

**Technical Expert Working Group  
for the revision of Directive 86/609/EEC on the protection of animals  
used for experimental and other scientific purposes**

**Final report  
Sub-Group Scope**

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# **Review of EU Directive 86/609/EEC**

## **Technical Expert Working Group**

### **Final Report from the Scope Sub-Group**

**In this report, ‘Members’ refers to members of the Sub-Group Scope of the TEWG, unless otherwise indicated. It should be noted that members were appointed in their personal capacity and that the views expressed are their individual expert views and not necessarily those of the national authority or non-governmental organisation that nominated them.**

#### **Introduction**

The TEWG (Technical Expert Working Group) Sub-Group tasked with addressing the question of the scope of Directive 86/609/EEC, together with aspects of the 3Rs and the desirability or otherwise of a Central Database, began its discussions on 1 July 2003 and posted its first draft report on the Circa website on 5 August 2003. A second draft report was posted on 31 October 2003 and summarised the opinions, and where consensus was reached, during subsequent discussions carried out via the Circa website and by e-mail, involving members of the Scope Sub-Group and also other members of TEWG. This third and final report takes account of further discussions during a meeting of the Sub-Group on 6 November 2003 and during a meeting of TEWG on 7 November. It is necessarily only a summary of discussions and further reference should be made to the more detailed arguments posted on Circa. Where there are detailed papers posted on Circa relating to specific topics, these are referred to in the text.

The discussions took place in the context of advice received from the European Commission that, in relation to the Directive, there was no specific competency for animal welfare at EU level. This competency was a matter for member states. The current Directive was based on a need for good functioning of the internal market and harmonisation of related practices across the EU. On this basis, the scope of the Directive could not extend to the use of animals in basic research or in education and training, although national legislation generally applied to these areas as well as to the areas covered by the Directive. It was understood, however, that legal opinion to the contrary was being submitted to the Commission for further consideration.

The work of the Sub-Group Scope was carried out based on the competency advised by the Commission. However, members unanimously agreed that the scope of the Directive should be extended to include animals used in basic/fundamental research and in education and training, if it were to be shown that there was no legal bar to this.

A member stressed that, since the TEWG had been tasked with advising specifically on technical aspects relating to animal use in procedures, ethical and political dimensions had not been considered (except in the case of Great Apes: see below). Discussions had proceeded on the basis that certain usages of animals would or might take place, not that they should. The member considered the Commission would need to consider these ethical and political dimensions in formulating its proposals.

## Scope and definitions

### What type of experiments should be included and how should 'experiment' be defined?

#### Background

The current Directive, in Article 2(d) refers to and defines 'experiment'. Within this definition, there is specific exclusion from the scope of the Directive of "the least painful methods accepted in modern practice (i.e. 'humane' methods) of killing or marking an animal" and of "Non experimental, agricultural or clinical veterinary practices". Primarily because of this reference to 'experimental', a 1993 opinion by the EC Legal Service excluded from the Directive's scope animals used in routine production methods (e.g. production of vaccine) due to the lack of experimental nature of the procedure.

#### Opinion

Members agreed that the use of the term 'experiment' had created an element of confusion, resulting in the above interpretation and a degree of illogicality. It was felt that it would be more appropriate for the Directive to refer to and define a 'procedure' rather than an 'experiment', such definition being "A combination of one or more technical acts carried out on an animal for an experimental or other scientific purpose and which may cause that animal pain, suffering, distress or lasting harm". This should be the basis for including or not including animals within the scope of the Directive and, therefore, routine production methods such as in the production of vaccines would be included, provided they met these criteria.

It was agreed by the Rapporteurs of the four Sub-Groups that definitions of 'technique' and 'project' should also be included if they were relevant to the final text of the revised Directive. These were as follows:

- Technique: A technical act on one or more animals carried out 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, laparotomy and withholding of food/water.
- Project: A coherent programme of work aimed at meeting a defined scientific objective or objectives and involving a combination of one or more procedures.

