more than a further 2-3 years. It was agreed that he would certainly retire at the age of 70, if he had not done so before. Given the events of 11 August, the views of his collaborators and the possibility that the Institute would be challenged to hold another audit should Dr Pusztai generate controversial research inimical to either NGO or big industrial interests, we decided that his current post-retirement contract should not be renewed. He was therefore informed that he would be retiring on 31 December, 1998. He was also encouraged to continue his lecturing commitments and special arrangements were made to allow him to continue as a consultant with measures to protect his financial interests. Therefore, although he was retiring during the course of his 69th year, he still had the opportunity to continue to be involved. He was neither "sacked" nor "prematurely retired".

We also sought to re-establish Dr Pusztai's reputation by asking him to produce full scientific papers. He was also informed that attempts to justify himself by discussing unpublished data would not be in his own interests. Dr Pusztai was also informed that if his peer reviewed and published work showed that the Audit Committee had been wrong in its judgements, this would of course be accepted by the Rowett Research Institute. A press conference was also offered if this proved helpful. Thus the challenge that we "gagged" Dr Pusztai related to

our insistence that he only discuss published work when speaking to the media. His research collaborators would also have to be consulted and agree to any public statements.

9.6 Dr Pusztai's Alternative Report

Dr Pusztai did not in the end produce a response to the Audit Report but what be termed an "Alternative Report" on 22 October. This he sought to have published. Dr Pusztai disputed two conclusions of the Audit Report relating to (a) what is termed substantial equivalence and (b) whether or not organ weight changes had occurred. Dr Pusztai also provided further new unpublished data from a study which had still been in progress at the time the Audit Committee's analysis of completed work. Dr Pusztai's Alternative Report was sent to the members of the Audit Committee and considered by the Rowett's Governing Body who invited Dr Pusztai to set out his views to their Scientific Subcommittee prior to his publishing.

We considered that this Alternative Report was unsuitable for publication as we sought to maintain the almost universally accepted policy of not releasing unpublished data. The general reader would also have found it exceptionally difficult to integrate the original Audit Report and all its data with the counterclaims made by Dr Pusztai. We considered it in Dr Pusztai's interests for him to set out the whole sequence of experiments in a coherent manner for publication.

We agreed with the collaborating organisations the precise wording of the Rowett's response to the Audit Report for a House of Lords Committee's hearing on GMOs due on 28 October, but indicated to the Hearing that Dr Pusztai had further views which would be made public in due course. We also devised a mechanism whereby the conclusions of the Audit Report could be released but the extensive experimental data would only be made available on personal request. This allowed both a policy of openness in terms of issues of intense public interest and yet preserved the possibility for Dr Pusztai of a full publication of his work. We confidently expected to have an integrated account of these studies by the end of 1998 since Dr Pusztai has been prolific in producing with collaborators an average of 22 papers per year over the last five years.

9.7 Recent events

Almost one month ago we became aware of claims made by colleagues and friends of Dr Pusztai on the Internet suggesting that it was the fundamental mechanism involving the use of a viral promoter to insert the lectin into a plant which was a problem. It was claimed that Dr Pusztai's transgenic GNA studies had now shown this by virtue of Dr Stan Ewen's histological analyses made in October 1998, ie weeks after the *World in Action* programme. We requested information on this from Dr Ewen, a long time collaborator of Dr Pusztai's, but first saw data on the Channel 4 news on 11 February. This had been made public at a press conference held in the House of Commons. Further details then emerged in an article in *The Guardian*.

Given the much publicised press conference and the seeming need of many media channels to find dramatic evidence of food dangers, political manipulation or industrial pressure, we reluctantly decided to change tack and release the Dr Pusztai's Alternative Report. We also released Dr Pusztai from any restrictions on his analyses of his unpublished lectin work since no purpose was being served by our continuing request for dealing with these issues in the proper scientific manner.

At no time has the Rowett Research Institute been under any political, industrial or other pressures. It has sought throughout to maintain the most responsible approach possible from a public interest standpoint.

9.8 Conclusions relating to Dr Pusztai

Dr Pusztai's concerns about the need for devising new safety tests for transgenic lectins are, in our view, valid. We judge, however, that his experiments to date are far too crude and preliminary to justify any claims for novel findings of either lectin-related or general biotechnological significance.

1 March 1999

Annex

The Authors

Philip James was a member of the UK's Food Advisory Committee of MAFF 1976 to 1989; of the Committee on Toxicity from 1983 to 1989; of the Advisory Committee on Novel Foods and Processes from 1986 to 1998 and of COMA from 1990 to 1999, with Chairmanship of the subgroup on nutritional aspects of novel foods. He was an adviser and then a member of the EU's Scientific Committee for Food from 1990 to 1995. Membership included the Nutritional Subcommittee and the newly established Novel Foods Subcommittee which produced guidelines for the current EU system for assessing novel foods. He is currently one of the eight independent European scientists on the broad interdisciplinary Scientific Steering Committee (SSC) based in the consumer related DGXXIV and a member of the *ad hoc* committee dealing with all BSE and related issues in the EU. He generated the proposal which is now the current basis for risk evaluation of BSE and now deals with analyses of Human Risk Exposure. He also serves on the Chairman's *ad hoc* group considering a broader approach to GMO issues.

Andrew Chesson is currently a member of the EU Scientific Committee on Animal Nutrition (SCAN) established within DGXXIV to consider those aspects of animal feed production and nutrition which could affect consumer health and safety. He was also selected to represent SCAN on the EU subgroup which considers applications for the release of GM plants under Directive 90/220/ECC. In addition, he is vice-Chair of the Ad Hoc Expert Group on Food Safety established by the OECD to consider the harmonisation of approaches to establishing the safety of novel foods (and feeds) including those derived from GM sources.

