EURACTIV

AN ANIMAL-FREE PATH TOWARDS EU'S SUSTAINABLE CHEMICAL AMBITIONS

EVENT REPORT | NOVEMBER 2021

https://eurac.tv/9UNr

With the support of

epaa
The European Partnership for Alternative Approaches to Animal Testing

AN ANIMAL-FREE PATH TOWARDS EU'S SUSTAINABLE CHEMICAL AMBITIONS

EVENT REPORT

https://eurac.tv/9UNr

Presented in October 2020, the EU chemicals strategy for sustainability is intended as a first step towards a zero pollution ambition for a toxic-free environment as a key part of the European Green Deal.

While its unveiling was widely welcomed as a step forward for human and environmental health, its presentation has sparked concerns from stakeholders, who warn that this would result in an increase in animals used for testing to fulfil its aims.

The question is, how can the EU maximise its sustainable chemical ambitions while also minimising the use of animals in scientific research?

In this Event Report, EURACTIV explores the steps that need to be taken in order to move towards animal-free science.

Contents

Two million animals stand in firing line of EU's new sustainable chemical ambitions

By Natasha Foote | EURACTIV.com

As such, panelists stressed that now is the time to revisit testing strategies, highlighting the potential that non-animal methodologies (NAMs) hold given that these can, in some cases, actually produce more accurate data. [Shutterstock / Jens Goepfert]

Requirements in the EU's chemical strategy for sustainability would see an additional two million animals used for testing unless a concerted effort is made to invest in alternatives to animal testing, stakeholders have warned.

Presented in October 2020, the chemicals strategy is intended as a first step towards a zero pollution ambition for a toxic-free environment as a key part of the European Green Deal.

While its unveiling was widely welcomed as a step forward for human and environmental health, its presentation sparked concerns at the time from stakeholders, who warned that this would result in an increase in animals used for testing to fulfil its aims.

And, with more details emerging about the strategy's ambitions, it seems these concerns are well-founded, according to stakeholders from the chemical industry.

Speaking at the annual conference of the European Partnership for Alternative Approaches to Animal Testing (EPAA), Dorothee Funk-Weyer, vice president of chemicals company BASF, pointed out that the dossier as it currently stands is already causing additional testing.

This means that, as the strategy's ambitions kick into gear to address the polymers of concern and place a stronger focus on neurotoxicity, immunotoxicity and endocrine

Continued on Page 5

Continued from Page 4

disruption, the expected associated developments of regulatory data requirements will further fuel this.

"All of [this] will lead to more testing," Funk-Weyer warned, estimating that more than two million additional animals would be required for this additional testing.

ONE SUBSTANCE, ONE ASSESSMENT

Green MEP Tilly Metz positioned herself as a staunch proponent of the chemicals strategy but warned that the number of animals used in testing will increase if it is not "implemented in the right way".

"Let us be clear, no one, or very few of us present today want less testing, but we want different testing without the use of animals," she stressed.

Specifically, stakeholders raised concerns over the proposed changes to the registration, evaluation, authorisation and restriction of chemicals (REACH) regulation, which Emily McIvor, member of the EPAA's mirror group, pointed out have been proposed without any impact assessment, "let alone one intended to estimate animal numbers".

Highlighting concerns over the "one substance, one assessment" approach, which aims to streamline chemical assessments, McIvor said that animal protection organisations and the regulatory scientists working within the mirror group both fear this could result in the loss of expertise in using non-animal approaches developed over the years.

Panellists stressed that now is the time to revisit testing strategies, highlighting the potential of non-animal methodologies (NAMs), given that these can in some cases actually produce more accurate data.

For example, BASF's Funk-Weyer pointed out that while they have their limitations for some more complex toxicology and whole organism tests, in many cases NAMs can also produce "more robust and less variable data".

This is because they do not have to comply with animal welfare regulations, she said, meaning that testers can conduct 'ring trials', or repeated tests from multiple laboratories, to corroborate data.

In comparison, in some cases just one positive reaction from one animal, which may have a particular sensitivity, may be sufficient for in vivo trials, she pointed out.

Furthermore, the test system can include human material, meaning there is no interspecies extrapolation needed, as is the case with animal studies, and, thanks to the fact that NAMs require less substance, they are often "cheaper and faster".

