

Heads of **U**niversity **B**iological **S**ciences

A One-Day Autumn Meeting of the Heads of University Biological Sciences, was held at the Royal Institute of British Architects, 66 Portland Place, London W1N 4AD, on Friday November 16th, 2001.

'THE EFFECTS OF RECENT LEGISLATION ON RESEARCH AND TEACHING IN THE BIOSCIENCES'

Introductory Remarks – Professor Paul Brain, Chairman of HUBS

Professor Brain graphically illustrated the impact of legislation on research and teaching in the Biosciences by looking at changes in these activities over his life in Higher Education between 1964 and the present. He was of the view that most of the changes (in terms of Health and Safety and Staff Development) were clearly beneficial but did note that legislation could exert a toll in terms of costs and administration time and could occasionally inhibit expressions of originality by undergraduates and postgraduates. It was also occasionally difficult to persuade staff to take on some of the associated responsibilities. Professor Brain hoped that the meeting would provide insights on how to stay ahead of the legislation 'game'.

The origins and development of legislation for the Biosciences – Dr Ian Gibson MP

Until 1997, I was Dean of Biology at University of East Anglia in Norwich. We drove the department up eventually to a grade five, through hard work and by working politically. We knew what messages to pass on and worked hard to achieve our aims. I wish I had known then all the things that I have learned from working in

Parliament. You pick up tricks of the trade in politics. There are some things that I would love to have time to put in a book. I still go back to my old department at UEA and visit those working there. I talk to staff about the problems they have getting through to the Department of Trade and Industry and research councils etc. Lecturers invariably complain about the various stresses and strains put on them and one has to assess whether these pressures are really necessary or not. Understanding some of these pressures, involves going back to the origins and development of legislation.

I undertook a small survey, asking different groups of people where they thought legislation originated. Media people said that legislation originates from them. They report issues, stir up any problems and make sure that politicians hear about them. The Senior Civil Service think they originate legislation. Backbenchers feel they bring problems to the media's attention, create some 'hype' around an issue and so they feel that they are the originators of legislation. My feeling is that it is never possible to trace exactly where legislation originates. It is like trying to pin down where original ideas come from, you can never find out because people always claim them for themselves.

Views, from the Universities I am involved with, generally come from the Vice Chancellor's Group. They have higher education meetings in London at which we have some real battles. I feel that there is still a feeling amongst politicians that universities don't do all the things they claim to do. They feel that the staff have long holidays and live an easy life. We have to move on from the view that Universities simply moan and re-educate the Government to find new ways of getting money into the system and new ways of doing things. The problem is that Government has made changes to the primary school system and is just starting to modify the

secondary school system. Nothing fundamental has happened to our Higher Education system as of yet. Margaret Hodge is starting to look into this topic but needs a steer, not from the Vice Chancellors, but from people like you. People who lecture in the universities are the people who can tell the government what is really going on.

You are all doing research and administration as well as teaching. Consequently, you will know that there is much legislation concerning biological materials, human embryos, and animal experiments. Legislation influences the way you work. All the new regulations and controls mean new forms to fill in and more administration to carry out. Much of this seems unnecessary to you and me and I am sure you have sat in your offices wondering who controls the release of new legislation. How does Government make new regulations? How does it come about? Why are some things highly regulated and others not? I am going to try and explain the process. As both employers and employees, legislation is important because it has an effect on our terms of work.

When I walked out of my University, I had no help in setting up my office. I got a grant but had to organise the set up of the office as well as hire people and be concerned about the provision of their pensions and contracts. In Universities, you have personnel departments to help you do all these things. They make good legal provisions as employers.

The Government really did get egg on its face in the recent stem cell debacle. I think I made better speeches then than I ever did in the days when I was lecturing, because I really cared that this work should be carried out in this country. It seemed for a while that UK Science was ahead of this game. We thought the legal advice we

had from the Government was fine because we cross-referenced everything. We asked, "Can we still do this 'so called' therapeutic cloning under this legislation that has just been passed?" I didn't think that we were going to win as we had so much opposition from religious lobbyists. We had to work really hard to overcome this. The Learned Societies got active very late in the process. The Royal Society thought they did their bit producing their usual 6-page document (which MP's never read anyway). If you want an MP to read something make it a half side of A4. This is not because they are lazy but because that is all the concentration time they have. MP's are inundated with information and ideas from different people.

We eventually won the stem cell debate after three big sessions. All were very good including impressive debates with all of the facts. The pressure groups were worried that scientists would create a human embryo. As scientists, we know how many attempts it took to create Dolly the sheep, and all about gene interactions. Now, of course, it turns out that the Pro Life group convinced a judge that the 1990 Act didn't cover nuclear transplants, as the only way to create an embryo was by egg and sperm fertilisation. There will have to be some emergency legislation.