It was agreed that non-invasive routine procedures, such as marking and any management or clinical veterinary duties carried out for the day-to-day well-being of the animals, should be excluded. Furthermore, clinical trials on target species such as farm animals should also be excluded as they are closely linked to good clinical practice and to include them would result in unnecessary bureaucracy without corresponding welfare benefits.

The question of identification methods such as microchipping was discussed during subsequent discussions of the TEWG, as they were regarded as more invasive. One view expressed was that such methods should not be included if part of the normal husbandry procedures, but should be an integral part of the procedure, and that the decision on this should be left to member states. A differing view was that they should be included if the distress was more than minimal and transient as they were part of the animals' whole life experience.

It was agreed that, in principle, a justification should be provided for the use of all protected animals, where such use met the definition of a procedure, even if it were not practicable to conform to all aspects of the Directive. This would be relevant to, for example, population studies and stock control of certain species.

A member of another Sub-Group drew attention to the distinction between vertebrate and invertebrate species and to the classification of certain species such as lampreys and hagfish. The member considered the revised Directive should be explicit with regard to which species were or were not covered by the classification 'vertebrate'.

#### Should animals killed for their tissues be included?

##### Background

As detailed above, Article 2(d) currently excludes humane methods of killing from the Directive's scope. In some EU countries, the decision has been taken to include animals killed solely for tissues within national legislation, in others they are excluded.

##### Opinion

Differing views were presented on this issue. Detailed arguments were presented, and should be referred to, on the Circa website. In summary:

The view presented by some members, including from other Sub-Groups, was that animals maintained and then killed specifically for collection of tissues (including organs and other body parts) should be included as their breeding and 'whole life experience' was for a scientific purpose and so as to ensure, for example, that the 3Rs principle applied and they received the same standards of care as animals used in scientific procedures, including in relation to the training and experience of staff involved. Inclusion of these animal numbers in the statistics would also provide an indication of the uptake of alternative (replacement/*in vitro/ex vivo*) techniques and inform the general public of the overall numbers of animals killed in order to carry out our scientific procedures. This view was supported by some members of other Sub-Groups.

The counter-argument presented by other members, including from other Sub-Groups, was that the Directive should only apply to the use of live animals for a scientific purpose and that the destination of the tissues after death has no impact on the welfare of the animal to be killed. Housing and training issues would already be adequately addressed more generally within the Directive. It was also considered that inclusion of animals killed for tissues would create potential and significant problems in

identifying and then issuing authorities (and licences) for facilities where such killing may take place. This would greatly increase the regulatory burden with no clear practical welfare benefit. It could also negatively impact the development of alternative methods using animal tissues.

It was agreed, however, that the primary concern with such animals should be their welfare. It was suggested that this could in practice be protected by ensuring that the authorisation of premises automatically meant that all animals of protected species contained therein were covered by the scope of the Directive with regard to housing and husbandry conditions, education and training of staff involved etc. Further consideration would need to be given to the need to authorise facilities, not otherwise covered by the Directive, where *ex vivo/in vitro* work was carried out, where this involved the killing of animals on site specifically for this purpose. The number of such facilities, and therefore the potential additional administrative load for national authorities, was unknown.

With regard to a specific concern raised regarding the collection of foetal calf serum, it was possible that, within the EU, no animals were produced specifically for this purpose and that such collection was as a by-product of animals killed for food in slaughterhouses. However, members considered further investigation into this was needed.

### What about so-called surplus animals?

#### Background

Under Article 17, breeding and supplying establishments are already required to record the number and the species of animals sold or supplied, together with deaths and other details. However, there are no specific provisions regarding animals that are bred but then not used in scientific procedures, for example notifying to national authorities and recording in the statistics. A review of 'surplus' animals carried out in the UK (Laboratory Animal Science Association: Surveys of the production and disposition of animals surplus to the requirements of scientific procedures – In press) had revealed that significant surplus only occurred with rodents and that these animals were generally supplied by breeders as food for use in zoos, wildlife parks etc. There was little or no surplus of species such as dogs, cats and non-human primates.

