

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

Extended 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

Member Organisations which responded (19 from 15 countries):

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)

Member Organisations which did not respond (17 from 12 countries, of which 8 countries did not respond at all):

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)

Note: these lists do not include the UK Research Councils

Austria: Fonds zur Forderung der wissenschaftlichen Forschung (FWF) (Austrian Science Fund)

Responder	Christoph Kratky (President)
Summary	Fully agree with concerns raised by the MRC
Agreement/disagreement with MRC concerns	
Article 8	Agree
Article 15	Agree
Article 16	Agree
Article 2	Agree
Article 32 and annex IV	Agree
Particular concerns about other articles	
General	Main reservations captured, no other concerns
To what extent are the views held commonly within the country, including by the national government	Views given are from the President and the relevant Board member in charge of these issues. They do not think that Austria and/or its Government are likely to share the concerns. Austria has a very restrictive policy towards the protection of animal rights and any experiments with primates are prohibited
How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government	They see little chance that the Austrian Government will interfere with the European parliamentary process on this issue

Belgium: Fund for Scientific Research-FNRS (FRS-FNRS)

Responder	Veronique Halloin (Secretary General)
Summary	Did not state whether agreed with concerns or not – currently putting a statement together
Agreement/disagreement with MRC concerns	
Article 8	Not stated
Article 15	Not stated
Article 16	Not stated
Article 2	Not stated
Article 32 and annex IV	Not stated
Particular concerns about other articles	
General	None given
To what extent are the views held commonly within the country, including by the national government	Matter is of particular interest for the FRS-FNRS and they are currently collecting inputs from their research community in order to put together a sound statement on the Directive
How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government	An ad hoc group composed of high level experts has been set up at the federal level to study the changes in the Directive and provide the European Parliament with the Belgian comments on it

Belgium: Research Foundation - Flanders (FWO)

Responder	Elisabeth Monard (Secretary General)
Summary	The FWO fully agrees with the MRC's concerns
Agreement/disagreement with MRC concerns	
Article 8	Agree
Article 15	Agree
Article 16	Agree
Article 2	Agree
Article 32 and annex IV	Agree. They attach great importance to this concern, as it affects all researchers performing animal experiments. It is essential that the requirements about care and accommodation of (larger) animals are not stricter than those used in current farm/zoo practice. In the revised directive, some unrealistic requirements about enrichment of housing appear to have been deleted (e.g. provision of straw for some species, which cannot be provided free from pathogens and poses practical problems such as obstruction of drains). This is a significant improvement and essential for the continuation of biomedical research in Europe.
Particular concerns about other articles	
Article 46 (the establishment of a national reference laboratory for the validation of alternative methods)	They share the viewpoint expressed in a position paper by the European Science Foundation in September 2008. They wonder if it is really necessary to have a national reference laboratory in each EU Member State and why different countries cannot collaborate and share research data
To what extent are the views held commonly within the country, including by the national government	Not stated (FWO's experts consulted for their response)
How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government	Not stated

Czech Republic: Czech Science Foundation (GACR)

Responder	Petr Mateju (President)
Summary	Fully agree with the MRC's concerns
Agreement/disagreement with MRC concerns	
Article 8	Agree
Article 15	Agree
Article 16	Agree
Article 2	Agree
Article 32 and annex IV	Agree
Particular concerns about other articles	
General	No other comments
To what extent are the views held commonly within the country, including by the national government	Not stated. Note that the protection of animals is in the jurisdiction of the Ministry of Agriculture (www.mze.cz), which is also responsible for the implementation of the EU directives in this domain. There are also professional associations participating in the legislative process and overseeing the adherence to the directives and principles, such as the Czech Laboratory Animal Science Association, a member of the Federation of European Laboratory Animal Science Associations (www.felasa.eu)
How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government	Not stated

Denmark: Danish Council for Independent Research (DFF)