"Therefore it is necessary to prioritise the research, but also the funding for this research, to close this gap to prevent animal testing from being needed," Funk-Weyer said.

REFINEMENT: MINIMISING ANIMAL HARM, MAXIMISING SCIENTIFIC VALIDITY

In cases where techniques cannot be replaced or reduced, panellists stressed the need to refine them to minimise the stress of an animal used during animal testing.

"In other words, refinement aims to minimise animal harm while maximising scientific validity," Inês Mendes Preguiça from the Faculty of Medicine of the University of Coimbra, Portugal, explained.

Mendes Preguiça nabbed the topped spot in this year's 3Rs Science Prize, awarded by the EPAA to researchers and students who develop alternatives to animal testing, for her work developing a non-invasive and stress-free method (HaPILLness) of oral drug dosing for rodents during tests.

This is normally a "stressful and invasive" procedure via a cannula inserted directly into the rodent's stomach, the researcher explained. Not only is this traumatising for the animal, but it can actually sway research outcomes given that the animal's response to stress can create physiological changes, she pointed out.

Mendes Preguiça hopes her technique, currently undergoing the evaluation process for European patent protection, will help minimise the suffering of the millions of rodents used for animal testing each year while also optimising research outcomes.

Regulators should walk the talk on non-animal methodologies

By Gerardo Fortuna | EURACTIV.com

Alternatives to animal testing are already available for companies in their decisions on the safe use of ingredients, including in silico (biological tests carried out entirely in a computer), in vitro (experiments conducted outside of a living organism) and genomics data. [SHUTTERSTOCK/STELLAE]

With different chemical-related proposals on the table, it is crucial to ensure that EU legislation is adapted to not include testing on animals, according to an industry expert.

"I'm not a politician, I'm a scientist, and in my work, I always look at the best science that is available to make decisions on safety," Rob Roggeband, senior director at the multinational corporation Procter & Gamble (P&G), told EURACTIV in an interview.

Roggeband is the industry co-chair of the European Partnership for Alternative Approaches to Animal Testing (EPAA), a platform that brings together the EU executive and the private sector to promote alternative approaches to animal testing.

He said the EPAA mission is to build confidence with the regulator and accept these alternative methods.

However, the new EU's chemical strategy could lead to more animal testing, a concern expressed by stakeholders on several occasions.

Presented in October 2020, the chemicals strategy is intended as a first step towards a toxic-free environment as a key part of the European Green Deal.

"I'd like to look at this [chemical strategy] as an opportunity to make progress even faster on non-animal methodologies (NAMs)," he said.

Complete animal-free science is still out of reach as there are situations where animal testing is needed, particularly in pharmaceuticals.

"There may be situations where you still need to do an animal study. But I would want that to be the exception," he added.

SCIENCE IS FASTER

Since 1986, the EU has been providing specific legislation for the protection of animals used for scientific purposes, with the latest revision occurring more than a decade

Continued on Page 7

Continued from Page 6

ago.

However, animals must be used systematically for clinical trials and testing chemicals under the existing legislative framework.

According to Commission figures, animals were used for scientific purposes 9.58 million times in 2017, mainly for research purposes (69%), regulatory use to satisfy legislative requirements, (23%) and routine production (5%).

Among the testing carried out for regulatory purposes, 61% involved medical products for humans, while 15% concerned veterinary medicinal products.

An unavoidable element in the NAMs development discourse is that science is continuously evolving while the regulatory framework can only partially capture this constant progress.

For Roggeband, regulators have been clever enough to put certain fast-changing aspects in the annexes of the legislation.

"This way, you don't need to overhaul the entire legislation, but you can do what they call adaptations to technical progress of legislation," he explained.

He added that making sure that the EU laws are adapted to NAMs remains crucial as some changes to regulatory texts are needed to evolve in this area.

"We need to walk together with the regulator on this, but they also need to walk the talk on NAMs," he said.

BEST SCIENCE AVAILABLE

These non-animal approaches include all test methodologies which do not involve new in vivo testing.

For Roggeband, private companies are always looking at what is already available in their decisions on the safe use of ingredients, whether it is in silico (biological tests carried out entirely by computer) or *in vitro* (experiments conducted outside of a living organism), even considering genomics data.

