STOA workshop

The use of animals for scientific research in Europe

Participants’ booklet
The use of animals for scientific research in Europe

STOA Workshop
Tuesday, 28 June 2022, 14:00 - 16:00
Room SPAAK 7C50 & online via WebEx Events

Participants’ booklet
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1. Programme

WELCOME

Christian EHLER, MEP and STOA Chair

INTRODUCTORY REMARKS

Maria LEPTIN, President of the European Research Council

OPENING SPEECH

Laura GRIBALDO, European Union Reference Laboratory for Alternatives to Animal Testing (EURL-ECVAM, JRC)

SCIENTIFIC OPINIONS

Meritxell HUCH, Max Planck Institute of Molecular Cell Biology and Genetics, Dresden
Peter LOSKILL, Institute for Biomedical Engineering, Eberhard Karls University, Tübingen
Bart HAAGMANS, Erasmus MC, Rotterdam
Karin FORSBERG NILSSON, Dept. of Immunology, Genetics and Pathology, Uppsala University
Ana Isabel MOURA SANTOS, Animal Welfare Body, NOVA Medical School, Lisbon

Q&A SESSION

CLOSING REMARKS

Christian EHLER, MEP and STOA Chair

The event will be held in English only, without interpretation.
2. Introduction

Towards a science-based EU action plan to end the use of animals in research and testing – fast lane for animal protection or roadblock for scientific progress?

In September 2021 the European Parliament adopted a resolution on plans and actions to accelerate the transition to innovation without the use of animals in research, regulatory testing and education. This resolution calls for the Commission to, together with stakeholders and Member States, 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 animal testing for cosmetic products is prohibited in the EU since 2009, animal testing in research facilities and universities still takes place. Animals used for testing are mainly mice but also others such as, for example, fish or frogs. Notably, animal testing is forbidden inside the EU if alternatives are available. Nowadays, technical advancements raise hope on the feasibility to replace certain experiments, that today rely on the use of animals, with more advanced cell culture techniques (in vitro experiments that use cells grown in culture media). Reliable research on disease and therapies needs a realistic approximation of the real organism. A usual important limitation is that cells in the human body are exposed to a 3D environment while classic and standardised cell culture often works in a 2D environment with cells growing next to each other on a plate. Experiments with animals are often used to mimick the 3D environment that real cells are exposed to in the human tissue. However, advanced 3D tissue culture systems are now more widely available allowing to perform certain experiments in a realistic three dimensional environment. This is especially important in the context of neurobiology or cancer biology and has the potential to replace certain experiments that so far rely on animals. Nonetheless, it is important to acknowledge that 3D culture has limitations. For example, it cannot represent a whole organism with its interconnections with multiple organs and cellular structures. Many processes, especially in the field of cancer or immunobiology are characterised by a complex interplay between different parts of an organism. To completely abstain from the use of animals to test and study these interplays is up to date not possible.

The resolution of the European Parliament on plans and actions to accelerate the transition to innovation without the use of animals in research has to be seen in context with other EU initiatives. Within the HorizonEurope programm the European Union aims to create a favourable research environment and strengthen the position of Europe in driving innovation. Equally, recent efforts of the BECA committee at the European Parliament have defined ambitious goals to fight cancer in Europe.

The interplay of these different aims and goals calls for a science-based discussion about the potential of an action plan to both foster animal welfare and drive technological innovation, and about potential risks of jeopardising European’s top position in science and development in medical and biomedical research. The event should bring together scientific experts and stakeholders to provide insights on the state-of-play, areas for improvements and future perspectives.

The event will feature perspectives from different active researchers from various disciplines, including virology, immunobiology and neurobiology.
3. Welcome and introductory remarks

3.1. Christian EHLER, MEP and STOA Chair

Christian Ehler has been an MEP since 2004 and a member of the Parliament’s Committee on Industry, Research and Energy (ITRE) for over a decade. He has been one of the leading figures in the design and implementation of the EU research and innovation (R&I) framework programmes, as rapporteur for both Horizon 2020 and Horizon Europe. He is the initiator of an ITRE working group dedicated to closer parliamentary scrutiny of EU R&I framework programme implementation and he is First Vice-Chair of the EP think thank STOA.

