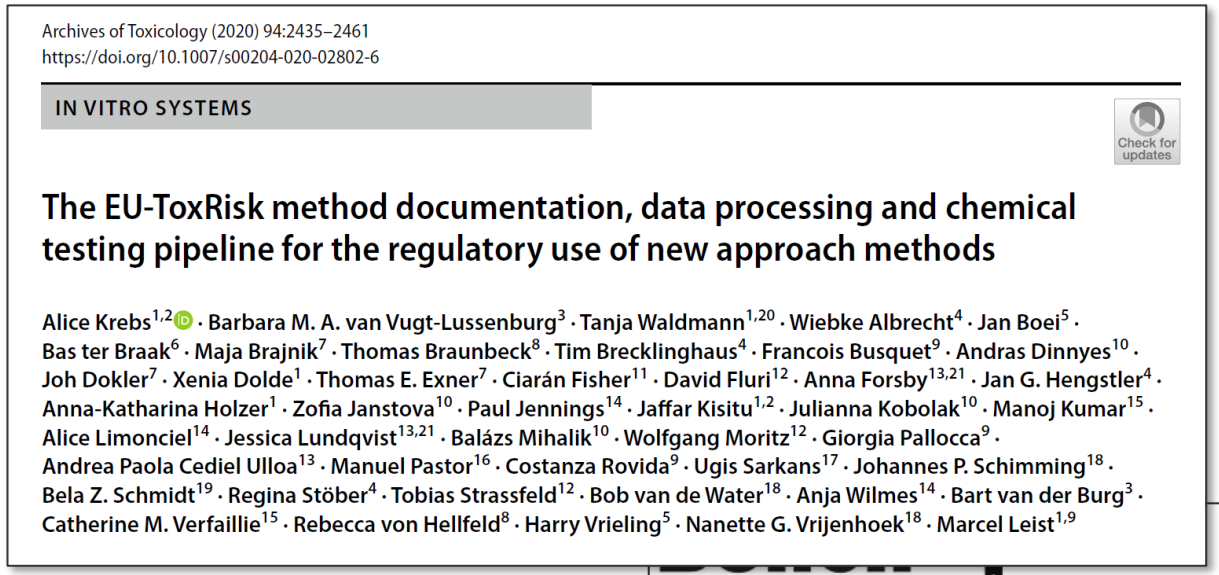
Bob van de Water

EU-ToxRisk Achievement: Guidance on method description.

RISK HUNT3R

150 test method descriptions uploaded on the EU-ToxRisk Knowledge Platform



Archives of Toxicology (2020) 94:2435–2461
https://doi.org/10.1007/s00204-020-02802-6