Responder	Jens Christian Djurhuus (Chair of the Board)
Summary	The DFF generally agrees with the MRC's concerns
Agreement/disagreement with MRC concerns	
Article 8	Agree. The non-human primates will be protected by the various precautions mentioned in chapter IV, and therefore the suggested restriction is not considered to be needed
Article 15	Agree. It is considered to be important to ascertain common European regulations
Article 16	Do not entirely agree. They find the suggested principle of defining clear criteria for the possible re-use of experimental animals quite reasonable
Article 2	Agree. It seems disproportionate to include invertebrates and larval forms in this Directive
Article 32 and annex IV	Agree. An often used experimental animal is the farm animal, also used under practical farm conditions
Particular concerns about other articles	
Fur animals (Annex IV (Section B7) and Annex IV (Section B5))	They have noted that among the farm animals mentioned, no fur animals are included, which means that the only species of this kind is ferrets. However, fur animal production has a considerable volume in several European countries, and mink is in this relation also often used in experimental work. Consequently, this species should be included in the directive
To what extent are the views held commonly within the country, including by the national government	Not noted (DFF views given)
How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government	The DFF have not been consulted by their national authorities about the consequences of the Directive but have decided to inform the Danish Ministry of Science, Technology and Innovation about their concerns, recommending that the issue be raised at the political level. The Danish Medical Research Council has decided to discuss the directive and the consequences for medical research at more length at their March meeting

Finland: Academy of Finland (AKA)

Responder	Sirpa Nuotio (Senior Adviser) on behalf of Markku Mattila (President of the Academy of Finland)
Summary	The scientific community in Finland widely shares the MRC's concerns regarding the proposed Directive, especially articles 2, 8, 15 and 16
Agreement/disagreement with MRC concerns	
Article 8	Agree
Article 15	Agree
Article 16	Agree
Article 2	Agree
Article 32 and annex IV	Agree
Particular concerns about other articles	
Article 20 (authorisation of animal-experimentation personnel)	It would be necessary to harmonise the requisite competence between the Member States. The Finnish experts had interpreted the Article regarding care and accommodation so that it would still be possible to do veterinary clinical research
To what extent are the views held commonly within the country, including by the national government	The scientific community in Finland agree with these concerns (the Academy of Finland contacted Finnish scientists and experts in this field)
How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government	They will send the information to the Minister of Agriculture and Forestry, Ms Sirkka-Liisa Anttila, and the Finnish Member of the European Parliament, Mr Esko Seppänen

France

(1): French National Institute for Agricultural Research (INRA)

(2): National Centre for Scientific Research (CNRS)

(3): National Institute of Health and Medical Research (Inserm)

This also includes summarised details of a common French position paper by the major French research organisations (Inserm, INRA, CEA and CNRS)

Responder	INRA: Marion Guillou (President and CEO) CNRS: Arnold Migus (Director General) Inserm: Andre Syrota (Director General)
Summary	<p>INRA support the revision of the Directive but also believe it should be balanced in maintaining the highest animal standards whilst not hampering scientific progress. In particular, it should take into account specificities of agricultural sciences and the use of farm animals, which is not currently the case (a major concern for INRA is to allow animal experiments under conditions that are specific to agricultural practices).</p> <p>CNRS (and the French research community) fully share the MRC's concerns and support a revision of the draft directive. Overly restrictive regulations would mean additional costs which would go into bureaucracy rather than into animal care and research activities and could cause animal experimentation to move to countries in which values and regulations give no guarantees. They have asked for modifications on a number of the draft's articles including the five of particular concern to the MRC.</p> <p>Inserm agree with the MRC's main concerns. They strongly support the revision of the directive. They agree that the present text will have a hard impact on their research activity (in particular) and on European science competitiveness.</p> <p>Overall: The common French position paper explains that adoption of the directive in its present form could have dramatic consequences on research activities in Europe and could even have a negative impact on animal welfare.</p>
Agreement/disagreement with MRC concerns	
Article 8	Agree (including INRA even though this issue does not directly affect their activities). The use of non human primates for scientific purposes is necessary (and studies on primates are deeply justified before they go ahead). CNRS have asked for modifications to the article relating to the limitation of research scope (basic research scope on primates should not be reduced) and ban on the use of apes (it is particularly dangerous to forbid the use of these animals in case of, for example, future major outbreak) and to article 10 (prohibition of wild-caught animal and exclusive use of F2 generation) (this would have dramatic consequences in terms of animal protection, principally a massive delocalisation of studies on primates in emerging countries)
Article 15	Agree
Article 16	Agree. This is an important issue for INRA – its impact will have an adverse effect on animal welfare by increasing animal usage unnecessarily. In addition, it should mention the fact that repeated use of one animal in one unique protocol should not be considered as “successive” procedures
Article 2	Agree. INRA believe that as well as increasing bureaucracy levels, the inclusion of these forms is arbitrary since sentience has not been