Examination of witnesses (Questions 207 - 219)

MONDAY 8 MARCH 1999

PROFESSOR PHILIP JAMES and DR ANDREW CHESSON

http://www.publications.parliament.uk/pa/cm199899/cmselect/cmsctech/286/9030815.htm

Chairman

207. Professor James, Dr Chesson, thank you very much for being with us this afternoon and helping us in this inquiry; although I noticed, Professor James, that you were in the public gallery for the end of the first session, I know you were not here for the whole time. So can I just remind you that we are, in this Committee, doing an inquiry into Scientific Advice to Government, and we are using this particular episode as a case study, on the type of advice the Government receives or has to contend with. We have taken evidence from Dr Pusztai for just under an hour, and it would, of course, be very convenient to now ask some complementary questions of you, Professor James, and we are most grateful to you for coming along this afternoon to help us. Would you like just to introduce yourself and your colleague, telling us your position and a little bit about yourself; we would be most grateful?

(*Professor James*) Thank you. I am sorry that I came late but I was in Committee Room 8, on the Food Standards Agency. I am Professor Philip James. I am Director of the Rowett, and, as Dr Pusztai has just been saying, I have other responsibilities. I think that you all have received our paper.

208. We have, and thank you for it.

(*Professor James*) So that I have European and UN responsibilities, in addition. Dr Andrew Chesson is one of the most senior members of staff of the Rowett Research Institute, and, as you see from your papers, he is heavily involved in not only the animal nutrition aspects of monitoring on a European basis but also was selected by that committee to be on the Genetic Modification Assessment Group that I, as a member of the Steering

Committee, was particularly involved in setting up, because of our concerns. And he also has a very senior Vice Chairman's position on the OECD committee that relates to genetic modification.

209. Professor James, we shall direct our questions to you, in the first instance, and if you wish to invite Dr Chesson to answer, of course, we will be pleased to hear. And Dr Chesson likewise, if there is something pressing that you wish to say, please try to catch my eye and I shall call you to answer. But could I start with a very fundamental question, Professor James, regarding Dr Pusztai and his work and the World In Action programme - because we understand that just two days after the World In Action programme was broadcast Dr Pusztai was suspended from his work on GM foods, his contract was not renewed, and yet at the time of the broadcast our evidence seems to be that you were happy with the broadcast and the fact that he was going to broadcast and possibly bring some publicity to your Institute—what happened in the two days following the broadcast that made you suspend Dr Pusztai from his work?

(*Professor James*) Thank you for those questions, they are very important, because it has been quite astonishing how events have been misrepresented, and in the paper I tried to present the process precisely. And the fact is that Dr Pusztai, a very distinguished scientist of the Institute, had been involved in media pieces relating to his general concern, which I understand he has presented to you, and when World In Action approached him I thought it proper that he should be allowed to reiterate those concerns. It is not true that, in fact, we were happy with the events on the day of August 10 at all, I was completely appalled to come in and discover that, in fact, we had no idea what the programme was going to show, although I had been assured by Dr Pusztai that, in fact, it was, again, the general concerns only that were going to be broadcast. And we were confronted with a huge outpouring of demands from regulatory authorities, industries, across the globe; by 9 o'clock in the morning we were receiving between 30 and 50 telephone calls an hour, and there were extensive discussions about ConA transgenic experiments, which, in fact, we knew were not in the public domain.[9] And so this was completely contrary to all the agreement and understandings and apparent process that we had been through. We, therefore, myself, my Deputy Director and Dr Andrew Chesson, went to see Dr Pusztai and relieved him of what was an enormous onslaught by the media, by 9 o'clock in the morning, on the Monday, and we discovered that, in fact, he had been grilled for a considerable period of time. And we were exasperated that, in fact, there was all this unpublished data, in odd forms, with completely different interpretations, relating to ConA, already out in the media. And the dilemma was, we did not know. He assured us that there was nothing coming up in World In Action, but we had no idea what was coming up in World In Action; but, given the extraordinary intensity of debate about what was going on, we thought that it would be proper to put the lid on what was being talked about by giving the minimum information possible, which was actually almost irrelevant to the nature of the studies, in other words, the ConA transgenic potato. And that is why we, on the Monday, tried to contain it, and, despite the fact that Dr Pusztai had released this in what we all recognised was an improper way, I tried to defend him by, in fact, simply stating, on the basis of the evidence that he presented to us, that this was what had been done, that actually we would be taking any discussions to the committee, we did not intend that these results should be generated and out in the public domain until they had been properly scrutinised, and we presented the minimum information possible.

210. Did it occur to you, Professor James, that, if you were unhappy with the amount of media publicity that Dr Pusztai was receiving, or the answers he might be giving, you could just have asked him to cease giving interviews to the press, without necessarily suspending him and preventing him having access to his own work? Did you not think the suspension was a very harsh way of dealing with the matter? And did you give Dr Pusztai reasons for the suspension, at the time?

(*Professor James*) The first question relates to the reasons for the suspension; they were entirely different reasons, because on the Tuesday evening, having defended Dr Pusztai, despite the release of unpublished data, for two days, to our horror we were told by his assistants that the experiments had not, in practice, been conducted. And, therefore, we were suddenly confronted with what I termed a complete disaster, in that we appeared to be portraying—

211. Can we just pause there? We are now being told, in this Committee, that there had been results broadcast on World In Action from experiments that had not been conducted; am I right, is that what you have just said?