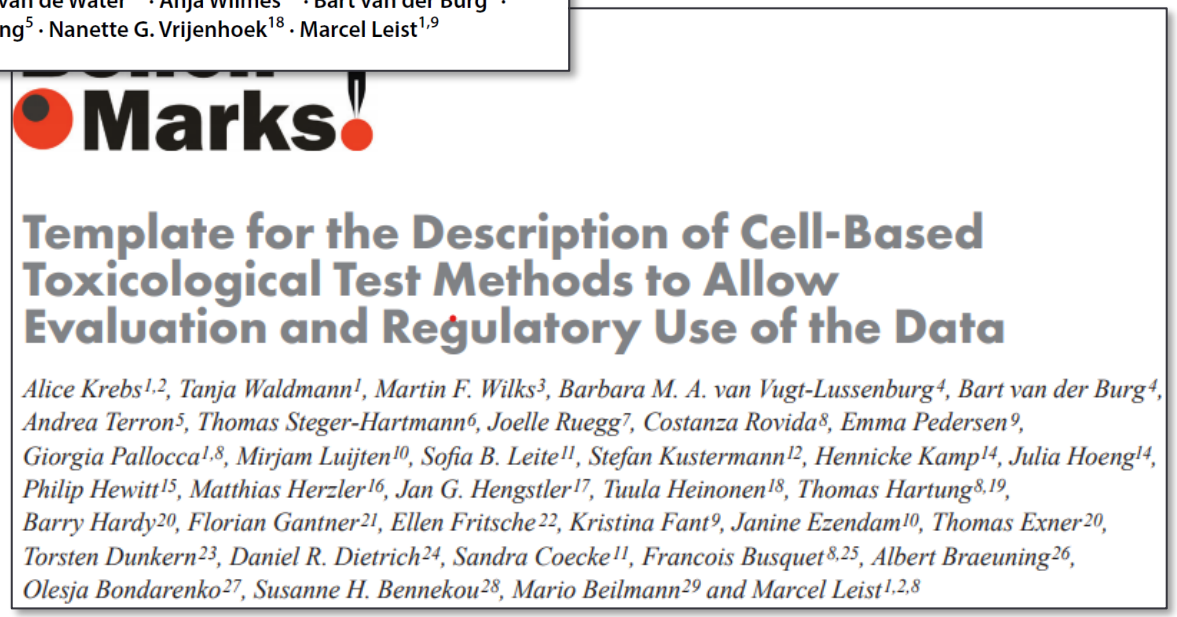
IN VITRO SYSTEMS

Check for updates

The EU-ToxRisk method documentation, data processing and chemical testing pipeline for the regulatory use of new approach methods

Alice Krebs[1,2] · Barbara M. A. van Vugt-Lussenburg[3] · Tanja Waldmann[1,20] · Wiebke Albrecht[4] · Jan Boei[5] · Bas ter Braak[6] · Maja Brajnik[7] · Thomas Braunbeck[8] · Tim Brecklinghaus[4] · Francois Busquet[9] · Andras Dinnyes[10] · Joh Dokler[7] · Xenia Dolde[1] · Thomas E. Exner[7] · Ciarán Fisher[11] · David Fluri[12] · Anna Forsby[13,21] · Jan G. Hengstler[4] · Anna-Katharina Holzer[1] · Zofia Janstova[10] · Paul Jennings[14] · Jaffar Kisitu[1,2] · Julianna Kobolak[10] · Manoj Kumar[15] · Alice Limonciel[14] · Jessica Lundqvist[13,21] · Balázs Mihalik[10] · Wolfgang Moritz[12] · Giorgia Pallocca[9] · Andrea Paola Cediel Ulloa[13] · Manuel Pastor[16] · Costanza Rovida[9] · Ugis Sarkans[17] · Johannes P. Schimming[18] · Bela Z. Schmidt[19] · Regina Stöber[4] · Tobias Strassfeld[12] · Bob van de Water[18] · Anja Wilmes[14] · Bart van der Burg[3] · Catherine M. Verfaillie[15] · Rebecca von Hellfeld[8] · Harry Vrieling[5] · Nanette G. Vrijenhoek[18] · Marcel Leist[1,9]

Krebs et al. Arch Toxicol. 2020 Jul;94(7):2435-2461.



Marks!

Template for the Description of Cell-Based Toxicological Test Methods to Allow Evaluation and Regulatory Use of the Data

Alice Krebs[1,2], Tanja Waldmann[1], Martin F. Wilks[3], Barbara M. A. van Vugt-Lussenburg[4], Bart van der Burg[4], Andrea Terron[5], Thomas Steger-Hartmann[6], Joelle Ruegg[7], Costanza Rovida[8], Emma Pedersen[9], Giorgia Pallocca[1,8], Mirjam Luijten[10], Sofia B. Leite[11], Stefan Kustermann[12], Hennicke Kamp[14], Julia Hoeng[14], Philip Hewitt[15], Matthias Herzler[16], Jan G. Hengstler[17], Tuula Heinonen[18], Thomas Hartung[8,19], Barry Hardy[20], Florian Gantner[21], Ellen Fritsche[22], Kristina Fant[9], Janine Ezendam[10], Thomas Exner[20], Torsten Dunkern[23], Daniel R. Dietrich[24], Sandra Coecke[11], Francois Busquet[8,25], Albert Braeuning[26], Olesja Bondarenko[27], Susanne H. Bennekou[28], Mario Beilmann[29] and Marcel Leist[1,2,8]

Krebs et al. ALTEX. 2019;36(4):682-699.

