

Innovating for safe and sustainable cosmetics without animal testing

Carl Westmoreland

27th December 2022

Protecting People



All Unilever's products and the ingredients they contain must be safe for consumers and for the people who work with them

Alternatives to animal testing

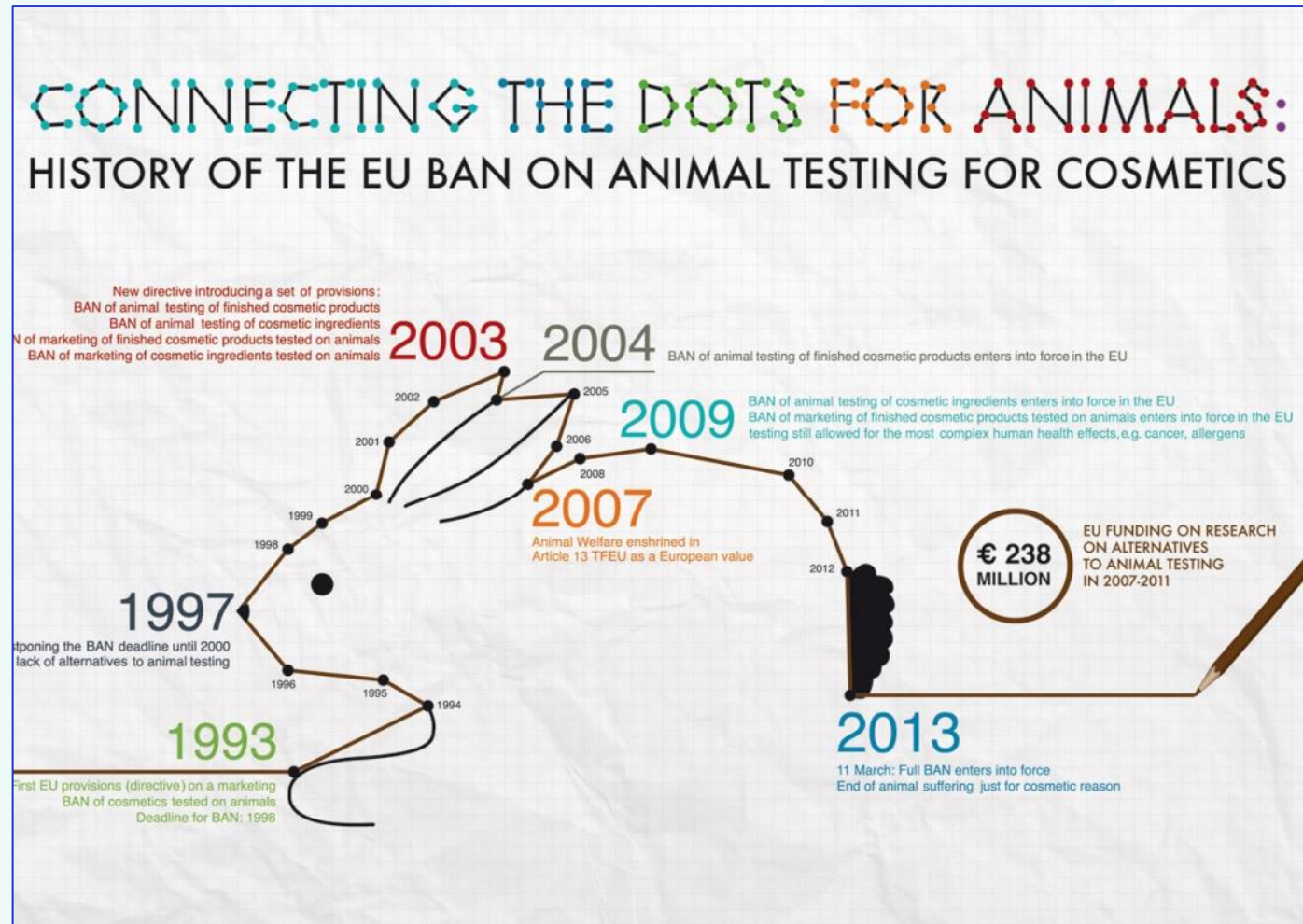
Our approach



We use a wide range of non-animal approaches to assess the safety of our products. Since the 1980s, our scientists have been developing and using alternatives to animal tests, e.g. computer modelling and cell culture-based experiments. We regularly present and publish our work, and continually collaborate with others to share our knowledge and apply exciting new science to assure product safety.

The history of bans on animal testing for cosmetic products and ingredients in the EU – Nearly 10 years since the ban

EU Cosmetics Product Regulation: (EC) No 1223/2009



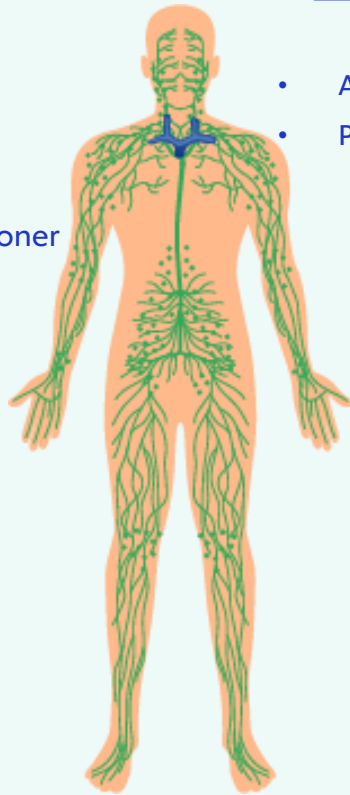
Source: https://ec.europa.eu/growth/sectors/cosmetics/ban-animal-testing_en

Assessing the consumer safety of cosmetic ingredients for the Cosmetic Product Regulation is exposure-led

