

New Approach Methodologies (NAMs)

Activities at the JRC

Elisabet Berggren

76th MEETING OF THE EFSA ADVISORY FORUM, 1-2 July 2020



The Joint Research Centre Mission

We are the science and knowledge service of the Commission
our mission is to support EU policies with independent evidence
throughout the whole policy cycle.



Unit F3: Chemicals Safety & Alternative Methods

**EURIL
ECVAM**

European Union Reference Laboratory for alternatives to
animal testing

3Rs

mandate under Directive 2010/63

- research & evaluation of non-animal approaches
- validation of alternative methods
- dissemination of information, knowledge sharing & promotion of alternative methods and the Three Rs



The background of the slide is a collage. On the left, there is a photograph of laboratory glassware, including a round-bottom flask and several test tubes, some containing colored liquids. The rest of the background is a textured image of many old, stacked books, suggesting a library or a collection of knowledge.

Unit F3: Chemical Safety & Alternative Methods

Regulation 1907/2006 on registration, evaluation, authorisation and restriction of chemical substances
'REACH'

Regulation 1107/2009 on the placing of **Plant Protection Products** on the market

Regulation 528/2012 on authorisation of **Biocidal** active ingredients and **Products**

Regulation 1272/2008 on classification, labelling and packaging of chemical substances and mixtures **'CLP'**

Directive 2001/82/EC on **Veterinary Medicinal Products**

Directive 2001/83/EC on **Human Medicinal Products**

Regulation 1223/2009 on **Cosmetic Products**

Community Strategy on **Endocrine Disrupters**

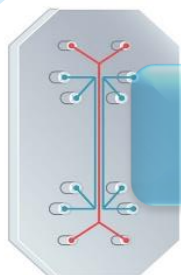
Community Strategy on combined exposures **'Mixtures'**

EU
chemicals
acquis:
>40
pieces of
legislation

Chemical assessment methodologies



Standards



ECVAM lab



Validation



Regulatory acceptance & implementation



Reliability & Relevance



<https://ec.europa.eu/jrc/en/science-update/innovation-collaboration-education-drive-progress-alternatives-animal-testing>

EURL ECVAM Status Report

on the Development, Validation and Regulatory Acceptance
of Alternative Methods and Approaches (2019)

Annex 1 — Summary status of the adoption of Test Guidelines based on *in vitro* methods in the OECD TG programme

Table 1 summarises the status of adoption of OECD test guidelines based on *in vitro* methods. It should be noted that beside TGs, also Guidance Documents and new projects on alternative methods were respectively adopted and included in the OECD Work programme. For additional information, please consult the OECD website of the Test Guidelines Programme: <https://www.oecd.org/chemicalsafety/testing/oecd-guidelines-testing-chemicals-related-documents.htm>

Table 1. Status of adoption of OECD Test Guidelines based on *in vitro* methods.



