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accompanying the

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the protection of animals used for scientific purposes

IMPACT ASSESSMENT

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1. EXECUTIVE SUMMARY

This impact assessment analyses the impacts of different policy options - including those put forward by stakeholders - for the revision of Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes. It is to a large extent based on an external study that was performed by Prognos AG for the European Commission, DG Environment, between January and December 2006[1].

Directive 86/609/EEC is the central legislative act of the European Community which harmonises Member States' rules protecting animals used for experimental and other scientific purposes. It was adopted in 1986 and has never been significantly changed. It is the first time ever that an impact assessment has attempted to identify, quantify and monetise impacts from policy changes in the area of experimental animals. Hardly any scientific literature about the impact of such policy changes on the welfare of animals and few official empirical cross-national statistical data exist. Some aspects of the assessments are therefore based on a cost model and on extrapolations from specific samples as well as from the EU-statistics on use of animals in scientific procedures (experiments) in the EU-25 in 2005[2].

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, suffering or distress including their impact on scientific results has become available. Furthermore, the ethical dimension of the use of animals in scientific procedures is not sufficiently reflected in the current provisions of the Directive.

To compensate for these weaknesses, a number of Member States have gone much further when adopting national measures. This has resulted in a highly diversified, unequal competitive environment for industry and the research community within the EU, 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[3], results in unclear provisions, inconsistencies and ambiguities, which in turn translate into transposition problems at Member State level.

Finally, the Directive does not explicitly refer to, nor ensure the full application of the Three Rs principle[4], even though it is now recognised as the leading principle in this field by all stakeholders. These fundamental problems are the catalyst for this revision process.

The problem analysis confirms indeed that four problems appear across 13 policy areas. These can be summarised as:

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1 The information contained in the study was correct at the time the study was finalised.

2 It should be noted that consistent data for Bulgaria and Romania were not available because the current Directive foresees a reporting period of every 3 years, and therefore the first systematic statistics from Bulgaria and Romania will only be available in 2009, covering the year 2008. This impact assessment therefore concentrated on data about the EU-25.

3 Council of Europe Convention ETS 123 on “the protection of vertebrate animals used for experimental and other scientific purposes”.

4 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.

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

c) Scientific problems concern low innovation and poor quality science resulting from delays of projects, potentially unnecessary duplication of procedures, 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 (leading to higher stress levels for animals) and obstacles to free movement of researchers due to different requirements for education and training.

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 about the acceptability of animal testing. This is further highlighted due to lack of transparency in the field.

The economic problems are mainly related to a non-level playing field. These can be clearly demonstrated when observing differences in average delays for authorisation of a project due to significantly varying legal requirements and administrative procedures; differences in the cost of housing and caring for animals; and differing requirements for the level of training and education for personnel. The latter problem also has a negative impact on the free movement of personnel when undertaking cross-border research projects. These problems are further exacerbated by differences in the scope of the national legislations; some animal species are not covered by legislation in some Member States, but even where covered there are big differences in administrative requirements leading to varying processing times and cost structures.

Animal welfare problems are caused by relatively weak provisions and ambiguities in the existing Directive and by unsystematic approaches among Member States. Together with scientific problems related to lower animal welfare standards, and a lack of transparency and accountability towards the public, combine to make a policy change necessary.

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 scientific procedures, and further promoting the implementation of the Three Rs principle.

Increased uptake of alternative methods will in return boost EU industry in accordance with the Lisbon Agenda. The revision of the Directive further strives to simplify the dispersed regulatory environment and ensure the competitiveness of EU research and industry. This will be achieved by harmonising the objectives and minimum requirements at EU level, while

leaving the Member States considerable flexibility to determine the most optimum mechanisms for their respective existing infrastructure, which is fully in line with the principles of subsidiarity and proportionality.

The assessment concludes that the identified problems will not improve autonomously or will further worsen over time if no action is taken. Four basic policy options for achieving the objectives have been screened: deregulation, no-policy-change, self-regulation and reinforcement of the existing Directive. Only one of these basic options proved viable, namely a significant upgrade of Directive 86/609/EEC.

Within the basic option of upgrading Directive 86/609/EEC, 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 the external study.

The most useful options to create a level playing field and improve the good functioning of the internal market within the European Community and to significantly increase animal welfare for all 12.2 million animals used annually in the Community are:

- Strengthening of the requirements for authorisation and ethical evaluation of projects – this would have a significant impact on levelling the current economic differences between Member States;

- Minimum housing and care standards – establishing harmonised compulsory housing and care standards would remove the current uneven competitive environment and prevent likely future problems related to an inconsistent implementation of new standards agreed at Council of Europe level. This would not benefit only user establishments but also breeding and supplying establishments, at the same time having a considerable impact on animal welfare;

- Inspections – standardised inspections among Member States would expose non-compliant establishments, ensuring enforcement and dissemination of best practises and improving public confidence.

Total cost increase of all favoured options could be close to 143.7 million € per year but would be largely attributed to those options which in return also provide the highest internal market and animal welfare benefits.

These costs should be mirrored against the benefits to animal welfare, innovation and science as well as society in terms of increased public accountability and transparency Authorisation of groups of projects for regulatory testing would reduce the average costs of this type of projects at the establishment level due to economies of scale. Positive impacts would also occur at the level of authorisation bodies in Member States due to more flexible and efficient handling of the procedures. Furthermore, industry and academia would benefit from specific deadlines for the authorisation decisions.

Some simplification benefits have been taken into account, especially related to group authorisations which will greatly reduce the administrative burden. Expected savings will be about 22 million € per year. Animal welfare benefits are not easily quantifiable in monetary terms. The benefits from reduced administrative costs and avoidable unnecessary testing

alone were estimated in the order of 90 million € per year by the external study. These, however, are not reflected in the estimated annual cost.

The cost increase also needs to be put into perspective with the following considerations:

- The current total expenditure of all user establishments for animal experimentation in the EU-25 was calculated to be in the range of 2.9 billion € per year. This means that the cost increase of 143.7 million € per year that is likely to be triggered through the revised Directive is relatively small (about 5%) in comparison to the current level of expenditure in the sector.

- While universities and other public research institutes may need transitional periods to adapt to the new requirements, some industrial sectors may be able to cope with new standards much faster because animal care costs make up only a small share of their total investments, e.g. pharmaceutical companies for which the costs to develop a new product may amount to 1 Bio € over 10 years.

- A significant share of these costs is due to the implementation of the revised guidelines for housing and care of experimental animals adopted by the Council of Europe. As the European Community is a Party to the Convention, it would have to implement the revised Guidelines anyway (deadline was 15 June 2007). Therefore, a significant share of the cost increase is caused by international obligations of the Community and cannot be attributed solely to the revision of the Directive.

- a 23 Mio € increase is attributed to the authorisation of projects. This reflects the scenario in which no Member State opts for the lighter authorisation process for projects consisting of only "up to mild" procedures and not involving the use of non-human primates.

- The benefits from reduced administrative costs and avoidable unnecessary procedures alone were estimated in the order of 90 million per year by the external study. These are not reflected in the estimated annual cost of 143.7 million.

- 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 could be improved, the benefits may be in the same order of magnitude as the financial costs of these options.

2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

a) Scientific studies and policy documents

Preparatory work for the revision of Directive 86/609/EEC started in 2002 when the European Commission's Directorate-General for Environment (DG ENV) requested an opinion on the welfare of non-human primates used in experiments from the Commission's Scientific Committee on Animal Health and Animal Welfare, SCAHAW. This Opinion, adopted by SCAHAW on 17 December 2002, is available at:

http://europa.eu.int/comm/food/fs/aw/aw_scahaw_en.html.

During the same period, the European Parliament drafted an own initiative report, with Jillian Evans as the rapporteur, calling for the European Commission to come forward with a

proposal to revise Directive 86/609/EEC. The report was adopted on 13 November 2002 and can be found at:

http://ec.europa.eu/environment/chemicals/lab_animals/pdf/evans_report.pdf

In 2003, DG ENV convened a Technical Expert Working Group, TEWG, to collect scientific and technical background information for the revision of the Directive. The experts from Member States, acceding countries (which are now Member States), industry, science and academia as well as from animal welfare organisations and other key stakeholders worked through a set of questions prepared by DG ENV. The final reports, completed in November 2003, can be found at:

http://ec.europa.eu/environment/chemicals/lab_animals/revision_en.htm

In 2004, the Animal Health and Animal Welfare Panel, AHAW, of the European Food Safety Authority (EFSA) was mandated to give a scientific opinion on four further questions in relation to the revision; on the sentience of invertebrate species and foetal/embryonic forms, the criteria for and the species that should be purpose bred and identification of the most humane methods of euthanasia for species most commonly used in scientific procedures. The Opinion was published on 14 November 2005 and is available at:

http://ec.europa.eu/environment/chemicals/lab_animals/scientific_en.htm

In January 2006, the European Commission published its Animal welfare Action Plan for the period 2006-2010. The European Parliament, in an own-initiative report drafted by Elisabeth Jeggle as the rapporteur, asked the Commission to come forward with a proposal to revise the Directive 86/609/EEC before the end of the year 2006. The resolution is available at:

http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P6-TA-2006-0417+0+DOC+PDF+V0//EN&language=EN

b) External study (Prognos report)

The input from the TEWG, SCAHAW and the AHAW Panel has provided a broad basis for different policy options for the revision. DG ENV decided in 2005 to perform a voluntary Impact Assessment to be able to critically review and assess these policy options and their impacts, to test the conclusions and to provide justifiable and (where possible) quantitative indications as to the related benefits and costs. In December 2005, Prognos AG was assigned to carry out a study to provide input to the Commission's Impact Assessment according to the revised Impact Assessment guidelines of the Commission's Secretariat General (SEC(2005)791).

The Prognos study followed a very systematic approach. In a first step, baseline data was gathered to substantiate the problem areas via stakeholder interviews and two questionnaires, one to stakeholders and one to the national contact points in 25 Member States.

The stakeholder questionnaire was sent to all major stakeholders including representatives of private and public users of animals (e.g. industry and academic institutes), industry, academic and professional associations, non-governmental organisations etc. The stakeholders were requested to forward the questionnaire freely to any other experts. From the 96 stakeholders who received the questionnaire, 66 filled it in and returned it.

DG Environment contacted the national authorities in the Member States that are responsible for the legislation concerning experimental animals and the implementation of Directive 86/609/EEC. From the 25 contact points that received the questionnaire, 17 filled it in and returned it.

The results of this survey were by far not as complete, detailed and fact-based as expected because many respondents were not able to provide new facts and figures on the use of animals for scientific purposes in their establishment or country. As only relatively limited data was available, the contractor developed a model about benefits and costs, and derived qualitative hypotheses from it about possible impacts of the respective options.

The results of this first phase were presented to stakeholders in a public internet consultation which the Commission performed from 16 June to 18 August 2006. The main results and identified needs for further research fed into the second phase of the study and the results thereof into the final report of Prognos[5].

c) Public Internet consultation

The internet consultation was open to participation for a period of nine weeks and consisted of two separate questionnaires, one directed more to the general public and one for experts and stakeholders in the field. However, no restrictions for participation were imposed.

The purpose of the consultation for the general public was to get an impression of public opinion in relation to the use of animals for experimental and other scientific purposes. The results of this consultation were published by the European Commission separately[6] and are perhaps more interesting in political terms rather than of direct relevance to this staff impact assessment paper.

With a total of 42,655 replies, the citizens' consultation received the third largest number of responses to a Commission internet consultation ever. While the results of this consultation are not comparable to those obtained from representative surveys, such as Eurobarometer, the large participation gives a strong indication of the public interest in this area.

A large majority of respondents supports measures at European level to increase the welfare of animals. For instance, 93 % of the respondents answered either "Yes, certainly" or "Yes, probably" to the question "Do you believe that more needs to be done to improve the level of welfare/protection of animals used in experiments by action at EU level?".

92% of the respondents were of the opinion that the European Community should play a leadership role in promoting in the international arena a greater awareness of animal welfare and protection, in particular regarding animals used in experiments.

The expert questionnaire served to verify, correct and complete the preliminary findings of the assessment of the options to revise the existing Directive. The questionnaire was addressed to experts in the area of animal welfare, animal testing, animal science, natural

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5 Published in September 2008 on the DG Environment Website under: http://ec.europa.eu/environment/chemicals/lab_animals/ia_en.htm

6 Published in December 2006 on the DG Environment Website under: http://ec.europa.eu/environment/chemicals/lab_animals/questionnaire2.htm

sciences (especially biology, medicine, pharmacology and toxicology), legal and economic affairs related to these areas and all those who were in a position to either confirm the identified impacts or provide factual, quantifiable information to the contrary. If experts did not support the preliminary findings, they were asked to provide further arguments accompanied by factual and quantitative data and if possible the source of their information.

283 respondents took part in the expert consultation, the vast majority of which were experts in the field of experimental animals. While the consultation revealed a lot of support for the preliminary hypotheses on the impacts, they provided only a limited amount of new facts or additional quantitative data.

The results of the internet consultation were published on the website of DG Environment in full. The main arguments and figures from the internet consultation regarding the preliminary hypotheses have been summarised in the external study as bullet points in grey boxes and have been taken into account in the final report of the external study. A number of conclusions have also fed into the legal drafting.

Whilst this Commission staff paper draws heavily on the Prognos study, it is also based on the much wider stakeholder and expert input over the last years.

d) Inter-service group

An informal inter-service group composed of representatives of various Directorate-Generals of the European Commission was set up and met several times in 2006 and 2007. Directorate-Generals involved were Environment (lead), Enterprise, Research, Joint Research Centre, Information Society and Media, Health and Consumer Affairs and in the later stages the Secretariat-General. Under the Commission rules, this Impact Assessment was performed voluntarily, thus no additional inter-service steering group was required. Instead, the informal inter-service group discussed both issues related to policy-making and to the impact assessment in an integrated way.

e) Commission Impact Assessment Board

This Impact Assessment was reviewed in March 2007 by the independent Commission Impact Assessment Board (IAB). The Board issued its Opinion on 16 March 2007 and emphasised the following positive elements about the Impact Assessment: The attempt to quantify and where possible monetise benefits and costs for each specific option, the inclusion of information about third country systems of experimental animal protection, the examination of links with other Community legislation and the inclusion of a glossary of terms. In light of the Board's recommendations, the following sections have been further improved: internal market problems, the section on self-regulation, the qualitative benefit dimension and the use of the standard model of administrative costs.

3. PROBLEM DEFINITION

Overview of the sector

The number of vertebrate animals used annually for experimental and other scientific purposes in the EU-25 is about 12.2 million. Most of them are mice and rats but bigger

animals are also used in significant numbers (e.g. about 20.000 dogs and about 10.000 non-human primates).

No official aggregated data are available about many key data of the sector but the external study performed by Prognos has estimated that about 1.330 establishments (industry, contract research laboratories and universities) in the EU-25 perform animal tests[7]. The number of breeders and suppliers of animals for experimental purposes is most likely in the range of several dozen only.

To get an impression of the distribution of projects across types of establishments the disaggregated data from the UK in 2005[8] may be instructive, even though other Member States may have a different structure:

- Universities: 68.0% of projects

- Commercial organisations: 12.6% of projects

- Government departments 3.6% of projects

- Other public bodies 9.4% of projects

- Non-profit organisations 4.2% of projects

- Hospitals: 1.2% of projects

- Public health laboratories 0.6% of projects

In conclusion, most animal tests are performed by universities and commercial organisations.

Commercial organisations can be further disaggregated into:

- Companies doing research in-house for their own product development (e.g. pharmaceutical, chemical, pesticide, food and feed producers). Even though only few of them complain openly about unfair competition from companies in Member States with lower animal welfare standards, their cost structure varies across Europe due to differences in the regulatory environment.

- Contract research institutes performing animal tests on behalf of other companies which have outsourced this task due to cost or expertise reasons. These companies can be expected to benefit most from a more harmonised internal market and a level playing field.

In addition, many universities are also affected by the functioning of the internal market in the area of animal experimentation, as they increasingly competing for industry sponsoring for their research, are tendering for public procurement (research) contracts and sometimes create their own commercial off-springs or branches.

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7 Prognos report 2007, Chapter 7, page 55.

8 See UK Home Office 2005: "Statistics of scientific procedures on living animals, Great Britain 2005", pages 64 and 66. The report is available at: http://www.homeoffice.gov.uk/rds/pdfs06/spanimals05.pdf

About 9.300 new projects involving animal tests are annually started in the EU-25 which often last for several years. An average project was estimated to cost about 300.000 Euros over three years[9]. However, it is clear that as a result of differences in scope, application, housing and procedural requirements, the estimated average cost is likely to differ significantly between Member States.

It should be noted that some Member States currently have a burdensome regulatory structure in this field. The revision will provide an opportunity to streamline these based on the best practice and thus contribute to simplification and at the same time close considerable loopholes in the existing Directive 86/609/EEC.

There is no representative organisation of user establishments but experimental animal scientists have formed professional associations in different Member States whose European organisation FELASA[10] is well-recognised in the field.

Problems identified

An initial problem analysis has shown four main problem dimensions across the three areas mentioned in the Commission Impact Assessment guidelines (economic, social and environmental aspects). These main problem dimensions can be described as follows:

a) Economic problems:

Competitive disadvantages for countries with high animal welfare standards resulting primarily from price differences (e.g. minimum requirements for housing), diverging regulatory and authorisation procedures and criteria in the Member States leading to variable delays and cost of projects, unsatisfactory (working) conditions of researchers, obstacles to horizontal mobility, increasing activist criminality. Similarly, same problems can be identified for the breeders of experimental animals, especially in terms of the cost of housing and care.

b) Environmental problems/Animal welfare:

Different levels of animal welfare resulting from a high number of animals not protected by the current Directive and from different standards that are in force. There are several arguments as to why current Community standards are insufficient: Most Member States have gone clearly beyond (some even far beyond) the current Directive which indicates that they consider the level of protection from the existing Directive as too low. The areas of variable legislative measures affecting animal welfare include requirements for ethical evaluation as well as housing and care standards. The Council of Europe, with a unanimous support from the EU, adopted in 2006 higher housing and care standards, clearly demonstrating its members' views on the necessity to increase these standards. Finally, the Commission regularly receives complaints from citizens about insufficient housing and care conditions and the related suffering of animals but these cannot be addressed by the Commission because the existing Directive does not provide even minimum requirements.

[9] Prognos report 2007, Chapter 7, p. 54.

[10] Federation of European Laboratory Animal Science Associations.

