Animal welfare standards expected of suppliers of antibodies to Research Council establishments

Wherever possible, antibodies should be sourced from UK SBS contracted (preferred) suppliers. Exceptions should be justified on scientific grounds and approved by the local Animal Welfare and Ethical Review Body (AWERB).

Regardless of where they are located, all suppliers of antibodies must operate in a manner consistent with the principles of the UK 'Animals (Scientific Procedures) Act 1986', amended 2012 (UK Government 2014), including the following key principles – compliance should be confirmed by the AWERB:

There must be no reasonable and practicable alternative method of producing the antibody (e.g. *in vitro*) that might replace animal use.

The antibody production protocols must be minimal in terms of the number of animals used, choice of species and severity of techniques applied, compatible with the production of satisfactory antibody.

The space allocations per animal should meet or exceed those in the Home Office 'Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes' (Home Office 2014) and Annex III to Directive 2010/63/EU (European Union 2010).

In addition, all suppliers must implement the principles in the funding bodies' document 'Responsibility in the Use of Animals in Bioscience Research: Expectations of the Major Research Council and Charitable Funding Bodies' (AMRC/BBSRC/DEFRA/EPSRC/MRC/NC3Rs/NERC/Wellcome Trust 2008, amended 2015). This includes housing the animals in appropriate social groups, with environmental enrichment, in high-quality living spaces conducive to good animal welfare.

In vivo production of monoclonal antibodies (mAbs) by the ascites method is unacceptable on animal welfare grounds and no longer scientifically necessary, except in rare cases (European Centre for the Validation of Alternative Methods 1998). The use of ascitic animals for mAb production *in vivo* should only be permitted when *in vitro* attempts at mAb production have failed or the use of animals is considered justified for specific diagnostic or therapeutic products. If *in vitro* production methods are not considered to be suitable, a full explanation should be given and approved by the ERP.

References

UK Government (2014) Animals (Scientific Procedures) Act 1986, amended 2012. www.gov.uk/government/publications/consolidated-version-of-aspa-1986

Home Office (2014) Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes. London: HMSO. www.gov.uk/government/publications/code-of-practice-for-the-housing-and-care-of-animals-bred-supplied-or-used-for-scientific-purposes

European Union (2010). Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the Protection of Animals Used for Scientific Purposes. Official Journal of the European Union, L 276, 33-79. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:en:PDF

AMRC/BBSRC/DEFRA/EPSRC/MRC/NC3Rs/NERC/Wellcome Trust (2008, amended 2015) Responsibility in the Use of Animals in Bioscience Research: Expectations of the Major Research Council and Charitable Funding Bodies. London: NC3Rs. www.nc3rs.org.uk/responsibility

European Centre for the Validation of Alternative Methods (1998) Statement on the Scientific Acceptability and Practical Availability of *In Vitro* Methods for the Production of Monoclonal Antibodies. Ispra: ECVAM. http://eurl-ecvam.jrc.ec.europa.eu/validation-regulatory-acceptance/doc-biologicals/MAb_statement.pdf