

WEDNESDAY 3 JUNE 2009

Present

Brooke of Alverthorpe, L
Brookeborough, V
Caithness, E of
Jones of Whitchurch, B
Livsey of Talgarth, L
Palmer, L
Sewel, L (Chairman)
Sharp of Guildford, B
Ullswater, V

Witness: **Ms Susanna Louhimies**, Policy Officer, Directorate-General Environment, European Commission, examined.

Q1 Chairman: Welcome. First of all, thanks very much for agreeing to come and talk to us and help us with our inquiry into this complex and potentially controversial subject. Can I start off by explaining a couple of things. This is a formal evidence-taking session of the Subcommittee, which means that a full shorthand note will be taken. You will be sent a copy of that shortly and you will be able to revise it in terms of any sort of minor errors that have crept in. The other thing is that we are being broadcast. Do not be concerned by that because we have never actually had any evidence that anybody ever listens to it. So there we are. I wonder if I could start, first of all, by inviting you, if you want, to make any sort of general opening statement, or would you prefer to go into a question and answer routine? Over to you, frankly.

Ms Louhimies: Thank you, my Lord Chairman. First of all, good morning everybody. My name is Susanna Louhimies; I work for the European Commission in the DG Environment, in the Chemicals Unit, and I am the Policy Officer dealing with the protection and welfare of animals used for scientific purposes. The Commission is delighted to be here to be able to

give evidence to you and give some clarity on questions that might need further explanation. We feel that our proposal is based on very strong scientific evidence and full stakeholder consultation. We also carried out an impact assessment which was then confirmed later on by the stakeholders. Finally, maybe, just one word about the process and where we are, at this moment in time. We have had the Parliamentary First Reading report adopted at the beginning of May and, a little bit exceptionally, the Council work is not as advanced as it normally is at this stage. Therefore, we are just finishing the first rounds of discussions at the Council. We do not have a lot of Member States' firm positions yet because lots of them are still in the middle of their internal consultation. The last point, maybe, is to say that the Swedish Presidency is putting this very high on their agenda and they would actually try to reach some kind of early Second Reading political agreement.

Q2 Chairman: What would that mean in terms of the calendar? When would you expect an early Second Reading to emerge?

Ms Louhimies: The way the Swedish have drafted the calendar, it looks like the December Agriculture Council is always reserved for the fishery matters, and therefore the work should really be carried out before the 19-20 November Agriculture Council. So it means work between September, when the Parliament is back and once they have decided on the rapporteur, until the end of October. So very hard work.

Q3 Chairman: Is the fact that you are going to have a new Parliament and new Commission likely to raise any problems?

Ms Louhimies: The new Parliament has the discretion that they can accept or they can refuse the result of the First Reading. It is quite uncommon, and because it got very high support at the First Reading it is unlikely to happen, but can happen.

Q4 Chairman: I wonder if I could ask some general questions to begin with. I suppose the first question is: why is there a need to go ahead with something like this? What is the general justification and reason for these proposals?

Ms Louhimies: Thank you, my Lord Chairman. It is a very good question and asked often. The reasons are three-fold: firstly, the current piece of legislation we have in place is old – quite out-dated; it is open to interpretation because it is based on a Council of Europe Convention text, and it is rather political than regulatory in nature; it lacks main elements like ethical evaluation and authorisation of procedures using animals, and it does not even explicitly mention the 3Rs principle – replacement, reduction and refinement. So we need to get that to the level that we are at today. Secondly, because of that reason, a lot of the Member States have adopted national legislation which widens the gap of standards between the different Member States in the EU, and that is, of course, contrary to the harmonisation of the internal market, and we have some evidence later on about that. Finally, obviously, the legislation has to follow the evolvement of the understanding of the humane and ethical treatment of animals that we have today compared to what the situation was in the late-1970s.

Q5 Chairman: And the objectives?

Ms Louhimies: Again, three-fold: we have to make sure that we are harmonising the internal market; secondly, we want to strengthen the protection of those animals we still need to use, because we do need them still; and there are not enough scientific alternative replacement methods available. So to increase the animal welfare and then, through the ethical evaluation, specifically, to reduce the numbers that we use today to the minimum necessary.

Q6 Chairman: You have mentioned the famous 3Rs – replacement, reduction and refinement. What is your idea of full implementation of replacement, reduction and refinement?

Ms Louhimies: On the 3Rs, we have a little change in this Directive to the *aspiration* that the current Directive has. The new Directive makes sure that the 3Rs cover also the breeding and housing. Originally, it was limited to the use of animals and we looked at how we can replace, reduce or refine their use, but especially the refinement element is now making sure that it covers the areas of breeding and housing of animals. The 3Rs implementation is very much linked to the ethical evaluation. That is the moment when it will be scrutinised. By systematic implementation of the 3Rs we will increase animal welfare but we also probably will be able to increase the value of the scientific results of the procedures.

Q7 Chairman: What is your feeling on how far reduction, replacement and refinement has gone so far? Or is it patchy throughout the Member States?

Ms Louhimies: There are two aspects: what the Member States are doing and how far we have come. I think we are doing a lot in the EU today; I think Europe is seen as the leader in the area of alternatives and the implementation of the 3Rs. Different Member States put in different efforts. We have a very good example from the UK: lots of efforts put into the 3Rs – the NC3Rs centre, for example. I think we can harmonise and get more resources into it through this revision as well.

Q8 Lord Brooke of Alverthorpe: If I may just follow up on your comments about the 1986 Directive, you said that this led to individual country legislation which varied and, in fact, the gap between some widened. How can you ensure that the new legislation which will be put in place does not lead to a further widening in standards?

