



Mr Neil Parish MEP
Chair, Agriculture and Rural Affairs Committee,
European Parliament,
60, Rue Wiertz, B-1047,
Bruxelles,
Belgium

EU Animals Directive 86/609

Dear Mr Parish,

I am writing to you in my capacity as President of EUROHORCs, the Heads of the European Research Councils. EUROHORCs' members have been considering the draft revision of the EU Animals Directive, as published by the Commission on 5 November 2008. One of the two Vice-Presidents of EUROHORCs, Sir Leszek Borysiewicz, has written to EUROHORCs' members to solicit their views. His letter is attached ([annex 1](#)), as is a summary of the responses received by 13 March ([annex 2](#)).

EUROHORCs is also aware of the updated ESF/EMRC statement which I understand you have seen and which is shortly to be published; indeed many members of EUROHORCs' organisations contributed to this piece of work. Overall, the responses to the EUROHORCs consultation agree with the points made in the ESF statement; though the comments from EUROHORCs ranged wider than those of ESF, and will no doubt be reflected in discussions between EUROHORCs' members and MEPs and with national Governments.

In the light of this weight of opinion reflected through Europe-wide bodies such as ESF and EUROHORCs, I trust that the Agriculture Committee will be giving very detailed consideration to the points made by the research community, in particular to ensure that revisions do not inhibit European competitiveness, nor reduce the strength of biomedical research in Europe.

Yours sincerely,

Professor Dieter Imboden

encs

cc Professor Liselotte Højgaard, EMRC Chair

EUROHORCs
c/o Swiss National Science
Foundation
Wildhainweg 3
3001 Berne
Switzerland

Phone: +41 (0)31 308 22 22
Fax: +41 (0)31 301 30 09
E-Mail: eurohorcs@snf.ch
Web: www.eurohorcs.org

President: Dieter Imboden
Secretary: Danièle Rod

Annex 1

Dear EUROHORCs member,

European Directive 86/609 on the protection of animals used in scientific procedures

I am writing to you as Vice-President of EUROHORCs, but also as Chief Executive of the UK Medical Research Council.

As you may be aware, the proposed revision to the animal research Directive is currently being discussed by the Agriculture Committee in the European Parliament. The Rapporteur is Neil Parish, a UK MEP. (There are two other Committees which have an interest in the Directive: the Environment Committee and the Industry and Research Committee. Both will debate it and submit reports to the Agriculture Committee for their consideration). The expected timetable is attached¹.

I have been involved in many discussions concerning the Directive, most recently at the EUROHORCs Steering Committee meeting in Frankfurt on 12 February. The Steering Committee agreed that I should write to seek your views on the Directive, and to ask how you (or others in your country) are proposing to influence the European Parliamentary process and/or to advise your national Government.

The draft Directive, as published by the Commission on 5 November 2008², is intended to improve harmonisation across the European Union and to improve animal welfare. EUROHORCs members have a significant interest in the outcome of discussions regarding the proposed amendments to the Directive and its impact on biomedical sciences in Europe. I, and other members of the Steering Committee, support the revision of the Directive - to update it and ensure it reflects current scientific developments and current best practice in animal welfare. We would also wish, however, that the revised Directive is proportionate and balanced in maintaining the highest animal standards whilst facilitating scientific progress. In addition, any additional bureaucracy and costs should be kept as low as possible, and the Directive should ensure that the competitiveness of European science is not compromised.

There are a large number of areas of concern, but in my view (and those of UK colleagues) the main ones are:

¹ *Deleted from here*

² Available at: http://ec.europa.eu/environment/chemicals/lab_animals/proposal_en.htm

EUROHORCs
c/o Swiss National Science
Foundation
Wildhainweg 3
3001 Berne
Switzerland

Phone: +41 (0)31 308 22 22
Fax: +41 (0)31 301 30 09
E-Mail: eurohorcs@snf.ch
Web: www.eurohorcs.org

President: Dieter Imboden
Secretary: Danièle Rod

1. **Restriction of use of Non-Human Primates (Article 8):** As drafted, the Directive is likely to limit the ability to undertake critical fundamental research using Non-Human Primates. This may impair the competitiveness of the EU in various sectors of biomedical research and R & D, as well as slowing innovation and the advancement of biomedical knowledge.
2. **Severity Levels (Article 15):** It is critical that the definition of severity banding be included in the main body of the Directive and not agreed subsequent to the adoption of the Directive as such definitions will impact on other areas of the Directive such as reuse. Again without clear definitions, the EU will become a less attractive environment in which to carry out research.
3. **Restrictions on reuse (Article 16):** The impact of this restriction is likely to have adverse effects on animal welfare by increasing animal usage unnecessarily, thereby increasing the cost and time of undertaking some research. Such limitations are likely to drive collaborative research out of Europe.
4. **Extension of scope of Directive to cover invertebrates and larval forms (Article 2):** Again this amendment is disproportionate by increasing bureaucracy with very minimal animal welfare gains. The increase in bureaucracy and cost that this provision is likely to have will make the EU a less attractive environment in which to undertake certain research, eroding the EU's fundamental research base and R & D in bioscience.
5. **Care and accommodation (Article 32 and annex IV):** Although there is an exemption from some of the requirements for animal welfare reasons, there should also be exemptions for scientific reasons. As drafted, the Directive would make it impossible to undertake certain veterinary or welfare research on farm or zoo animals if they had to be accommodated in facilities that were different from those used in current farm/zoo practice.

