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EAMBES newsletter
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Ongoing debate on animal testing

Animal testing is being subject of a warm debate at the EU level, following a public hearing held in the European Parliament on 11 May 2015 with the organisers of the 'Stop Vivisection' initiative.

The 'Stop Vivisection' campaign is an Italian-based pan-European initiative launched by citizens, signed by 1.2 million people, calling for "*the European Commission to abrogate directive 2010/63/EU on the protection of animals used for scientific purposes and to present a new proposal that does away with animal experimentation*".

The organizers of the initiative had the opportunity to present it to a joint session of several European Parliament committees: the Committee on Agriculture and Rural Development (AGRI) in association with the Committee on Petitions (PETI), the Committee on the Environment, Public Health and Food Safety (ENVI) and the Committee on Industry, Research and Energy (ITRE). The petitioners invited the Parliament to prompt an open debate, moving away from the predetermined convention that animal models are necessary.

The debate was controversial, with MEPs divided. On one hand, some positioned themselves in favour of the initiative, agreeing on the need to encourage and support the development of alternative methods, to facilitate the validation process and to ensure these methods become mandatory. On the other hand, other MEPs claimed that animal testing is crucial for the advancement of medical research and for the protection against severe diseases.

The voice of science was represented by Professor Francoise Barré, 2008 Nobel Laureate in Physiology or Medicine for her role proving that HIV causes AIDS, who put forward a very strong case for the importance of animal research in advancing medicine,

The Vice-President of the European Commission, Mr Jyrki Katainen, confirmed that the Commission will provide a formal response to the initiative by 3 June 2015 and agreed to the suggestion of the petitioners to organise a scientific conference in 2017 to evaluate the validity of animal research.

Although, it seems unlikely that the Commission repeals or alters the 2010 Directive on Animal Testing, the campaign may have make some headway in altering future policies.

In light of this, and as a response to this campaign, EAMBES, together with the Center for Alternatives to Animal Testing (CAAT) and the Virtual Physiological Human Institute for Integrative Biomedical Research (VPH), is working on a joint letter to reflect the position of a coalition of scientists on this controversial topic.

Juncker Plan: Horizon 2020 still to be cut

On 28 May 2015 an agreement was reached on the European Fund for Strategic Investments (EFSI) after 57 hours of negotiation in 8 rounds of trialogue between the European Commission, European Parliament and Council of the European Union.

The Regulation proposing a European Fund for Strategic Investments (EFSI), also known as the "Juncker Plan", aimed to mobilise at least € 315 billion in an investment plan to get Europe growing again. The EFSI had immediately received criticism as the proposal included taking €2.7 billion from Horizon 2020, heavily impacting basic research and more generally, innovation in the EU.

The result of the trialogue received a mixed response. The European Parliament had hoped to protect the Horizon 2020 and Connecting Europe Facility (CEF) budgets, with the Commission and the Council of the European Union both recommending cutting these mechanisms. While this was not nearly as successful as the Parliament hoped, the position of the political groups is that still made important negotiations.

However, though the consolidated text is not available, reports indicate that 2.2 billion Euros will be committed from the Horizon 2020 research budget. This is a reduction of 500 million Euros from the original commitment with 500 million Euros also being saved from CEF. The trialogue negotiations have protected a total of 1 billion Euros from Horizon 2020 and CEF which means that 1 billion will be found in the margins of the EU budget to compensate.

The most favourable result for the European Parliament is that the annual budgetary procedure is now central to the financing of the EFSI rather than an irrevocable budgetary commitment which the Commission and Council had originally insisted upon. This means that all political groups have committed to working each year in the Budget Committee to minimize the actual money withdrawn from Horizon 2020. It can be therefore presumed that each year, MEPs will work to find budgetary flexibilities to reduce the money that they commit from Horizon 2020.

Also on a positive note, the 500 million saved in Horizon 2020 commitments means that the European Research Council budget and the Marie Skłodowska-Curie actions, which form the 'Spreading Excellence and Widening' pillar of Horizon 2020, have been protected. This was

seen as a bottom line in negotiations and to this extent, negotiators will be pleased to have protected some basic research grants.