I don't want to go into the details of how politicians try to understand science but very few scientists ever go into politics. I think that there are six MPs at the moment who have some degree of understanding of how science is carried out. I asked Blair, did he think he was on top of the Genetic Modification question? It turned out that the day before, they had had a session on the Genetically Modified Organism issue but it took Tony twenty minutes to answer. After he had finished, I suggested that, if the answer took him twenty minutes, he was obviously struggling a bit.

As a scientist one can never give a simple yes or no answer. Sometimes, we don't know the answer to a question and sometimes we can only be sure to a degree that we have the answer. Also, there will always be someone, arguing against our view. Politicians don't understand that kind of level of debate. They want to operate in a black-and-white world. I think that is why sometimes the lawyers mess the whole thing up by trying to encapsulate everything into documents.

A list of amendments will be rushed through next week because of the events of September 11th. I am currently involved in writing a new document on Anti-terrorism and Security, affecting every one of you. Not because you really have terrorist property but because of what you keep in your labs. There will be a long list of toxins and organisms that you will need to keep accurate records for. It will mean more paperwork for everyone. Scheduled inspections will take place as well as surprise inspections to ensure everyone is complying with the new amendments to the legislation.

There is also another world that you are involved in, namely patenting. We are now moving into a 'knowledge-based economy'. That world is expanding and will be funded for many years to come. Patenting is all about wealth, competition and a globalised economy. This activity may be used eventually to measure the success of departments. We have to ensure that this is not the only measure of the worth of departments.

I would much rather see an index reflecting how Universities interact with their local communities. I remember a forty-page document on this topic needing twelve extra people in each department to implement it (one could not expect departments as

they are staffed now to take on the huge increase in activity). They would include many things of value including taking science to the community, talking to Women's Institutes and taking science into schools. I know that many of you do some of this already but that would be another way of measuring the success of your department and is likely to be foisted on you by Government.

If the Universities don't improve their lobbying of parliament, they will have no input into the measures selected. I really do see the strength of lobby groups in relation to departments. In the USA, every university has its lobby group on Capitol Hill. They are successful and have helped the Universities over there. Lobbying is not a culture Universities are used to in this country. I do think it is the way forward and we must find a way to make lobbying work for us. Some UK Universities have started to take this new culture on board. For example, the University of York recently held an evening where lots of MPs came along, and gave them some credibility and raised the profile of the University.

All ministers say, when I talk to them, 'There is no doubt about it, biology is the way forward'. Yet there doesn't seem to be a strong lobby for Biology in the university sector in parliament where decisions are made that affect you. Much needs to be done about that. I would have thought that HUBS as a group should think about areas where they could penetrate to input ideas.

I did a paper for 'Nature', in which we looked at the questions asked in the House of Lords over the last five to ten years (a total of 100,000). We found that the number of scientific questions had risen from 1% to 10% over this time. All the questions were on scientific issues and most were about biology. All areas of biology are major foci in discussions in Parliament.

Considerable protest surrounds many issues in science. All politicians knew animal experimentation was going to be a big issue when they sat down and discussed it. Few scientists were willing to stick their heads above the parapet everybody deciding that they wouldn't raise the issue. Once the importance of animal research to biosciences was recognised, however, legislation was immediately invoked to protect directors, scientists and so on. The police were given powers to pick up some of the (animal rights) activists. The issue is not going away. In the case of the GMO issue, trials were started before enough had been done to inform the public. The Government and the scientific community thought that they could just sweep the debate under the carpet and there would be no protests. Opponents of this technology are, however, very passionate. The stem cell debate can be returned to as another example of how scientists and Government should never sleep on these things, thinking that just because they have a successful piece of legislation, the debate is settled.

We have debated many issues over the last two years on the Select Committee for Science and Technology (on which I have just become the Chair). For example, we considered Cancer Services (now the National Cancer Research Institute) and established the National Cancer Act, ensuring that funding for research and treatment is taken each year from Government and allocated by the Cancer Institute to projects needing most funding. I think the process should be more democratic and control handed back to the Cancer community. Through the Learned Societies, we will start to see more clearly how much money goes into cancer research annually.

The Food Standards Agency (now run by John Krebs) provides an excellent model of how to inform the public. He uses the process very skilfully to elicit support and money from Government to develop food safety programmes in this country. The select committee has investigated many things in this area. We have looked at genetically modified food. We have even looked at driving licenses for diabetics and changed the law. We have looked at mobile phones and health. The hottest problem for my constituents is the location of mobile phone masts near their homes and schools. Because of all the uproar from the public, a £6 million suddenly went into research when we realised we didn't have the facts. That is another example of a subject that didn't seem at the time to be a major concern in the world of David Sainsbury and the average politician, but was important to the public. We became aware of this concern by means of our political surgeries.

How does the government get the information that it needs about these issues? They currently determine who are the superstars in this country and find individuals who will say calm and acceptable things. They rarely talk to the dissidents but one might argue that they stop and think sometimes. There is an establishment in science that perpetrates ideas. The Civil Service pick these up and pass them on to Government.