	established for all of them. The extension of scope of the Directive should only concern embryonic and foetal forms of mammalian species
Article 32 and annex IV	Agree. INRA state that this is a crucial issue for agricultural research. They believe that these housing conditions should be kept as guidelines and not as standards embodied in the Directive, allowing specific experimental conditions for farm animals. In any case, exemptions from some of the requirements should be allowed for scientific purposes
Particular concerns about other articles	
Overall	The revised directive decreases, without any scientific evidence, the possibilities of animal experimentation by increasing the administrative burden, and reducing research fields (which embodies a significant danger of research delocalisation to other areas outside of Europe where animal welfare is not a concern. This is not acceptable from animal welfare point of view and will also affect European competitiveness). This will hamper progress of European research related to human health, harm animal welfare and weaken European competitiveness
Article 3 (21), article 14, article 15 and article 43 (classification of procedures)	As drafted, the principles of a classification of severity procedures established by a committee of "concerned persons" cannot be accepted. Only a real scientific committee using published results has the competencies to introduce classification models
Articles 5, 14 and 19, and annexes II, IV and V (agricultural sciences and farm animal specifications)	It is crucial that animal experiments under conditions that are specific to agricultural practices are allowed in order to achieve EU agriculture competitiveness
Article 5 (purposes of procedures)	The list of purposes of procedures proposed is very restrictive and does not include the enhancement of production and welfare of farm animals - INRA propose the inclusion of a new clause 5(2d) for this purpose
Article 10(16) (interdiction of wild-caught and exclusive use of F2 generation)	This will have dramatic consequences in terms of animal protection, for example a significant increase in the number of animals in captivity and the massive delocalisation of studies on primates into emerging countries. See also article 8
Article 14 (1) and 14(2) (anaesthesia)	A number of research topics such as research on farm animal stress and welfare, etc., cannot be conducted under anaesthesia. Even though this article includes exemptions where anaesthesia is incompatible with the purpose of the procedure, INRA believe that this is insufficient and that clause 14-1 should be either removed or should include a clear exemption to allow experiments under normal conditions where anaesthesia is incompatible with the purpose of the procedure
Article 19(24) (animals' future after experiments)	Animals must not be set free after experimentation and reference to this must be removed (and the use of the term "setting free" is inappropriate for farm animals)
Article 25 (the system of administrative organisation, establishment of the permanent ethical review body)	INRA believe that the setting up of a permanent ethical committee per establishment is incompatible with transparent and credible management. They propose promoting the setting up of external ethical committees with local branches, which would be more suited to ensure independence of ethical evaluation
Articles 36-43 (administrative burden)	There are a number of measures that might add to bureaucracy
Article 46 (alternative methods to animal experimentation)	Presenting the development of alternative methods to animal experimentation as a mean to significantly reduce the number of animals used in research is a misleading argument
Housing	House conditions have been used outside their context. Also, recommendations become compulsory in experimental situations which will totally forbid certain types of experimentation
General	The text has many flaws and amendments have been proposed (more

	<p>details can be found in the annexes attached to the response). The main points are:</p> <ul style="list-style-type: none"> - In principle it is meant to be a directive but some provisions are so detailed and constraining that it can be compared to a regulation. The text should focus on principles and leave details to the next level of legislation - The text does not use rigorous terminology which introduces confusion (e.g. mixing the terms “ethics” and “good practices”) - The balance between ethical and scientific evaluation is not detailed - The Directive should allow animal experiments under conditions that are close to agricultural practices (essential for a number of research topics) - The European Commission can (without any appeal) adopt the directive annexes, which will be reviewed in 10 years - this is not acceptable - Annexes - in the proposal's annexes, there are some dispositions which may have important consequences
<p>To what extent are the views held commonly within the country, including by the national government</p>	<p>INRA: Not specifically stated but see below for CNRS</p> <p>CNRS: The major French research organisations (Inserm, INRA, CEA and CNRS) appointed a group of high-level experts to develop a common position and to establish contact with other European organisation as well as with EC officials and MEPs (particularly the AGRI, ENVI and ITRE Committees).</p> <p>The views are strongly supported in France, not only among the organisations performing research but also in government.</p> <p>Inserm: Inserm have responded after a number of discussion held with their different partners on the draft directive and the draft reports presented by the ITRE, ENVI and AGRI Committees</p>
<p>How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government</p>	<p>INRA: They have been deeply involved in the national and EU decision-making process together with other major French public research institutes (Inserm, CNRS and CEA). They have developed a common strategy to participate in the European parliamentary process, starting with working on the draft reports of the ITRE, ENVI and AGRI committees (some of their proposed amendments have been included in these reports). The French Parliament and the Government have been kept well-informed about these actions. As discussed with the other French organisations, they believe that adopting a common approach will provide more influence in the decision-making process.</p> <p>CNRS: They have been regularly in contact with their French counterparts and authorities. They have been following the scientific aspects of the issue closely, following debates in the European Parliament, informing MEPs and other key players in the European decision-making chain and proposing amendments to them.</p> <p>CNRS' views have been extensively communicated to key MEPs. They proposed 39 amendments to several French-speaking MEPs (33 of these have been tabled) and organised several meetings with key MEPs. They have met the Committee members and shadow Committee members. As a result, several of their proposals have been included in the draft reports for the ITRE and AGRI Committees.</p>

