

**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:

19 EUROHORCs member organisations from 15 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. 18 of the 19 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. 17 of the 19 organisations supported concerns relating to restrictions on re-use; however, one member organisation found the draft proposal presented to be quite reasonable, and another cannot currently predict how the public or government in their country would respond to these concerns.

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](#).

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, eight countries noted a belief that the views expressed were commonly held within their country, with five countries (France, Germany, Poland, Sweden, Turkey) reporting these to be in alignment with the view of national government. One 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, comments 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 (15 countries out of 24, 19 member organisations out of 36*):

Country	Member Organisation
Austria	Austrian Science Fund (FWF)
Belgium	Fund for Scientific Research-FNRS (FRS-FNRS)
Belgium	Research Foundation - Flanders (FWO)
Czech Republic	Czech Science Foundation (GACR)
Denmark	Danish Council for Independent Research
Finland	Academy of Finland (AKA)
France	French National Institute for Agricultural Research (INRA)
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)
Turkey	Scientific and Technological Research Council (TUBITAK)

(1b). Non-respondents (12 countries out of 24 (of which 8 countries did not respond at all), 17 member organisations out of 36*):

Country	Member Organisation
Estonia	Estonian Science Foundation (ETF)
France	Agence Nationale de la Recherche (ANR)
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)

*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; note that one of the two organisations in Belgium did not state their position). 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 (note that one of the two organisations in Belgium did not state their position) 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 (note that one of the two organisations in Belgium did not state their position)
Article 16	Agree: 13 (note that one of the two organisations in Belgium did not state their position) Cannot comment: 1 (Turkey cannot currently predict how the public or government in their country would respond to these concerns) Do not agree: 1 (Denmark does not fully agree – finds the principle quite reasonable)
Article 2	14 (note that one of the two organisations in Belgium did not state their position)
Article 32 and annex IV	14 (note that one of the two organisations in Belgium did not state their position)

(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
Article 5	Purposes of procedures	France
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
Articles 14(1-3)	Anaesthesia	France, 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	France, 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
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 (countries)
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: 7 (Austria, Belgium (one of the two organisations stated that discussions are currently being held), Czech Republic, Denmark, Hungary, Switzerland, Turkey (though concerns are shared by its Local Ethical Committees of Animal Research))
Government	Yes: 5 (France, Germany (Government is beginning to share the concerns), Poland, Sweden, Turkey) 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 (countries)
Austria	Nothing (little chance that Government will become involved)
Belgium	Federal level group of experts set up to report to the European Parliament
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 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
Turkey	Not stated

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.

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Extended summary (attached separately)