Ms Louhimies: The areas where we have differences today are to do with authorisation – authorisation of experiments – and the housing and care standards. These have been the two biggest areas where there has been a widening of gaps, and that has led to problems where, for example, the authorisation time, from the time of application to receiving the

authorisation, can vary anywhere up to 100 days. Therefore, the different operators in the different Member States are on a different footing. If we were to adopt the proposal as it is, we are looking at putting authorisation throughout the 27 Member States; we are looking at the minimum requirements for housing and care standards throughout the 27 Member States, and within the authorisation we are looking at setting time limits. So there are several measures that would streamline the current situation where the biggest differences are.

Q9 Lord Brooke of Alverthorpe: How do you make sure it is implemented?

Ms Louhimies: Implementation, as always, is a matter for the Member States' national authorities. So we will produce and adopt with Member States a Directive and then it is transposed into the national legislation. National legislation is enforced by the national authorities. However, we have built a lot of provisions in this proposal to increase transparency and, also, we have some standards for inspections. With those two, and increased transparency, we now believe it will also increase self-compliance automatically, but there are limits also to the inspections.

Q10 Chairman: Inspection is the key thing, is it not? Having a sufficiently rigorous and robust inspection regime is critical in this area. Do you think it could deliver that?

Ms Louhimies: The Commission is ambitious but we have to say that we based our proposal exactly on the results of the Technical Expert Working Group, which was agreed with the Member States. The Technical Expert Working Group was one of the first consultation processes we started, and it consisted of representatives of all Member States and main stakeholders, and they were presented with different elements that we would like to look at during this revision, and one of the elements was the inspection. The recommendation from that working group was to have two-yearly inspections covering not only the user

establishment but, also, breeding and supplying establishments, and have one of those inspections unannounced. That, it was felt, would give enough security and assurance.

Q11 Viscount Brookeborough: What are the issues and problems with today's registration?

Ms Louhimies: Problems and issues. Please correct me if I have misunderstood the question.

We felt that we needed to have a deadline there, and that is linked to the competitiveness of the EU research and EU industry vis-à-vis the outside world. When we look at other regions, regions where there is no authorisation or in regions where there are authorisations in place, we would want to make sure that our industry or research community is not disadvantaged by extremely long implementation of authorisation deadlines. However, the issue is with the Member State authorities because they are the ones who have to deliver, and obviously we may receive some resistance from some of the Member States who are to implement this.

Viscount Brookeborough: I am sorry; I used the wrong word; I meant "authorisation" not "registration". Thank you.

Q12 Earl of Caithness: Could you tell us something about the consultation process you entered into before you published your proposals?

Ms Louhimies: The consultation process has been very lengthy and very thorough. We started in 2002 already with this Technical Expert Working Group, and, as I have just mentioned, it consisted of representatives of Member States and all the key stakeholders. They worked for about six months to cover all the main elements we felt should be covered during this revision process. The results of that consultation process were then fed into the preliminary drafting, and the preliminary drafting was put under an impact assessment which was carried out by an expert outside contractor. That impact assessment study included yet another round of consultations - it included questionnaires to the national authorities; it included questionnaires to the stakeholders – and once the preliminary analyses were drafted

or rather identified they were then put out in the open in a public internet consultation. Alongside with that, we had a public consultation with the general public on general issues, and then we had the expert consultation specifically on these elements. We had a huge number of responses. We had over 12,000 expert comments. What is important to underline here is that the expert comments were coming from the users, so it is really the users who use animals on a day-to-day basis; over 50 per cent were from animal users. From the 51 per cent, the majority was from the public institutes and the rest from the industry. Then there were breeders involved, other stakeholders and NGOs, etc. All those consultation results were then fed into the final drafting and, also, to redirect our impact assessment.

Q13 Earl of Caithness: Did you consult outside the EU? When you have got your consultations, how do you balance something in which there is huge public interest against the scientific community's interest?

Ms Louhimies: I will cover first the issue of consultation outside of the EU. We had consulted other regions like the USA, Canada, Australia and New Zealand (Japan is very limited in terms of the legislation they have in place currently) - so to obtain all the information that was available. Also, the impact assessment did a search on the situation with the different Member States, and that is made available in the annex of the study. So we have looked at the situation vis-à-vis the EU and the outside world. The second question was about how do we reconcile the animal welfare and the public wishes, and then the science. The public consultation we organised for the general public was, in fact, the third largest public consultation the Commission has ever carried out, which indeed indicates there is a huge public interest in this matter. NGOs represent the public and they have been active from the very start in this process, but equally we have the European Parliament representing the public and they have a number of concerns they have produced an own initiative report back in 2002 by MEP Jill Evans as the rapporteur. So, based on all this information we have

gathered, the Commission started off with a very ambitious proposal and was looking at, also, answering the concerns of the public. Then that was put through this impact assessment, as I mentioned earlier, and this impact assessment then looked at the feasibility of these proposed provisions as well as the cost implications, as well as the benefits to the animal welfare where there are really some benefits to be harvested and, also, benefits to science because in some areas we are hoping to receive benefits for science. So that was the process that was balancing up these two parts. Then, as a result of this consultation, we have either abandoned some of the proposals we originally had or we have fine-tuned them or we have changed them, so it was taking this feedback from the consultation into account.

Q14 Earl of Caithness: Could you just send us a list of the people you have consulted in the UK, if that is at all possible?

Ms Louhimies: I will do my best. The issues for the public consultation and the expert consultation – some organisations, some respondents, preferred to remain anonymous. So we have a number of groups or respondents who have not given their names. I will try to collect a list as comprehensive as possible.