One of Dr Ehler’s main priorities is to ensure Europe’s excellence in science, technology and innovation in all sectors, including health, digital and climate. As rapporteur for Horizon Europe, he has put forward a number of instruments to reduce the administrative burden for researchers and SMEs, and for boosting public-private partnerships contributing to achieving EU climate and digital goals. Dr Ehler plays an instrumental role within EPP as the group’s coordinator for the ITRE Committee.

In the European Parliament, Dr Ehler is also member of the Delegation for relations with the US, and substitute member of the Committee on Culture and Education, the Delegation for relations with Israel and the Delegation for the Mediterranean.

@MEP_Ehler
3.2. Maria LEPTIN, President of the European Research Council

Professor Maria Leptin is the President of the European Research Council (took office from 1 November 2021). Prior to that, Professor Leptin served as Director of EMBO from 2010-2021. She also established a research group in Heidelberg at the European Molecular Biology Laboratory (EMBL). The group studies the mechanics of shape determination during development. After completing her studies in mathematics and biology at the University of Bonn and the University of Heidelberg, Professor Leptin worked for her PhD at the Basel Institute for Immunology, Switzerland (1979-1983) studying B-lymphocyte activation under the supervision of Fritz Melchers.

In 1984 she moved, as a post-doctoral fellow (1984-1987) to the Laboratory of Molecular Biology (LMB), Cambridge, UK, where she started her research on the embryonic development of Drosophila, joining the laboratory of Michael Wilcox. This work laid the foundations for her future work in the field of molecular morphogenesis. In 1988, she was appointed as staff scientist at the same institution. As visiting scientists in Pat O’Farrell’s lab at the University of California, San Francisco (UCSF) she began her work on gastrulation which became the core of her research interests at the Max Planck Institute for Developmental Biology in Tübingen, Germany, where she worked as group leader (1989-1994).

In 1994, Maria Leptin became Professor at the Institute of Genetics, University of Cologne, Germany, where she still leads a research group. She spent sabbaticals as a visiting Professor at the École Normale Supérieure, Paris, France (2001) and as visiting scientist at the Wellcome Trust Sanger Institute, Hinxton, UK (2004-2005). Professor Leptin is an elected member of EMBO, the Academia Europaea and the German National Academy of Sciences (Leopoldina), and an Honorary Fellow of the Academy of Medical Sciences. She is also Foreign Member of the Royal Society since May 2022.

@mleptin
4. Speakers

4.1. Laura GRIBALDO, European Union Reference Laboratory for Alternatives to Animal Testing (EURL-ECVAM, JRC)

MD, PhD in Microbiology and Virology, she has years of experience in the field of testing for safety assessment. She set up and managed a transcriptomic platform for the development of standardized assays in toxicology and she was responsible to support a programme ensuring harmonisation and validation of procedures in genetic testing for diagnostics purposes. For the Public Health Unit, she worked on Rare Diseases, representing JRC at the EUCERD meetings for the establishment of the European platform for rare diseases registry. Today, she is responsible for the studies on non-animal models in biomedical research at the Chemicals Safety and Alternative Methods Unit, where she works in the field of knowledge sharing, dissemination, education and training.

Key message:
The principle of the Three Rs, i.e. Replacement, Reduction and Refinement of animal use in basic, applied and translational research, as well as for regulatory purposes is firmly anchored in EU legislation, full replacement of animal testing being the ultimate goal. New Approach Methodologies including a variety of innovative technologies, such as in vitro methods using 3D tissues and cells, organ-on-chip, computational models (including AI) and ‘omics (genomics, proteomics, metabolomics) technology are developed, evaluated and integrated in assessment frameworks with a view to improve the efficiency and effectiveness of chemical and product hazard and risk assessment in a variety of regulatory contexts. Important activities to promote the development and use of non-animal approaches are also pursued in the areas of basic and applied research, where most of the animals are used, as well as for education purposes.
4.2. Meritxell HUCH, Max Planck Institute of Molecular Cell Biology and Genetics, Dresden

Dr Meritxell Huch is a Lise Meitner Max Planck Research Group Leader at the Max Planck of Molecular Cell Biology and Genetics in Dresden. In 2007, she obtained her PhD at the Center for Genomic Regulation in Barcelona, Spain and in 2008, she moved to the Netherlands to study Adult Stem Cells under the supervision of Professor Hans Clevers at the Hubrecht Institute. There, she isolated and cultured, for the first time, adult stomach stem cells and proved that these can be maintained and expanded in culture as gastric organoids, which formed the first “mini-stomachs” structures in vitro.