The Science and Technology committee also exposed the poor funding in Government agricultural research departments for foot and mouth disease and BSE. MAFF was a disaster. It had a budget year after year for scientific research and we looked at that. We also saw it was necessary to change the scientific establishment it was rooted in. New ways of ensuring feedback from the entire community involved in a research area (including dissidents) was

necessary. Of course, changes are never popular but at least everyone can now feel that they are being listened to.

Today's dissident can become the establishment of the future. I remember very clearly, as I am sure you will, Barbara McClintock. Nobody understood a thing that she used to talk about, until eventually the concepts of so-called, jumping genes and transposable elements were developed and her ideas all became understandable. This really sticks in my mind. When I was teaching, I used to give two lectures that weren't on the biology textbooks. One was on Scrapie and the other on McClintock. I just had a feeling that these topics didn't reflect the scientific establishment but were sources of some good ideas. It is good for students to learn that there are things that are not in the textbooks but might become important in the future.

We recently had a debate on human cloning and I think that the relationship between genetics and insurance has been clarified (Government is to change regulations). The debate will undoubtedly continue. The Home Office is concerned, not only with DNA testing, but also with terrorism, actions where the effects of biological materials may be important. I don't know if Government always gets the right information on such topics. We do not have a single organisation to speak for British science nor do we have anyone to speak on behalf of the biological community in this country. These are real problems and I am still trying to find a system that gets all the information from everybody into Government.

There are a variety of organisations currently in Parliament. There is the Parliamentary Office of Science and Technology, which is a group of about four people plus a director, who produce papers for MPs. What they do is look down the line at things they feel are

going to be important. They then, in a kind of simplistic way, try to explain the science behind it. Every MP and member of the House of Lords gets that information. The reports are regular and I was Chair of the last year when we were made a permanent feature of the House. It was run on the basis of three-year contracts. The only thing I couldn't do, was get any Government money to keep them going year after year. Each year, they have to beg the Clerk's Office to get that money. I think within a few years, they will become a permanent feature with their own funding, a recognition of the importance of science and technological matters.

One might ask the question 'Why we need regulations at all'. I think we need to understand as never before, that the public really need to be involved in decisions about science and technology. In the 1960's, scientists had a reputation of being arrogant and they never interacted with the public. Engaging the public was not an issue. Now, the public are very anti-science and expect science to be regulated. Mix-ups between sheep and cow brains do not endear science and scientists to the nation. Regulation shows we take issues seriously. The public are demanding higher standards and health and safety are big issues.

We need to have an open approach with the public and show them we are health and safety conscious. To me legislation is not about getting upset about the extra work, it is about getting ahead of the game. Biologists must set out what they think are priorities and ensure they run their agenda. I put to you, that lobbying MPs is part of this. Don't tell your Vice-Chancellors about the scientific issues that bother you, tell your MP!

British science is doing very well, but the ground is moving under our feet. I think we are going to have to move in terms of

encouraging young people to enter science. People do not appreciate the way scientists think and it is up to you to change the perceptions of the public from that of the 1960's culture to one of the future. To do both, we need to invest more money in the training of scientists. We need action; argument and media pressure to get the messages of Biology over. I am sure the door is open for biologists to put across their views to the Government, I just don't think that they are pushing hard enough at the moment.

'Potential For the Biosciences Federation to Interact With Legislators - A GM Material Perspective' Dr Alan Malcolm, Chief Executive of the IOB

In 1992, when I first went into food science, I became a member of the Technical Committee of the Food and Drink Federation representing the manufacturers. My predecessor came to talk to me in 1992 about GM technology and what it meant for the food and drink industry. He laid it on the line! He told us to wake up as the impact of this technology on our industry was going to be enormous.

It was six years later before the whole issue was blown out of the water on a television broadcast. Could you all just remind me what we scientists had done in that intervening six years? No one in this audience is unaware of the potential of GM technology. You have been teaching it to your students for the last five or six (possibly even ten) years, ever since cloning came along. So we didn't really cover ourselves with glory and most of my talk is going to be self-

flagellation. About us as Scientists, us as Biologists, us at the Institute of Biology, and us as members of those committees that produced enormous reports. We are all in it together! What I am hoping is that at the end we can say that we have all got to do better. I think that it is clear that we have got to do better because the consequences are unpalatable for us as scientists as well as for the students that you are teaching and their future careers.

The IoB has 16,000 members and we are the biggest of all the various biological organisations. It also has 78 affiliated societies, with a combined membership in excess of 100,000. The biggest is probably the Society for General Microbiology, which has well over 10,000 members and the smallest is the Society of Welsh Phycologists with around 20 members. This reflects the intellectual breadth of membership.