Q15 Baroness Jones of Whitchurch: I am not absolutely clear: when you say it was a public consultation did you do it with non-interested members of the public? Obviously, there are interest groups, but did you also do what we would call a Mori poll (I am sure there is an EU version of that)? Did you do a poll of that nature?

Ms Louhimies: The public consultation we did was based on the people's own interest, and therefore it is not comparable to an opinion poll that is getting an average number of people; this was based on people's interest in participating and coming up with their responses. However, for the expert consultation, we made sure that we advertised to all the stakeholders that we had consulted from the start and asked them to further advertise. So we tried to reach

as wide as possible a base for the expert consultation, but it was based on the people's initiative to respond to this consultation.

Q16 Baroness Jones of Whitchurch: Can I just follow that up? Were there big disparities country-by-country within Europe? In other words, were there one or two countries that were vehemently in favour of all your proposals and then others which were: "Actually, we don't really care"? Is there a big disparity between different countries?

Ms Louhimies: It is a very good question. I think for the general public consultation we can see differences. For the expert consultation, which looked at the details of all the options that we were putting forward, we have not actually made the analysis. We had 12,000 comments to go through and we did not go to that kind of analysis at that moment in time because we wanted to capture first what is relevant to the impact assessment and finding that correctly, and, secondly, to make sure that if there are any ideas for drafting or changes to the drafting that we should take on board we would capture those. So time did not allow us to do a further analysis.

Q17 Baroness Jones of Whitchurch: Was the UK one of those that was the most vehemently in favour of better animal welfare? Or was it more widely spread than that?

Ms Louhimies: I would say the UK is traditionally, and has always been, a very strong speaker in favour of high standards of animal welfare. I think it is also reflected in the responses that we are getting from your business people; they are used to your environment and they feel comfortable with your standards. I have to say that a lot of what is in the proposal could be aspiration from what you have here – certain elements that you have here – in your legislation. So I would say the UK would be very much one in favour of high standards and good animal welfare.

Q18 Chairman: Can I go back to the inspection issue? I have in front of me the amendments from the Parliament. Although we start off with the draft saying “inspections carried out by the competent authorities at least twice a year” there is an amendment from the Parliament which says: “national inspections shall be carried out by the competent authority on average once a year, with the competent authority adapting the frequency of its inspection on the basis of the risk analysis of each establishment.” If you are doing it “on average” once a year that means that some will be less than once a year. That does not seem to be particularly robust.

Ms Louhimies: My Lord Chairman, I would personally agree with that statement. The Commission position, at this state of play, because Member States’ position is not really known, is not to move away from our current proposal, and we would be standing behind our “twice a year”. In fact, in the provision it says it should be on a risk management basis, so that in cases where you have a huge establishment the frequency could be more often.

Chairman: Thank you for that clarification.

Q19 Lord Livsey of Talgarth: These questions are specific and refer to Chapter 2, the procedures and provisions for the use of certain animals. The proposal in Article 8 of that document limits the use of non-human primates to research related to life-threatening conditions. Can you comment on concerns that this would be too restrictive and might actually prevent research in the EU in other important areas of health, such as fertility? I notice in Article 8 it does actually refer to “debilitating clinical conditions in the human being”. Is that a let-out clause?

Ms Louhimies: Thank you, my Lord. The Commission feels that we need to be strict on what we do with non-human primates, and we need to be more severe in our scrutiny of what we do with the non-human primates, being the species closest to humans and capable of building up social groups and living in partnerships throughout their lifetime. We also feel

that the current provision – how we have worded it – should not pose undue difficulty in making that link between, for example, certain areas of research that is carried out today. We have a wealth of knowledge of the biology and anatomy of the human body today; we know what areas of the body are affected with different types of disease, and therefore the link should be able to be made between the non-human primate research and these areas. In addition to life-threatening we also talk about debilitating conditions in humans, and Recital 16 further clarifies and says that it has to be a condition that has an effect on the day-to-day functioning of the person. We feel that, for example, infertility could be considered in this category. We have references to it being considered as a debilitating condition, and we know that infertility can result in depression and it can result in psychosomatic disorders. Therefore, we feel that link can be made.

Lord Livsey of Talgarth: Thank you for clarifying that.

Q20 Chairman: Would you specify that at all in the Directive? Would you make it absolutely clear?

Ms Louhimies: The current text is in the hands of the Parliament and the Council. The amendments will be fed through - if there are amendments to the text and further clarification - the national authorities or the Parliament.

Chairman: Under “debilitating”, I take it, we would include diabetes and Parkinson’s.

Q21 Lord Livsey of Talgarth: I have another part of my question. The proposal in Article 10 (Annex III) sets dates, which vary according to the species, from when researchers in the EU will be able to use only non-human primates which are the offspring of animals bred in captivity. How confident are you that there will be sufficient availability of such animals by these dates? That is one point. The second point is: have you information about the implications? After that I would like to ask a simple question.