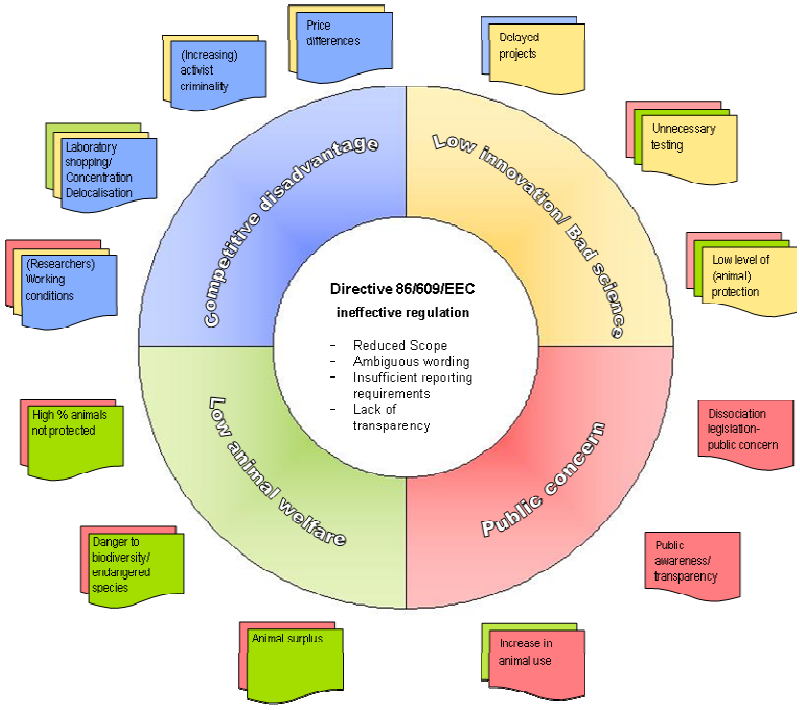
c) Scientific problems:

Low innovation / bad science resulting from delays of projects, potentially unnecessary testing and unnecessary duplication, 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 (leading to higher stress levels for animals) and obstacles to free movement of researchers due to different standards for education and training.

d) Public/societal problems:

Increasing dissociation between weak legislation and strong public concern, evolving from changed ethical and societal values and increased public interest about the acceptability of animal testing.

These four major problem dimensions and their sub-problems can be displayed in form of problem doughnut:



Taking these problem-dimensions as a starting point, a number of specific policy issues were identified in the course of the problem-analysis. These can be classified according to the following thirteen policy dimensions:

I. Scope

Current situation in Member States

Directive 86/609/EEC does not cover animals used in basic research, education and training and those that are merely bred and killed for using their tissues and organs. Neither does it cover any invertebrate species or the life stages before birth or hatching (embryonic and foetal forms), although for some of them there is scientific evidence that they are sentient beings.

A significant number of animals are currently used in basic research within the European Community. Out of the total 12.2 million vertebrate animals used annually for scientific procedures in the EU-25[11], approximately 4.1 million animals (35%) are used in this respect. These animals are mainly used by universities and private research establishments. The external study has found that 80% of Member States have covered basic research under national regulation[12]. This means that around 500.000 animals used in basic research in the remaining five countries are not afforded the same legal protection.

Around 1.5% of all animals are used in the fields of education and training. Their absolute number is about 200.000.

Around 40% of Member States do not have legislation in place which covers animals killed for their organs and tissue[13]. In most cases, euthanasia of animals for in vitro scientific work is not considered a scientific procedure. In some Member States, such as Sweden and the Netherlands, these animals are covered, whereas in some other Member States animals killed for in vitro experiments only have to be reported.

The situation regarding the inclusion of sentient invertebrates and foetal forms is even more diverse. The external study has found that at least 70% of Member States do not include these species and life stages[14], whereas Germany fully includes both vertebrates and sentient invertebrates, though there is no obligation for authorisation/ethical evaluation of projects with invertebrates.

Trends and implications

During the last 20 years since the introduction of Directive 86/609/EEC, a shift from in-vivo to in-vitro experiments can be observed. This has led to an increase in animals bred for the primary purpose to be killed for their organs and tissues. The use of foetal forms has also increased. The external study concluded that around 175,000 foetal forms of mammalian species (at the stage of at least 2/3 of gestation) are used in the European Community per year. Due to the increasing acceptance of the Three Rs principle[15] a further shift into these directions can be expected.

Problem dimension

The scientific developments during the last 20 years since adoption of the Directive have led to efforts at national level aiming at improving national legislation. However, these national legislative acts have resulted in a fragmented regulatory environment in Europe and consequently to varying competitive frameworks between Member States.

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11 The official EU statistics are from 2002 and cover the EU-15. However, an extrapolation allows an estimation on the corresponding figures for EU-25. The Commission report on the statistics of the year 2005 is available at http://ec.europa.eu/environment/chemicals/lab_animals/reports_en.htm.

12 Prognos report 2007, p. 16.

13 Prognos report 2007, p. 16.

14 Member States where invertebrates are not covered: Austria, (Belgium), Denmark, Estonia, Finland, France, Ireland, Spain, UK. Member States where foetal and embryonic forms are not covered: Austria, Belgium, Cyprus, Germany, Netherlands, Spain, (UK). Source: Prognos report 2007, p. 16.

15 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 famous book "The Principles of Humane Experimental Technique" by W.M.S. Russell and R.L. Burch in 1959.

The different levels of animal protection between Member States are undermining the objectives set out in the Protocol to the EC Treaty which formally recognises the welfare of animals as an element to be taken into account in Community policy making. Even though 20 Member States cover today basic research under their national legislation, the area of application differs significantly. Whereas in several Member States all scientific work in basic research involving vertebrate animals is covered, other Member States exclude, for example, field studies and some nutrition studies.

The EFSA Opinion of 2005 recommends extending the scope of the Directive to those invertebrates whose sentience is scientifically supported (cyclostomes, cephalopods and decapod crustaceans) and to foetal and embryonic forms from the last 1/3 of gestation until birth[16].

II. Authorisation of projects

Current situation in Member States

Authorisation procedures vary across Europe, and are particularly long and demanding in some Member States. The external study found that currently 21 Member States, covering nearly 90 % of animal use, require some form of authorisation of projects[17]. The regulatory setting for project authorisation in Europe is, however, complex. In most Member States, authorisation is primarily granted at a national level but Germany, the Netherlands, Belgium, Finland, Greece and Spain having explicitly decentralised systems of authorisation. Most Member States have some form of authorisation system at the individual project level, mostly in combination with authorisation for establishments and personnel. Ethical evaluation of the project is often a prerequisite for authorisation. In some Member States the procedures to obtain the first authorisation are significantly different from the procedures used for renewal of an existing authorisation[18].

Trends and implications

Stakeholders estimated that their costs of authorisation of projects make up approximately 3 to 4% of the overall costs of a project using animals[19]. The variance between Member States is significant, with 0% in those Member States without any project authorisation requirement and up to two-digit % in at least one other (one respondent in the expert internet consultation claimed up to 20%, although that figure seems too high because it would mean that in an average project of 300.000 €, about one full man-year of work would be spent on authorisation issues alone).

Most stakeholders agree that well informed authorisation procedures are required for a good prior evaluation of a project's possible negative consequences for animal welfare. Transparent and well informed authorisation procedures also contribute to the quality of the results.

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16 http://ec.europa.eu/environment/chemicals/lab_animals/scientific_en.htm

17 Prognos report 2007, p. 17.

18 It is important to note in this context that the terms "authorisation" and "ethical evaluation" are interlinked. This is especially important when discussing delays due to "authorisation". In the majority of cases, if not all, the authorisation process includes key elements of ethical evaluation. Therefore the stated "delays due to authorisation" are considered to cover also delays due to ethical evaluation and these are both reported in this section.

19 See Prognos report 2007, Chapter 7, p. 61.

Problem dimension

Though it contains reference to the authorisation or notification of projects, the current Directive does not require compulsory authorisation of projects, nor does it require compulsory notification of projects in all cases.

The average delay of a project using animals due to an authorisation in the Community is between 70 and 100 days in the EU-25, with significant differences between Member States varying from 0 (no authorisation) up to 200 days. Even if these periods in some cases include already the time needed for the ethical evaluation of the project, this variance results in an uneven playing field for user establishments in different countries.

One of the main reasons for long delays is the lack of transparent criteria and standards for the authorisation procedures. Most Member States´ authorities seem to have relatively unclear standards for the timing of these procedures and often also the criteria for decision-making seem from the applicants' point of view open to interpretation.

III. Ethical Evaluation of projects

Current situation in Member States

Almost every Member State has some system for ethical evaluation in place. These systems, however, differ to a great extent. Differences can be seen as regards e.g. the legal status of the system, the level at which ethical evaluation is implemented and the elements that are integrated in the evaluation process. Different combinations of these elements can be observed within the Member States.

Ethical evaluation of a project is normally performed by an ethical evaluation committee. Although it is not a requirement of European law, many Member States have installed ethical evaluation committees at establishment level. In seven Member States ethical evaluation at establishment level is mandatory and laid down in the legislation of the country. In countries with such a mandatory system, this legal status is valued positively[20]. Eight other Member States have installed such committees on a voluntary basis[21]. An additional two Member States have a mandatory system at regional level installed.

The external study has found that in 15 Member States, the Three Rs are part of the ethical evaluation, but the way this is implemented differs. In 13 Member States, harm-benefit analysis is part of the ethical evaluation[22]. 13 Member States have a severity classification system in place. The ways these systems are implemented again differ to a great extent.

The external study has calculated the number of experimental animals covered by compulsory ethical evaluation as 7.3 million in the EU-25 in 2005[23]. This means that for the use of 4.9 million animals, ethical evaluation of projects is not mandatory.

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20 Stafleu, F.R and J. Vorstenbosch; Animal Welfare Committees in the European Research Area, EC, 2005, p. 79. available at: http://ec.europa.eu/research/science-society/pdf/animal_welfare_final_en.pdf.

21 FELASA: Principles and Practice in Ethical Review of Animal Experiments across Europe; December 2005. Available at http://www.felasa.eu/recommendations.htm.

22 Prognos report 2007, p. 20.

23 Prognos report 2007, table on p. 20.

Trends and implications

Ethical evaluation is frequently mentioned as one of the key instruments to improve the scientific outcome and the welfare of experimental animals. Its main aim is to ensure that the use of animals is ethically justified. The benefits of ethical evaluation usually seem clear to those involved, but it is difficult to provide an objective (or quantitative) assessment of the value of the outcomes of the evaluation in practice. It is seen as having a high potential for contributing to a substantial reduction of unnecessary testing and for setting relevant incentives to increase the use of the concept of the Three Rs. Most stakeholders agree that ethical evaluation procedures are required for a good prior evaluation of the project's possible negative consequences on animal welfare. Transparent and well informed ethical evaluation also contributes to a high quality of scientific results, as well as to reducing animal numbers and animal suffering.

Problem dimension

The current practice on ethical evaluation and the level of protection of experimental animals differs very much across the European Community, making it difficult to compare the situation in the different Member States. Ethical evaluation, as one of the main elements of the authorisation if one is required, has a strong impact on the variances in the authorisation delays from 0 (no authorisation) up to 200 days. The users of animals have to take this into account with their resource allocation. These differences in national procedures result in the administrative burden varying significantly, consequently exposing animal users in different Member States to an uneven competitive environment.

It is clear that, if basic elements of ethical evaluation are not sufficiently harmonised in the Directive, the opportunities for the full implementation of the Three Rs cannot be exhaustively exploited and animal welfare and good science not optimised.

Furthermore, it is also unclear how under the current structure, in which neither ethical evaluation nor authorisation is required by some national legislation, compliance with the requirement of article 7(2) of the current Directive to use an alternative replacement method if one is reasonably and practicably available, is ensured.

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

Current situation in Member States

Permanent ethical review bodies go beyond the evaluation of particular projects. They aim at influencing the ethos of every establishment that breeds, supplies and uses animals, creating a 'culture of care' and ensuring proper consideration of ethical aspects and application of the Three Rs in all areas. The level at which ethical review strategies are established differs across Member States. The most common system within the European Community is based on committees at establishment level combined with a committee at a national level.

The external study has found that 18 out of the 25 Member States have a mandatory national ethical review committee in place. The remit of these committees however differs[24].

[24] Prognos report 2007, p. 22.

According to the external study, in seven Member States establishment-based review is mandatory (by virtue of statute or other binding requirement) and so all establishments in these countries carry out such local ethical reviews - though sometimes committees are shared between establishments. In the remaining countries there is no legal or other administrative requirement for local ethical review (with the exception of Spain where three administrative regions require it and nationally all State research centres are bound to perform it)[25].

Trends and implications

The external study concluded that ethical review bodies are becoming more and more common in Member States and are increasingly considered by a wide range of stakeholders as important instruments to improve the welfare of experimental animals.

Problem dimension

The existing, highly varied systems result in non-harmonised practices both within a country and between Member States. The highly diverse situation creates a non-level playing field in terms of resource requirements (staff, time) affecting not only user establishments but also breeding and supplying establishments. It leads to an imbalance of administrative burden between the different Member States and thus to an uneven competitive environment. It is also difficult to compare the national systems and to verify that animal welfare and the Three Rs are fully taken into account.

V. Housing and care standards

Current situation in Member States

Directive 86/609/EEC contains in its Annex II, non-binding guidelines on accommodation and care of animals. Member States have implemented them in a varying manner. In some Member States they are considered as compulsory minimum standards, in others they maintain the non-binding status of guidelines.

Annex II of Directive 86/609/EEC is based on the corresponding text of the Council of Europe Convention ETS 123 for the protection of vertebrate animals used for experimental and other scientific purposes. This Convention contains in its Appendix A non-binding guidelines for the accommodation and care of animals which have recently been revised to reflect the latest knowledge and scientific developments. The revised Council of Europe guidelines were adopted in June 2006 and Parties to the Convention are expected to implement them by June 2007.

The European Community is Party to the Convention and will therefore have to implement the revised guidelines. In addition, 13 Member States have ratified the Convention, covering 91% of animal use in the EU-25[26].

The revised guidelines foresee significant increases to the cage sizes and emphasise group housing and enrichment. The external study found that based on the factual feedback and

[25] Prognos report 2007, p. 155.

[26] The following 13 Member States of the EU-25 have ratified the convention: Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Netherlands, Slovenia, Spain, Sweden and United Kingdom. Bulgaria and Romania also ratified before their accession.

estimations from users and keepers of animals, at least 20% of both private and public establishments have already upgraded their facilities to comply with the revised guidelines[27].

Trends and implications

The revised Appendix A will apply to those countries who are parties to the Convention, currently only 12 out of the 25 Member States. However, the European Community will also need to update its guidelines in Annex II of Directive 86/609/EEC. Therefore, even those Member States who are not Party to the Council of Europe Convention will need to promote the revised guidelines.

Problem dimension

Currently, some Member States consider these guidelines as compulsory minimum standards whereas others use them purely as guidance. The fact that these guidelines are interpreted differently from one Member State to another places establishments (breeding, supply and user establishments) into a significantly different cost environment, depending on the Member State in which they are located, consequently distorting the internal market. This is unlikely to change without regulatory action at European level.

Member States have confirmed that the implementation of the revised housing and care standards as agreed at the Council of Europe will be considered in a similar manner as today, i.e. varying from non-binding to compulsory minimum. Due to the significant upgrading of these standards, this would suggest a strong possibility of further fragmentation of the internal market in the near future.

Since the current guidelines in Annex II of the Directive are non-binding, there is no assurance for minimum animal welfare requirements to be met, e.g. in terms of space allowance. This is not in line with the requirement to take into account animal welfare requirements as per the Animal Welfare Protocol to the Treaty establishing the European Community.

Inappropriate housing and care can lead to a number of physiological and behavioural changes in experimental animals that can heavily interfere with the test results and undermine their reliability[28].

VI. Transparency / Access to Information

Current situation in Member States

In most countries, public information about animal tests is made available through yearly statistical reports published by the responsible ministry. As a minimum, these reports include basic statistical information required to be reported to the Commission. Several Member States make authorisation information available to the public; few make essential parts of ethical evaluation reports publicly available. Some establishments publish more detailed information voluntarily in their annual reports.

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[27] Prognos report 2007, p. 205.

[28] See Annex of this document, EFSA 2005, p. 46-53, and most recently Baldwin and Bekoff 2007.

Trends and implications

The right of access to information is essential for a civilised society. If citizens are to exercise their democratic rights, and to make informed choices, they must have access to political, social, scientific and economic information. A basic principle behind most freedom of information legislation is that the burden of proof falls on the body asked for information, not the person asking for it. The requester does not usually have to give an explanation for his/her request, but if the information is not disclosed, a valid reason has to be given. In many countries, privacy or data protection laws may be part of the freedom of information legislation.

Problem dimension

Better regulation requires transparency about regulations and economic actors' behaviour. The right of citizens to information about public policies at Community level has been recognised in Regulation (EC) 1049/2001 about access to information. However, the current Directive 86/609/EEC does not provide a level of transparency called for by large proportion of stakeholders and the general public. It has been recognised by many companies and researchers that a consistent approach about transparency across Europe would benefit all interested parties.

A few countries such as Sweden, Denmark, and the Netherlands have implemented extensive public rights to information through their freedom of information legislation. In principle, these rights would enable interested members of the public to access extensive information on projects, except for company and personal details. Intellectual property rights and other trade secrets are also considered as restricted information and are not made available under freedom of information legislation.

The external study concluded that a majority of stakeholders would expect the revision of the Directive to include more public rights/better access to information. On the other hand, they stressed that great caution should be exercised to avoid that more transparency is used for political gain by animal rights extremists. It is also feared that this might lead to security issues for personnel. Many stakeholders point out that increased legislation in this area must be balanced against intellectual property rights concerns.

VII. Non-human primates (NHPs)

Current situation in Member States

Available data indicates that in 2002 about 9000 non-human primates (NHPs) were used in the 15 Member States which accounted for about 0.1% of all the experimental animals used in that year[29]. The data shows that more NHPs were used in the United Kingdom, France and Germany than elsewhere in the Community. The total use of NHPs in the EU-25 is estimated to be close to 10,000 per year: 75-80% of these animals are "Old World monkeys" (mainly cynomolgus and rhesus monkeys); 20-25% are "New World monkeys" (mainly marmosets

[29] This impact assessment report has tried to use the extrapolations or EU statistics for the animal use of the EU-25 in 2005 wherever possible. However, for the NHP section, the reference year is often 2002 because EU statistics had to be compared with CITES statistics, and 2002 was the most recent year for which both statistics existed at the time of writing.

and some tamarins); and some Prosimians (mainly lemurs). Other species used counted for less than 3%.

The use of Great Apes is very limited, with 6 animals in 1999 and zero in 2002 and 2005. The use of Great Apes is banned in some Member States, a total ban in the Netherlands, Austria and UK (no further authorisations issued); and a partial ban in Sweden where they can be used only for research relating to their own species.

