REPORT ON THE EVENT "A NEW TOOLBOX FOR CITIZENS' PROTECTION: IMPLEMENTING SCIENCE INTO EU POLICY"

THURSDAY 9 SEPTEMBER 2021 (VIRTUAL)

Organized by the consortia of the EU funded projects EU-ToxRisk and PATROLS, grant agreement numbers 681002 and 760813. These two consortia will present results on the assessment for chemicals and engineered nanomaterials (ENM) using animal-free methods.

This project has received funding from the European Union's **Horizon 2020** research and innovation programme under grant agreement No 681002

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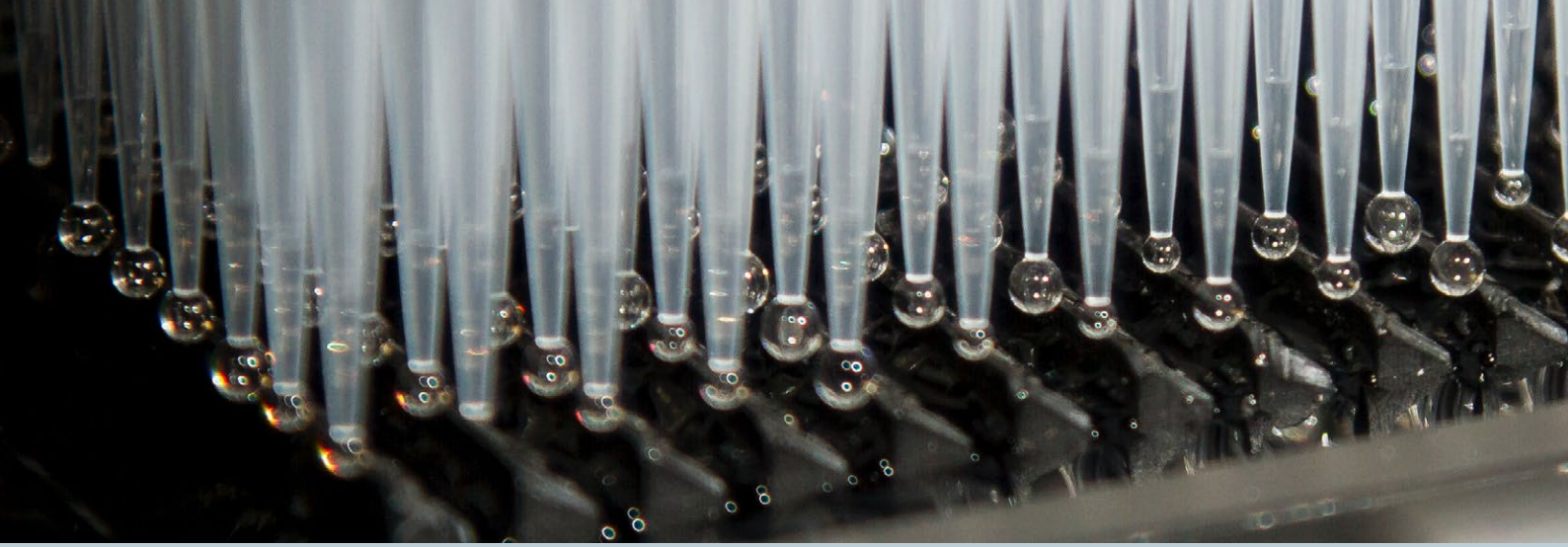

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List of acronyms

AOP	Adverse Outcome Pathway
ANSES	Agency for Food, Environment and Occupational Health & Safety
CRISPR	Clustered regularly interspaced short palindromic repeat
DG	Directorate-General
ENM	Engineered nanomaterials
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EURL ECVAM	European Union Reference Laboratory for Alternatives to Animal Testing
IATA	Integrated approaches to testing and assessment
JRC	Joint Research Centre
NAM	New approach methodology
OECD	Organisation for Economic Co-operation and Development
PMT	Persistent, mobile and toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
R&I	Research and innovation
US EPA	US Environmental Protection Agency

Workshop Recommendations towards targeted audiences

To Industry: Cooperation – It is crucial to have close cooperation between academia and industry during the development of new approach methodologies (NAMs). Industry can bring knowledge on demand for certain NAMs. In order to validate NAMs, the Industry can help when they pick up the most promising NAMs from research projects for in-house validation studies.

