

Next Gen Tools for Chemical Safety Assessment

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Unilever

**Safety &
Environmental
Assurance
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Acknowledgements:

Carl Westmoreland, Gavin Maxwell, Maria Baltazar, Paul Carmichael, Matt Dent, Steve Gutsell, Sarah Hatherell, Predrag Kukic, Hequn Li, Alistair Middleton, Iris Müller, Ramya Rajagopal, Georgia Reynolds, Andrew White & SEAC colleagues + collaborators



HUMANE SOCIETY
INTERNATIONAL

ZOOM WEBINAR

Regulatory Acceptance and Use of Next-Generation Approaches for Chemical Safety Assessment



July 13, 2022



9:00 EDT / 15:00 CET

Join us for a webinar to learn how state-of-the-art science is being used by corporate and government stakeholders in risk assessment and prioritisation to ensure protection.

Collaborating to modernise the scientific data & tools we use for making safety decisions – 15+ years of research & evaluation

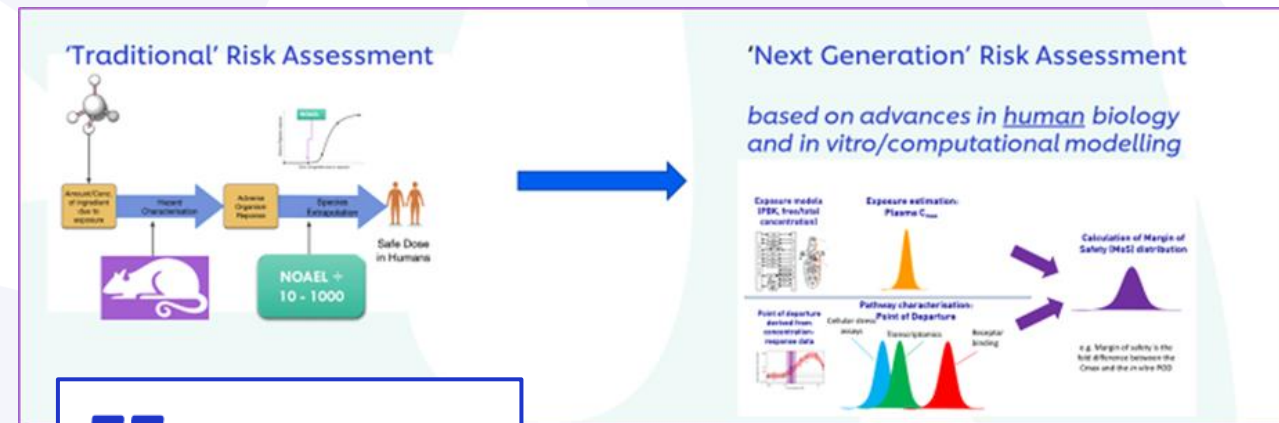


Overview & Background Context

Next Generation Risk Assessment (NGRA) using New Approach Methods (NAMs)

Data are needed for decisions on:

1. safety of consumers exposed to chemicals in products
2. safety of workers exposed to chemicals during product manufacture
3. safety of people & non-human species if exposed to chemicals in the environment



“Advances in science and technology mean that we can generate much more relevant safety data to protect people and the environment using modern non-animal approaches.”

Unilever : U.S. EPA and Unilever Announce Major New Research Collaboration to Advance Non-Animal Approaches for Chemical Risk Assessment

09/08/2015 | 09:01am EDT

Research collaboration will develop ground-breaking scientific approaches to better assess the safety of chemicals found in some consumer products without using animal data



Assessing Consumer Safety of cosmetics ingredients without new animal testing (required by EU Cosmetic Products Regulation, 10+ years experience)

Is the consumer exposure safe? A tiered approach is routine:

- Use all available safety data on the ingredient
 - clinical, epidemiological, animal (if dates permit), *in vitro*, etc.
- Exposure-based waiving (e.g. TTC – toxicological threshold of concern)

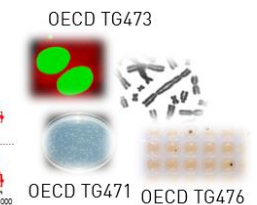
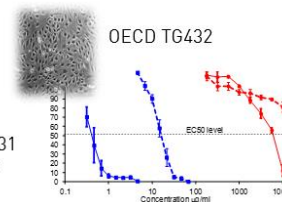
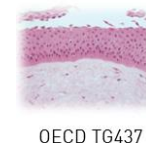
- *In silico* predictions