MEPs will continue to work on the 2016 budget to see how they can reduce the impact on research. Furthermore, the Commission will now be under pressure to back up its statements that EFSI funds would be able to enhance the European research and innovation framework. Finance Ministers are now expected to approve the Regulation at the Economic and Financial Affairs Council on 19 June 2015 and the European Parliament plenary vote on the Regulation will take place on the 24 June so that the EFSI will be operational by September.

Towards a Digital Single Market

On 6 May 2015, the European Commission published the Communication on a Digital Single Market Strategy for Europe[1], unveiling its detailed plans to create the Digital Single Market, one of the ten priorities of the President-elect, Mr. Jean-Claude Juncker.

The Strategy includes a set of targeted actions to be delivered by the end of 2016 and built on three pillars: (1) better access for consumers and businesses to digital goods and services across Europe; (2) creating the right conditions and a level playing field for digital networks and innovative services to flourish; (3) maximising the growth potential of the digital economy.

Objectives include a revision of copyright rules to reflect new technologies, and to make them simpler and clearer. In this regard, The Commission will make legislative proposals before the end of 2015 to reduce the differences between national copyright regimes and allow for wider online access to works by users across the EU, including through further harmonisation measures. This may be relevant for EAMBES members as this will very likely deal with the IPR of software, an area seen as fragmented and in need of policy attention.

Also of relevance is the fact that one of the key sectors foreseen under the Digital Single Market Strategy relates to eHealth and e-Care. The Commission defends the opportunities that digital technologies for health and care offer not only for citizens and health and care providers, but also for industry, "*by combining the high-tech, ICT, medical devices, pharmaceuticals, biotechnology and healthcare sectors*"[2] and allowing e-health and e-care solutions to overcome the barriers that prevent them from benefiting from the large potential of the internal EU market.

Within the second pillar, an integrated standardisation plan will be launched to identify and to define key priorities for interoperable standards, with a focus on essential sectors such as health. This would not only facilitate biomedical research, but the Commission expects improvements in interoperable ICT solutions and European standards to lead to increased data security and integrity to underpin citizens' confidence and trust in using e-health and m-health solutions. The Commission will set up a strategic forum for Member States and European Standard organisations to jointly discuss common priorities.

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[1] European Commission. 6 May 2015. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. A Digital Single Market Strategy for Europe. http://ec.europa.eu/priorities/digital-single-market/docs/dsm-communication_en.pdf

[2] European Commission. 6 May 2015. Commission Staff Working Document. A Digital Single Market Strategy for Europe - Analysis and Evidence. http://ec.europa.eu/priorities/digital-single-market/docs/dsm-swd_en.pdf

As a next step, with the backing of the European Parliament and the Council, the Digital Single Market should be completed as soon as possible.

The Competitiveness Council of the European Union already had a first discussion on the digital single market strategy on 28 May 2015 and adopted Conclusions on the digital transformation of European industry[3]. Ministers agreed that the strategy covers the most important issues for completing the digital single market and many referred to the importance of suitable copyright rules, interoperability, digital skills, increase the level of confidence and effective data protection rules. The Conclusions recognise the importance of the digital transformation also for the healthcare industry and the relevance of standards for the competitiveness of eHealth.

The outcome of the exchange of views and the conclusions will be taken into account in the discussions on digital single market policy planned at the European Council on 25-26 June 2015

The Communication from the Commission is available here and the Council Conclusions can be accessed here.

Research, high in the Council's agenda

On the occasion of the last Competitiveness Council, held in Brussels on 28 and 29 may 2015, Minister focused research-related topics, in the frame of targeted actions to produce tangible results in terms of economic growth and job creation. They covered the following issues.

Council conclusions on the European Research Area Roadmap and a more effective governance

The Council adopted Conclusions on the European Research Area Roadmap and a separate set of conclusions on reviewing ERA governance.

