



TEXTS ADOPTED

P9_TA(2021)0387

Plans and actions to accelerate a transition to innovation without the use of animals in research, regulatory testing and education

European Parliament resolution of 16 September 2021 on plans and actions to accelerate the transition to innovation without the use of animals in research, regulatory testing and education (2021/2784(RSP))

The European Parliament,

- having regard Articles 13 and 114 of the Treaty on the Functioning of the European Union,
- having regard to Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes¹,
- having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (the ‘REACH Regulation’)²,
- having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC³,
- having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products⁴,
- having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products⁵,

¹ OJ L 276, 20.10.2010, p. 33.

² OJ L 396, 30.12.2006, p. 1.

³ OJ L 309, 24.11.2009, p. 1.

⁴ OJ L 167, 27.6.2012, p. 1.

⁵ OJ L 342, 22.12.2009, p. 59.

- having regard to its resolution of 3 May 2018 on a global ban to end animal testing for cosmetics¹,
 - having regard to the Council conclusions of 15 March 2021 entitled ‘Sustainable Chemicals Strategy of the Union: Time to Deliver’ (6941/21),
 - having regard to the Commission report of 5 February 2020 entitled ‘2019 report on the statistics on the use of animals for scientific purposes in the Member States of the European Union in 2015-2017’ (COM(2020)0016),
 - having regard to the Commission communication of 30 September 2020 on a new European Research Area (ERA) for Research and Innovation (COM(2020)0628),
 - having regard to the Commission communication of 25 November 2020 on a Pharmaceutical Strategy for Europe (COM(2020)0761),
 - having regard to the Commission communication of 11 December 2019 entitled ‘The European Green Deal’ (COM(2019)0640),
 - having regard to the Commission communication of 27 May 2020 entitled ‘Europe’s moment: Repair and Prepare for the Next Generation’ (COM(2020)0456),
 - having regard to its resolution of 10 July 2020 on the Chemicals Strategy for Sustainability²,
 - having regard to Special Eurobarometer 340 on Science and Technology,
 - having regard to the second interim report on the online consultation on the Future of Europe and to the key conclusions from the citizens’ dialogues and citizens’ consultations,
 - having regard to the Commission communication of 3 June 2015 on the European Citizens’ Initiative ‘Stop Vivisection’ (C(2015)3773),
 - having regard to Rule 132(2) and (4) of its Rules of Procedure,
- A. whereas Directive 2010/63/EU on the protection of animals used for scientific purposes sets out the final goal of the ‘full replacement of procedures on live animals ... as soon as it is scientifically possible to do so’ and whereas it underlines that the use of animals for such purposes should only be considered where a non-animal method is unavailable; whereas, however, there has been little change in the overall number of animals used for scientific purposes since the entry into force of this directive, according to the latest data of 2018;
- B. whereas the directive requires transparency in the use of animals in science and applies to the use of animals in all disciplines, from basic research to applied research, the development of medicines and the safety testing of chemicals; whereas there is still a lack of transparency; whereas all Member States have enacted it in national legislation and whereas all sector-specific pieces of legislation, such as those pertaining to

¹ OJ C 41, 6.2.2020, p. 45.

² Texts adopted, P9_TA(2020)0201.

pharmaceuticals, food or chemicals, must be in line with the objectives of the directive, meaning that the use of live animals should only occur if there are no suitable alternatives available; whereas this alignment is necessary to protect human and animal health and the environment today;

