Ministeriet for Fødevarer,
Landbrug og Fiskeri

Udvalget for Forsøgsdyr
og Alternativer

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Recommendations regarding antibodies

from the National Committee for Laboratory Animals and Alternatives, Denmark

In 2020 the European Union Reference Laboratory for alternatives to animal testing (EURL ECVAM) published a Recommendation on Non-Animal-Derived Antibodies[1].

The Report recommends a considerable shift from animal use to non-animal methods for the production of non-therapeutic antibodies. Despite this, the Danish Committee does not consider it to be feasible at the present time to produce all non-therapeutic antibodies without the use of animals, bearing in mind the requirement in the Danish Law on Animal Experiments that methods which are to replace animal use must be judged to be equally suitable (§ 6, section 3).

The Committee is, however, of the opinion that the EURL ECVAM report should encourage competent authorities (the Animal Experimentation Council in Denmark) to ensure an ongoing process of evaluation of methods requiring animals, to see if they can be replaced by non-animal alternatives, on a case-by-case basis, both when evaluating applications and when following up permissions that have already been given. This is in accordance with the Danish law's requirement that permission is granted to specific types of experiment (§ 3, section 1), and that animals must not be used if non-animal methods can be assumed to be equally suitable (§ 6, section 3).

The Committee realises that it can be difficult to evaluate each individual antigen, and the antibodies it can be expected to produce. This will create extensive work and logistical problems with permissions for antibody production at larger establishments, if it is not possible to grant permission for the production of a larger group of antibodies.

Therefore, the Committee suggests that, when permission for antibody production is to be given, the establishment

- may still be given permission to produce antibodies against groups of antigens
- shall collaborate with a named expert in antibody production without the use of animals, as a condition for obtaining such permission
- fills out a form in connection with their annual report. This form should describe
  - the type(s) of antigen that have been used to produce antibodies
  - the method(s), with or without the use of animals, that have been used to achieve the aims, for each specific case
  - the efforts that have been made to ensure continued reduction in animal use when producing antibodies.

[1] https://publications.jrc.ec.europa.eu/repository/handle/JRC120199