Consumers

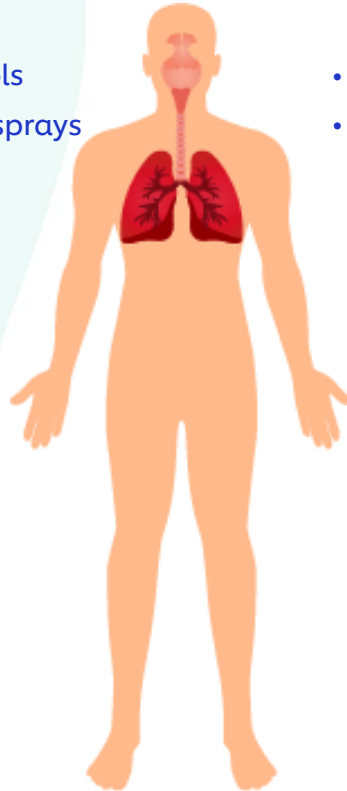
Skin

- Skin creams
- Deodorants
- Soap/cleansers
- Shampoo/ conditioner
- Shower gel



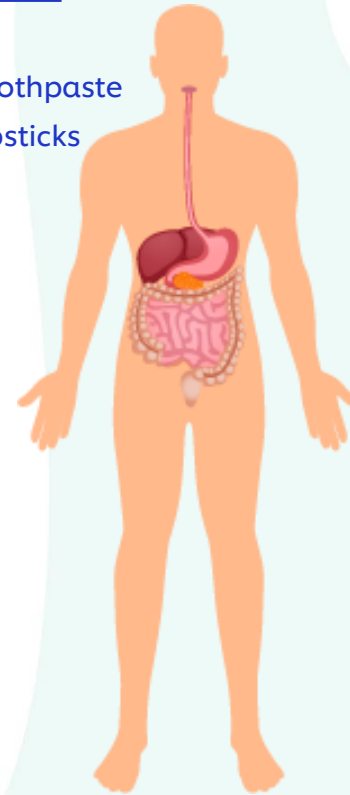
Inhalation*

- Aerosols
- Pump sprays

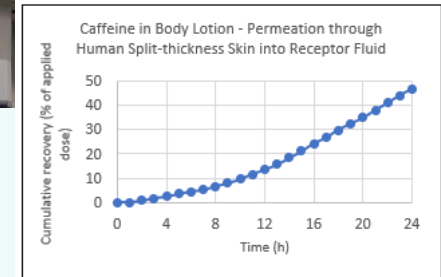


Oral

- Toothpaste
- Lipsticks

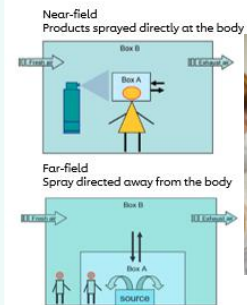


Skin Penetration

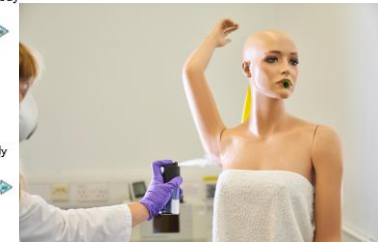


Inhalation

Exposure Modelling



Simulated consumer exposure methods



Steiling et al (2014) *Toxicology Letters*, **227**, 41-49

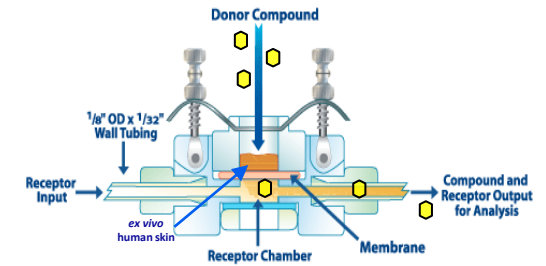
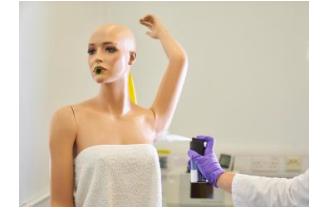
Assuring consumer safety without animal testing: Maximising use of existing information and non-animal approaches

- All our risk assessments are exposure-led

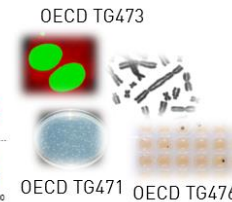
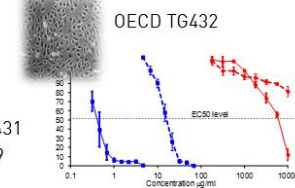
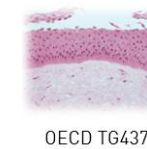


Table 2: Estimated daily exposure levels for different cosmetic product types according to Cosmetics Europe data (SCCNFP/0321/00; Hall et al., 2007, 2011).

Product type	Estimated daily amount applied	Relative amount applied (mg/g raw/d)	Retention factor ¹	Calculated daily exposure (µg/d)	Calculated relative daily exposure (mg/kg bw/d)
Bathing, showering					
Shower gel	18.67 g	279.20	0.01	0.19	2.79
Hand wash soap ²	20.00 g	-	0.01	0.20 ³	3.33
Hair care					
Shampoo	10.46 g	150.49	0.01	0.11	1.51
Hair conditioner ²	3.92 g	-	0.01	0.04	0.60
Hair styling products	4.00 g	57.40	0.1	0.40	5.74

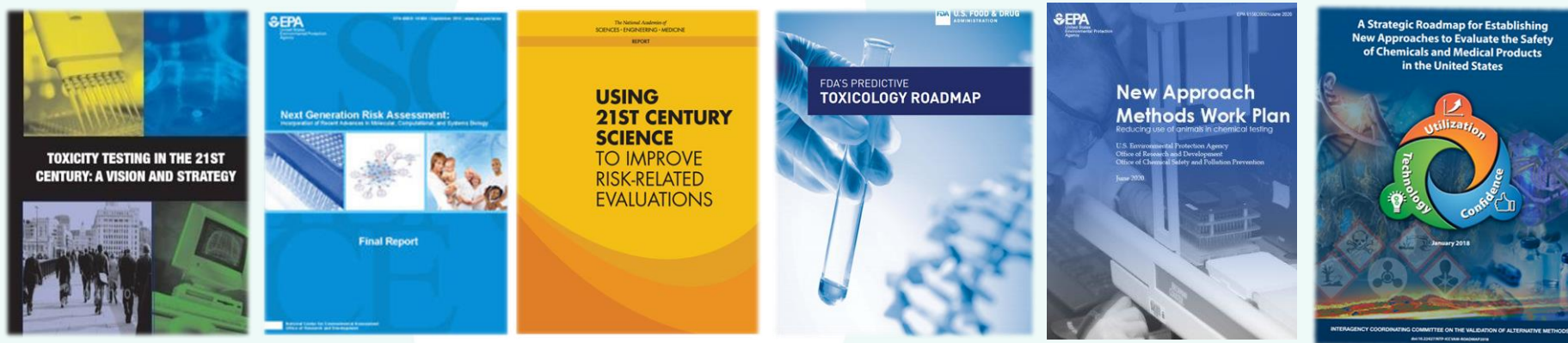


- Use all available safety data on the ingredient
 - Clinical, epidemiological, animal (if dates permit), *in vitro* etc
- Exposure-based waiving approaches (e.g. TTC, DST, Inhalation TTC)
- in silico* predictions
- History of safe use
- Read across
- Use of existing OECD *in vitro* approaches
- Next Generation Risk Assessment (NGRA)

