THE LABORATORY
ANIMAL BREEDERS
ASSOCIATION OF
GREAT BRITAIN

www.laba-uk.com

Response from

Laboratory Animal Breeders Association

to

House of Lords Inquiry into the Revision of the Directive on the Protection of Animals Used for Scientific Purposes

20 May 2009

The Laboratory Animals Breeders Association of the United Kingdom is submitting evidence focussed on those areas of the proposed revision to Directive 86/609 where its members have observed the most significant impact on their current operations and therefore the future competitiveness of their businesses.

Summary

Our members recognise the need to regulate the use of animals for scientific purposes in the European Union. A small number of specialist commercial breeders of laboratory animals supply the overwhelming proportion of the total number of animals used for scientific purposes both in the UK and other EU countries and are regarded as "critical suppliers" by many customers. Our capabilities commonly extend into key service areas utilising a unique combination of innovation, technical know-how and experience. Laboratory animal breeders and the biomedical research community are interdependent and an impact on competitiveness for the breeder sector has consequences for the academic, biotech, contract research and pharmaceutical sectors.

Our overall assessment is that the proposed regulations will bring additional costs and negatively impact our international competitiveness (Section I below). We assert that disproportionate mechanisms, specifically mandatory and highly detailed engineering standards for housing of stock animals in Annex IV, are being applied to achieve harmonisation and this has not been properly evaluated by impact assessment. The standards in Annex IV for space allocation for stock rodents significantly exceed the enforced UK standards set out in the Codes of Practice which already provide acceptable animal welfare. Flexibility and efficiency in achieving welfare standards will be lost and we will be obliged to divert the entire capital expenditure of our businesses to facility space for rodent and rabbit species for several years to come by enhancing the current UK standards. This will in turn bring additional costs to the whole research sector. Our analysis of the Commission's impact assessment on housing and care (Section II below) indicates it has underestimated the costs while the benefits to animal welfare have been greatly overstated yet these supposed benefits are not even supported by scientific evidence. The Commission has only set out one single policy option for housing and care standards in its impact assessment leading to the housing standards in Annex IV implemented by Article 32 being mandatory yet these are drawn from Council of Europe Convention ETS 123 which titles them as "guidelines"; likewise the Commission originally published this Convention as a "recommendation" in 2007/526/EC.

This regulation will create an uncertain investment climate in Europe for the commercial breeding of animals for scientific purposes and ultimately could compromise welfare by promoting relocation of activities outside the EU and a fragmentation of our efficient breeding colonies.

Section I

Evidence on "specific issues" indicated in the Call for Evidence

1. Objectives of the Directive: harmonisation and proportionality.

   a. We believe that some harmonisation of the framework of the regulations pertaining to the use of animals for scientific purposes is desirable to avoid distortions of the Single Market. Areas where harmonisation has the potential to avoid distortions in the market of relevance to our members include regulation of what sources of animals are permitted for scientific research and which species of animals must be purpose bred for use in scientific purposes. We understand the overall burden of regulation should be similar throughout the market if distortions are to be avoided; however, as detailed below, it appears to us that the Commission is ready to sacrifice competitiveness for a an extreme degree of harmonisation that does more to serve intellectual satisfaction of policy than the practical implementation of that policy in a dynamic market and challenging economic environment. We believe the very reasonable policy objectives cited by the Commission can be achieved with a lighter touch of regulation while still serving the needs of animal welfare.

   b. In the proposed Directive, the level of detail in some areas proposed for harmonisation goes far beyond what is required. The key example of this of direct relevance to our members is in Annex IV referred to in Article 32 which would set down as mandatory very precise "engineering standards" as they relate to the housing space allowances for all animal species likely to be used in scientific research. These engineering standards relating to cage sizes are not supported by scientific references, neither in the expert reports prepared for the Council of Europe revision to ETS 123 which recommended them as guidelines, nor in the Annex of references in the Commission's impact assessment. This is in contrast with the more meaningful "performance standards" set out in the general section of Annex IV which promote sound practices in animal care underpinned by scientific references. Although these detailed standards will permit more harmonisation, this is very much at the expense of competitiveness and will result in our obligation to undertake very significant costs when the economic climate is so adverse.

   c. Our view is that to cite mandatory housing space allowances for all classes and species of laboratory animals is a disproportionate response to avoid a distortion of the Single Market. The market is a very complex and there are many factors which influence the costs of operations, the revenue operations generate and therefore the profitability of the business. Of particular relevance is the cost of transportation of small laboratory animals such as rodents as this can be a significant component of the cost to the end user, and of course, this is a factor that is independent of the cost to produce and house the animal until its despatch.

   d. Cages sizes and stocking densities are not the exclusive determinant of fairness of competition and there is no evaluation in the Commission's own impact assessment of the diverse range of other operational factors and market forces. The Commission's impact assessment has been distorted by the assumption that cage sizes are an overwhelming factor in determining business competitiveness within the EU in this particular market.

