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ALTERNATIVES TO ANIMAL TESTING – THE STATE OF PROGRESS

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The EU ban on animal testing for cosmetic products came into force in 2013, although testing is still allowed in Europe for healthcare products and pharmaceuticals, as well as some chemicals and food.

The annual conference of the European Partnership for Alternative Approaches to Animal testing brought together European Commission officials, industry leaders and politicians to assess the progress of lawmakers and companies in adapting alternative testing methods, and the global progress towards a worldwide ban.

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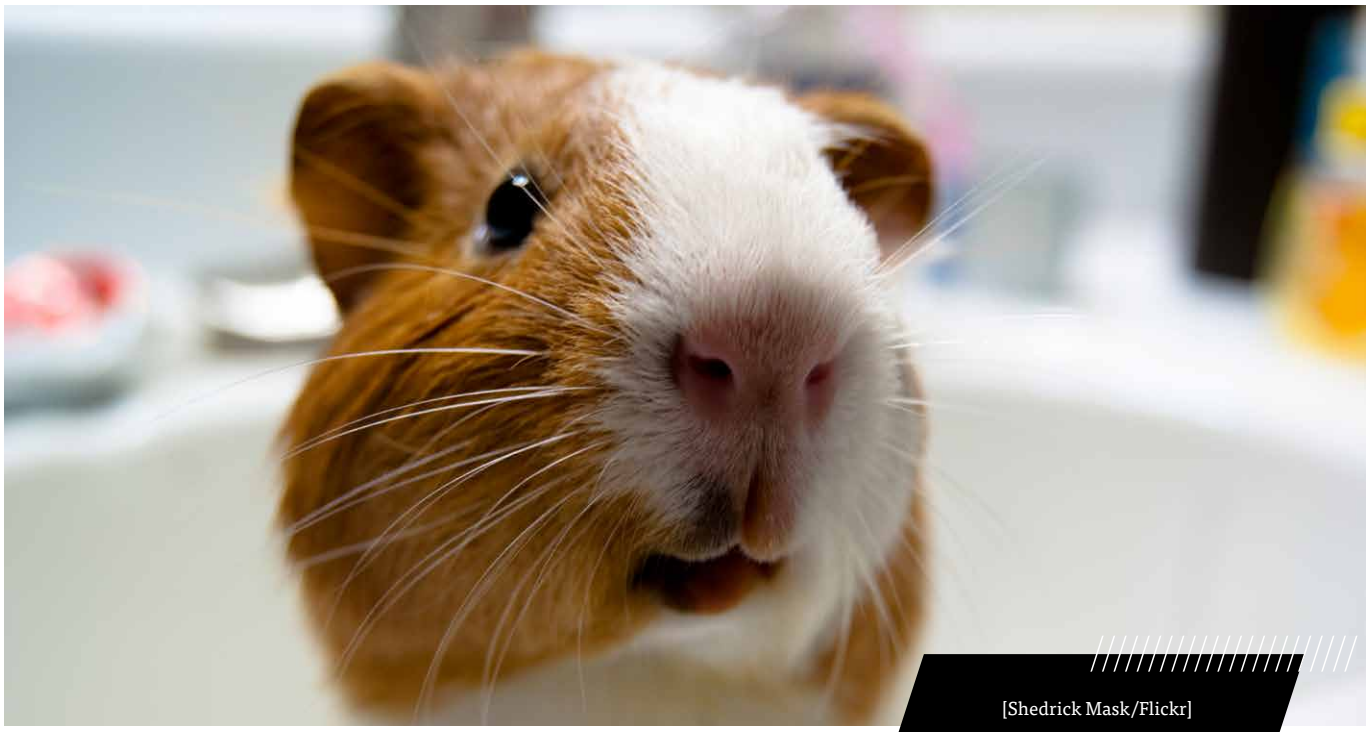
EU 'fully committed' to ending animal testing, insists Commissioner

By Benjamin Fox | EURACTIV.com



[Shedrick Mask/Flickr]

The EU remains "fully committed" to phasing out testing on animals, Internal Market and Industry Commissioner Elżbieta Bieńkowska told delegates at the annual conference of the European Partnership for Alternative Approaches to animal testing on 20 November.

Opening the event, Bieńkowska said that the EU had provided more than €500m for alternative projects, and continued to be a pioneer in driving alternatives to animal testing in the cosmetics industry, with the US, China, India, Brazil among the jurisdictions following the EU's progress.

"There are difficult challenges ahead of us," said Antti Peltomaki, Deputy Director General at DG Grow. He added that progress had been made on tests on eye irritation and skin sensitisation, but that there was a need to make progress on chronic organ toxicity.

Peltomaki added that the Commission had introduced knowledge and training schemes on alternatives to testing, as well as an information research centre on alternatives to animal testing.

TESTING BAN

Pointing to a European Parliament resolution calling for a worldwide ban on animal use in cosmetics testing, Peltomaki told delegates that the EU had raised the call for a global ban at a recent international symposium hosted by Japan.

