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The proposed new directive is published

The European Commission's proposed text for the new directive was published today

The first stage in the production of the new directive on animal experimentation has finished. After many years of deliberations, consultations and internal delays, the European Commission has adopted a draft wording and published it as a formal proposal for a new directive.

The full text can be found at:
http://ec.europa.eu/environment/chemicals/lab_animals/pdf/com_2008_543.pdf

This proposal has been sent to both the European Parliament (composed of the MEPs) and the European Council (composed of representatives from the Member States). Both these bodies will give it a first reading, making proposals for changes to each other and then, taking each others proposals and the Commission's reaction into account, they each have a second reading. All three bodies – Commission, Council and Parliament – have to reach agreement on the text. If they cannot do so after the two readings, there is a Conciliation Committee formed with representatives from all three bodies, which has a deadline to hammer out a compromise.

This whole process can take between 2 and 4 years.

What will the Parliament do now?

The European elections mean that the first reading cannot start immediately

The first reading of a proposed new directive has several necessary stages within the European Parliament. First it is referred to a particular committee for consideration and the committee appoints one of its members to be a rapporteur. The rapporteur prepares a report highlighting what needs changing in the proposed text, then the committee debates and votes on the report and proposed amendments. The resulting report and proposed amendments then go to the full parliament in plenary session, where they are debated and voted on again. Since the committees only meet once a month and it can take two or three months for the rapporteur to prepare their report, this process takes, on average, just under a year.

Currently, there are only five more meetings of the committees before the parliament suspends proceedings in April for the run up to the June elections, so it is impossible to complete the first reading before then. There is no point in only doing part of a first reading as about one third of the MEPs will change after the election and committee membership can change even more.

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So, it is unclear exactly what the parliament will do now with the proposal for a new directive on animal experimentation. It is certain to be referred to the Environment Committee, as they have dealt with everything on this subject before now. However, it is quite possible that the Research Committee will put in a bid for the proposal to be considered jointly by both committees. The committee or committees are unlikely to appoint a rapporteur immediately. They may decide to hold a preliminary debate or even public hearings. We will learn more in the next few weeks.

One thing is clear. The formal legislative process within the parliament will not start until the second half of the year.

Summary of the proposed directive

The summary below give the main changes from the old directive.

Scope

The directive will apply where animals are used or intended to be used in procedures or where they are bred specifically so that their organs or tissues may be used for scientific purposes.
(NB this wording would mean that most animals used as a source of tissue would not be covered as they are usually surplus breeding stock and not "bred specifically" to supply organs or tissues.)

The directive will cover the use of:
vertebrates
cyclostomes (hagfish and lampreys)
cephalopods (octopuses and squid)
decapod crustaceans (crabs, lobsters and prawns)
including:
a) independently feeding larval forms
b) embryonic or foetal forms for the last third of their development

Permitted purposes

Animals can be used in procedures for the following purposes:
a) basic research for the advancement of knowledge in the biological or behavioural sciences
b) translational or applied research aimed at:
i. the avoidance, prevention diagnosis or treatment of illness
ii. the assessment detection, regulation of modification of physiological conditions
c) the development, manufacture or testing of drugs, foodstuff or other products with the aims in b) above
d) protection of the environment in the interests of human welfare
e) research aimed at the preservation of the species
f) higher education or training
g) forensic inquiries

Non-human Primates etc

Primates must be purpose-bred for research and may only be used in procedures that are "carried out in relation to life-threatening or debilitating clinical conditions in human beings." It is made clear that this can include fundamental research. Research aimed at the preservation of the species is also permitted.

From the following dates primates used in research must be 'the offspring of non-human primates which have been bred in captivity."
Marmosets – as soon as Member States apply the directive.
Cynomolgus and Rhesus macaques – 7 years after Member States apply the directive

All other primates – 10 years after Member States apply the directive
When acquiring primates for research use, you must show proof that the breeding establishment has a strategy in place to increase their breeding of F2 animals.

The use of great apes is banned, although there is a 'safeguard' procedure to allow Member States, with the European Commission's agreement, to authorise their use for research that is considered essential for the preservation of the species or in relation to an unexpected outbreak of a life-threatening disease.

Endangered species (CITES Annexe A) can only be used for translational/applied research and testing, but not for basic research.

Stray and feral domestic animals cannot be used.
Animals taken from the wild cannot be used, although an exemption to this can be granted by a Member State on the basis of scientific justification.

The usual species (mice, rats, guinea pig, hamsters, gerbils, rabbits, frogs, dogs. cats and primates) must be purpose-bred, although an exemption to this can be granted by a Member State on the basis of scientific justification.

Severity of procedures

These are four classes of severity: up to mild, moderate, severe and non-recovery (ie killed while still under anaesthesia)

The Commission will establish criteria for the classification of procedures to be adopted by a regulatory committee.

