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| from:            | Secretary-General of the European Commission,<br>signed by Mr Jordi AYET PUIGARNAU, Director                                                                                                                                      |
| date of receipt: | 10 November 2008                                                                                                                                                                                                                  |
| to:              | Mr Javier SOLANA, Secretary-General/High Representative                                                                                                                                                                           |
| Subject:         | Commission Staff Working Paper accompanying the Proposal for a<br>Directive of the European Parliament and of the Council on the<br>protection of animals used for scientific purposes<br><b>SUMMARY OF THE IMPACT ASSESSMENT</b> |

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Delegations will find attached Commission document SEC(2008) 2411.

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 5.11.2008  
SEC(2008) 2411

**COMMISSION STAFF WORKING PAPER**

*accompanying the*

**Proposal for a**

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on the protection of animals used for scientific purposes**

**SUMMARY OF THE IMPACT ASSESSMENT**

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## SUMMARY

### 1. What are the problems?

Directive 86/609/EEC is the central legislative act of the European Community aiming at harmonising Member States' rules protecting animals used for experimental and other scientific purposes. It was adopted in 1986 and has never been significantly changed. Since the adoption of the Directive, significant progress in experimental techniques has been achieved and new scientific knowledge about the capacity of animals to feel pain and suffering has become available. Furthermore, the ethical dimension of the use of animals for experiments is not sufficiently reflected in the current provisions of the Directive. The Directive does not explicitly refer to, nor ensure the full application of the Three Rs principle<sup>1</sup>, even though it is now recognised as the leading principle in this field by all stakeholders.

To compensate for these weaknesses, a number of Member States have gone further when adopting national measures. This has resulted in a highly diversified, unequal competitive environment for industry and the research community, defeating the objective of the Directive to avoid fragmentation of the internal market. Furthermore, the wording of the Directive, closely following that of an international Convention, results in unclear provisions, inconsistencies and ambiguities, causing transposition problems.

The problem analysis confirmed that four problems appear across 12 policy areas:

a) Economic problems affecting the internal market include competitive disadvantages for countries with high animal welfare standards resulting primarily from price differences, diverging regulatory and authorisation procedures and criteria in the Member States leading to variable cost of projects and delays, unsatisfactory (working) conditions of researchers, obstacles to horizontal mobility and increasing activist criminality. Similar problems can be identified for the breeders and suppliers of animals, especially in terms of the cost of housing and care.

b) Animal welfare problems relate to different levels of animal welfare resulting from different standards that are in force and from a relatively high number of animals not protected by national legislation.

c) Scientific problems concern low innovation and poor quality science resulting from project delays, potentially unnecessary duplication of experiments, low incentive to develop and use alternative methods, risk of variable research results due to non-consistent scrutiny of study design and implementation of refinement, and obstacles to free movement of researchers.

d) Public/societal problems occur due to the increasing dissociation between weak legislation and strong public concern, evolving from changed ethical and societal values and increased public interest in the acceptability of animal testing.

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<sup>1</sup> The Three Rs Principle (Replace, Reduce and Refine the use of animals in experiments) is widely accepted as the guiding principles when using animals in experiments both at national and international (e.g. OECD, OIE) level. It dates back to the book "The Principles of Humane Experimental Technique" by W.M.S. Russell and R.L. Burch in 1959.

## **2. What are the policy objectives?**

The main objective of the European Commission in this field is to create a level playing field for researchers and industry. At the same time, in line with the Animal Welfare Protocol annexed to the EC Treaty, the proposal will aim at increasing the level of welfare and protection of animals used in experiments.

Increased uptake of alternative methods will boost EU industry. The revision of the Directive also strives to simplify the regulatory environment and ensure the competitiveness of EU research and industry.

## **3. What are the policy options?**

Four basic policy options for achieving the objectives have been screened: deregulation, no-policy-change, self-regulation and reinforcement of the existing Directive. Only an upgrade of Directive 86/609/EEC proved viable.

25 specific options were analysed:

### **I. Scope**

The options include extending the scope of animals and procedures covered under the current Directive 86/609/EEC to cover:

Option 1: animals used in basic research

Option 2: animals bred for their tissue and organs to be used in experiments or for other scientific purposes

Option 3: selected invertebrates species

Option 4: embryonic and foetal forms from the last third of gestation until birth

Option 5: animals used in education and training

### **II. Authorisation of projects**

A level playing-field should be established to guarantee minimum requirements for the authorisation of projects, while safeguarding competitiveness in the field of research:

Option 1: Authorisation of individual projects within 30 days

Option 2: Authorisation of a group of projects for regulatory testing

### **III. Ethical Evaluation of projects**

The revised Directive could make an ethical evaluation of all projects using animals mandatory and set out minimum requirements.

