

A wake-up call for European life science

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The decision by the Brescia Court of Appeals in Italy to uphold the guilty sentence on the management of Green Hill, a beagle breeding facility, is testament to the political reach of anti-animal research activists in Italy. The ruling is evidence, if it was needed, of the threat that activist groups and their political allies pose to biomedical research using animals in Europe. Italian activists had kept up a relentless campaign against Green Hill in the Lombardy region in Northern Italy. During a protest in 2012, a large group of people raided Green Hill, damaging the facility and stealing animals. Protesters were initially arrested, but the local court closed down the Green Hill facility and allowed the campaign groups to rehome all of the animals.

The Green Hill company was cleared of all charges in 2013, but the accusations were then redirected against four individuals working for Green Hill. Three of the individuals were found guilty of animal cruelty under laws written for companion animals. These convictions have since been upheld after an appeal. Green Hill's lawyers have announced that they will take the case to the Supreme Court of Cassation, Italy's highest court of appeal. The Green Hill site remains closed.

The antipathy toward animal research in Italy became clear again in 2015 when anti-animal research activists in Europe, mainly from Italy and Germany, collected over 1 million signatures for a European Citizens Initiative. This process allows citizens to request that the European Commission—the executive body of the European Union (EU) responsible for proposing legislation and implementing decisions—initiate a legislative proposal, in this case to phase out animal research. The European Commission saw sense and rejected the European Citizens Initiative. In doing so, it made a robust defence of the use of animal

models in research, but outlined four actions that the European Commission will take to accelerate the development and uptake of alternative methods in the context of Directive 2010/63/EU (*Official Journal of the European Union* L276, 33–79; 2010).

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Directive 2010/63/EU, on the protection of animals used for scientific purposes, sets the regulatory framework governing animal research in the 28 member countries of the EU. This legislation is due for mandatory legal review by the European Commission. The review is currently under way and will finish in 2017. The European Commission will evaluate the impact of Directive 2010/63/EU and assess whether it benefits or hinders scientific progress and the cultural change on animal welfare that was anticipated, in particular, harmonising measures to improve animal welfare and wider adoption of the 3Rs. The review will also seek particular feedback on the use of non-human primates in research.

Many in the research community saw the European Citizens Initiative as a dry run by activists, preparing them for the Directive 2010/63/EU review. In the view of individuals that are fundamentally opposed to animal research, Directive 2010/63/EU legitimizes animal research, impedes scientific progress and should be abolished. Demonstrating the opposite is key to maintaining the EU as a vibrant center of biomedical research and innovation in the

world. Directive 2010/63/EU is an essential piece of legislation that anyone in the EU planning or performing research involving live animals must follow. It sets the highest mandatory protection standards worldwide and seeks to reconcile the EU's need to continue doing research with concerns for animal welfare. Each member country of the EU transposed—or passed—Directive 2010/63/EU into its own national law.

There is no doubt that animal rights organizations behind the European Citizens Initiative gained support and momentum from activist campaigns and policy makers in Italy. The Italian transposition of Directive 2010/63/EU was made with major restrictions on research using animals. The law passed in Italy prohibited performing xenotransplants (organ transplants between two different species); prohibited the use of animals in studies researching substances of abuse; prohibited the breeding of non-rodent animals for research purposes in Italy; and imposed mandatory anaesthesia for every pain-inducing procedure, including ones as mild as blood sampling. The developments in Italy and the mobilization behind the 2015 European Citizens Initiative are a sharp reminder that we ignore low level activist campaigns at our peril. Although the European Citizens Initiative was defeated, activists believe that they have the wind in their sails. They are confident in their characterization that animal research impedes good science, and they will be making this claim as the review process continues.

Events in Italy and the European Citizens Initiative should be seen as a wake-up call to life science in Europe and beyond. We should not sleepwalk through the review of Directive 2010/63/EU—if we do, we may awaken to a nightmare situation in which animal research sees itself restricted by unworkable regulations.

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