Ms Louhimies: Thank you, my Lord. If I may I would like to be a little bit more generous with this response because it is a very complicated matter. We feel that the move over to the second or higher generation purpose-bred animals is needed for animal welfare, for scientific reasons and for biodiversity reasons. So we have several reasons for that. We have looked very carefully at the issue of cost and the demand and the supplies of the availability of these animals for EU use. The EU uses around 10,000 non-human primates a year, whereas the USA alone uses something like 50,000. So we are not the market leader in the demand. We are relying on our non-human primates to come from outside of the EU. The impact assessment study concluded that there are a number of uncertainties that are very difficult to predict because we are working in a global market. However, it concluded, also, that the price would not become the determining factor because the price of the animal out of the total cost of the project is marginal. The example the study was quoting was looking at a long-term average study using macaques; if the price of the macaques were to have doubled that would have had a 2.8 per cent increase in the total project cost. So the conclusion was that the price will not be the determining factor, but the determining factor will be the demand and supply. Will there be species available? Due to these uncertainties, the impact assessment concluded, also, that we should be flexible in what we can propose in the Directive. Often, certain parts of the proposal are looked at in isolation. In fact, what we have done here is that we have built a proposal which is composed of five different elements. First of all, we have these transitional periods which you mentioned in the Annex III. They are there based on the impact assessment study; they are there to give the push to that direction. We are not 100 per cent sure that these will be attained within the time limits that we have set. We have then an element which requires strategies to be put in place to provide an increasing number of second generation or higher generation purpose-bred animals. Furthermore, we have a requirement for the Member States to report specifically on the origins of the non-human

primates, so that we can follow up where these animals are coming from; are they second generation; are we getting increasing numbers of them? Then there is a review requirement for the Commission to carry out a review to analyse the situation where we are. Finally, we have a comitology procedure foreseen for Annex III, which allows the Commission, where appropriate, to revise these deadlines that have been set. So we are following very much the conclusion of the impact assessment. We want to make a push; without putting anything in the Directive the status quo would be highly unlikely to change, so we need the push there, but we build it in a flexible manner, so that, in case we need to, we can go back and we can revise these deadlines. The final comment I would like to say is relating to the demand and supply, because that was considered one of the biggest unknowns in this whole scenario. Just recently, in March of this year, there was a meeting on a US initiative called International Primate Plan. It is grouping together all the big players in non-human primate production and the users. In that meeting they agreed or they came to the conclusion that the aspiration and the objective should be to move away from first to second-generation, purpose-bred animals, so we have now confirmation that our proposal, moving to this direction, is also now supported worldwide and that would then positively impact on this biggest unknown that we have.

Q22 Lord Livsey of Talgarth: Thank you. That is a very comprehensive answer. Just to add to that (you have more or less answered my question from what you have just said), finally: the enforcement of this agreement, you are confident, will secure the objective?

Ms Louhimies: At this stage I will not talk about agreement or enforcement. It is a consensus that was agreed that that should be the way forward. There has been no discussion yet on the timeline because it is a complex issue and it is involving breeders in countries like China, Cambodia and Mauritius. So we talk about worldwide development, and this will not happen overnight. We will still have the first generation animals with us for quite some time,

but what the Commission would like is to kick off this move and follow and try to achieve it and speed up the process.

Lord Livsey of Talgarth: Thank you.

Q23 Viscount Ullswater: Perhaps not quite such a headline as non-human primates, but I notice now that in Article 2.2(b) invertebrates are to be included. Could you tell us: is that the first time that invertebrates are to be included? Is it really necessary that invertebrates should be included in such an all-embracing Directive as this one? Although they are specified in Annex I, are they the only ones that are ever used in experimentation? Do you know anything about the intensity of research in these sorts of animals – invertebrates?

Ms Louhimies: Thank you, my Lord. It is the first time we are proposing it at the EU level – yes, that is correct. The basis on which we are proposing this is a scientific report we requested in support of this Directive from the European Food Safety Authority that hosts the Scientific Panel on Animal Health and Animal Welfare. They looked at a number of issues and one of the issues was to look at the sentience of invertebrate species, based on their biology but, also, their pain system development, their behaviour, cognitive ability and memory retention - so: if I am experiencing stimuli that are adverse do I want to go back to those stimuli again? Based on these different criteria the opinion concluded that the groups we have included in Annex I should be provided protection in case they are used in procedures that have a likelihood of causing pain or suffering. It is the first time, at the EU level, that we are doing this. The UK is looking at some. There are also other regions that are covering invertebrate species under their legislation, for example New Zealand. Are these the only ones and at what level of intensity they are used? Unfortunately, because they are not covered by legislation in larger scale, we do not have any reliable data on the extent of their use.

Q24 Viscount Ullswater: Do you feel this might have any repercussions for the fishing industry?

Ms Louhimies: I would not think so because fish have been protected already, since 1986. So the fishing industry, I would not see how that would be affected, but obviously if there is more information on what the link is we would be willing to examine that.

Q25 Chairman: Do you think it has any implications for the catering industry – food safety?

Ms Louhimies: We are talking here about only animals that are used or intended to be used for the purpose of experiments, and we know that, for example, the method of killing lobster in the food industry is not necessarily what the scientific community would consider the most humane, but it is not covered by this Directive.

Chairman: Let us go on to severity classifications.

Q26 Baroness Jones of Whitchurch: You will know what your own proposals are but, as I understand it, the European Parliament has come up with a different set of classifications. I wondered if you saw any merit in that. Could you see some arguments as to whether theirs should be adopted rather than the ones that the Commission have come up with? I suppose that is my first question: do the alternatives have merit?

Ms Louhimies: Thank you, my Lord. The European Parliament is actually filling in a part of the Directive a package that we wanted to fill in at the end of the adoption process. They are providing the detailed criteria which we left to be carried out and filled in later on, so they are proposing criteria which are mainly based on the Swiss criteria. When we the Member States and the Parliament, will determine the final criteria for the EU, I think all existing criteria and good practice should be looked at, and should be looked at in detail. We have a number of Member States who have severity classifications in place today and have lots of experience,

and therefore we should look at all the available information also outside of the EU, like Switzerland and also other regions.

Q27 Baroness Jones of Whitchurch: I thought the Parliament was, also – without going into the detail of the criteria – to suggest different classifications then.