"There is a big variation in speed. The EU is a front-runner but many countries are much more reluctant," said Thomas Forster, Vice-President of Henkel.

Forster noted that there are still

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some countries who ban the import of animal-free testing methods. All tissues currently have to be cleared through customs.

He said that the EPAA should strive for global acceptance of OECD guidelines which are not accepted in all countries, and to reach an agreement on ingredient-based safety assessment.

This message was backed up by EPAA industry co-chair, Charles Laroche. "We need to ensure that alternative methods and promotion of education go hand in hand," he said.

Laroche told delegates that there were six ongoing projects on skin sensitisation, clostridial vaccines, human rabies vaccines, acute toxicity, international harmonisation of 3Rs in biologicals and enhancing the prediction of carcinogenic potential of agrochemicals.

"The biggest strength of the EPAA biologicals team is its diversity", said DG ENV's Katrin Schotte.

Schotte said that the Commission was focusing on "low hanging fruit", specifically on abolishing animal tests such as the general safety test.

"We do not propose a replace test, only that a test which does not have scientific value should be scrapped," she said.

The general safety test was initially developed in the 1900s, using lab mice to assess the presence of toxic phenol in diphtheria medicine.

EPAA had also issued a letter to the WHO encourage the deletion of the two tests for innocuity from WHO recommendations but had still not received a reply, Schotte told delegates.

Pyrogenicity testing is the new focus area, of the EPAA's biologicals team, said Schotte, pointing out that the Rabbit Pyrogen tests are still conducted for biological products despite alternative assays being available.

CUT OUT CONFUSION

"Most members of the public know what they want but not about the rules and regulations, there was a lot of confusion about the actual requirements on animal testing," said Julie Girling, a centre-right MEP, who co-drafted the European Parliament's April 2018 resolution calling for a global ban on animal testing.

Girling said that in her work she had sought to "cut out the confusion between overlapping EU agencies" when it came to implementing EU law on alternatives to animal testing.

"We agree than there is a need for change to a more humane and more reliable system, but it will also need a lot of methods to end," said BASF's Robert Landsiedel during the panel discussion

Christian Desaintes, an official in the European Commission's Research and Innovation DG, said that the EU executive had provided more than €700 million to more than 200 projects since 2000.

He added that the Commission and industry were already pooling resources via the EU's FP7 programme. Meanwhile, the Horizon 2020 programme had provided finance for more than 70 research projects to the tune of over €200 million.

Maurice Whelan, head of the EU Reference Laboratory for Alternatives to Animal Testing, told the conference that one of the challenges was how to exploit new types of data in regulatory decision making.

"We have spent hundreds of millions on generating data but it is never used," said Whelan, adding that "one of the key reasons why scientists don't share data is because there's not articulation of how it was obtained."

"We're getting to a stage where the scientists can't understand their own data."

"We want to see that alternative tests are as good as human tests", said Kristina Wagner of the Eurogroup for Animals.

"What we expect is a strategy of how to do this. There are so many new methods coming out but there needs to be some strategy that really streamlines what is done, and when, and what is funded," she added.

"I think there is a movement in society to be more sustainable in what we do, and to be more ethical. To not just talk about freedom of research but to focus on the legal requirement to phase out animal testing."

PIONEER

"By pooling resources we have achieved a lot since our creation in 2005," said Renate Weissenhorn, EPAA Commission co-chair.

"EPAA is strong and striving in an environment that is changing. It has been a pioneer and will be a pioneer in the future," Weissenhorn concluded.

EU still leads the way on animal testing alternatives, industry representative says

By Benjamin Fox | EURACTIV.com

Charles Laroche is EPAA's Co-Chair. [EPAA]

The EU continues to lead the world in balancing ethics with science, although the gap with other regions is "significantly" narrowing, Charles Laroche, industry co-chair of the European Partnership for Alternative Approaches to Animal Testing.

Charles Laroche spoke with EURACTIV's Benjamin Fox.

The EU has always thought of itself as a pioneer in balancing ethics with science. Is Europe still leading the way when it comes to alternative methods to animal testing?

Indeed, for more than 20 years the EU has been a pioneer in balancing ethics with science particularly for what the replacement of animal testing by alternative methods is concerned. However, in the last years, we have noticed that the gap with all the regions, particularly North America, has been narrowing significantly.

Has the EU ban and the work of organisations such as the EPAA shaped testing methods elsewhere in the world?

We can say that EPAA has been

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paving the way for stronger and more effective cooperation between sectors. The EPAA Partners Forum, for example, has been developed as a means to stimulate synergies and promote cross-fertilization not only between sectors but also regions across the world.

EPAA has also invested in disseminating best practice in other regions. In particular China and Brazil through education and communication tools. Recently, the EPAA work on the harmonization of 3Rs in biologicals, allowed the WHO to delete Abnormal Toxicity Testing (ATT) from their requirements for human vaccines.

What are the main challenges faced by the industry to implement alternative methods?

