

Chiara Milan¹, Alessandra Roncaglioni¹, Leonello Attias², Silvia Alivernini², Ralf Knauf³, Giuseppina Gini⁴, Frank Lemke⁵, Emilio Benfenati¹

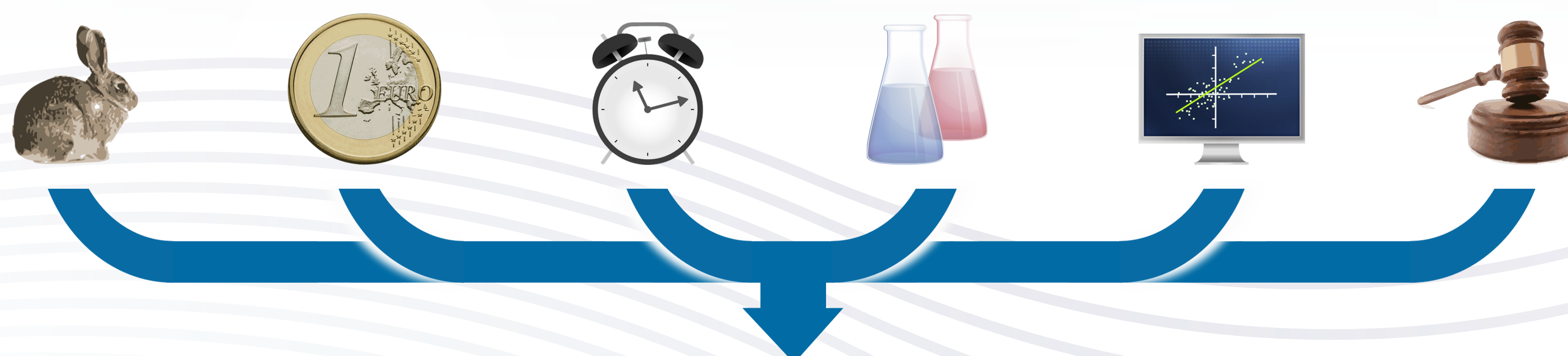
¹ IRFMN, Istituto di Ricerche Farmacologiche Mario Negri, Via Giuseppe La Masa 19, 20156 Milan, Italy

² ISS, Istituto Superiore di Sanità, Viale Regina Elena 299, Rome, Italy

³ FEDERCHIMICA, Federazione Nazionale dell'Industria Chimica, Via Giovanni da Procida 11, Milan, Italy

⁴ POLIMI, Politecnico di Milano, Dipartimento di Elettronica e Informazione, Piazza Leonardo da Vinci 32, Milan, Italy

⁵ KM, KnowledgeMiner Software Frank Lemke, Duererstrasse 40, Panketal, Germany








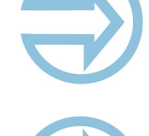

PROMOTION OF **NON-TESTING METHODS (NTM)** FOR THEIR USE IN THE **REACH** CONTEXT LINKING **SCIENTISTS, REGULATORS AND INDUSTRIES**

TO EVALUATE AND VALIDATE EXISTING NTM FOR THEIR APPLICATION ACCORDING TO REACH NEEDS

Objectives

- To verify the possible **USE** and **PERFORMANCES** of the non-testing methods (**QSAR MODELS** and **READ ACROSS**) for **REACH**;
- To identify **REQUIREMENTS** and **CONSTRAINTS** originating from the **REACH** legislation;
- To identify **SAFETY ASSESSMENT FACTORS** for the non-testing methods;
- To identify the **BEST APPLICABILITY** for a safer use of the non-testing methods;
- To **INTEGRATE DIFFERENT NON-TESTING METHODS**, achieving superior performances.

Main Actions

- 1  Survey of current methods for the compliance to the **REACH** legislation.
- 2  Identification of the criteria for the non-testing methods for the **REACH** legislation.
- 3  Identification of suitable experimental databases/data sets for the ecotoxicological, toxicological and environmental endpoints for **REACH**.
- 4  List of (Q)SAR models for the ecotoxicological, toxicological and environmental endpoints for **REACH**, and their review.
- 5  Validation of non-testing methods (including read-across).
- 6  Identification of boundaries for best use of models (applicability domain) and of the assessment factors.
- 7  Architecture for integration of different non-testing methods for best performances and coverage of applicability.

List of Results which will be evaluated

- | | |
|---|---------------------------|
| • Skin sensitization, oral acute toxicity, carcinogenicity and mutagenicity | ➤ Toxicological group |
| • BCF and persistence | ➤ Environmental group |
| • Acute fish toxicity and acute daphnids toxicity | ➤ Ecotoxicological group |
| • LogP and Solubility | ➤ Physical chemical group |