EU-ToxRisk Achievement: Advanced novel test methods

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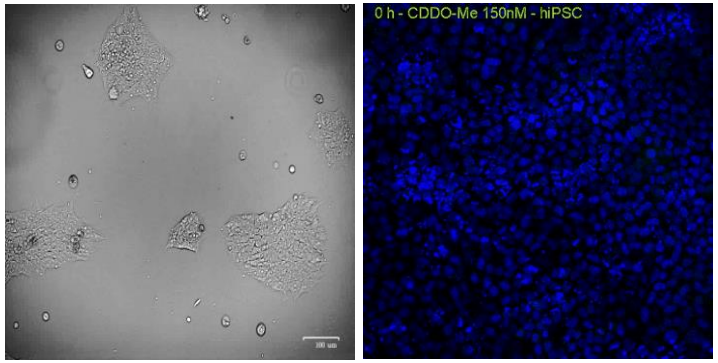
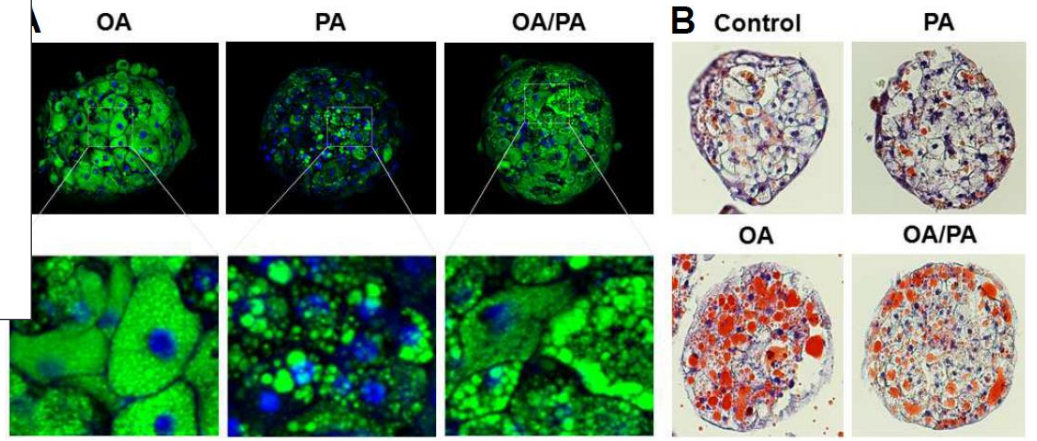
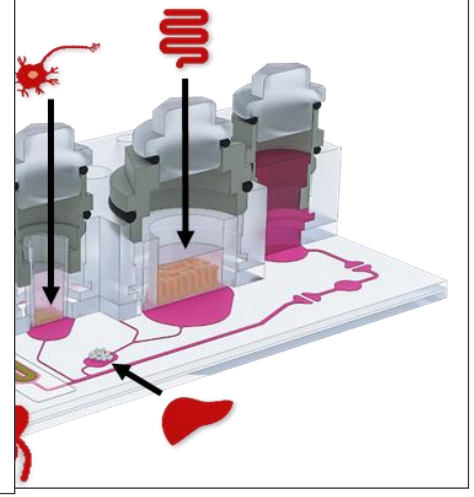
CRISPR-based fluorescent reporters in stem cells