	<p>They are also co-organising (with the Science and Technology Options Assessment Committee) a visit at the Primatology Centre in Strasbourg and a lunch debate with Françoise Barre-Sinoussi, Nobel Prize Winner in Medicine, at the European Parliament in Strasbourg.</p> <p>They suggest that EUROHORCs issue a common position statement (as a short letter) on the revision of the directive, to be broadly disseminated throughout the European Institutions.</p> <p>Inserm: Inserm, together with the other French public research institutes has been participating strongly in the European parliamentary procedure. This has included close contact with MEPs and administrators and the AGRI, ENVI and ITRE Committees, in order to explain their point of view and influence the vote on those Committees' draft reports. They proposed a number of amendments to the draft reports (see above under CNRS). They are still working on this phase with the view of the vote in the AGRI Committee in late March.</p> <p>They have agreed with the other French public research institutes to continue their common approach in order to increase the impact in the decision-making process.</p> <p>In addition, an exchange of information and a co-ordination of their action have been established with their colleagues from the UK Bioscience sector, German Research Foundation, Max Planck Society and Leibniz Association. They also participated in the Science Policy Briefing organised by the EMRC and a position paper will be addressed to MEPs in the next few weeks. The same process is being carried out with the French Academies of Sciences Medicine and Pharmacy.</p> <p>As for the national parliaments, the French Parliamentary Office for Scientific and Technological Assessment is at present preparing a report on the animal experimentation and alternative methods. Inserm are highly involved in this. Through their Spanish, German and British colleagues from the EMRC Expert Group, they are in the process of contacting the key parliamentary in each country to have more indirect influence on the MEPs.</p> <p>With their common approach with other French public research institutes as well as with their colleagues from Germany, the UK, Spain and the ESF/ERMC, they will continue to approach MEPs in order to influence the parliament deliberations</p>
Notes	<p>The French responses were accompanied by several explanatory documents (in which more detail can be found):</p> <ol style="list-style-type: none"> 1. The common position statement of the French RPOs (incorporated into the summary) 2. Three documents with comments on the Directive 3. Three zip files with 39 proposed amendments (in French). Most of these have been officially tabled by French-speaking MEPs

Germany

(1): Deutsche Forschungsgemeinschaft (DFG) (German Research Foundation)

(2): Max Planck-Gesellschaft (MPG) (Max Planck Society)

This also includes summarised details of a joint statement of the DFG, MPG and the **Leibniz Association** on the current draft of the directive.

Responder	DFG: Matthias Kleiner (President) MPG: Rüdiger Hesse (Head of Brussels Office) but questions specifically answered by Thomas Dantes (policy officer and expert of the Max Planck Society)
Summary	They welcome the efforts to standardise the basic conditions for the use of laboratory animals within Europe. The objective of the revision is intended to be a combination of animal protection and feasibility for research purposes. Freedom of research, gain in scientific knowledge and international competitiveness must not be hindered. DFG: Fully agree with the MRC's concerns. They fundamentally welcome the revision of the old directive but are also concerned about the serious dangers to basic research in Europe associated with the new regulations included in the proposed directive MPG: very much aware of concerns about the Directive and agrees with the MRC's five concerns
Agreement/disagreement with MRC concerns	
Article 8	Agree (of particular concern). Aside from the fact that special consideration of non-human primates is not technically justifiable, basic research should be permitted
Article 15	Agree (of particular concern). This point plays a central role in the document and brings with it far-reaching regulatory consequences. The classification of procedures should be subject to the same process as the directive and published with it. A ban on prolonged strain-inducing experiments is not acceptable
Article 16	Agree (of particular concern – the proposals for re-use of animals are unrealistic and instead should be replaced by the requirement for an overall assessment using the 3Rs principle)
Article 2	Agree. Article 2(2) should be removed
Article 32 and annex IV	Agree
Particular concerns about other articles	
Basic research (for example, articles 7, 8, 42(4) and 15(2))	The draft threatens to place shackles on basic research, which can expect to experience a standstill or at best a considerable slow-down in the gain of scientific knowledge. As a result, basic research in certain areas would be at a disadvantage compared to application-oriented research or research required by law and basic research on some species/prolonged strain-inducing experiments would be prohibited. Also, basic research on endangered species must be permitted as long as animals specially bred for the purpose can be used. The impact on basic research is the gravest concern of the