Use and trends

The main biomedical research areas using NHPs are safety testing of pharmaceuticals, quality control of vaccines, and fundamental and applied research. At present some scientific procedures require the use of NHPs e.g. for polio or Hepatitis C vaccine research, HIV research and investigations into higher cognitive function. A high proportion of NHPs (> 70%) are used in applied studies and regulatory testing, therefore further support for the development and implementation of alternative methods could be effective to reduce the number of animals used. Strategies are being developed in order to establish and maintain non-human primate tissue banks and primate-derived cell culture collections in order to optimise the use of this material but these are at present still inadequate to replace a substantial part of NHPs in biomedical research.

There are insufficient data available to estimate whether the use of NHPs is decreasing in Europe. In the Netherlands the number of NHPs decreased from about 400 in 2000 to about 300 in 2004, but in the UK there was an increase from about 3700 to 4200 in this period.

The USA, together with Japan, are the main users of NHPs in research and testing. Most recent statistics show that 52.279 NHPs where used in research, testing and teaching in the USA in 2002. For Japan, no accurate figures are available as no mandatory reporting system is in place, but, based on data from CITES (2002), their use was estimated to be 6000-7000 animals per year[30].

In 2002 about 75-80% of the NHPs used for scientific purposes in the EU were Old World monkeys. About 7000 of these animals were imported from outside the EU. Only a few were second or higher generation (F2+) purpose-bred[31].

The most frequently used NHPs in the European Community are macaques (cynomolgus and rhesus monkeys) and marmosets; in the UK the ratio of Old to New World is about 3:1. The reproduction cycle for marmosets is 2-2.5 years (breeding age reached at 1.5-2 years, with a 4-month gestation period). One litter consists of 2-3 progeny. The reproduction cycle for macaques is longer, approximately 4-5 years (breeding age reached at 4 years, with a 5-6-month gestation). A litter usually consists of only one progeny.

Problem dimension

Non-human primates are species with highly developed social skills and behavioural manners that are to some extent similar to those of human behaviour. Due to the similarities with human beings, the ethical justification of their use is a sensitive issue and a subject of serious

[30] Prognos report 2007, p. 25.
[31] Prognos report 2007, p. 25.

debate. There is increasing (public) concern regarding their potential use in scientific procedures and their welfare is not considered sufficiently assured by the wording of the current Directive.

A particular problem arises from the fact that it has turned out to be difficult for several species to establish self-sustaining breeding colonies. Many NHPs are therefore caught in the wild and bred so that their first generation offspring (F1) can be used for research. There is significant evidence that catching these highly aware and social animals from the wild causes significant suffering and distress, both for themselves and for their remaining group and family members. The subsequent transport both in terms of distress and injuries add to these concerns. Several stakeholders have therefore advocated to move towards self-sustaining breeding colonies and only allow the use of second (F2) or higher generation captive-bred NHPs in scientific procedures. In that case, the need to catch NHPs in the wild would be significantly reduced.

On the other hand, there is a clear need for NHPs in biomedical research, due to the above mentioned similarities to the human species. For example, they are used to tackle severe diseases such as diabetes, AIDS, malaria, Parkinson's, Alzheimer's etc.[32]. Furthermore, they are important for the development and quality control of vaccines, where Europe plays a leading role in the world (around 85% of the global supply is produced in Europe) to which with the current scientific knowledge no alternatives are yet available.

In their natural habitat, NHPs live in complex environments and the social dimension is vital for their well-being. If the physical and social environment is inadequate, the NHP is usually not a good model in research. Therefore, animal welfare and quality of science are closely linked. As a consequence, research on NHPs is more cost-intensive than research on other mammalian species. Special consideration must be paid to Great Apes where the discussion about NHPs is the most controversial. Their use is quite rare, although some scientists are against a total ban because new emerging diseases might make it necessary to use Great Apes for the development of vaccines and treatments.

VIII. Inspections

Current situation in Member States

All Member States have an infrastructure for periodic inspections. The frequency of inspections varies significantly from one Member State to another.

Trends and implications

Inspections are highlighted as one of the main tools for ensuring compliance with legislation and minimum requirements. Some Member States have over the recent years made specific investments to increase the training of inspectors and the frequency of visits. In the UK for example, an establishment can have multiple inspections over a period of one year, many of which are unannounced.

[32] See also the Opinion of the Commission's Scientific Steering Committee about non-human primate use (2002): http://ec.europa.eu/food/fs/sc/ssc/out253_en.pdf.

Problem dimension

The Directive does not specify any frequency of inspections apart from being periodic. Some Member States have therefore developed the practice of inspecting establishments several times per year whilst others do hardly any inspections at all. This situation creates a stricter regulatory environment in some Member States than in others and undermines trust in the proper enforcement of standards, thereby itself creating incentives to deviate from official standards. This undermines the concept of a level playing field and legal certainty for breeders, suppliers and users.

Since there are no effective Community wide minimum standards for inspections, there is a low public perception of levels of compliance and enforcement by the authorities. Furthermore, if inspections are announced prior to the visit, it may result in providing an unrealistic picture of the day-to-day running of the establishment. In case full compliance is not assured, animal welfare may be compromised. The Commission regularly receives complaints from citizens about alleged infringements of the existing legislation[33].

IX. Education and training

Current situation in Member States

The external study found that all Member States have set (minimum) legal requirements for the competence of personnel working with experimental animals. Several Member States referred to their system as being in accordance with the FELASA guidelines for the education and training of persons (Belgium, Slovenia, the Netherlands, Lithuania (B and C category))[34], while others have very different standards in place.

Demonstrating/maintaining personnel competence however is required only in approx 35% of the Member States, covering approximately four million of total animal use in Europe. The other 65% of Member States do not have specific requirements in place for demonstrating/maintaining competence[35].

Trends and implications

A "Code of conduct for education and training of persons working with laboratory animals" of the European Convention ETS 123 was adopted by the Multilateral Consultation in 1993. Four categories of persons are defined who must have had appropriate education and training:

Category A: Persons taking care of animals

Category B: Persons carrying out procedures

Category C: Persons responsible for directing or designing procedures

Category D: Laboratory animal science specialists

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33 29 incorrect/non transposition and bad applications cases opened under Directive 86/609/EEC (11 concerning transposition, 18 on bad applications). 15 of these were confirmed as infringements by the Commission.

34 Prognos report 2007, p. 27.

35 Prognos report 2007, p. 27.

Countries that ratified the Convention ETS 123 have agreed to ensure that these guidelines will be circulated among the persons responsible for education and training of those working with experimental animals, to encourage these persons to follow these guidelines in their courses; and to encourage those responsible for education and training to establish programmes to allow the fulfilment of the requirements of the Convention for all persons working with experimental animals.

Problem dimension

The current Directive does not specify the necessary competence of the personnel, nor how competence can be kept up-to-date and is demonstrated. Staff qualifications determine to a great extent the costs of institutes and laboratories. Differences in the levels of training and qualifications across Member States lead to differences in the cost of developing and performing a project. The differences in the requirements for the personnel also make it difficult to participate in projects in another Member State restricting their freedom of movement.

Lack of competence can also seriously undermine animal welfare e.g. when performing a procedure or euthanasia on animals, as well as having a deleterious effect on the scientific outcomes and their reliability. Qualified and well-trained personnel are therefore essential for good animal welfare, good science, and the human dimension of use of animals in scientific procedures. People working with animals should be trained specifically to reduce suffering of animals during their whole lifetime. This is currently not ensured since the Directive does not give specific requirements for education and training or demonstrating competence.

X. Avoiding unnecessary duplication

Current situation in Member States

No systematic instruments apart from ethical evaluation and authorisation are employed by Member States to avoid unnecessary duplication of testing[36]. Retesting is a legal requirement with few exceptions for medical products for human and veterinary use which are imported from third countries. The only instruments possibly contributing to a reduction of duplication in this area are Mutual Recognition Agreements between exporting countries and the European Community. However these instruments only cover specific issues and are thus not able to abolish the requirement to test all products coming from that exporting country. For imported vaccines there is an option for Member States to retest, which 10 – 15 Member States actually use[37].

Trends and implications

One of the leading principles of the Three Rs is to avoid unnecessary testing on animals. However, due to the different laws, administrative procedures in authorisation and inspection arrangements in the Member States, it cannot be excluded, that duplication of testing may

[36] The new chemicals policy REACH is an exception in that respect because it foresees mandatory data-sharing and prior evaluation of testing proposals by the new European Chemicals Agency. However, based on estimations produced by the Joint Research Centre of the Commission in 2003, REACH will only concern about 2-3% of all animals used for experimental and other scientific purposes per year, so relying on REACH mechanisms alone to address unnecessary duplication does not seem sufficient.

[37] Prognos report 2007, p. 29.

occur. The external study has concluded that in Europe approximately 160.000 animals per year are subject to unnecessary duplication in regulatory testing[38]. There are no reliable data about unnecessary duplication in other areas (basic research, applied research) but little incentive may exist to knowingly duplicate scientific procedures using animals on the same substance in applied research (e.g. due to early patent protection of active ingredients in pharmaceuticals). A similar disincentive to duplicate exists in basic research (e.g. due to strict scrutiny of any project proposals by funding bodies and peer reviews by scientific journals).

Problem dimension

Currently, there is no harmonised approach in Europe to ensure an effective exchange of relevant information and data regarding animal use in scientific procedures. Authorisation and inspection bodies as well as researchers do not have the necessary overview of objectives and results of all scientific procedures carried out each year on more than 12 million animals in the EU-25 alone. Although it can be argued that scientists usually have an excellent overview of the literature within their respective fields of specialisation, negative experimental results (although equally valuable), are often not reported.

XI. Use of CO_2 for euthanasia

Current situation in Member States

The Commission has produced guidelines on humane methods of euthanasia[39]. Some Member States use these guidelines as such. The use of CO_2 is recommended for killing many common species of animals used in scientific procedures.

Trends and implications

CO_2 is one of the most commonly used methods of euthanasia. It is the most convenient method for euthanasia of large numbers of rodents (quicker and less resource-intensive than alternatives). If used in optimal conditions, CO_2 may also be less stressful than manipulations required for injections or physical methods.

Establishments do not use a single method of euthanasia but rather a combination of several methods according to the type of project or the circumstances and the species in question. For example, if there is a necropsy (dissection of the dead body to determine the cause of the death or changes produced by a disease) at the end of a toxicology study, the animal may be anesthetized with a suitable method, and then exsanguinated. If there is no necropsy, CO_2 is used (on conscious animals), or pentobarbital over-dosage, if less than 2-3 rodents (mice/rats) are to be killed at the same time.

Problem dimension

The Directive itself neither specifies nor gives any guidance as to the most appropriate methods of killing per type of species. Applying CO_2 is a relatively cost effective way to kill certain species of animals whilst alternative gases are more expensive and pose different

[38] Prognos report 2007, p. 29.

[39] See Close et al. 1996: Recommendations for the Euthanasia of experimental animals: Part 1. In: Laboratory Animals, vol. 30, pages 293-316; Close et al. 1997: Recommendations for the Euthanasia of experimental animals: Part 2. In: Laboratory Animals, vol. 31, p. 1-32.

requirements for their use. If some Member States are banning CO_2 as a method for euthanasia on welfare grounds for some or all species while other Member States do not, different cost structures for breeders and users occur across the community. This puts establishments in high standard countries in a different cost environment, distorting the internal market.

In terms of animal welfare, recent research shows that CO_2 is aversive to all vertebrates, some species seem to find even low concentrations (10-20% by volume in air) aversive. However, there is insufficient scientific data yet available on the aversiveness of alternative gases. The EFSA opinion recommended using CO_2 only when an animal is first rendered unconscious via another method[40].

XII. Statistical reporting

Current situation in Member States

The current Directive foresees that MS have to report statistics at least every three years to the Commission. To implement this, Member States have voluntarily agreed to report on 8 analytical categories:

– species, numbers and origin of animals used, re-use

– purpose of the experiments

– toxicological or safety evaluation for types of products/endpoints

– animals used for studies of diseases

– animals used in production and quality control

– origin of regulatory requirements for animals used in toxicological and other safety evaluations

– animals used in toxicity test for toxicological and other safety evaluations

– type of toxicity test carried out for toxicological and other safety evaluations

In addition, the external study found that nine Member States report on transgenic animals and seven report on animals killed for their tissue/organs separately in their national reporting[41].

Trends and implications

The current situation with statistical reporting in Europe is characterised by an increasing quality of data. Since 1991, the Commission has published statistical reports on the use of animals in experiments in the European Community. The format for reporting data was harmonised in 1997 at European Community level. Based on this reporting system, both the

[40] http://ec.europa.eu/environment/chemicals/lab_animals/scientific_en.htm

[41] Prognos report 2007, p. 31.

quality and coherence of data has constantly increased over the years. The 5th statistical report, covering the year 2005, contains data from all 25 Member States.

Problem dimension

The availability of sound data on the number of animals used for experimental and other scientific purposes is essential for public policy-makers working in the field of animal protection. To ensure a level of confidence on the data, the basis for the data requirements should be uniform and enforceable. However, the current basis is only secured by a voluntary agreement and thus not legally enforceable. Furthermore, the analysis of the statistical data currently available shows that there are central fields of political and public interest which are not yet covered by the existing statistical reporting system. The use of genetically modified animals, which are increasingly used in scientific procedures are not specifically reported through the existing system, neither are animals killed for their organs and tissues. The severity classes to which animals have been subjected are not identified either.

Finally, the current statistical reporting system only focuses on overall numbers of animals used for experimental and other scientific purposes but there are no data available on how many projects per establishment category (public/private) are carried out in the European Community per year. This makes identification of trends and impacts of policy changes difficult and hinders good policy making.

XIII. Promotion of alternative test methods

Current situation in Member States

Directive 86/609/EEC in its Article 23 calls for the Commission and the Member States to encourage research into the development and validation of alternative methods. However, only a few Member States (e.g. Germany, Netherlands, Austria, UK) are known to have set up national centres to develop or validate alternative methods to animal tests[42]. Including laboratories, which could also serve such a purpose, a maximum of 12 Member States have such national centres in place[43].

Trends and implications

As a response to Article 23, the Commission set up in 1991 the European Centre for the Validation of Alternative Methods, ECVAM[44]. The concept of validation was not yet clear at the time and thus an extensive amount of work was put into clarifying and optimising pre-validation and validation procedures and criteria, not only in EU but also internationally (ICCVAM, OECD). Today, the validation process is well established and increasing numbers of candidate methods are being proposed for validation.

ECVAM is currently addressing the potential validation of a significant number of methods that are a result of a number of research projects under the Community Framework Programme for Research. Not all test methods may successfully pass pre-validation and

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42 Information of ECVAM (European Centre for the Validation of Alternative Methods) and ZEBET (Zentralstelle zur Erfassung und Bewertung von Ersatz- und Ergänzungsmethoden zum Tierversuch in Germany; http://www.bfr.bund.de/cd/1433).

43 Information by ECVAM.

44 SEC(91) 1794, Communication of the European Commission to Council and the European Parliament.

further validation. Nevertheless, the number of tests entering the pipeline has been increasing over the last few years and is not expected to level off. Suitable methods need to be available to cover the requirements of the Cosmetics Directive. REACH and new developments in the medical area may spark even a further increase.

Problem dimension

Even though the ECVAM structure and working methods have now been established, several problems remain:

1. The current infrastructure is not equipped to cope with this increasing demand and there is a lack of suitable methods but also available resources to carry out the required validation studies. It is important to note that the role of ECVAM is to co-ordinate validation studies at the Community level, however, several participating laboratories are required for each validation study (inter-laboratory validation in order to ensure reproducibility and transferability).

2. Time delay is an additional bottle-neck to the process on ECVAM co-ordinated validation studies. Due to the requirements for transparency, the administrative procedures to launch a validation study take an average one year delaying the process significantly.

3. Participating laboratories often have problems finding suppliers or storing their chemicals in a purity that is necessary to perform effective validation studies[45].

Subsidiarity

The European Community has the right to act on the identified problems and is better placed than the Member States alone to tackle them:

- The EC Treaty provides the European Community in Article 95 with a legal base to adopt measures to approximate Member State provisions laid down by law, regulation or administrative action, in order to ensure the functioning of the internal market.

- The Protocol on protection and welfare of animals annexed to the EC Treaty requires the European Community and the Member States to pay full regard to the welfare requirements of animals in formulating and implementing the Community's agriculture, transport, internal market and research policies.

- While most of the identified problems fall under a competence shared by the Community and the Member States, the problems cannot be sufficiently solved by the Member States themselves because action or non-action by the Member States has created the problems of distortion of the internal market in the first place, as has been shown in detail above.

[45] Information by ZEBET.

4. POLICY OBJECTIVES

The overall, general and specific objectives for the revision of Directive 86/609/EEC are:

Overall objective: Strengthen the Single Market and reduce unfair competition

Primary objective: Strong convergence of standards that ensures a level playing field for industry, researchers, breeders and suppliers of experimental animals

Specific objectives

Reduce unfair competition and distortion of internal market for companies, research institutes and universities by

- harmonising the minimum requirements in areas such as scope, authorisation including ethical review, and minimum standards for housing and care in order to level the regulatory driven
    - cost and time factors for establishments performing scientific procedures involving the use of animals
    - cost for breeders and suppliers of experimental animals
- stepping up enforcement of legislation by ensuring minimum inspections throughout the Member States
- increasing transparency in line with better regulation principles
- encouraging research into alternative approaches and improve conditions for innovation

Secondary objective: In line with the Animal Welfare Protocol annexed to the EC Treaty, a significant improvement in animal welfare and protection over the life time experience of experimental animals

Specific objectives

Improve animal welfare by ensuring a minimum scrutiny and standards of all animal keeping and use for experimental purposes by

- Implementation of ethical evaluation of projects and permanent ethical review body in establishments to ensure full compliance with the Three Rs.
- Minimum criteria for housing and care, and inspections
- Ensure protection of all animals for which there is scientific evidence that they are sentient (including selected invertebrates, certain foetal and embryonic forms, animals used in basic research, those bred for tissue).

These objectives are in line with the Lisbon Strategy calling for the internal market to be further harmonised, the regulatory environment simplified and high-quality research and development fostered.

The objectives also support the implementation of the 6th Environment Action Programme which foresees in Article 7(2)a) and b) that the development and validation of alternative testing methods should be reinforced.

5. POLICY OPTIONS

a) Four basic options

In the course of the discussions with experts and stakeholders, four basic policy-options have been developed:

1.) No Policy-Change:

One option could be to keep the current situation unchanged. This would mean that the existing Directive 86/609/EEC would not be revised and that the given standard of community legislation and national implementation would be continued.