One of the main challenges we are facing for implementation of alternative methods is the willingness of member states competent authorities to accept them. In this context, one of the EPAA key priorities is to organize training and knowledge sharing as we are and have been doing on skin sensitization with ECHA support.

There are still many jurisdictions where testing on animals is still required, and companies are required to conduct animal and non-animal tests to have access to those markets. What progress has been made towards a global ban on testing, or on avoiding this regulatory divergence?

The EU institutions have continuously tried to convince third countries to recognize the alternatives to animal testing within the frame of regulatory requirements. More recently the European Parliament has adopted a resolution calling on the European Commission and Council to make sure that the EU ban on animal testing is not weakened by any ongoing negotiations.

Brexit is going to become a reality next March, with or without a deal. Will Brexit have any impact on animal testing? Is there any danger of diverging standards?

In respective of Brexit, we can say that the UK has always been a front-runner for where animal welfare is concerned. This is something which is going to stay in the future.

The EPAA is now 13 years old. What will your priorities be for the next decade?

We will continue to facilitate at the same time, the pace of development, acceptance of new methodologies and the dissemination of progress made. The goal of the EPAA will stay to share information on alternatives to help accelerate validation and acceptance.

OPINION

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

More holistic approach needed for alternative methods in advancing safety assessment

By Julie Girling

Julie Girling is a British MEP with the European People's Party (EPP), currently member of the ENVI committee.

At the 14th Annual Conference of the EPAA (European Partnership for Alternative Approaches to Animal Testing), I was invited to host a panel discussion exploring the theme of the conference: pooling resources to promote the use of alternative methods for advancing safety assessment, writes Julie Girling.

Julie Girling is a member of the European Parliament for the European People's Party.

As we approach the end of 2018, it is important to take stock of developments in this critical field, successes and where work still needs to be done.

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It is an almost universally accepted principle, with widespread political support that the use of animals for regulatory and safety testing should be severely limited to the most practical degree possible, with the implementation of the three R's (replacement, reduction, refinement) the basis for regulation or codes of practice in this area of research and development.

That a given, it would be unwise to simply outlaw a scientific method that has provided tangible results in medical and pharmaceutical advances for decades. What is more, the stick approach to regulation – a method I am by nature cautious of – has often proven to be woefully inadequate when set against facilitation, synergy and nudge economics.

A more holistic approach is required if consensual progress is to be made while still allowing safe products developments to emerge.

In the European Parliament, there are opportunities to focus on the specific issue of animal testing, though systemic and multifaceted problems are typically addressed when the primary legislation is itself under scrutiny, the Cosmetics Regulation one example.

None the less, where it is appropriate, legislators do act. I have submitted an amendment to the draft PEST report currently going through the ENVI Committee. In the review of the Union's authorisation procedure for pesticides, I called for a process that 'ambitiously seeks to minimise animal test methods'.

Though the wording may be altered, I am confident any compromise will adequately reflect that sentiment, with support from across the political spectrum highlighting again the consensus to reduce animal testing where possible.

Despite the importance of legislative reforms, the most effective progress has been made through stakeholder relationships, particularly public-private partnerships. The EPAA is a great example of where expertise can be brought together to pursue a beneficial purpose. Such organisations should represent an efficient use of public resources and an ability to leverage private contributions to provide streamlined objectives and a focused delivery.

Examples of the above synergies in the public sector include projects to harmonise databases between agencies (e.g. EFSA, ECHA, EMA), to avoid duplication and to facilitate sharing of animal testing data. Similarly, in the private sector, interoperability between sectors and collaborative sharing of data can be highly effective in progressing alternatives (for example, the EPAA carcinogenicity projects in the pharmaceutical and agrochemical sectors).

The inception of the future joint safety database will be the crowning achievement, and the argument it should be transparent and publically accessible as possible is convincing.

The development and validation of non-animal alternatives can take years, requiring substantial and sustained budgets. When setting those budget lines or advocating future research calls such as Horizon Europe it is incumbent on stakeholders to make the most effective case and ensure its proper communication.

Alternative methods will require new protocols and their adoption requires education and skills training. Support for this is important and needs more focus, especially for laboratories and technicians. It is also vital that dissemination activities, particularly in the regulatory area are not only taking place in the EU but also globally.

For example, the European Parliament outreach programme is driving towards a UN resolution for a global ban on animal testing of cosmetics – a resolution that has been agreed at Plenary. In this context, it is key that public campaigns on animal welfare not only call for a ban but also for alternatives to ensure continued human and environmental safety.

I am confident that public and political pressure will continue to facilitate progress, and recent developments point towards that end. However, there is still serious work to be done and a focus at the international level is critical in reducing animal based trials.

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Contact us

Goksen Caliskan
Senior Manager
goksen.caliskan@euractiv.com
tel. +32 (0)2 788 36 79

Sarantis Michalopoulos
Reporter
sarantis@euractiv.com
tel. +32 (0)2 226 58 28