	DFG. Basic research is a vital prerequisite for applied research projects. This special characteristic is not considered in the draft and a discrimination of basic research occurs in several articles of the directive
Special attention to certain species	The special attention given to certain species of animal due to their emotional or genetic similarity to humans is not scientifically tenable. This criticism includes the restriction of use of non-human primates as well as the special guidelines for the use of cats and dogs
Article 14(3) (anaesthesia)	Should be amended to state that anaesthesia must not affect the results of the procedure
Article 15 (strain categories)	The introduction of strain categories is good in principle but it is not acceptable that they are to be defined separately from the directive and will not be adopted until 18 months after its publication, as they play a central role within the document
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)	One of the issues addressed by this article is the point at which genetically modified animals can no longer be included in an experimental procedure but must rather be considered an established line. This point should be changed to take into consideration the breeding generation instead
Article 20(3) (time limit on the authorisation of animal-experimentation personnel)	The five-year time limit on the authorisation of animal-experimentation personnel contravenes the principle of equality among different occupational groups and should be removed
Article 24 (specification of "staff")	Qualified animal caretaker must be added to the specification of "staff"
Articles 24(2), 25 and 26 (overlapping of competencies)	This results in a overlapping of competencies and should be replaced by the possibility to retain proven national structures
Excessive bureaucracy (for example, articles 24(2), 25, 37(3), 37(4), 40 and 38) and international competitiveness of Europe	Several passages of the draft lead to extremely excessive bureaucracy in the monitoring and authorisation of animal experiments. To keep from endangering the international competitiveness of Europe, research must not be encumbered by such excessive bureaucracy
Articles 30 and 31 ("history files" and mandatory marking for dogs, cats and non-human primates)	This should be expanded to include farm animals; also, no lifetime logging of information on specific species should be done
Article 33(6) (joint inspection by member states)	This has not been stipulated to date in any EU directive and should be removed
Article 34 (controls by the European Commission)	This has little or no benefit for the practical protection of animals and should be removed
Article 37(4) ("independent parties")	Who these are should be clarified or the point removed
Article 38 (retrospective assessment of a project)	This is new in Germany and may have a negative impact on scientifically supported, hypothesis-oriented work. This should be removed or instead replaced by a requirement of a neutral final report for each project
Articles 41 and 42 (project duration and lack of simple extensions)	The directive should grant its member states the possibility of establishing national regulations and exceptions should be permitted for specific cases
Article 43(1) (time limits for the authorities)	This could lead to delays and instead should be replaced with the introduction of an assumption of authorisation for all

	procedures
<p>To what extent are the views held commonly within the country, including by the national government</p>	<p>DFG: German science organisations (both applied and basic research organisations) share the same opinion – a joint meeting of the three organisations and representatives of other research organisations, academia, pharmaceutical research associations and medical associations illustrated a strong agreement in concerns.</p> <p>Government delegates are becoming aware of this problematic issue. In the European Parliament, the lead for the issue lies with the German Federal Ministry of Food, Agriculture and Consumer Protection. Scientific issues are not the central focus of the Ministry and its position towards the directive is not known to the DFG at present</p> <p>MPG: Generally speaking there is a lot of concern in the scientific community in Germany about the possible negative consequences for biomedical research if the proposed directive were passed and implemented as proposed in the draft.</p> <p>Regarding the Government, animal research and the respective animal welfare act are dealt with by the Ministry of Agriculture and Consumer Protection (BMELV). Up to now this ministry has shown little sensitivity for the concerns of the scientific community. The other important ministry - the Ministry of Science and Education (BMBF) - is concerned about the possible consequences of this directive and in favour of changes. It remains to be seen how active the BMBF will lobby the BMELV behind the scene. Due to party politics (both ministers belong to the conservatives) there seems to be a certain reluctance to push the BMELV openly to take up scientific concerns.</p> <p>However, the activities of the scientific community show first results in drawing political attention to the issue (see below).</p>
<p>How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government</p>	<p>DFG: The DFG and other research organisations from Germany have sent a letter to the MEPs of the three relevant committees, raising key points of general criticism as well as specific comments on all articles of concern. The DFG have also informed the delegates of the relevant committees of the German Federal Parliament and the Federal Assembly. They have also met MEPs to express their concerns in individual meetings.</p> <p>They think it is essential to achieve a delay in the decision-making process on the revision of the directive beyond the end of the legislative period. If this does happen, further concerted activities in Brussels would be necessary to inform the new MEPs as early as possible about the concerns.</p> <p>They suggest that EUROHORCs should try to use their influence by contacting the members of the European Parliament and informing them about the serious consequences of the current revision for European research activities. They think that a common EUROHORCs</p>