- History of safe use

- Read across from comparable ingredients

- Use of existing OECD *in vitro* approaches

- Next Generation Risk Assessment (NGRA)



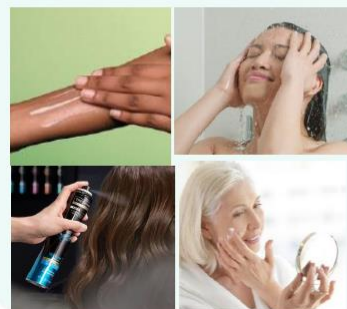
Next Generation Risk Assessment (NGRA)

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

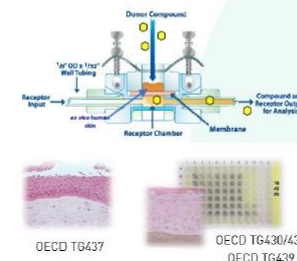


[Safety Homepage « Safety Science in the 21st Century \(tt21c.org\)](http://tt21c.org)

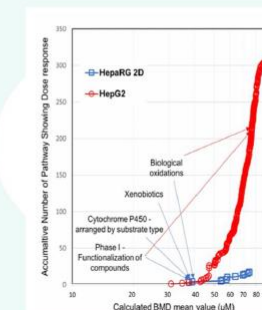
Next Generation Risk Assessment is highly interdisciplinary



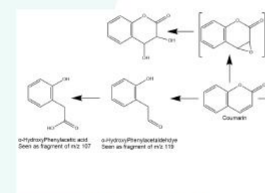
Risk assessment



Biology



Bioinformatics



Chemistry

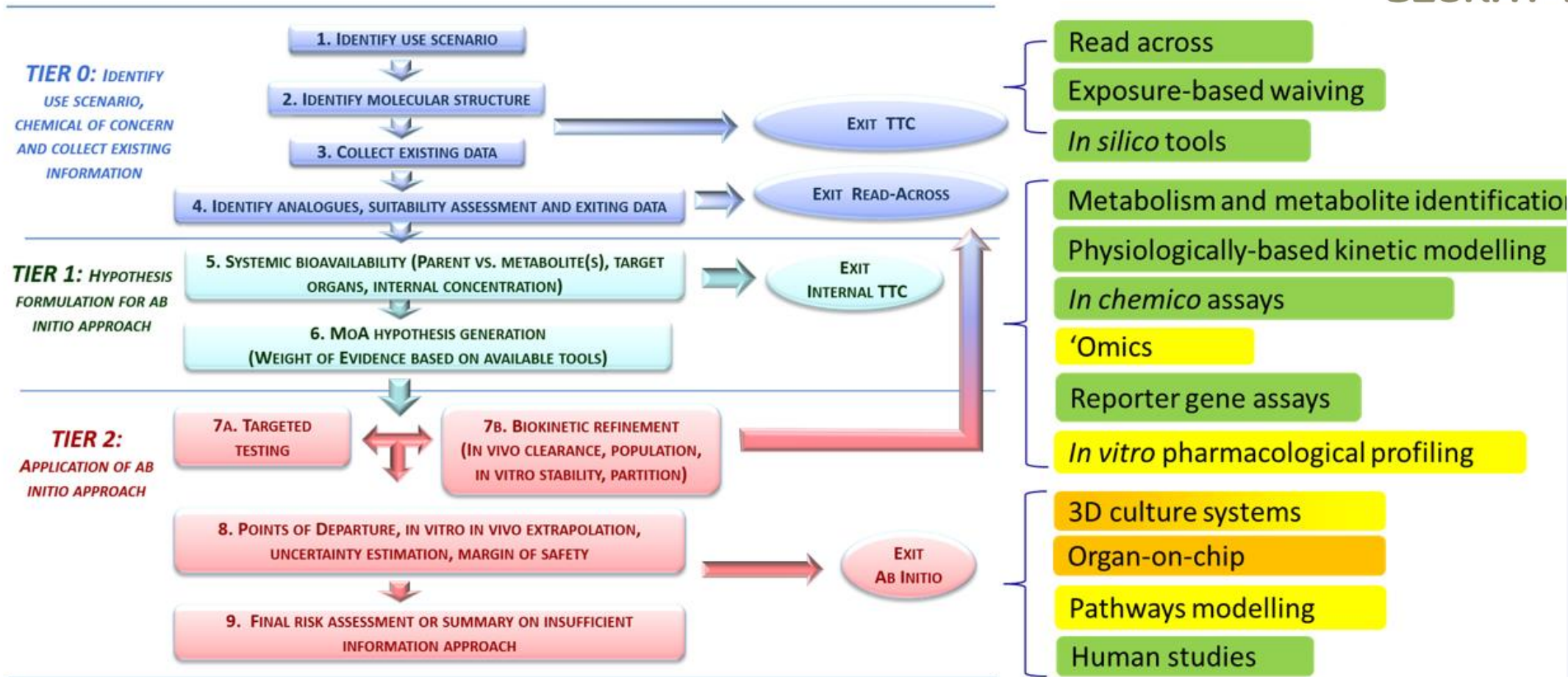
$$y_t = \underbrace{\begin{bmatrix} w_{g,1}^{(1)} & \dots & w_{g,1}^{(m)} \\ \vdots & & \vdots \\ w_{g,n_y}^{(1)} & \dots & w_{g,n_y}^{(m)} \end{bmatrix}}_C \underbrace{\begin{bmatrix} \phi_g^{(1)}(x_t, u_t) \\ \vdots \\ \phi_g^{(m)}(x_t, u_t) \end{bmatrix}}_{\varphi_g(x_t, u_t)} + e_t$$