(*Professor James*) I did not say that, but that, in addition, is true.

212. Right. Please continue?

(*Professor James*) It is quite important to understand that, the discussion that had occurred, and you have to be clear that I believe that Dr Pusztai was confronted with an unusual scenario that he had never actually had to cope with before, which is why, on Monday morning, we withdrew him from the media circus; we did not suspend him. We then continued, and I requested that we saw all the data, because there were some extraordinary stories going round and we were being asked to receive delegations from all over the world, being flown in because this was now the biggest story. All my colleagues in Germany, Denmark, you name it, they were spending their whole time in television and radio studios. We still held, and I made it very clear, that we sent that right information on what I thought were ConA transgenic experiments to the Ministry of Agriculture, because I was appalled that this had actually emerged in this way. It was not until the second day, when the assistants returned, that, at a quarter to five, I turned and asked to receive those same results from the previous day, the transgenic ConA studies, and she looked at me as though I was crazy, because those experiments had not been done.

Mrs Curtis-Thomas

213. Could I ask, Professor James, why the James Provan press release was issued on the 10th?

(*Professor James*) I think that that was, I had telephoned him to say that we were desperately trying to contain things, and he decided to put out his own press release, because he believed, on the basis of what I had told him, having been briefed by Pusztai, that, in fact, there was a general issue. And, although I emphasised repeatedly that the ConA was purely a theoretical model and construct, the principle that Pusztai had already published repeatedly for five years still applied, namely, that, in fact, if lectins—and it had been taken to the Ministry, as I made clear in press releases and everywhere else, we would still need actually to take this on board. I think that Mr Provan, who is a Euro-MP, was apparently in a position, I discovered subsequently, where he was very concerned about the whole of the European Parliament's approach to this. So he saw that he should actually highlight the fact that we needed to evaluate these things properly. Of course, he is Chairman of the Board; I had no control over what he did. I knew that he was going to do something, and you now have that press release.

214. Did you actually see the press release, prior to it being released, to comment on its accuracy?

(*Professor James*) I saw the original press release and suggested verbal changes. I did not see the final one until it went.

Chairman

215. But you knew that Dr Pusztai did not see that press release?

(*Professor James*) Thank you for that reminder. I had forgotten that.

Dr Turner

216. There seems to be some confusion here, given that we have heard from Dr Pusztai—

(*Professor James*) I am sorry, I was not here.

217. That he at no time, on the programme, or in advance of it, spoke about experiments with ConA genetically modified potatoes, so it is hardly surprising that there had not been a series of experiments using such potatoes. Yet you are telling us that one of the reasons for his dismissal was that you had the impression that he had been talking about experiments on ConA genetically modified potatoes and were horrified to find that no such experiments had actually been done, when Dr Pusztai tells us he had never said they had been done and obviously had never done them. Am I wrong in being slightly confused here?

(*Professor James*) No, you are not wrong in being confused at all. And the point is that we subsequently discovered, on the Monday night, when the programme came out, that ConA, as such, had not been specified. But when, in the morning, everybody was talking, and I think we could look for the transcript of BBC programmes, where the correspondents had been in discussion with Dr Pusztai, as I was informed—I had no proof of that—they were talking about ConA transgenic experiments of 110 days with five rats per group, and so on. And when I went down and saw and discussed this, we all came to the conclusion that, in fact, we were being presented, apparently, now, incorrectly, with transgenic ConA studies. I managed the media circus at the

Institute and Dr Chesson went to the BBC studios and did three hours, trying to defend Dr Pusztai's whole views, on the basis that, unfortunately, ConA transgenic data had been leaked.

218. But it did not exist, so how could it have been leaked, as we are led to understand?

(*Professor James*) Yes, exactly, but we actually understood that the transgenic ConA studies had been conducted; so did the media. We actually, on the Tuesday evening, turned and asked to see the transgenic ConA, and only then discovered they had not been done. I then actually had Dr Chesson coming to me, and I said: "Dr Chesson, Andy, do you realise that they haven't done the transgenic ConA?" and he said: "You must be joking. I've actually been defending Pusztai all yesterday on the media, on the basis that these transgenic did show this", and so on.

219. So where did those mythical experiments come from?

(*Dr Chesson*) I think there is some slight confusion. There was a long-term study made with conventional potatoes, to which—

Examination of witnesses (Questions 220 - 239)

MONDAY 8 MARCH 1999

PROFESSOR PHILIP JAMES and DR ANDREW CHESSON

220. Spiked with ConA?

(*Dr Chesson*) Spiked with ConA, and I think that is simply where the confusion came in, that this had been presented, and certainly implied in the World In Action programme, that these were actually transgenic potatoes when, in fact, they were not.

Dr Gibson

221. Who wrote the press release, on the Monday; who wrote that?

(*Professor James*) It was a mixture of three of us, Dr Pusztai, Dr Chesson and myself.

222. But Dr Pusztai denies that he did it; you said he saw it and had ratified it?

(*Professor James*) That, strictly speaking, is not true. I first drafted something, and I cannot now remember the sequence. Dr Pusztai rewrote a whole segment of it and Dr Chesson did. The error on that one was not only that I wish I had delayed it for two days. In fact, that would have helped us a lot, at the Institute, but the other thing was, none of us actually double-checked the press release, so Dr Pusztai did not see that final check, I think.

Dr Williams

223. On that Monday morning, when there was all the publicity, should you not just have called Dr Pusztai to come to see you, and all of this confusion of the ConA would have been resolved in five minutes, over coffee?

