



Ethics review of animal experiments in Europe under Directive 2010/63/EU

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The fundamentally revised and expanded European legislation (Directive 2010/63/EU) protecting animals used in research now covers evaluation and authorization procedures, and includes aspects that were not included in the previous Directive (86/609/EU). These aspects (e.g. predicted benefit, 3Rs compliance, severity, harm-benefit analysis) correspond to what is typically covered by an “ethics review”, although this term is not used in the Directive. How and by whom projects are to be evaluated was left to individual Member States (MS) to determine. As part of the ANIMPACT project (<http://www.animpact.eu>), we are exploring the ethics evaluation and authorization process within the European Union. As of March 2015, we have confirmed information for 19 MS. The available information shows considerable diversity between MS as regards the approach to evaluation and authorization. In many MS there is a combination of several approaches. The two most common approaches are i) that the projects are only evaluated and authorized at a national level (the evaluation is conducted by a national committee and the authorization provided by the national competent authority) and ii) that the projects are evaluated at institutional, local or regional level (by a committee) combined with an evaluation at a national level (by a committee and/or officers) with the authorization being provided also at a national level. Committee size and composition also vary. Most committees include scientific expertise and veterinary expertise, whereas expertise in law, ethics and alternatives to animal experiments is less common. Committee members from outside the scientific and technical community are most often representatives of special interest groups (mainly animal welfare associations), whereas genuine lay members are rare. In the presentation, we will discuss potential underlying reasons for MS opting for these different approaches, and the consequences for the project evaluation process.