To Regulators: Validation – The validation[1] and robustness of NAMs are crucial for the acceptance of new methods by regulators. However, the validation process is costly and takes time. Finding approaches to speed up the validation process and uptake of NAMs by regulators is recommended.

To European Commission/Member States: Training – A focus on training opportunities in implementation and data interpretation of NAMs for industry and regulators is encouraged, to increase acceptance of newly developed methods.

To European Commission/Member States: Funding – Future EU and Member States funding strategies must include sufficient funds for the validation of NAMs. Current funding streams result in a "bottleneck" whereby methods are well scientifically developed, but not sufficiently progressed for regulatory uptake.

To European Commission: Roadmap – A roadmap describing targeted actions towards replacement category of tests should be considered for phasing out laboratory animal uses in the EU in a timely manner.

To Researchers: Scientific projects focused on the development of NAMs should publish their results following FAIR (Findable, Accessible, Interoperable, Reusable) data principle to increase knowledge transfer between research projects and speedy progress in the advancement of NAM applicability. These projects should include defined outlines of requirements for validation processes of the developed NAMs.

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[1]. Test method validation is a process based on scientifically sound principles (5)(6) by which the reliability and relevance of a particular test, approach, method, or process are established for a specific purpose. (According to OECD Guidance document on the validation and international acceptance of new or updated test methods for hazard assessment).

Speakers' list

Chair - technical session
Jana Drbohlavova works for the EU Commission Directorate-General (DG) Research and Innovation.

Chair - open session
Tilly Metz who is a Luxembourg Member of the European Parliament for Déi Gréng Party (Greens).

Presenters

Katrin Schutte works for the EU Commission DG Environment where she is responsible for the chapter registration and partly evaluation of the chemical's legislation REACH.

Anne Gourmelon works for the Organisation for Economic Co-operation and Development (OECD) where she is the principal administrator for the test guidelines program.

Elisabet Berggren works for the EU Commission DG Joint Research Centre (JRC) which hosts the EU Reference Laboratory for alternatives to animal testing (EURL ECVAM).

Christophe Rousselle works for the French Agency for Food, Environment and Occupational Health & Safety (ANSES).

Bob van de Water is Professor of Drug Safety Sciences at Leiden University. He has over 30 years research experience in mechanistic toxicology and integrating this knowledge into innovative non-animal test systems. These tools are licensed to Leiden University spin-off service providers for chemical safety assessment. He is coordinator of the EU-ToxRisk and RISK-HUNT3R projects and currently chairing the EU ASPIS cluster of projects on non-animal approaches for next generation risk assessment.

Shareen Doak is Professor of Genotoxicology and Cancer at Swansea University medical School. Shareen is co-lead of the *In Vitro* ((non-animal)) Toxicology Group and is a UK and EUROTOX Registered Toxicologist. Shareen's research interests focus on the DNA damaging potential of engineered nanomaterials and subsequent consequences on human health. Her interests extend to the development of advanced 3D culture models and mechanism-based bioassays for safety assessment to reduce the need for animal testing, which is a key focus of the H2020 PATROLS project, which she coordinates.

Key points of the presentations during the technical session

The goal of the event was to offer a comprehensive overview of the current EU strategies for citizens' health protection and their main aims and furthermore, to provide feedback and dialogue with two of the most relevant toxicological EU-funded projects on how their results can help support EU strategies, with regard to the implementation of NAMs[2]. The technical part of the event was chaired by Jana Drbohlavova who introduced the main objective of the technical session as to share new methods and strategies to avoid animal testing, which is in line with the EU Chemicals Strategy for Sustainability of the EU Green Deal.

