

CHEMICALWATCH

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US and EU experts discuss collaboration on new toxicology tools

FDA says joint work is essential to define the path forward and catalyse change

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The US Food and Drug Administration (FDA) wants to collaborate with European researchers in developing new toxicology tools that advance non-animal based safety science and health research. Speaking at a European Parliament workshop in Brussels Donald Prater of the FDA's Europe office said that "collaboration is essential to define needed pathways and catalyse change".

He said the FDA and the National Institute of Health in the US have launched a new regulatory science programme including support for novel approaches for transforming toxicology. Dr Prater echoed the general consensus amongst experts at the meeting that 21st century toxicology is moving away from animal-based techniques.

"It is clear that *in vivo* animal studies may not be the gold standard that new toxicology methods are compared against," he said. "There is a need to determine the relevance of *in vitro* results to what occurs in humans rather than what occurs in rodents and other test animals."

Troy Seidle, of both Humane Society International and AXLR8, an EU coordination project that is working to accelerate development and integration of advanced tools into health research and safety testing, said "investment in innovative, human-relevant tools and technologies for research and safety testing is key to unlocking the major human health questions that animal models have failed to address."

The new EU research and innovation framework programme Horizon 2020, that is currently before various EU Parliamentary committees, provides "an historic opportunity for Europe to take the lead in this global paradigm shift," he said.

The AXLR8 project suggests that an investment from the EU and industry of at least €325m should be committed to research for advancing and implementing a 21st century safety testing programme. Key AXLR8 recommendations are a public-public partnership between the EU and US and a public-private partnership with industry.

European and US collaboration was also highlighted by Julia Fentem, head of Unilever's Safety and Environmental Assurance Centre in the UK. "Horizon 2020 is an opportunity for EU-US transatlantic research collaboration and substantial EU research investment in safety science," she said. "The EU needs to start to increase its investment in this space... we have the opportunity to bring the EU and US work in this area under one umbrella."

Research outputs will enable the EU to have a strong scientific and policy voice on chemical and product safety at the OECD and in other international fora, continued Dr Fentem.

Maurice Whelan, head of the Systems Toxicology Unit and the European Union Reference Laboratory for Alternatives to Animal Testing (Eurl Ecvam), at the European Commission Joint Research Centre (JRC), commented on the level of consensus among workshop speakers: "I've been curious to see how different people are presenting the same ideas in different ways."

In his opinion Horizon 2020 should be supporting a safety assessment paradigm that is knowledge-driven rather than observation-driven. It must rely on "understanding toxicity rather than simply observing its effects".

It is critical that there is continuity and that all knowledge be shared from a central place, he said. "It sounds simple but we've been dreadful at it." With an extensive research programme of its own and its heavy involvement in key international collaborations, the JRC/Ecvam is ideally placed to provide an organisational hub and an overall reference point for pan-European efforts, he said.

Other speakers included Lisbeth Knudsen of the University of Copenhagen who said "the time is here to join and shape modern toxicology for a human-related assessment" and Marcel Leist, director of the Centre for Alternatives to Animal Testing in Europe and of the University of Konstanz, who said that we "now have a comprehensive toxicological toolbox for faster testing and better consumer protection."

The final speaker, Gill Langley of HSI, publicly-launched a new HSI report on advancing safety science and health research with innovative non-animal tools. She said the report was a "key resource for Horizon 2020 proposals".

The workshop was hosted by MEP Mario Pirillo of the progressive alliance of socialists and democrats. He said that "we have to explore means of research other than animal testing" and that Horizon 2020 should "boost modern and effective tools for human health and safety".

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