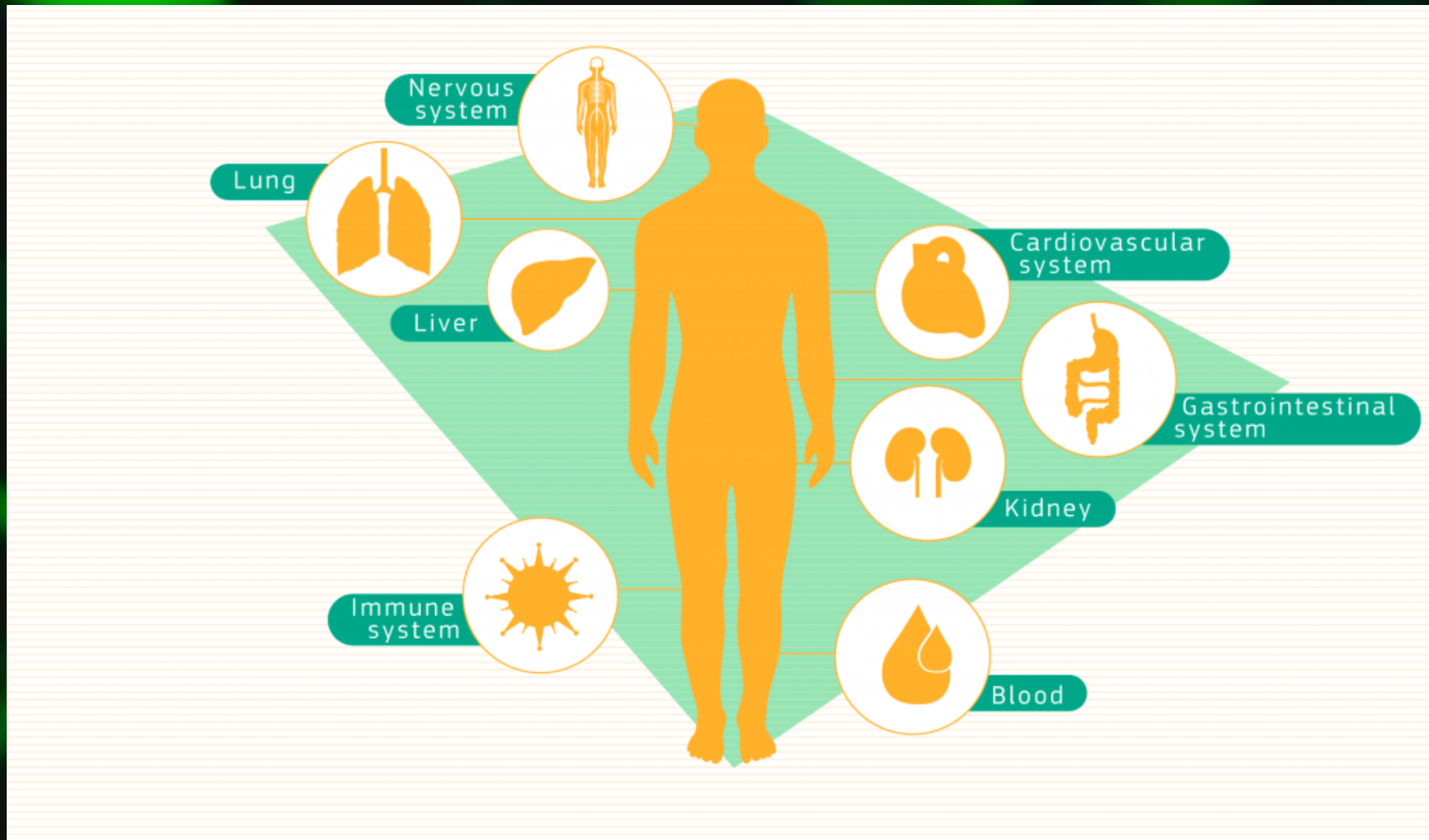
European
Commission

<https://tsar.jrc.ec.europa.eu/>
JOINT RESEARCH CENTRE



Tracking System for Alternative methods towards Regulatory acceptance (TSAR)

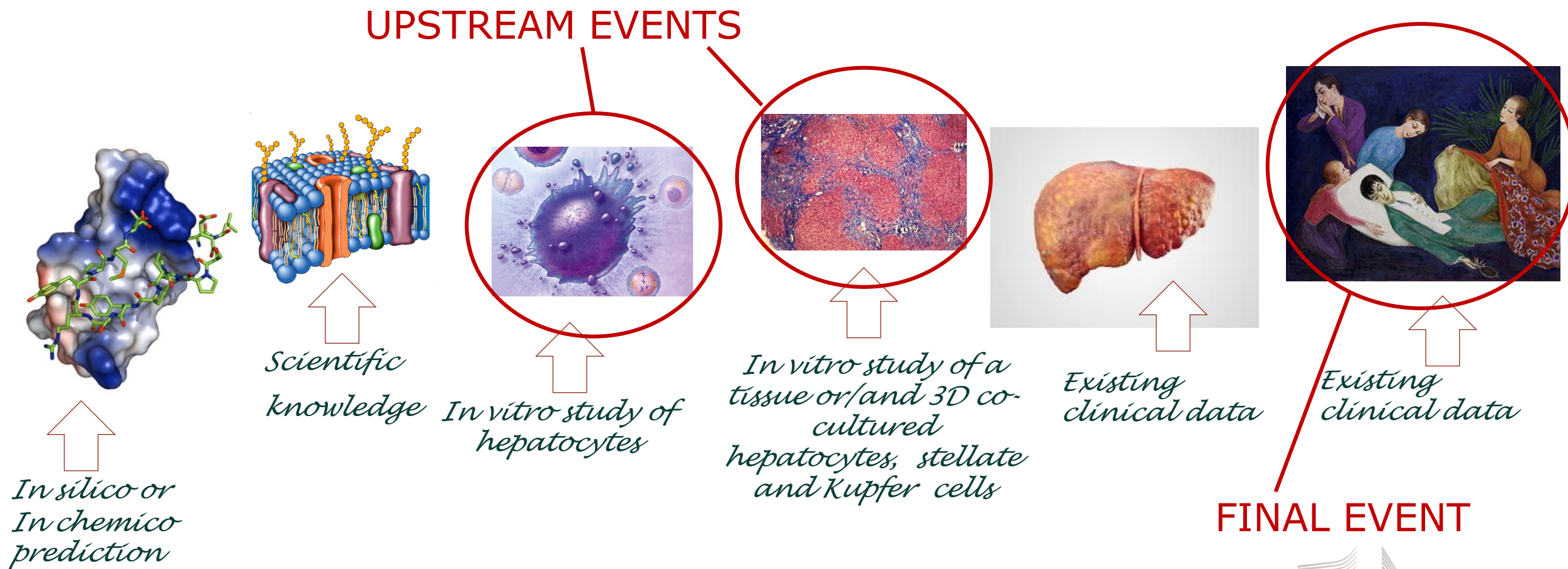
Replacement in acute systemic toxicity testing