Katrin Schutte presented different strategies and projects that promote non-animal approaches within the EU Chemicals Strategy for Sustainability. She stated that increased support for the use of NAMs in chemical risk assessment is planned and that the activities she presented will strengthen the protection of human health and the environment. Additionally, she presented goals for the revision of the REACH registration that will include new endpoints in future risk assessment of chemicals to gather information on critical hazard properties. Furthermore, the revision will include the chemical safety assessment for chemicals produced at low tonnage (1-10 tonnes/year substance) which may lead to further animal testing.

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2. *In silico* approaches, in chemico and *in vitro* assays including high-throughput and high-content techniques, omics with a focus on metabolomics, the use of exposure data in terms of volume and use. (Definition under development according to New Approach Methodologies in Regulatory Science – Proceedings of a scientific workshop Helsinki, 19-20 April 2016)

Anne Gourmelon summarized that the harmonization and sharing of testing standards, practices, tools, methodologies, and data is crucial to allow a sustainable risk assessment. In her opinion coming challenges will include mixtures, persistent, mobile, and toxic (PMT) substances, and advance material testing. The promotion of knowledge exchange and common guidance is critical to face these issues in a timely manner. Identified issues under discussion include increasing the utility of *in vitro* data, difficult to test chemicals in aquatic and *in vitro* systems, the combinations of NAMs to predict adverse effects in humans, and global acceptance of NAMs.

Elisabet Berggren concluded that we should work on shaping a more efficient management of chemicals based on the real complexity of the chemical universe we are exposed to. This strategy should generate meaningful data without data collection substance by substance and should include i) a prioritization of chemicals to assess, ii) testing of low tonnage chemicals on the market and iii) harmonization through different pieces of legislation, including assessment of combined exposure and mixtures. She also stated that a better understanding of regulatory applicability and a comprehensive gap analysis of the current available NAMs spectrum is crucial to steer the resources towards the most urgent needs and maximize the utility of funding into new research initiatives.

Christophe Rousselle presented the European Partnership for the Assessment of Risks from Chemicals (PARC), a 400 million euros co-funded partnership under Horizon Europe that will connect more than 200 institutions from 28 countries and EU agencies. He stated that PARC will constitute a unique opportunity to bring together the regulatory and R&I communities involved in risk assessment of chemicals all over Europe and promote a more holistic approach. The project will also develop a Next Generation Risk Assessment road-map that will include adverse outcome pathways (AOPs)/ integrated approaches to testing and assessment (IATAs), exposure-driven assessment, (re)use of data and modelling tools.

Bob van de Water presented the outcomes of the EU-ToxRisk project. The vision of the project was to drive a paradigm shift in toxicology towards an animal-free, mechanism-based integrated approach to chemical safety assessment. The almost completed project has demonstrated that the structured integration of both *in silico* and *in vitro* NAMs can quantitatively inform on toxicokinetics and toxicodynamics, allowing for decision-making in read-across driven chemical safety assessment. The project delivered several innovative NAMs that better reflect human biology and pathophysiology. The project furthermore demonstrated that an active open and dynamic interaction between academic, industry and regulatory stakeholders is key to the successful implementation of NAMs for regulatory purposes.

Shareen Doak summarized PATROLS's aim to establish and standardize a battery of innovative, next generation hazard assessment tools to better predict adverse effects caused by long-term, low dose engineered nanomaterial (ENM) exposure in human and environmental systems to support regulatory risk decision making. She presented the results of the project and showed that PATROLS has delivered a suite of more representative *in vitro* tools tailored to better understand human and environmental hazards following exposure to ENMs. She proceeded to state that these novel testing approaches can be implemented as part of a safe-and sustainable-by-design strategy, to minimize the need for animal testing in regulatory safety assessment. In terms of challenges, Shareen pointed out that there is a need to increase the speed of integrating NAMs into regulatory testing frameworks, as standard validation requirements take too long, and proposed to find a more dynamic approach to acceptance and use of NAMs. She furthermore explained that the applicability domain of NAMs needs to be established, considering new emerging technologies and advanced materials

