

Joint Research Centre
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Advancing safety assessment without animals: EURL ECVAM

Video transcript

Welcome to the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM)!

With this video, we want to show you what we're doing to advance the safety assessment of chemicals without the use of animals.

"Each day we use many products essential for our life and important for our hygiene and well being. In order to ensure that they cause no harm, all consumer products must undergo safety testing. To protect workers, chemicals also need to be assessed for their potential risks during the manufacturing process."

For testing the safety of chemicals, laboratory animals are still widely used. However, the European Union is strongly committed to animal welfare policy and the promotion of alternative methods in order to eliminate or minimise the use of animals for scientific purposes.

This policy is also reflected in EU legislation. A complete marketing ban on cosmetics containing new ingredients tested on animals has been in force since March 2013. This completes the phasing out of animal testing for cosmetics that started in 2004. Other legislation, such as the EU Regulation on Chemicals (known as REACH), requires the use of alternative methods wherever possible. This includes experiments on cells and tissues – also called in vitro methods – and computer based models.

Compared to animal experiments, alternative approaches are usually more cost effective and less time consuming. Being based on a thorough scientific understanding of physiological processes leading to toxicity, they can help us to understand how and why a certain chemical can affect the human body. And experiments using alternative methods can comply with the same international quality standards applicable for traditional animal testing.

"The European Union Reference Laboratory for Alternatives to Animal Testing was established in 2010 due to the increasing need for new methods to be developed and proposed for validation in the European Union. EURL ECVAM is hosted by the European Commission's Joint Research Centre in Ispra, Italy, and has a staff of some 50 scientists. It builds on the experience and achievements of the European Centre for the Validation of Alternative Methods, active in this field since 1991."

"In EURL ECVAM we coordinate and promote the development and use of alternative methods in regulatory testing as well as biomedical research. An important aspect of our work is the validation of alternative (in vitro) methods to ensure that they are fit for purpose. Recently we've established EU-NETVAL – a network of highly qualified laboratories across the EU that will support us in our validation studies. We also act as a focal point for the exchange of information by providing, for example, public databases and information systems on alternative methods."

"EURL ECVAM also relies on external scientific advice and the collaboration with regulators from EU member states. Dialogue with its stakeholders, such as industry, the biomedical research community, consumer organisations and animal welfare groups, is equally important. "

Advanced biotechnologies are facilitating the development of alternative methods. In particular, new tests based on using human cells or engineered tissue promise to better predict the potential toxic effects to humans when compared to laboratory animals. Alternative approaches are therefore not only important for ethical reasons but can also contribute to enhancing protection of the consumer and the environment.

"In vitro toxicity data can only be used to satisfy legal requirements for safety assessment if they are of the highest quality in terms of their reliability and traceability. Ideally too, the data produced with an alternative method should be accepted in different countries worldwide to facilitate global trade. This can be achieved by establishing internationally accepted test guidelines based on alternative methods and by working with a quality system such as GLP, or Good Laboratory Practice."

"To promote international standardisation and harmonisation therefore, EURL ECVAM works extensively with many different organisations within the EU and around the world, such as the OECD, (the Organisation for Economic Cooperation and Development), the International Cooperation on Alternative Test Methods, the European Partnership for Alternatives to Animal Testing and of course our own network of validation laboratories, EU-NETVAL."

"In EURL ECVAM, a promising alternative method will undergo a process called validation to ensure that it is fit for the intended use. Validation addresses a series of key questions, such as: Is the method reproducible in different laboratories? And is it suitable to predict a certain toxicological effect? Once the results of a validation study have been reviewed by a group of independent experts, EURL ECVAM issues a recommendation that specifies how the method can be used for different applications in order to avoid or minimise animal testing. "

In vitro techniques are not the only tool available however; advanced computational methods are also being developed to exploit the ever increasing speed and performance of computers.

"Toxicology is traditionally based on animal experiments and computational methods have the advantage of being faster, cleaner and providing information on the mechanistic basis of toxicological effects."

The approach relies on the computer-based generation of information on the properties of chemicals and on their potential toxicological effects on human health.

"A mathematical model that we are developing describes the body as a set of interconnected compartments, representing the human organs and the blood. These models describe what happens when a chemical enters the body: adsorption (via skin, lungs, or intestine), distribution (throughout the overall body), metabolism (usually occurring in the liver), and excretion. These models support the determination of safe exposure levels – to protect workers and consumers alike."

Alternative methods must be suitable for the testing the thousands of chemicals that end up in the products we buy. Although many new in vitro methods are becoming available, their validation poses a significant challenge. Typically it can take many months or even years to generate the data needed to fully evaluate their performance. To tackle this problem, EURL ECVAM is using a fully automated robotic in vitro testing platform that can deliver the results that we need in a fraction of the usual time.

"The advantages of High Throughput Screening, or HTS, are: reproducibility, a high level of precision, and of course the possibility to generate a lot of data in a short time. 100s of chemicals can be tested in one experiment. And apart from speeding up the validation process, HTS methods can be more readily taken up and used by industry and other ends-users. "

"EURL ECVAM disseminates information on many aspects of alternative methods through a series of publicly accessible databases and tools. For example, our Database on Alternative Methods – known as DB-ALM,

provides a wealth of information on well over 150 in vitro methods allowing laboratories around the world to use them. Another tool we have allows the tracking of a method's progress through validation, review and regulatory acceptance at the EU level and beyond."

"EURL ECVAM's work leads to tangible results: many internationally accepted test guidelines are based on methods validated by EURL ECVAM. In 2013, for example, two in vitro methods recommended by EURL ECVAM have been accepted by the OECD in the field of eye irritation, and are now available for use by companies and governments worldwide, reducing the need to test chemicals in the eyes of rabbits."

"Besides looking at individual methods, EURL ECVAM also cooperates with key stakeholders to devise holistic solutions to achieve reduction and replacement in particular areas of animal testing. In 2013 for example, we released our EURL ECVAM strategy on how to achieve animal-free assessment of chemicals for skin sensitization, an over-reaction of the immune system resulting in skin allergy. Achieving the aims outlined in this strategy will result in the saving of 10s of thousands of animal lives in the coming years."

"In December 2012 a team of EURL ECVAM scientists was awarded the LUSH International Science Prize for an innovative way of using data from in vitro experiments. We designed and demonstrated a high-throughput system to categorise chemicals based on their potential to cause liver toxicity."

"EURL ECVAM has a solid reputation in supporting EU policies in the area of alternatives to animal testing. We are proud of our achievements so far. We'll continue to look for smart ways to translate the results of innovative European research into 21st century tools and approaches ready for application. This new Life Science building is one of two recently constructed on the Ispra site of the European Commission Joint Research Centre, and is the new home of EURL ECVAM. It provides us with the interdisciplinary research environment and state-of-the-art laboratories that we need to play our role within the European research framework Horizon 2020, as a hub for advancing safety assessment science without animals."

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