Mathematical and statistical modelling

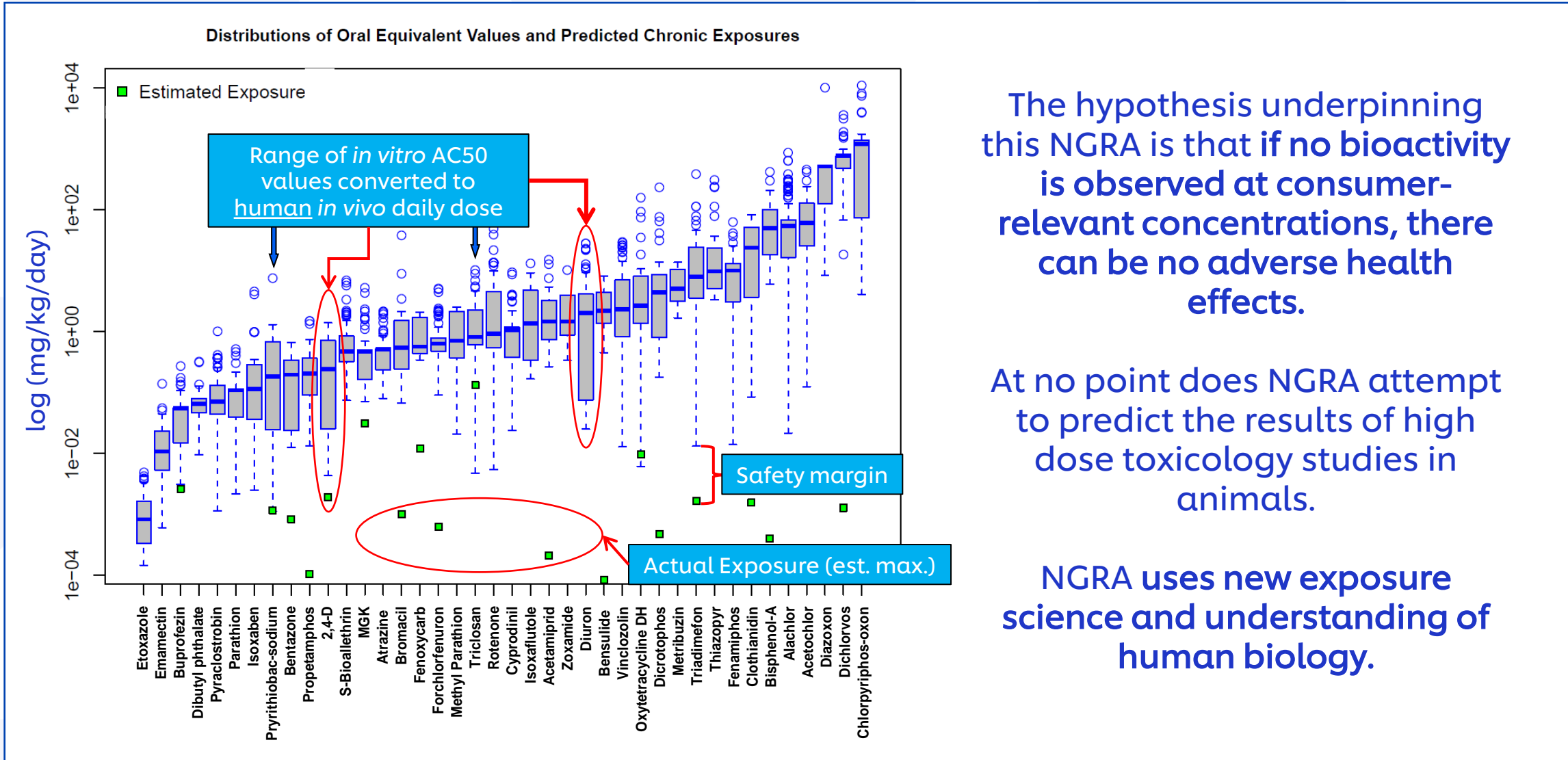
[Unilever, Safety & Environmental Assurance Centre \(SEAC\) – YouTube](#) US SoT March 2020 – NGRA concept & approach

