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MRC Medical Research Council

BIOSCIENCES FEDERATION

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UK bioscience sector Declaration of Concern on the revision of EU Directive 86/609 on animal experimentation

We represent key bioscience organisations in the UK. Between us we reflect the perspective of academia, industry, SMEs, charities and other research funders, as well as patient and medical groups.

We welcome the opportunity to update the European Directive 86/609, which we hope will result in: a greater emphasis on the 'three Rs' of Reduction, Refinement and Replacement; harmonisation of animal welfare standards across Europe; and balanced regulation that is consistent across Member States.

Our organisations support all efforts to bring a balanced approach to the revision of the Directive. However, we remain deeply concerned that elements of the draft revised Directive could have a number of potential adverse impacts on bioscience research, on medical and scientific progress and on scientific and commercial competitiveness, both in the UK and across Europe. Many of the proposals could damage research or drive it abroad, while others could present unworkable administrative burdens without any gain in animal welfare.

We wish to reiterate our belief that animal research remains essential for the following purposes: to develop fundamental biological knowledge; to help deliver new medicines and treatments for citizens across the globe; and to protect the health of humans, animals and the environment (for example through the regulatory testing of medicines for safety, or the impact of chemicals on the environment, or through conservation research).

We believe that, without animal research, scientists across Europe would not have been able to deliver many new medicines and treatments for patients. We can see no way that medicines for diabetes, asthma, leukaemia and medical procedures such as blood transfusions and transplant surgery could have been developed without animal research. There are many challenges facing the world today, such as discovering treatments for diseases such as HIV/AIDS, tuberculosis, Alzheimer's and Parkinson's, where animal research is likely to play a vital role.

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It isn't just humans that benefit. Nearly all of the medicines and clinical procedures that we use for animals, in both the veterinary and farm animals setting, were also developed through fundamental or applied animal research.

We must co-operate to improve animal welfare and promote the 3Rs, and we must guard against introducing new measures and bureaucracy that have no tangible animal welfare benefits and will stifle vital research. Unfortunately, many of the proposals in the revised Directive that was published in November 2008, and some of the amendments since proposed, could undermine animal welfare either directly or by driving research abroad, or would hinder bioscience with little or no animal welfare benefit.

Our organisations have submitted detailed comments on hundreds of aspects of the proposed Directive from our sector. A few areas of particular concern are detailed in the annexe to this Declaration. If such proposals were to go ahead, we would face so many restrictions and problems in so many areas of animal research that we would undoubtedly see a rapid downturn in European biomedical science. This could result in a significant loss of expertise in many fields of research, such as neuroscience and vaccine research, where we are currently among world leaders. We could also see wholesale export of research outside the EU, to the detriment of animal welfare and to the disadvantage of patients across Europe, and indeed the world.

In summary, to ensure the EU adopts a proportionate approach to regulating animal research, we need to balance several factors: health, wealth and social benefits; EU scientific and industrial competitiveness; and, importantly, animal welfare and the three Rs. The bioscience sector is committed to working with European institutions to ensure that the revised Directive achieves this balance. We hope that the European Parliament Agriculture committee can play its part in the crucial vote next week to help ensure an appropriate regulatory framework that promotes good research, while addressing improvements in animal welfare.

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Annex

We wish to highlight **just a few** of the areas
in particular in the November draft that are problematic.

Article 2 - Scope
Extension of species covered by the Directive to certain classes of invertebrate (other than adult cephalopods), including larval forms as well as embryonic forms of vertebrate animals, would present an unworkable administrative burden without any gain in animal welfare, given that for most such forms sentience has not been scientifically established.

Article 8 - Non-Human Primates (NHPs)
We agree that careful harm-benefit assessment is required before primate use in research is authorised; in most countries that assessment already exists. However, we disagree with attempts to impose sweeping restrictions on, or to phase out or ban, NHP use. This could have a serious negative impact on the ability of fundamental and applied science to bring much needed medical advances to UK citizens and patients across the world.

Article 10 - Animals bred in captivity
A blanket restriction of use to second generation (F2) NHPs (ie offspring of animals that have been bred in captivity) could be problematic. It requires a feasibility study to assess the impact on animal welfare and the availability of NHPs to EU researchers.

Article 15 - Classification of severity levels
It is very important that severity levels of procedures are properly and precisely defined within the Directive, not least since this is relevant to important judgements elsewhere in the Directive. Clear bands must appropriately encompass all levels of regulated use, so as to encourage refinement from one band to a lower one.

Article 16 - Re-use
The proposed restrictions on re-use of animals would make it extremely difficult to maintain some research programmes in the EU and could seriously restrict technical developments that promote the 3Rs.

Article 32 and annex IV - Care and accommodation
The Directive, as originally proposed, is overly prescriptive about cage sizing and environmental requirements. As well as greatly increasing costs for research, some proposals are actively deleterious to welfare. The commercial pressures on breeders to move out of high-cost countries could have very negative consequences for welfare.

Article 43 - Authorisation of decisions
The administrative implementation of the Directive must be clear and well-defined. It is currently confused and unnecessarily bureaucratic, with potential for unnecessary delays and restrictions to research that would not promote welfare or the 3Rs.

Article 44 - Sharing of data
Mandatory data-sharing proposals fail to recognise existing initiatives to avoid unnecessary duplication of animal research, the degree of success already achieved and the technical and legal difficulties involved. They are impractical to implement, would have a detrimental impact on the competitiveness of both industrial and academic research, while there is no evidence that significant welfare benefit would result.