Option 1: Compulsory ethical evaluation of projects with minimum requirements

Option 2: Introduction of retrospective assessment of all projects

#### **IV. Permanent Ethical Review Body and National Animal Welfare and Ethics Committee**

A combination of a national animal welfare and ethics committee for ethical review co-ordination and an ethical review body at establishment level could ensure consistent ethical review.

Option 1: National animal welfare and ethics committee

Option 2: Permanent ethical review body in each establishment

#### **V. Housing and care standards**

The Directive could incorporate elements of the Council of Europe's revised Appendix A to Convention ETS 123 as compulsory minimum standards.

Option 1: Compliance with the revised Appendix A to the Council of Europe Convention ETS 123

#### **VI. Transparency / Access to information**

The Directive could incorporate minimum requirements on transparency and public accountability by requiring non-confidential information on ethical evaluations and project authorisation to be made publicly available.

Option 1: Non-confidential information from the ethical evaluation reports and project authorisation decisions to be made publicly available

#### **VII. Non-human Primates (NHP)**

The revised Directive could reinforce the ban on wild-caught NHPs and further restrict the research areas in which NHP can be used. A gradual switch to permitting use of second-generation (F2) and higher generations of purpose-bred NHPs could be desirable. The use of Great Apes could be highly restricted.

Option 1: Shift to only use of F2 and subsequent generations of purpose bred NHP

Option 2: Ban of the use of Great Apes with very limited exceptions

#### **VIII. Inspections**

The Directive could harmonise the minimum requirements for annual inspections to two (one unannounced). A system of European Community inspections could also be envisaged.

Option 1: Minimum twice-yearly inspections by national authorities (one unannounced)

Option 2: EC inspections

#### **IX. Education and training**

The revised Directive could incorporate minimum training requirements for personnel and set requirements for demonstrating and maintaining competence over time, to reduce different cost environments.

Option 1: Requirement for competence and minimum elements for education and training

## **X. Avoiding duplication of animal experiments**

A centralised Community-wide database for information on project authorisation and scientific results could be established. This could allow knowledge sharing, and provide transparency on results.

Option 1: Establishing a centralised database

## **XI. Use of CO<sub>2</sub> for euthanasia**

The Directive could detail humane methods of euthanasia to remove cost advantages for establishments due to method choice. The use of CO<sub>2</sub> could be prohibited unless the animal is unconscious prior to its exposure.

Option 1: Prohibit use of CO<sub>2</sub> unless animals are first rendered unconscious by exposure to anaesthetic gases

## **XII. Statistical Reporting**

The revised Directive could increase the quality of annual statistical reporting of Member States by introducing the following elements:

Option 1: Number of genetically modified animals, certain invertebrate species and embryonic and foetal forms (excluding larvae) in the last third of their development

Option 2: Numbers of animals killed for use of their organs and tissues in scientific procedures

Option 3: Numbers of projects and types of establishments

Option 4: Severity classification<sup>2</sup> of the experiments

## **XIII. Promotion of alternative test methods**

Every Member State could designate a national reference laboratory to speed up the validation of animal testing alternatives.

Option 1: National reference laboratories

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<sup>2</sup> The severity of an experiment is classified based on the duration, intensity and frequency of potential pain, suffering or distress caused to an animal.

#### 4. What are the impacts of the specific options?

The 25 specific options were analysed and evaluated, where possible in a quantified and monetised form. Benefits were assessed based on the four problem dimensions, costs were evaluated separately for user establishments and public authorities. In some cases, the original options were revised in the light of the results of an external study performed by contractor, Prognos AG.