Following these studies, Meritxell Huch moved her research focus to the understanding of tissue progenitors during regeneration. Research that is still the focus of her independent lab and where she has made very important contributions to our understanding of development, regeneration and disease. She described that liver cells can be unlimitedly expanded in vitro as liver organoids, which can be used to model human liver biology and disease in a dish. In addition, she found that adult mouse pancreas cells can also be expanded long-term in vitro, an accomplishment never achieved before. In February 2014, she joined the Gurdon Institute at the University of Cambridge as a junior Group Leader, to start her own lab. In 2019, Meritxell Huch was awarded the first Lise Meitner excellence program award from the Max Planck Society and moved her lab to the Max Planck Institute in Dresden, where she continues her research on understanding tissue regeneration and its implication in disease. Since becoming independent, her lab has established the first human liver cancer organoid model that recapitulates liver cancer in a dish; has described that hepatoblasts are heterogenous and can be clonally expanded as hepatoblast organoids and that epigenetic remodelling, in the form of DNA (hydroxy)methylation changes, is crucial to induce cellular plasticity during regeneration. For these achievements, she has received several awards including the Women in Cell Science Prize from the British society, the NC3Rs award for pioneer work with huge potential to reduce the number of animals in research, the EMBO young investigator award or the BINDER prize.

Key message:

The discovery of human biological principles and novel therapeutics for a wide-range of human diseases has greatly benefited from the emergence of novel in vitro culture systems that recapitulate tissues in a dish, such as organoid models or organ-in chip methodologies, among others. This has already enabled the reduction of the number of animals used in biology, toxicology and drug discovery. However, these are still reductionists systems that do not capture the complexity of the human organs neither the organ-to-organ communication. Hence, to gain holistic understanding of processes that occur at the level of the entire organism (e.g. secondary effects caused by a drug) animal studies are required and unavoidable.

@MeriHuchlab
4.3. Peter LOSKILL, Institute for Biomedical Engineering, Eberhard Karls University, Tübingen

Prof. Dr. Peter Loskill is W3-Professor for Organ-on-Chip Research at the Eberhard Karls University Tübingen and the Natural and Medical Sciences Institute (NMI) as well as Chair of the European-Organ-on-Chip-Society (EUROoCS). He graduated in 2012 from Saarland University with a PhD in Physics and thereafter worked as a postdoctoral fellow at UC Berkeley. In 2015, he was named as one of Technology Review’s “Innovators under 35 Germany” and awarded a Fraunhofer ATTRACT starting grant. He now heads the µOrgano-Lab and the 3R Center Tübingen for In vitro Models and Alternatives to Animal Testing. The interdisciplinary µOrgano-Lab (https://www.organ-on-chip.uni-tuebingen.de) combines approaches from engineering, biology, physics and medicine to generate and apply novel microphysiological tissue models recapitulating complex human biology in vitro. The 3R Center Tübingen (https://www.the3rs.uni-tuebingen.de) aims to provide all scientists in Baden-Württemberg with low-threshold access to novel alternative methods to animal testing.

Key message:

As a research community, especially in academic research, we have to manage to break with moulds and habits with respect to animal models. If we want to study human (patho)physiology, we need physiological models based on human tissue.