[Unilever - Safety & Environmental Assurance Centre at Unilever Global IP Limited – YouTube](#) US SoT March 2022 – integrating NAMs in NGRA for consumer safety decisions

NGRA: tiered testing and human health assessment approach



NGRA: aim is protection of health, not prediction of animal data



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.

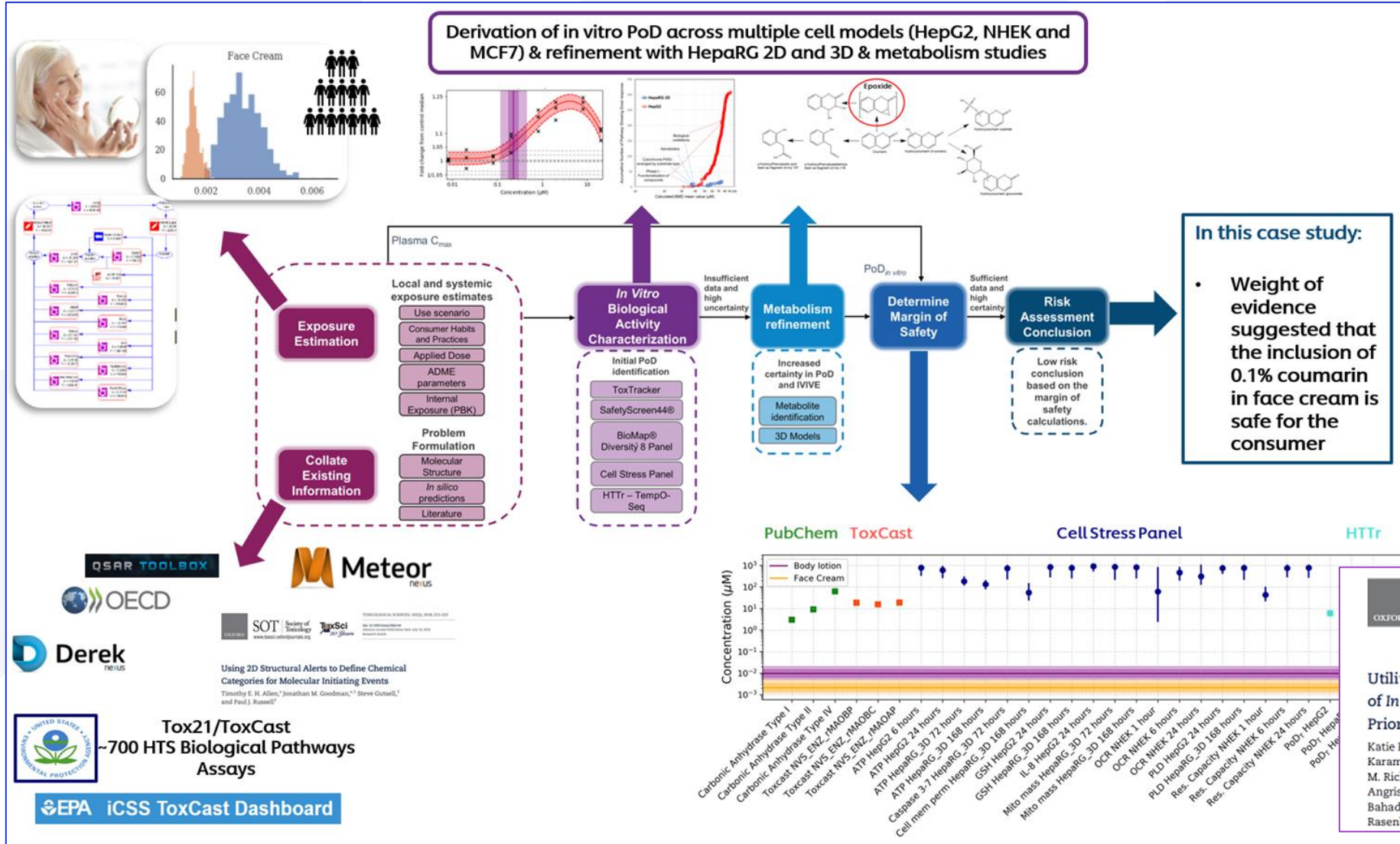


A large toolbox of modern scientific methods (NAMs) is used

Not a prescriptive set of tools, but driven by the safety assessment

Exposure tools to inform level of Systemic Exposure

Bioactivity tools to provide Points of Departure: *Bioactivity - Exposure Ratio*



OXFORD SOT Society of Toxicology academic.oup.com/toxsci Tr-X Spotlight

Utility of In Vitro Bioactivity as a Lower Bound Estimate of In Vivo Adverse Effect Levels and in Risk-Based Prioritization
 Katie Paul Friedman, Matthew Gagne, Lit-Hsin Loo, Panagiotis Karamertzanis, Tatiana Netzeva, Tomasz Sobanski, Jill A. Franzosa, Ann M. Richard, Ryan R. Lougee, Andrea Gissi, Jia-Ying Joey Lee, Michelle Angrish, Jean Lou Dorne, Steven Foster, Kathleen Raffaele, Tina Bahadori, Maureen R. Gwinn, Jason Lambert, Maurice Whelan, Mike Rasenberg, Tara Barton-Maclaren, and Russell S. Thomas

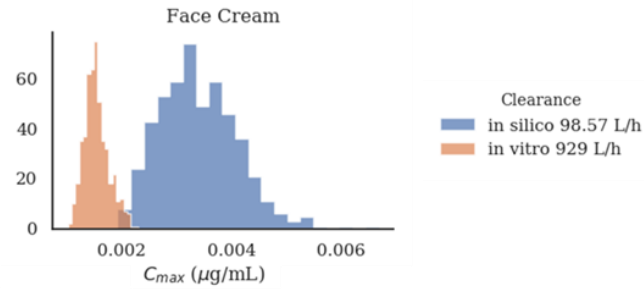