	<p>statement would be of stronger influence than activities of national agencies.</p> <p>They also suggest that national research organisations inform their national governments about this issue.</p> <p>MPG: The joint statement has been sent to the respective three EP committees (AGRI, ENVI, ITRE) and its members, and first talks have been held (and are scheduled) between German scientists and members of these committees. In addition, the joint statement has been sent to the ministries (BMBF & BMELV), the respective committees in the German Parliament (Bundestag) and the ministers in the 16 states responsible for science and animal experimentation. In the Bundestag's science committee this statement served as an eye opener. The draft directive was on the agenda of a recent committee meeting but not for discussion (it is postponed to a later meeting as it is now recognised that there is a need for further deliberation and discussion). Subsequent contacts and talks with the committee members will follow. In the German Bundesrat, the ministers of several states have also expressed concern for the possible negative consequences of the proposed directive and called for further deliberations in recent meeting. Further steps in Germany, however, have to take into account that there will be federal elections in Autumn 2009.</p>
Notes	<p>The joint statement of the DFG, MPG and the Leibniz Association on the current draft of the directive is summarised above but further details can be found in the document itself (sent with both organisations' responses)</p>

Hungary: Hungarian Scientific Research Fund (OTKA)

Responder	Elod Nemerkenyi (Assistant of International Affairs)
Summary	Fully agree with the MRC's concerns
Agreement/disagreement with MRC concerns	
Article 8	Agree
Article 15	Agree
Article 16	Agree
Article 2	Agree
Article 32 and annex IV	Agree
Particular concerns about other articles	
General	No other comments
To what extent are the views held commonly within the country, including by the national government	Not stated
How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government	Not stated

Italy: Italian National Agency for New Technologies, Energy and the Environment (ENEA)

Responder	Luigi Paganetto (President)
Summary	Fully agree with the MRC's concerns. They want the revision to produce high quality standards and ethical approaches in animal research while facilitating the progress of science
Agreement/disagreement with MRC concerns	
Article 8	Agree
Article 15	Agree
Article 16	Agree
Article 2	Agree
Article 32 and annex IV	Agree
Particular concerns about other articles	
Necessary expertise required for people directly involved in management of animal facilities and experimental procedures [probably refers to article 20]	Each country would have to introduce its own rules and definitions of the appropriate expertise for authorising people who have a role in animal experimentation
To what extent are the views held commonly within the country, including by the national government	<p>Many Italian organisations have been involved on this topic. AISAL (Italian Association for the Laboratory Animal Sciences), IPAM (Italian Platform of Alternative Methods), EFPIA (European Federation of Pharmaceutical Industries and Associations) and other stakeholder organisations have already sent their opinions and comments to FELASA (Federation of European Laboratory Animal Associations), recognised as a focal point in the EC.</p> <p>The draft report of the Agricultural Committee's report was published on the European Parliament website. It reported numerous amendments, which represent the major issues raised especially by the Europeans scientific community (including Italy) as a result of debate (among scientists and animal protectionists). Nevertheless, some topics are still a matter for discussion (as stated above).</p> <p>The Italian Government recently asked many specialists and associations to write a brief comment and suggestions on the revision with the aim of addressing the important concerns mentioned by the MRC</p>
How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government	See above

Poland: Council for Science

Responder	Professor Kazimierz Stepień (Chairman)
Summary	An attempt to over-regulate this matter by the European Directive may harm research in the EU. The Polish position (as given here) is in line with most of the MRC's concerns but they also believe that some of the EC proposals should undergo further analysis
Agreement/disagreement with MRC concerns	
Article 8	Agree
Article 15	Agree
Article 16	Agree
Article 2	Agree
Article 32 and annex IV	Agree
Particular concerns about other articles	
Article 25 (the system of administrative organisation, establishment of the permanent ethical review body)	Requires consideration - the proposed solutions result in significant increase of administrative costs of scientific entities. Since 1997 in Poland there has been a reliable system for issuing permits for conducting animal research and for control of scientific entities (based on Local Ethics Committees)
Article 46 (setting up of national reference laboratories)	Needs further discussion - some Member States may find it difficult to establish such a national laboratory without the financial support of the Community
Article 47 (national animal welfare and ethics committees)	As for article 25
To what extent are the views held commonly within the country, including by the national government	The Polish position (the official opinion of the Ministry of Science and Higher Education) was worked out in co-operation with scientists and representatives of Non-Governmental Organisations (NGOs) dealing with animal protection issues. It was approved by the European Committee of the Council of Ministers
How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government	The National Ethics Committee in cooperation with Local Ethics Committees and NGOs dealing with animal protection issues are preparing their opinion on "Proposal for a Directive of the European Parliament and of the Council on the protection of animals used for scientific purposes", which will be submitted to the EC