#### Opinion

The view put forward by several members was that the current Directive appropriately applied to the use of live animals in procedures. The key point, addressed under Article 5, was that designated facilities should be maintained, staffed and operated to provide appropriate care and welfare standards for all animals maintained therein. Commercial considerations meant that no breeder would knowingly breed more animals than required. A means of control without adding further bureaucracy would be to ask ethical review processes/committees to maintain oversight of breeding programmes so that production of any animals additional to those required to meet scientific needs was monitored. Other members also referred to the practical difficulties involved.

The counter-view was based on arguments similar to those for inclusion of animals killed for tissues (see above). This would include the need for the animals to be covered by the scope of the Directive for the various protection measures to apply (apart from Articles 5 and 14 which already apply via Article 15(1))

However, members were in agreement that the same provision as for animals killed for tissues (above) should apply, i.e. the protection provided under the authorisation of premises.

### Should some or all species of invertebrates be included?

#### Background

The Directive currently applies only to “any non-human vertebrate”. Certain species of invertebrates are, however, included in the national legislation of some countries, both within and outside the EU (e.g. UK, some Scandinavian countries, Australia Capital Territories, New Zealand), on the basis of their ability to experience pain, suffering, distress or lasting harm. The UK currently only includes *Octopus vulgaris* in its national legislation but is considering the inclusion of additional cephalopod species. A further analysis of the available data was understood to be taking place in France, but it was not known when this would be completed.

#### Opinion

Members were generally in agreement that the critical point to be considered in extending the scope of the Directive beyond vertebrates was the capacity or otherwise of non-vertebrate species to experience pain, suffering, distress or lasting harm, i.e. their sentience. The class of invertebrates on which a body of research data is available in this respect is the cephalopods (see document posted by Hubrecht on 22 July 2003 on Circa).

As this is an area in which further scientific data may become available in time, Members generally considered it would be appropriate to make provision to include some invertebrate species at some future date. Therefore, in order to allow such inclusion without a revision of the Directive itself, it was proposed that the scope of the text should cover all vertebrates together with any invertebrate species listed in a separate new Annex to the Directive. Inclusion of any invertebrate species in this Annex should only occur on the basis of sound scientific evidence as to their sentience and ability to feel pain, as assessed by a Scientific Committee of experts appointed by the EC (but applying the precautionary principle).

Insufficient evidence is available at the present time to consider the inclusion of any invertebrate species other than of cephalopods. One member of the Sub-Group considered that there was already sufficient evidence available regarding the ability to feel pain and cognitive functions of *Octopus vulgaris* to give at least this species the ‘benefit of the doubt’ and to include it in such an Annex. This view was supported by other members. The view of a further member was that it would be appropriate, for reasons of consistency, for such evidence to be considered by the proposed Scientific Committee of experts, rather than advocate the inclusion of any cephalopods at the present time.

The view of a further member was that, because of the implications for resourcing, the focus should be on vertebrates before extending the scope of the Directive to include invertebrates.

### Should foetal and embryonic forms be included?

#### Background

The definition of 'animal' in the current Directive excludes foetal or embryonic forms. Some member states have decided to include in national legislation such forms beyond a certain stage of pregnancy, e.g. in the UK, 50% gestation for all species, however this seems to be an arbitrary figure as the appropriate timing will vary from species to species. Sheep and guinea-pigs are well-developed at birth, whereas rats are relatively immature and may not be capable of such sensory perceptions until several days after birth. A criterion for determining the appropriate stage of pregnancy may be the development of the cerebral cortex and when it reaches a stage at which it can register sensory experiences. However, even in the case of humans, where more data are available, opinion is divided: the UK's Royal College of Obstetrics and Gynaecology does not consider there is foetal awareness before 26 weeks of pregnancy and UK law allows abortion up to the 24<sup>th</sup> week, whereas Professor Glover of Queen Charlotte's and Chelsea Hospital believes that fetuses over 17 weeks may feel pain.

#### Opinion

Members agreed that there should be provision to include foetal and embryonic forms in the scope of the Directive, based on their capacity to feel pain. However, there was uncertainty around the stage at which this occurs and, therefore, when the provisions of the Directive should apply.