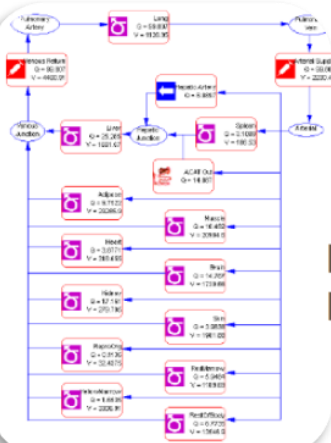
Hatherell et al (2020) Toxicological Sciences, 176, 11-33

Moxon et al (2020) Toxicology in Vitro, 63 104746
 Li et al (2022) Toxicol. Appl. Pharmacol., 442 115992



Key tools in our NGRA approach for systemic effects (NAMs Toolbox)

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 Boveri, Andrew J. Brown, Jacques Homan, Wolfgang Juratnik, 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 eradicating 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 to incur the associated substantial and regulatory burden.

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 to reduce the incidence of type A ADRs.

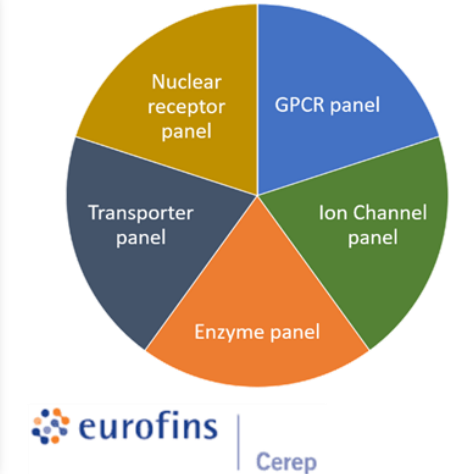
In vitro pharmacological profiling involves the screening of compounds against a broad range of targets (receptors, enzymes, transporters, etc.) that are chosen from the scientific

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 currents of native I_{Ca} in heterologously expressed human voltage-gated potassium channel subfamily 11 member 2 (hKCNJ2), also known as hERG7. 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 an *in vitro* pharmacological profiling should occur. Nevertheless, the general need for most pharmaceutical companies 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.

