

To the attention of

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**CONTENT: Italian transposition of Directive 63/2010/EU of the European Parliament and the Council on the protection of animals used for scientific purposes adopted on 22<sup>nd</sup> September 2010.**

The Directive 63/2010/EU on the protection of animals used for scientific purposes has replaced the previous Directive 86/609/EEC, which aim at abolishing disparities between legislative, regulatory and administrative provisions of Member States regarding the protection of animals used for experimental purposes or other scientific intentions, in order to avoid barriers in the internal market.

The Directive has been properly transposed into the majority of Member States, though not in Italy.

The new European legislative framework was transposed in Italy with the Legislative Decree 26/2014, which however prescribes more restrictive constraints than the Directive.

**Prohibition of using animals for researches on organ xenotransplantations and on substances of abuse.**

The Italian Legislative Decree 26/2014 prohibits the use of animals in the research on organ xenotransplantations (art. 5, par. 2, lett. d). This practice is largely used in experimental treatments for very severe diseases, as a routine technique in any biomedical research laboratory.

This provision could prevent the continuation of research aiming at creating organs fully compatible with the recipient organism (human being) which is used for organ transplantations in humans, starting from the insertion into a host animal through injection of induced stem cells. It would also prevent the production of biological heart valves derived from swine, consequently obstructing the treatments of aortic stenosis and damaged heart valves.

In this context, extremely harmful circumstances will occur regarding both the progress of research and the fulfilling of patients' requests.

Moreover, the prohibition of the use of animals in the research on substances of abuse (art. 5, par. 2, lett. e) will stop any research aiming at investigating the mechanisms of action of such substances. These substances are becoming increasingly widespread with devastating effects in terms of permanent damages (e.g. neonatal withdrawal syndrome, caused by using drugs/medicines throughout pregnancy). More generally, it will endanger research on eating disorders, such as bulimia and anorexia.

The Italian Legislative Decree 26/2014 introduces a three-year moratorium for the entry into force of such prohibitions (art. 42, par. 1) and it allows the continuation of research activities until 31<sup>st</sup> December 2016.

However, it already affects the possibility to have access to European grants and funding (on issues subject to prohibition) and it consequently reduces Italy's research ability within international forums.

### **Prohibition of using animals in university courses**

The Italian Legislative Decree 26/2014 prohibits the use of animals in university courses, except for physicians and veterinaries (art. 5, par. 2, lett. f). The large majority of experiments in the laboratories is however performed by biologists, pharmacists, bio-technologists, who will be prevented to get an adequate education during university studies. The Italian Legislative Decree thus undermines practical training of great part of future Italian researchers, putting them in a position of competitive disadvantage compared to other Member States' colleagues who may benefit from better training, thus having more opportunities to enter the job market and the research community.

### **Prohibition of breeding dogs, cats and non-human primates**

The Italian Legislative Decree 26/2014 prohibits to breed dogs, cats and non-human primates, but it allows their use over the Italian territory (art. 10, par. 5). This provision lead to the closure of all Italian breeding centers – many of them connected with academic activities – and it implies the need to purchase abroad animals to be used for experiments. There will be a deterioration in the treatment of animals, who will be forced to bear long and stressing journeys to be carried to the Italian research centers. Moreover, a high transport costs will be faced.

### **Conclusions**

The implementation of the Directive required to Member States to adopt high standard of animal protection, in order to avoid the distortions of internal market resulting from disparities among national legislations. Therefore the legislation has to ensure the balance of two opposite needs: the protection of animals used for experimental purposes, and equal conditions for Member States' companies and research bodies in developing substances or products freely marketed in the EU.

Considering that the free movement of goods, services and capitals over the territory of the Member States, as well as the free, fair competition among companies established over the EU territory, are fundamental principles of the European Union, the Italian Legislative Decree 26/2014 does not respect these principles. It undermines the training of entire categories of future scientists and it establishes a set of conditions which seriously jeopardizes the future of the Italian research compared to the other European countries.

Aware of the difficulties to reach a balance among different and sometimes opposite requests, we appreciate the positive work carried out at European level, which led to the approval of Directive 63/2010/EU.

**Given the importance of the results achieved by the scientific research so far, as well as the future outcomes, we hereby represent the concerns of the Italian Research and we ask the European Commission to carefully assess the national legislation in order to align it with the fundamental principles of the European Union.**