Ms Louhimies: Yes. However, at this moment in time the Commission would not like to move from its Proposal, as I said before. Also, in this particular case, because it is very much linked to the other provisions, we have based our proposal on having criteria for three levels of severity and non-recovery grouping, and therefore we would like to keep that grouping because it has a link with the other provisions in the Directive.

Q28 Baroness Jones of Whitchurch: It did seem rather odd that you are not going to explain the criteria until 18 months down the line. Can you give us some idea of why there is going to be that delay? What steps do you have to take, because this is a rather crucial issue about pain, to be frank. Why is it going to take so long? What steps do you have to go through to come up with a sensible proposal?

Ms Louhimies: Thank you, my Lord. That is a very valid question and it has been asked several times. At the time of drafting, the Commission was of the opinion that we have currently enough common knowledge and understanding of what the main categories of these criteria are because they are used by scientists in a number of Member States today. Therefore we left only the fine-tuning, the limits between the different categories to be fine-tuned afterwards, together with providing examples of these different categories. We do understand the urgency of this matter and we realise that it has been picked out as one of the key issues. For that reason we have sent out recently invitations to Member States and to all main stakeholders to come together to an expert working group which will convene on 9 and 10 July. We hope that by the end of this expert working group looking at all the current

evidence and current experience that we have that they will be able to agree what should be the criteria that we will be using in the EU. The results of that expert working group work will then be fed into the European Parliament and the Council for their discussion.

Q29 Baroness Jones of Whitchurch: Presumably one of the tasks of this group will be to pin down the scientific measurement of pain so that it is no longer subjective but becomes much more measurable? Presumably, in most cases, you can actually measure the level of distress, through increased hormones or whatever, that an animal is going through, so that will be one of the tasks to move away from it just being the operatives' best guess?

Ms Louhimies: Definitely and that is a very good comment. That is exactly what we are looking at. We are looking at clinical signs that are objective as a way of determining the animal stress and suffering and pain, so we are looking at clinical science that can be easily explained to the technicians dealing with the animals.

Chairman: We will move on to care and accommodation standards. Baroness Sharp?

Q30 Baroness Sharp of Guildford: Article 32 and Annex IV set out the minimum standards for care and accommodation of animals and we understand that these standards were originally aspirational standards but as they stand now they are being specified as norms. Could you explain to us what evidence led you to justify setting these standards in Annex IV as norms and what do you estimate to be the cost implications for Member States of adopting such standards?

Ms Louhimies: Thank you, my Lord. I probably will take a little bit longer with this one as well because it is a complicated issue again. As you rightly say, they were developed at the Council of Europe as guidance. They were developed with Member States, with full stakeholder involvement and with expert consultation that took over seven years. Furthermore, it was based on the animals' needs in terms of fulfilling their ethological and

behavioural needs, and that was then backed up with scientific information and scientific evidence, and when the information was not available then we used common best practice as the basis. The outcome of that work was a balancing act between the economic needs and needs of animal welfare, supported by scientific information and best practice. Therefore, we feel that there is enough animal welfare, scientific and economic justification to use some of these elements in our Directive. The whole of the Council of Europe guidelines have been transposed into the EU legislative framework through a Commission decision as a Commission Recommendation, so we already apply as guidelines all of these that were agreed at the Council of Europe. What we are proposing here is going beyond that. We take in certain elements which can be applied 100 per cent of the time in 100 per cent of the cases and which can be legally held in front of the court, and those have been put into the Directive, provided it is reasonable to demand so. That has a very big impact on the harmonisation of the internal market. As I said a little bit earlier, one of the elements that has created the distortion of the current uneven playing-field for the operators is the level of standards that we have on housing and care, and therefore we feel that we need to address this issue because that is the way to level the playing-field considerably. I think those are the main points.

Q31 Chairman: It is where you level the playing-field, is it not, in this one, and what is the justification for a particular threshold?

Ms Louhimies: The justification for using these ones was that it was based on the latest science available then about animal welfare. There was an understanding of animals' needs, their level of suffering, et cetera, and that was already balanced against economic needs, and therefore we feel that it is justifiable. We have a situation where some Member States have already implemented them as the legal minimum and we also have Member States who want to go even further, so therefore we feel that this strikes a balance between the different ends of the scale.

Q32 Baroness Sharp of Guildford: I think there is a real fear amongst the pharmaceutical companies who are users of the research based on animals that the setting of these standards might lead to research going outside the EU to countries which do not adhere to these sorts of standards. Is there much worry that there might be a knock-on effect in that way?

Ms Louhimies: The Commission does not believe that that would be the case. We have no evidence of transfer of research in the pharmaceutical industry due to high standards of animal welfare or a strict regulatory environment. A good case example is the UK which has a very large and profitable industry with research and you have one of the highest standards in the EU already. Another point of example is Switzerland, so we have examples that would contradict that statement. Relocation is a very complex issue. We feel that the drivers for the relocation are elsewhere, especially now with the economic recession going on. We look at where the construction is cheap, we look at whether the infrastructure is sufficient to support it, and we look at perks that different host governments provide. For example, China today is very much pushing to have non-human primate research over there. They are wanting to limit the exports of non-human primates. They want to attract foreign companies to come in. We feel that there are other drivers. One specific driver in this area is the existing expertise. We have examples of that both inside and outside the EU. The EU has expertise in vaccine production. 80 per cent of vaccines are produced in the EU, and we are collecting more and more research in this area and we are getting more companies establishing here because the expertise and scientific infrastructure is here. Therefore we feel those are not reasons why it would take place. In the proposal itself we have specific provisions to try to make the administrative burden as minimal as possible. We have foreseen a number of measures there. We have foreseen, for example, group authorisation for regulatory testing to reduce the administration around it. We have foreseen a lighter authorisation structure for projects that consist only of “mild” procedures and do not use non-human primates. Also those ones

would be exempted from non-technical summaries and retrospective assessment. Finally, if there is no response given by the authorities in 30 days for this last group, the project can start. We have filled in a number of elements in the proposal that would make sure that the competitiveness remains here. One element is important. We have drafted the Directive in a way that it will look at objectives that have to be met, but it does not necessarily state how they should be achieved, and therefore the Member States have a main role to play in how they implement these requirements, these objectives. It also gives, we feel, an opportunity to some Member States to look critically at the internal structure and how we have managed today. We need to achieve these objectives: is this the optimum and least bureaucratic way of achieving it? We feel that we have built the elements that would keep the competitiveness of our industry and research over here.