|                                                 | <b>BENEFITS</b><br>(quantified where possible) |      |                                  | <b>COSTS</b><br>(monetised where possible)         |     |            |
|-------------------------------------------------|------------------------------------------------|------|----------------------------------|----------------------------------------------------|-----|------------|
| I Scope –<br>Option 1 –<br>Basic research       | Animal welfare                                 | ++   | 500.000 animals                  | Costs for public authorities                       | -   | 80,000 €   |
|                                                 | Control                                        | +++  |                                  | Costs due to authorisation                         | --  | 4 Mio €    |
|                                                 |                                                |      |                                  | Costs due to ethical evaluation                    | --  | 2.6 Mio €  |
|                                                 |                                                |      |                                  | Delays due to authorisation and ethical evaluation | -   |            |
| I Scope –<br>Option 2 –<br>Tissues              | Animal welfare                                 | +++  | 1.8 Mio animals                  | Cost of experiments using tissue and organs        | -   |            |
|                                                 | Public accountability and transparency         | +++  |                                  | Cost to public authorities                         | -   | 320,000 €  |
| I Scope –<br>Option 3 –<br>invertebrates        | Animal welfare                                 | ++   | Animals used in 1000 experiments | Costs for public authorities                       | -   |            |
|                                                 | Control                                        | ++   |                                  | Costs for user establishments                      | --- |            |
| I Scope –<br>Option 4 –<br>foetal forms         | Animal welfare                                 | (++) | 175.000 mammalian animals alone  | Costs for public authorities                       | -   | 12.6 Mio € |
|                                                 | Control                                        | +++  |                                  | Cost for user establishments                       | -   | 845.000 €  |
| I Scope –<br>Option 5 –<br>Education & Training | Animal welfare                                 | ++   | 199.000 animals                  | Costs for public authorities                       | -   | 35.000 €   |
|                                                 | Control                                        | +++  |                                  | Cost for user establishments                       | -   | 1.4 Mio €  |

|                                                   |                                                       |     |                                          |                                                                     |     |            |
|---------------------------------------------------|-------------------------------------------------------|-----|------------------------------------------|---------------------------------------------------------------------|-----|------------|
| II<br>Authorisation -<br>Option 1 -<br>individual | Animal welfare                                        | ++  | 950.000<br>animals                       | Costs for MS<br>without project<br>authorisation                    | - - | 57,000 €   |
|                                                   | Animal welfare<br>(additional)                        | +++ |                                          |                                                                     |     |            |
|                                                   | Control and<br>transparency                           | ++  |                                          | Costs for MS with<br>project-<br>authorisation                      | +   | 11,500 €   |
|                                                   | Control and<br>transparency<br>(additional)           | +   |                                          | Cost for user<br>establishments in<br>MS without project<br>author. | -   | 11 Mio €   |
|                                                   | Competitiveness                                       | +++ |                                          | Cost for user<br>establishments in<br>MS without project<br>author  | -   | 12.6 Mio € |
| II<br>Authorisation -<br>Option 2 -<br>group      | Costs for users /<br>Competitiveness<br>SMEs/research | +++ | reduction of<br>21.2 Mio €               | Public image                                                        | -   |            |
|                                                   | Costs for public<br>authorities                       | ++  | 1.9 Mio €<br>(reduction of<br>700,000 €) | Animal welfare                                                      | 0   |            |

|                                         |                                                   |     |                                             |                                        |     |                           |
|-----------------------------------------|---------------------------------------------------|-----|---------------------------------------------|----------------------------------------|-----|---------------------------|
| III Ethical<br>Review (A) -<br>Option 1 | Animal welfare                                    | +++ | 11.7 Mio<br>animals /<br>371,000<br>animals | Administrative<br>costs to enterprises | - - | 9 Mio € (7 Mio<br>€)      |
|                                         | Awareness and<br>work satisfaction<br>researchers | ++  |                                             | Competitiveness                        | - - |                           |
|                                         | Quality of science                                | ++  | up to 70 Mio<br>€                           | Costs for public<br>authorities        | - - |                           |
|                                         | Level playing<br>field                            | ++  |                                             | Delay of projects                      | -   |                           |
| III Ethical<br>Review (A) -<br>Option 2 | Transparency                                      | ++  | 12.1 Mio<br>animals                         | Cost to<br>establishments              | - - | revised option<br>4 Mio € |
|                                         | Quality of science                                | ++  |                                             | Costs to national<br>authorities       | - - |                           |



|                                  |                                  |     |                  |                                        |     |  |
|----------------------------------|----------------------------------|-----|------------------|----------------------------------------|-----|--|
| IV Ethical Review (B) - Option 1 | Transparency                     | ++  | 12.1 Mio animals | Costs infrastructure                   | -   |  |
|                                  | Public accountability            | +   |                  | Costs infrastructure for Member States | -   |  |
| IV Ethical Review (B) - Option 2 | Animal welfare                   | +++ | 12.1 Mio animals | Costs for establishments               | - - |  |
|                                  | Ethical discussion and awareness | ++  |                  |                                        |     |  |

|                                       |                     |     |                  |                                      |       |          |
|---------------------------------------|---------------------|-----|------------------|--------------------------------------|-------|----------|
| V Housing & Care - Option 1 - ETS 123 | Animal welfare      | +++ | 12.1 Mio animals | Upgrading costs for smaller animals  | -     |          |
|                                       | Science             | ++  |                  | Upgrading costs for larger animals   | - - - |          |
|                                       | Level playing field | ++  |                  | Yearly Costs for user establishments |       | 37 Mio € |

