

A public warehouse for toxicity data

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Part of the SEURAT-1 cluster, TOXBANK (Supporting Integrated Data Analysis and Servicing of Alternative Testing Methods in Toxicology) has developed a series of tools for the scientific community which are expected to help them replace repeated-dose systemic toxicity testing historically carried out in animals.

The new web-based tools, which are publically available, revolve around a dedicated warehouse for toxicity data management and modelling that collects results from SEURAT-1 projects and other sources including public databases. They also include a 'gold standard' compound database and repository of selected test compounds, as well as a reference resource for cells, cell lines and tissues of relevance for in vitro systemic toxicity research carried out in SEURAT-1.

Dr Emilio Benfenati, Head of the Laboratory of Environmental Chemistry and Toxicology at the Mario Negri Institute in Italy and coordinator of the project, explains how it will eventually reduce the need for in vivo testing, what stakeholders can expect until and after the project's end, and how other sectors, which still use in vivo data, will also benefit from it.

Where do you stand with the development of the TOXBANK data warehouse and the overall project objectives?

A production version of the TOXBANK data warehouse has been implemented that provides access to the processed data and protocols from the experiments, along with relevant public information. This

includes the development and/or customization of web-based interfaces for linking and uploading data, including raw, processed and model results.

Each step of the experiments is linked to protocols describing the procedures. A web-based user interface for searching, browsing, and filtering the results has been implemented to provide access to all protocols and data in a way that is sensitive of any intellectual property restrictions on access. The system has been implemented as a series of REST-based web services which enable interoperability with other systems across the cluster as well as with external resources.

The TOXBANK data warehouse has been publically accessible since the autumn of 2014. We are now incorporating the public data on reference compounds into the warehouse, supporting the meta analysis and risk assessment being carried out in the SEURAT-1 case studies. Thus, the 'engine' is ready, and is now being populated with data arising from the different SEURAT-1 projects, as well as with external data, such as ToxCast.

What do you think will be the impact of your work on research in this field?

The TOXBANK project establishes critical infrastructure and service functions to all SEURAT-1 projects, providing a centralized and standardised set of data resources, compounds, and biological samples, accompanied by standardized operating procedures and guidance. The provision of quality sources of compounds, cells and tissues for research will promote novel human cell-based assays that will facilitate more accurate evaluation of toxicity.

These resources will ensure that the alternative in vitro assays developed

by SEURAT-1 researchers are guided and supported from an early stage of design so as to maximize their chances of reaching the pre-validation stage as defined by ECVAM and eventually receiving validation and regulatory acceptance as required under REACH. Thus, regulatory agencies are our target beneficiaries for this infrastructure.

REACH also places a significant demand on the businesses operating in the European marketplace that are involved in importing and manufacturing products involving chemical entities. Wherever possible, companies are required to address the '3R' principles as well as to evaluate and potentially use and report on alternatives. Thus, industry is another major target for our infrastructure, since industry-standard resource facilities such as TOXBANK are required for safety assessment activity. SMEs in particular will be challenged by REACH as they generally do not have in-house tools and knowledge resources for assessment work.

We should also have a beneficial impact on Cosmetics Europe and other organizations affected by the Cosmetics Directive, which places a very strong 3R requirement on consumer product companies, by requiring that all systemic toxicity animal experiments are replaced by 2013.

Finally, we expect to generate a snowball effect where all data will progressively be made available, with the possibility of exploring the multiple associations between different sets of data. We think that there will be heightened impact due to the fact that the results of TOXBANK are easily accessible from a simple computer.

When will the platform be fully operational?

TOXBANK can already be used. To date, 61 protocols and data on 39 assays have been uploaded into the data warehouse, with 8 investigations currently being prepared.

TOXBANK also translated the data files and databases made available by the US EPA into the ISA-Tab so as to upload them into our data warehouse. The project will end in December 2015, thus we expect further data collection from our SEURAT-1 partners in the final months.

What can you tell us about the researchers' feedback so far?

TOXBANK has been presented at various conferences and events. The interest focuses on two aspects. First a practical issue: access to data which is usually hidden in reports from individual experiments. TOXBANK provides stakeholders with a 'panoramic' perspective on the data, which can be exploited to minimize the use of animals. The [cosmetic industry](#) is of course very interested in the weight-of-evidence perspective in order to assess the safety of cosmetic ingredients. For this industrial sector it is vital to optimize the use of all data.

The second reason for interest is theoretical: in general terms, the ability to fully exploit the data. This is of interest not only to the cosmetic industry. Regulators involved in REACH are also looking with interest at the results of TOXBANK and SEURAT-1. EFSA is also actively working on the use of all data and methods producing information from a weight-of-evidence perspective. In even more general terms, researchers are interested in extending the access and the use of the data. This is strategic for toxicology.

You will hold the TOXBANK public forum in October. What can stakeholders expect from this event?

The event is dedicated in particular to industrial stakeholders. The cosmetic industry is forced to explore all possible ways to prove the

safety of cosmetic ingredients, without resorting to animal tests. For this industrial sector it is vital to get sufficient evidence of the safety of their ingredients as soon as possible. TOXBANK will help by enabling the exploration of available data on substances in a transparent and efficient manner, integrating evidence from multiple sources, which would otherwise be difficult to merge. What TOXBANK provides is an advanced, powerful platform. But this event will also be an opportunity to get in touch with stakeholders, and solicit future interaction as well.

Do you feel that the EU is on the right track in meeting its objective of replacing animal testing?

The EU is a complex entity, with many different Member States, and many regulations. It indeed aims to replace [animal testing](#), but there are other objectives such as human safety and the protection of the environment, which in some cases may conflict with the phasing out of animal testing.

Surely the EU is very close to the replacement of animal testing for cosmetic ingredients, but other regulations go in a different direction. To replace animal testing while at the same time protecting human health and the environment, we need a shift similar to what was done for instance in the USA, with a unified strategy embracing different regulatory agencies and a common vision.

What are your plans after the project ends?

The EU, with the H2020 initiative, plans to keep supporting research on the replacement of animal testing. A new project, called EUTOXRISK21, will proceed along this way, joining tens of laboratories. Some of the partners of TOXBANK will participate in this new project, which is due to start in January 2016, and the experience

and the resources of TOXBANK will certainly be useful.

More information: For more information, please visit TOXBANK project website: toxbank.net/

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