- C. whereas previous animal testing has contributed to advances in developing treatments for human health conditions, as well as medical devices, anaesthetics and safe vaccines, including COVID-19 vaccines, and has also played a role in animal health;
- D. whereas in 2017 the use of animals for scientific purposes was reported 9,58 million times; whereas the main purpose was research (69 %), followed by regulatory use to satisfy legislative requirements (23 %) and routine production (5 %); whereas among the testing carried out for regulatory purposes, the majority involved medical products for humans (61 %), followed by veterinary medicinal products (15 %) and industrial chemicals (11 %)¹; whereas non-human primates have been used for such testing in some parts of the EU and many other types of animals have been used for scientific purposes every year; whereas in a single year up to 12 million² animals are bred and killed for the purpose of animal testing without being used in actual experiments;
- E. whereas the toolbox of non-animal testing models is growing and shows the potential to enhance our understanding of diseases and accelerate the discovery of effective treatments; whereas this toolbox includes, for example, new organ-on-chip technology, sophisticated computer simulations, 3-D cultures of human cells for drug testing and other modern models and technologies;
- F. whereas the Commission's Joint Research Centre (JRC) has produced a series of reports listing and describing advanced non-animal models in seven disease areas, with a view to accelerating the development of these technologies; whereas, however, EU research, innovation and education initiatives should be fully aligned with the priorities identified in these reviews;
- G. whereas, while formal encouragement for non-animal methods is unique to the EU, there are bureaucratic hurdles to their acceptance, their use is not properly enforced and funding for their development remains inadequate;
- H. whereas European citizens have consistently demonstrated support for an end to the use of animals for scientific purposes;
- I. whereas within the Commission, the Directorates-General for Environment, for Health and Food Safety, for Internal Market, Industry, Entrepreneurship and SMEs, for Research and Innovation and the JRC all have responsibilities for different areas of animal research and testing, and whereas there is no formal coordination mechanism to

¹ Report from the Commission to the European Parliament and the Council: 2019 report on the statistics on the use of animals for scientific purposes in the Member States of the European Union in 2015-2017, p. 16 (COM(2020)0016) <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0016&from=EN>

² Report from the Commission to the European Parliament and the Council on the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes in the Member States of the European Union, p. 7 (SWD(2020)0015) <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0015&from=EN>

ensure an active, coherent and synergy-based approach to achieving the full replacement of animals;

- J. whereas the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA) have put in place strategies to actively reduce and replace animal testing, but the European Chemicals Agency (ECHA) still has to put in place a reduction and replacement strategy and has asserted that immediate targeted investment is required in order to develop effective non-animal predictive toxicology methods and directly support regulatory objectives;
 - K. whereas the positive impact on animal welfare in the EU of the landmark ban on animal testing for cosmetics has successfully shown that phasing out the use of animal testing is feasible without jeopardising the development of the cosmetics sector; whereas, however, there are still regulatory requirements for continued animal testing for effects on workers handling chemical ingredients exclusively used in cosmetics, and their impact on the environment; whereas, nevertheless, the setting of clear deadlines for the phasing out of such testing in the EU has driven innovation in EU companies and has enjoyed public support;
 - L. whereas the replacement of animal testing by advanced non-animal methods will be necessary to achieve the Commission's ambitious health and environmental goals set out in the NextGenerationEU recovery plan and the European Green Deal, and whereas where validated non-animal alternatives are already available, these must be given priority;
 - M. whereas certain Member States have adopted national implementing measures that ensure a high level of protection of animals used for scientific purposes, while others only apply the minimum requirements laid down in Directive 2010/63/EU;
1. Calls on the Commission to improve coordination to achieve the goal set out in Directive 2010/63/EU by establishing a high-level inter-service taskforce, involving all key Directorates-General and agencies, to work with the Member States and relevant stakeholders to draw up an EU-wide action plan, with the aim of driving the active phase-out by reducing, refining and replacing procedures on live animals for scientific and regulatory purposes, as soon as scientifically possible and without lowering the level of protection for human health and the environment, while accelerating the development of the alternative animal-free methods, technologies and instruments necessary for change; stresses that a clear and ambitious timeline and list of milestones should be set out to incentivise progress;
 2. Highlights that past use of animals-based research has contributed significantly to advances in the treatment of many human health conditions and played a role in animal health, and stresses that although phasing out the use of animals for scientific purposes is the ultimate goal, non-animal methods are not yet available across all scientific research areas; underlines also that there are cases where animal experiments are still needed to gain scientific insights in the long search for an effective remedy for certain diseases due to the current unavailability of non-animal methods; highlights that the Joint Research Centre recognises that heavy reliance on animal testing can hinder