(*Professor James*) I am terribly sorry, you have not understood. I had two and a half hours with my deputies and senior managers, interrogating the team about all their research, and, on the basis—

224. Including Dr Pusztai?

(*Professor James*) Yes, of course.

225. And yet there was this confusion about experiments that had not been carried out, over ConA?

(*Professor James*) Yes.

Chairman

226. As we understand it, Professor James, you decided not to renew Dr Pusztai's contract before you had got the results of the audit: why was that?

(*Professor James*) As I made clear in my submission, Chairman, that decision was only made on Tuesday night, and it was not a dismissal, which were the words used, Dr Pusztai was not sacked.

227. A failure to renew contract, is what I used, and I think you will probably agree that was correct?

(*Professor James*) That is correct, and the decision was made, as I specified, that, in fact, Dr Pusztai had actually presented information which turned out not to be true. There was confusion in his group as to what studies had actually been conducted; his collaborators, as I point out in the paper, were outraged, in two different dimensions of calibration, and said that they now wanted to have a completely new arrangement in working with the Institute. That was not at my initiative, that was spontaneous, on the Monday and the Tuesday, and I have had to cope with that, systematically, since. And the third issue was very simple, that, as I again put in the paper, Dr Pusztai had now gone through seven, or whatever it is, post-retirement contracts. He was now coming up to the 68th birthday, his 69th year of the time, and we normally deal with a series of three-year programmes; we had agreed that he would not go beyond 70. I was confronted: if I gave him another contract, and he came up with some lectin experiment that was startling in its nature, people are going to turn round and say: "Have you had that audited, and was the experiment right?". And, on that basis, I decided that, in fact, it was inappropriate to actually continue his contract; but we took explicit care to make sure that his expertise could continue in a consultant mode, and we went through great trouble to do that.

228. Were all decisions at that time taken by you, your colleagues and the Institute, free of any interference from London, or Whitehall, or the Cabinet Office?

(*Professor James*) Totally free from any influence, at any level, whether it is political, industrial, please name it, it was based exclusively on the whole issue of how one conducts a world-class institute, where it is not allowed to present unpublished material.

229. And you had no `phone call from Whitehall or the Cabinet Office, suggesting that what was going on might be detrimental to the nation, and you should do something about it?

(*Professor James*) If I had, I would have ignored it, Chairman. I did not have it.

Chairman: So the answer is, you did not.

Dr Jones

230. Dr Pusztai said that the Rowett Institute's press officer was present at the filming; is that correct?

(*Professor James*) Only for the first part; she had to leave, for complex reasons, which I only discovered much later, to my horror.

231. And, in relation to this confusion over the ConA—I have just looked at the transcript and there is no mention of ConA in the transcript; I have only had a quick look.

(*Professor James*) No, no; if I try—but do you want to answer that?

(*Dr Chesson*) There is an implication, because the transcript refers to two series of long-term experiments, and the only two, long-term, 110-day experiments conducted at the Institute were one with the spiked ConA and one with a transgenic modified potato.

232. Yes, but, surely, if people were familiar with the work of Dr Pusztai, they would realise that ConA is obviously a very damaging toxic compound, whereas the GNA is much milder, so it is much more likely that he would be working with GNA in these kinds of experiments, surely? Surely, your experts would have realised that? Where did this ConA come from?

(*Dr Chesson*) It was part of Dr Pusztai's experimental programme, and it was used—

233. But not on GM?

(*Professor James*) Yes.

(*Dr Chesson*) Yes, it was, actually.

(*Professor James*) Here is a statement, which is in the transcript of the World In Action programme, the whole of which effectively states that two different transgenic potato lectin preparations were being tested; and I, of course, on Monday night, assumed that was true.

Dr Gibson

234. Is it cloned, the gene, into another promoter, the ConA; had you got it cloned?

(*Dr Chesson*) The ConA potatoes have never been tested; they were produced, but the programme ran out before they were ever actually tested.

Dr Jones

235. They have never been tested, and you mention ConA; it might be understandable if you had put both of them in, but you have only mentioned the ConA, not the GNA. I just cannot understand it. You said, Professor James, that Dr Pusztai had become confused about which experiments had actually been completed; it seems that the Institute is very confused about what ...

(*Professor James*) I am astonished that you should say that, except in relation to the event. You were quite right that we were really very confused about what experiments had been conducted. We knew that there were two experimental transgenic potatoes that were going to be tested, and we were shown, the only data that we were shown on a long-term basis, on the Monday morning, was the ConA data.

236. So, in relation to this press release, you say that Dr Pusztai rewrote a paragraph; what does that paragraph refer to? Which particular bit would you say he had a hand in?

(*Professor James*) If you are talking about the first press release—

237. The one on 10 August?

(*Professor James*) He had the opportunity of looking at it all, of course.

238. So, even though he did not see the final press release, he would have seen—

(*Professor James*) He effectively saw it.

239. He would have seen a press release which referred to ConA experiments and not to GNA experiments?

(*Professor James*) Absolutely; that is absolutely right.

Examination of witnesses (Questions 240 - 259)

MONDAY 8 MARCH 1999

PROFESSOR PHILIP JAMES and DR ANDREW CHESSON

240. What were you hoping to achieve, in agreeing that Dr Pusztai would appear on World In Action?

(*Professor James*) I was hoping to achieve the statement that under no circumstances were we in the business of suppressing any scientist with disparate views, if those views had been published, and he had actually presented his views on two previous television programmes. I thought it was entirely proper for Dr Pusztai to be able to highlight the fact that if lectins were being used transgenically we had to be clear about the potential effects of those lectins, not just on insects but also on the mammalian gut.

