

The use of animals for the generation of high quality antibodies remains necessary for research and therapeutic applications

EU-LIFE alliance urges the European Commission not to support a blunt ban on the immunization of animals for the generation of antibodies

[EURL ECVAM](#), the European reference laboratory for the validation of animal testing alternatives that is part of the European Commission's Joint Research Center recently published¹ a recommendation that "animals should no longer be used for the development and production of antibodies for research, regulatory, diagnostic and therapeutic applications". It considers that "EU member states should no longer authorize animal immunisation where robust scientific justification is lacking" and rely fully on the use of naïve or synthetic antibody libraries.

While fully supporting the mission of EURL ECVAM, the [EU-LIFE](#) alliance is of the opinion that naïve or synthetic antibody libraries are currently not a full alternative in important areas of scientific research as well as diagnostic and therapeutic applications. **The EU-LIFE alliance therefore urges the authorities not to support a blunt ban on the immunization of animals for the generation of antibodies. Based on the information available today, the EU-LIFE alliance also cannot support a full phase-out of animal immunization.**

Antibodies are proteins that are produced as part of human immune defense. The role of antibodies is to recognize and neutralize proteins that are foreign to our body such as those from disease caused by bacteria and viruses. Because of their ability to bind to proteins with high specificity and high affinity, antibodies are very widely used in scientific research as a reagent and have very important diagnostic and therapeutic applications. Herceptin® (against breast cancer) and Remicade (against Crohn's disease) are just two examples of many dozens of antibodies that are currently on the market as medicines.

The EU-LIFE alliance of leading European research institutes in life sciences:

- Have the experience that immunisation of animals, when compared to the use of naïve or synthetic antibody libraries, leads to the generation of larger panels of antibodies which are of higher quality. This difference is even larger when the target for which an antibody needs to be generated is of high complexity. It is on this point and for this reason that animal-derived antibodies are creating very significant societal benefits.
- Are of the opinion that naïve or synthetic libraries and accompanying *in vitro* maturation technology cannot provide the same guarantees to result in an optimal antibody as animal immunisation can. Synthetic antibodies are less 'developable' and have a higher failure rate during clinical development.
- Are witnessing the important role that animal-derived antibodies are playing in our current efforts to overcome the COVID-19 pandemic, not only in COVID-19 related

¹ EURL ECVAM Recommendation on Non-Animal-Derived Antibodies, published 15 May 2020.



research but also as potential prophylactic and therapeutic agents, and in diagnostics and epidemiology.

The EU-LIFE alliance therefore:

- Considers that the immunisation of animals for the generation of high-quality antibodies remains highly necessary, both for scientific research and for diagnostic and therapeutic applications.
- Is of the opinion that a blunt ban on the immunisation of animals for the generation of antibodies but also a phase-out would lead to a significant loss of societal benefits. It would create a serious handicap for European research institutions resulting in slower R&D trajectories, lead to R&D moving away from Europe, and potentially result in European patients and consumers being deprived of the best possible products.
- Supports the use of naïve or synthetic antibody libraries where they offer a realistic perspective to select an optimal antibody for the application, and on the condition that the antibody libraries and the accompanying technologies are accessible under reasonable conditions.

The EU-LIFE members attach high importance to animal welfare and replace the use of animals where there is a true alternative. When animals are used to generate an antibody, the number of animals is reduced to the lowest number possible, for instance by immunising with cocktails of antigens, and optimized animal-friendly adjuvants are used that do not cause discomfort.

EU-LIFE, encompassing 15 leading research institutes, more than 550 independent research groups, 125 research infrastructures and over 7500 researchers and staff is fully committed and willing to collaborate with EURL ECVAM and other authorities in the improvement of alternatives for animal testing.

Barcelona, 13th october 2020

About EU-LIFE

EU-LIFE is an alliance of research centres whose mission is to support and strengthen European research excellence (www.eu-life.eu). EU-LIFE members are leading research institutes in their countries and internationally renowned for producing excellent research, widely transferring knowledge and nurturing talent. Since its foundation in 2013, EU-LIFE has been an active stakeholder in European policy participating regularly in the EC policy dialogue.

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For more information

Marta Agostinho, PhD | EU-LIFE Coordinator

Email: marta.agostinho@eu-life.eu | Mobile: +34619570820 | <http://eu-life.eu/>