Briefing – Authorisation of Projects

Proposal for a Directive on the protection of animals used for scientific purposes (revising Directive 86/609/EEC)

Eurogroup For Animals and Animal Defenders International (ADI) support full ethical and scientific review and authorisation applied to **ALL** projects

We consider the draft position of the Council acceptable, however, we urge you to ensure applications classified as 'moderate' are **NOT** included for tacit approval.

Background

All projects falling within the scope of the Directive must be subject to **a formal authorisation process** by national authorities. Member States may deal with the authorisation of procedures on animals in different ways, but the Directive must lay down the essential requirements of the process.

Additionally, it is essential that every project involving procedures on animals undergoes a thorough **ethical/scientific evaluation** as an integral part of the authorisation process. This is already integrated into the regulatory system in some Member States, where ethical evaluation takes place at both a national and local level, but it is not required by the current Directive. In the revised Directive, ethical and scientific evaluation must be a mandatory part of the process of authorisation at national level in each country.

The purpose of ethical/scientific evaluation is to ensure that the necessity and justification for animal use is critically assessed, and that the negative impact of research on animal welfare is reduced as far as possible by fully implementing the 3Rs (replacement, refinement, reduction). Central to ethical/scientific evaluation is **a harm/benefit analysis** which takes account of all potential harms to animals throughout their life including physical and psychological harms associated with breeding, transport, housing, husbandry, handling, procedures and their effects, and euthanasia. Appropriate **experimental design and implementation of all 3Rs** are also key factors that must be addressed by the ethical evaluation.

Our views on the present positions indicated by the different institutions are outlined below:

Commission

A central feature of the Commission's proposal is the system of ethical review and authorisation of all projects, with a provision for reduced requirements regarding evaluation of projects classified as 'up to mild' under certain circumstances. Twenty-one Member States, covering nearly 90% of animal use, currently require some form of authorisation of projects and comprehensive authorisation is already in place in 78% of the Member States. The Commission's proposal will not impose any additional bureaucratic burden for the majority of Member States.[1]

[1] http://ec.europa.eu/environment/chemicals/lab_animals/ia_en.htm

European Parliament

The European Parliament position significantly reduced the number of procedures which could be evaluated by the Competent Authority by no longer requiring any level of central authorisation for projects classified as ‘up to mild’.

The European Parliament position would permit a derogation of authorisation to 'notification' only of projects classified as ‘up to mild’ and also those not involving NHPs after ethical review by the a permanent ethical review body (PERB) at institution level. This has far reaching consequences because the allocation of the severity classification (and thus the decision as to whether or not the Competent Authority should authorise the project) would be left in the hands of the establishment who put forward the project. This system is in every respect not viable as it cannot be partly regulated by the Competent Authority and partly by the establishment itself.

It is clear that one of the many problems with the European Parliament position is that there would be no independent harm-benefit assessment and assignation of the severity classification for so-called mild projects. The effectiveness of PERBs is also in considerable doubt since the Council is looking at downgrading them to ‘Animal Welfare Bodies’ with no remit for ethical and scientific evaluation.

Council

The Council position requires application for approval for all projects, including those which may eventually be deemed to have ‘tacit approval’. Council indications are to introduce a new Article (41A) allowing 'tacit approval' of projects carried out for the purpose of regulatory or diagnostic testing which are classified as ‘non-recovery’, ‘mild’ or ‘moderate’ .

The position of Eurogroup and ADI during the trialogue discussions

Ultimately, the proposal put forward by the Commission which, in the case of projects classified as ‘up to mild’ (and not involving NHPs), allowed authorisation to be deemed to have been granted if the competent authority failed to reach a decision within 30 days, is one that animal protection and replacement funding groups were not happy with because we would wish to see full ethical and scientific review and authorisation applied to **ALL** projects

We were even less happy with the position of the European Parliament, because that reduced the level of scrutiny to be applied to projects classified as ‘up to mild’.

We are not entirely happy with the Council position because there is still a presumption that some projects would be subject to ‘tacit approval’.

However, should discussions focus solely on developing a plausible decision based on the positions of the European Parliament and Council we urge you to consider the following:

All procedures, whatever the level of severity, should require a project proposal, non-technical project summary and ethical and scientific evaluation as a minimum. We believe there is a risk that animals could be exposed to moderate procedures listed in the proposed new Article 41(A) without any licensing, where the severity was misjudged or where a series of “mild” procedures increased the overall severity.

Following detailed analysis and careful consideration of the position of the European Parliament versus that of the Council we urge you to support the position of the Council with the following recommendation:

The proposed ‘Authorisation through tacit approval’ (Article 41A [New Article 39A])’ must only go as far as including:

- procedures classified as ‘non-recovery’, or ‘mild’ and not using non-human primates. We urge you to ensure those classified as ‘moderate’ are **NOT** included for tacit approval.

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