@pe_losk
4.4. Bart HAAGMANS, Erasmus MC, Rotterdam

Bart Haagmans is associate professor at the Viroscience department, Erasmus Medical Center Rotterdam. His research line focusses on the pathogenesis of viral infections and especially those viruses that emerge through zoonotic transmission, as a basis for interventions and medical countermeasures. He is a recognized leader in the field of Coronaviruses. Studies on MERS led to a more detailed understanding of the biology of this emerging virus and to novel intervention strategies to contain the outbreak. Dr Haagmans brings a strong track record of fundamental and applied research on development of reagents and protocols for molecular and serological detection of emerging viral pathogens, including SARS-CoV-2. He has more than 230 publications on the identification and characterization of novel emerging viruses, their transmission and pathogenesis and the development of vaccines using in vitro as well as a range of in vivo animal models. He is an expert consultant for WHO, FAO and OIE.

Key message:

As a virologist I have been involved in studies on the pathogenesis of viruses and the development of intervention strategies to tackle newly emerging viruses. These studies included animal research to study the behavior of viruses in vitro as well as in vivo. Animal models developed were employed for example for the preclinical testing of novel vaccine candidates. The recent COVID-19 pandemic has demonstrated the need for appropriate models to evaluate the efficacy of interventions. One such example relates to the use of chloroquine in COVID-19 patients, initiated solely on in vitro experiments. The lack of efficacy of this drug in these patients was consistent with the inability of this compound to inhibit viral replication in animal models when tested after phase 1 studies using chloroquine failed. In a recent essay (Genzel et al., Current Biology 30, R1009–R1035, September 21, 2020) several researchers from the Netherlands argued that the use of animals is essential for the advancement of human and veterinary health. Advances on alternative methods have not progressed enough to be able to replace animal research in the foreseeable future. This trend has led first and foremost to a substantial increase in the administrative burden and hurdles required to make timely advances in research and treatments for human and animal diseases. The current COVID-19 pandemic clearly highlights how much we actually rely on animal research. COVID-19 affects several organs and systems, and the various animal-free alternatives currently available do not come close to this complexity. Although the aim to progress towards research without animals is laudable, we argue that the use of animals is essential for the advancement of human and veterinary health, and will likely be so for the foreseeable future. We trust that governments, policy makers and animal activists realize that animal studies are an indispensable part of fundamental and applied research and also essential for the development of new medical treatments. Instead of the current trend to curtail animal research, we should, while maintaining optimal care for each experimental animal, all work together to make animal research as efficient and effective as possible such that rapid responses to newly emerging health threats can be achieved.

@bart_haagmans
4.5. Karin FORSBERG NILSSON, Dept. of Immunology, Genetics and Pathology, Uppsala University

Karin Forsberg-Nilsson is Professor of Stem Cell Research at Uppsala University, Sweden, and SciLifeLab Group Leader. She is currently the Dean of the Faculty of Medicine at Uppsala University. Additionally, she is Guest Professor at University of Nottingham, UK.

Professor Forsberg-Nilsson obtained her PhD in 1992 from Uppsala University and did a postdoc in developmental neurobiology 1994-1996 at the National Institutes of Health, Bethesda; MD, USA. During the late 1990’s she held various leadership positions in the pharmaceutical and biotech industry. After returning to academia, she focused her research on neural stem cells and brain tumors. She has served as Deputy Secretary General at the Swedish Research Council and on the Innovative Medicines Initiative Scientific Advisory Board. Between 2014-2020 she was the Head of Department for the Department of Immunology, Genetics and Pathology at Uppsala University.

Professor Forsberg-Nilsson’s research focus is the intersection between cancer and neurobiology, combining neural stem cell knowledge with expertise in brain tumor biology and genetics. She is the author of >80 publications in subject areas ranging from growth factors, stem cells, regenerative neurobiology and brain cancer. The goal of her laboratory is an improved treatment of malignant brain tumors.

**Key message:**

The scientific community is committed to implementing the 3R principles. An unprecedented development of new research technologies contributes to reducing the number of animals used in research. However, these animal-free methods cannot entirely replace the use of animals. To continue to deliver new treatments for diseases, medical research still requires the use of animals to confirm hypotheses. Animals are thus indispensable to understand mechanisms involving the whole body, with complex communication between tissues and organs. The brain is a prime example of this. For example, induced pluripotent stem cells can be matured to become neurons in 3D structures termed "organoids". However, these “mini brains” only mimic early development, and not a mature brain. They also lack circulation and have no immune system, making them unfeasible to replace animals at the present time.
4.6. Ana Isabel MOURA SANTOS, Medical School, Universidade NOVA de Lisboa

Having a Biology degree and a PhD in Neurobiology has been teaching Physiology to Medical students at the NOVA Medical School of the NOVA University Lisbon since 1996. Started her research activities studying post-natal maturation of the central nervous system with animals models and has moved to the use of alternative methods for the study of ion channels expression during cell differentiation.