241. And did you make it clear to Dr Pusztai, in agreeing that he should appear on the programme, that he should not discuss unpublished results?

(*Professor James*) Absolutely, and repeatedly.

242. Do you think there are any circumstances when it is acceptable to discuss unpublished research, publicly, in this way?

(*Professor James*) That last phrase allows me to say, I do not think it is.

243. And yet your press release discusses unpublished research; it refers to preliminary findings?

(*Professor James*) Yes. That is why that was an issue. What were we going to do, everybody was talking about all this data. Our attempt was actually that that was the only statement that would be made, which I deeply regretted having to make, at the time.

244. So, whilst you did accept that more research needs to be done, you do not make it clear that these are unpublished results and that, normally, you would not discuss unpublished results, but you have been forced to do so because of Dr Pusztai breaking what you saw as the agreement that he should not discuss unpublished results?

(*Professor James*) I think I should have had a relook at those press releases. If you look at the bottom of that press release, I think it just does talk about that we are not in the business of presenting unpublished data and we are going to process it through the proper channels, does it not?

245. It says they are going to "be extended and a full analysis will be published as soon as possible."

(*Professor James*) That is right.

246. Be extended? it is still your intention to extend these experiments?

(*Professor James*) The experiments are still under way.

Dr Williams

247. There is a real problem for us here, and that is that you say that it is not right to discuss unpublished work; as I understand, all of the evidence taken by the advisory committee in that report comes from the commercial companies, all of that is unpublished. This is not democratic, is it? We cannot discuss the evidence because it is not published; there is no published evidence. So we leave it completely to the advisory committee and its good members to take all of these decisions on our behalf, where all of the evidence comes, simply, in good faith, from the commercial companies?

(*Professor James*) Now you are shifting, through you, Chair, the—

248. There is a hollow democratic deficit here, is there not?

(*Professor James*) I think it is a very fair challenge, that much of the information that comes into these expert groups comes from commercial companies, usually in a confidential mode, and there is a need to make sure that there is public interest research in this dimension. But I think it is unwise for you to put the strict parallels between a scientist presenting data actually which had not been done, but let us leave that for a time, but scientists who produce evidence that has not been scrutinised by others and peer reviewed and then suddenly talking about it in public, that is a different point. If you had said to me: "Why shouldn't Dr Pusztai's unpublished data go to the Novel Foods Committee, in comparable mode to that of commercial data?", of course they should.

249. But how is the general public out there to decide on the safety of GM foods when nothing is published on the safety of GM foods?

(*Professor James*) That is why, Chairman, in our submission, we actually take this on. You have been concentrating—and I have suddenly realised, at the beginning—you are making the Dr Pusztai episode as an interesting thing to try to unravel the process of advisory groups. It seems to me that—forgive me for saying so—it is not really a very good way of exploring the issues, because, as we set out in the first two-thirds of our paper, there are major questions of concern, and it really is quite important to try to get it right. I think that, what I termed at the time the muddle, is actually singularly unhelpful, in any mode of operation. What we have been attempting to do is to suggest a new principle in terms of food standards; I have actually been going for

the principle of openness. So there is absolutely no suggestion, under any circumstances, that I would have suppressed Dr Pusztai's views, if they were difficult for a government, or industry, or anybody.

250. But you have?

(*Professor James*) I have not.

251. He was retired with a gagging clause.

(*Professor James*) He was retired with the specific injunction that he should produce the papers through the proper scientific mode, and then I offered him, publicly and in writing, a press conference as soon as those were published.

Mr Beard

252. You announced an audit of Dr Pusztai's work the day after all the concerns were raised about the interpretation of his research. Why did you conduct this inquiry through an audit mechanism, when audits are usually associated with investigating fraud?

(*Professor James*) Because there was a system in Britain, with the Medical Research Council, where, frankly, we had been assuming for two days that there had been a whole set of experiments, and, as is displayed in our evidence, factually, those experiments had not been conducted. In fact, the major study, the accounts on the immunology, had not even been started. On the Tuesday, when I discovered this, let alone when filming took place, there were groups telephoning us, across the world, saying they did not believe a word of it and they wanted to come and see the primary data, because they did not believe that the studies had been done. Therefore, it was a defence of Dr Pusztai. I did not for a minute believe that Dr Pusztai had actually been guilty of fraud. That is totally out of character, and, therefore, he was temporarily suspended for 12 days, and only from that part of his work relating to lectin.

253. Do you accept Dr Pusztai's assertion that the audit was not conducted properly?

(*Professor James*) Dr Pusztai actually does not believe that the individuals who were chosen to conduct that audit were competent across the range of expertise that he construed to be appropriate. Following that audit, he received the audit's report, was asked for comment, we think we went through the proper procedures, and he was asked for comment and he was invited to present his views to the Scientific Sub-Committee. He was invited to present his views to a broader grouping, and, in the end, as a result of our discussions, we came to the conclusion that we did not want to proceed with these alternative processes, as I understood it. And after a very short time Dr Pusztai wanted everything in writing, and therefore it was much more difficult to have the sort of discussions that you might expect me to have. And, therefore, if you look at the correspondence, we were desperately trying to nurture an outstanding scientist, who has done an enormous amount of good work, but who had now got himself into a terrible fix. The best way to actually cope with that, in my view and in the view, I believe, of most scientists around the world, was to process it, and we were desperate for him to process it rapidly for publication. That has not happened, unfortunately.