I would be grateful if you could let me know:

- i) Whether you agree/disagree with the above concerns?
- ii) Whether you have particular concerns about other articles, and what these are?
- iii) To what extent you believe these views are held commonly within your country, including by your national government
- iv) How you (or others in your country) are proposing to influence the European Parliamentary process and/or to advise your government?

EUROHORCS
c/o Swiss National Science
Foundation
Wildhainweg 3
3001 Berne
Switzerland

Phone: +41 (0)31 308 22 22
Fax: +41 (0)31 301 30 09
E-Mail: eurohorcs@snf.ch
Web: www.eurohorcs.org

President: Dieter Imboden
Secretary: Danièle Rod

In view of the tight timetable, I would welcome your response by 1 March. I will then attempt to summarise the views received, recognising there may be considerable differences, which we can then all use to ensure that the legislation meets its main aims without compromising European science. In adopting a common approach which can accommodate a diversity of opinions, I believe we will provide added weight in informing and influencing the European Parliament in its deliberations. The results of this summary will also be discussed at EUROHORCs General Assembly, but from the timetable you will appreciate that this will be too late to be relevant to the proposed Parliamentary timetable.

Yours sincerely,

Sir Leszek Borysiewicz
Vice-President, EUROHORCs

Chief Executive
Medical Research Council

[Enc]

EUROHORCs
c/o Swiss National Science
Foundation
Wildhainweg 3
3001 Berne
Switzerland

Phone: +41 (0)31 308 22 22
Fax: +41 (0)31 301 30 09
E-Mail: eurohorcs@snf.ch
Web: www.eurohorcs.org

President: Dieter Imboden
Secretary: Danièle Rod

European Directive 86/609 on the protection of animals used in scientific procedures:

Summary of the opinions of the members of EUROHORCs on the main areas of concern on the revised draft of the directive:

1. Restriction of use of Non-Human Primates (Article 8)
2. Severity Levels (Article 15)
3. Restrictions on reuse (Article 16)
4. Extension of scope of Directive to cover invertebrates and larval forms (Article 2)
5. Care and accommodation (Article 32 and annex IV)

Specifically:

- i) Whether they agree/disagree with the above concerns
- ii) Whether they have particular concerns about other articles, and what these are
- iii) To what extent they believe these views are held commonly within their country, including by their national government
- iv) How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government

Summary:

16 EUROHORCs member organisations from 14 countries submitted a response to Sir Leszek's letter of 16 February. There was general agreement that revision was needed, to bring the directive up-to-date and for harmonisation; however, all expressed concerns about the draft currently presented, highlighting the need to balance animal welfare and research considerations.

i) Whether they agree/disagree with the above concerns, and ii) Whether they have particular concerns about other articles, and what these are

All the members who responded endorsed the concerns raised in relation to severity levels, the extension of the directive to cover invertebrates and larval forms and care and accommodation. 14 of the 15 organisations supported concerns on the restriction of the use of Non-Human Primates; however, one member organisation supported the introduction of scientific justifications for these types of procedures as long as essential experiments can be performed. 14 of the 15 organisations supported concerns relating to restrictions on re-use; however, one member organisation found the draft proposal presented to be quite reasonable.

A number of additional concerns were raised by members, many of which related to the potential for over-regulation and administrative burdens. Further information on specific concerns are outlined at [\(3\)](#) and at [Annex 1](#).

EUROHORCs
c/o Swiss National Science
Foundation
Wildhainweg 3
3001 Berne
Switzerland

Phone: +41 (0)31 308 22 22
Fax: +41 (0)31 301 30 09
E-Mail: eurohorcs@snf.ch
Web: www.eurohorcs.org

President: Dieter Imboden
Secretary: Danièle Rod

iii). To what extent they believe these views are held commonly within their country, including by their national government, and iv) How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government.

Of the organisations which responded, seven noted a belief that the views expressed were commonly held within their country, with four (France, Germany, Poland, Sweden) reporting these to be in alignment with the view of national government. Once member organisation, FWF, noted that the Austrian national government was unlikely to share these concerns in view of the very restrictive policy towards the protection of animal rights (all experiments involving primates are prohibited).