Summary of panel discussions

Validation of NAMs is the bottleneck to replacement of animal methods at the regulatory level; the methods will only be applied by regulators if they are fully validated. However, validation is very time-consuming and costly and there is an urgent need to think of better and faster or different ways to validate NAMs. The panelists reported that, although NAMs were successfully developed in the EU Horizon 2020 projects, funding and the limited timeframe of the projects were insufficient to include the formal validation of the new NAMs under the research projects, and this should be addressed in the funding of comparable future projects. Shareen Doak reported that within the PATROLS project, researchers did not have enough funding nor time to bring NAMs through the validation stage. The argument related to the importance of validation was seconded by Anne Gourmelon, who agreed that the validation of the most promising NAMs should be considered in the funding and timeline of future research projects. She also emphasized that regulators depend on robust, validated methods and that this is a key requirement for the acceptance of NAMs. She agreed with Christophe Rouselle that the presented project PARC represents a good opportunity with regard to the validation of NAMs due to the funding level and time prescribed. Bob van de Water added to the discussion that there exists no incentive for regulators to use NAMs, and if acceptance through validation cannot be achieved due to the high costs, maybe it can instead be achieved through the application of case-studies that demonstrate the robustness of the methods. Elisabet Berggren added to this saying that robustness is a key attribute of NAMs expected by regulators and continued to say that there might be possibilities to group NAMs, and make them attractive for industry to be picked up for in-house validation studies. This might create opportunities to speed up the validation process.

With regard to the One Substance One Assessment strategy and the REACH revision, Katrin Schutte indicated that the possibility of some level of harmonization of testing requirements under different regulatory bodies might occur as a result, although this has not been explicitly defined as a direct goal. The implementation of NAMs in regulation will not be included in the form of a defined long-term strategy with milestones and phase-out targets according to Elisabet Berggren. As this is the first time that NAMs are discussed in the context of regulation at the EU parliamentary level, the discussion will be more pragmatic. Katrin Schutte added that NAMs will be considered for the information requirements of the 2022 REACH revision.

It was urged that for a successful strategy for phasing out animal tests it is crucial to have a concrete roadmap and that in this context closer cooperation between regulatory agencies like the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) would be beneficial. When asked by Tilly Metz if the banning of all mammal tests in the EU by 2035 would be achievable (comparable to what US EPA has recently set out) the panelists agreed that this would be possible. They pointed out that if there exists a definitive date, this pushes the process and NAMs into application, as was the case for the cosmetics industry. Massive investments into the development of NAMs have been made by the EU, however, to finish this process, more funding is needed especially for the steps of validation and implementation of methods. Another crucial step in this process is increased communication around the implementation of NAMs, as Shareen Doak explained. Meetings like this one increase the reach of the research projects and help to involve relevant stakeholders. When asked by MEP Tilly Metz what they expect of the newly appointed director of ECHA, Shareen Doak stated that she would like to explore the hesitation of regulators when it comes to the acceptance and integration of NAM data and would ask the director what it would take to change ECHA's opinion to increase the consideration of such approaches. Bob van de Water wondered if ECHA would be willing to move away from the dogma that *in vitro* tests should predict *in vivo* lab animal adverse outcomes and raised the question whether this prediction is important if human protection is the main objective. He stated that this discussion is also important in regards to the REACH revision.

With regards to the measures that need to be instated to promote NAMs within the regulatory bodies, there was a wide agreement among panelists that training in the application of NAMs, as well as the interpretation of the data derived from NAMs is important.

It was also stated by Bob van de Water and Christophe Rousselle that the involvement of industry in the development of NAMs in research projects was crucial for the success of NAM development. Bob van de Water reported that in the EU-ToxRisk and RISK-HUNT3R projects, cooperation with industry is close. Shareen Doak reported that within the PATROLS project, a Contract Research Organisation tested one of the developed models and additionally performed market research to determine the potential client base. She concluded that these interactions are of high importance for method development and to bring the models

forward. Bob van de Water added that in his experience industry is hesitant to spend money on NAMs because of likely rejection decisions on dossiers by regulators. However, Elisabet Berggren added that the industry is already widely using NAMs internally, and that they would like to get more out of these methods.