The view of several members was that the UK's 50% through gestation should be used, at least for all large mammalian species other than rodents. This was based on data relating to sheep and non-human primates but provided for a 'safety margin' with regard to when fetuses/embryos of these species may feel pain. However, the members were not in a position to form a scientific opinion as to when a rodent foetus or new-born may be capable of suffering, although suggested the final 20% of pregnancy may be appropriate for rodent and poultry species.

As the 50% was an arbitrary figure if applied to all species protected under the Directive, the counter-proposal from other members was to stipulate birth as the 'default', but to have a technical annex to the Directive listing those species where sufficient evidence was available to state a specific period of gestation, as assessed by a Scientific Committee. This would take account of the likelihood of wide species variation as to when the capability to suffer has developed and would allow revision of the Annex as and when new scientific information was available.

Other possibilities would be to have the opening of the eyes as the default, as proposed by a member of another Sub-Group, or to make the stage for inclusion a

required area for ethical review processes to consider. The latter may not be a practicable option and could lead to variation between states and establishments.

### Should larval forms be included?

#### Background

The definition of ‘animal’ in the current Directive includes “free-living larval and/or reproducing larval forms”. There are, however, significant difficulties with including these forms in such a way that all provisions of the Directive apply, in particular the impracticality of making an accurate count. For example, many fish larvae are free-living vertebrates capable of ingesting food in the form of algae and plankton. Halibut larvae are 3-4 mm long at hatching and immediately are active, swim and search for food, and would therefore be covered by a revised Directive. However, there could be up to 1,000,000 in a tank. It would be impossible to count them and, in addition, the numbers at the start could then drop dramatically due to natural attrition and not due to the procedure.

#### Opinion

Data on whether and when larval forms are capable of feeling pain are likely to be even scarcer than is the case for foetal and embryonic forms. The initial opinion of the Sub-Group was that the ability to be free-living and capable of independent feeding may provide the best indicator available. In order to take account of the practical difficulties of counting, some members proposed a compromise that the numbers of larval (and embryonic and foetal) forms be excluded from the statistics. This would provide protection for the animals in relation to care, housing and use, thus ensuring that welfare was properly considered, while avoiding the practical issues of, for example, counting very large numbers of small larval fish.

### How should purpose-bred be defined?

#### Background

The current Directive defines ‘bred animals’ as those “specially bred for use in experiments in facilities approved by, or registered with, the authority”. A supplementary question has been raised regarding whether ‘purpose-bred’ should be taken as referring to F1 animals and subsequent generations, or only to F2. This question is of particular relevance to the use of non-human primates, which may currently be bred and supplied from parents caught from the wild.

#### Opinion

In the first report of this Sub-Group, members considered the definition of 'bred animals' in Article 2 of the Directive appeared satisfactory, but that it should be amended to cover the '... potential use in procedures ...', for consistency with other parts of a revised text. The new use of 'procedures' in the definition of a purpose-bred (as opposed to 'bred') was consistent with the substitution of 'procedures' for 'experiments', however the inclusion of 'potential' may be inconsistent with one opinion in 'What about so-called surplus animals?' above.

There was a separate issue regarding the supply of F1 or F2 non-human primates. This created a considerable amount of discussion, although primarily involving members of other Sub-Groups. No consensus was reached. Detailed arguments may be found on the Circa website.

The view expressed by several members was that only F2 animals should be supplied and used, in line with the recommendation of the report of the EC's Scientific Committee on Animal Health and Animal Welfare (SCAHAW). This was based on both conservation and animal welfare considerations as, respectively, all primates are listed on CITES Appendices I or II and trapping causes primates a great deal of suffering. Reference was also made to the slow progress in overseas breeding centres producing increasing numbers of F2 offspring so as to reduce dependence on feral animals (a requirement of the UK Home Office).

The counter-view from several other members was that any limitation of supply to F2 animals at the present time would jeopardise ongoing and new research programmes into major disease conditions and would certainly require a regulatory impact assessment. One of these other members also questioned the claimed welfare implications of trapping animals and pointed out that the slow progress in moving to supply of F2 offspring was because breeding itself was very slow. This meant that any restriction to supply of F2 could not be a realistic objective for at least a further 10 years.