There are an awful lot of us biologists around and I am sure that you know that entries to Biological Sciences at Universities in the last two or three years have surpassed chemistry. I am sure that you also all know that, at a Graduate level, Biology has been popular for a very long time. Everybody is saying that Biology is the growth area.

The IoB has an income (and this is not intended as an excuse but it is important that you put it into context) of just over £1.2 million per annum and net assets of £1.5 million. I have mentioned Chemistry already and I am not trying to knock anybody during the course of this talk but just trying to illustrate some facts. My original degree is in Chemistry and I have a great love of the subject although it is no longer a growth area. The Royal Society of Chemistry has 45,000 members meaning that their membership is three times that of the Institute of Biology. They have been around

for a long time being 150 years old. They have an income of over £20 million per annum with assets of over £50 million. They are therefore enormously richer, bigger and more powerful than the Institute of Biology. They are not, I would suggest, bigger and more powerful than the combined activities of all the various biological organizations. In contrast to any of the biological organizations, the RSC does a good job in lobbying parliament and getting their message across to the public.

I have been asked to talk on a subject that has been occupying a fair amount of my time over the last few years. What we actually did and what went wrong with genetically modified food and crops.

When the issue of genetically modified crops and food came up there were three things that the public (and therefore the legislative) were concerned about. I must make it very clear that parliament rarely thinks up its own agenda. It responds to what the daily newspapers report. Parliament has to have answers to those reports. The effect that we have on legislation in the absence of public of public acceptance and public push is practically negligible and I think that some of the topics Ian (Gibson) mentioned this morning illustrate that.

So what were the issues that the public were, quite correctly, concerned about?

Was the food safe to eat?

What was the effect of GM crops on the environment?

Was it ethical and moral to produce GM food?

I think, if I were looking for achievements, we have had one or two in this area in the last ten years. When I started giving talks to Women's Institutes all of those questions came up simultaneously.

At that time, the Prince of Wales was giving his view saying that we were not intended to meddle with genes. So people were concerned about this issue, listened to him and he got fantastic publicity. We have to remember that anything the Prince of Wales says will have a large public impact, anything Ian Gibson says will have a little less impact and anything that you or I say will have only a small influence on public awareness. That is a problem, but we have to face up to the fact that the media are more interested in the outrageous statements made by people with wacky ideas, than they are about comments by solid, sensible, intelligent, boring scientists. But the ethics and morality question has nearly gone. People are no longer arguing about 'is it wrong to tinker with genes?' Now that they understand that the insulin that diabetics inject is a GM crop. If it is no longer an ethical problem, then it must be the actual application at the end of the process that is judged, not the fundamental science.

Very few people now say that GM foods are unsafe to eat. There is some recognition of the fact that 250 million Americans have been stuffing GM Soya into their mouths for the last five years, and none have yet dropped dead. Fascinatingly, no one has yet brought a legal case in America. Bearing in mind that Americans love nothing better than having legal suits against each other, so it can't be that bad. I think that that type of message, after hammering on and on and on, has gone through so hardly anybody says that GM food is unsafe. The question is now should I have a right to choose whether I eat GM food or not'. It is, I feel, now the ethics of choice rather than the ethics of the science itself.

Of course, we can all see that there are still questions about the safety of GM foods. It is our challenge as scientists to persuade people to allow the experiments to be done on which to base a

scientific outcome. When the media asks 'Can you guarantee that it is safe to grow?' the answer of scientists is 'Well....' When scientists then take one, two, or even ten pages to provide the 'answer', the media loses interest. We have to find a slightly more concise way of actually getting across the message.

So who discussed, 'Is it safe to eat?' The Nutrition Society (one of our affiliated members) quite clearly had a role to play in this exercise, but they are even smaller than the IoB. They have a couple of thousand members and well under a million pounds. Obviously, they publish articles in their journals and magazines about GM food, they don't have the resources to employ major PR campaign managers to have lunches with influential people or, for example, to organise a road show. The Institute of Food Science and Technology produce excellent briefings for its members, but I have to say that most of these came out five or six years after we were first warned of the potential impact. British Nutrition Federation produced leaflets and booklets, but only in the last couple of years. There was still an enormous time delay in producing any of this information.