Member organisations in France, Germany, Poland and Sweden have produced joint position statements, comment or opinion papers to influence the process and are working closely with MEPs and relevant European Parliament Committees. Within the smaller countries, most organisations are working with local Ministries and directly with MEPs.

Member organisations in France and Germany have recommended there should be a common position statement from EUROHORCS and call for all national research organisations to inform their national governments.

(1a). Respondents (14 countries out of 24, 16 member organisations out of 36*):

Country	Member Organisation
Austria	Austrian Science Fund (FWF)
Belgium	Research Foundation - Flanders (FWO)
Czech Republic	Czech Science Foundation (GACR)
Denmark	Danish Council for Independent Research
Finland	Academy of Finland (AKA)
France	National Centre for Scientific Research (CNRS)
France	National Institute of Health and Medical Research (Inserm)
Germany	German Research Foundation (DFG)
Germany	Max Planck Society (MPG)
Hungary	Hungarian Scientific Research Fund (OTKA)
Italy	Italian National Agency for New Technologies, Energy and the Environment (ENEA)
Poland	Council for Science
Republic of Ireland	Science Foundation Ireland (SFI)
Spain	Spanish National Research Council (CSIC)
Sweden	Swedish Research Council
Switzerland	Swiss National Science Foundation (SNSF)

(1b). Non-respondents (14 countries out of 24 (of which 9 countries did not respond at all), 20 member organisations out of 36*):

Country	Member Organisation
Belgium	Fund for Scientific Research-FNRS (FRS-FNRS)
EUROHORCS c/o Swiss National Science Foundation Wildhainweg 3 3001 Berne Switzerland	
Phone: +41 (0)31 308 22 22 Fax: +41 (0)31 301 30 09 E-Mail: eurohorcs@snf.ch Web: www.eurohorcs.org	
President: Dieter Imboden Secretary: Danièle Rod	

Estonia	Estonian Science Foundation (ETF)
France	Agence Nationale de la Recherche (ANR)
France	French National Institute for Agricultural Research (INRA)
France	French National Institute for Research in Computer Science and Control (INRIA)
France	French Research Institute for Exploitation of the Sea (IFREMER)
Germany	Fraunhofer Gesellschaft (FhG)
Germany	Helmholtz Association of German Research Centres (HGF)
Greece	National Hellenic Research Foundation (NHRF)
Iceland	Icelandic Centre for Research (RANNIS)
Italy	National Institute of Nuclear Physics (INFN)
Italy	National Research Council (CNR)
Luxembourg	National Research Fund Luxembourg (FNR)
Norway	Research Council of Norway
Portugal	Science and Technology Foundation (FCT)
Republic of Ireland	Enterprise Ireland
Slovenia	Slovenian Research Agency (ARRS)
The Netherlands	The Netherlands Organisation for Applied Scientific Research (TNO)
The Netherlands	The Netherlands Organisation for Scientific Research (NWO)
Turkey	Scientific and Technological Research Council (TUBITAK)

*Not including UK Research Councils

(2). Agreement with the MRC's concerns:

Concern	Number of respondents (countries)
Overall agreement with MRC's concerns	14 (all). General agreement that revision needed, to bring the directive up-to-date and for harmonisation, but all have concerns about the draft and the need to balance animal welfare and research considerations
Article 8	Agree: 13 Partly agree: 1 (Spain supports the introduction of scientific justifications for these types of procedures as long as essential experiments can be performed)
Article 15	14
Article 16	Agree: 13 Do not agree: 1 (Denmark does not fully agree – finds the principle quite reasonable)
Article 2	14
Article 32 and annex IV	14

(3). Particular concerns about other articles:

Article Number	Subject	Countries
Article 3 (21), article 14, article 15 and article 43	Classification of procedures	France
Articles 5, 14 and 19, and annexes II, IV and V	Agricultural sciences and farm animal specifications	France

EUROHORCS
c/o Swiss National Science
Foundation
Wildhainweg 3
3001 Berne
Switzerland

Phone: +41 (0)31 308 22 22
Fax: +41 (0)31 301 30 09
E-Mail: eurohorcs@snf.ch
Web: www.eurohorcs.org