The problem descriptions in section 3 have presented a number of problems and trends of concern. The existing Directive will not be able to address these problems and trends effectively and no-policy-change is therefore not a viable option. The Directive also needs to be adapted to scientific progress and new animal techniques 20 years after its inception, and the opportunity should be used to review its effectiveness in the different areas and upgrade the standards where necessary.

It has been suggested that the Commission could rather focus on implementation and better enforcement of the existing Directive instead of upgrading it. However, given that the protection level provided by the current Directive is not very ambitious and has many loopholes, there is little that the Commission could actually enforce before the Directive is revised. In view of the complaints about poor animal welfare and handling in establishments that the Commission receives, and the problems on correct transposition partly arising from the unclear legal wording and inconsistencies in the text[46], it seems therefore better to first upgrade the existing Directive and then focus on better implementation and enforcement in a second step.

2.) Self-regulation

A basic option that was discarded for most policy dimensions was self-regulation. Several reasons make such an approach impractical across most of the policy dimensions:

- Firstly, this in a way represents the status quo/business as usual scenario where the problems mentioned above are not adequately addressed.

- Secondly, there are no suitable European or even national organisations of breeder, supplier or user establishments who could monitor or enforce a clear policy. For instance, while a US-based international self-regulation body for welfare standards of experimental animals actually exists (AAALAC), to a large extent it just reinforces existing national or European legislation and can therefore not serve as a substitute but only as an add-on to legislation. Currently only 29 out of an estimated 1,300 breeder, supplier and user establishments in the European Community are accredited with AAALAC (mostly national branches of multinational pharmaceutical companies).

[46] As an example, it is difficult to determine whether procedures entailing severe pain are allowed. Article 8, paragraph 3; Article 10; and Article 12, paragraph 2, seem to contradict.

- Thirdly, using ethical evaluation as an example that clearly demonstrate how some existing national legislations go much further than others, creating an uneven playing field especially in terms of administrative delays and resource requirements. Such variance in administrative delays, which can have direct implications for competitiveness, is unlikely to be addressed successfully through self-regulation.

- Fourthly, the experience of the Commission with voluntary agreements has not always been very good, as can for example be seen when examining the voluntary agreement of European car producers to reduce their CO2 emissions which is likely to fail to deliver the agreed results.

- Finally, there seems to be a move away from voluntary agreements in industry as well so that any voluntary scheme set up by the Commission may not be very credible. The main problem industry fears concerning voluntary agreements are free-riders whose market access may be difficult to control without state action. A recent call for legislation instead of voluntary agreements in the energy efficiency area was issued by the white goods industry association Ceced[47].

3.) Deregulation:

In theory, the existing Directive could be repelled and the regulatory competence fully transferred to the Member States, with the European Community level remaining to provide only recommendations and playing an active part in exchanging information on good practices and alternative methods.

This option of deregulation was not pursued further because all Member States have existing national legislation that implements the original Directive. Most Member States exceed the requirements of the Directive. Also, deregulation would naturally lead to an even more uneven playing field and more acute problems with the Single Market. Furthermore, the impact of deregulation would fail to address the calls from experts, stakeholders, Member States and policy makers who have reached a broad consensus during the last few years on the fact that a revision of the current Directive is necessary. Finally, deregulation is clearly not advisable in view of the international commitments (Council of Europe) of the European Community. The question therefore is not whether the EC should regulate but how it should regulate.

4.) Reinforcement of the existing European Community legislation:

A fourth option could be to reinforce the European Community regulation by revising the existing Directive. This would mean that in specific areas, where evidence shows that a Community wide harmonisation could considerably contribute to a reduction of existing obstacles to the functioning of the internal market and to the enhancement of the welfare of experimental animals, a revised Directive could set clearer and more harmonized standards.

This option is justified by the fact that Directive 86/609/EEC has not succeeded in harmonising the internal market. In many relevant policy dimensions, such as scope, education and training, authorisation or housing and care, the absence of a level playing field leads to unfair competition and distortion of internal market for companies, research institutes

[47] See ENDS Europe Daily, 22 March 2007.

and universities. Good practice examples of selected Member States could be used as a starting point to develop a higher level of legal and procedural convergence throughout Europe.

This option is also justified by the fact that both the scientific context and the policy-problems have significantly changed since 1986. Although, for instance, the level of animal protection in Europe has increased in recent years, the statistics are showing an increase of the total number of animals used per year in most Member States.

b) Choice of legal instrument

Based on the reflections about the four basic options, the fourth basic option (reinforcement of the EC legislation) was developed further. In this context, the question of the legal instrument was discussed in relation to the subsidiarity principle. In theory, both a Regulation or a Directive would be possible to address the problems and trends of concern.

A ***Regulation*** would have the advantage of simplifying the regulatory environment in Europe and may be the better instrument to ensure a level playing field for all establishments, regardless of their location. On the other hand, a Regulation may be too rigid to encompass all the existing regulatory systems that have developed over the last 20 years in the Member States, and changing these completely would be a significant cost factor. Finally and most importantly, the principle of subsidiarity would caution against using a Regulation in this field. Member States can be expected to develop a good system suitable for their national or regional administrative system as long as certain minimum standards are set at European level. Moreover, the Protocol on Animal Welfare annexed to the EC Treaty foresees explicitly that "the legislative or administrative provisions and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage" shall be respected. A Regulation would not seem an appropriate instrument in such a sensitive area.

In view of these arguments, the Commission considers that a Directive is a more suitable instrument in this field and proposes to revise the existing Directive 86/609.

c) Subsidiarity

The analysis of these basic policy options has shown that the proposed policy objectives cannot be sufficiently achieved by the Member States alone and can be better achieved at Community level.

Specific options for each policy dimension have been defined and are outlined in the next section.

d) Specific policy options

I. Scope

The options include extending the scope of animals and procedures covered under the current Directive to create a uniform regulatory environment within the European Community. This would result in a more competitive level playing field in this respect and protect at least 4.1 million additional animals currently not covered by the Directive.

Option 1: Extend the scope to cover animals used in basic research

Option 2: Extend the scope to cover animals bred for the primary purpose of their tissue and organs to be used in experiments or for other scientific purposes (but without requiring a project authorisation for the euthanasia if it is performed by competent person using a method appropriate to the species)

Option 3: Extend the scope to cover selected invertebrates species (Cyclostomes, Cephalopods and Decapod crustaceans)

Option 4: Extend the scope to cover foetal and embryonic forms from the last third of gestation until birth

Option 5: Extend the scope to cover animals used in education and training

II. Authorisation of projects

In view of the large differences in authorisation practices in Europe, a level playing-field should be established to guarantee comparable minimum requirements for the authorisation of projects while ensuring a smooth processing of applications to safeguard the competitiveness of Europe as a research place in line with the Lisbon Strategy. The introduction of compulsory authorisation for individual projects with a maximum deadline of 30 days for public authorities to decide on applications could be a highly effective instrument to harmonise the internal market and enhance animal welfare.

Option 1: Authorisation of individual projects with compliance check

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

III. Ethical evaluation of projects

An effective ethical evaluation for scientific uses of animals could be mandatory in every European country as a central element of authorisation requirements in order to harmonise the internal market and ensure minimum standards of animal welfare.

(1) An important option for the revision of the Directive could be to make ethical evaluation of projects mandatory. The revised Directive could contain a list of minimum requirements for ethical evaluation such as:

(i) Implementation of the Three Rs in which every project has to be critically evaluated to see if the concepts within the Three Rs framework have been sufficiently taken into account. Minimum elements could include:

- Justification of the scientific objectives
- Justification of the proposed use of animals and procedures
- Origin, numbers, species and life-stages of animals with justification
- Demonstration of lack of alternative methods
- Demonstration of competence of persons involved in the project

- Use of anaesthesia, analgesia and other pain relieving methods
- Reduction, avoidance and alleviation of any other form of animal suffering from birth to death
- Housing, husbandry and care conditions in the context of procedures
- Use of early and humane endpoints
- Experimental strategy and statistical design to minimise animal numbers and animal suffering
- Assessment of life time experience, including the re-use of animals
- Avoidance of unnecessary duplication of procedures

(ii) Severity classification of procedures which aims at categorising the procedures by the level of physical pain, physiological perturbation, or mental distress the procedures may inflict on an animal, and their duration.

Whereas some Member States systematically apply severity classification, most Member States have little or no experience in this area. Consideration could therefore be given to minimum requirements. In addition, it could be beneficial to give practical guidance for this severity assessment.

(iii) Harm-benefit analysis at a project level aims at quantifying, not in mathematical terms, the harm to the individual animal in terms of suffering, pain, distress etc and the likely benefit to humans, animals and the environment.

(2) An additional option would be to require retrospective assessment of the benefits and harms in all projects.

Option 1: Compulsory ethical evaluation of projects with minimum requirements

Option 2: Introduction of retrospective assessment of all projects to record deviations and evaluate factual harm and realized benefit

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

A combination of a national committee for co-ordination of ethical review matters within the Member States and a local ethical review body at an establishment level may be useful to ensure a consistent implementation of ethical review requirements, creating an improved level playing field for research and industry, and at the same time aiming at improved welfare for animals. The tasks of a national committee could include:

Establishment and publication of requirements for ethical evaluation of projects and local ethical review body.

Promotion and co-ordination of Three Rs approach at a national level to help ensure good animal welfare and good science.

Option 1: Introduction of a national animal welfare and ethics committee with a minimum harmonised remit

Option 2: Introduction of a permanent ethical review body in each establishment

V. Housing and care standards

The revised Directive could incorporate elements of the Council of Europe's revised Appendix A to Convention ETS 123 as compulsory minimum standards with appropriate transitional periods for implementation. This would create a competitive level playing field within the European Community (and between Member States and non-Member States who are Parties to the Convention), avoid further distortion of the internal market and bring the Directive in line with current scientific and technical knowledge to increase animal welfare.

Option 1: Requiring as a minimum standard compliance with the revised Appendix A to the Council of Europe Convention ETS 123

VI. Transparency / Access to information

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

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

VII. Non-human Primates (NHPs)

The revised Directive could reinforce the ban on wild-caught NHPs and could further restrict the research areas in which NHP can be used. A gradual switch to only allowing use of F2 (second-generation) and higher generations of purpose-bred NHPs could be desirable regarding animal welfare and biodiversity. 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 revision of the Directive could harmonise the minimum requirements for annual inspections at the level of two, one of which could be unannounced, to reduce distortions in the internal market caused by varying levels of enforcement across Member States. A system of European Community inspections could also be envisaged to increase public confidence.

Option 1: Minimum twice yearly inspections by national authorities of which at least one unannounced

Option 2: European Community inspections

VIX. Education and training

The revised Directive could incorporate some minimum training requirements for the different categories of personnel and set requirements for demonstrating and maintaining competence over time, to reduce different cost environments that establishments find in different Member States.

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

X. Avoiding unnecessary duplication

A significant reduction of duplication in regulatory testing would require changes in numerous legislative requirements at Member State level. This policy approach, however, cannot be addressed by a revision of the given horizontal Directive. However, compulsory authorisation and ethical evaluation of projects would partly address this problem.

In view of this situation, the general approach of a revised Directive regarding the reduction of unnecessary duplication could be setting-up a centralised European Community-wide database collecting information on project authorisation and scientific results in each Member State.

The database could also provide a discussion platform where scientists and inspectors could exchange their experiences, problems and good practices. As far as possible, information on practices in third countries could also be collected. This could contribute to increasing the knowledge, especially in basic research, and provide more transparency on results, not systematically published so far.

Option 1: Setting up a centralised European Community-wide database

XI. Use of CO_2 for euthanasia

The revised Directive could incorporate a list of humane methods of euthanasia to be used for experimental animals to ensure that no cost advantages occur for establishments in Member States where inhumane methods of killing are not yet banned. Within such a common list of methods, the use of CO_2 could be prohibited unless the animal is rendered unconscious prior to its exposure to the CO_2.

Option 1: Prohibition to use CO_2 unless the animals are first rendered unconscious by exposure to anaesthetic gases such as halothane

XII. Statistical Reporting

The revised Directive could increase the quality and usability of annual statistical reporting of the Member States by introducing the following elements so that future revisions of the legislation can be based on improved data:

- the number of genetically modified animals and of certain invertebrate species and foetal and embryonic forms (excluding larvae) from the last third of development

- numbers of animals killed for the primary purpose of their organs and tissues to be used in scientific procedures

- numbers of projects and types of establishments

- severity classes of the scientific procedures to which animals have been subjected

XIII. Promotion of alternative test methods

The revised Directive could foresee that every Member State designates a national reference laboratory to contribute to the validation of alternative methods. These laboratories could specialise in a specific area of expertise (e.g. development toxicology, carcinogenicity, biologicals, etc.) and also contribute to hands-on training of scientists in the validation of alternative methods[48].

Option 1: National reference laboratories

[48] Proposal by ZEBET.

6. ANALYSIS OF IMPACTS

a) Methodology and structure of this chapter

The impacts have been assessed across all 13 policy dimensions with benefits assessed according to the four problem dimensions (Economic problems, Environmental problems/Animal welfare, Scientific problems, Public/societal problems) and costs were assessed according to whether they occur for user, breeder or supplier establishments or for public authorities.

The basic benefit and cost model is based on the methodology of the external study, normally assessing the impacts against existing Member State legislation. The relative strength of an impact is qualified as "slight", "moderate" and "high" according to the feedback from stakeholders. It is clear that these qualifications express subjective views because many of the impacts are very difficult or impossible to measure in absolute figures. The strength of animal welfare impacts is expressed in terms of one, two or three pluses (+, ++ or +++) in the tables on page 62-68 and is summarised in the overview table on page 69.

The following assumptions and extrapolations were made in line with the European animal use statistics and the external study[49]:

- Number of establishments in the EU-25: about 1.330

- Number of newly started projects in the EU-25 per year: about 9.300

- Number of newly used vertebrate animals in EU-25 per year: about 12.2 million

- Number of personnel working with animal tests in the EU-25: about 150.000

- Average hourly wage for researchers and public officials in the EU-25: about 35 €

- Average cost and length of a project in EU-25: 300.000 € over three years

It will be indicated if an option has been discarded or revised in the light of the impact assessment or comments received in the expert internet consultation.

It should be noted that potential environmental impacts of the revision (e.g. resulting from upgraded housing or waste after animal testing) turned out to be negligible. A serious aspect that was scrutinised was the assertion by some stakeholders that biodiversity will be endangered when continuing to use non-human primates for research. The Commission has found no indication that this is really a problem for those species used in large numbers for research. Research plays an insignificant role for biodiversity in comparison to the destruction of habitats, e.g. of tropical forests, that should be urgently addressed via conservation policies.

[49] Prognos report 2007, Chapter 7.

b) Impacts per option

I. Scope

This section assesses the extension of the scope of animals and procedures covered under the current Directive to create a uniform regulatory environment within the European Community for at least 2.7 million animals currently not covered by the Directive. This would consequently result in a more competitive level playing field in this respect.

Option 1: Extend the scope to cover animals used in basic research

This option would create a level playing field for all user establishments in the EU. The main beneficiaries would be universities in high standard countries which already had to comply with strict obligations while their scientific colleagues in other countries did not have to spend resources on high animal welfare. The option would put establishments like universities which are increasingly competing for EU research money into a level playing field and contribute both to the internal market and the European Research Area.

The extension of the scope to cover animals used in basic research would improve the welfare of 500,000 animals (15% of all animals used for basic research in the EU-25 in the year 2005) in the five Member States not currently covering basic research. Two thirds of the respondents to the internet consultation supported this general assessment.

The extension would have a moderate positive impact on animal welfare and a strong positive impact on the control of the use of these animals. For establishments in these five Member States, moderate costs between 6.6 million € and 10.0 million € per year would occur due to the requirement for authorisation and ethical evaluation. Costs for public authorities in these five Member States would increase slightly between 80.000 € and 160.000 € per year.

It should be noted that the impacts identified for this particular option are already covered in sections II to XII within the aggregate figures[50]. However, for transparency reasons and to enable a targeted impact analysis, these figures are specified in section I, again in disaggregated form. Care needs to be taken however not to double-count the benefits and costs indicated here.

[50] This section about scope is special in the sense that almost all impacts identified will only occur if the other options (introduction of Authorisation, Ethical evaluation, Inspections, etc) are taken up in the revision of the Directive 86/609/EEC. This means that one must carefully distinguish between impacts that are already identified in the subsequent sections (II to XII) and those which occur *in addition* due to an extension of the scope. Actually, only the impacts identified for scope options 2, 3 and 4 are additional impacts beyond those identified in sections II to XII. The reason for this is that the calculations in sections II to XII are based on the five models explained in Chapter 7 of the Prognos report and these in turn are based on the EU statistics on animal use in 2002 or 2005. The EU statistics already include the number of animals used for basic research and for education and training even though these animals are not yet protected under Directive 86/609/EEC. The situation is different for animals killed for their tissues, selected invertebrates and foetal forms because their number is not yet included in the EU statistics and therefore, impacts from an extension of the scope to cover them are not yet included in sections II to XII.

Option 2: Extend the scope to cover animals bred for the primary purpose of their tissue and organs to be used in experiments or other scientific purposes with an exemption for authorisation if euthanasia is performed by a competent person using a method appropriate to the species

This option would approximate the legislative provisions of the Member States because some currently cover these animals in their legislation whilst others do not which leads to differing cost structures for experiments using such tissues and organs.

The extension of the scope to cover animals bred for the primary purpose of their tissue and organs would significantly improve the welfare of about 1.8 million animals in the EU-25, due to better breeding, housing, care and euthanasia. While the preliminary finding of a "significant" improvement of animal welfare was contested by over 40% of the respondents to the expert internet consultation, the general idea of the option was broadly accepted. Only minor additional costs for establishments would occur if, as suggested by this option, euthanasia is performed by a competent person and therefore does not need authorisation.

It is contested why animals bred for their tissue and organs to be used for in vitro tests should receive better protection than those bred for their tissue to be used for food or fur. The main counter argument is that the scientific reliability of in vitro test results depends on high-quality tissues that can better be ensured by a strictly controlled environment.

Option 3: Extend the scope to cover selected invertebrates species (Cyclostomes, Cephalopods and Decapod crustaceans)

This option would have a small but positive impact on the harmonisation of Member States' rules and regulations and therefore benefit the internal market.

The extension of the scope to cover selected invertebrates species as recommended by EFSA[51] would improve the welfare of the animals involved. The preliminary assumption of a significant increase in animal welfare was not supported by one third of the respondents in the expert internet consultation, but a general improvement was not contested. The costs to public authorities and additional administrative burden for user establishments are estimated to be moderate, due to their low share in total project costs, but cannot be quantified.