"We make decisions on the safe use of ingredients for workers, consumers, and the environment, without necessarily defaulting to a tick box approach on animal studies," he said.

An "enormous amount of knowledge" generated over the past few years on the human genome and mechanisms of action for toxicology in humankind have helped companies and researchers make decisions on safety.

"It's not easy as you have to put all these pieces of the puzzle together to make decisions, but there are already possibilities to do that," he said.

This also means that using the best science available does not necessarily involve resorting to animal studies.

"The wrong place to start would be to say: let's do all this animal testing at a very high dose that does not have any relevance for human safety risk assessment," he added.

As they become increasingly available, these new methodologies should not be confined to Europe.

"We should also apply NAMs to the other countries and outside of Europe," Roggeband said, pointing out that third countries are also making progress in this area.

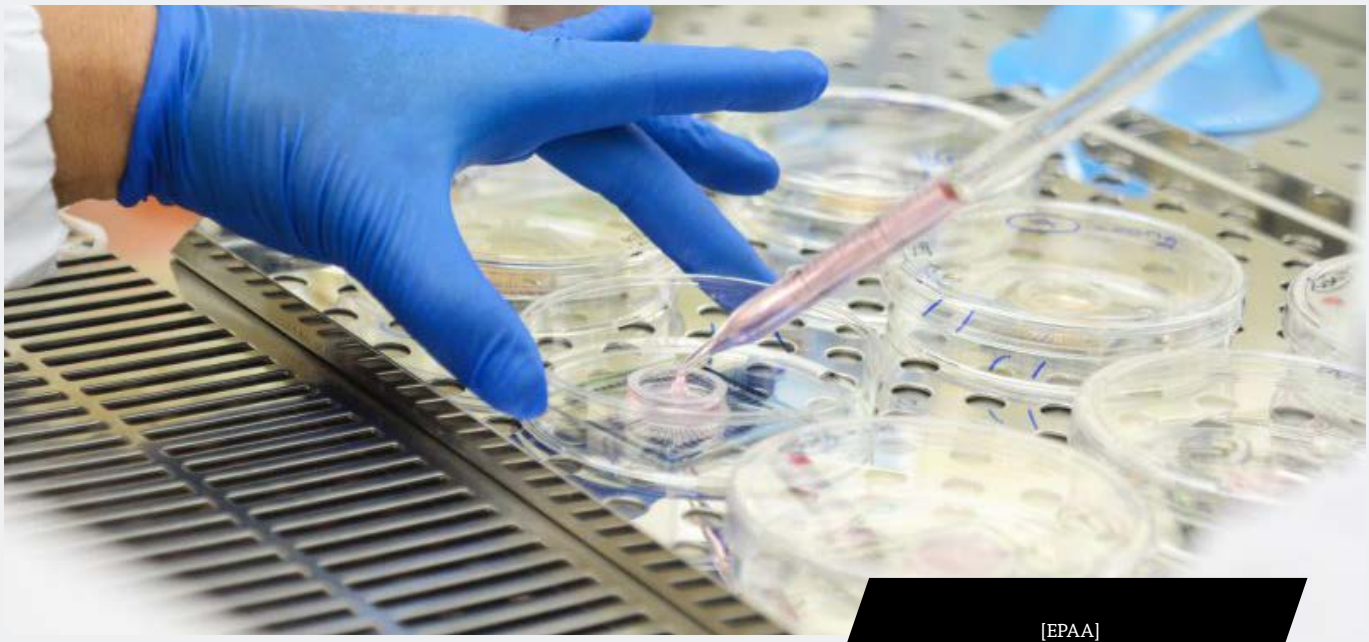
However, safety standards remain the usual red flag in applying NAMs globally. "We should never compromise on safety to consumers and workers. It is our golden standard," he concluded.

PROMOTED CONTENT

DISCLAIMER: All opinions in this column reflect the views of the author(s), not of EURACTIV Media network.

Staying at the forefront of alternatives to animal testing

By Maurice Whelan | European Commission's Joint Research Centre (JRC)



[EPAA]

The EU is leading the way in protecting animals used for scientific purposes and transitioning to chemical safety assessment using alternative methods. But how can we remain in pole position and accelerate our move away from conventional animal tests?