President: Dieter Imboden
Secretary: Danièle Rod

Articles 7, 8, 42(4) and 15(2) (for example)	Basic research (including on endangered species)	Germany, Switzerland
Article 10(16)	Interdiction of wild-caught and exclusive use of F2 generation	France
Article 14(3)	Anaesthesia	Germany
Article 15	Strain categories	Germany
Article 17(1)	The point at which genetically modified animals can no longer be included in an experimental procedure but must rather be considered an established line	Germany
Article 19(24)	Animals' future after experiments	France
Article 20	Authorisation of animal-experimentation personnel	Finland, Italy, Spain
Article 20(3)	Time limit on the authorisation of animal-experimentation personnel	Germany
Article 24	Specification of "staff"	Germany
Articles 24(2), 25 and 26	Overlapping of competencies	Germany
Articles 24(2), 25, 37(3), 37(4), 40 and 38 (for example)	Excessive bureaucracy and international competitiveness of Europe	Germany
Article 25	The system of administrative organisation, establishment of the permanent ethical review body	Poland
Articles 30 and 31	"History files" and mandatory marking for dogs, cats and non-human primates	Germany
Article 33	Inspections to be carried out by the competent authority	Spain
Article 33(6)	Joint inspection by member states	Germany
Article 34	Controls by the European Commission	Germany
Articles 36-43	Administrative burden	France
Article 37(4)	"Independent parties"	Germany
Article 38	Retrospective assessment of a project	Germany
Articles 41 and 42	Project duration and lack of simple extensions	Germany
Article 43(1)	Time limits for the authorities	Germany
Article 46	The establishment of a national reference laboratory for the validation of alternative methods	4 (Belgium (also expressed by European Science Foundation), France, Poland, Sweden)
Article 47	National animal welfare and ethics committees	Poland
Annex IV (Section B7) and Annex IV (Section B5)	Fur animals	Denmark
Not given	Housing	France
Not given	Special attention to certain species	Germany

EUROHORCS
c/o Swiss National Science
Foundation
Wildhainweg 3
3001 Berne
Switzerland

Phone: +41 (0)31 308 22 22
Fax: +41 (0)31 301 30 09
E-Mail: eurohorcs@snf.ch
Web: www.eurohorcs.org

President: Dieter Imboden
Secretary: Danièle Rod

General	For example: increased bureaucracy and limitation of research fields; the text has many flaws (for example in terminology); some provisions are so detailed and constraining that it can be compared to a regulation	France
General	Over-regulation may harm research	Poland
General	Structural set-up of the directive needs to be improved	Switzerland

(4). To what extent are the views held commonly within the country, including by the national government:

Area	Views held commonly
Research community	Yes: 7 (Finland, France, Germany, Italy, Poland, Republic of Ireland, Sweden) No: N/A Not known: 1 (Spain - discussions are currently being held) Not stated: 6 (Austria, Belgium, Czech Republic, Denmark, Hungary, Switzerland)
Government	Yes: 4 (France, Germany (Government is beginning to share the concerns), Poland, Sweden) No: 1 (Austria – has a very restrictive policy on animal rights) Not known: 2 (Denmark, Spain – discussions are currently being held) Not stated: 8 (Belgium, Czech Republic, Finland, Hungary, Italy, Republic of Ireland, Switzerland)

(5). How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government:

Country	Activities
Austria	Nothing (little chance that Government will become involved)
Belgium	Not stated
Czech Republic	Not stated
Denmark	Will inform the relevant Ministry
Finland	Will inform the relevant Minister and MEP
France	Contact with French counterparts (common position statement), MEPs and the relevant European Parliament Committees (including getting proposed amendments tabled), exchange of information and a co-ordinated approach with counterparts in other countries, and other activities such as meetings
Germany	Joint position statement, shared with MEPs, the relevant European Parliament Committees and the relevant delegates of their government/parliament
Hungary	Not stated
Italy	Italian organisations have sent opinions and comments to FELASA, points have been raised with the Agricultural Committee, and the Government has asked for comments and

EUROHORCS
c/o Swiss National Science
Foundation
Wildhainweg 3
3001 Berne
Switzerland

Phone: +41 (0)31 308 22 22
Fax: +41 (0)31 301 30 09
E-Mail: eurohorcs@snf.ch
Web: www.eurohorcs.org

President: Dieter Imboden
Secretary: Daniele Rod

	suggestions on the revision
Poland	Opinion paper to be submitted to EC
Republic of Ireland	Will inform the relevant Minister
Spain	Discussions are being held at the national level through the Ministry of Science and Innovation with active participation of scientists
Sweden	Swedish comment paper and preliminary Government memorandum produced, plus contact with MEPs
Switzerland	No active lobbying as not a member of the EU

Additionally, both France and Germany suggested that there should be a common position statement from EUROHORCs. Germany also suggested that national research organisations should inform their national governments about the situation.

13/03/2009

EUROHORCs
c/o Swiss National Science
Foundation
Wildhainweg 3
3001 Berne
Switzerland

Phone: +41 (0)31 308 22 22
Fax: +41 (0)31 301 30 09
E-Mail: eurohorcs@snf.ch
Web: www.eurohorcs.org

President: Dieter Imboden
Secretary: Danièle Rod