We have already mentioned the Royal Society. Please don't misunderstand me, as I am not in any way knocking it. I sat on their committee that produced their briefing paper on GM crops just over two years ago. Once again, there was a six year gap between what scientists knew was coming, and the Royal Society getting it's act together and producing it. The document was produced in 10pt font without a single picture or illustration, and it ran to 16 pages. This was because we put into it everything we knew. We had to because we are scientists and couldn't possibly leave any stone unturned. At whom was that document aimed? Only a scientist could possibly have wanted to read it, and he/she would have known what was in it anyway, because the technology has been a

major piece of biology for a decade now. Members of Parliament are not going to read through 16 pages of 10pt font with no pictures. The *Daily Mail* certainly isn't either. So, although the document was produced, I suggest that it was a defence mechanism rather than a pro-active piece of education. It was produced because the Society couldn't be seen *not* to have said something. But it was produced without any really serious thought about who was going to read it or what they were going to do with it. There wasn't even a usable abstract! Liam Donaldson and Sir Robert May produced another document on this topic in 1999. It is produced rather like a Methodist Church in-house magazine, being 20 pages long, stapled together and having no pictures. Again, it has been done, but who is going to read it? The British Medical Association did slightly better. Their report is glossy and looks much more attractive and is laid out in an easy to understand format. Again, it was only produced in 1998 and it sat on the fence saying that they don't know whether GM food is safe to eat or not. The Food and Drink Federation produced documentation but who is going to believe them as they are food and drink manufacturers, having a vested interest in peddling the stuff. It didn't matter how good their science was, the fact that it came from a commercial voice meant that it was going to be discarded by the majority of people. The majority of the science that Monsanto put out to the public was good but their PR was completely hopeless.

There have been a lot of unexpected consequences of such debacles. Monsanto was desperate to retrieve its reputation and was desperate to find people who were trusted, who would say what they wanted them to say. There was, however, no way that the Institute of Biology could be seen to accept sponsorship from Monsanto for anything at all. I would also guess that your university departments would be very cautious about taking money from

Monsanto. We were also offered money from Novartis (not for GM research but simply to educate scientists to be able to talk to the media). We had a tremendously difficult discussion as to whether it was acceptable to take any money for anything from Novartis. Of course, if we look through food and drink companies there are very few that have not been involved with this type of technology. So the mere fact that scientists feel they will be tainted by being involved with sponsorship from such organisations, has affected the ability of academic scientists to work with them, to publish with them or to be sponsored by them in any way. This has a tremendous consequence on the research of you and your colleagues and, I suspect, probably for the research prospects of some of your students.

Now we shall move on to the organizations that produced legislation regarding effect that GM crops have on the environment. The British Ecological Society, the Royal Society and Monsanto all produced their own forms of documentation.

The RSPB were not at all happy with the consequences of controlling insect populations, plant pathogens and the knock-on effect this would have on bird populations. Roughly ten years ago, the RSPB was a rather genteel rather than a campaigning organization. When Barbara Young took over the Chief Executive position of the RSPB, turned it into a major political campaigning organization. It now has around five million members and the RSPB has a major voice. That has been done in ten years. If you can do that with a comparatively small genteel charity, why can't scientists get their act together the way the RSPB have? English Nature, not surprisingly, have been very vocal about GM Crops as there is no doubt that there will be an effect on the environment, but it is a matter of balance to the extent of which is good and which is bad.

Now let's have a look at the others on the opposition side. Most have some scientific credibility. They include Greenpeace, Friends of the Earth, Gene Watch and two years ago we counted and came up with 30 different fringe groups campaigning vigorously (and in some cases violently) against GM technology. They were far, far better organised. Their web sites were better than our web sites; they had more publicity, appeared on more television programmes and caused a lot of damage to scientific research. The point is the rest of us really are a bit scared. What is the point of us sticking our necks out? There is teaching and research to do. Which Vice-Chancellor is going to give brownie points to whomever on his or her staff spends half an hour arguing with Paxman, and probably making them look a bit foolish? Even if they win the battle is that a sensible use of academic's time?

The Nuffield Institute of Ethics produced a very valuable document, but again only last year. The debate had been raging a long time before it came out. It is an excellent review but then again designed as a long review for an enthusiastic amateur. The Royal Society produced documentation as we have already discussed. Christian Aid didn't help the scientific debate by discussing the potentially negative effects on developing countries through the application of technology. I am always curious about how we can get people to differentiate between the fundamental science and its application. The fact that it may be immoral to have a particular application does not imply that the original science itself is immoral. I don't think that there is any attempt at all in trying to get that message across to the general public. For example, if only Faraday could have anticipated the electric chair, would we have actually banned the use of electromagnetic induction to produce electricity in 1845?

We undoubtedly have a weakness in that there are too many of us with too many diverse and different points of view. This has been noticed. In the last 3 or 4 years, Michael Clark (Ian Gibson's predecessor as the Chairman of the House of Commons Select Committee) said to me 'you biologists, you don't really have a very big impact because we don't notice you very much. You don't make enough noise. Isn't it possible you could do something about this?' David Sainsbury, of course, is hardly in a position to comment on how we should organise ourselves. He notices, however, that the Chemists and the Physicists manage to speak with single voices, whereas there are nearly a hundred different voices speaking on behalf of biology. So with all of those views it must be difficult for a busy politician to sort through them all. Sir Bob May actually wrote to me saying very politely that he could not help noticing that the Biologists were a bit of a rag-tag group, and that somebody somewhere should do something about it.