Republic of Ireland : Science Foundation Ireland (SFI)

Responder	Frank Gannon (Director General)
Summary	Generally agree that harmonisation across Europe to bring consistency in improved animal welfare is a high priority. They are also in general agreement with the MRC's areas of concern in so far as they relate to animal usage in Ireland
Agreement/disagreement with MRC concerns	
Article 8	Agree
Article 15	Agree
Article 16	Agree
Article 2	Agree
Article 32 and annex IV	Agree
Particular concerns about other articles	
General	No specific additional concerns
To what extent are the views held commonly within the country, including by the national government	They anticipate that their views would reflect the views nationally
How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government	Their efforts to get a more considered and official position from Ireland have proven elusive. They will speak to the relevant Minister and officials to ensure that they are aware of the MRC's letter and concerns

Spain: Spanish National Research Council (CSIC)

Responder	Rafael Rodrigo (President)
Summary	Agree with most of the MRC's concerns. Regarding the revisions as a whole, they consider it an advantage that projects and not isolated procedures will be evaluated. The possibility of authorising multiple regulatory testing procedures under one group authorisation will reduce bureaucracy
Agreement/disagreement with MRC concerns	
Article 8	Partly agree. They fully agree with the introduction of scientific justifications for these types of procedures as long as essential experiments can be performed. Society demands more scientific reasons in order to authorise experiments with non-human primates and the scientists will have to prove the absolute necessity of their experiments
Article 15	Agree – the criteria and clear definition for the classification of the severity of procedures should also be included in the revised directive; this classification should not be agreed afterwards because of its important impact in areas such as re-use
Article 16	Agree – they agree with the re-use of animals but it should be based on scientific criteria with the limitations imposed by the classification of the cause of pain. While re-use may reduce the number of sacrificed animals, it may jeopardise the scientific conclusions obtained in any subsequent experimental procedure that lack a clear knowledge of the interaction with the first procedure
Article 2	Agree – they think that this modification will directly affect their researchers. The incorporation of these forms and animals will considerably increase bureaucracy in institutions. The inclusion of embryos from the last third of their normal development will affect studies on thin cell differentiation and the physiology of organs/ systems of great importance in regenerative medicine – this will reduce the competitiveness of their researchers. The incorporation of cyclostomes, cephalopods and decapod crustaceans does not seem to have a very strong scientific justification
Article 32 and annex IV	Agree that there should also be exceptions for scientific reasons
Particular concerns about other articles	
Article 20 (authorisation of persons)	The regulation of those who take care of the animals has been suppressed – they consider this a disadvantage
Article 33 (inspections to be carried out by the competent authority)	The number of inspections has been increased to two – this will have an important economic impact. The reporting/reviewing of projects/procedures by the competent authority will also have an economic impact
Advantages of the revision	
To what extent are the views held commonly within the country, including by the national government	Discussions are currently taking place (see below)
How they (or others in their country) are proposing to influence the European	An ethics committee has been created in CSIC and the regulation of the use of animals in scientific procedures is currently being discussed at the national level through the

Parliamentary process and/or to advise their government	Ministry of Science and Innovation with active participation of some of their scientists
---	--