2. International competition: competitiveness

   a. Higher welfare standards involving more generous space allowances imply higher costs and in this regard there will be a negative impact on the competitiveness of our industry. The current proposals would require our members to commit our entire capital expenditure for several years to come to expand current facility space while at the same time accepting the legislation is aimed at reducing the market for these very same animals. Our investment would result in increased costs which will have to be absorbed by the biomedical research sector and would be made at a time when there is a very unfavourable economic environment.

   b. Of particular relevance to our members are the mandatory space allowances specified in Annex IV of the proposed Directive as these are generally much more generous than those mandated as minima in third countries. Likewise the space allowances for stock rodents and rabbits are significantly more than those required under the current UK Codes of Practice issued under Animals (Scientific Procedures) Act. As stock animals at breeders are supplied to all users for scientific purposes, any additional costs will inevitably be absorbed in both the private and public sector; likewise incremental upward adjustment of space allowances will increase the costs to house animals and therefore diminish the available investment in other areas.

   c. As stated above, the regulation being considered aims to reduce the market for laboratory animals while requiring further investment in facility space. This creates an uncertain investment climate and is compounded by a diminution of our international competitiveness which could lead to private sector investment being made outside the EU. This could have the consequence of further diminishing the market for our members in the EU and neither aids nor favours long term capital investment decisions.

3. Care and accommodation (Art. 32): standards producing harmonisation

   a. Article 32 of the proposed revision to the Directive makes Annex IV mandatory and this highlights regulatory creep by adoption of recommendations and guidelines as normative standards. In this regard it should be noted that Annex IV is derived from the Council of Europe Convention ETS 123 Appendix A titled as guideline; likewise the Commission originally published this same Convention as a "recommendation" in 2007/526/EC. The expert reports which form the basis of the species specific provisions used for ETS 123 Appendix A are pertinent as best practice was used to inform the guidelines, usually upgraded from current UK standards, when scientific evidence or references were lacking. Indeed the report from the expert group for rodents and rabbits is explicit in Section II.1.1 "… *the exact numeric values for minimum cage sizes and heights as well as for maximum stocking densities can never be scientifically evaluated and "proved". Working out minimum requirements with respect to animal welfare and to supposed well-being of laboratory animals is a political question*."

   b. Mandating the standards in ETS 123 Appendix A will certainly assure harmonisation but only on the assumption each EU country implements, inspects and enforces in a similar manner. However, harmonising by upgrading to such high standards which lack scientific evidence implies significant actual cost with a compromise to competitiveness.

Section II

Evidence on "additional issues" to those indicated in the Call for Evidence: Analysis of the Commission's Impact assessment on for EU Directive 86/609 and the proposed revisions relating to Article 32 and Annex IV

1. The full impact assessment for this proposed Directive published by European Commission (*Commission Staff Working Paper SEC(2008) 2410/2, Impact Assessment*) is flawed in several key respects due to the incomplete and inconsistent data analysed. There are several arguments for why the impact assessment justifying the chosen option to adopt Council of Europe Convention ETS123 as a minimum standard is not valid. Key elements from the impact assessment are discussed in the paragraphs which follow.

    a. We believe the assessments are not robust due to the limitations highlighted on page 8 of the full impact assessment regarding the contracted survey to gather the data: "*The results of this survey were by far not as complete, detailed and fact-based as expected because many respondents were not able to provide new facts and figures on the use of animals for scientific purposes in their establishment or country. As only relatively limited data was available, the contractor (Prognos) developed a model about benefits and costs, and derived qualitative hypotheses from it about possible impacts of the respective options*."

    b. Although a percentage of establishments is quoted on page 48 of the impact assessment as complying with the new standards in CoE ETS 123 Appendix A, this figure is specified as a "preliminary finding" and therefore cannot be relied upon given the diversity of respondents and non-respondents to the survey. The full survey data have never been published. In fact the sampling through the survey is likely to be biased towards those users who are more likely to be in full compliance and does not take account of how a small number of breeders supply the overwhelming majority of animals to user establishments.

    c. Our members found the questions in this key survey in 2006 to be ambiguous and open to interpretation. We would assert other respondents would share our view. This no doubt has lead to a great deal of extrapolation by the contractor (Prognos) which has not assisted the Commission to produce an objective impact assessment.

2. Three main documents have been published and are available on the DG ENV website: http://ec.europa.eu/environment/chemicals/lab_animals/ia_en.htm

    a. Commission Staff Working Paper SEC(2008) 2410/2, Impact Assessment.

    b. Commission Staff Working Paper SEC(2008) 2411/2, Summary of the Impact Assessment.

    c. Prognos Report June 2007, "draft summary", Study on the impacts of different options for the Revision of the Directive 86/609 on the protection of laboratory animals.

3. The only option considered for "housing and care standards" (page 36 of the impact assessment) was to require "as a minimum standard compliance with the revised Appendix A of Council of Europe Convention ETS 123."

a. This option ignores that Appendix A of ETS 123 is clearly titled as "Guidelines for the accommodation and care of animals" and its formulation was never intended as minimum normative standards given the diversity of systems in use.

b. It is also of note that Commission Recommendation of 18 June 2007 is "on guidelines for the accommodation and care of animals used for experimental and other scientific purposes (2007/526/EC)" and recommends "Member States should pay regard to the guidelines set out in the Annex to this Recommendation".