There is a tremendous amount of political feeling that we could, should and need to do a better job than previously. In spite of all this, the Institute of Biology has not done such a bad job. We have put to Government over two dozen documents over the last year on topics ranging from antibiotic resistance to GM crops, through stem cell research, to animal welfare and environmental questions. All of these documents have been in response to questions asked by Government. I would have thought, however, that we should be leading politicians. We ought to be leading these questions but we need the resources to do that. As it happened, the Institute organised a workshop on biological weapons in July and as a result of that produced a briefing sheet on our web site in the first week of December. We should be leading the debates on biological weapons,

climate change, antibiotic resistance, stem cell research, cloning, renewable energy and waste management.

Wouldn't it be better if we handled the PR thing up front and explained to the public why that research is being done, what the benefit is to society for doing it, why it is necessary to do research and what precautions are in place? That is not a trivial undertaking.

Questions to Alan Malcolm

Paul Brain

What is happening to the proposed Biology Forum?

Answer

There is a meeting next Friday of the organizations with the largest numbers of members where we will be discussing what shape and form the new federation should take.

Paul Brain

We know that the HUBS is small in membership but we did think that in terms of training most of the biologists in the UK then maybe we ought to have been invited to this discussion

Question to Paul Brain

Ian Gibson

How do you as scientists get on in departments now with the PR machine in universities? We have suddenly got PR conscious universities and they always appoint one person with £8,000 a year, which shows how seriously they feel about it! I always remember that the appointee never had any sense of what was going on in research and in the department around them.

Answer by Paul Brain

I can only speak from my own experience and certainly our PR body only responds to individuals who have let the PR person know about what is going on. They do have the right to veto certain areas. For example, they are not keen to discuss animal research, but they will give a great plug to something on gene research, which might involve animals somewhere down the line, but as long as animals are not mentioned it seems to be okay.

Working with Home Office Legislation -Prof. Bruce Matthews, University of Bristol

Firstly, I would like to briefly summarise something which you are probably all very familiar with, the legislation which controls work on animals, the Animals (Scientific Procedures) Act 1986. The Act makes provides protection for animals used for experimental and other scientific purposes. The other scientific purposes mentioned include education and scientific training. It applies to all vertebrates (other than Man) including one octopus species *Octopus vulgaris*. The act is supplemented by the notes of guidance, which are updated regularly by the Home Office.

The Act encompasses many aspects of work on animals but, from our point of view, has a few very important points. As stated previously, it applies to all vertebrates except man that are used for experiments or other scientific purposes and in procedures that are likely to cause pain, suffering, distress or lasting harm to the said animals. It does not cover behavioural studies, which do not harm the animals but simply observe them.

The Act superseded the old Cruelty to Animals Act [1866], which was much less restrictive. The introduction of the new Act increased

bureaucracy, form filling and controls needed to operate. Essentially, it restricts such procedures to those that have been approved by the Home Office in a Project License. These procedures are only to be carried out by persons holding a Personal License. Training and a test must be passed before a Personal License can be awarded. The procedures must be specified and be carried out in designated establishments (each room must be listed on the certification) and the operator must have held a personal license for at least a year before a specific project license will be awarded. The experiments are generally carried out on purpose-bred animals. These are the important features of the Act, which apply to us.

In my view, the Act does a very good job and the problems we encounter are rather more to do with its implementation, rather than its content. Many people would agree with the Home Office on their web site where they make the bold statement that the Act "is widely viewed as the most rigorous piece of legislation of its type in the world. It offers a high level of protection to animals whilst recognizing the need for research and finding new methods"

Problems with Implementing the Act

There are usually delays in granting Project Licenses and amendments to existing licenses. Different Inspectors look at varied details of procedures that are permitted under the Act. There may be differences between the Named Veterinary Officers and others in the control of procedures within establishments, interference with academic freedom by the Ethical Review Process (as a signature is required and this can cause delays) and the actual cost of the Ethical Review Process is an extra capital expense that must be added to the costings. Changes in specifications for animal accommodation may be very costly. For example, there was recently a minor change in cage size (an increase in height of

2mm), which caused many problems as all cage sizes had to be changed. The environment in which the animals must be kept has to be constantly monitored including the temperature and humidity of the accommodation. There are also restrictions in the use of animals in teaching. Under the old Act, one could get permission to teach and use animals in demonstrations but now an additional project license for specific taught classes has to be obtained.

Delays in the granting of Project Licenses and amendments to existing Project Licenses were exacerbated by the introduction of the Ethical Review Process in 1999. Such delays have been discussed at length by several groups including the expert group on Efficient Regulation (set up by Ian Purchase, Manchester) and the UKLSC (sub group chaired by Nancy Rothwell) contributing to the current Select Committee that is lobbying MPs. There are also recommendations for Best Practice, which have been recently published and have improved animal welfare enormously. The expert group on Efficient Regulation says, however, that some establishments have gone far beyond what was proposed as Best Practice and there should be a more streamlined approach. The Home Office have also recently brought out a review of Best Practice.