Sweden: Swedish Research Council

Responder	Karin Forsberg Nilsson (Deputy Secretary General of the Scientific Council for Medicine)
Summary	Agree with the MRC's concerns. The revision will need to balance the best animal welfare with the need to support research involving animal experimentation. While there is definitely a need to modernise the Directive and for harmonisation across Europe, some concerns remain, from both a scientific and an animal welfare point of view
Agreement/disagreement with MRC concerns	
Article 8	Agree
Article 15	Agree
Article 16	Agree
Article 2	Agree
Article 32 and annex IV	Agree. Note that the requirements for care and accommodation in annex IV are minimum requirements. Sweden already has stricter requirements in many cases
Particular concerns about other articles	
Article 46 (the establishment of a national reference laboratory for the validation of alternative methods)	It is unrealistic to build national reference laboratories, and even more so within a year. This is an area where collaboration at the European level would work well to validate a large number of methods. As the article now reads, there is great risk of duplication of efforts, which will counteract harmonisation and co-operation. Instead, specialised laboratories could be built that are not related to the national level. They believe that this is an area where the European dimension may be used to show its strength
To what extent are the views held commonly within the country, including by the national government	<p>The revision was sent for a consultation by the Department for Agriculture to 28 Swedish organisations, including governmental agencies, universities, the pharmaceutical industry, veterinarian associations, funding agencies, the review boards for ethical applications in animal experiments, the Swedish Institute for Infectious Disease Control, the County Administrative Boards and animal welfare organisations. The comments were summarised at a hearing organised by the Department for Agriculture.</p> <p>The final standpoint of the Swedish Government has not been communicated. A preliminary Swedish view is presented in a memorandum from the Government, in which they agree with the decision of the European Commission to revise the directive (because one of the reasons is to increase animal welfare within the EU). The Government ambition is that it should be possible for a member state to have more far-reaching national regulation on animal welfare, and it also believes that all use of animals in research should build on the 3Rs principle. The revision stresses this principle, which the Government strongly supports</p>
How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government	They and many other organisations have acted by passing their views and comments to the Department of Agriculture, as described above. Through this, a thorough and detailed review has been forwarded to the Government. They and others participated through hearings and

	information/briefings for members of parliament before the release of the Government memorandum. In addition, they have contacts with the Swedish representation in Brussels
--	--

Switzerland: Swiss National Science Foundation (SNSF)

Responder	Elisabeth Mitter (Scientific Officer, International Co-operation)
Summary	Agree with most of the MRC's concerns. The directive needs revision, both concerning its legal structure and inclusion in the European environment and its advances which may severely influence research in Europe
Agreement/disagreement with MRC concerns	
Article 8	Agree
Article 15	Agree
Article 16	Agree
Article 2	Agree
Article 32 and annex IV	Agree
Particular concerns about other articles	
Basic research	Basic research is taken as a direct building block of applied research, an understanding which in turn would imply that basic research without immediate or predictable output would have to be considered second ranked by the directive
General	In general, they believe that the structural set-up of the directive needs to be improved
To what extent are the views held commonly within the country, including by the national government	Not stated (response provided by their Department of Biology and Medicine). In Switzerland, recent movements show that society has important ethical reservations concerning animal experimentation. The SNSF believes that future revisions of legislation will result in more stringent conditions, and they see it as their duty to comply with changes in ethical perceptions, as long as they are scientifically documented and do not result in an obligation to abstain from or significantly reduce research which is conducted in service of the good of humanity and of the knowledge society
How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government	As Switzerland is not a member of the EU, they will not be active in any lobbying or similar activities
Notes	More detailed answers to the points are available in German

Turkey: Scientific and Technological Research Council (TUBITAK)

Responder	Güliz Sütçü (Scientific Programmes Assistant Expert)
Summary	Agree with concerns raised by the MRC (apart from article 16 which they cannot currently comment on). The definitions must be made clear and the severity levels must be set so as not to make animal research impossible or to impair the competitiveness of the EU, but to ensure best practice in animal welfare as well as to ensure scientific developments and progress
Agreement/disagreement with MRC concerns	
Article 8	Agree. Currently, Turkey does not use non-human primates in biomedical research but they agree with the concerns and especially feel that although restriction of their use in biomedical research is right ethically it may cause disadvantage with regard to the EU's worldwide competitiveness in scientific research
Article 15	Agree (necessary to determine the severity levels much more clearly)
Article 16	Cannot currently comment. At the moment they cannot predict how the public or government would respond to these concerns before they are actually implemented (they think that the national government should make new laws and policies concerning these issues, though new regulations about them would be probably expected because of the involvement of Turkey in the EU)
Article 2	Agree (also consider that an extension would make the control mechanisms much more difficult). TUBITAK believe that they can take a strong role in the legislation of national scientific policies of Turkey by organising seminars/courses
Article 32 and annex IV	Agree (no additional concerns)
Particular concerns about other articles	
General	No additional concerns
To what extent are the views held commonly within the country, including by the national government	These concerns are widely accepted by the Turkish government and by their Local Ethical Committees of Animal Research.
How they (or others in their country) are proposing to influence the European Parliamentary process and/or to advise their government	Not stated

Kathryn McRae
Senior Information Analyst
Corporate Affairs Group

06/04/2009