Concluding the technical session Elisabet Berggren stated that researchers including those at ECVAM should continue their path and focus on strong cooperation and outreach programs to relevant stakeholders to be involved in the development of NAMs.

Bob van de Water highlighted that the availability of cutting-edge technology such as CRISPR[3] and stem cell-based methods is a valuable contribution to the development of NAMs, which should be pursued more in the future. He pointed out that this also requires training of regulators to be able to work with the results of these NAMs once they are validated and applied.

Shareen Doak agreed to this, stating that the community needs to invest more effort into proper communication, demonstrations and workshops to increase acceptance of NAMs among regulators.

[3] RNA-guided nuclease-based approach poised to transform developmental biology by providing a simple, efficient method to precisely manipulate the genome of virtually any developing organism.

https://eutoday.net/news/environment/2021/implementing-science-into-eu-policy

Posted on Sep 11, 2021

Conference: "A new toolbox for citizens' protection: Implementing science into EU policy"

A high level conference has heard about the work being undertaken by two pioneering EU funded projects whose aim is partly to find innovative alternatives to animal testing.

Animal testing remains a highly sensitive issue and there are growing calls for the practice to be outlawed, including by the chemical industry.

Speaking at an online event in Brussels called "A new toolbox for citizens' protection: Implementing science into EU policy" were Prof Bob van de Water, from the EU-ToxRisk project and Shareen Doak, coordinator of the PATROLS project.

Both explained their work with the two projects, which are coming to the end of their terms, and agreed on the need for speedy implementation of any findings and recommendations.

Prof van de Water said the aim of EU-ToxRisk is to "drive a required paradigm shift in toxicological testing away from 'black box' animal testing with the ultimate goal being to deliver testing strategies to enable reliable, animal-free hazard and risk assessment of chemicals."

Van de Water, of Leiden University, said his project is almost in its final stage with just a few months left and has been supported by the EU Horizon 2020 programme in the EU's last funding period.

He explained his project, saying, “The project is all about the protection of the human population from chemicals, most of which are tested on animals including for pharmaceuticals. We want a more independent approach to this. What is also important is that we talk to each other about this and that we define strategies, such as the use of stem cells, to help the regulators who, after all, have to make the decisions at the end of the day. The question is how we can apply all this for hazard and risk assessment by the regulators and industry. We also need to looking at ways of bringing new applications faster to validation and implementation.”

He added, “We continue this journey.”

PATROLS, meanwhile, is an international project combining a team of academics, industrial scientists, government officials and risk assessors. Its aim is to deliver "advanced tools and methods" for nanomaterial safety assessment which will, it is hoped, minimise the necessity of animal testing.

Shareen Doak is coordinator of the PATROLS project, who is based at Swansea University in South Wales and is a professor of toxicology. She admitted that, with the pandemic, they had been working in “challenging times.”

She said, “There are a lot of parallels with EU-ToxRisk and the challenges it faces are shared by us.

“Our project was launched in 2018 and this is our final month. We have 24 partners in 14 countries and the aim has been to better support regulatory risk assessment and we have developed advanced 3 D models of the human lung. What we did is ensure it could report on a range of hazards in order to evaluate toxicity. We extended the use of these models for other things.”

She added, “What we have is a suite of methods which give us greater insight into this issue and Nano-material exposure. This is important.

“Implementation of these methods is the key now because there is only so much you can do in four years of this project. But we have tried to transfer our knowledge to ongoing research and testing approaches. We need to integrate these new methods and tools as soon as possible but that is not so easy.

“This is our final month but, today, I have tried to showcase a bit what we are doing,” she said.

Both projects, worth about €40m, have received funding from the European Union’s Horizon 2020 research and innovation programme.

The workshop’s objective was to offer an overview of current EU strategies for citizens’ health protection and their main aims. It also sought to provide feedback and dialogue with two of the most relevant toxicological programmes - EU-ToxRisk and PATROLS - on how their results can help deliver EU strategies.

A third aim was to identify key steps for further implementation of the EU’s flagship Chemical Strategy for Sustainability.