The new Act restricts the use of animals in teaching. This means that fewer animals are being used in practical classes and the pharmaceutical industry is concerned that graduates do not have training in the use of animals in research. The Act does permit the use of live animals for education and training purposes, but one has to make a case that these aims cannot be achieved by alternatives such as video recordings. Using recordings obviously has less impact than when the practical is actually undertaken by the student. To combat this reduction in practical skills of students,

short courses are now being arranged jointly by the Physiological Society and the Pharmacological Society, for students in their 2nd year BSc to do course work for their personal licenses and then spend the summer before their 3rd year actually working with animals.

The Act does not restrict the use of animals in teaching if the procedures to which they are subjected do not cause pain, suffering, distress or lasting harm (animals are allowed to have a reduced body weight of up to 15% without it being classified as lasting harm). Restrictions also do not apply if the animals are first killed by one of the methods listed in Schedule 1 of the Act. But what is the difference ethically between killing an animal for scientific purposes and using a tissue after it is dead, and giving an animal a terminal anaesthetic and using its tissues for scientific purposes before it has died?

Other related issues include the terrorist activities of animal welfare extremists, which impose security requirements on establishments, increasing costs and causing considerable inconvenience. The Freedom of Information Act may cause concerns for workers on laboratory animals. There are also Health and Safety concerns regarding animal allergens. If allergic reactions to animals are shown, the animals must be confined to animal houses to protect people from them.

Q Ian Montgomery

We work on wild animals. Are we covered under the Act?

A

What do you do? Do you cause harm or distress? If you are only identifying a species then it is not an experimental procedure to

take a sample for identification purposes. You are not allowed to investigate the amount of a certain isotope from that sample though.

Q David Hoole

What is the definition of 'wild'? I work on fish, so does it matter if it is wild or purpose bred?

Safety Legislation - Supportive or Suppository Mr Bernard Mallows, Director of Safety Services, University of Cardiff

All employers have a common law duty of care. Employers must understand the risks inherent in work and protect against foreseeable injury. Providing adequate materials, plant and premises usually discharges this common law duty of care. Information, instruction and training with systems of work, effective supervision and (most importantly) competent staff are also essential.

Statute Law is mainly criminal and is written in Acts of Parliament, Regulations and Orders, Approved Codes of Practice and Guidance. The Health and Safety at Work Act (HASAWA) states that employers have the obligation and duty (as far as is reasonably practicable) to ensure the health, safety and welfare of all employees whilst at work. It also states that the employer should provide, healthy and safe systems at work; a healthy and safe working environment; safe plant, machinery, equipment and appliances; safe methods for handling, storing and transporting; adequate instruction, training and supervision as well as a safe method of access to and egress.

There is also a lot of supportive legislation, which includes the COSHH regulations, Ionising Radiation regulations, Pressure Systems regulations, Genetic Modification regulations, good laboratory practice regulations and RIDDOR (Reporting of Injuries Diseases and Dangerous Occurrences regulations) among others. COSHH requires employers to control risks from biological agents and to make suitable and sufficient risk assessments, to take all necessary steps to prevent exposure, provide information and training for staff on risks associated with hazardous substances and on how to prevent accidents, monitor exposure and carry out health surveillance. RIDDOR states that employers must report any significant injury or disease, certain types of ill health, any accident or disease involving absence from work for more than three days and to record and identify trends to highlight areas exhibiting a lack of control. Other supportive standards and codes of practice are ACDP guidance (Advisory Committee on Dangerous Pathogens), BS EN 12128:1998 Biotechnology, Laboratories for research, BS 5726-2, -4 Microbiological safety cabinets etc, Anthrax – safe working and prevention of infection HS (G) 174 and finally managing health and safety aspects of research in HE and FE education 2000. There are also further supportive legislations known as the 'six pack' of European health and safety regulations. These include Workplace (Health, Safety and Welfare) Regulations 1992 – Approved Code of Practice, The Management of Health and Safety at Work Regulations 1992 – Approved Code of Practice (amended 1999), a Guide to the Provision and Use of Work Equipment Regulations 1992, Work with Display Screen Equipment: A Guide to the Health and Safety (Display Screen Equipment) Regulations 1992, Manual Handling of Loads: A Guide to the Manual Handling Operations Regulations 1992 and finally A Guide to the Personal Protective Equipment at Work Regulations 1992.

The Management of Health and Safety at Work Regulations impose a number of obligations on employers. Employers must carry out risk assessments and have arrangements for planning, organisation control, monitoring and review of protective and preventative measures. Employers must also appoint 'competent persons' and ensure that procedures are followed in the event of serious and imminent danger. They must also co-ordinate measures with other employers sharing the same workplace, provide training to employees and give information to employees, non-employees and temporary workers. The common theme within these regulations is risk assessment, training and competent persons.