There was, however, agreement that promoting the development of self-sustaining primate breeding centres within the EU would allow better oversight of standards and reduce welfare concerns, provided that there was effective balancing of supply with demand.

Members agreed that, although it was desirable to move as quickly as possible to supply of F2, there were significant practical issues with supply at the present time. It was proposed that this might be appropriately addressed by means of an EC resolution. It was further agreed that there should be a presumption that F2 animals would be used, but that it would be for the national authority to determine whether the use of F1 was justified if F2 were not available. Such a decision should take into account the availability of a strategy by the breeding centre to move towards only F2 supply of primates.

One member's view was that an impact assessment would be essential before any decision was made regarding the supply of F1/F2 primates.

A further area of discussion involved the authorisation of third country (i.e. non-EU) breeding centres. This aspect is more appropriately addressed within the Sub-Group Authorisations report.

#### Should a definition of a “pet” and “stray” animal be included?

##### Background

There is no definition of “pet” or “stray” animal in the current Directive. However, although there is no mention of “pet” animal in the text, “Stray animals of domestic species” are referred to in Article 19(4).

##### Opinion

Definition of “stray animals” should only be applicable to species among those included in Annex 1, which should therefore be obtained only as purpose-bred animals. Animals of these species obtained other than in line with the requirements of Annex 1 should only be used where there is a scientific justification, only to be permitted as a specific exemption on a case-by-case basis. Specifically, however, use of animals of these species from other sources should not be permitted on grounds of expediency or cost. A definition of ‘stray’ should make reference to the lack of presumed or claimed human ownership of the animal.

As there was no mention of “pet” in the current Directive and no proposal to include this wording, a definition was not considered necessary.

#### Should general exemptions be allowed and on what grounds could specific exemptions be granted?

##### Background

The current Directive refers to both general and specific exemptions but without defining either. It is presumed that a general exemption may apply, for example, to allowing the use of non-purpose-bred animals of a species listed in Annex 1 for an unlimited period of time in any types of procedure, whereas a specific exemption would apply, for example, to the use of such animals for a specified purpose on one occasion or a limited number of occasions.

##### Opinion

Members agreed that use of a general exemption was unsatisfactory and could lead to unnecessary or inappropriate use of animals because of the lack of need to examine the justification for such an exemption on a sufficiently regular basis. It was further agreed, however, that there should continue to be provision for specific exemptions on a case-by-case basis where a scientific justification was provided to, and agreed by, the national authority.

As certain of these exemptions could apply to animals imported from sources in countries outside the EU, and therefore not subject to the protection provided by the Directive, the possibility and practicalities of some type of monitoring procedure of

such sources should be examined, either as part of the provisions of the Directive or as requirements within national legislation.

### What species should be included in Annex 1 to the Directive?

#### Background

Species listed in Annex 1 are those used in experiments that must be ‘bred’ animals (unless a specific exemption has been obtained – see above). The list of species in the current Annex 1 does not appear a logical one and no information is available on why the various species were originally included or others added. The rationale is therefore unclear.

#### Opinion

Members agreed that criteria should be established on which to base inclusion of a species in Annex 1. Such criteria might include: numbers required for procedures; practical and commercial aspects of establishing breeding; disease-free requirements; other welfare aspects (for example, in the case of dogs, moving an animal from a street to a laboratory environment); and social/public concerns (for example, concern that pet cats and dogs might be used). On this basis, most species currently included would remain so.

As an example, the minipig has become a widely-used laboratory species, obtained from commercial suppliers where they are bred in a controlled environment similar to that to be experienced at user facilities. Their inclusion would therefore seem logical and in the interests of sound principles of scientific research and welfare.

Other species to be considered for inclusion could be ferrets and some hamster species in addition to *Mesocricetus auratus*. Conversely, the current inclusion of Quail (*Coturnix coturnix*) should be re-considered. One member suggested, however, that poultry and a number of other avian species should be included.