4. The impact of the proposed regulation is significantly understated (page 70 of impact assessment): the benefit in terms of animal welfare is overstated and not supported by scientific evidence while the monetarised costs are understated and incomplete. Therefore the impact of the chosen option (page 85 of impact assessment) is not properly assessed. Also given a very significant burden of costs will fall on a small proportion of all establishments, no attempt has been made to consider this.

a. The species-specific sections to Appendix A are based on proposals by expert groups but the experts make clear that scientific evidence was often not available. Section 4.5.1 specifies the space allowances as being "*suggested minimum animal enclosure sizes*" and these are included in the species specific sections. Section II.1.1 of the rodent and rabbit expert working group report states " … *the exact numeric values for minimum cage sizes and heights as well as for maximum stocking densities can never be scientifically evaluated and "proved". Working out minimum requirements with respect to animal welfare and to supposed well-being of laboratory animals is a political question*."

b. It is strongly asserted in the Impact Assessment on page 48 that animal welfare will be enhanced and the major changes are related to cage sizes. However the scientific evidence for these specific enclosure sizes is not referenced in the expert working group report for rodents and rabbits and is not included in the Annex to the Impact Assessment though references are included to justify the other more general standards (pages 92-93).

c. There is no monetarisation for the upgrading of small animal facilities and for the capital expenditure that would be required; this is a significant impact as the costs will contribute to the users costs. For this reason the costs of implementation are significantly underestimated (pages 70, 71, 77). The omission of capital expenditure also means that the impact on those small number of breeders providing the vast majority of animals has not been evaluated and this cost for breeding facilities is extremely high in relative terms to user facilities given this is the focus of their work. Furthermore there is no acknowledgement that the capital expenditure which will be demanded must be considered as being relevant when considering the transitional period and that the operational changes required will demand re-equipping and construction of new facilities to breed and supply the same number of animals.

d. The impact of the chosen options (page 70, 85) are not properly assessed given that a very significant burden of costs will fall directly on a very small proportion of all establishments given the impact on breeding establishments. Therefore the burden of the cost will be directly absorbed in a disproportionate manner by breeders before these costs can be absorbed more generally in the market place through increased pricing. How markets respond to an increase in pricing is a major factor in determining whether a level playing field is retained.

5. The policy objective of reducing unfair competition and distortion of the internal market (page 29) is focussed on costs for breeders due to housing standards and fails to acknowledge that the market and market forces are a great deal more complex.

a. Cages sizes and stocking densities are not the exclusive determinant of fairness of competition and there is no evaluation in the impact assessment of the diverse range of other operational factors and market forces. The impact assessment has been distorted by the assumption that cage sizes are an overwhelming factor in determining business competitiveness within the EU.

b. The imposition of minimum enclosure sizes imposes a burden which diminishes competitiveness with respect to third counties and this indirectly could diminish animal welfare by creating a disincentive to continue to invest in European versus US or Asian operations for global companies.

6. The policy objective of a significant improvement in animal welfare cites minimum criteria for housing and care but the benefit to animal welfare is not supported by scientific evidence.

a. It is strongly asserted in the Impact Assessment on page 48 that animal welfare will be enhanced though the major changes are related to cage sizes. However the scientific evidence for these specific enclosure sizes is not referenced in the expert working group report for rodents and rabbits and is not included in the Annex to the Impact Assessment though references are included to justify the other more general standards (pages 92-93).

7. There is no policy objective (page 29) relating to competitiveness and the risk of allowing activities such as breeding and supply to be conducted from third countries which do not fall under the scope of this proposal to revise the Directive.

a. The imposition of minimum enclosure sizes imposes a burden which diminishes competitiveness with respect to third counties and this indirectly could diminish animal welfare by creating a disincentive to continue to invest in European versus US or Asian operations for global companies.

8. The impact assessment has not considered the standards which are currently inspected and enforced in other countries and whether those standards meet the requirements for high quality animal welfare.

a. A strict and detailed Code of Practice has existed in the UK from 1986 with reduced stocking densities in relation to those proposed in the revised Appendix A of ETS 123. The UK stock holding floor space allowances have never been cited as being inadequate or directly leading to compromises in animal welfare.

b. The UK has had a strict regulatory inspection regime that has included the breeding facilities for all species within its scope and the UK has been continuously self-sufficient in breeding and supplying animals from within its borders. This significant use of animals combined with a strict inspection and monitoring regime has not been considered in the impact assessment and is significant practical evidence supporting appropriate standards in animal welfare.

9. There is a contradictory assertion for which there is no evidence regarding the transitional period which would be required by breeders given the facilities are continuously used and close to full capacity.

a. The assessment on page 48 of the analysis of impact relating to the housing and care standards is incomplete in its consideration of the translational period which would be required; specifically there is no evidence put forward to contradict the information cited in this paragraph from Prognos report that a ten year transitional period is required to indicate the conclusion " *… breeding establishments can be expected to be able to cope with the new requirements earlier*".