Jana Drbohlavova, (pictured) from the European Commission, who chaired the four-hour workshop, told participants, “The aim of today’s event was to showcase the new strategies for risk assessment of chemicals and alternative testing to animal testing.

This is all in line with the EU's chemical strategy for sustainability and the EU Green Deal. As we have heard today there are clearly lots going on in order to meet these ambitious EU objectives, including the creation of an open platform on the safety aspects of chemical risk assessment. We have had some very interesting presentations including the OECD's chemicals safety procedures and methods. Much of this work is complex, time consuming and costly but it is still fascinating."

Kathrin Schutte, a European Commission policy officer at the environment directorate, said, "One of the commission's main ambitions is for a toxic free environment. This is what we are working towards and industry using safe chemicals which are controlled. We all agree these ambitions are quite high and addressing them will need new solutions and new technologies. We want to reduce dependency on animal testing – to move away from such testing - and also to improve the quality of testing. in the many different streams there is much increased support for new methods for risk assessment."

Another keynote speaker, Anne Gourmelon, of the OECD, explained some of the organisation's work in the field, saying, "We help countries to have tools for conducting their risk assessments. Our objectives include promoting good practices, providing dialogue on technical issues related to chemicals management, and a mutual acceptance of data on animal testing. We also try to promote non animal approaches to chemical safety."

Elisabeth Berggren, of the EU's Joint Research Centre, who was also spoke, told the event about its work on non animal science, saying, "The chemical strategy aims to ensure that new ideas can be accepted and implemented on a global scale. This is necessary because it is estimated that some 2.7 percent of all total global deaths is due to chemicals which is not a small figure, also, the environmental effects of chemicals is alarming. Europe is the 2nd biggest producer of chemicals and our work is to protect health and help EU industry towards producing green chemicals.

"What is risk management? Well, in the first case you have to decide that certain things are not acceptable while in the 2nd case you need to assess what is acceptable. We need to move away from the idea of having complete data for everything and start to create what I would call new comfort zones and sustainable development," she added.

Another speaker was Christophe Rousselle, a toxicologist with ANSES, who, based in France, works with three EU agencies on an environmental scheme called PARC.

He told the event, "The aim is to protect human and environmental health, to support the chemical strategy. promote, to also promote R&D and to make data available for all users. We will also try to promote new risk assessment through training. We also want to help establish permanent dialogue between scientists and regulators.

"With the PARC project, we will monitor human activity on the environment and look at current knowledge gaps."

The Commission's zero-pollution ambitions contained in the Green Deal were also touched upon several times during the half day event.

A key component of the Green Deal is the Chemical Strategy for Sustainability, published nearly one year ago.

On August 9, the commission launched a public consultation on the revision of the Regulation on the classification, labelling and packaging of chemical substances and mixtures ("CLP Regulation"). The revision is one of the 85 actions planned in the chemicals strategy and seeks to achieve a higher level of protection of citizens and of the environment against hazardous chemicals.

The consultation will gather the views of citizens, institutions and organisations from the public and private sectors.

The virtual event, on Thursday, heard that the chemicals strategy will require tools and methods in several areas. This includes the next generation of advanced safety assessment tools delivering new chemicals that are safe and sustainable to protect people and the planet. Another aim is that such tools and methods that can be used by regulators to harmonise responses. It is also hoped new technologies will help in the reduction of animal use for safety testing.

The chemical strategy, it was said at the event, is expected to result in significant revisions of the EU legislative framework, such as the Cosmetics Regulation and the REACH Regulation, to deliver "a toxic-free environment."

The event heard that while toxicity testing on animals is costly and highly time-consuming (up to the animal's entire life span), the number of chemicals whose toxicity is still unknown continues to grow.

It was said that if concrete steps are not taken in the near future to accelerate a transition to non-animal models, not only will the number of the animal experimentations increase, but the EU's ambitions could result in a backlog of new chemicals "stuck in the review processes."

Alternatives to animal testing, also known as New Approach Methods (NAMs), promise to fill the knowledge gap, the event was told.

