HOW IS CURRENT EU REGULATION PERCEIVED BY BENCH SCIENTISTS?

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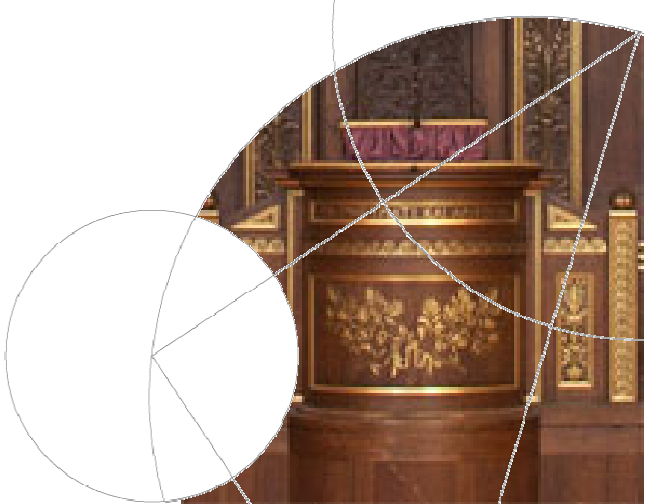

BACKGROUND

- **The successful implementation of Directive 2010/63/EU depends on how it is received by key actors with a practical or a strategic role in relation to research and development involving animal research**
- **In this presentation we will focus on one specific group of actors: Bench scientists**
- **In an online stakeholder workshop to be held in February 2017 we will also bring in two further stakeholders: pharma industry and funders**

THE POINT OF STUDYING PERCEPTION OF BENCH SCIENTISTS

The Directive aims at changing practices in several European countries. However it does not instruct directly on how to act upon those principles and leaves room for institutional and individual interpretation

- **Law is constrained by social institutions, cultural values, everyday practices and legal consciousness (Anleu, 2000)**
- **Actions are constrained by contextual 'barriers', embedded within and occurring as part of social practices (Warde, 2005) and 'the routine accomplishment of what people take to be "normal" ways of life' (Shove, 2004: 117)**
- **How bench scientists enact scientific practices and animal experimentation, as well as how they experience, use, interpret, negotiate and confront the several domains of the directive will be of the outmost importance while accessing its efficacy**

AIM OF THIS TALK

- **To find out what bench scientists see as a good regulatory regime**
- **To determine how the directive and regulations build upon it compare with that regime**

- **Note: Bench scientists are aware of their own national regulation and may only indirectly be aware of the directive**

CHARACTERISTICS OF INTERVIEWEES

- 26 bench scientists, with two exceptions, all from universities
- Most biomedical but also a few from basic or animal science
- Worked in 3 EU countries: Portugal (8), UK (9), and Denmark (9); and were, with two exceptions, native
- There were 12 females and 14 males
- Age ranged from 35 to 64 years with an average of 50 years – so an overweight of senior people
- Worked with a range of species: Mice (16), pigs (3), fish (3), goats and sheep (2), and rats (1)

FOUR MAIN THEMES

1. Is regulation needed, and if so, why?
2. What is good and proper regulation?
3. How well does the actual regulation function?
4. How are changes in regulation perceived?

IS REGULATION NEEDED, AND IF SO, WHY?

- **Wide agreement that regulation is needed for two reasons:**

  1. **Because it protects the researchers**
  2. **Because without regulation some researchers would go beyond what is an ethically acceptable way of treating animals**

PROTECTION OF RESEARCHERS

"… much better for us to have this kind of system [where experiments are approved by a committee with representatives of animal welfare organisations] because it takes away that kind of speculation, that must be terrible, … to sit in a situation where you don't want to tell what you do, you don't want to put signs on your building that this is the lab of something because then you know people would come in and, and burn it, or you would be attacked …" DK

"I think it protects us, as well as the animals, that we have a system that's very clear … It means that we can safely say with honesty that we are doing the experiments under an umbrella of regulation that requires us to take into account animal welfare and to have … a valuable purpose to the experiment." UK

PREVENTING THAT SOME GO TOO FAR

"… there is the potential for the researcher to be so motivated by his purposes that he puts aside … the other side, and that's why it's necessary to have regulations and the 3Rs and have inspections and have protocols and have somebody in external review." DK

"… some people would do a lot of experiments which could cause a lot of suffering in animals so I think it's good." DK

"… the paperwork acts as a way of reminding everybody what the point of this is and then what the considerations are that kind of underpin everything." UK

"… I can't say that there shouldn't be legislation relying on people's common sense, there is no common sense, that's why there are regulations." PT

WHAT IS GOOD AND PROPER REGULATION?

- **A good regulatory system is:**
  - **Without a too long, bureaucratic and time consuming application process**
  - **Run by competent people**
  - **With reasonable and not too restrictive standards**
  - **Flexible**
  - **Consistent over time**
  - **Proportional compared to regulation of other forms of animal use**
  - **Fair level compared to other countries**

VIEWS ON GOOD AND PROPER REGULATION REFLECT EXPERIENCES WITH THE OPPOSITE

- All the descriptions of what is a good regulatory system are going together with concerns about deficiencies in the actual system.
- Particularly in Portugal there are concerns about the competent authority being slow
- In UK there are complaints about lack of consistency across Home Office inspectors
- General concern about lack of flexibility, long waiting times and unnecessary paperwork

