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Animal Friendly Affinity Reagents (AFAs): making animal immunisation obsolete

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Valued at a staggering 80 billion dollars, the global antibody industry produces an indispensable resource that is relied upon by scientists, healthcare professionals and consumers, in all areas of research, safety testing, health and the environment. However, it is an industry that uses millions of unaccounted-for animals with important animal welfare implications [1]. With the emergence of the news regarding mistreatment of animals at a US antibody production facility [2] and the availability of numerous replacement methods, it is timely to reflect upon a golden opportunity for replacement. Animal Friendly Affinity reagents (AFAs) encapsulate all binding molecules that are generated recombinantly using naïve (non-immunized) B- lymphocyte or synthetic gene repertoires, selected *in vitro* by phage, ribosome or yeast display. These are typically antibodies, but also include non-antibody affinity reagents, such as DARPins, affibodies, monobodies, anticalins, and others [3,4]. AFAs do not necessitate animal immunisation at any stage of production, making the use of animals obsolete [5]. Commercially available or developed in-house, they have wide ranging applicability, equal or greater specificity and affinity to a huge repertoire of antigens and offer greater control over their properties, generation time and cost. Directive 2010/63/EU legislates for the replacement of animals used in scientific procedures where alternatives exist. Yet despite the irrefutable maturation of the growing number of techniques to produce AFAs and an abundance of literature to support, animal derived antibody production continues to be authorised. Non-technical summaries do not reflect the status quo. Twenty years ago, ECVAM workshop reports [6,7] advised EU Member States that "in the near future", phage display "without prior immunisation of B-cell donors (would) avoid the need to use living animals" so it is incomprehensible that such an enormous area of needless animal use continues to be overlooked and that the opportunity for replacement has not been seized. To stimulate an EU led replacement program, ensuring Directive 2010/63/EU is implemented, we have engaged in discussions with EURL ECVAM and Directorate-General for the Environment. We recommend that the following actions be prioritized: the replacement of animal immunization methods for antibody production within EU Member States, including the import of antibodies and antibody containing products; adherence to European standards by manufacturers from outside the EU; the establishment of an expert working group to set up a roadmap for replacement; implementation programs to ensure that antibody producers are fully supported and that European statistics on the number of animals used for experimental and other scientific purposes should include data on the use of animals for antibody production as an independent category. These actions must be reinforced through international co-operation and nationally, by agencies who execute government regulation at operational level for commercialised products or who safeguard our health and the environment and should include their import, to avoid that production is outsourced to regions where animal welfare is less well regulated. For the full length article, see Gray et al., 2016 [8].

References

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