The question whether the inclusion of selected invertebrates into the scope would boost the demand for tests with vertebrates is relevant. In theory, a relative price increase of using invertebrates in comparison to using vertebrates could lead to a higher demand for using vertebrates. Because a possible price increase for using invertebrates can not be quantified, the question whether the demand for vertebrates would be boosted cannot be answered. What seems important however is not to protect only a single species within a class of invertebrates because that could shift the demand to closely related species. This may be the reason why in the UK, not a single octopus vulgaris was used since this species was protected in 1995 but why other cephalopods continue to be used in neurological research.

[51] See http://ec.europa.eu/environment/chemicals/lab_animals/scientific_en.htm

Discarded option:

The suggestion to include all invertebrate species into the scope of the Directive was discarded at a very early stage because the potential animal welfare benefits due to lack of scientific supportive evidence would not have been proportionate to the costs.

Option 4: Extend the scope to cover foetal and embryonic forms from the last third of gestation until birth

This option would put research establishments like universities which are increasingly competing for EU research money for new technologies onto a level playing field and contribute both to the internal market and the European Research Area.

The extension of the scope to include foetal and embryonic forms from the last third of gestation as recommended by EFSA[52] would probably improve moderately the welfare of the 175.000 mammalian foetal forms involved in the EU-25, given that about one third of the experts in the internet consultation did not agree with the assumption of a high increase in animal welfare[53]. The cost increase for user establishments for mammalian foetal forms is estimated to be 12.6 million € per year. The costs for public authorities would be low with an estimated total increase by about 846.000 € per year.

It is expected that the costs from extending the scope of the Directive to non-mammalian foetal and embryonic forms in the last third of development will be negligible. While the vaccines industry is using large amounts of chicken embryos, these do not normally reach the threshold of the last third of development before the scientific procedure is carried out. It should also be noted that some Member States (e.g. the United Kingdom) protect foetal and embryonic forms from half-way through development. The more conservative approach foreseen in the proposal for the revised Directive 86/609/EEC should therefore not disturb the research and production of vaccines.

Option 5: Extend the scope to cover animals used in education and training

This option would put institutions of higher education like universities which are increasingly competing for EU research money onto a level playing field and contribute both to the internal market and the European Research Area.

It would also moderately improve the welfare of the about 200.000 animals annually used for education and training in the EU-25. Around 60% of the respondents to the expert consultation supported this analysis[54]. The costs increase is estimated to be minor. The external study concluded that for user establishments, the costs increase will be in the range of 1.4 million € per year, for public authorities it is likely to be around 35.000 Euro per year[55]. These low figures are based on the assumption that only 158 additional projects would come under the scope and that average costs per project in education and training are lower than for standard projects.

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52 See http://ec.europa.eu/environment/chemicals/lab_animals/scientific_en.htm

53 Prognos report 2007, p. 97 and 101.

54 Prognos report 2007, p. 103 and 106.

55 Prognos report 2007 p. 107.

It should be noted that the impacts identified for this particular option are already covered in sections II to XII within the aggregate figures[56]. However, for transparency reasons and to enable a targeted impact analysis, these figures are specified in section I, again in disaggregated form. Care needs to be taken however not to double-count the benefits and costs indicated here.

II. Authorisation

This section assesses the impacts from harmonisation of the authorisation procedures covered by the Directive. The aim is to introduce comparable minimum requirements for authorisation and thereby to establish a level playing-field in Europe.

Option 1: Authorisation of individual projects with compliance check

This option has a high potential to contribute to a level playing field in Europe because many of the time and cost factors affecting user establishments relate to differing authorisation systems across Member States and the internal market is further distorted because some Member States do not require authorisation at all.

Authorisation of individual projects would significantly increase welfare for about 950.000 animals in the four Member States which do not yet have any authorisation system for projects. This impact would occur due to the assurance that minimum legal requirements are met by the applicants. A reduction of unnecessary scientific procedures using animals can also take place. The welfare of the remaining 11.2 million animals can be slightly increased as well, due to an assurance that minimum legal requirements are met by the applicants. No increase in project delays is to be expected if the authorisation procedure is implemented in an efficient way and if the objectives are harmonised throughout the Member States. Around 60% of the experts consulted supported this preliminary assumption.

The implementation of project authorisation in the four countries combined with the introduction of a compliance check in all 25 Member States would lead to an increase in costs for user establishments of about 23 million €. The cost increase for public authorities would be 58.000 € per year for the four Member States, while the introduction of the compliance check in all 25 Member States would lead to a cost increase of up to 390.000 € per year. Yearly costs for public authorities of Member States are estimated to be increased by about 450.000 Euro. 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

[56] This section about scope is special in the sense that almost all impacts identified will only occur if the other options (introduction of Authorisation, Ethical evaluation, Inspections, etc) are taken up in the revision of the Directive 86/609/EEC. This means that one must carefully distinguish between impacts that are already identified in the subsequent sections (II to XII) and those which occur *in addition* due to an extension of the scope. Actually, only the impacts identified for scope options 2, 3 and 4 are additional impacts beyond those identified in sections II to XII. The reason for this is that the calculations in sections II to XII are based on the five models explained in chapter 7 of the Prognos report and these in turn are based on the EU statistics on animal use in 2002 or 2005. The EU statistics already include the number of animals used for basic research and for education and training even though these animals are not yet protected under Directive 86/609/EEC. The situation is different for animals killed for their tissues, selected invertebrates and foetal forms because their number is not yet included in the EU statistics and therefore, impacts from an extension of the scope to cover them are not yet included in sections II to XII.

project consisting of only "up to mild" procedures and not involving the use of non-human primates.

It should also be noted that in the current authorisation systems some duplication of activities may occur which creates avoidable costs that could be saved if the systems were restructured along the lines of best practice.

Any authorisation fees that may be passed on from public authorities to user establishments via a full cost recovery scheme may vary from Member State to Member State. But these will be negligible in comparison to the costs for user establishments induced by the requirement to prepare an application for authorisation.

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

As some Member States have already some sort of group authorisation or "thematic licensing" in place, this option could harmonise the requirements to the benefit of all user establishments across the Community and improve their competitiveness.

Authorisation of groups of projects for regulatory testing would reduce the average costs of this type of projects at the establishment level, due to economies of scale. Positive impacts would also occur for authorisation bodies of the Member States, due to more flexible and efficient handling of the administrative procedures. Around 60% of the experts supported this analysis, around 15% did not agree.

Total costs of project authorisation for user establishments and public authorities in the EU-25 would be reduced to 92 million € per year if groups of projects could be authorised so that the average number of authorisation procedures per establishment would be reduced to five per year. This compares favourably to the normal scenario where all projects would have to be authorised one by one. Given that the total cost for user establishments and public authorities in the EU-25 would under the normal scenario be about 114 million € per year, the savings would be around 21.9 million € per year.

III. Ethical Evaluation of projects

The revised Directive could set minimum requirements for ethical evaluation as part of the authorisation of projects. Retrospective assessment of the benefits and harm in all projects would have provided a further option.

Option 1: Compulsory ethical evaluation of projects with minimum requirements

This option addresses the question of whether all researchers and companies in Europe have a similar chance to get their animal projects approved or not, while the current situation leads to different access to using animals across the European Community.

The introduction of a compulsory ethical evaluation of projects would have positive impacts due to its high potential to improve both animal welfare (via the Three Rs) and the quality of science (via a prior evaluation of the research design). Such a requirement would also provide an incentive to science and industry to innovate according to the concept of the Three Rs. Almost two thirds of the respondents supported this general assessment. Although the introduction of a severity classification system would be time consuming for countries that do not have such a system in place, the benefits are likely to outweigh these costs. Severity

classification would improve and speed up the harm benefit analysis after the initial work of setting it up.

Model calculations by Prognos have shown a substantial positive effect for animal welfare due to the potential for a European Community-wide reduction of animal use by up to 8 % of animals used in the 12 Member States which do not yet have fully implemented ethical evaluation systems. This would concern about 371.000 animals per year)[57].

The benefits for science can be monetised. If one assumes that 3% of the animal studies performed are of such a low quality that they should rather not have been performed and that this would have been detected via the scrutiny of the experimental design within the improved ethical evaluation, the annual benefits in the 25 Member States would be in the range of 90 million €[58].

Introducing a harm-benefit analysis would increase the administrative burden for the Member States which do not yet have such a system in place. Yet, the overall assessment is positive due to the important impact that harm-benefit analyses can have on the reduction of suffering of animals, as well as their numbers. In consequence, animal research may become more cost-effective.

Based on an extrapolation using data from the Netherlands, Prognos has calculated that total yearly costs for setting up a complete system would amount to about 9 million € in the Member States which currently do not yet have a compulsory ethical evaluation of projects in place. It would lead to savings in the range of 70 million € per year in the medium-term, due to a reduction of animal use[59].

Option 2: Introduction of retrospective assessment of all projects to record deviations and evaluate factual harm and realized benefit

Whereas harm-benefit analysis would be done prior to the research, retrospective assessment would be done after the research has been finalised, to evaluate the results and compare it with the predicted harm and benefits. Retrospective assessment gives the opportunity to learn from the past in order to improve future research projects and may provide more accurate information. It also has the potential to verify in the long term which types of animal tests have really been useful for the progress of science and which have been rather unreliable. This can help to increase animal welfare slightly[60] in the short-term but also drive innovation to areas where animal tests could be relatively easily replaced in the medium-term.

On the cost side, the preliminary assessment indicated that introduction of retrospective assessment for all projects would lead to a high increase in costs in the short and medium term

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57 Prognos report 2007, p. 164.

58 No reliable quantitative data exist about the percentage of studies that are performed but are useless because of a bad experimental design. However, a recent publication found out via six case studies and meta-reviews of scientific literature that the experimental design of animal studies is often of surprisingly poor quality. See Nature, 21 December 2006, p. 981, and a related study by Prof. Ian Roberts (London School of Hygiene and Tropical Medicine) 2006: Testing treatment on animals: Relevance to humans (project number RM04/JH18/IR), available at www.pcpoh.bham.ac.uk/publichealth/nccrm/publications.htm. Hence, 3% is a conservative estimate.

59 Prognos report 2007, p. 164.

60 Prognos report 2007, p. 175/176.

while it is yet uncertain if the objectives of "learning from mistakes" and achieving more accurate data collection on severity and benefits are met. Potential benefits can be expected to become visible only after several years. A small majority of respondents supported this general assessment.

Introduction of retrospective assessment for all projects would lead to an increase in costs of about 20 million € per year in the short and medium term in the EU-25.

Revised option:

In the light of the arguments presented above and supported by many experts during the internet consultation, the Commission proposal for a revised Directive 86/609/EEC now only foresees a retrospective assessment for *selected* types of projects (e.g. those of highest predicted severity class and those involving non-human primates). Retrospective assessment can be expected to be most beneficial in these cases and costs can be expected to be reduced to about 4 million € per year.

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

An ethical review body goes beyond the evaluation of a particular project. It aims at creating a 'culture of care' in each establishment to ensure proper consideration of ethical aspects and the implementation of the Three R principle in all areas of animal breeding, housing and use. While the ongoing ethical review has to take place in the vicinity of the establishment in order to understand its internal decision-making, an additional national body could be useful to set guidelines.

Option 1: Introduction of a national animal welfare and ethics committee with a minimum harmonised remit

The introduction of a national animal welfare and ethics committee with a minimum harmonised remit could increase consistency of implementation of the Directive as well as transparency, due to an assurance that guidelines are set for all establishment-based ethical review strategies. This facilitates compliance across the Community and has at least slightly positive impacts on animal welfare (they could be substantial in case this option would be combined with mandatory ethical evaluation of all projects)[61].

There would be additional costs for Member States when setting up such a committee or aligning their system to the possible new European requirements but these costs were estimated to be low.

Option 2: Introduction of a compulsory ethical review body in each establishment

Minimum requirements for an ethical review body would have a moderate benefit on working towards a level playing field. A less diverse competitive environment between the EU Member States would be the result.

[61] Prognos report 2007, p. 183.

The introduction of a compulsory ethical review body at establishment level has a high potential of increasing the level of animal welfare and has the potential to be beneficial to the debate about ethical aspects within and maybe even between different establishments (if provisions are made for the exchange of information between local and national frameworks).

A compulsory system is valued positive since it provides the mechanism with the legal status that is often needed to be accepted and respected by other staff members of the establishment. In countries were establishment-based committees do not have such a formal status, this can be a serious drawback in terms of legitimisation towards stakeholders[62]. Only a compulsory system guarantees that minimum requirements are implemented.

Furthermore, there would be slightly positive impacts on the work satisfaction of personnel due to a more constructive and animal friendly atmosphere with an ongoing focus on the Three Rs and good science.

V. Housing and Care

The revision of the Directive could envisage elements of the revised Appendix A to the Council of Europe Convention for the protection of vertebrate animals used for experimental and other scientific purposes (ETS 123) to become a minimum standard, with a transitional period for implementation. This would create a competitive level playing field within the European Community and at the same time increase animal welfare.

Option 1: Compliance with ETS 123

Making elements of the revised guidelines of ETS 123 mandatory would significantly approximate Member States' rules and regulations which differ significantly and put breeder, user and supplier establishments in a very different environment of requirements for physical investments, depending on their location. It would prevent further fragmentation of the internal market in the near future which would otherwise be highly likely given that several Member States have announced that they will implement parts or all of the new housing and care standards agreed at the Council of Europe in different binding ways while some Member States would leave them completely non-binding.

A significant increase in the welfare of all 12.1 million animals used annually in the EU-25 through better housing and care standards could also be expected[63]. This will lead to more reliable scientific results and improve the mental well-being of personnel. More than half of the respondents of the expert consultation supported this analysis, only around 17% did not agree.

The benefits for science can be monetised. If one assumes that currently only 3% of the animal studies performed in all 25 Member States yield unreliable results due to inconsistent or unsuitable housing and care conditions and that this would not happen if the revised ETS 123 standards had been mandatory, the annual benefits in all Member States would be in the range of 90 million €.

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62 Stafleu, F.R and J. Vorstenbosch: Animal Welfare Committees in the European Research Area, EC 2005, p. 79.

63 Prognos report 2007, p. 200.

Many of the general provisions and recommendations of the revised guidelines for health, transport, quarantine, acclimatisation, isolation, watering, feeding, cleaning, records and identification are already in place in many establishments, as these are integral parts of good scientific/laboratory practice to obtain reliable and reproducible scientific results. Major changes required are mostly related to the new cage sizes, the mandatory use of environmental enrichment (e.g. floor covering, nesting material and for some species elevated platforms) and the mandatory group housing and socialising of animals.

Based on data from university facilities run under full-cost recovery schemes, the external study has estimated that yearly costs will increase by about 37 million €. This figure includes additional cage costs depreciated over 5 years as well as additional care costs and is equivalent to about 6% of project costs (about 1.3% of total animal research costs). Preliminary findings indicate that 35% of establishments in the private sector and 20% in the public sector have already adapted their facilities to the new standards.

Revised option:

In the light of the arguments and data presented above and supported by many experts in the internet consultation, the Commission proposal for revising Directive 86/609/EEC foresees staggered transitional periods, dependent on the type of species. Facilities for smaller species (mice, rats, other small rodents) will need to be given only a transitional period of five years from now, while bigger ones (especially dogs and non-human primates) will require about 10 years from now to spread the costs. A few large breeding establishments indicated that they would most probably require up to 10 years from now because they normally use close to 100% of their facilities (need to plan, obtain permits and build new premises to accommodate bigger space allowances per animal)[64]. However, some other large breeders as well as many of the smaller breeding establishments can be expected to be able to cope with the new requirements earlier.

VI. Transparency / Access to information

This section assesses the impact of extending the rights of the public to better access to information about the use of animals for scientific purposes. However, increased openness in this area must be balanced against concerns about intellectual property rights and safety of personnel and property.

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

Making non-confidential information publicly available would substantially improve accountability and the public image of the sector. Provided that personal safety issues and intellectual property rights are adequately considered, direct and indirect costs for user establishments and authorities should be low. While around 44% of the respondents of the expert consultation supported this analysis, about one third questioned the effectiveness and feasibility of this option. Some stakeholders pointed out that this option was tried in the UK and turned out too expensive. Therefore, the UK has introduced a system based on the publication of non-technical summaries of projects produced by the applicant for project authorisation.

64 Prognos report 2007, p. 205.

Revised option:

In the light of the arguments presented above and supported by several experts in the internet consultation, the Commission proposal for revising Directive 86/609/EEC foresees a system based on the publication of non-technical summaries of projects produced by the applicant for project authorisation.

Making such non-technical summaries publicly available would substantially improve accountability and the public image of the sector and would contribute to the need to increase understanding of the public as to why animal experimentation is carried out and how it is justified. Personal safety issues and intellectual property rights would be adequately addressed as the author of the summary would be the animal user.

Direct and indirect costs for user establishments and authorities would be low. The external study has calculated that the annual costs for the implementation of such a system in the EU-25 would amount to 520.000 €[65].

VII. Non-human primates (NHP)

Introducing minimum standards for the breeding, using and care of non-human primates would prevent future distortions of the internal market which may arise from different policies pursued at Member State level, including the potential that policies that benefit user establishments in one country (e.g. the requirement to move to F2+ animals) could divert resources away from breeding and keeping up the supply of F1 animals from breeders in third countries to user establishments in other Member States. A coordinated medium-term approach at EU level will therefore be beneficial.

The assessments in this section focuses on impacts in case the use of non-human primates would be restricted to second and higher generation captive-bred animals (F2+). This would require a significant change from the current practice in the EU-25 where for many species, first-generation captive-bred animals (F1) are often used and the breeding stock is constantly renewed by catching new animals from the wild.

This assessment takes place against a serious debate about whether it is ethically justified at all to use non-human primates in scientific procedures. Although their use is important and cannot be substituted in some areas, it is nevertheless controversial whether their high sensitivity and awareness makes them a good scientific model under current breeding, housing and care conditions.

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

Biological background

The species most concerned by a requirement to shift F2+ are macaques because they have so far not been bred extensively in captivity. For macaques, the shortest possible transitional period would be about 7 years from now but it is very unclear when breeding colonies could achieve self-sustainability in practice, even though a few breeding centres in the European

65 Prognos report 2007 p. 215.

Community and elsewhere have successfully started to breed very small numbers of F2+ macaques.

For some other species such as marmosets no transitional period would be needed since they have been breeding well in captivity in the European Community for several years or even decades.

Animal welfare impacts

On the one hand, high animal welfare impacts can be expected for an estimated 1300 macaques which are currently caught from the wild annually in Mauritius and other Asian countries which causes them suffering in terms of injuries and mortality during capture and transport, distress due to change of environment including breaking up of family ties[66].