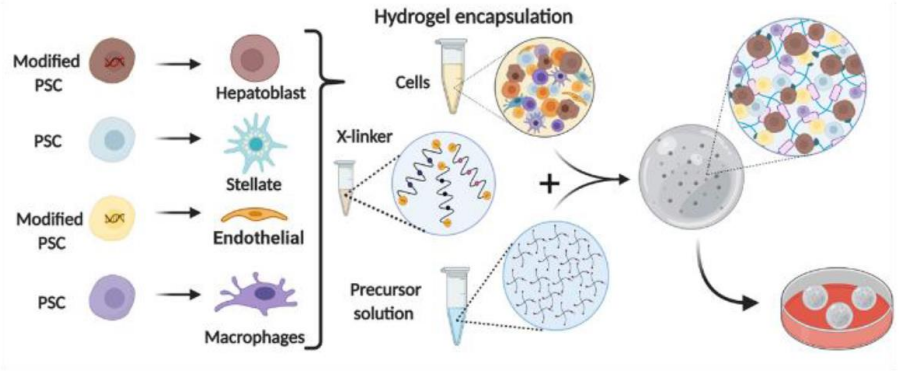
Diseased liver microtissues



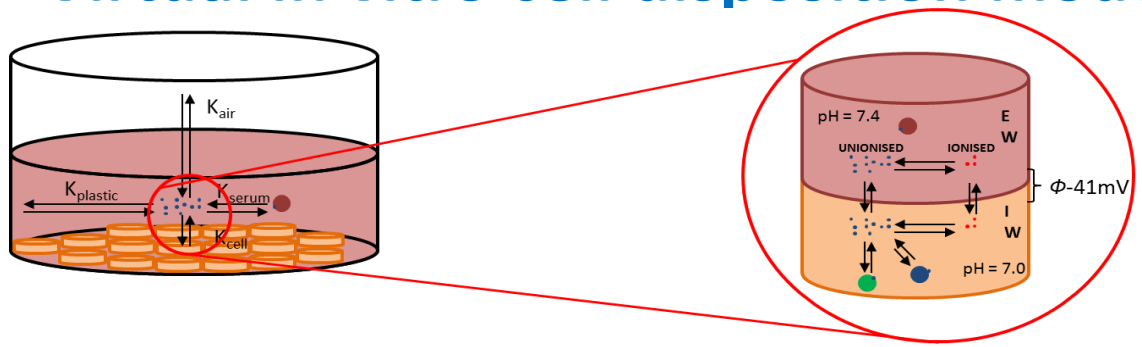
Four-organ-chip



Stem cell-derived multi-liver-cell model

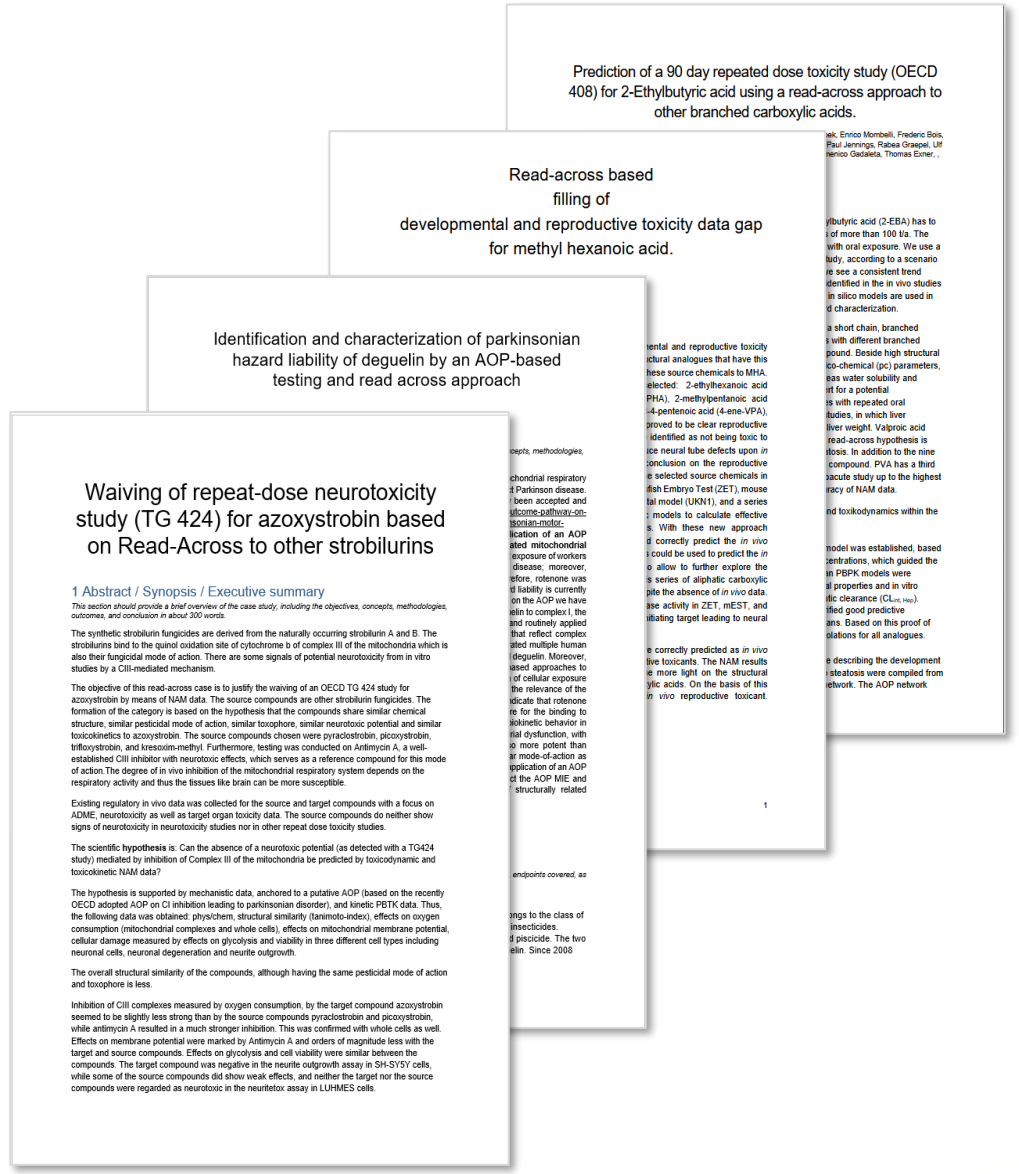


Virtual in vitro cell disposition model



EU-ToxRisk Achievement: Advisory document on regulatory requirements for acceptance of NAM-assisted RAx

RISK HUNT3R




ASPIS

Animal-free
Safety assessment of Chemicals:
Project cluster for
Implementation of novel
Strategies

ASPIS

Revolutionary defensive tool, designed to push forward into the opposing army, joining forces for better protection