Prieto et al. "Investigating cell type specific mechanisms contributing to acute oral toxicity". Altex, 2018 doi:10.14573/altex.1805181

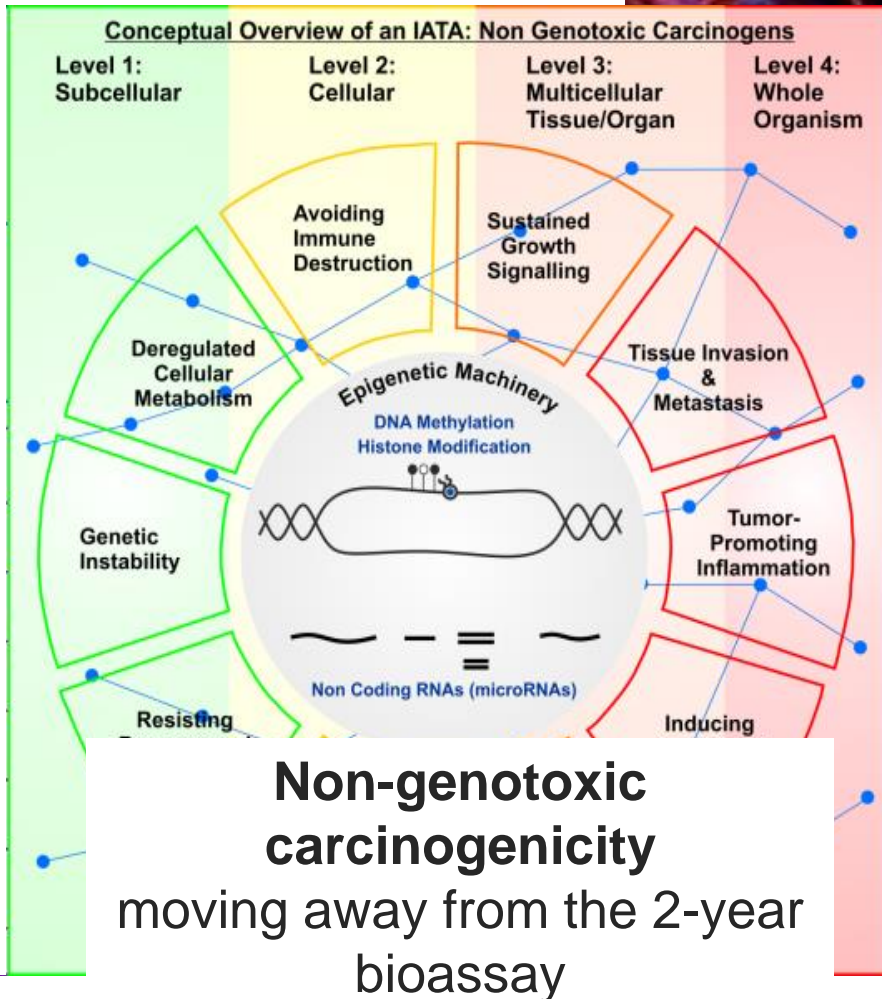
Selected as best manuscript
published in ALTEx in 2019

AOP upstream events leading to systemic toxicity



Integrated Approaches to Testing and Assessment

OECD Guidance on application and interpretation of in-vitro DNT assays



OECD Guidance on the Characterisation, Validation and Reporting of PBK Models

Integrated Approaches to Testing and Assessment (IATA) Case Studies Project



Cross-endpoint evaluation



Thank you



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