

New Approach Methodologies (NAM) based Next Generation Risk Assessment (NGRA) in food safety risk assessment in Unilever

Tang D, Hepburn P, Punt A

^a *Unilever Safety and Environmental Assurance Centre, Colworth Science Park, Sharnbrook, Bedfordshire MK44 1LQ, UK;*

Safety and Environmental Assurance Centre (SEAC) in Unilever

SEAC is Unilever's global centre of excellence in Safety & Sustainability Sciences, part of R&D's Safety, Environment & Regulatory Sciences Capability.

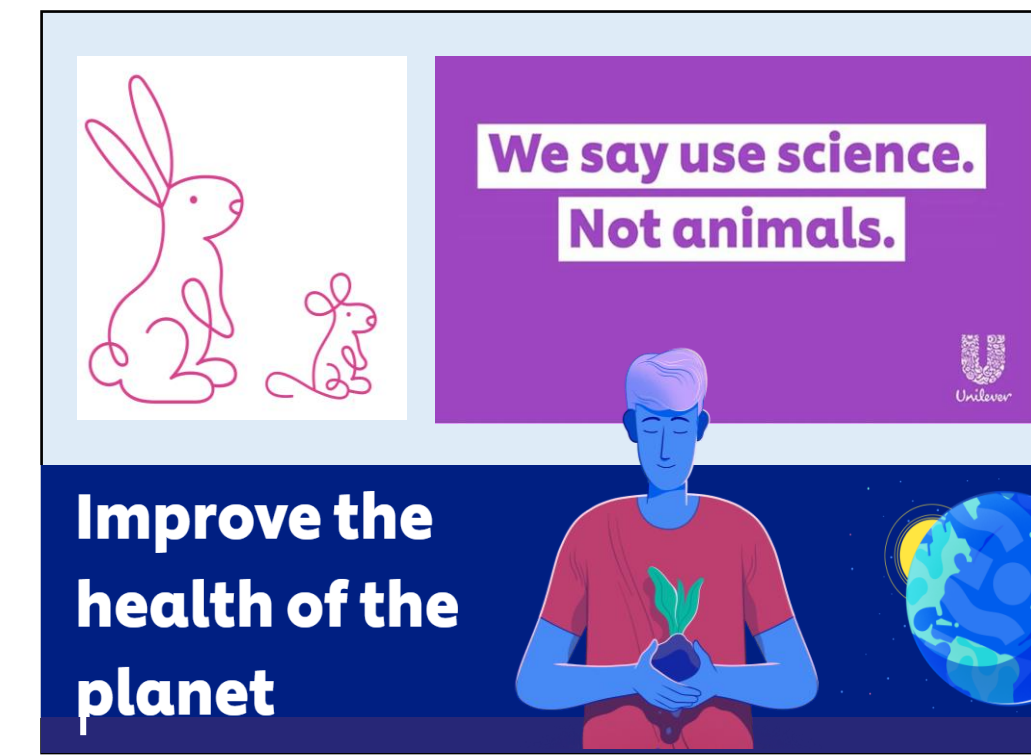
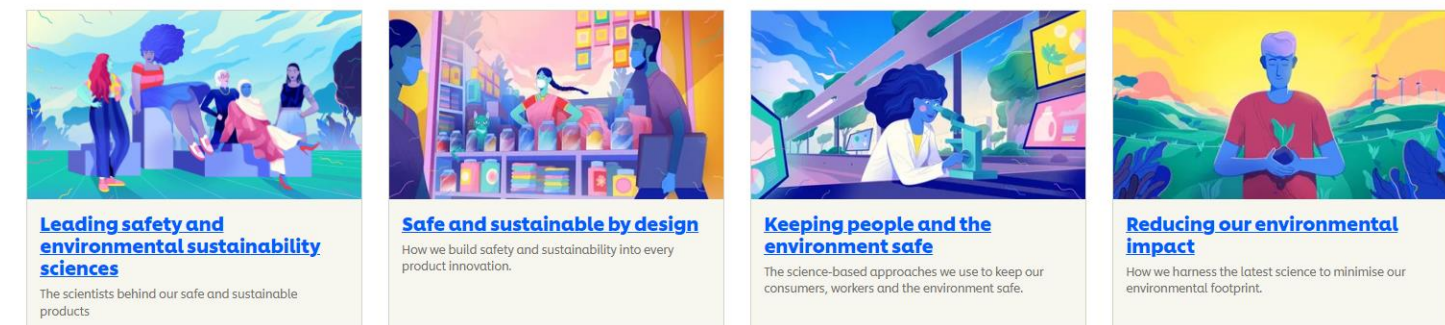
Diverse, multi-disciplinary team of ~150 scientists based at Colworth, UK; ~70 miles north of London

Highly collaborative, working with over 70 academic, industry, government & NGO partners worldwide

Team SEAC's purpose is to protect people & the environment by ensuring:

- Unilever's products & innovations are **Safe & Sustainable by Design without animal testing**
- Our scientists & capabilities are **industry-leading with high business impact via Unilever's Products & Brands**
- Safety & Env. Sustainability **policies & regulations are based on modern science**

Much of our strength lies in our shared Values – to be an **inclusive, supportive & collaborative** Team that is **pioneering, transparent & high-performing** with a strong focus on **learning & wellbeing**.