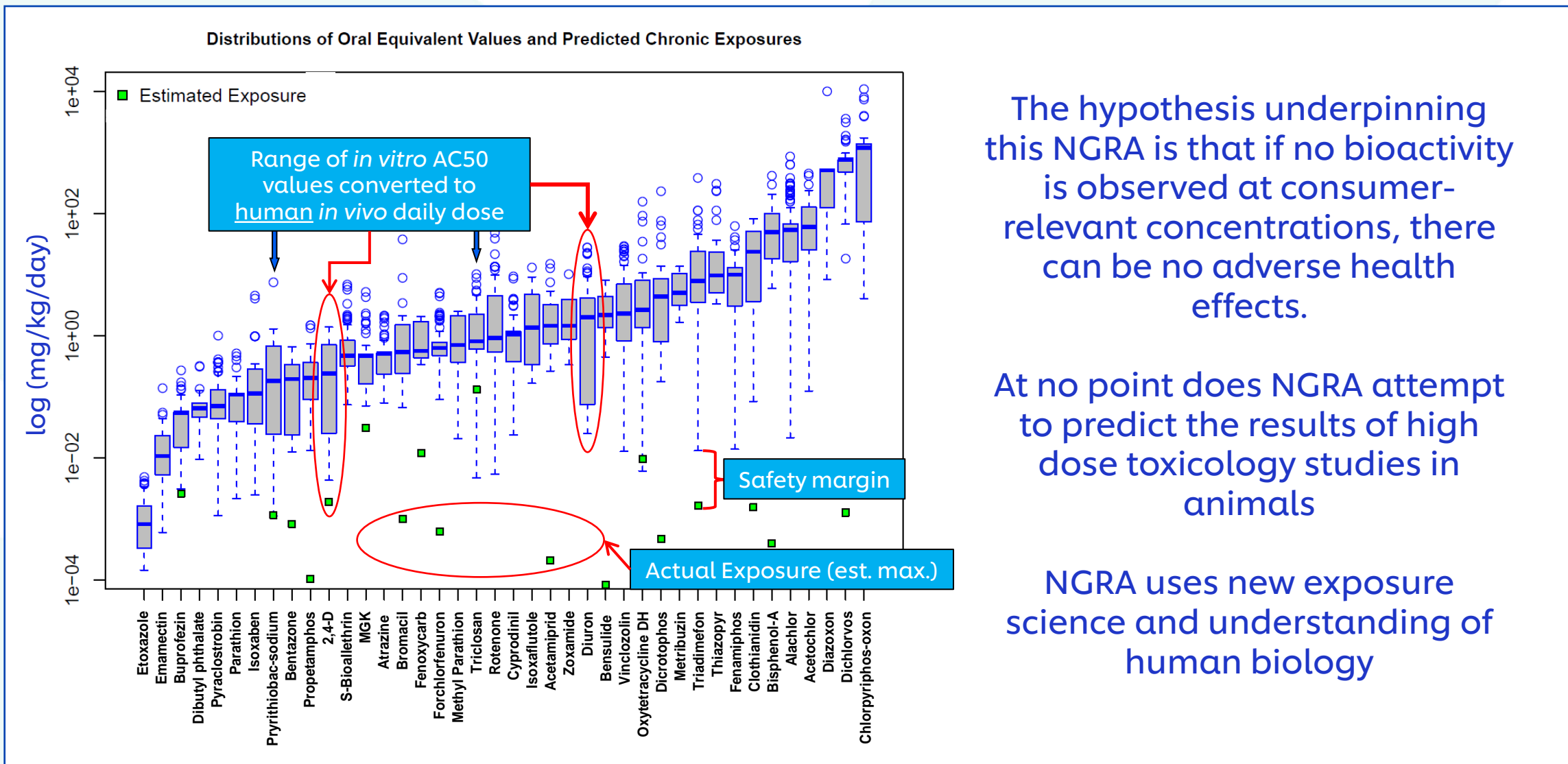


Next Generation Risk Assessment (NGRA)

NGRA is defined as an exposure-led, hypothesis-driven risk assessment approach that integrates New Approach Methodologies (NAMs) to assure safety without the use of animal testing



NGRA: Protection not prediction



The hypothesis underpinning this NGRA is that if no bioactivity is observed at consumer-relevant concentrations, there can be no adverse health effects.

At no point does NGRA attempt to predict the results of high dose toxicology studies in animals

NGRA uses new exposure science and understanding of human biology



Recognition of Next Generation Risk Assessment (NGRA) in cosmetic safety assessment

Computational Toxicology 7 (2018) 20–26

Contents lists available at ScienceDirect

Computational Toxicology

journal homepage: www.elsevier.com/locate/comtox

Principles underpinning the use of new methodologies in the risk assessment of cosmetic ingredients

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ARTICLE INFO

ABSTRACT

Consumer safety is a prerequisite for any cosmetic product. Worldwide, there is an ever-increasing desire to bring safe products to market without animal testing, which requires a new approach to consumer safety. 'Next Generation Risk Assessment' (NGRA), defined as an exposure-led, hypothesis driven risk assessment approach that integrates *in silico*, *in chemico* and *in vitro* approaches, provides such an opportunity. The customized nature of each NGRA means that the development of a prescriptive list of tests to assure safety is not possible, or appropriate. The International Cooperation on Cosmetics Regulation (ICCR) therefore tasked a group of scientists from regulatory authorities and the Cosmetic Industry to agree on and outline the principles for incorporating these new approaches into risk assessments for cosmetic ingredients. This ICCR group determined the overall goals of NGRA (to be human-relevant, exposure-led, hypothesis-driven and designed to prevent harm); how an NGRA should be conducted (using a tiered and iterative approach, following an appropriate literature search and evaluation of the available data, and using robust and relevant methods and strategies); and how the assessment should be documented (transparent and explicit about the logic of the approach and sources of uncertainty). Those working on the risk assessment of cosmetics have a unique opportunity to lead progress in the application of novel approaches, and cosmetic risk assessors are encouraged to consider these key principles



International Cooperation on Cosmetics Regulation (2018)



European Commission: Scientific Committee on Consumer Safety (2021)

SCCS/1628/21

Scientific Committee on Consumer Safety

SCCS

THE SCCS NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION 11TH REVISION

Scientific Committees

in Consumer Safety
in Health, Environmental and Emerging Risks

3-4 RELEVANT TOXICOLOGICAL TOOLS FOR THE SAFETY EVALUATION OF COSMETIC INGREDIENTS

The SCCS has been closely following the progress made with regard to the development and validation of alternative methods and updated its NoG on a regular basis taking progress into consideration.

Besides validated alternatives, the SCCS may also accept, on a case-by-case basis, methods that are scientifically valid as new tools (e.g., "omics" technology) for the safety evaluation of cosmetic substances. Such valid methods may not have necessarily gone through the complete validation process, but the Committee may consider them acceptable when there is a sufficient amount of experimental data proving relevance and reliability and including positive and negative controls.

According to the Cosmetics Regulation, the experimental studies have to be carried out in accordance with the principles of Good Laboratory Practice (GLP) laid down in Council Directive 87/18/EEC. All possible deviations from this set of rules should be explained and scientifically justified (SCCNFP/0533/02).

3-4.1 NEW APPROACH METHODOLOGY (NAM) AND NEXT-GENERATION RISK ASSESSMENT (NGRA)

Whereas the terminology of "Alternative Test Methods (ATMs)" does not cover all available tools e.g., *in silico* methodology, the more general term, New Approach Methodology (NAM) has been introduced. As for cosmetics and their ingredients, testing and marketing bans apply with respect to animal use and also the obligation exists to only use validated replacement alternatives, the need for validated non-animal alternative methods for chemical hazard assessment is much more important in Europe for compliance with the Cosmetics Regulation than for other regulatory frameworks. NAMS may include *in vitro*, *ex vivo*, *in chemico* and *in silico* methods, read-across, as well as combinations thereof. Therefore, before any testing is carried out for safety evaluation, all information on the substance under consideration should be gathered from different available means. A set of criteria, universal across initiatives, to evaluate NAMS fit-for-purpose was developed by a multi-stakeholder group and may support greater consistency across different initiatives (Parish et al., 2020).