Was Animal Facility Manager between 1999 and 2014 and Vice Dean of the NOVA Medical School between 2014 and 2021. Has been President of the Portuguese Laboratory Animal Sciences Association - SPCAL between 2010 and 2013. Has been Honorary Secretary of Federation of European Laboratory Animal Science Associations - FELASA - from 2011 to 2017 and was FELASA President 2019-20. Served on the FELASA Accreditation Board for Education and Training as a full member from 2009 to 2018 where is an external expert since 2019. Is an AAALAC Ad Hoc expert since 2018.

Committed with openness and transparency has been part of the core group that wrote the original LAS Transparency declaration in Portugal in 2017. Is a member of the Board of the European Animal Research Association since January 2022. Since 2004 has organized several Laboratory Animal Science (LAS) training courses in Portugal. Chaired international LAS Scientific Congresses in Portugal and has participated as a member of several Scientific and Organizing Committees of European LAS Congresses.

Key message:

Directive 2010/63/EU places the greatest emphasis on the welfare of animals in research, as reflected in the high standards required for issuing personal and project licenses, in all Member States. While non-animal methods have replaced some animal experiments, particularly in regulatory testing, biomedical research still depends deeply on studying full living organisms. They remain essential to understand the underlying mechanisms of disease and help us devise therapies to tackle them. If ‘Full Replacement’ is to be achieved, it will not be through popular petitions, regulations, deadlines or legal decisions, but through scientific developments. Moreover, giving priority to banning animal research would not only hamper biomedical advancements, but would also shift attention from the more readily achievable goal of ‘Full Refinement’, i.e. going beyond minimising and preventing animal harm, to maximize ‘positive welfare’ of the animals still necessary, allowing them ‘a life worth living’ and ideally ‘a good life’, while ensuring the quality of scientific results. Key steps for improvement should include fostering a Culture of Care in all establishments performing animal research, involving societal representation, furthering scientists’ and staff education and training in animal welfare through continuing professional development, and regular competence assessments. Consistent funding in the 3Rs research and not only on replacement and creating a living repository for the most recent refinements methods available may also be strategies to consider.
5. About STOA

5.1. Mission

The Panel for the Future of Science and Technology (STOA) forms an integral part of the structure of the European Parliament. Launched in 1987, STOA is tasked with identifying and independently assessing the impact of new and emerging science and technologies.

The goal of its work is to assist, with independent information, the Members of the European Parliament (MEPs) in developing options for long-term, strategic policy-making.

The STOA Panel

The STOA Panel consists of 27 MEPs nominated from eleven permanent parliamentary committees: AGRI (Agriculture & Rural Development), CULT (Culture & Education), EMPL (Employment & Social Affairs), ENVI (Environment, Public Health & Food Safety), IMCO (Internal Market & Consumer Protection), INTA (International Trade), ITRE (Industry, Research & Energy), JURI (Legal Affairs), LIBE (Civil Liberties, Justice and Home Affairs), REGI (Regional Development) and TRAN (Transport & Tourism).

Eva KAILI is the European Parliament Vice-President responsible for STOA for the second half of the 9th parliamentary term. The STOA Chair for the second half of the 9th parliamentary term is Christian EHLER with Ivo HRISTOV and Ivars IJABS elected as 1st and 2nd Vice-Chairs respectively.

The STOA approach

STOA fulfils its mission primarily by carrying out science-based projects. Whilst undertaking these projects, STOA assesses the widest possible range of options to support evidence-based policy decisions. A typical project investigates the impacts of both existing and emerging technology options and presents these in the form of studies and options briefs. These are publicly available for download via the STOA website: www.europarl.europa.eu/stoa/.