On the other hand, the move to F2+ animals would increase the required breeding population by at least 10.000 animals, leading to a moderate negative animal welfare impact for these additional animals. It is not clear what would happen to the about 800 male surplus whose female counterparts are used for replenishing the breeding stock.

It is also not clear what would happen to the 1300 animals currently caught in the wild and used for breeding F1 animals for the European market. In some countries of origin, they are considered as imported pests which tend to destroy agricultural fields and endogenous wild-life (e.g. in Mauritius). It is therefore likely that they would either be killed or still be caught in the wild and used for breeding for the US and other markets outside the European Community.

Most experts agree that there is currently a higher world demand than world supply for macaques to be used in research. Therefore breeders would in the short run easily be able to sell the same amount of F1 animals to countries outside the European Community than they currently export to the European Community. Such a supply shift could only be prevented by a global move to use only F2+ animals. While the Commission would be happy to encourage more international activities in the area of experimental animal welfare in the context of the OIE (World Organisation for Animal Health), prospects for an international agreement about the use of F2+ are currently dim.

Impacts for users and science

If a shift to use only F2+ NHPs was required at very short notice, the impacts on science and competitiveness would be highly negative.

Even with a suitable transitional period, a requirement to shift to F2+ animals would lead to a price increase for about 7.000 macaques annually imported into the European Community because of longer breeding cycles and higher costs from maintaining a significantly larger breeding colony.

The move to F2 animals via a transitional period could also decrease annual supply of F1 animals by about 10% during this period, leading to a reduction/outsourcing of research from

[66] Prognos report 2007, p. 224.

the European Community to other countries. Both the United States and China have been mentioned in this respect.

Revised option

In the light of the arguments presented above and supported by experts in the internet consultation, the Commission proposal for revising Directive 86/609/EEC foresees a system differentiating between different types of species, in line with their reproductive behaviour and patterns of use:

- For marmosets, no transitional period is necessary.

- For macaques, a reasonable transitional period of 7 years from now for the transition to F2+ is set. The progress and suitability of this deadline should be closely monitored.

- For all other NHP species, a transitional period of 10 years from now is envisaged with a review clause to assess possible new information about the supply, demand and welfare implications for lesser used species. For rarely used NHP species, an F2+ requirement may turn out not to benefit animal welfare at all, as this might require setting up breeding colonies for these species where none exist today. Surplus may easily be produced and would need to be killed and/or incentives would be created to increase the use of these species, once the offspring is available which would have negative impact on animal welfare as a whole.

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

A ban on the use of Great Apes has in theory a highly positive effect on animal welfare, Great Apes being our closest ancestors with highly developed social capacities. In practice, the animal welfare benefit in the EU may be only minor because no such animals have been used in experiments in the EU since at least 1999. However, such a ban may inspire other countries to pursue a stricter Great Ape policy and could indirectly have a high animal welfare benefit in third countries.

The negative impact on research in Europe would be low as already at this stage, the number of Great Apes used is zero. The impact on the level playing field would be minor but positive, due to increased legal certainty.

The only realistic scenario for a need to perform scientific procedures with Great Apes may be the development of treatments for new devastating diseases that might occur in the future.

Discarded option:

Some stakeholders have suggested that a central breeding facility should be set up at European level to continue to breed Great Apes for research purposes, just in case they would ever be needed for such emergencies.

However, this option was not pursued further in view of three arguments:

- First of all, there is no current need for such research in Europe.

- Secondly, one limited but well equipped centralised facility at global level would be sufficient for this purpose, but several third countries including the United States already maintain such facilities, so there is currently no need to establish an additional one in Europe.

- Thirdly it should be noted that the costs would be significant and divert public funding away from more immediately useful biomedical research. The United States have a moratorium on breeding Chimpanzee's since 1997[67], for the same ethical reasons as mentioned above and to avoid further significant costs (daily housing and care costs for a single Chimpanzee was reported to be in the range of 30-40 US$ in the internet consultation).

VIII. Inspections

Inspections are one of the main tools for ensuring compliance with legislation and minimum standards. A harmonisation of the requirements for inspections could help to create a level playing field in the European Community.

Option 1: Minimum of two inspections per year by competent authorities of which one unannounced

The proposed system of inspections would have positive impacts for animal welfare, public perception and transparency. The costs for Member States would increase moderately when intensifying the level of inspections. Nearly half of the respondents in the expert consultation supported this analysis, whereas about 23% disagreed.

The new standard of inspections would lead to a moderate increase in animal welfare for the 12.1 million animals concerned. The cost increase for establishments is relatively low with 922.000 € per year, confined to the day of inspection. Costs for all 25 Member States could amount to a maximum of 3.1 million € per year. If all Member States had a fully centralised inspections system, annual costs would be about 3.1 million €. If all Member States had a fully decentralised inspections system, costs would be lower due to reduced travel distances, travel times and ticket costs and would be in the range of 2.5 million. € per year.

Revised option:

In the light of expert responses in the internet consultation, the Commission proposal to revise Directive 86/609/EEC includes a minimum of two inspections and a reference to a risk-based approach to inspections. A further proposal is to make sure that inspection reports actually get passed on from the inspectors to national authorities. In some countries with decentralised or local systems this information currently does not get passed on from the inspector.

Option 2: European Community inspections

European Community inspections could further contribute to ensuring a level playing filed for all breeder, supplier and user establishments in the European Community.

However, they would not result in a significant increase in animal welfare unless disproportionately high resources were spent to render these inspections effective and

[67] Source: http://www.sciencemag.org/cgi/content/full/315/5811/450

sufficiently frequent. A majority of around 65% of participants in the internet consultation supported this analysis, and only around 7% did not agree.

A stand-alone Community inspection system to inspect all user establishments twice per year by a centralised European inspectorate would lead to total costs of 4.2 million. € per year to be paid from the Community budget. This seems disproportionate.

Revised option:

One could instead model the European Community inspections after the audit-oriented inspections system currently maintained already by the Commission's Food and Veterinary Office (FVO) in Dublin in the area of food safety and farm animal welfare. In that case, costs would amount to 240.000 € per year in addition to the costs of national inspections. Total inspection costs for Member States and European Community together would then be between 3.33 million € (if all Member States had centralised inspection systems) and 2.73 million € (if all had Member States had decentralised inspection systems).

The audit-oriented inspections system of the FVO relies on inspections mainly by competent authorities in the Member States but performs an audit of each Member State's inspections and enforcement system on average every three years, including discussions with public officials in the Member States and a selected number of on-the-spot checks in user establishments.

The Commission proposal for the revision of Directive 86/609/EEC also foresees that Member States should set up programmes for joint inspections between national inspectors of one country and senior experts from another country. Member States could second their senior experts for a mission in another Member State.

IX. Education and Training

Qualified and well-trained personnel are essential for good animal welfare, good science and the human dimension of scientific procedures using animals. It is therefore essential to include in the revised Directive the key elements that should be included in the training requirements for obtaining initial and maintaining competence over the entire professional life, appropriate for the different categories of personnel.

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

Harmonised education and training would substantially decrease existing obstacles to horizontal mobility of researchers in the European Community.

Appropriate education and training would also improve the implementation of the Three Rs and ensure respect of their welfare requirements of animals before, during and after procedures. Almost 80% of the respondents to the expert internet consultation supported this analysis, only about 1% disagreed.

The welfare of 12.1 million animals concerned would increase significantly and would lead to a higher job satisfaction of those having direct contact with animals on a daily basis as confirmed during the internet consultation.

The benefits for science can be monetised. If one assumes that currently 3% of the animal studies performed in all 25 Member States yield unreliable results due to incompetent handling by not ideally trained personnel and that that this would not happen if all personnel had been properly trained and had been required to participate in a refresher course at least every five years, the annual benefits in all Member States would be in the range of 90 million €.

Total costs for a system of a mandatory refreshment course of 40 hours for personnel every five years in the EU-25 would amount to 38 million. € per year (on average 28.000 € per establishment per year.

X. Avoiding unnecessary duplication

No specific instruments apart from ethical evaluation and authorisation are employed to reduce unnecessary duplication of testing. However, in vertical legislation such as REACH[68], several tools are foreseen such as mandatory data sharing, requirements for the recognition of data generated elsewhere and mutual acceptance agreements. The general approach of a revised Directive could nevertheless have been to set up a centralised Community-wide database to avoid unnecessary duplication by collecting information on project authorisation and scientific results in every Member State. It should be noted, however, that not all duplication of procedures is unnecessary, one may even argue that replication of scientific procedures to verify if the results can be reproduced is an essential part of science, especially when developing and validating new test methods.

Option 1: Setting up a centralised European Community-wide database

A centralised Community-wide database may help to prevent some duplication of regulatory testing by providing neutral, timely and comprehensive information about all non-confidential aspects of authorised projects in Europe. However, the resource required to establish, administer and maintain such a database would be very high and casts doubts about the efficiency of this option. About 40% of the respondents to the expert consultation supported this analysis, 23% disagreed.

A minor improvement for animals used in basic research could be expected due to a lower risk of unnecessary duplication. However, a general database covering only a minor share of relevant information in an unsystematic way (regulatory testing has a share of about 22% of all animal use) would hardly contribute to a general improvement in animal welfare. But it would introduce unnecessary bureaucracy and decrease the scientific competitiveness of the European Community.

The external study has calculated that total yearly costs for maintaining and using a Community-wide database would amount to 6.5 million Euro and that one-off development and installation costs would be about 30.000 €[69]. However, these costs could be too optimistic in view of the fact that other international databases related to test results have incurred considerably higher development costs (e.g. IUCLID[70] database at around 2 million Euro).

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68 Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; Official Journal of the European Union (OJ L 396, 30.12.2006, p. 1).

69 Prognos report 2007, p. 277.

70 International Unified ChemicaL Information Database.

Discarded option:

In light of the arguments presented above, a general EU database would not substantially address the issue of unnecessary duplication of animal procedures, if any. In view of the significant costs of a database, this option has not been included in the Commission proposal for the revision of Directive 86/609/EEC.

Revised option:

However, the Commission is planning to prevent any potential problems of unnecessary duplication without recourse to a new central database in this horizontal Directive. More cost-effective measures could be:

- to promote integration of smaller databases into vertical legislation such as REACH
- to identify which vertical European Community legislation could be changed to create an incentive to decrease the overall level of regulatory testing with potential unnecessary duplication
- to reinforce activities at international level to adopt mutual recognition agreements

XI. Use of CO_2 for euthanasia

The revision of the Directive could incorporate a list of humane methods for euthanasia to be used for experimental animals. This would contribute to fair conditions in the internal market because higher costs of euthanasia in some countries disadvantage them in comparison to users in Member States with lower standards.

Option 1: Prohibition to use CO_2 unless the animal is rendered unconscious prior to its use

The prohibition to use CO_2 without rendering the animal unconscious by another method before would increase animal welfare. Such a requirement would entail higher costs. This preliminary finding was supported by around 30% of the respondents in the expert consultation. The external study has calculated that the total cost increase for all establishments in the European Community would amount to at least 46 million €[71]. In addition, there is a lack of studied alternatives to the use of CO_2 with regard to their aversiveness.

Discarded option:

Because the effect on animal welfare cannot be quantified, the lack of non-aversive alternatives and the costs that would be significant, this option was not further pursued in the Commission proposal to revise Directive 86/609/EEC.

[71] Prognos report 2007, p. 284.

Revised option:

An alternative option that can be implemented relatively cheaply while awaiting further research results on available alternatives would be to prohibit exposing animals to pre-filled chambers of CO_2 . This option will have no significant cost implications to the users.

XII. Statistical Reporting

The availability of sound data on the number of animals used for experimental and other scientific purposes is essential for policy-makers as well as for other interested actors. The analysis of the statistical data currently available shows that there are central fields of political and public interest which are not yet covered by the existing statistical reporting system.

Option 1: Inclusion of genetically altered animals, some invertebrate species and embryonic and foetal forms (excluding larvae) in the statistical reporting

Although there is no direct impact on animal welfare, a better statistical reporting system would highly contribute to better informed policy-making both at European Community and national level. It would also increase transparency and thus provide better information for the general public and in some cases provide an opportunity to improve the image of the research community. More than half of the respondents to the expert consultation supported this analysis, whereas around 23% did not agree with it, mainly fearing that new statistical categories might lead to misunderstandings by giving the impression that the number of used animals has significantly increased, although no change has occurred in reality.

The external study has calculated that an inclusion of genetically altered animals, selected invertebrates and embryonic and foetal forms would provide more detailed information on 2.4 million animals (2.3 million genetically altered animals and 175.000 foetal forms of mammalian species) in the EU-25 and would thus be highly beneficial to a better monitoring of their use at Member States and Community level. Consequently, a moderately positive impact on the enhancement of national and European policy-making can be expected. Prognos has calculated that total costs for user establishments from a requirement to report statistics on transgenic animals and foetal forms of mammalian species would amount to 7.4 million € per year[72].

Option 2: Inclusion of animals killed for the primary purpose of their organs and tissue to be used in experiments

Although there is no direct impact on animal welfare, a better statistical reporting system would moderately contribute to better informed policy-making both at Community and national level. It would also increase transparency and thus provide better information for the general public and in some cases provide an opportunity to improve the image of the research community. Around 53% of the respondents to the expert consultation supported this analysis, while around 17% disagreed.

[72] Prognos report 2007, p. 290.

The external study has estimated that total costs for user establishments from reporting on the 1.8 million animals killed annually for their organs and tissue would amount to 4 million € per year[73].

Option 3: Inclusion of numbers of projects and types of establishments in the statistical reporting

Inclusion of numbers of projects and types of establishments would provide a more comprehensive picture on the overall number and structure of animal experimentation in Europe, thus contributing to a better monitoring at Member State and Community level. The associated costs would be negligible.

Option 4: Inclusion of severity classes to which animals have been subjected to in the statistical reporting

Although there is no direct impact on animal welfare, an improved statistical reporting system would lead to better informed policy-making both at European Community and national level. It would also increase transparency and thus provide better information for the general public and in this case provide an opportunity to improve the image of the research community. Almost 60% of the respondents to the expert consultation supported this overall analysis, and only around 12% disagreed.

The external study has found that few user establishments and Member States have experience in this field and that a cost quantification is therefore not possible[74].

XIII. Promotion of alternative test methods

Option 1: National Reference laboratories

It is assumed that 20 additional Member States would have to set up national reference laboratories and each one would participate with in 2-3 validation studies per year. In addition, they may contribute significantly to the development of alternative test approaches.

Benefits

There will be several layers of benefits:

1. Time saving of almost two years seem possible for the validation of individual methods[75]. This could significantly speed up innovation in this field.

2. Reductions in animal numbers are possible:

- In the context of the new European chemicals policy REACH, it has been estimated that a substantial amount of animal use under REACH could be reduced by alternative approaches, in particular regarding tests for reprotoxic properties[76].

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73 Prognos report 2007, p. 292.

74 Prognos report 2007, p. 306.

75 Information by ZEBET (Zentralstelle zur Erfassung und Bewertung von Ersatz- und Ergänzungsmethoden zum Tierversuch in Germany).

76 Information by ECVAM (European Centre for the Validation of Alternative Methods).

- As an example, based on the past experience, the following alternative methods, validated by ECVAM have had a positive impact:

- Pyrogenicity: About 200.000 rabbits per year could be saved in Europe by the use of five blood cell methods for monitoring side effects such as fever reactions arising from contaminants of injectable drugs[77].

- Acute aquatic toxicity: The number of fish used in acute aquatic toxicity testing for hazard classification could probably be reduced by 65% if an "Upper threshold level concentration" (UTC) approach is used[78].

Costs

a) One–off costs

One-off infrastructure costs to upgrade an existing public laboratory to a national reference laboratory would be in the range of 100.000 €, based on data from ECVAM. If 20 Member States would have to upgrade existing public laboratories to be able to perform the function as national reference laboratory, the one-off cost would be about 2 million €.

ZEBET[79] suggested that at least five of the national reference laboratories should be equipped with material that allows them to apply standard techniques of molecular biology. Assuming that this may cost an additional 500.000 € in five cases, the total one-off cost would be about 4-5 million €.

These costs do not include training costs for personnel or building costs.

b) Ongoing costs

Annual costs for a full validation study (3 GLP laboratories over 3 years) per laboratory is estimated to be in the range of 40.000 to 100.000 € or about 0.5 to 1 full-time equivalent of researchers depending on the type of method under validation and whether additional animal tests are necessary in case of reduction/refinement alternatives. Total on-going annual costs for 25 Member States together would (under the assumption of 50% overhead costs) be around 1.5 -3 million €.

Part of the costs could potentially be recouped if the national reference laboratory would offer training seminars for hands-on training of industry and other experts at a significantly high price.

Industry and public authorities (in future research budgets) may be able to save some current costs in the medium term if certain alternative tests turn out to be cheaper than the current standard animal tests.

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77 See http://ecvam.jrc.it click 'news events and meetings' then 'press releases'.

78 See ESAC Statement of 20-21 March 2006.

79 Zentralstelle zur Erfassung und Bewertung von Ersatz- und Ergänzungsmethoden zum Tierversuch (ZEBET) in Germany; http://www.bfr.bund.de/cd/1433.

7. INTERNATIONAL SITUATION

a) Third countries

Even though the revised Directive will reinforce the international leadership role of the European Community in the area of animal welfare, it should be noted that a number of third countries have several of the options discussed in this impact assessment already in place.

Australia

As of 1st September 2005, the Animal Research Regulation 2005 came into effect, replacing the 1995 Regulation under the Animal Research Act of 1985. Australia has also recently (2004) upgraded its animal welfare code of practice including a strong emphasis on ethical evaluation. In addition, Queensland protects cephalopods and some crustaceans.

Canada

Canada is likely to review their guidelines on non-human primates in the coming years. There is currently no prohibition to use F1 or wild caught non-human primates and implications from moving towards F2 have not been studied. With regard to the revised Council of Europe guidelines on housing and care, the document will serve as one of the documents for the basis of discussion when revising space allowances for different species. The work has already started for rats.

China

Not much is known about the level of experimental animal welfare in China, therefore for the time being, the welfare level can be assumed as low. However, China is planning to expand its role in global animal research and is well aware that this will require a significant upgrading of its standards. The Chinese authorities seem very interested in cooperating with European authorities on how to improve its welfare standards and how to establish a reliable documentation and inspection system.

India

India protects all species (including all, not only selected, invertebrates) and requires approval of projects by a national committee. It legislation dates back to 1960 but has been supplemented in 1998.

New Zealand

The range of animals protected by legislation in New Zealand has been widened to include all animals that are capable of feeling pain. The definition of animals under the Act therefore includes mammals, birds, reptiles, amphibians, fish, crabs, crayfish, squid and octopus.