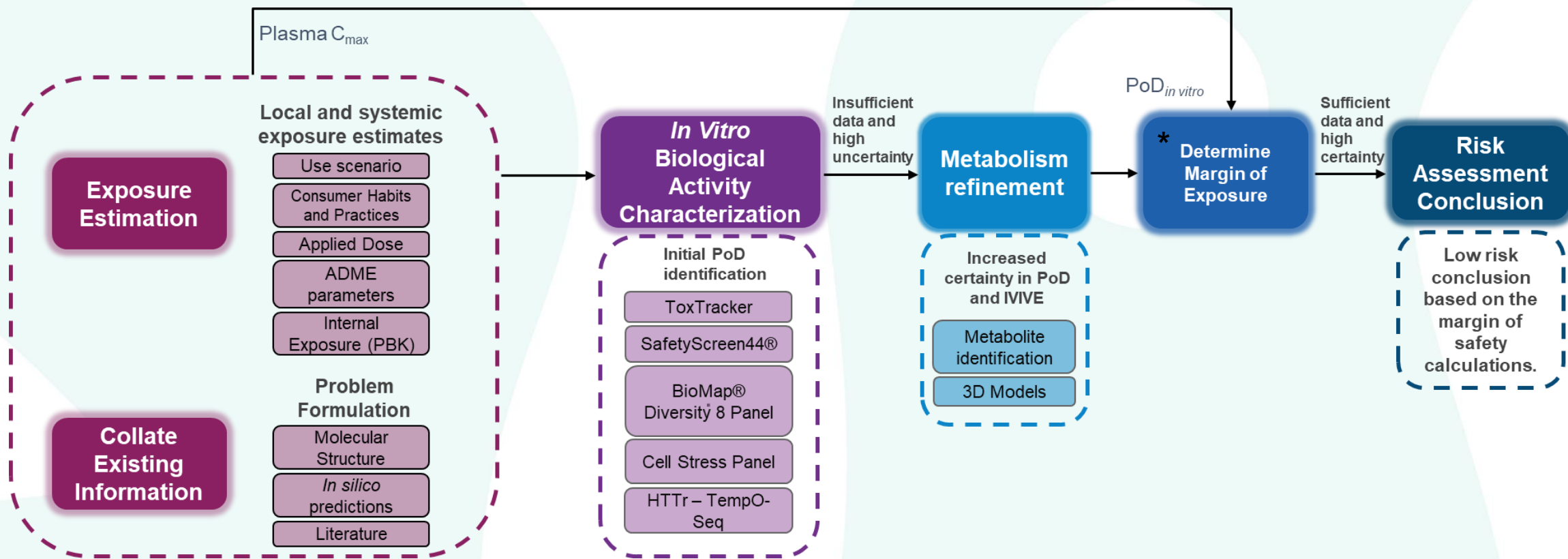
Many efforts are ongoing to modernise toxicological safety evaluation and to look for non-animal methodology that can be used for the risk assessment of compounds that after long-term exposure could be at the origin of systemic toxicity. One of these approaches is referred to as NGRA (USEPA, 2014). The principles underpinning the application of an NGRA to cosmetics have been defined by the International Cooperation on Cosmetics Regulation (ICCR), a platform of regulators and cosmetics industry from the EU, the US, Japan, Canada and Brazil (Dent et al., 2018). NGRA is a human-relevant, exposure-led, hypothesis-driven risk assessment designed to prevent harm. It integrates several NAMS to deliver safety decisions relevant to human health without the use of experimental animals. An NGRA should be conducted using a tiered and iterative approach, following an appropriate literature search and evaluation of the available data, and using robust and relevant methods and strategies. Given the novelty of NGRA and the current lack of regulatory guidance on the use of a variety of NAMS in decision-making, it is important that the assessment should be transparently documented and explicit about the logic of the approach and sources of uncertainty (Dent et al., 2018). A general NGRA workflow is described in Figure 5 (Berggren et al., 2017). The tools useful for safety evaluation of cosmetic ingredients, which could also be used in case NGRA would be taken as a possible workflow in the future, are described in chapters 3-4.2 to 3-4.14. Threshold of Toxicological Concern (TTC) and internal TTC (iTTC) approaches as a risk assessment tools are described in 3-5.2.

The SCCS adopted this guidance document at its plenary meeting on 30-31 March 2021

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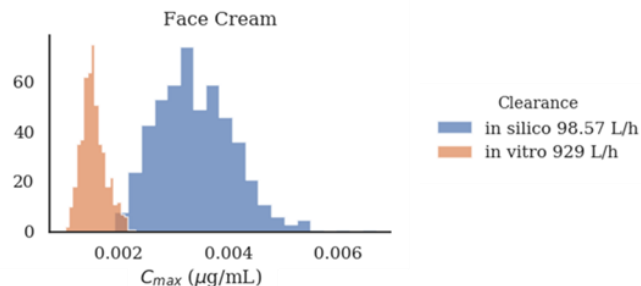
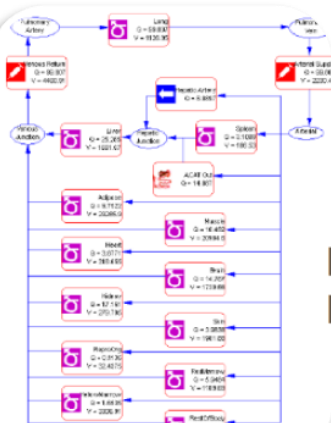


NGRA: case study workflow for systemic effects



Key tools in our NGRA approach for systemic effects

PBK Modelling



Toxicology in Vitro (2020), 63, 104746

In vitro pharmacological profiling

PERSPECTIVES

A GUIDE TO DRUG DISCOVERY – OPINION

Reducing safety-related drug attrition: the use of *in vitro* pharmacological profiling

Joanne Brevet, Andrew J. Brown, Jacques Homan, Wolfgang Juronick, Arun Sridhar, Gareth Waldron and Steven Whitbread

Abstract In vitro pharmacological profiling is increasingly being used earlier in the drug discovery process to identify undesirable off-target activity profiles that could hinder or halt the development of candidate drugs or even lead to market withdrawal if discovered after a drug is approved. Here, for the first time, the rationale, strategies and methodologies for *in vitro* pharmacological profiling at four major pharmaceutical companies (AstraZeneca, GlaxoSmithKline, Novartis and Pfizer) are presented and illustrated with examples of their impact on the drug discovery process. We hope that this will enable other companies and academic institutions to benefit from this knowledge and consider joining us in our collaborative knowledge sharing.

Decreasing the high attrition rate in the drug discovery and development process is a primary goal of the pharmaceutical industry. One of the main challenges in achieving this goal is striking an appropriate balance between drug efficacy and potential adverse effects as early as possible in order to reduce safety-related attrition, particularly in the more expensive late stages of clinical development. Gaining a better understanding of the safety profile of drug candidates early in the process is also crucial for reducing the likelihood of safety issues limiting the use of approved drugs, or even leading to their market withdrawal, having no impact on the patient and/or on the environment.

target (or targets), whose secondary effects are due to interactions with targets other than the primary target (or targets) that is off-target interactions. Off-target interactions are often the cause of ADRs in animal models or clinical studies, and careful characterization and identification of secondary pharmacology profiles of drug candidates early in the drug discovery process might help reduce the incidence of type A ADRs.

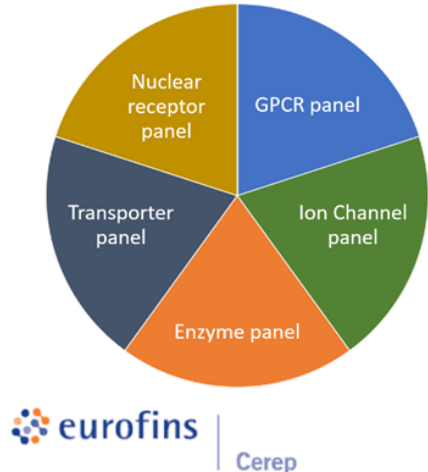
In vitro pharmacological profiling involves the screening of a compound against a broad range of targets (receptors, enzymes, ion channels, transporters, etc.) that are chosen from the scientific

safety testing of drug candidates and are designed to prevent serious ADRs from occurring in clinical studies.