254. In the background paper that you gave us, Professor James, it refers to a fear that Dr Pusztai continuing with his research might "generate controversial research inimical to either the NGO or big industrial interests". Is that a good reason for retiring him?

(*Professor James*) No, it is not; but the point is that if, in fact, without this saga, we had not had to institute an assessment of whether or not, in fact, he had conducted the studies, that would not be an issue. In my Institute we have 20 groups, often doing highly controversial research, in relation to NGOs and so on; the problem was that we would be challenged in the future. If you have had to look to decide whether those experiments had been done on this occasion, how are we going to cope with the challenge, did he do it, did he actually conduct these new experiments? And the logic of that was, let us get around and have a different system, where we are not faced with that challenge; it was a logical consequence, it seems to me.

Dr Gibson

255. It has been quite a PR disaster all the way through really, has it not, and there is plenty of experience, in the Food Research Institute and in cancer developments, that people go to the press with stories, and it does

not end up in this terrible way? How would you stop it happening again, what lessons have you learned, and how would you organise things better?

(*Professor James*) Thank you for that question, because I think that one of the most startling things that came to me, and the same was spontaneously said to me by my colleagues throughout Europe, was that the media response to this story was truly quite beyond anything I had ever imagined. And, just to give an illustration, we were `phoned to be told that, on German television, all three channels were going with updates every three hours, on what was new and what we could do, and it was accelerating from the Monday, through the Tuesday, into the Wednesday. And I think that what has come home to my colleagues, as well as myself, is that when we are dealing with these issues, we, in the scientific world, have underestimated the extreme anxiety about food safety that relates to these mysterious processes that are controlled distantly from the individual. I do not think that I had understood that. So I actually believe that we should have taken, in retrospect, far greater precautions to make sure that Dr Pusztai was helped in not actually even putting a nuance across, in World In Action. In retrospect, it would have been wonderful, would it not, if he had not taken part; but that is retrospect.

Dr Jones

256. Would it not have been better to have made sure that he said accurate things on the programme?

(*Professor James*) Exactly.

Mr Jones

257. You say that you underestimated the public concern. Why did you underestimate it; and do you think that the public concern has been heightened because of disasters like BSE?

(*Professor James*) Why did we underestimate it: every individual that I know involved in food safety, public health, throughout the globe, has been astonished by the reaction. So I am not alone in being phased. And what I have been trying to do, in response to Dr Gibson, is to learn from that. And what I think I have learned is that we have, as a society, completely underestimated the way in which—I do not think it is just BSE—that has amplified it in Britain, but if it were just BSE why would one have the same extraordinary response in Japan, Australia, Denmark, Finland. I think it is the fact that we are in a new dimension relating to food and safety and public health. I did an analysis for the European Union, to try to persuade them of this problem, and, if you actually analyse the public's approach, they are terrified by something over which they have no control, that is either unnatural, that they are not told about, and so on, and so on, and you can categorise the ten things—

Dr Gibson

258. But, Professor James, all you had to do was to pick up a `phone to Grahame Bulfield, at Roslin, who went through the same experience, did he not, with Dolly the sheep, thousands of cameras there, but they handled it much better; the unknown human cloning, and so on, they did not have the same repercussions? There was an instant reaction from politicians, in the States and here, on that issue. So why had you not learned from that experience, and it is in the same country, after all?

(*Professor James*) Thank you. Talking to Grahame Bulfield, they actually realised that they were into a mega-issue, and they prepared for it beforehand. In fact, Graham decided to put a team, if I remember correctly, he was talking to me about this a short while ago, I think it was a team of six, they decided to assign to it; they found that they had to completely change their strategy, but, in fact, they were astonished themselves. But they did not have, one, a completely unexpected thing; two, the whole issue of human cloning was a consequence of this concept, it was not a direct issue relating to something that actually was being fed to you in the supermarket, over which you had no control, and so on and so forth. I think it is not fair to make the parallel.

Chairman: We have only got a few minutes left. We have got five questions really, on advisory systems and regulatory bodies, and the first one is with Dr Kumar.

Dr Kumar

259. In your submission, you say that "the UK has an exceptionally good reputation for the quality and the range of scientific advice available to it for policy-making purposes". Would you say that the structures

providing that scientific advice are suitably open to inputs from non-scientific quarters; and how important is such input?

(*Professor James*) I think it is well known that major groups of industrialists are very keen, it would only be understandable if they looked at the various groups of advisers and attempted to make sure that they understood where those advisers were coming from; so I think that the industrial interest in advisory groups is extraordinarily intense. That is why I believe that these advisory groups have to operate in a very open and proper way, and that was part of my series of proposals for a Food Standards Agency.

Examination of witnesses (Questions 260 - 267)

MONDAY 8 MARCH 1999

PROFESSOR PHILIP JAMES and DR ANDREW CHESSON

Dr Turner

260. Do you think the principle of substantial equivalence to assess the safety of novel foods is satisfactory, both for food safety and consumer confidence?

(*Professor James*) Answer, no, and we set out in detail why we think that there are new approaches to that. One can get into a wonderful, four-hour debate on what one means by substantial equivalence and its implications in the regulatory process for sifting data. I do not know whether Dr Chesson would like to add anything on that.

(*Dr Chesson*) Yes, I think there is a tendency to assume that all genetically modified foods are equivalent and much the same thing. I think there are some areas in which substantial equivalence plays a much more important part than in others. I do not particularly have any great concerns about the relatively few constructs which have gone through the regulatory systems in the UK and in Europe to date, but I think we are looking at such a very large, potential range of transgenic crops and foodstuffs in the future that I think the whole concept, the framework, of substantial equivalence will assume increasing importance. And, I think, used in the way that it is currently used, I do not think it will necessarily be adequate for that purpose.