Within any safe system of work there needs to be a comprehensive risk assessment. No employer has been prosecuted for having a brief risk assessment but there have been prosecutions for employers having **no** risk assessment. There are five key elements to a safe system of work, identifying the hazards, assessing the risks, instituting control measures, monitoring those control methods and reviewing the system. So looking at these five elements a little more closely, how do we identify hazards? Firstly we need to find out *who* is going to do the work and *who* may be affected by the work. We must also ascertain *what* materials and equipment these people are going to use. We must also find out *where* they are working, *when* they are going to do the work (what time of day, month or year) and *why* they are doing it.

When identifying '*who*' will be doing the work, you need to look at all people coming into contact with the activity. The obvious people are scientists, technicians and students. We must also identify the less obvious candidates such as service and support staff, cleaners, visitors, emergency services, vets and we must always include that elite band of hazards, professors!

Identifying the *'what'*, we must look at our COSHH regulations, which include all chemicals (sensitisers in particular) as well as any biological agents including microorganisms, parasites, cell cultures and allergens. Particular attention must be paid to infectious agents and waste of all sorts.

The *'what'* also describes the agents that may be present and how they might be encountered (as cultures, clinical samples, animals, allergens, or as waste and effluent). We also need to decide to what hazard groups they belong, what disease they may cause and how they would be transmitted. ACDP hazard groups for biological agents exist, which can be classified into groups. Group 1 are agents unlikely to cause human disease whereas Group 2 agents can cause human disease and may be a hazard to employees but are unlikely to spread to the community (usually effective prophylaxis or treatment is available). Group 3 agents can cause severe human disease and may be a serious hazard to employees and can spread to the community (but again there is usually effective prophylaxis or treatment). Group 4 agents can cause severe human disease, are a serious hazard to employees, are likely to spread to the community and cannot be countered by effective prophylaxis or treatment.

The *'what'* also covers slips trips and falls, accounting for the majority of accidents. Sharps, animal bites and scratches are also a problem and they carry secondary effects such as possible infection and sensitisation. Burns and scalds must also be included along with consequences of manually handling things such as cages, stores, animals and equipment. We must also remember to assess the plant, equipment and procedures including centrifuges, caging and cage cleaning, ventilation, heating and humidification, the lighting and noise within the working area, the electrical power supply, sterilisation and autoclaves. It is also important to remember waste

disposal and ensure that it is worked into the costings, as it is an important duty of care.

When identifying the '*where*' we must look at size and capacity, the layout of the laboratories and whether they are fit for their purpose. This includes containment details including the mortuary and animal facilities. Lastly, we must ensure that the premises are secure from both attack and theft.

When completing a risk assessment we must always remember, "If there is a risk, the best solution is to remove the hazard completely". We must investigate if there is any potential to cause harm, how does the activity cause harm and how the exposure can occur. Exposure usually occurs through the eyes or skin by inhalation, ingestion, scratches, bites and cuts. We need to ascertain how many people will be affected and for what duration. Once these risks have been identified we need to decide what training is necessary and appoint a competent person to assess this.

It is also important to assess the biological risk. We must again evaluate the risks by ascertaining the likelihood of exposure and infection and determine if there are any workers that are particularly susceptible. We must then control the risk and to do this we must identify what control measures are required, whether it be containment, decontamination or vaccination.

Control of biological risk is important and as an employer you must be seen to cover elimination, substitution as well as isolation of the worker and the work by containment. You must also provide safe systems of work as a preventative and introduce permits. Health surveillance should also be carried out and strict rules maintained about personal protective equipment. It is no good providing

protective equipment and not enforcing its use. There must also be a plan in place for use in emergency situations. The law requires employers to control safety, so it is an important management issue. Managers and supervisors must be responsible. The law is often broken when workers do not wear Personal Protective Equipment and the supervision lets them get away with it. Safety is often treated differently within departments, as the allocation of departmental safety functions can sometimes be regarded as a punishment. This means that the most competent person may not be appointed to the departmental safety position and the issue is marginalized.

There must be some form of monitoring. Are the controls in place? Do the controls work? Are the controls effective and are they maintained? There must also be reviews on a regular basis, at least after each project. Reviews should also be undertaken if there is a change in personnel, activity, substance used or locality. Most importantly, there must be a review after any accident to prevent any further incidents.

In conclusion, legislation is generally supportive but often felt to be excessive. Much of it is prescriptive and repetitive. The British Standards and Codes of Practice are also supportive. Your own Specific Operating Procedures (designed exactly for your need) are of the greatest benefit but they must relate to current legislation. You must beware because, if they are not followed, they can be used against you as examples of Best Practice. If HUBS adopt an ostrich approach to health and safety and bury their heads in the sand, then HSE and other statutory bodies will use Safety Legislation and COPs as a Suppository.