The *in vitro* pharmacology assay that is absolutely required by regulatory authorities is that measures the effects of new chemical entities on the ion channels of native I_{Ca} in heterologously expressed human voltage-gated potassium channel subfamily 11 member 2 (hKCNJ2), also known as hERG. The mechanism by which blockade of hERG can affect potentially fatal cardiac arrhythmias (torsades de pointes) following a prolongation of the QT interval is well characterized^{1,2}, and the assessment of this ADR is one reason why this assay is a mandatory regulatory requirement. Receptor binding studies are also recommended as the first tier approach for the assessment of the dependence potential of novel chemical entities³.

However, current regulatory guidance does not describe which targets should constitute an *in vitro* pharmacological profiling panel and does not indicate the stage of the discovery process at which *in vitro* pharmacological profiling should occur. Nevertheless, the general view for most pharmaceutical companies is to perform this testing early in drug discovery to reduce attrition and to facilitate better prediction of ADRs in the later stages of drug discovery and development.

Here, for the first time, four major pharmaceutical companies (AstraZeneca, GlaxoSmithKline, Novartis and Pfizer) share their knowledge and experience of the innovative application of existing screening technologies to detect off-target interactions of compounds. The objective of this article is to describe the rationale and main advantages for the use of an *in vitro* pharmacological profiling panel to reduce both pre-clinical and

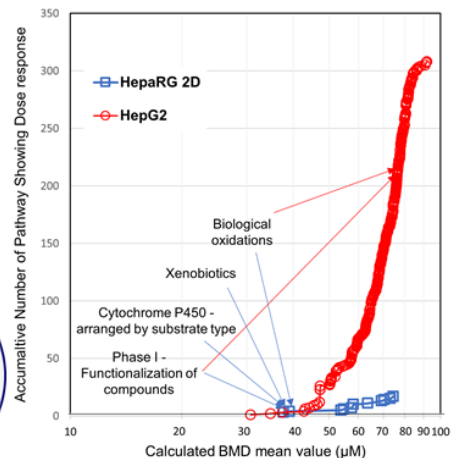
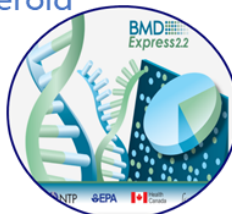


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Transcriptomics

- Use of full human gene panel ~ 21k
- 24 hrs exposure
- 7 concentrations
- 3 cell lines HepG2/ HepaRG/ MCF7
- 3D HepaRG spheroid

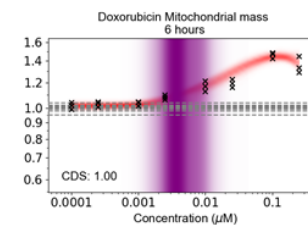
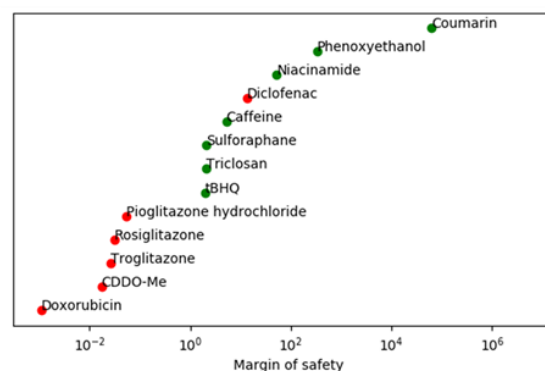
BMDexpress 2



Cellular Stress Pathways

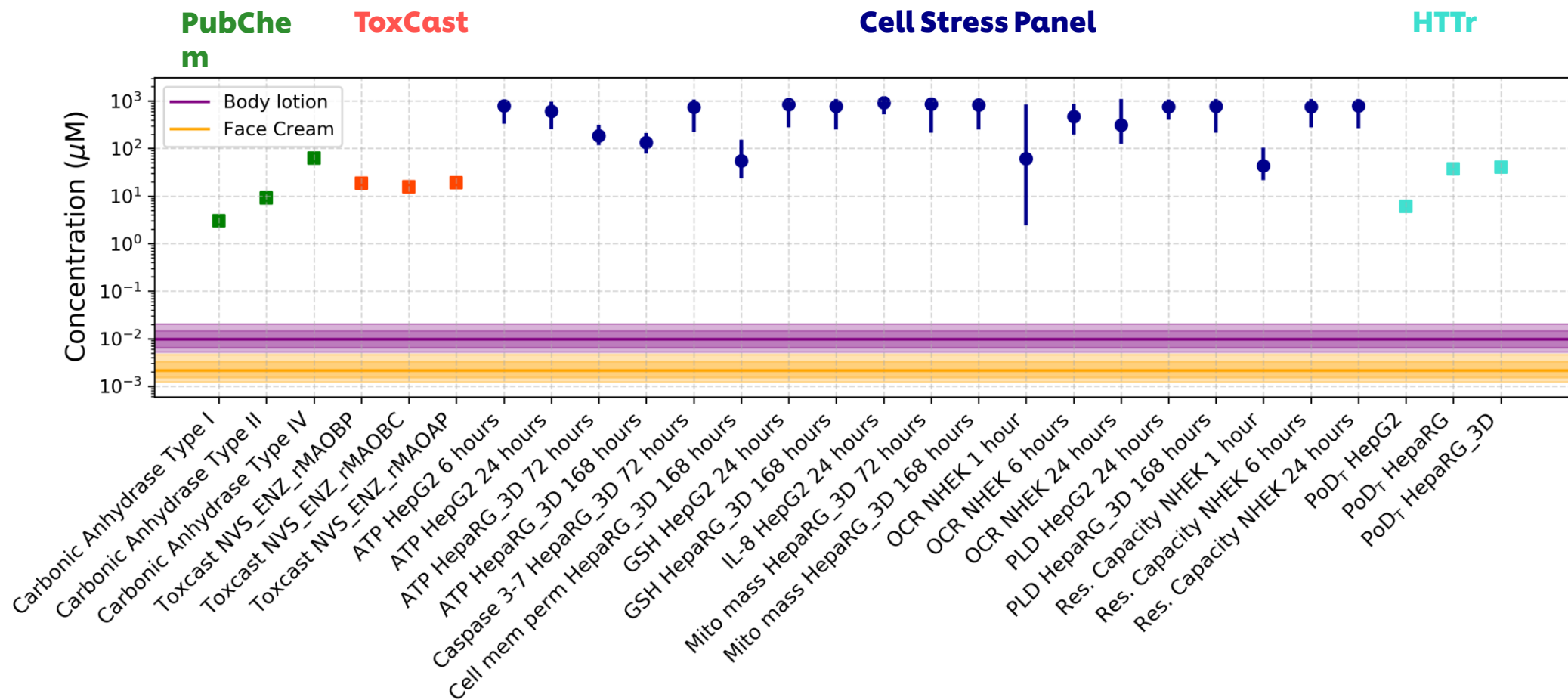
13 chemicals, 36 Biomarkers; 3 Timepoints; 8 Concentrations; ~10 Stress Pathways

