



COMMISSION DES COMMUNAUTÉS EUROPÉENNES

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AVIS DU COMITÉ DES ÉVALUATIONS D'IMPACT

**PROPOSITION DE DIRECTIVE DU PARLEMENT EUROPEEN ET DU CONSEIL
RELATIVE A LA PROTECTION DES ANIMAUX UTILISES A DES FINS
SCIENTIFIQUES**

{COM(2008) 543}
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{SEC(2008) 2411}



Brussels, 16 March 2007
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Opinion

Title **Impact Assessment on a directive on the protection of animals used for experimental and other scientific purposes**

(Draft of 28 February 2007)

Lead DG **DG ENV**

1) Impact Assessment Board Opinion

(A) Context

This proposed directive would replace the directive 86/609/EC. Work on the revision of the old directive started in 2002 with a request by DG ENV for an opinion from the Scientific Committee on Animal Health and Animal Welfare. In 2002 the European Parliament adopted a report requesting the Commission to revise the directive. In 2003 a technical expert working group was convened to collect information. In 2004 the Animal Health and Animal Welfare Panel was mandated to give a scientific opinion. In 2006 the Commission published its Animal Welfare Action Plan for 2006-2010. The European Parliament then again asked the Commission to come forward with a proposal to revise the old directive.

(B) Positive aspects

- (1) To the extent possible, the benefits and costs of each policy option are quantified and monetised. The results are presented in summary tables, which are very informative, even if their legibility could be improved.
- (2) The IA report provides information on animal welfare regimes in both developed and developing countries, as well as the situation in international organisations.
- (3) An examination of links with other Community legislation is made, and where appropriate (REACH and Good laboratory practice) explained in sufficient detail.
- 4) The IA report contains a glossary explaining in plain language the technical terms used throughout the report.

(C) Main recommendations for improvements

The recommendations below are listed in order of descending importance. Some more technical comments will be transmitted directly to the author DG.

General recommendation: the necessity/ subsidiarity test should be applied to each of the 12 problem areas. Indeed, it is not clear why all sub-options should be addressed through reinforcement of legislation and not, for instance, through self-regulation and this should be discussed.

(1) In describing the problem, market distortions resulting from differences in national legal frameworks should be more clearly demonstrated. The IA report should clearly identify and analyse the market at stake, and more specifically the significance of the cross-border elements (including the global perspective and the competitiveness of EU vis-à-vis the rest of the world). On the problem of animal welfare the IA report clearly states that there are differences in national standards, but it should also state whether these standards are inadequate in any part of the EU and/or whether proposed EU minimum standards would be more stringent than those currently applied in MS.

(2) Self regulatory instruments seem to be discarded too early. It appears that at least some objectives (e.g. ethical evaluation) could be addressed through self-regulation rather than by a Directive. Should this be not the case, the IA report needs to explain in more detail on what specific grounds self regulation is discarded.

(3) Assessment of cost-efficiency of qualitative improvements in animal welfare needs to be strengthened. The benefits of the proposal are mainly assessed by identifying the number or percentage of animals falling within the scope of regulatory protection. This makes it difficult to assess the cost-efficiency of qualitative improvements. Should such analysis not be possible for the EU level, it should be clearly explained and – where feasible – supported by examples. The applied methodology should also allow for assessment of whether the current level of protection in the EU is sufficient or not.

(4) The EU Standard Cost Model (SCM) seems not to have been fully employed and the deviations from the EU SCM should be explicitly identified and justified. The proposal will lead to an increase in administrative burdens, likely to arise from additional authorisation procedures and inspections, as well as statistical requirements. The costs have been assessed as a percentage costs for a given project and are presented in an aggregated format. The SCM table should be completed with disaggregated data, in particular on the number of entities, frequency per year and price and time per action. Otherwise it will be difficult to examine administrative burden implications of alternative policy options. Also, any ex-post assessment of administrative costs might be difficult.

To the extent this initiative may produce simplification benefits at EU or MS level, they should be clearly presented in the IA report.

(D) Procedure and presentation

Shortening of the IA report should be considered, as it amounts to nearly 60 pages.

2) IAB scrutiny process

Reference number	2003/ENV/063 (catalogue item)
Author DG	ENV-D-1
External expertise used	No
Date of Board Meeting	Written procedure
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