It is hoped, several participants said, that these will provide risk assessors and regulators with "faster, more reliable and ethical solutions by enabling them to better identify, classify and ultimately remove hazardous substances from the environment."

Separately, MEPs are set to vote on new initiatives aimed at phasing out animal testing.

During next week's plenary session in Strasbourg MEPs will vote on an important text on non-animal testing, a move welcomed by EU-funded project coordinator.

The motion for a resolution concerns the 10 million laboratory animals used yearly in the EU and calls for an Action Plan to facilitate the transition to innovation without the use of animals in research, regulatory testing and education.

The EU is currently funding three other research projects aiming to advance the safety assessment of chemicals without the use of animal testing: PrecisionTox, ONTOX and RISK-HUNT3R.

Led respectively by the University of Birmingham, Vrije Universiteit Brussels and the Leiden University, these have formed the "ASPIS cluster" which gathers 70 research organisations and will receive €60m over the next 5 years to develop ethical solutions for the advancement of regulatory testing.

The project coordinators, Professor John Colbourne, Prof. Mathieu Vinken and Prof. Bob Van de Water, have backed the parliamentary initiative saying they hope it will soon be translated into the EU legislative framework.

The coordinators state "The Motion for Resolution of the European Parliament is timely to accelerate this transition and meet the EU ambition to lead on the next generation for risk assessment in Europe and worldwide."

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https://www.eureporter.co/environment/animal-welfare/2021/09/13/european-parliament-to-vote-on-animal-free-research-testing-and-education/

ANIMAL TESTING

European Parliament to vote on animal-free research, testing and education

PUBLISHED 3 WEEKS AGO ON SEPTEMBER 13, 2021
By **Guest Contributor**

***Anyone who is familiar with Ralph, a test rabbit mascot that is subject to Draize eye irritancy test in cosmetics labs and suffers from blindness, will wonder how such cruelty is still acceptable in an age of advanced science and technology. The* Save Ralph *video went viral all over the world and became most probably the reason why Mexico recently joined the ranks of states, which banned animal testing for cosmetics. So did the EU back in 2013. The EU plans to go even further by adopting a resolution on "a co-ordinated Union-level action to facilitate the transition to innovation without the use of animals in research, testing and education" this week (15 September),* writes Eli Hadzhieva.**

Although the EU encourages the use of non-animal methods, such as the new organ-on-chip technology, computer simulations and 3-D cultures of human cells, research shows that archaic methods, such as "50 percent lethal dose" killing half of the millions of test animals, are still widely in use. Moreover, evidence growingly shows that some animals, such as rabbits and rodents, are completely different species from humans to be seen as reliable proxies for the protection of human health from chemical risks. For example, drugs, such as thalidomide, TGN1412 or fialuridine, aimed at treating morning sickness, leukaemia and Hepatitis B respectively, proved totally safe for animals but could not be tolerated by humans.

According to the European Commission, the European chemicals strategy for sustainability increased support for use of Non-Animal Methodologies (NAMs) in Chemicals Risk Assessment, especially with several Horizon 2020 projects (ASPIS Cluster comprising RISK-HUNT*3R*, ONTOX and PrecisionTOX projects), the upcoming REACH and Cosmetics Regulation revisions, the new project of the European Partnership for Alternative Approaches on NAMs use in risk assessment, PARC with the objective of transitioning to next generation risk assessment and a Strategic Research and Innovation Agenda. The global acceptance of non-animal and innovative approaches to chemical safety is also high on the OECD agenda.

A webinar organised on 9 September by EU-ToxRisk and PATROLS, two multi-stakeholder projects funded by the EU's H2020 Program, illustrated the limitations of the existing in vitro (test-tube experiments) and in silico (computer-simulated experiments) hazard detection systems while showcasing a new toolbox to conduct animal-free assessments for chemicals and nanomaterials. EU-ToxRisk project coordinator Bob van der Water from Leiden University highlighted his vision "to drive a paradigm shift in toxicology towards an animal-free, mechanism-based integrated approach to chemical safety assessment" through an established NAM toolbox based on in vitro and in silico tools and novel next generation NAM toolbox components. He emphasised advanced novel test systems, such as CRISPR-based fluorescent reporters in stem cells, stem-cell derived multi-liver-cell model, diseased liver micro-tissues and four-organ-chip while highlighting that NAMs should rapidly be integrated into regulatory testing frameworks.