Norway

The legislation for animal experimentation in Norway applies to live mammals, birds, toads, frogs, salamanders (newts), reptiles, fish, and crustaceans thus including also some invertebrate species.

Switzerland

Switzerland has a very strict animal welfare legislation, which was last amended in 2001. There is a specific emphasis on education and training requirements as well as on both prospective and retrospective assessment of scientific projects using animals.

United States

The US system is largely built on self-assessment but foresees establishment-based "Institutional Care and Use Committees" (IUCACs). These are obligatory and should perform an ethical evaluation of projects and provide for a permanent ethical review body in case an establishment receives a research grant from the National Institute of Health (NIH), which is often the case. While normally mice, rats and birds are not protected by the US Animal Welfare Act, they have to be appropriately cared for in case grants are accepted from the National Institute of Health (NIH).

b) Council of Europe

The Council of Europe Conventions ETS 123 has inspired Directive 86/609/EEC at its inception in the early 1980s and its recently updated Housing and Care Standards will likely be similarly influential. Currently 13 Member States are Parties to the Convention ETS 123, with two new ones becoming a Party in summer 2007, as well as Switzerland and Norway.

The Council of Europe has also adopted a number of other Conventions dealing with animal welfare matters. These Conventions cover areas such as:

- transport of animals
- animals kept for farming purposes
- protection of animals for slaughter
- protection of pet animals

The Community is a party to the farming Convention. However, several pieces of Community legislation exist in the areas of transport of animals and slaughter.

c) World Organisation for Animal Health (OIE)

The World Organisation for Animal Health (OIE) has recently begun to discuss whether experimental animal welfare should be addressed at global level. While it may still take a long time until the first global guidelines on experimental animal welfare may be adopted and implemented, the Commission is planning to step up its activities in this area with OIE. A natural starting point for global harmonisation could be to try to agree to make some of the new housing and care guidelines developed by the Council of Europe a global standard.

d) Outsourcing/European Community competitiveness

The external study has established via its stakeholder questionnaire that scientific procedures using animals are sometimes outsourced from the European Community to third countries but that this is more likely due to wage differentials and specialist expertise sought for than due to the stringency of animal welfare legislation[80]. The section which included this finding was supported by about 50% of the experts who participated in the internet consultation while about 25% did not agree.

[80] Prognos report 2007, p. 18.

8. INTERACTION WITH OTHER EUROPEAN LEGISLATIVE ACTS

Directive 86/609/EEC is a horizontal directive providing for minimum standards when animals are needed in scientific procedures. The pieces of Community legislation referred to below are mainly sector related, whose focus is on gathering information, which sometimes needs to be fulfilled by performing tests on animals, to reduce risks for the safety and health of humans and the environment. It is therefore clear that elements such as housing and care standards, ethical evaluation, a permanent ethical review body and education and training are not addressed in this other legislation.

Also it should be born in mind that the regulatory use of animals as required by the legislation referred to below, covers only 22 % of the animal use in the European Community. The vast majority of animals are used in the areas of basic, translational and applied research (including early product development stages).

In line with the Lisbon Agenda to ensure the competitiveness of the EU industry, two specific measures have been foreseen to ensure fast handling of authorisation requests under the revised 86/609/EEC.

Firstly, the proposal foresees a possibility to request a group authorisation when the purpose of the project is to fulfil regulatory requirements. This will not only reduce the processing times but also the resource and manpower requirements arising from the authorisation. Secondly, the proposal includes a deadline for the authorities to deliver their decision within 30 days (in exceptional cases within 60 days). As explained in section 3.II in this document, the current uneven playing field varies from zero to 200 days but averaging to 70-100 days.

a) REACH (Regulation (EC) No 1907/2006)

The REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation is the only European legislative act requiring proposals for animals tests to be approved at European level (by the European Chemicals Agency) before new tests can be carried out. This raises the question of how the REACH approval requirement at European level and the new authorisation requirements proposed for the revised Directive 86/609/EEC for national or regional level can be coordinated in a way that they reinforce each other's objectives without overlap.

It is important to note that the objectives of these authorisations are very different. On the one hand the proposal for the revised Directive 86/609/EEC aims at ensuring full implementation of the Three Rs, the competence of the people involved and that the project is supported by harm-benefit analysis. On the other hand, for REACH, the main objectives are to ensure that the proposed test is necessary and scientifically the most appropriate for the purpose and that it fulfils the information requirements to support the risk assessment to protect workers, consumers and the environment.

There is still ample opportunity within the Agency to streamline administrative procedures to ensure efficient operation between the two pieces of legislation to their mutual benefit. The same applies to the revised Directive, as sufficient room for manoeuvre is left to the Member States for optimum implementation.

In terms of practical functioning of REACH and the proposed revised Directive, two areas have been identified requiring closer attention:

- most importantly, the time delay that could occur for the producer/importer to perform tests.

- the potential contradictory decision to approve a test method using animals by the Agency and the authorisation decision made under revised Directive.

There are two types of approval decisions under REACH:

1. The testing plans are proposed by the producer/importer to the Agency (in which case there is no time limit to carry out the tests). The Agency has 180 days (and in case of phase-in substances between 2 and 4 years) to approve the tests to be carried out. The Agency also has to subject the testing plan to a 45 day public consultation period.

   As the authorisation decision under this Directive is taken much earlier, within 30 (max 60) days, additional delays will not result from the implementation of this Directive. Moreover, the ethical evaluation under the proposed Directive may allow additional benefits to be gained by further facilitating the review by the Agency.

2. REACH foresees that the Agency may impose binding decisions on testing requirements for substances during evaluation. In the case of non compliance with information requirements or the identification of further information needs, the Agency can require a company to perform a specific test in a given time period.

   To ensure that authorisation under Directive 86/609/EEC would not contradict other regulatory decision making bodies, specific wording to accommodate this has been foreseen in the proposal.

   Finally, concerning time delay and the deadline imposed by the Agency for the tests in the second case, the specific provisions foreseen in the proposal requiring the authorisation decision to be communicated within 30 (maximum 60) days would ensure that no additional delays arise from the application. These deadlines can be further accommodated by the Agency when establishing internal administrative and operational procedures.

b) Other sectoral legislations

The revised Directive will apply equally to all other regulatory testing (e.g. for cosmetics, pharmaceuticals, food and feed, pesticides, toys, etc.). The costs and benefits of revising the Directive 86/609/EEC have already been assessed in this impact assessment. It can be assumed that significant animal welfare benefits will occur while the additional costs are acceptable.

No significant coordination problems between horizontal and sectoral legislation are likely to occur because both the revised Directive and the sectoral legislation consists of Directives and allow Member States to find suitable arrangements without overlaps in national legislation. None of the other sectoral legislation foresees a prior approval of animal tests at Community level, therefore no contradictory decisions at different levels can occur.

c) GLP (Directives 2004/9/EC and 2004/10/EC)

Good Laboratory Practice (GLP) is a quality assurance system based on very careful planning and documentation of scientific procedures and thus has very different objectives to those mentioned before. It increases confidence in the test results and should therefore be mandatory for all regulatory tests involving animals. It can also significantly reduce the inspection workload of competent authorities because of the careful documentation and because GLP inspections are already performed regularly and can be seen as complementary to any inspections system set up by the revised Directive.

9. COMPARING THE OPTIONS

a) Overview table showing the benefits and costs per option[81]

	BENEFITS (quantified where possible)			**COSTS** (monetarised where possible)		
I Scope – Option 1 – Basic research	Animal welfare	++	500.000 animals	Costs for public authorities	-	80,000 €
	Control	+++		Costs due to authorisation	- -	4 million €
				Delays due to authorisation	- -	
				Costs due to ethical evaluation	- -	2.6 million €
				Delays due to ethical evaluation	-	
I Scope – Option 2 – Tissues	Animal welfare	+++	1.8 million animals	Cost of experiments using tissue and organs	-	
	Use of alternatives	+		Cost to public authorities	-	320,000 €
	Public accountability and transparency	+++				
I Scope - Option 3 - invertebrates	Animal welfare	++	Animals used in 1000 scientific	Costs for public authorities	-	

[81] Mainly based on Prognos report 2007, p. 305-312.

			procedures			
	Control	++		Costs for user establishments	- - -	
I Scope - Option 4 - foetal forms	Animal welfare	(++)	175.000 mammalian animals alone	Costs for public authorities	-	12.6 million €
	Control	+++		Cost for user establishments	-	845.000 €
I Scope - Option 5 - Education & Training	Animal welfare	++	199.000 animals	Costs for public authorities	-	35.000 €
	Control	+++		Cost for user establishments	-	1.4 million €

	BENEFITS (quantified where possible)			**COSTS** (monetarised where possible)		
II Authorisation - Option 1 – individual	Animal welfare Animal welfare (additional)	++ +++	950.000 animals	Costs for MS without system of project authorisation	- -	57,000 €
	Control and transparency	++		Costs for MS with system of project authorisation	+	11,500 €
	Control and transparency (additional)	+		Cost for user establishments in MS without project autho	-	11 million €
	Competitiveness private sector	+++		Cost for user establishments in MS without project author	-	12.6 million €
	Competitiveness	++				

	public sector					
	Accountability and transparency	++				
II Authorisation - Option 2 – group	Costs for users	+++	reduction of 21.2 million €	Public image	-	
	Competitiveness and SMEs	++		Animal welfare	0	
	Competitiveness and research	++		Duplication of testing	0	
	Competitiveness of industry and innovation	+++				
	Administrative costs for users	++				
	Costs for public authorities	++	1.9 million € (reduction of 700,000 €)			

	BENEFITS (quantified where possible)			**COSTS** (monetarised where possible)		
III Ethical Review (A) - Option 1	Animal welfare	+++	11.7 million animals/ 371,000 animals	Administrative costs to enterprises	- -	9 million € (7 million €)
	Transparency	+++		Competitiveness	- -	
	Reducing animal suffering	+++		Costs for public authorities	- -	
	Awareness and work satisfaction researchers	++		Delay of projects	-	
	Reduction of animal numbers	++	371,000 animals			
	Quality of science	++	up to 70 million €			
	Level playing field	++				
	Innovations	++				
	Societal impacts (ethical approach):	+				
III Ethical Review (A) - Option 2	Transparency	++	12.1 million animals	Cost to establishments	- -	20 million € (revised option 4 million €)
	Quality of science	++		Costs to national	- -	

				authorities		
	Reduction of animals	+		Competitiveness	-	
	Reduction of animal suffering	+				
	Duplication of scientific procedures using animals	+				
IV Ethical Review (B) - Option 1	Transparency	++	12.1 million animals	Costs infrastructure in relation to overall research costs	-	
	Public accountability and objectivity	+		Costs infrastructure for Member States	-	
IV Ethical Review (B) - Option 2	Animal welfare	+++	12.1 million animals	Costs for establishments	- -	
	Increase level ethical discuss./ awareness	++				
	Work satisfaction	+				

	BENEFITS (quantified where possible)			**COSTS** (monetarised where possible)		
V Housing & Care - Option 1 – ETS 123	Animal welfare	+++	12.1 million animals	Upgrading costs for establishments regarding	-	

				smaller animals		
	Science	++		Upgrading costs for establishments regarding larger animals	- - -	
	Societal concerns	+		Length of transitional period	0	
	Level playing field	++		Yearly costs for user establishments		37 million €
	Public accountability and ethical concerns	+++				
VI Transparency - Option 1	Public accountability and transparency	++		Cost to establishments	---	26 million € (revised option: 520,000 €)
	Image of research and animal experimentation	+		Costs for Member States	-	
				Fear of extremist activity	-	
				Competitiveness	-	

VII Non-human primates - Option 1	Animal Welfare	+/-	+++ for 1,300 animals, -- for 12,000 animals	Costs for establishments	--	
	Public Concern	++		Scientific need	---	

	Biodiversity	+/0		Outsourcing/ Competitiveness	--	
VII Non-human primates Option 2	Animal Welfare	++		Research	-	
	Public Concern	++		Central Facility to cope with future demand	---	

	BENEFITS (quantified where possible)			**COSTS** (monetarised where possible)		
VIII Inspections - Option 1 - national	Animal welfare	++	12.1 million animals	Impact for establishments	-	0.9 million €
	Accountability and transparency	+++		Costs for Member States	--	3.1 million € / 2.5 million. €
VIII Inspections - Option 2 - EU inspections	(Animal welfare)	(++)	12.1 million animals	Costs for establishments	-	
	(Accountability and transparency)	(+++)		Efficiency	--	
				Costs to MS	-	
				Costs to EU	---	4.2 million € (revised option between 2.7 million € and 3.3 million €)

IX Education and Training	Animal welfare	+++	12.1 million	Additional costs to national	-	

- Option 1			animals	authorities		
	Quality of science	+++		Additional costs to establishments	--	38 million €
	Free movement of people/workers	+++				
	Job satisfaction of personnel	+++				

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

	BENEFITS (quantified where possible)			**COSTS** (monetarised where possible)		
XI CO2 - Option 1	Animal welfare	?		Impacts to establishments	- - -	46.2 million €

XII Statistical Reporting - Option 1	Monitoring and public accountability	+++		Administrative burden	-	7.4 million €
	Image of research and industry	+				
	Policy making	++				
XII Statistical Reporting - Option 2	Monitoring and public accountability	+++		Administrative burden to users	-	4 million €
	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	- -	
				Administrative burden to Member States (impact distribution)	- -	

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 million € Annual costs 1,5 – 3 million €
	Promotion of innovation	+++		Costs to industry	++	Some alternative tests may allow cost savings
	Public awareness	++		Efficiency gains for public research budgets	+	Some alternative tests may allow cost savings

b) Analysis of the options

ba) Options in the order of capacity to improve harmonisation of the internal market

- Authorisation Option 1 and 2 – Authorisation of individual projects including a compliance check and ethical evaluation with decisions to be taken within 30 days, but allowing group authorisations in the area of regulatory testing

- Housing and Care - Minimum housing and care standards along the lines of the ETS 123 Appendix

- Inspections Option 1 – Two inspections per year of which at least one unannounced

- Education and training Option 1 – Minimum standards

- Introduction of a compulsory ethical review body in each establishment

- Ethical Review Option 1 – National body to issue guidance

bb) Options in the order of capacity to enhance competitiveness

Education and Training – Option 1 - Investment in top scientists, higher mobility

Promotion of alternative methods – Option 1: Investment in research and innovation

Authorisation - Option 1: Project authorisation within 30 days

Authorisation - Option 2: Group authorisation saves money and time

Ethical Evaluation - Option 1: Potential to save animal lives and costs

Promotion of alternatives – Option 1: Potential to save current testing costs

Transparency - Option 1: Summaries explain research to public

Avoiding Duplication – Option 1: Database can save more than it costs

It should be noted that all measures improving the internal market (see above under letter ba) also contribute to competitiveness.

It should also be noted that a consistent approach at EU level will allow the European Community to take credible initiatives at international level (e.g. in the context of the World organisation for Animal Health – IOE) to move towards establishing global standards for animal welfare which would not only improve animal lives globally but also contribute to European competitiveness.

bc) Options in the order of annual animal welfare benefits

Ethical Review Option 2 – Permanent Body: 12.2 million animals +++

Education and Training – Option 1: 12.2 million animals +++

Housing and Care Option 1 – Standards: 12.2 million animals +++

Scope Option 2 – Tissues: 1.8 million animals +++

Inspections Option 1 – Minimum 2: 12.2 million animals ++

Ethical Evaluation Option 1 – Ethical evaluation 0.37 million animals +++, 11.7 million animals ++

Author. Option 1 – Project authorisation: 0.95 million animals +++, 11.2 million +

Ethical Evaluation – Retrospective: 12.2 million animals +

Scope Option 1 – Basic Research: 0.5 million animals ++

Ethical Review Option 1 – National body: 12.2 million animals +

NHP Option 1 – Move to F2+: 1300 highly sensitive animals +++, 12.000 –

NHP Option 2 – No use of Great Apes: +++ in theory, but none used since 1999

Scope Option 3 – Invertebrates: 1000 scientific procedures ++

Scope Option 4 – Immature forms: 0.17 million mammalian animals ++

Scope Option 5 – Education: 0.20 million animals ++

Avoiding Duplication – Option 1: 0.16 million animals (+)

Promotion of alternatives – Option 1: Not quantifiable, but can be significant

bd) Options ordered according to the annual monetary costs

Cost increases:

Housing and Care Option 1 – Standards: 37 million € annually

Education and Training – Option 1: 38 million €

CO_2 – Option 1 – Full ban: 46.2 million € one-off

Author. Option 1 – Project authorisation: 23 million €

Ethical Evaluation Option 1 – Ethical evaluation: 9 million €

Ethical Evaluation – Retrospective: 4 million €

Scope Option 4 – Immature forms: 13.5 million €

Statistics Option 1 – Invertebrates etc.: 7.4 million €

Scope Option 1 – Basic Research: 6.6 million €***

Avoiding Duplication – Option 1: 6.5 million €

Inspections Option 2 – EC Inspections: up to 5.1 million €

Inspections Option 1 – Minimum 2 national: up to 4.0 million €

Statistics Option 2 – Tissue animals: 4 million €

Promotion of alternatives – Option 1: up to 3 million € annually, plus 4-5 million € one-off

Scope Option 5 – Education: 1.4 million €***

Transparency Option 1 – Public summaries: 0.52 million €

Scope Option 2 – Tissues: 0.32 million €

Cost savings:

Authorisation Option 2 – Group authorisation: -21.9 million €

Ethical Evaluation – Option 1 : -70 million €

Promotion of alternatives – Option 1: Not quantifiable

Further cost savings are likely to realise through the lighter authorisation process for project consisting of only "up to mild" procedures and not involving the use of non-human primates. However, these have not been quantified.

*** It should be noted that the impacts identified for Scope Options 1 and 5 are already covered in those covered by the other options, especially for Authorisation and Ethical Evaluation. However, for transparency reasons, these figures are specified in this section again in disaggregated form. Care needs to be taken however not to double-count the benefits and costs indicated here.

c) Administrative costs

The Commission Impact Assessment Guidelines contain an Administrative Cost Model which recommends presenting the administrative costs for each option. It should be noted that this section does not specify additional costs beyond those identified in the previous chapters but simply presents them in a different format.

It should also be noted that the assessment provided in this section concerns only the changes (in plus or in minus) of the administrative costs as compared to the current status. It does not provide a baseline assessment of the current administrative costs that already occur due to the existing legislation currently in place in the Member States.

	Will it entail "administrative costs" for public authorities?	Will it entail "administrative costs" for breeders, suppliers and users?
Extending the scope of the directive to cover further species/immature forms/ animals killed for their tissues	Yes: Will entail additional Authorisation decisions and Ethical review (1.2 million €)[82]	Yes: will entail additional authorisation applications and proposal submission for ethical review (12.6 million €)[83] No: Housing and care standards (if any additional costs occur in this respect at

[82] It should be noted that the impacts identified for scope options 1 and 5 are already covered in those covered by the other options, especially for Authorisation and Ethical Evaluation, therefore only the additional costs for scope options 2, 3 and 4 were included here.