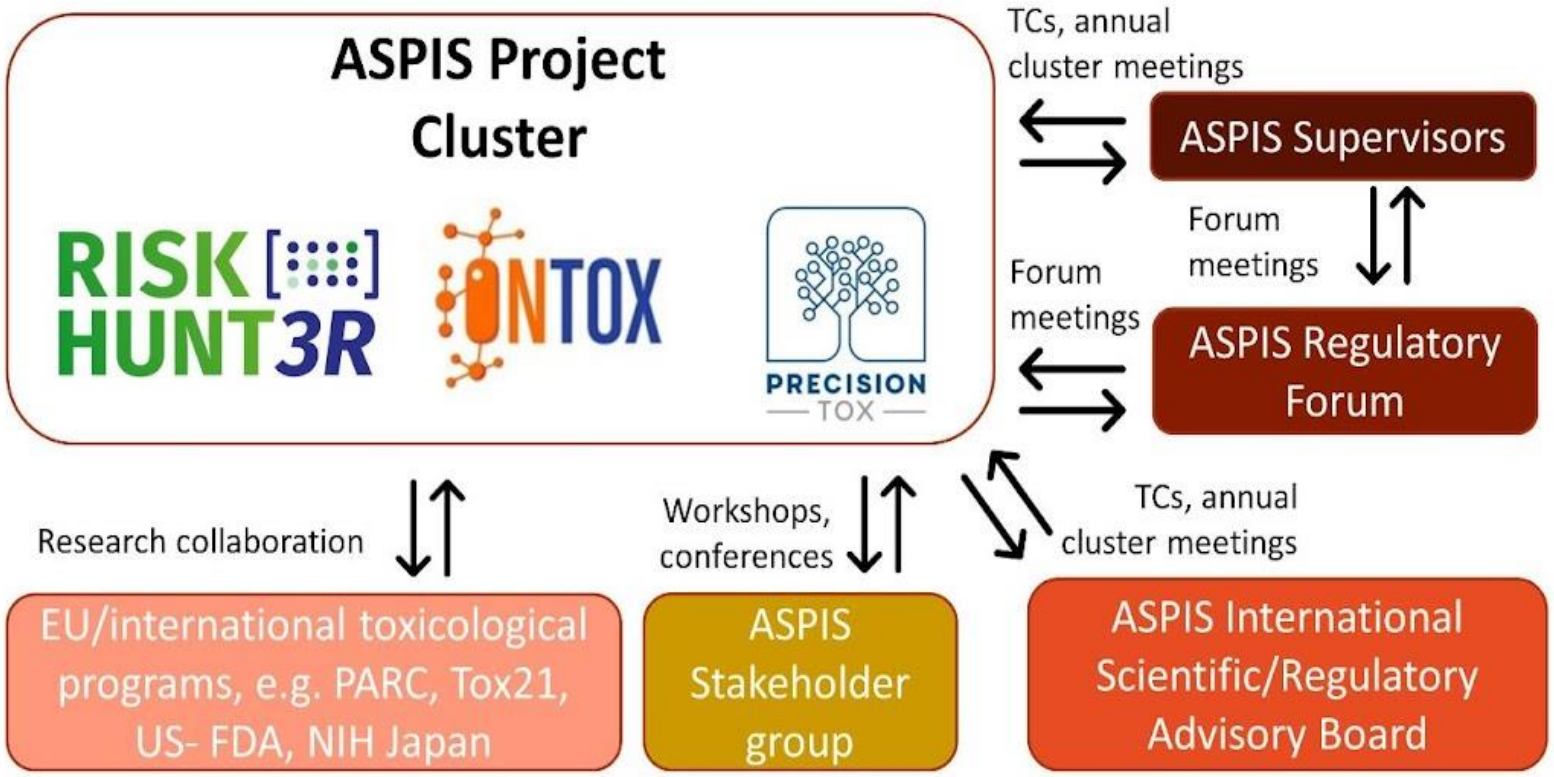
ASPIS: "Animal-Free Safety Assessment of Chemicals: Project Cluster for Implementation of Novel Strategies"

- 2021-2026 under H2020
- €60M funded budget
- 70 institutions united in 3 projects across 16 EU countries + US

Objectives

- **advance NAMs** for the protection of human health and the environment
- **improve certainty** in the safety assessment of chemicals
- facilitate practicably implementable **non-animal solutions** in various public (e.g. regulatory agencies) and private (e.g. industry) sectors
- **translate results, methods and solutions** from the scientific research community into **safety assessment practice**
- **promote regulatory uptake** and **commercial exploitation of NAMs**
- contribute to the **3R principles**

ASPIS interaction with satellite entities



Background of NGRA approaches

Food for Thought ...

