



An argument for the creation of a permanent independent “Directive 2010/63/EU Working Group on the use of animals for scientific purposes”

1. Directive 2010/63/EU establishes a series of advisory bodies, charged with:

Animal-Welfare Bodies: Articles 26 and 27

The AWB must be created in **each** breeder, supplier and user, including those dealing with animal welfare, and a scientific adviser for users. They must also receive input from an Article 25 designated veterinarian expert. There is a proportionality clause: small-scale breeders, suppliers and users can meet the AWB requirements by other means.

The AWB has various duties (Art. 27) inter alia:

- “(a) advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use;
- (b) advise the staff on the application of the requirement of replacement, reduction and refinement, and keep it informed of technical and scientific developments concerning the application of that requirement;
- (c) establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the establishment;
- (d) follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise as regards elements that further contribute to replacement, reduction and refinement; and
- (e) advise on rehoming schemes, including the appropriate socialisation of the animals to be rehomed.”

They also have duties in ensuring appropriate record keeping.

Competent Authorities: Article 59

Member States must “designate one or more competent authorities responsible for the implementation of this Directive.” These can be public or private bodies and their duties are described at various points in the Directive - principally they are concerned with approvals and inspections. The criteria for designation is competence (expertise and infrastructure, and a freedom from conflict of interests).

The Commission has created a list of Competent Authorities:

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



Since 2002, the Commission has also employed ad hoc Expert Committees advising on specific issues on request, and has brought the National Competent Authorities together for various harmonisation discussions. This has been very successful in catalysing the harmonisation of the MS law in the area

Nine consensus papers have been either agreed or endorsed by the NCAs.

- http://ec.europa.eu/environment/chemicals/lab_animals/interpretation_en.htm

National committees for the protection of animals used for scientific purposes: Article 49.

Member states must also establish a National Committee for the Protection of Animals used for Scientific Purposes. to “advise the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice.” And to exchange information and share best practice within the Union.

2. What is striking about this arrangement is, first, how productive it has been. There is a large amount of activity in relation to animal welfare in scientific uses. However, there is a lack of clarity for the legal structure of the Committees. There is, also, a heavy reliance on the MS adopting harmonising best practice. There seems to be a degree of overlap between the Competent Authorities and the National Committees, with the former being the National Contact Points, and the bodies brought together to form a degree of consensus and harmonisation.

3. The Analogy and success of the “Article 29 Working Party” of the Data Protection Directive 95/46/EC

Under the Data Protection Directive a similar problem is addressed: how, when regulated by Directive, with a degree of MS discretion either overtly or hidden in the interpretation of language, can harmonisation be achieved. Under 95/46/EU, MS are required to create “Supervisory Authorities” which are charged with the implementation and operation of Data Protection their domestic jurisdiction. As in the Directive 2010/63/EU, there can be more than one national supervisory authority under the Directive. The problem of harmonisation is addressed in Article 29 of 95/46/EC: “A Working Party on the Protection of Individuals with regard to the Processing of Personal Data,



hereinafter referred to as 'the Working Party', is hereby set up. It shall have advisory status and act independently.”

Its Duties are outlined in Article 30, to:

“(a) examine any question covering the application of the national measures adopted under this Directive in order to contribute to the uniform application of such measures;

(b) give the Commission an opinion on the level of protection in the Community and in third countries;

(c) advise the Commission on any proposed amendment of this Directive, on any additional or specific measures to safeguard the rights and freedoms of natural persons with regard to the processing of personal data and on any other proposed Community measures affecting such rights and freedoms;

(d) give an opinion on codes of conduct drawn up at Community level.”

The important difference between the two Directives is the authority of the Committees. Under 95/46/EC, the Working Party has a standing authority to act under its own motivation, whereas under 2010/63/EU the authority is not created in the primary legislation.

4. Conclusion The adoption of a clear, Directive authority for MS-nominated representatives (either from the Competent Authority or the National Committee) to form a Directive 2010/63/EU Working Party on a similar mandate to the Article 29 Working Party, could be a logical next step to strengthen the harmonisation process - particularly when linked to the EURL-ECVAM. The construction might be slightly different from the DPD arrangement - the Commission, for example, could also nominate particular experts in different fields to ensure a strong scientific input into the discussions, or other stakeholders to ensure a wide representation of views.

It is worth noting the success of the Article 29 Working Party and the further strengthening of this independent Committee under the General Data Protection Regulation 2016/679 in the European Data Protection Board. The EDPB duties are more extensive than the Article 29 Working Party, perhaps inappropriately more so when considering a model for 2010/63/EU, but it is a trajectory that might be considered in time.