|                            |                                              |    |  |                         |     |                           |
|----------------------------|----------------------------------------------|----|--|-------------------------|-----|---------------------------|
| VI Transparency - Option 1 | Public accountability and transparency       | ++ |  | Cost establishments to  | --- | revised option: 520,000 € |
|                            | Image of research and animal experimentation | +  |  | Costs for Member States | -   |                           |

|                                    |                |       |                                                |                                    |     |  |
|------------------------------------|----------------|-------|------------------------------------------------|------------------------------------|-----|--|
| VII Non-human primates - Options 1 | Animal welfare | +/-   | +++ for 1300 animals,<br>-- for 12.000 animals | Costs for establishments           | --  |  |
|                                    | Public concern | ++    |                                                | Scientific need                    | --- |  |
|                                    | Biodiversity   | + / 0 |                                                | Outsourcing/ Competitiveness       | --  |  |
| VII Non-human primates Opt 2       | Animal welfare | ++    |                                                | Research                           | -   |  |
|                                    | Public concern | ++    |                                                | Central Facility for future demand | --- |  |

|                                              |                                   |       |                   |                           |     |                                           |
|----------------------------------------------|-----------------------------------|-------|-------------------|---------------------------|-----|-------------------------------------------|
| VIII Inspections - Option 1 - national       | Animal welfare                    | ++    | 12.1 Mio. animals | Impact for establishments | -   | 0.9 Mio €                                 |
|                                              | Accountability and transparency   | +++   |                   | Costs for Member States   | --  | 3.1 Mio. € / 2.5 Mio. €                   |
| VIII Inspections - Option 2 - EU inspections | (Animal welfare)                  | (++)  | 12.1 Mio animals  | Costs for establishments  | -   |                                           |
|                                              | (Accountability and transparency) | (+++) |                   | Costs to EU               | --- | 4.2 Mio € (revised option 2.7 to 3.3 Mio) |

|                                      |                                 |     |                  |                                          |    |          |
|--------------------------------------|---------------------------------|-----|------------------|------------------------------------------|----|----------|
| IX Education and Training - Option 1 | Animal welfare                  | +++ | 12.1 Mio animals | Additional costs to national authorities | -  |          |
|                                      | Quality of science              | +++ |                  | Additional costs to establishments       | -- | 38 Mio € |
|                                      | Free movement of people/workers | +++ |                  |                                          |    |          |
|                                      | Job satisfaction of personnel   | +++ |                  |                                          |    |          |

|                          |                                     |     |                        |                                        |     |                                                 |
|--------------------------|-------------------------------------|-----|------------------------|----------------------------------------|-----|-------------------------------------------------|
| X Duplication - Option 1 | Animal welfare – basic research     | (+) | slight positive effect | Cost to establishments                 | --- | 6.2 Mio €                                       |
|                          | Animal welfare – regulatory testing | 0   |                        | Administrative costs for Member States | --  | 173,000 €                                       |
|                          | Cost reductions for Member States   | +   |                        | Resource requirements at an EU-level   | --- | 30,000 € one-time costs, 105,000 € yearly costs |

|                   |                |     |  |                           |     |            |
|-------------------|----------------|-----|--|---------------------------|-----|------------|
| XI CO2 - Option 1 | Animal welfare | +/- |  | Impacts to establishments | --- | 46.2 Mio € |
|-------------------|----------------|-----|--|---------------------------|-----|------------|

|                                      |                               |     |  |                       |   |           |
|--------------------------------------|-------------------------------|-----|--|-----------------------|---|-----------|
| XII Statistical Reporting - Option 1 | Monitoring and accountability | +++ |  | Administrative burden | - | 7.4 Mio € |
|                                      | Policy making                 | ++  |  |                       |   |           |

|                                      |                                             |     |  |                                        |    |         |
|--------------------------------------|---------------------------------------------|-----|--|----------------------------------------|----|---------|
|                                      |                                             |     |  |                                        |    |         |
| XII Statistical Reporting - Option 2 | Monitoring and accountability               | +++ |  | Administrative burden to users         | -  | 4 Mio € |
|                                      | Image of research and industry              | +   |  | Administrative burden to Member States | -- |         |
|                                      | Policy making                               | +++ |  |                                        |    |         |
| XII Statistical Reporting - Option 3 | Monitoring and policy making                | ++  |  | Administrative burden to users         | -  |         |
|                                      | Transparency                                | ++  |  | Administrative burden to Member States | -- |         |
| XII Statistical Reporting - Option 4 | Monitoring and policy making / transparency | +++ |  | Administrative burden to users         | -- |         |
|                                      | Public awareness                            | +++ |  | Administrative burden to Member States | -- |         |