261. Do you want to see any changes, that you would want to recommend, to both the principle and the practice of the Advisory Committee on Novel Foods and processes' assessments?

(*Professor James*) We proposed in our papers that, in fact, there needs to be a much more proactive approach to developing novel science, which, as it were, goes in parallel with these exciting developments in molecular biology. And we believe that, in fact, there is a series of scientific technical innovations that can be applied to enhance the confidence that we have that there are no unpredictable effects, as a result of transgenic inserts. And Dr Chesson, as a result of his detailed analysis of the various portfolios being put forward, and because he is involved both personally and in an Institute that is involved in trying to develop these novel techniques, we actually believe that there are mechanisms now that are coming into play that we should actually begin to use, and would give greater confidence both to the professionals and to the public.

Mr Jones

262. Can I ask you about labelling of GM foods. What changes would you like to see, and how far should labelling go? Should you, for instance, have to label products which are not genetically modified, apart from the root of the product, which might be modified, in order to make it less attractive to pests, or frogs, or whatever?

(*Professor James*) I think that the issue of labelling, in terms of GMOs, is at present a mechanism whereby people might be allowed to discriminate, and it is a standard response which is totally to be expected. But where we come from is that, as you look at what is happening out there, I find it very difficult to believe that any labelling mechanism is going to be of any use in ten years' time. And that is why we have spent so much time trying to think how to enhance the safety assurance of the GMO process. We think that that is more important than trying to devise ever more complex and, essentially, difficult systems to monitor GMOs. I do not believe that in the future this is going to be possible, unless you create a complete, separate food system,

where, under no circumstances, are GMOs used at all. Otherwise there are going to be GMO plants throughout the food chain.

Dr Jones

263. But that will not work for products that have already been approved, will it; we will still need labelling for those?

(*Professor James*) Sorry. That is why I prefaced my remarks. I think there is labelling now, and the standard response is: "We must have labelling", fine, I am not against labelling. I am just saying that, actually, if you look at it, I do not think it is going to work. That is all I am saying.

Dr Williams

264. First, I just want to tag on something to that area. You say that, in ten years' time, you take it that there is an absolute inevitability that our food production, in ten years' time, will be dominated by GM crops?

(*Professor James*) I did not say dominated, but that, in fact, there would be so many GM crops that they would, essentially, pervade the food chain.

265. My next two or three questions are on the proposal by the Royal Society, amidst others, that there ought to be some overarching body, above the Advisory Committee on Novel Foods and Processes, above ACRE and above, perhaps, the Food Standards Agency, too, in this area. What is your view on that proposal?

(*Professor James*) As I put in our report, I think that, obviously, it is important to have the linkages made, but I do believe, at the moment, and Dr Chesson may disagree with me, that the environmental issues are really very complex and very different from the health issues. Therefore, I see that the health issues will predominantly relate to the Food Standards Agency, but I do believe that the overarching system proposed by the Royal Society, in effect, under my original proposals, would be dealt with by virtue of conjoint groups, between Environment and Food Standards Agency, for example.

266. Where would consumers fit into that structure?

(*Professor James*) That is the beauty of the Food Standards Agency, if it goes through, the consumer representation, public interest representation, is extremely important, and that is why it should be there.

267. Right; but we heard earlier on that the Advisory Committee on Novel Foods and Processes has one consumer representative, one ethics specialist, and, otherwise, I do not know, eight or ten food company and academic scientists in this field. What kind of balance would you see within the Food Standards Agency and within, if there were to be an overarching body, should not the consumers have something like a third of the total representation, not just a token one?

(*Professor James*) I think it is important that I make a distinction between consumer and public interest, I think it is better to talk about the public interest, not just about consumer groups. I think that I have never thought it wise to specify a proportion, but I totally agree with you that tokenism is inappropriate, and I do believe that, if the public, in Britain, and, indeed, in Europe—it is the same—if we are going to make any headway, in terms of trying to properly allay and not simply con people, I think there is a need for a completely different process. And that is why, to go back to the Pusztai affair, for me, personally, it was so tragic, because, in fact, there are legitimate issues of science which Dr Pusztai had contributed to so marvellously, and the question is how to get these legitimate interests locked into a process. I have been trying to do that for quite some time. I do not think we have got it right, and I think we are going to have to evolve a system, because if we do not do things better than we do now we are going to be running into a crisis every few months.

Chairman: I am going to finish there, and I am going to finish on that note, because I was delighted, Professor James, that you felt generous and honest enough to finish with a tribute to the work of Dr Pusztai over all the years that he has been an experimental scientist. And, although there has been controversy in these last few weeks, it is very heartening, I think, for this Committee to hear you pay tribute to Dr Pusztai in that way at this time. However, may I thank you for your evidence this afternoon and the evidence you gave us in writing before the Committee meeting; can I thank you, too, Dr Chesson, for the support you have given; and thank you both for assisting us in this difficult but very interesting inquiry. Thank you.

Supplementary Memorandum submitted by the Rowett Institute following the evidence session

of 10 March 1999

http://www.publications.parliament.uk/pa/cm199899/cmselect/cmsctech/286/9030819.htm

The evidence that ConA transgenic potatoes were the prime interest of Dr Pusztai in his discussions with *World in Action* and the media prior to the Rowett's discovery of this unpublished data in the public domain is overwhelming.

1.The *World in Action* press release sent out well before the broadcast, ie during or before the weekend of 8-9 August, states: "Scientists have discovered that rats fed genetically modified potatoes suffered stunted growth and damage to the immune system after a 100 days".