On the first ones, the Council endorsed the roadmap 2015-2020 for the European Research Area (ERA), which aims at identifying and focusing on measures that can provide the greatest benefits for Europe's science, research and innovation systems.

The conclusions call on the member states and the Commission to start the implementation of the top action priorities identified in the roadmap through appropriate actions in their action plans or strategies by mid-2016.

On its Conclusions on the review of the ERA advisory structure, the Council set out the next steps to review the governance to make the advisory structure more efficient and effective.

The advisory work for the development of the ERA is currently undertaken by the European Research Area and Innovation Committee (ERAC) and a number of other different ERA-related groups, which include the European Strategy Forum on Research Infrastructures (ESFRI), the Strategic Forum for International Science and Technology Cooperation (SFIC), the High Level Group on Joint Programming (GPC), the Helsinki Group on Gender in Research and Innovation (HG), the ERA Steering Group on Human Resources and Mobility (SGHRM) and the ERAC working group on knowledge transfer (KT).

[3] Council of the European Union. Draft Council conclusions on the digital transformation of European industry. http://data.consilium.europa.eu/doc/document/ST-8993-2015-INIT/en/pdf

Also on the ERA but on a different note, the upcoming Luxembourgish delegation informed the ministers that the Presidency's work programme on competitiveness will endeavour to boost initiatives that will contribute to the implementation of the European Research Area.

The Conclusions are available here and here.

Council conclusions on open, data-intensive and networked research as a driver for faster and wider innovation

The Council adopted conclusions on open, data-intensive and networked research as a driver for faster and wider innovation, supporting the establishment of the right framework conditions for research and innovation focused on big data and for strengthening the whole data value chain in Europe. The Conclusions stress the importance of data for digital transformation of industry.

They can be accessed here

Debate on open and excellent European science: "Science 2.0"

The Council held a policy debate on open and excellent science, as a follow up to the Science 2.0 public consultation, carried out by the Commission from July to September 2014 in order to gather the views of stakeholders on the future of science.

Many delegations supported the main thrust and expressed interest on the idea of developing a European open science agenda, which could contribute to the further development of the ERA and to increase the quality and impact of science as well as spreading excellence and widening participation in research and innovation.

As an essential precondition, it was outlined the need to adequately and actively engage in the open science process researchers, students, universities, funding bodies, businesses and other stakeholders.

Among other specific actions that could be taken to move forward towards an open science wide- concept, it was mentioned:

– To remove barriers to the free flow of data taking into account adequate protection to prevent abuses;

– To design appropriate incentives and develop common standards for data sharing and promote data literacy;

– To facilitate greater access to publicly funded scientific publications;

– To integrate open science into education programmes.

Some countries announced that they are starting to integrate aspects of open science into their national programmes.

EU funds robot-based technologies to speed up rehabilitation

In January 2015 took off RETRAINER, a project aiming at developing robot-based technologies to speed up the rehabilitation of patients who have suffered a stroke, by facilitating the recovery of arm and hand function. Partially funded by Horizon 2020, the EU framework programme for research and innovation, the project is due to receive 2.8 million euro over 4 years.

The consortium, led by ABACUS, a company focused on the design and development of technologically advanced products and services, and 9 partners from Austria, Germany, Italy and Switzerland, will be working on two systems that could be either used in combination or as a stand-alone: RETRAINER S1 AND RETRAINER S2.

RETRAINER S1 is a robot intended to support the user when necessary and to train and improve the mobility of the limb when there is residual functionality. Arm movements are supported by the combined action of a passive exoskeleton for weight relief and Neuromuscular Electrical stimulation (NMES) delivered to several arm muscles in a controlled manner. RETRAINER S2 consists on a wearable NMES system with multiple arrays of electrodes for hand rehabilitation facilitating the grasping function.

The systems will undergo control clinical trial with end users to assess their efficacy in rehabilitation. Certification and qualification of the system will be pursued.

More information on the project available here.