CONCERNS ABOUT COMPETENT AUTHORITY

"I think there should be local committees which analyze things through dialogue, that would be more efficient. [With the competent authority] sometimes after a month or more there is no answer, and then there are questions and one answers and they say yes or ask more things. They don't seem to have the capacity to respond, or so I imagine, and it's something very distant. I think it would work better if there were local committees with more dialogue and more dynamic." PT

"That type of very bureaucratic regulation is not good at all. It doesn't benefit the collaboration with researchers, one should try to alert researchers, one should make an effort (...) one has to be careful with how one does things and bureaucracy doesn't help." PT

LACK OF CONSISTENCY

"… what is frustrating is when … there is sometimes a lack of consistency, so one person's interpretation is different to another …" UK

"… there are home office inspectors who cover a certain region and in my experience the average term of the home office inspector … is about 18 months [laugh], so every 18 months we get a different one, on average (…) there's a considerable personal perspective on things and which will vary between inspector to inspector …" UK

HOW WELL DOES THE ACTUAL REGULATION FUNCTION? – POSITIVE VIEWS

- **Even though it takes time to write applications to regulatory bodies this time may be well invested – it may lead to better research**
- **Focus on 3Rs is a win-win for research quality and ethics**
- **The licensing process is useful when it comes to defending animal experiments to the public**

POSITIVE VIEWS

"… it´s another level of bureaucracy, but I think in generally it leads to better projects …" UK

"… I think is fine, we spent … time on it, but normally this is just making the protocols more efficient. (…) We think we have been much better in planning and thinking before we start." DK

"… all aspects of the Home Office regulations of animal work, which includes the 3Rs, are a positive additive to science. And enabling you to produce science, which, first of all, has justification, and secondly is robust, and reproducible." UK

"[When we] finally get the license to do it well then my speculations about if this is ok are gone and that makes it much easier to talk with anyone about animal experiments …" DK

HOW WELL DOES THE ACTUAL REGULATION FUNCTION? – NEGATIVE VIEWS

- **Too rigid requirements for licensing of individuals (e.g. students) helping out in the lab**
- **Too much time is wasted on filling out applications and waiting for responses.**
- **Science by nature has a dynamic element but this fits badly with the regulation system with detailed license applications for 5-year projects**
- **Too much focus on reduction at the cost of statistical power**
- **Regulation, directly and indirectly, imposes costs which at the end of the day goes from the actual research or the care of the animals**

NEGATIVE VIEWS

"… originally (…) I could as a responsible investigator involve PhD students, or medical students in the carrying out of experiments, so they were allowed to help out as long I did the solution, now this no longer possible …" DK

"…regulations] makes [my work] more expensive. (…) It is basically because things need to be checked, I mean record keeping, we have one person working in the fish facility who is basically all day putting things in a data base, that's all she does and she has to be paid." UK

"… maybe after 5 years, or 4 years, there is discovered a better way to anesthetize them. More new knowledge about how to painkill, but then I have to use the old way because that's what we got the license to do …" DK

MORE NEGATIVE VIEWS

"As a result of regulation] I have spent a lot of time trying to explain to people what I'm doing and why I'm doing it. (...) it used a lot of my time that I could have used for something else (...) I'm using more and more time filling out forms, but it's not changing in what I'm doing.(...) it's putting [strain] on my family life because I'm using my time filling out forms instead of playing with my kids." DK

"I think it's, that's a heavy process in Denmark.(...)It's really difficult. Awkward and that destroys also our competition because we are way behind, I can wait for a year then everybody [else] is publishing right. (...) I think in other places, they do all these experiments, I mean all my collaborators do experiments. And I never heard them complain about a 1 year process, I mean that´s ridiculous. (...)" DK

HOW ARE CHANGES IN REGULATION PERCEIVED?

- **In general not much awareness of a change associated with the Directive**
- **Combination of a centralized competent authority and a local committee system can be viewed as a extra burden (Portugal and UK) – on the other hand several appreciate the close working relation with the local committee**
- **Rigid requirement for education before participating in work with animals causes problems**
- **EU directive is a compromise – necessary but also leading to inconsistencies**
- **Focus on 3Rs is welcomed**

- **The focus on 3R's is welcomed because**
  - **They are a good way to limit suffering and reduce numbers of animals used**
  - **They remind us that we are dealing with animals, not only doing research**
- **The 3R's are for some just summarising practices that are already routinize**

"I don´t think so much about [the 3Rs] it´s just a law, I mean these are natural things of our everyday work to try to ensure that when the researchers come to the laboratory animal facility with a proposal for a project they have already done all the in vitro work so that they cannot go further with that." DK

OVERALL NOT A DRAMATIC CHANGE

"… really I don´t think it has changed a lot because the same laws which are now implemented in the new directive was already implemented in Denmark for, for most cases, so we've not seen really a big change with EU directive, of course the, the categorization of the experiments categories of severity is something new, but really - all experiments were already categorized …" DK

CONCLUSION

- **Bench scientists see a clear need for regulation of animal use**
- **They also to a large degree share the intentions behind the directive – not least when it comes to the implementation of the 3Rs**
- **There are critical concerns – to some degree differing across countries – about the functioning of the actual regulation**
- **Widespread worry about too much paperwork and lack of flexibility in the licensing process**
- **Other parts (e.g. cage sizes) is just accepted**

ANNOUNCMENT

Webinar

The Way Forward with European Legislation on Animal Experimetation

A Stakeholder Perspective

Wednesday 22 February 2017, 3-4 pm CET

Registration link will be available on ANIMPACT webpage from next week