- Exposure scenario adopted for chemical is 'low risk'** (from consumer goods perspective)
- Niacinamide (food, cosmetics)
 - Caffeine (beverages, cosmetics)
 - Phenoxyethanol (cosmetics)
 - Sulfuraphane (food)
 - tBHQ (antioxidant)
 - Triclosan (antimicrobial)
- Exposure scenario adopted for chemical is 'high risk'** (from consumer goods perspective)
- CDDO-Me (drug)
 - DEM (industrial chemical)
 - Doxorubicin (drug)
 - Diclofenac (drug)
 - Troglitazone (drug)
 - Pioglitazone (drug)
 - Rosiglitazone (drug)



Toxicol Sci (2020), 176, 11-33




Exposure and PoD are plotted and used to derive a Bioactivity-Exposure Ratio (MoE/BER)



PoD = Point of Departure
 MoE = Margin of Exposure
 BER = Bioactivity / Exposure ratio
 HTTr = High throughput transcriptomics



Are Non-animal Systemic Safety Assessments Protective? A Toolbox and Workflow

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ABSTRACT

An important question in toxicological risk assessment is whether non-animal new approach methodologies (NAMs) can be used to make safety decisions that are protective of human health, without being overly conservative. In this work, we propose a core NAM toolbox and workflow for conducting systemic safety assessments for adult consumers. We also present an approach for evaluating how protective and useful the toolbox and workflow are by benchmarking against historical safety decisions. The toolbox includes physiologically based kinetic (PBK) models to estimate systemic C_{max} levels in humans, and 3 bioactivity platforms, comprising high-throughput transcriptomics, a cell stress panel, and *in vitro* pharmacological profiling, from which points of departure are estimated. A Bayesian model was developed to quantify the uncertainty in the C_{max} estimates depending on how the PBK models were parameterized. The feasibility of the evaluation approach was tested using 24 exposure scenarios from 10 chemicals, some of which would be considered high risk from a consumer goods perspective (eg, drugs that are systemically bioactive) and some low risk (eg, existing food or cosmetic ingredients). Using novel protectiveness and utility metrics, it was shown that up to 69% (9/13) of the low risk scenarios could be identified as such using the toolbox, whilst being protective against all (5/5) the high-risk ones. The results demonstrated how robust safety decisions could be made without using animal data. This work will enable a full evaluation to assess how protective and useful the toolbox and workflow are across a broader range of chemical-exposure scenarios.

Key words: Bayesian modelling; new approach methodologies; point of departure; physiologically based pharmacokinetics; probabilistic risk assessment.

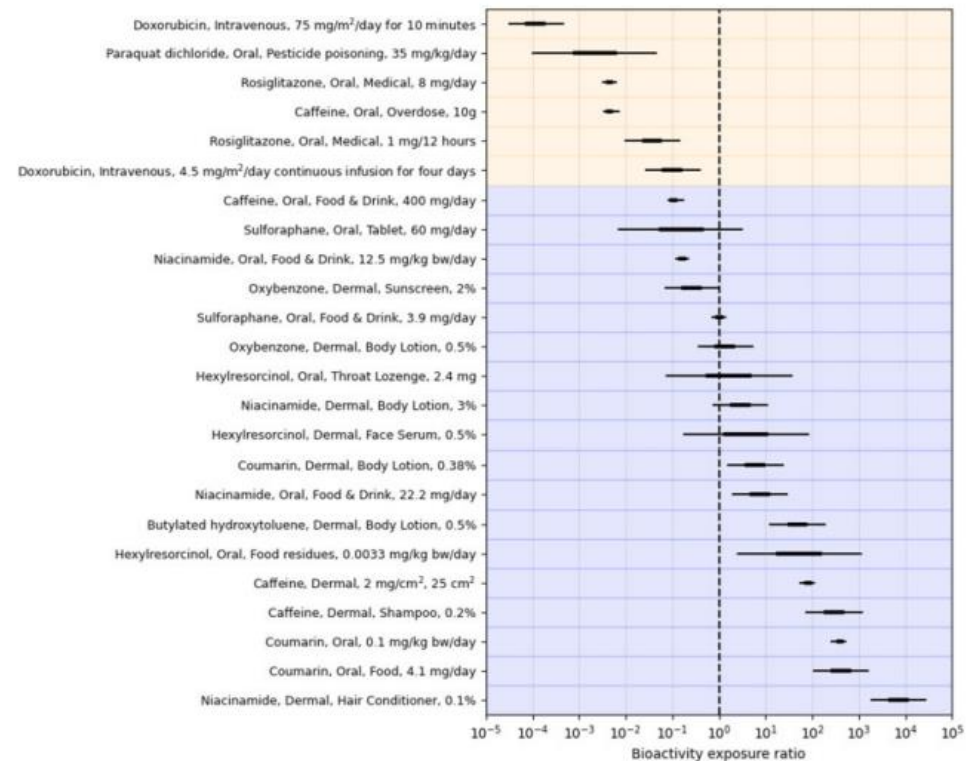
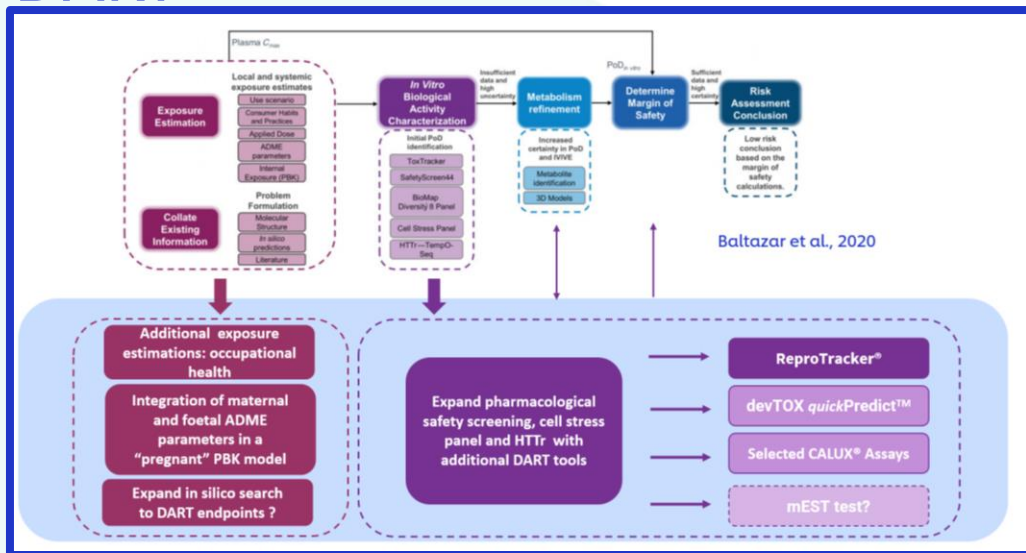


Figure 5. Centered 50% and 95% credible intervals summarizing the distribution of the bioactivity exposure ratio (BER) when using all available predicted C_{max} estimates. Background colors indicate the assigned risk category for each benchmark chemical-exposure scenario assigned at stage 1 (blue—low, yellow—high). The vertical dashed line indicates a BER equal to 1.