[83] Same remark as in the previous footnote.

		all)
Authorisation of projects	Yes: Authorisation decisions (0.06 million €)	Yes: Authorisation applications (23.6 million € cost increase for Option 1, but 21.2 million € cost savings for Option 2)
Ethical evaluation	Yes, but small effect is negligible	Yes: proposal submission for ethical evaluation and maintenance of infrastructure (committee members etc) to perform the ethical evaluation (9 million €, but reduces animal testing costs by 70 million €)
Housing and care	No	No
Retrospective ethical evaluation	Yes, about 2 million € (revised option).	Yes, about 2 million € (revised option).
Transparency/Access to information	Yes, but small effect is negligible	Yes (0.52 million €)
Special rules for non-human primates	Yes, but small effect is negligible	Yes, but small effect is negligible
Inspections	Yes (3.1 million €)	Yes (0.62 million €)
Education and Training	Yes, but small effect is negligible	Yes, but small effect is negligible
Database to avoid duplication	Yes (0.1 million €)	Yes (6.2 million €)
Using CO2 to kill animals	Yes, but small effect is negligible	No
Extending statistical reporting obligations	Yes, but small effect is negligible	Yes (7.4 million € for Option 1, 4 million € for Option 2)
Promotion of alternatives	Yes, but small effect is negligible	No
Marking of the animal	Yes, but small effect is negligible because these obligations are close to the existing Directive	Yes, but small effect is negligible because these obligations are close to the existing Directive

Record keeping	Probably not because record keeping simplifies the work of inspectors. However, the small effect is probably negligible because record keeping is already now obligatory	Yes, but small effect is negligible because record keeping is already now obligatory and only slightly increased for new documents

Revision of Directive 86/609/EEC One part of the proposed new Directive transposes the revised Council of Europe Guidelines on Housing an Care						Tariff (€ per hour)*		Time (hour)		Price (per action or equip)*	Freq (per year)	Nbr of entities	Total nbr of actions	Total cost	Regulatory origin (%)			
No.	Ass. Art.		Type of obligation	Description of required action(s)	Target group	i	e	i	e						Int	EU	Nat	Reg
1	Art. 3(1) (a)		Application for individual authorisation (mammalian foetal forms)	Processing additional project applications	Public authorities	38		5		190	165[84]	27	4455	0.9m €[85]		X		
2	Art. 3(1) (a)		Application for individual authorisation (mammalian foetal forms)	Filing forms and tables	certain user establishments	43		83		3550[86]	5,3	670[87]	3550	12.6m €		X		
3	Art. 31		Application for individual	Processing additional	Public authorities	38		6		228	63[88]	4	252	0.06m €		X		

84 Average per Member State if 3 500 projects are distributed equally.

85 Without costs for animals killed for their tissues.

86 Based on weighed average of the data presented by Prognos in report, page 102 (costs per project public/private).

87 Assuming that no institute is only killing animals for tissues and that only 50% of establishments using live animals also kill animals for their tissues.

88 Assuming that no institute is only killing animals for tissues and that only 50% of establishments using live animals also kill animals for their tissues.

			authorisation	applications for individual authorisation														
4	Art. 31		Application for individual authorisation	Filing forms and tables	some user establishments	43		190		8180	7	187	1309	9.7m €		X		
5	Art 31		More demanding application due to compliance check	Filing forms and tables	all user establishments	43		35		1493	7	1339	9305	14.0 million €				
6	Art. 36 (4)		Application for group authorisation	Reduced number of applications to be processed	Public authorities	38		6		228	minus 100 [89]	27	minus 2700	minus 0.7m €		X		
7	Art. 36(4)		Application for group authorisation	Filing forms and tables	certain user establishments	43		190		8180	minus 4	670[90]	minus 2680	minus 21.1m €		X		
8	Art 32		Ethical evaluation	Preparing document justifying animal	all user establishm	43		45		1918	7	670[91]	4590	9m €		X		

[89] Average number of avoided project applications per Member State in the 27 Member States, based on 5 project authorisations per establishment per year (instead of 7 without group authorisation) and 1339 establishments.

[90] Based on the assumption that regulatory testing projects are performed by 50% of all establishments.

[91] Based on extrapolations of number of establishments (Prognos report 2007, p. 55).

				testing	ents													
9	Art 35		Non-technical project summaries for publication	Writing and submitting them for Ethical Evaluation	all user establishments	43		1, 5		60	7	1339	9300	0.52m €		X		
10	Art 29		Two inspections per year	Inspection of breeder, user and supplier establishments	Public authorities	58 [92]		20		1158	2	1339	2678	3.1m €		X		
11	Art 29		Two inspections per year	Inspection of breeder, user and supplier establishments	all breeder, user and supplier establishments	43		8		344	2	1339	2678	0.92m €		X		
12	Art 33		Retrospective ethical evaluation	Filing forms and tables	User establishments	43		35 [93]		1505	2	670	1340	2m €		X		
13	Art 33		Retrospective ethical evaluation	Processing additional submissions	Public authorities	38		35 [94]		1505	2	670	1340	2m €		X		

[92] Includes travel costs.

[93] Estimation based on Prognos report 2007, p. 176.

[94] More conservative estimate than Prognos report 2007, p. 176.

14	Art 39(2)		Statistical Reporting	Collecting and submitting information	User establishments	43		37		1591	10	470[95]	4700	7.4m €		X		
15	Art 39(2)		Statistical Reporting	Collecting and submitting information	User establishments	43		14		602	10	670[96]	6700	4.0m €		X		

Total administrative costs:	45.08m Euro

* It should be noted that the external study is based on a complex cost model that takes into account the wage differential across the 25 Member States weighed according to the number of projects and establishments estimated to be related to each of these Member States to calculate the total costs. The cost per unit (1 hour of work) in this table has on the other hand been calculated via a simple linear equation to make this table consistent.

[95] Based on the assumption of 3500 projects with foetal forms and 1200 projects with GMO animals per year (assumptions in the Prognos report 2007 on page 289 and 290), on average 10 projects per user establishment obliged to report such statistics, average length of a foetal form project assumed only a few weeks but at high cost, standard model used for GMO animals and no overlap between GMO establishments and those using foetal and embryonic forms.

[96] Based on the assumption that 50% of current user establishments have on average 10 such projects involving killing animals for in-vitro tests, that the average length of such a project is 3 years (assumption made in the Prognos report 2007 on page 89) and that the number of independent suppliers is negligible.

10. CHOSEN OPTIONS

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

In terms of proportionality, only the option of banning CO2 seems to entail costs that are out of proportion in relation to its unquantifiable animal welfare benefits. The remaining policy options do not go further than what is necessary to achieve the objectives of the revision and are as simple as possible (principle of proportionality).

Therefore the options that are justified are:

- Extending the scope to cover animals used in basic research, animals bred for the primary purpose of their tissue and organs, selected invertebrates species, foetal and embryonic forms in the last third of their 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 with a minimum harmonised remit 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 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 of which one unannounced;

- Appropriate education and training standards;

- Specific conditions for the use of CO2;

- Improving the data for policy-making via improved statistics.

- National reference laboratories.

The total costs of these options is about 143.7 million € per year which may decrease over time as animal care staff gains more experience with the new housing and care standards. These costs are not evenly spread, but are higher in Member States with low current standards. The cost increases can be largely attributed to the three options which contribute most to the harmonisation of the internal market and also provide the highest animal welfare benefits. Therefore, the benefits in terms of Single Market and animal welfare outweigh these costs.

The combination of these specific options combines legal certainty with sufficient flexibility. The proposed options therefore represent a mix of best practices from around the world and enhance the European Community's international leadership role on animal welfare.

The cost increase from the chosen options needs to be put into perspective with the following considerations:

- The current total expenditure of all user establishments for animal experimentation in the EU-25 was calculated to be in the range of 2.9 billion € per year. This means that the cost increase of 143.7 million € per year that is likely to be triggered through the revised Directive is relatively small (about 5%) in comparison to the current level of expenditure in the sector.

- While universities and other public research institutes may need transitional periods to adapt to the new requirements, and this has been catered for, some industrial sectors may be able to cope with new standards much faster because animal care costs make up only a small share of their total investments, e.g. pharmaceutical companies for which the costs to develop a new product may amount to 1 billion € over 10 years.

- A significant share of these costs is due to the implementation of the revised guidelines for housing and care of experimental animals adopted by the Council of Europe. As the European Community is a Party to the Convention, it had to implement the revised Guidelines anyway (Commission Recommendation 2007/526/EC of 18 June 2007). Therefore, a significant share of the cost increase is caused by international obligations of the Community and cannot be attributed solely to the revision of the Directive.

- 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 benefits from reduced administrative costs and avoided unnecessary testing alone were estimated in the order of 90 million € per year by the external study. However, these have not been reflected in the total cost.

- 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 could 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 agriculture, transport, internal market and research policies. At the same time, they cannot be better carried out by Member States individually.

11. MONITORING AND EVALUATION

The Commission will monitor the transposition of the Directive, any implementation and enforcement problems, together with the Member States. The final indicators to monitor and evaluate progress towards the objectives of the revision of the Directive can only be established once the Directive is adopted. However, a preliminary list could include:

Related to Objective 1 - Strong convergence of standards that ensures a level playing field for industry and the researcher community:

Harmonising the minimum requirements in areas such as scope, authorisation and ethical review for carrying out scientific procedures using animals: **number of complaints about non-level playing field.**

Levelling the administrative cost and time factors of scientific procedures using animals: **variance of administrative costs and time factors across the Member States; price differences of experimental animals and regulatory tests between different Member States.**

Related to Objective 2 - Significant improvement in animal welfare and further promotion of the implementation of the Three Rs:

Improve animal welfare by ensuring a minimum scrutiny of animal experimentation by

- Implementation of ethical evaluation of projects and an ethical review body in establishments to ensure full compliance with the Three Rs: **retrospective assessment, non-technical summaries;**

- Minimum standards for housing and care: **percentage of establishments who have upgraded by year until the end of the transitional period;**

- Minimum standards for inspections: **numbers of inspections performed and number of infringements; numbers of joint inspections; numbers of EC inspections;**

- Ensure protection of animals for which there is scientific evidence of their sentience (invertebrates, foetal forms, basic research, bred for tissue) **number of new species/life-stages protected by the scope, new species/life-stages introduced by comitology;**

- Encouraging research into alternative approaches and improve conditions for innovation: **number of methods developed and undergone validation per year, and regulatory approval of validated methods.**

Further general indicators:

- numbers of animals used in scientific procedures

- number of EC infringement cases registered

- numbers and pattern of wild caught, F1, F2+ non-human primates used

12. TERMINOLOGY

Term	Definition for the purposes of this impact assessment
Alternative method	A method that reduces the number of animals required for the same purpose (Reduction Alternative), refines the method to reduce pain, suffering and distress and/or to enhance animal well-being (Refinement Alternative), and replaces the method with one not using live, sentient animals (Replacement Alternative).
Establishment	Any installation, building, group of buildings or other premises and may include a place which is not wholly enclosed or covered and mobile facilities; • "breeding establishment" means any establishment where animals are bred with a view to their use, or for the primary purpose of using their tissue or organs, in procedures; • "supplying establishment" means any establishment, other than a breeding establishment, from which animals are supplied with a view to their use in procedures; • "user establishment" means any establishment where animals are used for procedures
Ethical Evaluation	A process of evaluating the justification, design and consequences to science, society, environment and animal welfare of a particular piece of research, for example a project proposal that can be carried out prior to, during, or after the lifetime of a project.
Ethical Review Committee	A specific mechanism/strategy for carrying out an ethical evaluation or wider ethical review and whose members reflect a recognised skill base as well as representation.
Ethical Review Body	A broad concept with specific objectives to ensure that all production, keeping and use of animals for experimental and other scientific purposes is carefully considered, adequately justified, carried out and followed up so that the animals are treated as humanely as possible, incorporating the Three Rs principles throughout, as well as providing a forum for an on-going, wider discussion on the use of animals in scientific procedures.
Experiment	See scientific procedure
Genetically altered/modified animal	An animal in which the heritable DNA has been intentionally altered, or the progeny of such an animal(s), or of an animal with a mutation recognised as harmful. This includes animals

	produced by genetic modification or by induced mutagenesis, or animals created by nuclear transfer procedures, as well as harmful mutant lines arising from spontaneous mutations. This definition excludes animals with changes that are not heritable, such as gene therapy interventions or DNA immunisations.
Harmonisation	Applying the same legislative requirements in all European Community countries (or in some cases within a Member State).
Humane endpoint	A biological or chemical response, that can predict pain, distress, suffering or impending death that is not necessary, to achieve the scientific objective.
Humane killing	A method of killing that causes no avoidable pain, distress or other suffering to the animal(s) concerned.
In vitro	Literally meaning in glass, an experimental technique that may involve animal organs, tissues and cells taken from dead animals.
In vivo	Scientific procedures involving a living animal with its whole body systems intact in order to study what happens in the body itself.
Project	A coherent programme of work aimed at meeting a defined scientific objective or objectives and involving a combination of one or more procedures.
Regulatory testing	Testing required by national, European or international legislation.
Scientific Procedure	A combination of one or more technical acts carried out on an animal for an experimental or other scientific purpose, with known or unknown outcome, and which may cause that animal pain, suffering, distress or lasting harm.
Technique	A technical act on one or more animals for an experimental or other scientific purpose and which may cause that animal or those animals pain, suffering, distress or lasting harm. Examples of technical acts would be gavage, injection e.g. saline or other substance, laparotomy, withholding of food/water, giving an anaesthetic.
Three Rs	Replacement of scientific procedures by those not using live animals, Reduction of animal use, Refinement to lessen pain, suffering, distress and to enhance animal well-being.

13. FURTHER INFORMATION AND FEEDBACK

The website of DG Environment contains useful information about the revision, the existing legislation and future developments:

http://europa.eu.int/comm/environment/chemicals/lab_animals/revision_en.htm

In case further factual information on this Impact Assessment is available in quantified or monetised form and with the source of the information indicated, readers are requested to send this information to the following functional mailbox with the keyword “Impact Assessment” in the subject heading.

env-laboratory-animals@ec.europa.eu

ANNEX

Inappropriate housing and care of experimental animals can lead to a number of physiological and behavioural changes that can heavily interfere with the test results and undermine their reliability:[97]

- *Exposure to inappropriate temperatures:* Some species are very sensitive to changes in temperature, and effects can be seen on behaviour, food and water consumption, and growth rates (Svendsen, 1994). Significant deviations from the thermo-neutral zone can result in significant distress, morbidity and even death.

- *Exposure to inappropriate Relative Humidity:* Although many species will tolerate well variations in relative humidity, for some species extreme variations can adversely affect wellbeing, breeding performance, and, by affecting the rate of heat loss, can affect activity and food intake (Stille et al., 1968; Clough, 1982; 1984).

- *Inadequate ventilation:* Poor air quality (e.g. elevated carbon dioxide or ammonia levels) can lead to abnormal behaviour and increased susceptibility to respiratory disease (Lipman and Perkins, 2002).

- *Exposure to inappropriate noise:* Loud, unexpected and unfamiliar sounds, including ultrasound, can disrupt breeding programmes and may cause behavioural disturbances (Gamble, 1982; Sales et al., 1994).

- *Lack of appropriate nesting/bedding materials:* can increase neonatal mortality rates or cause abnormal/stereotypic behaviours (Hubrecht et al., 1992; Weidenmayer, 1997a; Reinhardt, 2004)

- *Inappropriate lighting:* Too bright or too dark light or unsuitable lighting patterns over a 24h period can disrupt breeding cycles, and can cause retinal changes (O'Steen et al., 1972).

- *Unsuitable diet can lead to* poor growth or obesity, nutrient deficiencies or excesses and effects on breeding performance (Coates, 1999).

- *Lack of social and environmental enrichment:* Failure to provide an appropriate environment and social contact has been demonstrated in many species to lead to behavioural problems, stress and physiological abnormalities, including increased susceptibility to disease. Animals in enriched environments may be better able to cope with novel and unexpected changes and thus show a more uniform response (Rose, 1994; Baumans, 1997). In some areas of research; this has been shown to radically affect the scientific outcomes (Rose, 2002 presented at the 4th World Congress on Alternatives).

For example, individual housing has frequently been shown to be stressful for mice. Detrimental effects of individual housing include both, behavioural and physiological abnormalities usually referred to as 'isolation stress' or 'isolation syndrome' (e.g. Baer, 1971; Brain, 1975; Haseman, 1994). There is evidence that subordinate male mice prefer company to being housed individually, even if that companion is dominant (Van Loo and Baumans,

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[97] See also EFSA 2005 Scientific Report, p. 46-53 - http://ec.europa.eu/environment/chemicals/lab_animals/scientific_en.htm.

1998). Gerbils develop extensive stereotypic digging if they are not given the chance to dig burrows, or if they are not provided with an artificial burrow (Wiedenmayer, 1997). There is evidence that hamsters housed in non-enriched cages are more stressed than hamsters housed in enriched cages (Kuhnen, 1997) and that enclosure size and stocking densities induce stress responses that may affect health and welfare (e.g. Sørensen DB et al., 2005).

- *Inadequate breeding management* may lead to breeding immature animals; genetic abnormalities, early weaning losses and poor temperament (GV-SOLAS, 1999).

- *Inadequate health management and monitoring* can lead to overt clinical disease and deaths (Poole and Evans 1982), reduction in growth rate and breeding performance (GV-SOLAS, 1999; FELASA, 2002).

A major source of variance in some animal studies is contamination or infection with microbial agents; elimination of these agents contributes to the standardization of scientific procedures using animals (Johnston and Nevalainen 2003). In experimental animals good health status not only means absence of clinical disease, but also absence of numerous specified etiologic agents of disease (example certain murine viruses which may enhance or compromise the immune response). For example, Gärtner (1990) showed that Mycoplasma pulmonis increased rat kidney weight considerably. Consequently, when kidney weight was the scientific outcome measure, 5 times as many rats were required to reveal a significant difference.

- *Genetic contamination* is a real risk even with proper colony management, and may go undetected unless genetic monitoring schemes are in place (Benavides, 1999).

- *Inappropriate handling of animals:* The influence of humans, for example during handling, may cause significant variance in results, and hence should be subjected to stringent control (Davies and Balfour, 1992; ILAR, 2002).

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[98] See also EFSA Scientific Report 2005, p. 123-128 - http://ec.europa.eu/environment/chemicals/lab_animals/scientific_en.htm

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