European legislation
Impact on the scientific use of animals

NEWSLETTER May 2015

Workpackage 2 Webinars

Workpackage 2 (legal and licensing processes) is currently carefully analysing the Directive 2010/63/EU from a legal perspective and providing support for all other WPs regarding legal issues and data protection. In April two webinars, hosted by David Townend of Maastricht University, provided an excellent platform for exchange between all WPs on the nature of European Law, how this Directive fits into the EU legislative landscape, and on the 3Rs as a legal instrument.

News from Workpackage 3 (Ethical Issues)

First results of workpackage 3 are online available (see link below). This first report presents the result of a mapping of the different approaches to evaluation and authorization of projects with animals in different Member States. Specifically, the mapping has focused on general organization and expertise and representation in evaluation bodies.

Methodology used

The methodology was defined taking into account the need for complete and reliable information in combination with a strong motivation to avoid overloading competent authorities (CA) with requests for detailed information. It was therefore decided as a first approach to combine a web search with contacts with individuals in each member states who are independent of the respective competent authorities and who are persons with whom the team had previous contacts. For the web search a standard document structure was developed and filled in using the information available on the internet (official websites - government,

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competent authorities, other entities involved in the ethical review process). The next step was to confirm, correct, complement and/or update the information with the key national contact persons, who were nearly all connected with the ethical review process, as members of ethics committees, technicians, etc. This initial informal approach was complemented by a later formal contact with each competent authority (MS authorities for Directive 2010/63/EU/ National contact points as per article 59 of the Directive). They were asked to confirm, correct, and/or update the information already obtained through web search and personal contacts.

Results

So far competent authorities (CA) in 16 Member States have responded, allowing the process to be completed for these countries. There is considerable variation in organization as regards at which level the evaluation and the authorization of biomedical research involving animals takes place. In many MS there is a combination of several approaches. The two most common approaches are:

- the projects' evaluation and authorization at a national level (evaluation conducted at national level, by a national committee; authorization is also provided at a national level, usually by the competent authority)
- the projects' evaluation at institutional/local or regional level combined with an evaluation at a national level with the authorization being provided also at a national level (evaluation primarily conducted by a committee at an institutional, local or regional level; after this step applications are sent to national entities for a second evaluation, by committees and/or officers).

For the full published report please follow this link:
http://www.animpact.eu/sites/default/files/images/WP3_firstresults_2nd%20Report_0.pdf

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