Some of STOA’s projects explore the long-term impacts of future techno-scientific trends, with the aim to support MEPs in anticipating the consequences of developments in science. Alongside its production of ‘hard information’, STOA communicates its findings to the European Parliament by organising public events throughout the year. STOA also runs the MEP-Scientist Pairing Scheme aimed at promoting mutual understanding and facilitating the establishment of lasting links between the scientific and policy-making communities.

Focus areas

STOA activities and products are varied and are designed to cover as wide a range of scientific and technological topics as possible, such as artificial intelligence, blockchain, 5G, genetic engineering, antibiotics resistance, internet addiction, face recognition, pollution, sustainable agriculture, COVID-19 and health in general.

These activities are clustered within three main thematic areas: Artificial intelligence & other disruptive technologies, The new Green Deal, and Quality of life. In addition, STOA’s work addresses four cross-cutting policy areas: Science, technology and innovation; Societal and ethical challenges; Economic challenges; and Legal challenges.
ESMH

The European Science-Media Hub (ESMH), operating under the political responsibility of the STOA Panel, is a platform to promote networking, training and knowledge sharing between the European Parliament, the scientific community and the media. The ESMH creates a network among policy-makers, scientists and media involving science, academia, educational and research entities, and professional associations of journalists and scientists.

For journalists and media representatives, the ESMH organises training sessions and workshops on current technological developments, both as subjects of their reporting and as means of facilitating their work. Via media monitoring and media intelligence tools, the ESMH follows the most popular topics in the field of science and technology on different platforms including journals, newspapers and social media.

The ESMH makes information available to journalists, other media and citizens about new scientific developments, as well as about scientific topics that attract media attention, and promotes information based on evidence.

Centre for AI (C4AI)

To intensify its activities in the field of artificial intelligence (AI), STOA has launched its Centre for AI (C4AI). C4AI was established by decision of the STOA Panel on 19 December 2019, and was announced at the high-level STOA workshop 'The Future of Artificial Intelligence for Europe', which took place on 29 January 2020 at the European Parliament in Brussels.

Within the context of STOA and based on decisions of the STOA Panel, C4AI produces studies, organises public events and acts as a platform for dialogue and information exchange on AI-relevant topics within the Parliament and beyond. In particular, it provides expertise on the possibilities and limitations of AI and its implications from an ethical, legal, economic and societal perspective. Through these activities, C4AI aims to contribute to the quality and coherence of discussion and policy-making as the EU seeks to coordinate its efforts and influence global AI standard-setting.
### 5.2. STOA Panel members

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AGRI: Agriculture and Rural Development
CULT: Culture and Education
EMPL: Employment and Social Affairs
ENVI: Environment, Public Health and Food Safety
IMCO: Internal Market and Consumer Protection
INTA: International Trade
ITRE: Industry, Research and Energy
JURI: Legal Affairs
LIBE: Civil Liberties, Justice and Home Affairs
REGI: Regional Development
TRAN: Transport and Tourism
5.3. STOA administration

**Directorate-General for Parliamentary Research Services (EPRS)**
Anthony TEASDALE, Director-General

**Directorate for Impact Assessment and European Added Value**
Wolfgang HILLER, Director

**Scientific Foresight Unit (STOA)**
Marcus SCHEUREN, Head of Unit

- Luisa ANTUNES
- Philip BOUCHER
- Andrés GARCÍA HIGUERA
- Vasco GUEDES FERREIRA
- Nera KULJANIĆ
- Zsolt G. PATAKI
- Antonio VALE

**European Science-Media Hub (ESMH)**
Svetla TANOVA, Coordinator
Vitalba CRIVELLO
Eszter FÁY
Carolien Martina NIJ ENHUIS
Emilia BANDEIRA MORAIS

**Assistants**
Michal HUBAR
Rachel MANIRAMBONA
Marie-Noëlle MPOLESHA MISENGA

**Trainee**
Tobias HOFFMANN

**Contact:**
Scientific Foresight Unit (STOA)
Directorate for Impact Assessment and European Added Value
Directorate-General for Parliamentary Research Services (EPRS)
European Parliament
Rue Wiertz 60
B-1047 Brussels
Tel. +32 2 284 1629
E-mail: stoa@europarl.europa.eu