Re-use

Definition: Using an animal that has already used in a procedure, when a different animal on which no procedure has previously been carried out could also be used.
To apply this definition, consider each example that comes to mind and apply the test "at this point, could one substitute a different animal which had had nothing done to it". This wording thus allows continuing use (eg surgical preparation and then an experiment) as part of the same procedure.

Restrictions
a) the first procedure must be classified as 'mild', although an exemption to this can be granted by a Member State on the basis of scientific justification.
b) the animals general state of health and well-being has been fully restored
c) the further procedure must be classified as 'mild' or 'non-recovery'
d) If an animal has been used first in a severe procedure, it can only be re-used once in a further procedure.

Authorisation
Individuals require authorisations to carry out:
a) procedures
b) humane killing
c) Supervision of projects or procedures
d) Supervision of animal care staff

Authorisations for a maximum of 5 years.

Institutions require authorisation:
a) for breeding, supplying or using animals in procedures
b) the person responsible for the institution must be named
c) the institution must have staff to ensure that projects are carried out in accordance with their authorisations and to deal with undue suffering or non-compliance, including:

i. animal care and welfare staff
ii. designated veterinarian (for advisory duties)

d) the institution must have a permanent ethical review body

Permanent ethical review body

Its functions are to:

a) Provide advice to staff on ethics, animal husbandry and the three Rs
b) Establish internal procedures for monitoring animal welfare
c) Review all projects annually, to check compliance with authorisations
d) Keep records of all advice given to staff and licence-holders

Project authorisations

National authority can give authorisations for projects for up to 4 years based on an ethical evaluation of the project including:

a) Scientific or legal justification of the project
b) Application of the 3 Rs in project design
c) The severity of the procedures involved
d) Harm-benefit analysis (is the animal use and suffering justified by the expected advancement of science that ultimately benefits human beings, animals or the environment.)

The ethical evaluation shall be performed in a transparent manner, by integrating the opinion of independent parties.

The ethical evaluation will determine whether the project should also be assessed retrospectively. All NHP projects must be retrospectively assessed.

Decisions on authorisations must be communicated to the applicant within 30 days of submission. Failure to communicate such a decision shall, for any non-primate projects which only include up to mild procedures, will result in automatic approval of the project. In exceptional circumstances, for complex project, this limit can be extended to 60 days.

Non-technical project summaries

Subject to safeguarding confidential information, non-technical summaries will cover the objectives of the project, numbers and types of animals to be used and potential suffering, application of the 3 Rs, whether retrospective assessment is required and outcome of the retrospective assessment. These summaries will be published for all authorised projects.

These summaries must be included in all project applications, except that Members States can decide to use a reduced project application system (which does include such summaries) for any non-primate projects which only include up to mild procedures.

Care and accommodation

The ETS123 guidelines will be mandatory requirements.

Inspections

a) All Member States must have an appropriate infrastructure with sufficient numbers of trained inspectors
b) Each establishment will have at least 2 inspections a year by the national authority
c) At least one of these must be unannounced
d) Larger establishments to have more frequent inspections
e) The Commission may undertake controls of the infrastructure and operation of inspections

Alternatives

Each Member State must designate a national reference laboratory for the validation of alternative methods.
The Commission will set the work priorities for these national reference laboratories.

The main points of concern

This list highlights the main points of concern as seen by a core group of ECBR representatives.

1. The proposal to limit the use of macaque primates to second generation born in captivity animals from 7 years after the directive comes into force. It is simply not clear at present whether it will be possible to breed enough F2 primates to meet this requirement.

2. The proposal to limit re-use of animals to cases where the second procedure is mild or terminal. This could considerably reduce the amount of re-use, which would make the research projects affected harder to conduct and more costly. It would also increase the numbers of animals used and, in some cases, increase the amount of animal suffering.
3. The proposal that the competent authority had to carry out ethical evaluations of all project applications “in a transparent manner, by integrating the opinions of independent parties”. Confidential information needs to be protected (something that is included in the provision for non-technical summaries). The meaning of this clause is unclear, which could mean that its interpretation is ultimately decided by court cases, when animal protection groups seek the right to be involved in the assessment of applications.

4. The proposal that the Commission would define the severity categories by a regulatory committee procedure after the Directive was in force. Since there are restrictions on certain procedures (eg in re-use) to certain severity categories, the decisions reached by this committee procedure could have significant effects.

5. The proposal that institutional ethical review bodies should conduct annual reviews of all projects would create an unjustified burden of administration.
6. The proposal that the European Commission would have the power to ‘undertake controls of the infrastructure and operations of national inspections’ – ie have the power to tell Member States how to carry out their inspections – appears dangerous. It seems likely that this would be used in response to complaints that the inspection process was not working properly. This means that campaigning groups who mount infiltrations and exposes could pressure the commission into effectively taking over the inspection of the alleged misbehaving establishment.