An alternative suggestion is that Annex 1 could be made redundant by a general principle that experimental animals should be purpose-bred unless there was a scientific necessity in a particular case. This would, however, lead to a large number of specific exemptions, e.g. in the case of farm animals.

It was recommended that species to be included in Annex 1 should be determined by an appropriate Scientific Committee once criteria for inclusion have been agreed.

### How should species in CITES (Appendix 1) be treated?

#### Background

Under the existing Directive, it is the responsibility of each Member State to ensure that animals considered as endangered under Appendix I of CITES (Convention on International Trade in Endangered Species of Fauna and Flora) and Annex C.1. of Regulation (EEC) No 3626/82 are prohibited, with certain exceptions.

## Opinion

Members agreed the current Article was generally satisfactory and that the stated exceptions should remain, so as not to preclude use where there may be an overriding and exceptional scientific justification. However, the Regulation had been superseded by Council Regulation (EC) No 338/97 and minor changes were required for clarity to the wording of the exceptions, for example as follows:

- research aimed at preservation of the species in question, or
- essential biomedical purposes where there is an exceptional scientific justification and where it is proven that the objective cannot be achieved by the use of:
  - o a non-animal method or methods; and/or
  - o animals of a species not listed in Appendix I of CITES or Annex A of Council Regulation (EC) No 338/97.

The national authority would make the decision on whether such use was justified, as part of its authorisation process.

### Should the use of Great Apes be banned?

#### Background

It is acknowledged that Great Apes are qualitatively different from other non-human primates, for example their level of self-awareness. There was therefore a higher level of concern regarding their potential use in procedures. This had led to their use being banned (e.g. the Netherlands, UK) or partially banned (e.g. in Sweden, use only for research relating to their own species). However, it is also maintained that their use is essential in certain areas of research, e.g. Hepatitis C, and may be required in the event of a major new disease.

#### Opinion

There was considerable discussion involving several TEWG members but no consensus.

The view put forward by several members, including from other Sub-Groups, was that it was indefensible for their use in research to continue. This view was based on Great Apes' cognitive abilities, strong and complex social bonds and awareness, range of emotions and level of consciousness, and on the level of public concern regarding their use and welfare.

The view of several other members, including from other Sub-Groups, was that a ban was not appropriate as there was already robust provision within the Directive relating to the use of any animals considered as endangered under Appendix 1 of CITES and Annex C1 of Regulation (EEC) No 3626/82. This only allowed their use if there was an overriding scientific justification for (a) research aimed at the preservation of the species in question, or (b) essential biomedical purposes (under certain conditions as stipulated – see CITES section of this report). The national authority would have a

key role in this to ensure the cost-benefit analysis was rigorously applied, as would the ethical review process.

A further view of a Sub-Group member was that their use should only be allowed for research aimed at the preservation of the species in question.

### **Practical implementation of the 3Rs**

How can the use of the 3Rs approach be demonstrated in an experiment and how should an authorisation request include the 3Rs concept?

#### Background

Although the 3Rs of Reduction, Replacement and Refinement, as expounded by Russell and Burch, are covered in the text of the current Directive (Article 7, paras 2 and 3), there is no specific mention of the 3Rs principle.

#### Opinion

Members agreed that the lack of a specific reference to the 3Rs was an omission which should be rectified so as to stress the importance of this principle as a cornerstone of the Directive. It would therefore be appropriate to include a brief explanation of the 3Rs in the introductory recitals. Furthermore, Article 7 para 3, dealing with reduction and refinement, should be re-worded for improved clarity. For example:

Where a procedure has to be performed, the following principles must be applied:

- (a) pain, suffering, distress or lasting harm (either resulting from the procedure or associated with the housing and husbandry conditions) must be avoided wherever possible or otherwise kept to a minimum;
- (b) to this end, animals with the lowest degree of neurophysiological sensitivity must be used (consistent with the objectives of the procedure);
- (c) the minimum number of animals must be used (consistent with the objectives of the procedure).

Although the wording of (b) above is similar to that in the current Directive, a member of another Sub-Group queried whether this was practicable to determine.