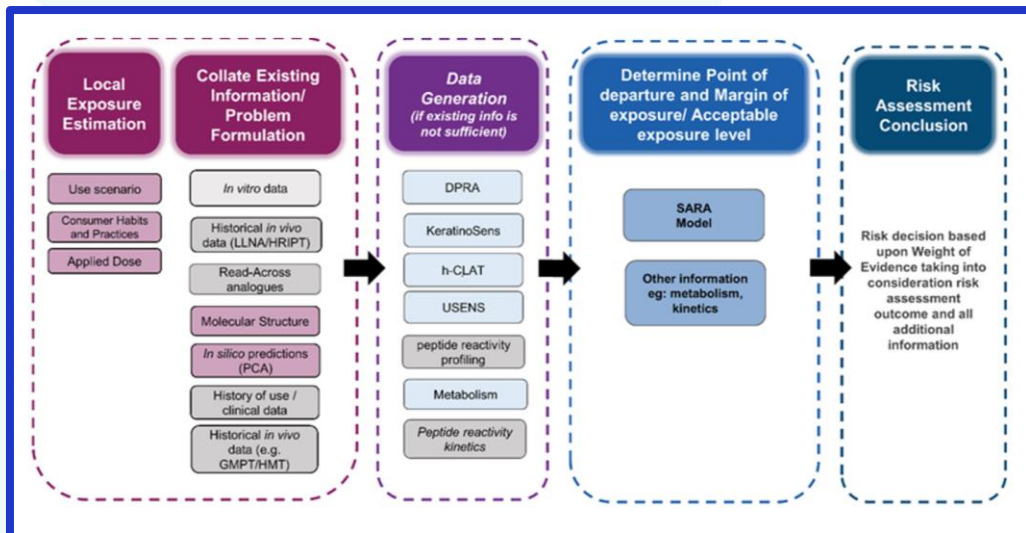
Other NGRA approaches for human health

DART*



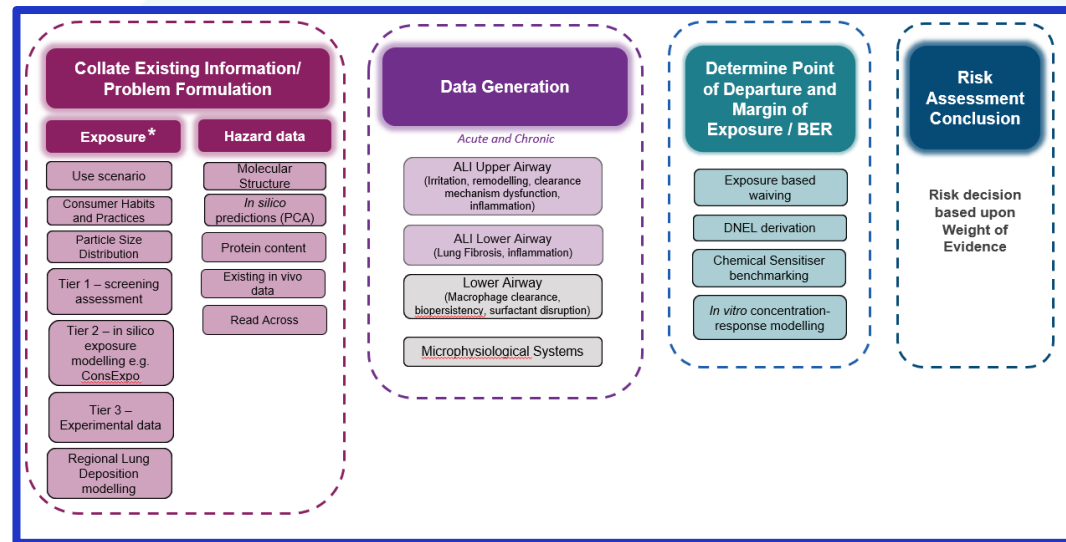
Rajagopal et al (2022) Front Toxicol, 4, 838466

Skin Sensitisation



Reynolds et al (2021) Reg Tox Pharmacol, 127, 105075

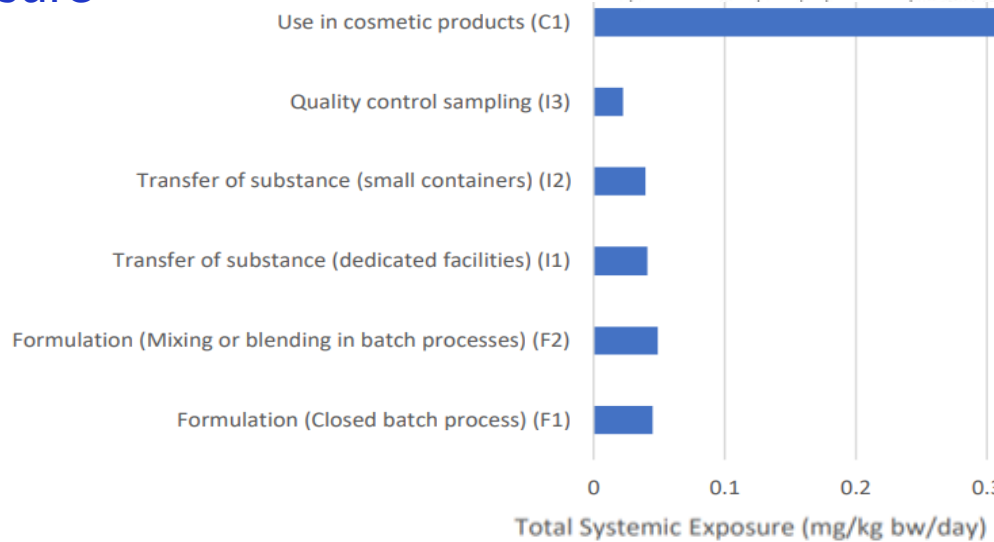
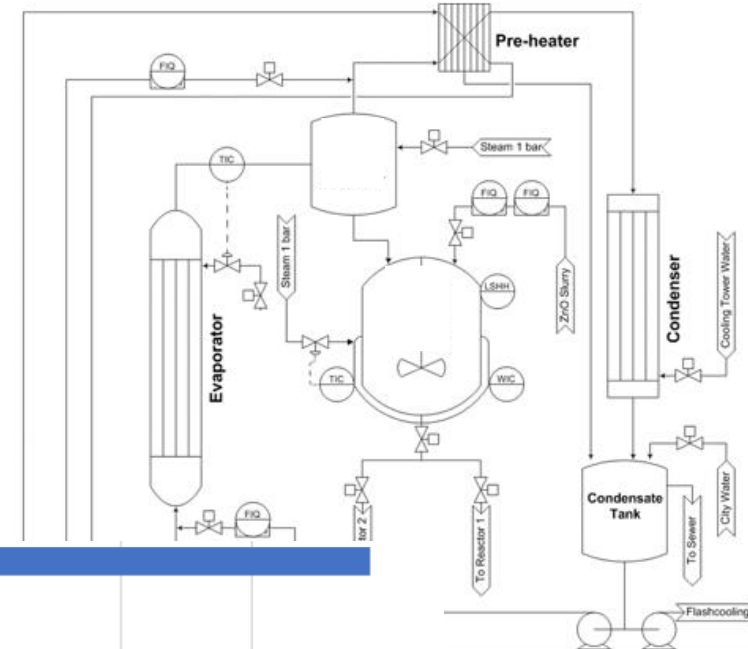
Inhalation



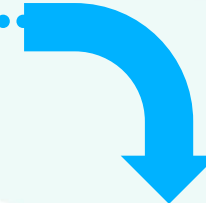
* DART = Developmental and Reproductive Toxicology

NGRA and Worker Safety

- Understanding worker exposure
 - Routes
 - Levels of exposure
 - Personal Protective Equipment
- NGRA for worker safety
 - BER approach for worker exposure



Recognition of NGRA in cosmetic safety assessment...