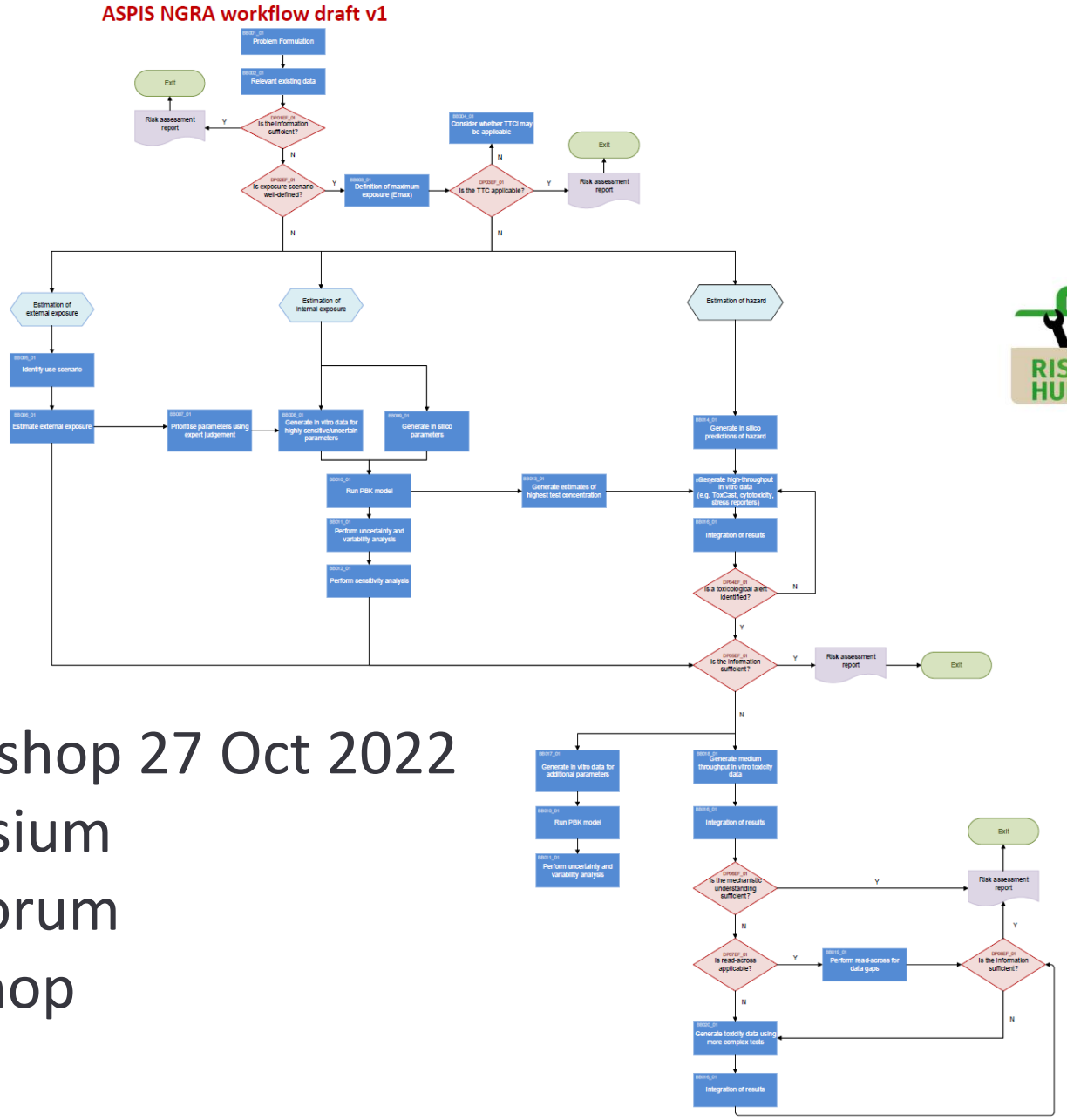
Ready for Regulatory Use: NAMs and NGRA for Chemical Safety Assurance

Paul L. Carmichael[1,2], Maria T. Baltazar[1], Sophie Cable[1], Stella Cochrane[1], Matthew Dent[1], Hequn Li[1], Alistair Middleton[1], Iris Muller[1], Georgia Reynolds[1], Carl Westmoreland[1] and Andrew White[1]

[1]Safety & Environmental Assurance Centre (SEAC), Unilever, Sharnbrook, Bedfordshire, UK; [2]Toxicology, Wageningen University & Research, Wageningen, The Netherlands

ALTEX (2022), 399, 419	The assessment is...
OBJECTIVES	1. focused on safety
	2. exposure-led
	3. hypothesis-driven
	4. based on adversities (rather than "perturbations")
	The assessment uses...
PROCEDURE	5. consideration of all existing info
	6. tiered and iterative approaches
	7. robust and relevant methods and strategies
	The assessment includes...
DOCUMENTATION	8. documentation and quantification of uncertainty
	9. documentation of all steps and the rationale for conclusions