NAM based NGRA in food safety

Chemical safety assessment has been undergoing a paradigm shift over the last decade, with the development of New Approach Methodologies (NAMs),

Such paradigm shifts has been recognised by a number of authorities in food safety, notably, FDA and EFSA, for example:

- EFSA incorporating the development and integration of NAMs as part of their 2027 strategy
- FDA is also working to advance alternative methods for regulatory use

In addition, organisations such as BfR, FDE, ILSI are also organising task force, conferences, workshops and publications to advocate NAM based risk assessment method in food safety.

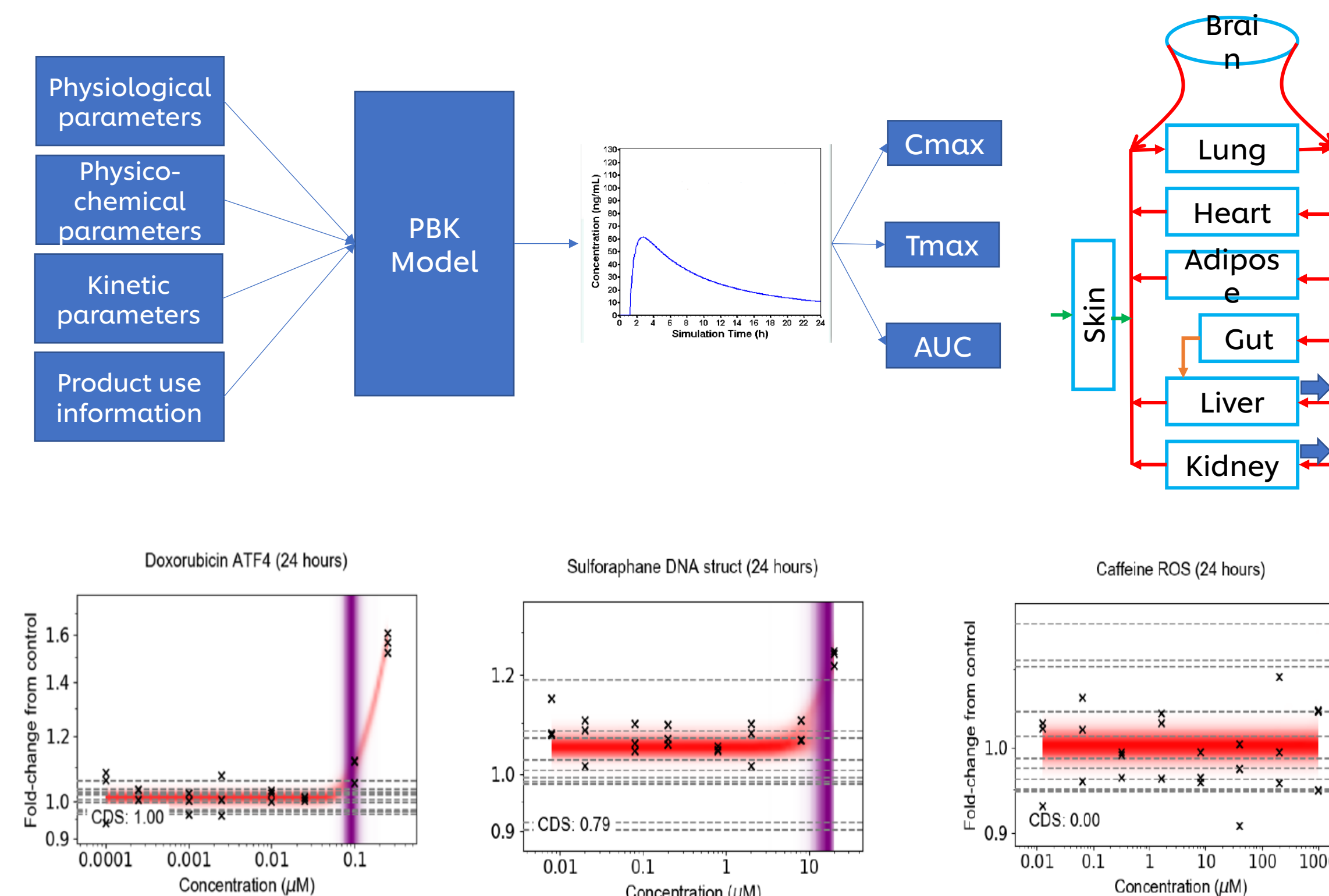
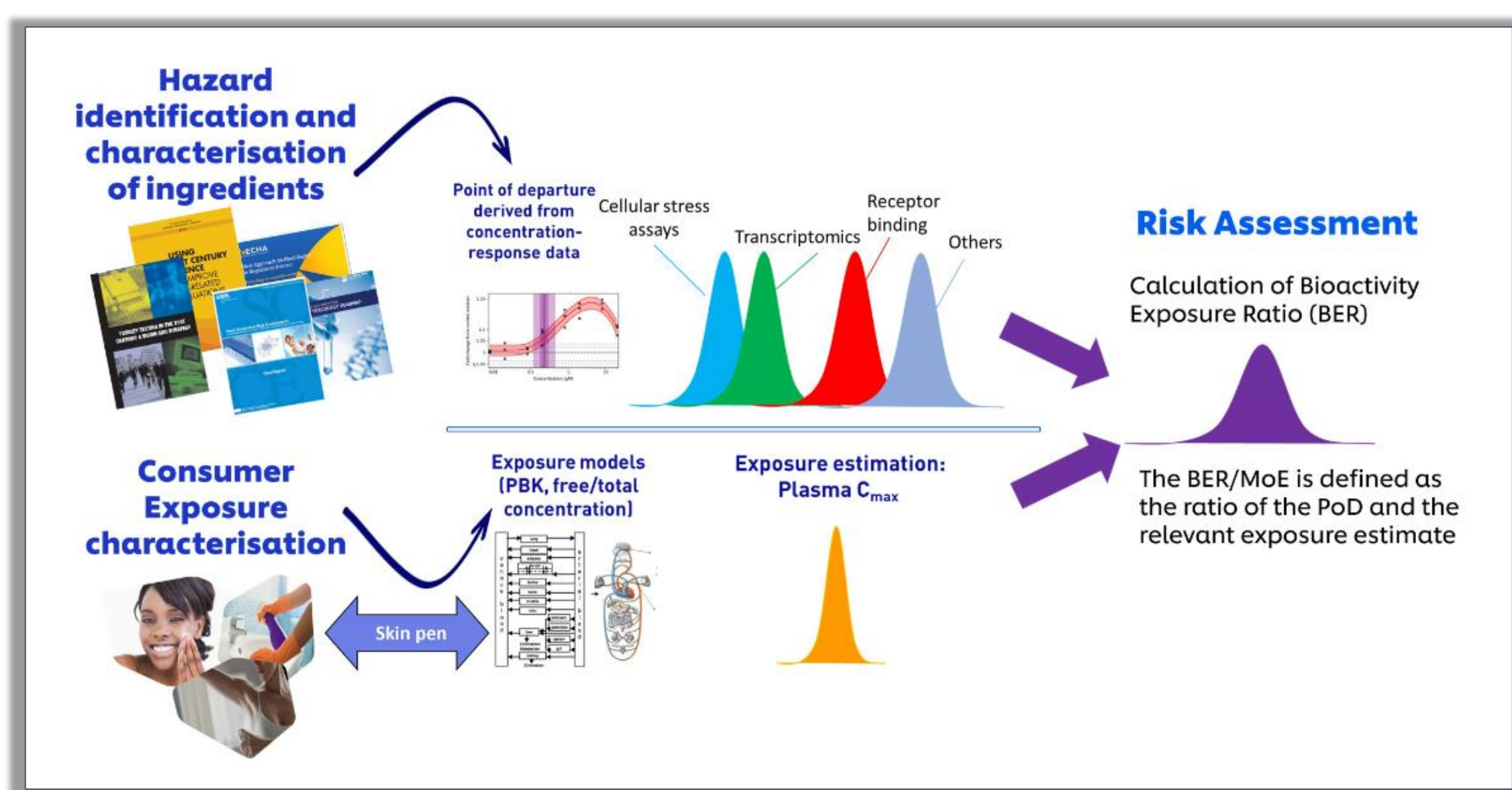


Unilever has built a reputation for world-class scientific capability in managing food safety in a responsible way through the value chain

SEAC focus its scientific capability to maintain and develop our world class reputation for food safety

As Unilever shifts its portfolio to more plant-based and vegan foods, and with the development of New Approach Methodologies (NAMs), SEAC actively promotes the development and application NAMs in food safety risk assessment both inside Unilever and with various external stakeholders.