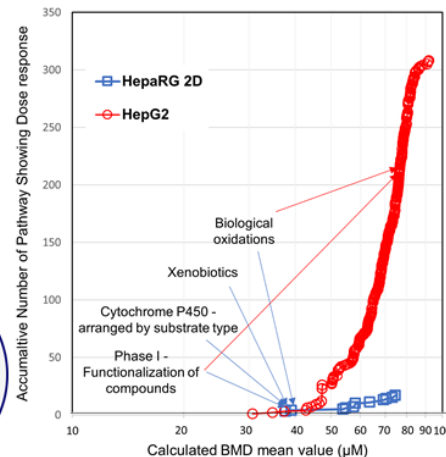
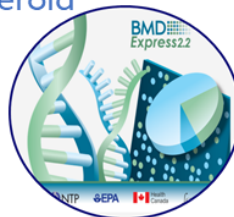
Here, for the first time, four major pharmaceutical companies (AstraZeneca, GlaxoSmithKline, Novartis and Pfizer) share their knowledge and experience of the innovative application of existing screening technologies to detect off-target interactions of compounds. The objective of this article is to describe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



Transcriptomics

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

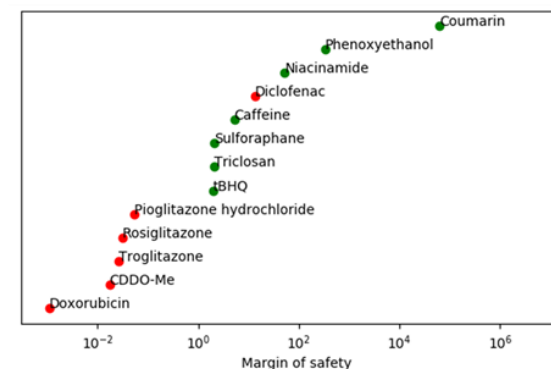
BMDexpress 2



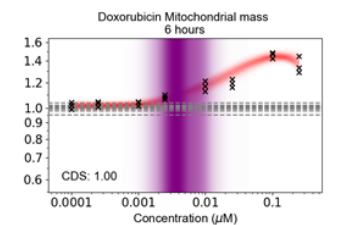
Cellular Stress Pathways

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]
 - Sulforaphane [food]
 - tBHQ [antioxidant]
 - Tricosan [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]