It was not considered appropriate to include requirements for the practical implementation of the 3Rs within the text of the Directive. The major need was to focus on the outcomes of the ethical review and authorisation procedures rather than prescribe the mechanisms. It was therefore for the applicant to be able to demonstrate to the satisfaction of the national authority how the 3Rs would be applied in his/her research. Similarly, requiring a named statistician as a mandatory part of the review process (a mechanism), was not considered appropriate as the need was for the applicant to show that the minimum number of animals consistent with the aims of the experiment would be used (an outcome).

## Central Database

### Is there a need for a central database?

#### Background

Duplication of studies of any kind, where there is not a scientific need, is to be avoided as a waste of resources and time. There is also a moral obligation to avoid unnecessary duplication of studies where these involve the use of animals, and to share information wherever practicable. One method that has been proposed to minimise duplication is for information about the existence of studies to be made available on a database.

#### Opinion

It was not possible to reach agreement on the value or practicability of a central database of animal tests. Details of the opposing arguments are contained primarily in the papers posted on Circa.

One member considered that there was a perception, but a lack of convincing evidence, that a significant number of studies carried out on animals simply repeated others already concluded, but that this perception did not reflect practice within the European pharmaceutical industry. Repetition would add time unnecessarily to the already lengthy and expensive R&D process and in any event the likelihood of two companies studying exactly the same compound, aimed at the same mechanistic target, and under identical conditions were extremely remote. Early patenting of compounds also prevented this. Where studies on a compound were repeated, for example on a compound from a competitor company, this would be because it was necessary to validate results against a novel compound under exactly the same conditions. Searches of the literature were routinely carried out, both by using databases such as Medline and by studying posters, conference proceedings and competitor intelligence.

A database of authorised work, apart from providing minimal benefits, could also be misleading, as studies may vary in details. Defining these differences could be extremely time-consuming and put confidentiality at risk. Furthermore, any system for sharing data that required assessing the 'value' of studies, particularly those early in the R&D process, would be highly problematic and effectively make a system unworkable. It was unclear also how any requirement could extend to studies carried out in non-EU countries, thus placing EU industry in an uncompetitive situation.

This view was supported by members of other Sub-Groups, who also considered any such database unworkable and confirmed that similar considerations would apply to any proposed database of tests carried out within the chemical industry.

The opposing view presented by another member of this Sub-Group drew attention to papers such as the EU Commission proposal for a new chemicals regulation (REACH), the DG Sanco report on pesticides regulation, and others that referred to the need for existing data to be made available so as to avoid duplication of testing. The member defined duplicate testing specifically as that resulting from a researcher

either not knowing a test has already been carried out or else knowing this but not being able to access the data. This definition would therefore not include repeat testing where there was a scientific justification, e.g. to validate previous data or where other variables were of relevance. The member proposed (see paper on Circa) a possible scheme administered by an EC agency by which adequate safeguards could be put in place to respect true commercial confidentiality and to provide for compensation to the company originally carrying out the studies. As a consequence of this, he proposed that a revised Directive should specifically prohibit duplicate testing, except in cases where there was a scientific justification (addressed via a cost-benefit analysis). The need for a database was supported by another member.

Although agreement could not be reached on this topic, it was considered there could be benefit in further examination of the workability of an EU system to look at duplicate testing, as defined by the member above, with suitable provisos regarding commercial confidentiality and personal details. One possible mechanism would be to carry out a pilot study in a particular area of research. Another member considered the need for academic confidentiality would also need to be taken into account.

Members suggested, as a separate proposal, that a database of alternative methods (applying to all of the 3Rs), at European level, could be of great value as information on such methods was currently often only obtainable by searching a number of separate databases, with a lack of consistency of keywords and therefore variable results. It was understood that ECVAM was currently carrying out a pilot study in this area but that, at the present time, it applied primarily to toxicology and the replacement alternative. It was recommended that sufficient resources be made available to ECVAM to allow this work to be developed as swiftly as possible so as to provide a comprehensive EU alternatives/3Rs database covering all relevant areas. It was, however, stressed that this initiative should not detract from the efforts of other groups relating to databases addressing similar issues.

