

FELASA statement on a proposal from the Laboratory Animal Science Association (LASA) for the European Community to adopt retrospective reporting of scientific procedures on animals

FELASA is composed of independent European national and regional laboratory animal science associations and was established by them in 1978. It can speak for laboratory animal scientists and technologists in more than twenty European countries and has Observer status at relevant EC fora.

As a science-based association, FELASA considers it has a responsibility to comment on any issue or change that may affect the use and welfare of animals in experimental or other scientific procedures. FELASA has therefore been actively involved in the ongoing discussions and consultations on the revision of the EU Directive EC86/609, which determines the minimum requirements for the regulation of animal experimentation by member states of the EU.

LASA proposal on retrospective reporting of scientific procedures on animals

The UK's Laboratory Animal Science Association (LASA), which is a constituent member association of FELASA, has proposed to the European Commission that the statistical reporting of scientific procedures carried out on animals should be performed retrospectively. LASA considers that this would provide more accurate data, increase transparency, and help promote refinement. A copy of LASA's full proposal is attached as Annex A.

FELASA position on the proposal

1. FELASA has considered LASA's proposal and in principle supports the concept of retrospective reporting for the reasons detailed by LASA.
2. FELASA specifically supports the principle of retrospective reporting of severity and considers it can provide more meaningful data of the distress or pain that may be suffered by animals during scientific procedures.
3. Adoption of retrospective reporting should be in such a way that it does not significantly increase the overall administrative burden placed on research facilities and should be in place of, and not additional to, any other method of reporting, e.g. prospective.
4. Any system of retrospective reporting must be straightforward to implement and an appropriate lead-in/adaptation time should be allowed so as to enable those involved with reporting to become familiar with the new processes involved.
5. The data produced by retrospective reporting should be simple enough to be readily understandable by the general public.

FELASA, as a scientific association representing those involved with animal experimentation throughout Europe and with access to a wide range of expertise, will be happy to assist the European Commission by advising further on this or any other issue relevant to the revision of Directive EC86/609 and the conduct of animal experimentation within Europe.

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Annex A – LASA proposal

Statistical reporting and the Three Rs:

Why Europe should adopt retrospective reporting of scientific procedures on animals

1. Current methods of counting animal procedures in Europe

At present, there is no standard method of reporting statistical data on animal use across Europe:

- some countries, e.g. the UK, report animal procedures when they are started ('prospective' reporting);
- some, e.g. the Netherlands, report procedures when they are finished ('retrospective' reporting);
- whereas Switzerland reports animals 'in use' during a given year.

Prospective reporting means that animals are counted in the *Statistics* in the year in which they enter procedures, whereas retrospective reporting means that animals used in procedures that cross year-end(s) will not be counted until the subsequent (or later) year(s). However, if this thought to be a problem, it can be overcome – see 3iii below.

2. Disadvantages of prospective reporting

- (i) Reporting procedures started in a given year does not always reflect the eventual use of the animals.

This can be a particular problem with GA animals, which in the UK make up one third of the animals used. With prospective reporting all GA animals produced in a year must be recorded but often it is not certain whether they will subsequently be used for breeding, for samples for post-mortem analysis or subject to additional procedures. If used for a procedure in the subsequent year they are likely to end up being counted again leading to inflated statistics.

- (ii) Reporting when procedures are started will not permit collection of data on the actual experience of the animals.

Note that 'prospective' reporting of the use of animals according to the severity limits of procedures into which they are entered would greatly over-estimate actual severity of any suffering. For example, animals may be entered into a procedure which has a substantial upper limit yet in practice very few may reach that limit and many may undergo no more than mild pain, suffering, distress or lasting harm.

3. Advantages of retrospective reporting

- (i) Reporting animal use when procedures are finished provides more accurate data on how animals are actually used (cf. (i) above – prospective reporting does not always reflect eventual use of animals).
- (ii) Retrospective reporting also enables data to be collected on the actual experience of the animal undergoing the procedure, including the severity of any suffering experienced and the duration of the procedure.

Reporting the actual effects of procedures on animals would bring a number of benefits, including:

- *Increased transparency* – providing public information on the severity of animal experiments;
- *Promotion of refinement* – helping to identify opportunities for refinement and, on a year-to-year basis, allowing for assessment of the impact of refinements, in terms of changes in the

• That is, an upper limit to the suffering an animal can be caused in a given protocol – set at the licensing stage

experience of animals undergoing the modified procedures – and so documenting good welfare practice.

(iii) Retrospective reporting allows identification of longer-term procedures lasting more than a year. Although, as noted above, the use of some animals will not be reported in the year in which the procedures are started, this difficulty can be overcome (if necessary) by also reporting the number of procedures started but not finished in a given year (as in the Swiss system).

4. A mixed prospective and retrospective reporting system is not viable

If there is to be retrospective reporting, it should be the sole method, used 'across the board' in order to:

- (i) enable cross-referencing of data on different aspects of animal use (e.g. purpose vs. severity); and
- (ii) avoid the additional bureaucratic burden of collecting two different sets of data – one at the start and one at the end of procedures.

Selecting a sub-set of procedures for retrospective reporting of severity in a given year (alongside an otherwise prospective system of reporting) would not reduce the burden of mixed reporting, because systems would need to be in place to collect severity information should it be required. Moreover, reporting the severity of only some categories of procedure would not enable any overall estimate of the welfare 'costs' to animals of experimentation, and could lead to public misinformation.