|                                                  |                                                                              |     |  |                                              |    |                                                          |
|--------------------------------------------------|------------------------------------------------------------------------------|-----|--|----------------------------------------------|----|----------------------------------------------------------|
| XIII Promotion of alternative methods - Option 1 | Animal welfare increase through Reduction in animal use or method refinement | +++ |  | Costs to Member States                       | -  | One-off costs 4-5 Mio €, plus annual costs 1,5 – 3 Mio € |
|                                                  | Promotion of innovation                                                      | +++ |  | Costs to industry                            | ++ |                                                          |
|                                                  | Public awareness                                                             | ++  |  | Efficiency gains for public research budgets | +  |                                                          |

## 5. How do the options compare?

The following are the most useful options to create a level playing field within the European Community and to increase the welfare for all 12.2 million animals used annually in the Community:

- Strengthening the authorisation and ethical evaluation of projects would have a significant impact on levelling economical differences between Member States;
- Minimum housing and care standards would remove the current uneven competitive environment for users and breeding and supplying establishments, whilst improving animal welfare;

- Standardised inspections would expose non-compliant establishments, ensuring enforcement and improving public confidence.

## **6. Which options were finally chosen and what are their impacts?**

In the light of the table above, it becomes clear that some of the options that provide for the highest animal welfare benefits also create the highest costs (Housing and Care standards, Education and Training standards). However, inspections costs are relatively low and the cost for transparency in the form of non-technical summaries is almost negligible.

Only the option of banning CO<sub>2</sub> seems to entail costs that are out of proportion vis-à-vis benefits. The remaining policy options do not go further than what is necessary to achieve the objectives of the revision (principle of proportionality).

Therefore the options that are justified are:

- Extending the scope to cover animals used in basic research, animals bred for their tissue and organs, selected invertebrates species, foetal and embryonic forms in the last third of development before birth or hatching and animals used in education and training;
- Authorisation of individual projects including a compliance check and ethical evaluation with decisions to be taken within 30 (maximum 60) days, but allowing group authorisations in the area of regulatory testing and lighter authorisation process for projects consisting of only "up to mild" procedures and not involving the use of non-human primates;
- Introduction of a national animal welfare and ethics committee to issue guidance;
- Introduction of a permanent ethical review body in each establishment;
- Minimum housing and care standards along the lines of the ETS 123 standards;
- Improving transparency and access to information by publishing non-technical project summaries;
- Improving welfare of non-human primates through limiting further the research areas in which they can be used and via a shift to use only F2 and subsequent generations of purpose bred animals after a transitional period specific for certain types of species;
- Banning the use of Great Apes with very limited exceptions;
- Improving enforcement by twice yearly inspections by national authorities (one unannounced);
- Appropriate education and training standards;
- Specific conditions for CO<sub>2</sub> use;
- Improving statistical information;
- National reference laboratories.

Total cost increase of favoured options could be 143.7 Mio € per year but would be largely attributed to those three options which in return also provide the highest animal welfare benefits. It is important to note that 23 Mio € attributed to the authorisation of projects reflects the scenario in which no Member State opts for the lighter authorisation process for project consisting of only "up to mild" procedures and not involving the use of non-human primates. The cost increase has to be assessed against the total costs for animal experiments which were calculated to be around 2.9 Bio € per year in the EU-25. However, it is understood that universities and public research institutes may need transitional periods to adapt to new requirements, whereas some industrial sectors may be able to cope with new standards much faster.

The benefits from reduced administrative costs and avoiding unnecessary testing were estimated at around 90 Mio € per year. To calculate the net cost increase of the revision, one may subtract these 90 Mio € savings from the 143.7 Mio € gross costs increase. The net cost increase would then be about 51 Mio € per year.

Further benefits/savings from improved science are not yet included. For some options with a very high potential to improve animal welfare, the corresponding benefits for science can be monetised. If only a few percentages (1-3%) of the studies that currently suffer from a weak experimental design, inappropriate housing and care standards or not fully competent personnel can be improved, the benefits may be in the same order of magnitude as the financial costs of these options.

All of the actions have been scrutinised to check that they pass the necessity test. They are necessary to fulfil the requirements of the Protocol annexed to the EC Treaty to pay full regard to animal welfare requirements in formulating internal market and research policies. At the same time, they cannot be better carried out by Member States individually.