NOTE: Dr Pusztai only had data of stunted growth in his ConA (Jackbean) studies. The GNA (snowdrop) studies showed no stunted growth as he re-emphasised to Prof James and Dr Chesson on the morning of 10 August. In terms of immune results, there were none on genetically modified potatoes fed for 110 days at the time of the broadcast, let alone when filming took place in June. The only data available were on ConA treated potatoes and these turned out to be the spiked, not the transgenic potatoes. Only late on 11 August was this revealed by Dr Pusztai's assistant. The Rowett had no knowledge of the ConA studies until the morning of 10 August, nor any media contact relating to GMOs until the afternoon of 10 August.

2.National newspapers quoted evidence on ConA or the Jackbean in their editions available on the morning of 10 August. Thus *The Express* newspaper's environmental correspondent John Ingham states: "British scientists showed for the first time that a crop given the genes of another species could cause health problems in animals which ate it".

"They found that rats fed potatoes given a bean gene suffered from slightly stunted growth and were likely to be more vulnerable to disease. The expert who led the governement funded research claimed that the British public were being treated like `guinea pigs' in the rush to bring GM foods on to the market."

"`Professor Pusztai fed rats for 110 days on potatoes given a bean gene to make it resistant to insects. He said: `these potatoes are designed to affect insects, so we wanted to know what impact they would have on higher mammals'."

"`The effect was slight growth reductions and an effect on the immune system. We do not know whether it was temporary or irreversible.'"

NOTE: In this *Express* article quotations are used for text which was not in the *World in Action* press release so presumably came from the personal discussions between Dr Pusztai and *The Express* newspaper as stated by Dr Pusztai. Only ConA transgenic experiments are discussed in relation to GM foods with no mention of GNA transgenics.

3. *The Times* on the morning of 10 August contained an article by Nigel Hawkes entitled "Gene potatoes damage rats' immune systems". The article specifies "Professor Arpad Pusztai of the Rowett Research Institute" as providing him with a series of quotes throughout the article. The third paragraph has Nigel Hawkes' account of the studies as follows: "the trials have been carried out on potatoes carrying genes from both the snowdrop and the Jackbean. The genes are responsible for producing proteins called lectins, which protect the parent plants from aphid and nematode attack. Potatoes resistant to these pests could be valuable."

"But lectins are known to damage immune-system cells, so the feeding experiments with rats were designed to see if the damage occured when the lectins were present in the potatoes. In the case of the snowdrop lectin, no such effect was observed, but the jackbean lectin did suppress the immune system."

Then Nigel Hawkes quotes as from Dr Pusztai as follows: "`The feeding trial went on for 110 days, equivalent to 10 years in human terms. The result' he said `emphasised the need for proper trials of all modified crops.'"

"`If you start with the idea that a gene isn't toxic, and just go through the motions, you won't find anything,' he said. `But that isn't good enough. You have to really demonstrate that there are no harmful effects. Our modified potatoes will only be released after such tests have been completed, and I can tell you that the one with jackbean in it will not be released at all.'"

NOTE: Dr Pusztai identifies the Jackbean-modified potato study as showing the toxic effects and implies that there were other studies, presumably with the snowdrop, referred to by Nigel Hawkes as the experiment of lesser concern.

4.Reuters, London, 10 August. "Genetically modified potatoes can damage the immune systems of rats, according to British research released today that calls into question the safety of the new food technology".

"Professor Arpad Pusztai of Aberdeen's Rowett Institute said he had fed five rats on genetically modified potatoes that carried genes from the snowdrop and jackbean for 110 days—equivalent to 10 years in human terms."

"His research showed that the rats suffered from slightly stunted growth and were more likely to be vulnerable to disease. It was thought to be the first time that trials of genetically modified food had showed harmful effects."

NOTE: This release may explain the global interest in the stunted growth and vulnerability to disease (elsewhere related to the immune system) which was the basis for all telephone calls from 9 am on Monday, 10 August 1998. All the telephone calls related to ConA (Jeackbean), presumably because the immune data and stunted growth only applied to the supposedly completed ConA transgenic data.

5.Evidence from the broadcast *World in Action* programme itself on the evening of 10 August 1998. The transcript specifies as follows:

"Andrew Brittain: `Rats have fed two different kinds of genetically modified potatoes which are not on sale and have never been eaten by humans. The rats ate them for more than 100 days, the human equivalent of 10 years'."

Later by Andrew Brittain: "animals fed on one kind of research potato remained perfectly healthy. But rats given the other set did show ill-effects. The Professor is so concerned about the implications of his discovery, he's decided to publicise his findings early. Tonight, he reveals them for the first time".

Arpad Pusztai: "The effect was slight growth retardation and an effect on the immune system. One of the genetically modified potatoes, after 110 days, made the rats less responsive to immune effects".

Note: On 10 August Dr Pusztai had no immune results from any genetically modified potato experiments fed for 110 days. Professor James and Dr Chesson were told on Monday morning 10 August, by Dr Pusztai, to ignore the GNA studies since they showed no effects. Professor Bremner, Deputy Director of the Rowett, was also told on the afternoon of 10 August by Dr Susan Bardocz, leader of the Pusztai team, when challenged as to whether spiked or transgenic ConA studies had been conducted responded that they had "looked at all combinations". It was the Rowett's insistence on seeing all the data, particularly on GNA, which led on Tuesday evening, 11 August, to the discovery that no transgenic ConA studies had been conducted and that no immune studies were available on 110-day-fed transgenic GNA potato experiments.