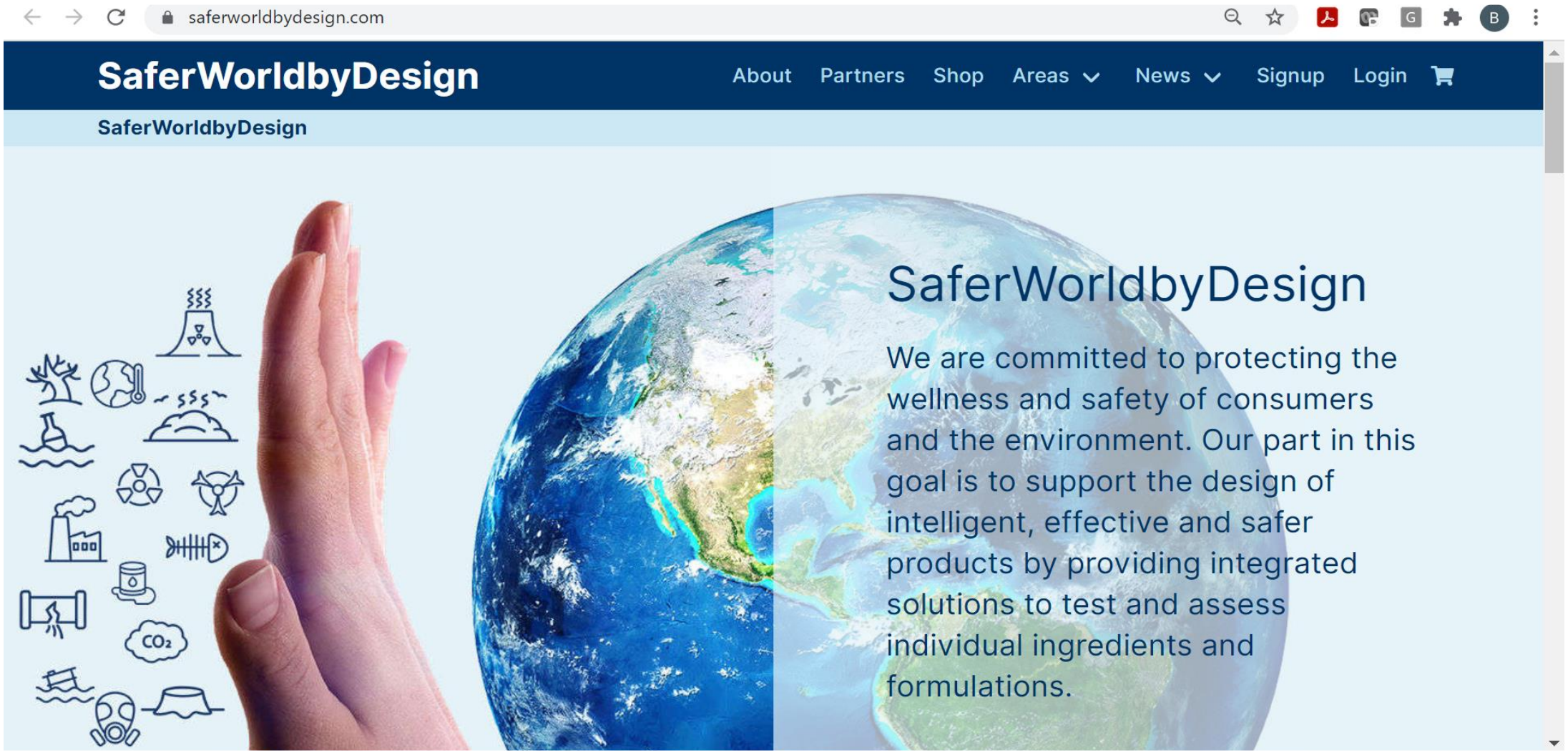
ASPIS NGRA workflow



- ASPIS partner workshop 27 Oct 2022
- ASPIS Open Symposium
- ASPIS Regulatory Forum
- Stakeholder workshop
- Case studies


ASPIS
open
symposium
www.aspis-cluster.eu
24-25 nov 2022
Sitges - Spain

EU-ToxRisk Achievement: SaferWorldbyDesign



Critical issues for discussion.

- Need to facilitate ‘validation’ of science driven test methods.
- Requirement to enhance access of test methods for stakeholders.
- Need to break the (stakeholder) barrier for NAM application in NGRA.

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Thank you!

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 964537.