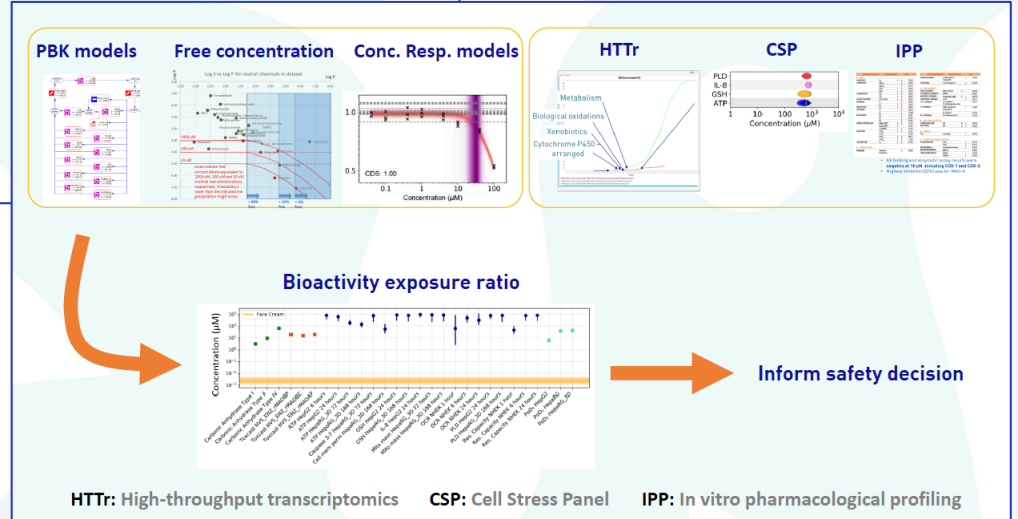
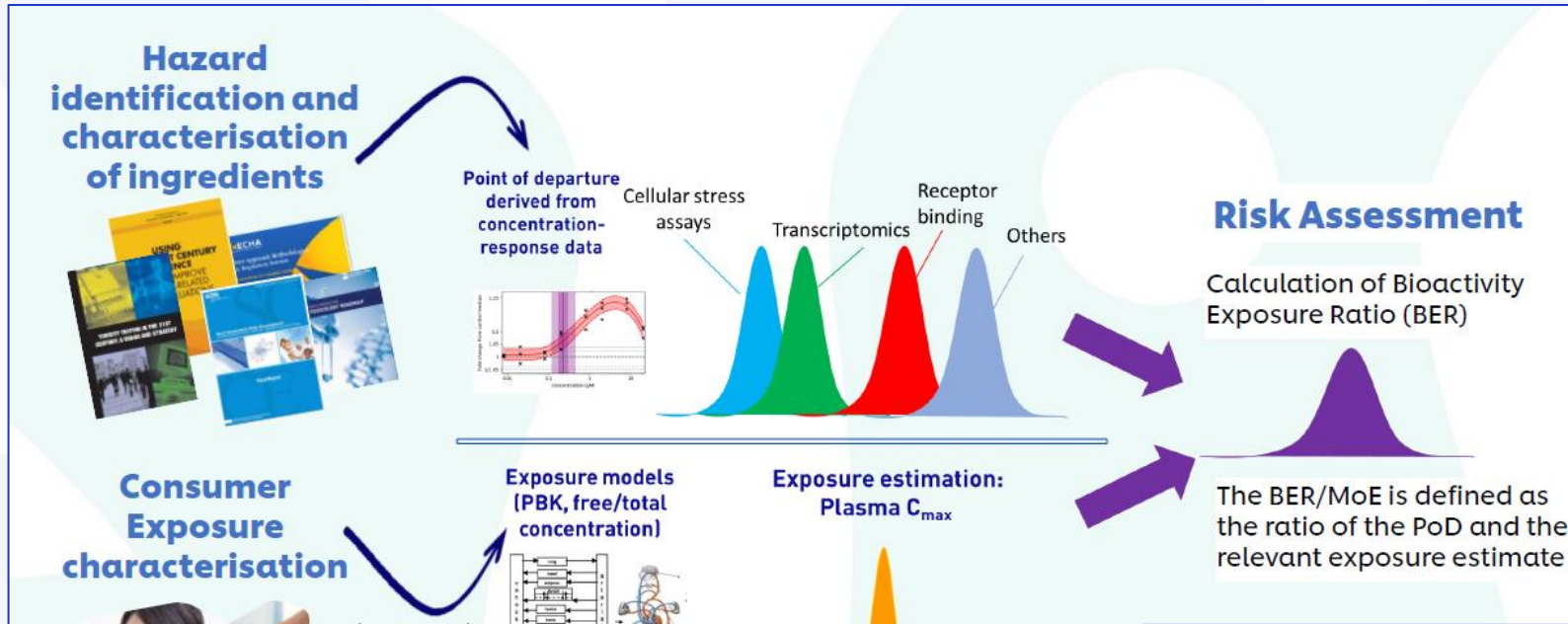


cyprotex
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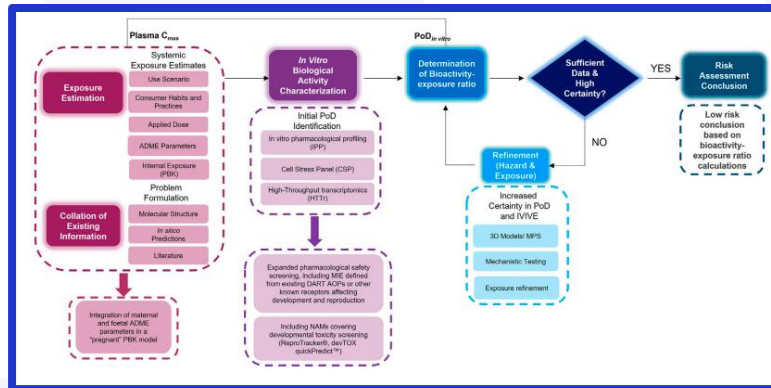
Toxicol Sci (2020), 176, 11-33

