Alternative Non-Testing methods Assessed for REACH Substances

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ANTARES is a **LIFE-funded project** (contract LIFE08 ENV/IT/0435), which stems from the need to verify the use and potential of alternative methods to animal testing for the REACH Regulation. For this it's necessary to understand the requirements and limits that the REACH legislation presents for alternative methods and identify factors and areas of best application for their safe use. The diffusion and the continuous improvement of these methods can not be separated from the integration and harmonization between them, as well as by an extensive and specific dissemination of their results.

Introduction, Objectives & Methods

The EU Regulation REACH, which entered into force in 2007 in the EU, represents today the most advanced system in the World to register, evaluate and authorize Chemical Substances.

According to latest estimates, about 40.000 substances will be processed in 3 phases, starting with high production volumes (from 1000 t) and the most concerning substances. The deadline of the 1st phase has been November 30, 2010.

To correctly evaluate the impact on the environment and human health, Industry will pay a high cost (billions of euros), and millions of animals might be sacrified to produce the necessary toxicity data.

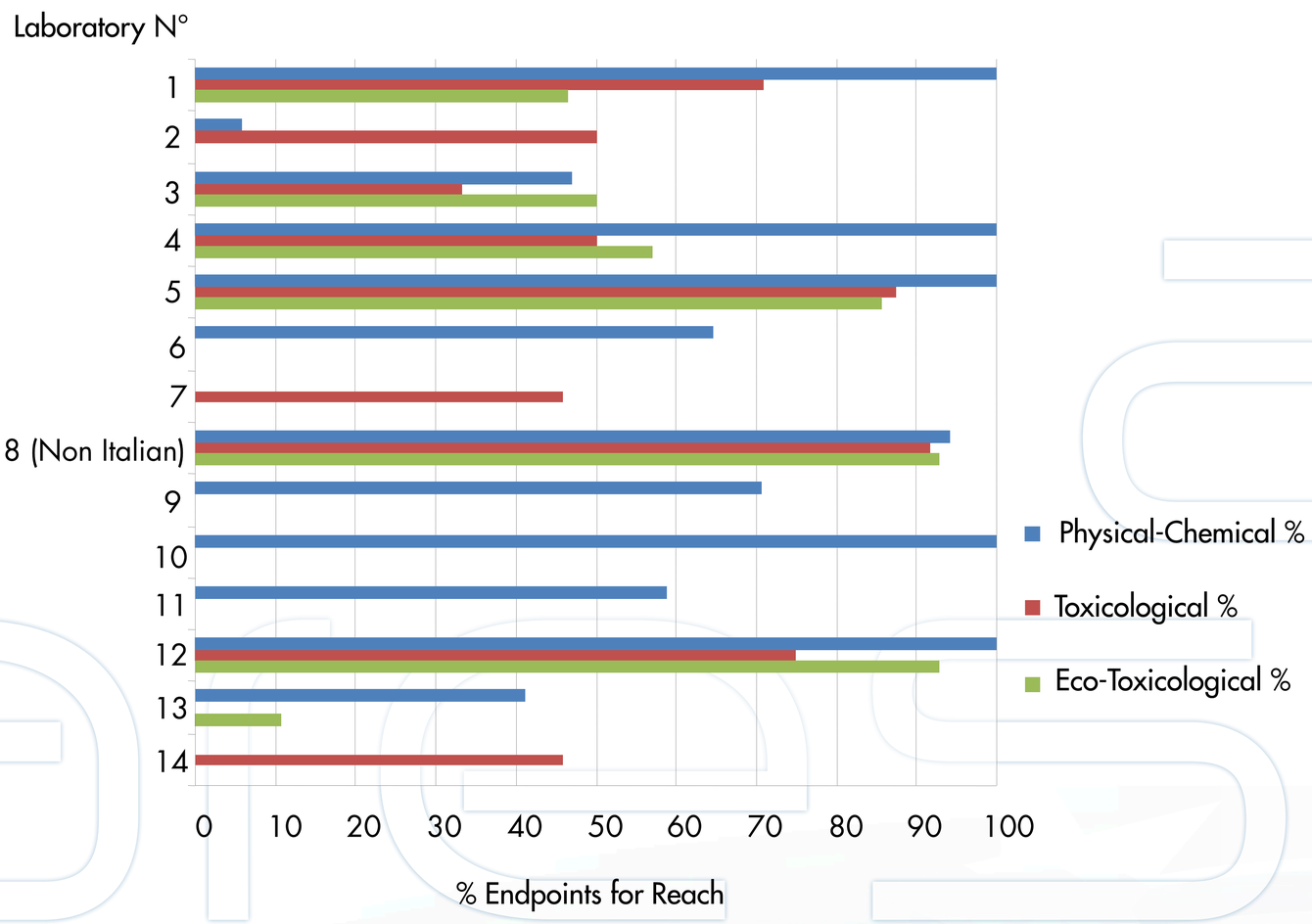
To limit these problems, REACH legislation promotes the use of non-testing methods, including Read Across and quantitative structure-activity relationship (QSAR). Read Across bases the evaluation of the unknown compound on the values of similar chemicals, while QSAR uses some chemical descriptors to evaluate the toxicity. Experience on the validity, predictivity and feasibility of these tools is still under discussion.

ANTARES WANTS TO EFFECTIVELY ADDRESS THE PROBLEM TO CHECK HOW TO USE THE NON-TESTING METHODS, FOR WHICH ENDPOINTS AND IN WHICH WAY

- ANTARES made an *overview* on current common methods to evaluate their practical availability, costs, number of animals, etc. to identify higher requirements for the alternative methods.
- Actions were taken to produce an *overview of laboratories which can provide the current tests*.

Results

REACH Endpoint Laboratory Capabilities in Italy



- Numerous contacts were launched with PUBLIC and PRIVATE LABORATORY STRUCTURES in ITALY.
- Most of the collaborating companies offer phys-chem testing, 7 laboratories offer toxicological and/or ecotoxicological testing.
- 12 Italian laboratories have indicated GLP certification.
- A well-known GLP certified European laboratory also collaborates in the project.
- 5 Italian companies offer tests for at least 50 % of REACH tox endpoints, 4 of them can conduct equal/more than 50 % of REACH ecotox endpoint testing.
- Some laboratory indicated in vitro/alternative testing capability.
- The non-Italian laboratory covers more than 90 % of all requirements, one Italian laboratory has same capabilities.

Conclusions

The monitoring of the Italian laboratory situation for REACH testing will continue to update the situation for GLP certification on tox and ecotox testing activities/capabilities.
The next registration deadline 2013 will involve many substances which need new studies compared to the 2010 registered substances.

THE INVENTORY HERE SHOWN IS NOT REFLECTING THE COMPLETE PICTURE OF ITALIAN LABORATORIES, SINCE IT IS BASED ON INFORMATION DELIVERED BY THE COMPANIES

Contribution for graphics: VITTORIO CASTIGLIONI, Istituto di Ricerche Farmacologiche Mario Negri