## **Statistics**

### **Background**

Members had noted that reference had been made on several occasions during their discussions to the compilation of EU statistics of animal use. It was considered that Article 13 of the current Directive was thoroughly unsatisfactory as, in particular, it fails to define the frequency of collection of information on animals used in member states and of making information publicly available. It also does not define the responsibility of the EU to collate and publish such information on an EU-wide basis.

### **Opinion**

It was agreed that the purposes of collecting such data include:

- provision of information to the general public, in the spirit of openness
- ability to identify and monitor trends in usage
- ability to identify anomalies/issues and seeking explanations
- investigation and explanation of trends, taking any necessary action

One example would be a sudden increase in use of a species that was only available from a non-purpose-bred source. This could point up the need for a breeding centre to be set up.

Statistics should be reported to the national authority once each year, collated and published within the member state. Each member state should also report them to the EC, who should collate all submissions and publish EU-wide figures, also on an annual basis.

A key aspect of publication of EU statistics would be providing a critical evaluation, as it is widely recognised that the 'bare' numbers do not reflect the 3Rs. It would be necessary to present the data in a user-friendly form, analyse the data and explain trends, anomalies or other aspects of the results.

The considerable resource required by all involved in this process was acknowledged and had to be taken into account against the potential benefits. However, this resource commitment could be minimised by the use of a standard computerised form (possibly to be published as an Annex to the Directive). It was recommended that the EC enter into a dialogue with member states (and with the Council of Europe) to agree the content of such a form, to be used for collection of the same statistics in the same format within member states and at European level.

One member pointed out that if the tables of statistical data were provided as an Annex, it must be possible to update them as required but that it would have to be understood from the outset that experience in the UK has shown that it can take up to 3 years from agreeing a revised content or format to being able to gather accurate information. The member considered this was also an area where compliance costs may have to be balanced against the value of any changes subsequently considered.

Members agreed not to make specific proposals at this time with regard to what data should, or should not, be included in the statistics (but see above regarding practical aspects with larval/foetal/embryonic forms), as they were informed that the UK's Animal Procedures Committee was commencing a broad public consultation on this issue. The results of this consultation were expected to be available by late 2004. The results of this consultation could therefore inform EU deliberations without delaying the revision of the Directive, as the details of data to be collected would be contained in an Annex to the Directive and not the main text. Details of the consultation are at <http://www.apc.gov.uk>.

## **Transport**

### **Background**

It was drawn to members' attention that the EU Transport Directive was currently under revision. It was therefore necessary to consider these to ensure that specific requirements relating to transport of laboratory animals were appropriately covered. Comparable discussions on relevant Conventions within the Council of Europe were also taking place but, in these cases, representatives from the Working Party examining housing and care of experimental animals were also involved in the Working Party discussions on transport.

## Opinion

It was agreed that the proposed revision of the Transport Directive appeared adequately to cover specific requirements relating to laboratory animals. For example, the general provisions applied to all vertebrate species, but there was also specific mention of the needs of laboratory animals, such as the transportation of animals on which procedures had been carried out. However, members agreed there would need to be further consideration of this by the relevant EC departments/groups, so as to ensure the specific needs of laboratory animals were indeed adequately covered under a revised Transport Directive.

Regardless of the outcome of the above, members considered that it would be appropriate for Directive 86/609 to make reference to transportation in Article 5, and in particular for the cost-benefit analysis to take account of aspects of transportation that could impact on the welfare of the animal.

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### **Composition of the Sub-Group Scope:**

Pilar Leon Arnaiz/Maria Teresa Villalba	(Spain)
(name withheld)	(Ireland)
Lázló Pallós	(Hungary)
Klaus Meier	(CEFIC)
Robert Hubrecht	(ISAE)
David Thomas	(ECEAE)
Graham Moore (rapporteur)	(EFPIA)
Jürgen Vogelgesang (chair)	(DG Environment)

The Members of the TEWG were expected to act as individuals and not as representatives of the national authority or non-governmental organisation that nominated them.

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11 November 2003