progress in certain fields of disease research¹, in which animal models fail to capture key features of human disease, and considers that moving towards alternative models could enable new breakthroughs acknowledges, furthermore, that experiments that are carried out on animals because of the unavailability of non-animal methods must only take place in optimal conditions that minimise pain, distress and suffering and protect the welfare of the animals concerned;

3. Underlines that the action plan should include ambitious and achievable objectives, reduction targets and timelines to be set under the overarching reduction and replacement goal in order to incentivise change, with concrete and coordinated actions accompanied by indicators, as are applied to other EU policy areas, and should use the ALURES statistical EU database as a point of reference, leading to absolute and sustained reductions in the number of animals used across the EU for scientific purposes;
4. Stresses that the plan should include, inter alia, proposals for better implementation and enforcement of existing initiatives, including a well functioning system of controls;
5. Highlights the need to deepen the European Research Area and for the plan to build on research undertaken in the EU to date and to include mechanisms for the preferential funding of non-animal methods across all EU research and innovation initiatives, as such alternative methods bring additional costs and investment needs; points, therefore, to the need for increased and targeted funding under Horizon Europe for advanced non-animal models; calls on the Commission, the Council and the Member States to make sufficient medium- to long-term funding available to ensure the fast development, validation and introduction of alternative testing methods to replace animal testing methods, particularly for key toxicological endpoints; calls on the Commission to fully implement its commitment to the grouping of substances and the use of generic risk assessments as important means to better protect human health and reduce animal testing;
6. Calls on the Commission to set reduction goals in consultation with relevant agencies, in particular ECHA and EFSA, through a more proactive implementation of the current regulations on the safety of chemicals and other products, and to support the reduction goals by using a fully connected and interoperable EU chemical safety database; recalls that Article 13 of REACH requires that the test method requirements be updated as soon as non-animal methods become available;
7. Highlights that the private sector can be actively involved in the plan, in particular companies willing to switch to non-animal models, as well as start-ups developing and perfecting them, through participating in collaborative approaches to phasing out animal testing; believes that government bodies must take on a coordinating role and enter into a positive and constructive dialogue with the sector, allowing for bottom-up solutions; calls for a better coordinated, cross-sectoral and EU-wide approach across all Member

¹ Dura, Adelaide; Gribaldo, Laura; Deceuninck, Pierre (2021): EURL ECVAM Review of non-animal models in biomedical research - Neurodegenerative Diseases. European Commission, Joint Research Centre (JRC) [Dataset] PID: <http://data.europa.eu/89h/a8fd26ef-b113-47ab-92ba-fd2be449c7eb>

States and all EU agencies, including via the cross-sectoral European Partnership for Alternative Approaches to Animal Testing;

Education and training

8. Urges the Commission to work together with Member States to prioritise actions to educate, train and retrain scientists, researchers and technicians in using advanced non-animal models and in sharing best practices, and to raise awareness of validated non-animal models both among safety assessment experts and among those involved in evaluating project proposals and attributing funding;
9. Stresses the need for a sustained training and education effort to ensure the widest possible knowledge of alternatives and processes in laboratories and among competent authorities;
10. Points out that academic institutions have an essential role to play in terms of promoting alternatives to animal testing in scientific disciplines and disseminating new knowledge and practices, which are available but not always widely used;
11. Highlights the need to work within international structures to speed up validation and acceptance of alternative methods, ensure knowledge transfer and provide financial support to non-EU countries, where scientists may be unaware of alternative methods and where testing facilities may lack the necessary research infrastructure;
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12. Instructs its President to forward this resolution to the Council and the Commission.