Chairman: Having opened the issue of international competitiveness a little earlier than I anticipated, can I invite Lord Brooke to develop it.

Q33 Lord Brooke of Alverthorpe: If I may come back to the comments which you made about the standards practised in the UK and the British Government's position. Nonetheless there is concern that whilst broadly our Government, I understand, is in support of the objectives which you are seeking, they feel that you have taken some of the practices here, adopted the objectives, but in fact have devised inefficient and clumsy methods and bureaucratic approaches which will be more costly than the present practices and will add to problems over international competitiveness. What would you say to those accusations?

Ms Louhimies: Thank you, my Lord. I would say that we would need to look at the individual items that would be presented. We do not feel that the way that we have worded it increases bureaucracy unnecessarily. We have been very flexible in terms of saying that we would require authorisation and we would require ethical evaluation. We do not determine what is the best body to do those tasks, so in one Member State it could be one single central

body doing both tasks and another Member State could implement it by having a regional ethical evaluation body and having central authorisation, so all these different possibilities of implementation are there to make sure that the current infrastructure is being used to the optimum and we do not need to reinvent the wheel when it is functioning well.

Q34 Lord Brooke of Alverthorpe: Is there not a shift from the requirement for self-policing and notification to actually having central authorisation?

Ms Louhimies: The Directive does not say that. The Directive requires authorisation and it is for the Member States to decide who is the competent authority to carry out that task. It may well be that a Member State can decide that a regional ethical evaluation committee will be also assigned the competent authority hat to authorise and that could be done in a single process. It really does not require specific ways of implementing it. It describes the objectives to be met and it is for the Member States to decide how they are going to achieve that.

Q35 Lord Brooke of Alverthorpe: So you would argue then that the British Government's claim that this is a substantial additional bureaucratic charge which is going on operations is invalid?

Ms Louhimies: I would not go that far. I would like to discuss the details with the British Government. I think that would be the best way to say it!

Q36 Chairman: Have you got any evidence, in the area of academic research, of academics who use animals in their research, and they may be employed by universities in the EU but they also make sure that they have appointments or interests in the Far or Middle East and so they do their animal experiments there?

Ms Louhimies: When we did our consultation the biggest respondent group was from academic research. 33 per cent of the comments came from academic research. We do identify in the impact assessment that academic research will have more costs or rather that they would require longer transitional periods for certain elements than the private sector. For example, the current level of housing and care and the upgrading of it, in 2006, 35 per cent of the private sector had already updated to these new standards but in the Economic Area that was 20 per cent, so we see a difference there because they are also competing on funding money. I am not quite sure if I answered your question on the interaction.

Q37 Chairman: I was just wondering whether you had any evidence that, because of even the present level of the regulatory burden, academics are making sure that their animal research is being carried out in the Middle and Far East rather than the EU?

Ms Louhimies: I would in fact argue the opposite. Industry has a better chance of relocating but academic research is very much in the host country. They do do combined studies and they do international co-operation in an increasing manner, but I would say that industry is the first one to move if there were to be relocation due to that. As I said earlier, we do not really have evidence that high regulation and good animal welfare would actually translate to transportation of the research.

Chairman: Data-sharing, Lord Palmer?

Q38 Lord Palmer: We were on a site visit two weeks ago and I was intrigued by the amount of data-sharing that obviously goes on, particularly within the Union, but the proposal under Article 44 requires Member States to share research data (subject obviously to safeguarding confidential information) in the interests of avoiding unnecessary duplication of procedures. What evidence do you think there is that procedures are currently being duplicated unnecessarily? Perhaps if I then could go on to a supplementary: does the proposal

require more data-sharing than already happens, for example through scientific publication of research? What assessment have you carried out of the impact of extending data-sharing?

Ms Louhimies: Thank you, my Lord. Data-sharing is an important question because there we can cut testing if there is unjustified use of animals. We looked during the impact assessment for evidence of unnecessary duplication. We have to differentiate between two types of testing on animals: those that are required by regulation and by legislation e.g. for chemical safety or pharmaceutical safety, and then we look at the basic research and applied research. The situation is very different in these two areas. In the regulatory testing area there is duplication. It is duplication that is derived from legislation that requires retesting of pharmaceutical ingredients when they come in from outside of the EU. In terms of vaccines there is an option for Member States to retest but not an obligation. Nevertheless, ten to 15 Member States use that option to retest when the vaccine arrives here when it has been tested previously outside of the EU. Based on these calculations, it was estimated that there are about 160,000 animals used for retesting for regulatory purposes.

Q39 Lord Palmer: 160,000?

Ms Louhimies: 160,000 on a yearly basis.

Q40 Baroness Sharp of Guildford: They will be rats and mice.