Maurice Whelan is Head of the Chemical Safety and Alternative Methods Unit at the European Commission's Joint Research Centre (JRC).

As an integral part of the JRC, the EU Reference Laboratory for alternatives to animal testing, better known as ECVAM, has been developing, validating and promoting scientific methods to replace animal tests for 30 years.

Since 1991, we've worked on over a hundred methods at various stages of development, validation and regulatory acceptance. The first ECVAM-validated methods were proposed as test guidelines for skin corrosion in 1998 and since then, considerable progress has been made in Europe and across the globe. As more scientifically valid alternatives become available, our laws dictate that they must be used. However we still face the challenge of how to eventually provide all the toxicological information needed to fulfil regulatory requirements using only non-animal approaches.

MEANINGFUL COLLABORATION DRIVES PROGRESS

When tackling challenges, we

Continued on Page 9

Continued from Page 8

often think first about science and technology gaps and how we might fill them. But equally important is assembling the right team that can make things happen. The European Partnership for Alternative Approaches to Animal Testing (EPAA) is unique in that it brings together the European Commission with companies working with a wide range of chemicals, including those used in the pharmaceutical, cosmetic, agrochemical, fragrance and detergent sectors.

EPAA project teams combine extensive knowledge and expertise on science, technology, regulation and policy, which ensures a holistic approach to address well-formulated objectives. This is illustrated by a new project on New Approach Methodologies (NAMs) that builds on the successful EPAA blue-sky workshop on repeated dose toxicity held in 2019. The goal is to use case studies to figure out together how to deploy NAMs in the most effective and credible way to generate the data required to inform decisions on occupational and consumer safety.

SAFE AND SUSTAINABLE CHEMICALS

The Chemicals Strategy for Sustainability sets out ambitious and far-reaching objectives to achieve the EU's zero pollution ambition, a key commitment of the European Green Deal. Much of the focus is on enhancing the protection of human health and the environment through several initiatives, many of which will likely require the provision of additional toxicological data to assess more chemicals for a wider range of adverse effects. However, the strategy also outlines ways to avoid unnecessary animal testing, including assessing and regulating substances in groups, improving the sharing of information, and making better use of 'academic' data in safety assessments.

Moreover, the Commission is looking specifically at how proposals to extend REACH information requirements could be addressed in some way using NAMs. And for this we'll have to look from two perspectives -at the reliability and relevance of the NAMs themselves, but also at how information requirements can be formulated to better match the type of mechanistic data that NAMs typically deliver. It is very fitting then that the theme of this year's EPAA annual meeting (27 Oct) is "How can EPAA help the successful implementation of the EU Chemical Strategy for Sustainability".

INVESTING IN TARGETED RESEARCH

The EU continues to invest in research to ensure that the right scientific knowledge and tools are available for NAM-based approaches to chemical safety assessment. The EU-ToxRisk project, funded to the tune of 30 MEuro under Horizon 2020, has just come to the end of its 5 years. It has delivered on several fronts, including showing very convincingly how NAMs can be used to support chemical grouping and read-across to avoid the generation of new animal data.

The EURION cluster of 8 individual projects received approximately 50 M Euro from H2020 and is about midway through its programme. It is focusing much of its effort on NAMs for identifying endocrine disruptors. Just recently, the ASPIS cluster commenced its broad array of research activities. It comprises the Ontox, PrecisionTox and RiskHunt3R projects and benefits from about 60 M Euro of EU funds.

TRANSLATING SCIENCE INTO SOLUTIONS

For science to have impact, research strategies need to consider the particular needs of regulation and industrial end-users. Critically too, progress depends on being able to address complex toxicological effects of most concern, such as those contributing to reproductive disorders, neurodegenerative diseases and cancer. As scientifically credible solutions emerge, the community needs to do more to ensure they are sufficiently standardised and validated to be acceptable and deployable for regulatory applications. All this is possible through cooperation, determination and a strong belief in our common goals.

For information on
***EURACTIV** Event Reports...*

Contact us

Gerardo FORTUNA
Agriculture & Health Editor
gerardo.fortuna@euractiv.com
tel. +32 (0) 2 788 36 69

Teresa DOMINGUEZ
EU Affairs Senior Manager
teresa.dominguez@euractiv.com
tel. +32 (0) 47 601 78 26