Shareen Doak, the Coordinator of PATROLS from Swansea University highlighted the knowledge gaps regarding long term effects of realistic engineered nanomaterial (ENM) exposures for human and health environment while demonstrating innovative methods, such as extrinsic ENM properties, advanced ecotoxicity tests, heterotypic in vitro models of the lung, GIT and liver etc. "These methods are tailored to better understand human and environmental hazards and should be implemented as part of the EU's safe and sustainable-by-design strategy to minimise the need for animal testing", she said.

"The biggest challenge is the acceptance and the implementation of NAMs. Standard validation requirements are too long and the applicability domain of NAMs needs to be established considering new emerging technologies", she added.

In an earlier statement, the ASPIS Cluster expressed support for the motion for resolution of the European Parliament describing it as "timely to accelerate an animal-free transition and meet EU ambition to lead on the next generation for risk assessment in Europe and worldwide" all by welcoming EU efforts "which will translate into regulatory and industrial practices that will better protect human health and the ecosystems, by enabling us to identify, classify and ultimately remove hazardous substances from the environment".

The moderator of the webinar MEP Tilly Metz (Greens, Luxembourg), also shadowing the European Parliament's resolution, said that she hopes that the final resolution will contain the following elements: "Concrete steps to phase out animal testing, precise roadmaps and studies, a coordinated approach by EU agencies, such as the European Food Safety Authority and the European Chemicals Agency and fast implementation of new advanced methods".

This gives a lot of food for thought for policymakers in a make-or-break moment for Ralph and his animal and human friends. It's time that words translate into action and the regulatory environment evolves in line with new realities on the ground while giving a breathing space to these promising and safe animal-free technologies by adopting a dynamic approach to accept and use them. This will not only allow us to live up to the zero-pollution ambition in the Green Deal but will also deliver "a toxic-free environment" both for animals and humans.

Workshop Agenda

Technical Meeting

Time	Talk	Speakers
14:00 – 14:15	Introduction and the round table of speakers	Jana Drbohlavova (Chair) (EU Commission DG Research and Innovation)
14:15 – 14:30	European Commission chemicals strategy for sustainability	Katrin Schutte (EU Commission DG Environment)
14:30 – 14:45	Application of OECD guidelines for risk assessment	Anne Gourmelon (Organisation for Economic Co-operation and Development, OECD)
14:45 – 15:00	Break	
15:00 – 15:15	The European strategy towards non-Animal Science	Elisabet Berggren (EU Commission DG JRC - EURL ECVAM)
15:15 - 15:30	An overview on the Partnership for the Risk Assessment of Chemicals (PARC), an initiative under the Horizon Europe programme.	Christophe Rousselle (French Agency for Food, Environmental and Occupational Health & Safety, ANSES)
15:30 – 16:00	The contribution of the H2020- funded research projects EU-ToxRisk and PATROLS to the presented strategies.	– Bob van de Water (EU-ToxRisk coordinator) – Shareen Doak (PATROLS coordinator)
16:00 – 16:15	Break	
16:15 – 17:00	Discussion panel: how implementation of new policy strategies will ensure citizens' health protection?	
17:00 – 17:15	Wrap-up	Jana Drbohlavova (EU Commission DG Research and Innovation)

Open Meeting

Time	Talk	Speakers
17:30 – 17:40	Introduction and aim of the meeting	Moderated by MEP Tilly Metz
17:40 – 17:50	Report from the technical meeting (part I)	Bob van de Water (EU-ToxRisk coordinator)
17:50 – 18:00	Report from the technical meeting (part II)	Shareen Doak (PATROLS coordinator)
18:00 – 18:25	Q&A	Moderators
18:25 – 18:30	Wrap-up	Moderators