Ms Louhimies: Yes. We feel that the regulatory testing is best addressed by vertical legislation because we have legislation requiring this so we have to address these areas. We have already ensured that the chemicals legislation addresses data-sharing very strongly to make sure that we do not have unjustified retesting. Pesticides is following the same line. We have cosmetics legislation with very specific provisions actually prohibiting animal testing, so the Commission feels that regulatory testing should be addressed within the sectors. It is very unlikely that you would have duplication between sectors because you are

using your substances for very different purposes, so the likelihood of the testing requirements being the same is very limited. When we move over to the basic research and applied research, applied research is a very problematic area because we talk about innovation proprietary data and that is a very difficult area to tackle. When we talk about basic research the only evidence we could find of unjustified duplication would be in the areas where research results are “negative”, meaning that I have a hypothesis at the start of my project but my hypothesis has not proven to be correct. That kind of result is not very interesting on a newsflash basis. Scientific journals are not interested in having that. Therefore you will have difficulties in getting it peer-reviewed and you will have difficulties getting these results published. We have in bilateral consultation and discussion with professors heard comments saying that, “Yes, I have experienced myself that an experiment that I was carrying out was a little bit along the same hypothesis that somebody had already done but I only found out about that after the event.” We have some evidence but it is an area again which is very, very difficult to tackle. How do you tackle that? In our proposal we have addressed it and we have foreseen a provision that says that Member States should step up efforts to share data which is generated by the use of animals, so we have made a provision there, but how that will be implemented in practice will be discussed with the Member States.

Q41 Lord Palmer: Would registration help, do you think?

Ms Louhimies: We looked at a databank at an EU level as one of the options to start off with, and that was when we started off identifying the different areas, and we said that an overall data-sharing by registering all the projects into one big databank was not feasible. That was also confirmed by the impact assessment. The work required to be put into it with very questionable benefits, especially if it is cross-sectoral, was too much to merit the building up of such a databank.

Q42 Chairman: The reality in basic research is that you will get a number of teams that are doing broadly the same sort of thing and working up and they will be very possessive of their data until it is finally submitted for peer review.

Ms Louhimies: That is exactly correct. The problems with data come in the area of applied research but also very much in the area of fundamental research. That also is linked to the funding because universities are competing on funding not only in the EU but internationally. Therefore it is a very, very problematic area to tackle.

Q43 Chairman: Do you want to tackle that area because it seems to me that you would destroy the whole basis of how basic research is conducted if you do?

Ms Louhimies: We wanted to tackle it at least in terms of seeing what could be done, especially when I refer back to the negative results, because that is an area that people are not generally keen on publishing. That is the only area where we heard that there was evidence that there was unjustified duplication and therefore that is the area that we wanted to tackle.

Chairman: Negative results? OK.

Q44 Baroness Jones of Whitchurch: Surely in the pharmaceutical sector, for example, it would be fantastically secretive and fantastically competitive and the last thing they would want to do is share it? Is there any way that you think that you can break down some of that innate secretiveness?

Ms Louhimies: We have good evidence of the pharmaceutical industry especially stepping up their efforts in terms of voluntary agreements. I think this is an area where we have to tackle it with the tools that we have. In one part we can try regulation but especially in the development phase, at the very early stage of the development phase, it is almost impossible to tackle it because it is their income and bread and butter at the end of the day. When it comes to the later testing when the ingredients are already analysed, the pharmaceutical

industry is today setting up certain specific areas of testing where they are trying to share the data to see what can be achieved in terms of a reduction in numbers.

Q45 Lord Brooke of Alverthorpe: If I may stay on the same theme. The Germans did not accept that the 1986 Directive applied to academia in Germany. That is still the position, as I understand it; yes or no?

Ms Louhimies: I would need to double-check and confirm the current situation in Germany but my understanding is that it is not covered by this Directive. However, our proposal ---

Q46 Lord Brooke of Alverthorpe: --- That was going to be my second question.

Ms Louhimies: --- is to cover basic research.

Earl of Caithness: On your first point on regulatory research, what work are you doing to minimise the chances of retesting in the EU by getting agreements with other countries to meet certain standards? As I understood it, quite a lot of stuff was being retested in the EU which was coming from outside the EU. Surely it would be much better to get them to agree a standard so that it does not have to be retested here?

Q47 Chairman: That raises some issues!

Ms Louhimies: My Lord Chairman, I think if you want me to be brief, it is a very, very complex area. We have different areas the pharmaceutical area: we can talk about the chemicals legislation. The Commission is taking the initiative at an international level, both for chemicals and for pharmaceuticals. There is international classification and harmonisation of pharmaceuticals in the human medicine area and the veterinary medicine area which is looking at accepting and providing similar test requirements globally. We are working on the same thing under the OECD to make sure that we have test methods, so that when a chemical substance is tested here the results would be accepted elsewhere. We are very much in favour

of international harmonisation in all fields of testing. There are similar activities going on in the pesticides area as well. In fact, there are good results especially deriving from the pesticides side where they have identified areas where there is still redundant testing taking place, so we are working at an international level to get harmonisation at the international level.

Chairman: Let us move on to the illusive level playing-field.

Q48 Viscount Brookeborough: I think you have answered quite a lot of how you wish to achieve it. When the document *Questions and answers on revising the Directive for the protection of animals* states that the proposal “strikes a balance between promoting research and competitiveness”, one thing I do not fully understand is if the data is largely shared and the universities know what is happening, at what stage does it become the property of the pharmaceutical business, because they are the competitive side and once they get the data they might produce a drug that other pharmaceutical businesses have not yet produced?

Ms Louhimies: I am not a specialist in the proprietary data area. I will probably be able to get some information for you afterwards but I will not be able to answer that question unfortunately.