Method/tools used for NAMs in SEAC



Advocacy and Collaborations



Collaboration on Product Safety in China

Reference:

Baltazar MT, Cable S, Carmichael PL, Cubberley R, Cull T, Delagrangre M, Dent MP, Hatherell S, Houghton J, Kukic P, Li H, Lee MY, Malcomber S, Middleton AM, Moxon TE, Nathanail AV, Nicol B, Pendlington R, Reynolds G, Reynolds J, White A, Westmoreland C. A Next-Generation Risk Assessment Case Study for Coumarin in Cosmetic Products. *Toxicol Sci.* 2020 Jul 1;176(1):236-252. doi: 10.1093/toxsci/kfaa048. PMID: 32275751; PMCID: PMC7357171.

Bowes J, Brown AJ, Hamon J, Jarolimik W, Sridhar A, Waldron G, Whitebread S. Reducing safety-related drug attrition: the use of in vitro pharmacological profiling. *Nat Rev Drug Discov.* 2012 Dec;11(12):909-22. doi: 10.1038/nrd3845. PMID: 23197038. EFSA, EFSA Strategy 2027, 2021

EFSA, EFSA Strategy 2027, 2021

FDA, Advancing New Alternative Methodologies at FDA, 2021

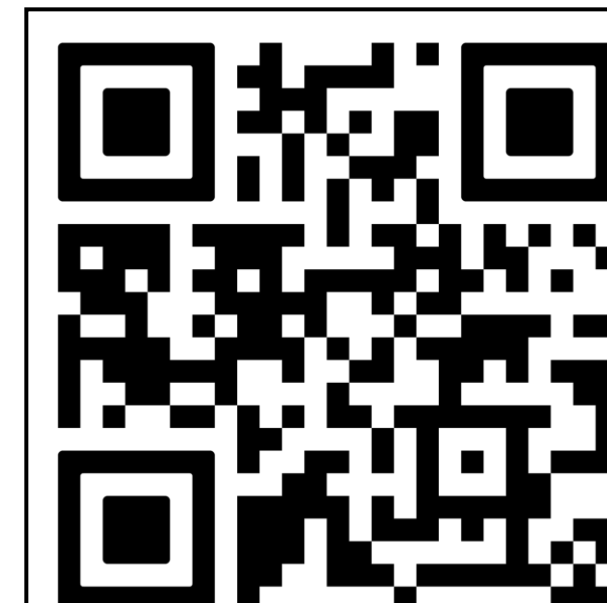
Hatherell S, Baltazar MT, Reynolds J, Carmichael PL, Dent M, Li H, Ryder S, White A, Walker P, Middleton AM. Identifying and Characterizing Stress Pathways of Concern for Consumer Safety in Next-Generation Risk Assessment. *Toxicol Sci.* 2020 Jul 1;176(1):11-33. doi: 10.1093/toxsci/kfaa054. PMID: 32374857; PMCID: PMC7357173. Letswaart R et al., 2020 *EBioMedicine*;57:102837

Li H, Reynolds J, Sorrell J, Sheffield D, Pendlington R, Cubberley R, Nicol B. PBK modelling of topical application and characterisation of the uncertainty of Cmax estimate: A case study approach. *Toxicol Appl Pharmacol.* 2022 May 1;442:115992. doi: 10.1016/j.taap.2022.115992. Epub 2022 Mar 25. PMID: 35346730.

Lynch JJ 3rd, Van Vleet TR, Mittelstaedt SW, Blomme EAG. Potential functional and pathological side effects related to off-target pharmacological activity. *J Pharmacol Toxicol Methods.* 2017 Sep;87:108-126. doi: 10.1016/j.jvascn.2017.02.020. Epub 2017 Feb 16. PMID: 28216264. Middleton et al., (2022) *ToxicolSci*, 189(1), 124-147

Moxon TE, Li H, Lee MY, Piechota P, Nicol B, Pickles J, Pendlington R, Sorrell J, Baltazar MT. Application of physiologically based kinetic (PBK) modelling in the next generation risk assessment of dermally applied consumer products. *Toxicol In Vitro.* 2020 Mar;63:104746. doi: 10.1016/j.tiv.2019.104746. Epub 2019 Dec 16. PMID: 31837441.

Smit JA, Afzal AM, Allen CHC, Svensson F, Hanser T, Bender A. Systematic Analysis of Protein Targets Associated with Adverse Events of Drugs from Clinical Trials and Postmarketing Reports. *Chem Res Toxicol.* 2021 Feb 15;34(2):365-384. doi: 10.1021/acs.chemrestox.0c00294. Epub 2020 Dec 22. PMID: 33351593.



SAFETY SCIENCE IN THE 21ST CENTURY
For more information visit
<https://seac.unilever.com/>