... Could similar, NAM-based approaches also be used for chemical registration?

Computational Toxicology 7 (2018) 20–26

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Principles underpinning the use of new methodologies in the risk assessment of cosmetic ingredients

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Generalists that integrate each of the appropriate data from corporate and external sources; the overall harm; the literature base; the level of uncertainty of the application

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REGULATORY TOXICOLOGY

A framework for chemical safety assessment incorporating new approach methodologies within REACH

Nicholas Ball¹ · Remi Bars² · Philip A. Botham³ · Andreea Cuciureanu⁴ · Mark T. D. Cronin⁵ · John E. Doe⁵ · Tatsiana Dudzina⁶ · Timothy W. Gant⁷ · Marcel Leist⁸ · Bennard van Ravenzwaay⁹

International Cooperation on Cosmetics Regulation (2018)

Scientific Committee on Consumer Safety
 SCCS

THE SCCS NOTES OF GUIDANCE FOR THE TESTING OF
 COSMETIC INGREDIENTS AND THEIR SAFETY
 EVALUATION
 11TH REVISION

Scientific Committees
 on Consumer Safety
 on Health, Environmental and Emerging Risks

The SCCS adopted this guidance document at its plenary meeting on 30-31 March 2021

Regulatory Toxicology and Pharmacology

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Use of New Approach Methodologies (NAMs) in regulatory decisions for chemical safety: Report from an EPAA Deep Dive Workshop

Carl Westmoreland^a, Hans J. Bender^b, John E. Doe^c, Miriam N. Jacobs^d, George E.N. Kass^e, Federica Madia^f, Catherine Mahony^g, Irene Manou^h, Gavin Maxwellⁱ, Pilar Prieto^f, Rob Roggeband^l, Tomasz Sobanski^j, Katrin Schütte^k, Andrew P. Worth^f, Zvonimir Zvonar^h, Mark T.D. Cronin^c

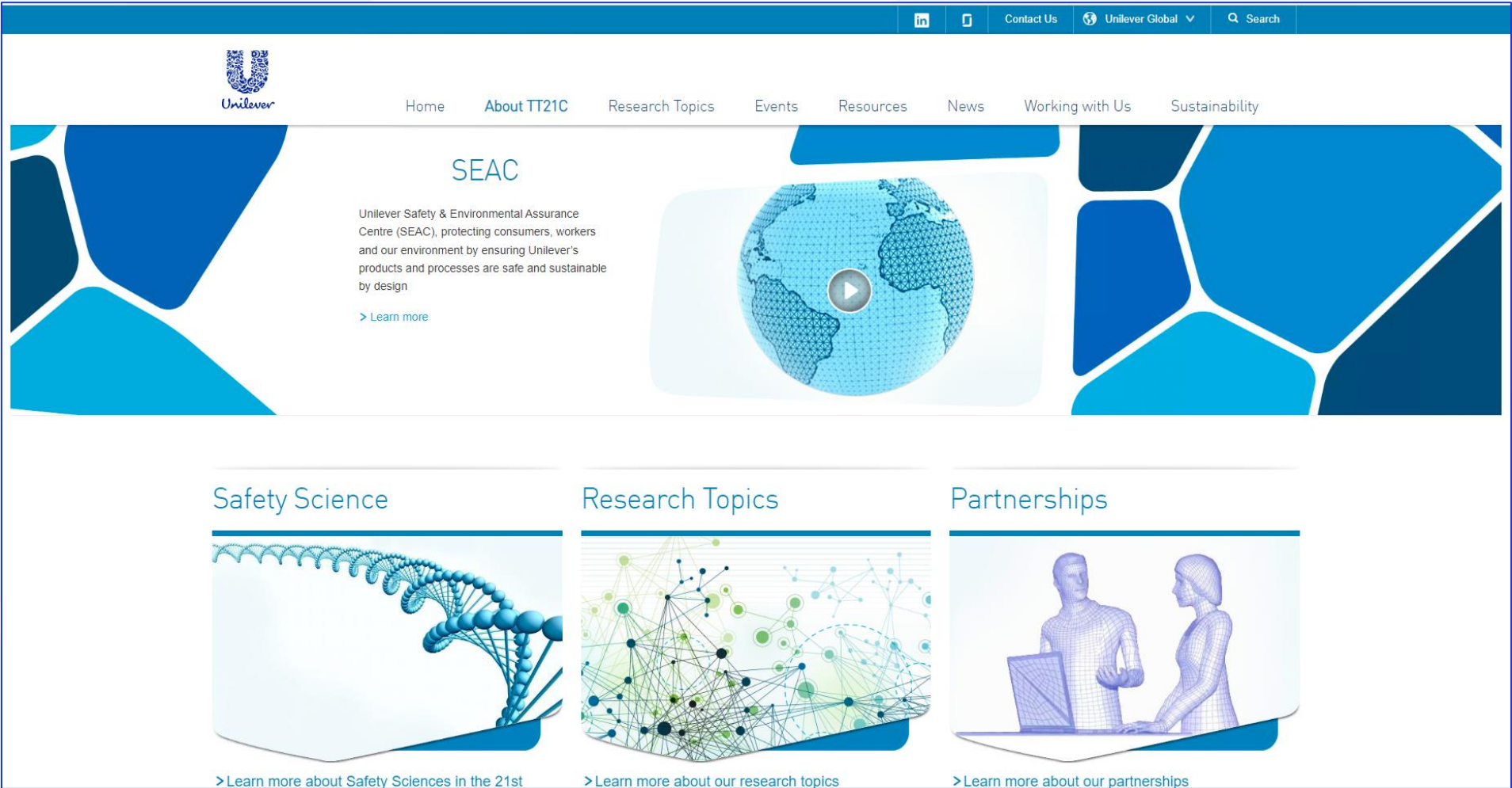


Scientific Committee on Consumer Safety (2021)

The importance of scientific partnership and publication



SEAC's Scientific Website



The screenshot shows the SEAC website homepage. At the top, there is a blue navigation bar with social media icons for LinkedIn and Facebook, and links for 'Contact Us', 'Unilever Global', and a search function. Below this is the Unilever logo and a main navigation menu with links for 'Home', 'About TT21C', 'Research Topics', 'Events', 'Resources', 'News', 'Working with Us', and 'Sustainability'. The main content area features a large blue graphic with the text 'SEAC' and a description: 'Unilever Safety & Environmental Assurance Centre (SEAC), protecting consumers, workers and our environment by ensuring Unilever's products and processes are safe and sustainable by design'. A 'Learn more' link is provided. To the right is a globe with a play button icon. Below this are three sections: 'Safety Science' with a DNA helix image and a 'Learn more about Safety Sciences in the 21st' link; 'Research Topics' with a network diagram image and a 'Learn more about our research topics' link; and 'Partnerships' with an image of two people at a laptop and a 'Learn more about our partnerships' link.



tt21c.org

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