Protection of animals used for scientific purposes

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This Communication sets out the Commission's legal and political conclusions, the actions it intends to take and the reasons for taking these in line with Regulation (EU) No 211/2011 on the Citizens' Initiative (Stop Vivisection).

"Stop Vivisection" is the third European Citizens' Initiative submitted to the European Commission on 3 March 2015. It was signed by 1.17 million citizens.

The Initiative asks the Commission:

- to abrogate Directive 2010/63/EU on the protection of animals used for scientific purposes and put forward a new proposal aimed at phasing out the practice of animal experimentation, making compulsory the use - in biomedical and toxicological research - of data directly relevant for the human species.

The organisers underline that (i) there are clear ethical objections of EU citizens to animal experiments; (ii) the animal model is not suitable to predict human responses and that animal testing hinders the development of new and more efficient methods in research.

Assessment of the citizens initiative: the Commission shares the Citizens' Initiative's conviction that animal testing should be phased out. This is the ultimate goal of EU legislation. However, the Commission:

- does not share the view that scientific principles invalidate the 'animal model'. Indeed, despite differences with humans, animal models have been the key scientific drivers to develop almost all existing effective and safe medical treatments and prevention measures for human and animal diseases;
- is of the opinion that animal experimentation does not pose an obstacle to developing alternative research tools. The use of animals in research actually provides a mechanistic understanding of the biology of animals and humans, which enables the development of more ethical, cost-effective, predictive and faster alternative methods. The Commission recognises the limitations of both animal models and alternatives, and constantly follows up and supports new developments for improved predictive methods.

Continued need for Directive 2010/63/EU: the Directive states that the final goal is a full phasing out of animal testing, but acknowledges that animal use is still necessary on the way to reaching this goal. Directive 2010/63/EU modernised and further harmonised rules on animal use across the EU in line with the most ambitious global standards and hence greatly increased the welfare of animals in scientific research and testing.

The Directive implements the Three Rs - to replace, reduce and refine animal use in Europe - and the Commission underlines the importance of continued efforts by all players, from Member States to the research community, to reach these goals.

At the same time, Directive 2010/63/EU is the catalyst for the development and uptake of alternative approaches, which is in line with the request of this Initiative.

Abrogating the Directive would not prevent the use of animals in experiments. It would instead deregulate the way in which such experiments are carried out, make the animals concerned more vulnerable and hinder the perspectives of developing alternatives. The Commission underlines that, for the time being, animal experimentation remains important for protecting human and animal health, and for maintaining an intact environment. It therefore does not intend to submit a proposal to repeal Directive 2010/63/EU and is not intending to propose the adoption of a new legislative framework.

Actions to be taken: the Commission will take the following actions to accelerate the development and uptake of non-animal approaches in research and testing:

1. Accelerating progress in the Three Rs through knowledge sharing: translating knowledge across disciplines and sectors accelerates progress in the Three Rs. Relevant knowledge is wide-ranging and can include scientific understanding of fundamental biological processes, how to refine animal experiments to minimise potential pain and suffering, how to optimally design non-animal approaches to tackle research questions or assess the safety of a substance, or how to characterise and standardise novel models to ensure that they are fit-for-purpose. A number of platforms and networks exist that contribute greatly to the advancement of the Three Rs, some of which are facilitated by the Commission. However, the systematic sharing of information and knowledge could likely be further enhanced.

Building on existing activities of the Commission, relevant EU agencies and OECD, the Commission:

- will analyse technologies, information sources and networks from all relevant sectors with potential impact on the advancement of the Three Rs,
- will present by end 2016 an assessment of options to enhance knowledge sharing among all relevant parties. The assessment will consider how to systematically accelerate knowledge exchange through communication, dissemination, education and training.

2. Development, validation and implementation of new alternative approaches: the Commission will continue to support the development, validation and implementation of alternative approaches for regulatory and research use. This will include close cooperation between the Commission, Member States and international organisations and be supported, as appropriate, by EU programmes.

3. Enforcement of compliance with the Three Rs principle and alignment of relevant sector legislation: the Commission will actively monitor compliance with Directive 2010/63/EU, in particular the Three Rs principle. By end 2016, the Commission will examine regulatory requirements in the relevant sector legislation mandating animal testing to assess if the legislative text enables an efficient up-take of available alternative approaches.

4. Engaging in a dialogue with the scientific community: the Commission will stay in close dialogue with the scientific community at EU and

international level to identify alternative test methods, and will organise a conference by end 2016 on how to advance towards the goal of phasing out animal testing. The Commission urges the Member States, acting within their competences, to take account of the concerns raised in this initiative and to step up their efforts to fully implement and enforce Directive 2010/63/EU, and to actively participate in the development of alternative approaches.