Viscount Brookeborough: Thank you. It is just that there obviously is competition but the more you try to go for shared data, what I am not quite clear on is exactly when the serious competition gets it. Even looking at share prices and the price of a drug related, it has been a lot of interest.

Chairman: There are real difficulties about sharing data and how you try and offload cost.

Q49 Viscount Brookeborough: Connected with that a little bit, and I hope you might be able to say something, the type of research done, whether it is with F1 or F2 mammals of any kind, the argument that we were given when we went to a research place the other day was

that it compromises the scientific results, because they will not be pure results because if they are not F2 and they have not been bred primarily for experimentation, ie if you capture from the wild, they are contaminated by all the things that they come on in the wild. The pharmaceutical industry is a very large industry and it relies on pure research. How come they are even prepared to contemplate research from anything other than F2 or animals that have been bred purely in an isolated society? Surely, it almost ought to be self-regulating because it is such big business? I understand that there are all sorts of other issues like counterfeit or less well-regulated areas, and I am not talking about that, I am talking about the major issue.

Ms Louhimies: Thank you, my Lord. That is a very good question. Why is the pharmaceutical industry ready to compromise? I think we have to look at the species' appropriateness to mimic conditions in humans. In the pharmaceutical area of testing often the last testing phase before the clinical trials going into humans is done on non-human primates because they are the closest to us. The next factor that is in the picture is the availability of the animals. Non-human primates are not available to supply the demand that is there today. There are other elements ---

Q50 Viscount Brookeborough: Why not, because they have had so many years in order to do it?

Ms Louhimies: The big difference with non-human primates for example, compared to rats and mice, is first of all their reproductive cycle. If we talk about macaques, and I will have to double-check, they only reach sexual maturity at the age of five years and their offspring consist of 1 progeny so we are talking about a very different type of animal compared to rats or mice or rabbits. The availability of those animals is not there. There are also claims about their breeding in captivity. There are claims by breeders in Mauritius who say that when they get the F1 generation and compare them as breeding parents to the ones that they are picking

up from the wild, they are not as good breeders as the ones taken from the wild. There is more obesity and there are other factors that come into play, so it is not necessarily the case that they are easier to breed. On the other hand, we know that for example with marmosets, which are also used in regulatory testing in the EU, we are using second or much higher generation purpose-bred animals for years but they are easier to breed in captivity. So I think it is a question of what you can do with the animals that you have available. One last comment I would like to mention is the herpes virus. In Mauritius we have a colony of macaques which is completely herpes-free and that is having implications for the workers working with these animals because herpes, as everyone knows, can be passed from the animals to the workers, and sometimes the herpes virus may interfere with the results of the testing that you are doing. The macaques that we are getting from China, Cambodia and Vietnam, for example, can be tested for herpes at the time when they are sold but we cannot say that they come from a herpes-free colony and the herpes can still become active later on. There are several issues in relation to what can be used in which kind of testing environment and that affects their availability.

Q51 Viscount Brookeborough: On the question itself, have you have got anything else to say about level playing fields? You have already addressed it largely in Europe. Do you have anything else to say about world opinion or international opinion as to the documents that you are bringing forward?

Ms Louhimies: We have not received too much feedback from other regions. One thing maybe that I would like to mention is that a lot of the elements that we have in our proposal are also mimicked in the other regions.

Q52 Viscount Brookeborough: Providing they are policed properly?

Ms Louhimies: Yes, I wanted to come back to in which way because in some cases they are embedded in the legislation and in some regions they are in the guidance. If we take the US, for example, their legislation is not providing protection for certain species but those certain species are still covered by the requirements from the funding bodies, and when the funding bodies are then giving money away they require the same standards to apply to all species. In Australia and New Zealand, they have very similar requirements of ethical evaluation and authorisation, so we have a lot of the elements that we have built in mimicked in other areas, but not necessarily in the hard-core legislation; they can be guidance and they can be codes of practice as well.

Q53 Chairman: We are nearly there, I think. Can I just go back really to the beginning almost and where we are with the process. At the First Reading on 5 May the Parliament agreed a number of amendments to the proposal. The Commission, as I understand it, explained in the debate that you could accept in full or in part 83 of the 200-odd amendments that have been proposed. Can you tell us the main impact on the proposal of the amendments that you are accepting and where you still disagree with the Parliament?

Ms Louhimies: Thank you, my Lord Chairman. I have a slight problem with a very concrete answer in this area because the Commission's final response to the Parliament vote is not yet adopted by the College and therefore I cannot go into the details. However, as I mentioned earlier, we do not know the situation with the Member States and we do not know which direction they are heading. At this moment in time it would be very unwise for the Commission to move. Any proposal that would touch on the significant structure or the main elements of our proposal we would not be likely to move towards, at this moment in time. I am talking about issues like authorisation, loosening of reuse requirements, loosening of the requirements for non-human primates, the independence of the ethical evaluation, and the principle of authorisation, and those are core key elements of our proposal, cornerstones of

our proposal, and we would not like to move on any of those areas. The likely areas that we would be moving on would be insignificant in terms of the main core issues.

Q54 Chairman: Could you help us with identifying the more insignificant ones?

Ms Louhimies: Unfortunately I would need to wait for the College to get there, my Lord Chairman.

Q55 Chairman: When will you be able to do that?

Ms Louhimies: I would not like to commit the College. Hopefully in the coming weeks.

Q56 Chairman: Could we be in touch with you or would you be in touch with us on that?

Ms Louhimies: Gladly.

Chairman: Thank you very much. OK, I think that is it, thank you very much indeed. That was really very, very helpful in helping us to understand the thinking of the Commission and the arguments, so thank you very much indeed.