Integrating these approaches to make safety decisions



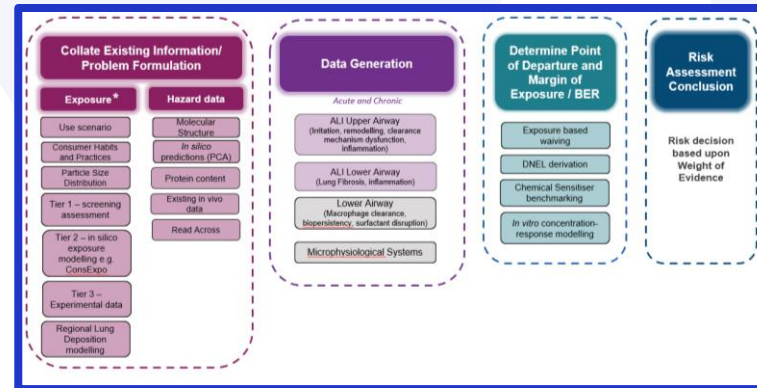
Unilever frameworks for using NAMs for Consumer Safety decisions

Developmental & Reproductive



Rajagopal et al (2022) *Frontiers in Toxicology*, doi: 10.3389/tox.2022.838466

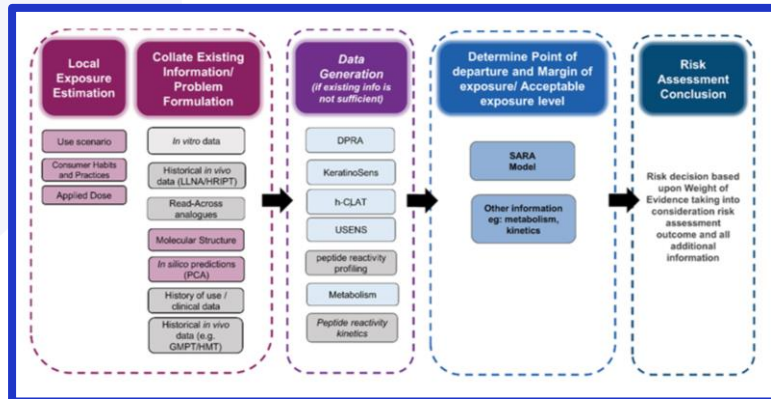
Inhalation



Ongoing Evaluations - Unilever working with government agencies

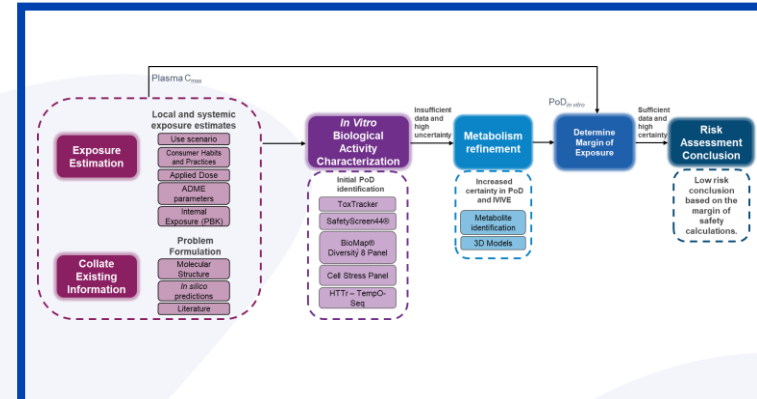


Skin Sensitisation



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

Systemic



Baltazar et al (2020) *Toxicol Sci*, 176, 236-252



Evaluating the NAMs Toolbox

Are non-animal systemic safety assessments protective? A toolbox and workflow

Alistair M. Middleton^{1*}, Joe Reynolds¹, Sophie Cable¹, Maria Teresa Baltazar¹, Hequn Li¹, Samantha Beven², Paul L. Carmichael¹, Matthew Philip Dent¹, Sarah Hatherell¹, Jade Houghton¹, Predrag Kukic¹, Mark Liddell¹, Sophie Malcomber¹, Beate Nicol¹, Benjamin Park², Hiral Patel³, Sharon Scott¹, Chris Sparham¹, Paul Walker¹, Andrew White¹

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³Cyprotex Discovery Ltd, No. 24 Mereside, Alderley Park, Macclesfield, Cheshire, SK10 4TG, United Kingdom.

Toxicological Sciences - accepted for publication

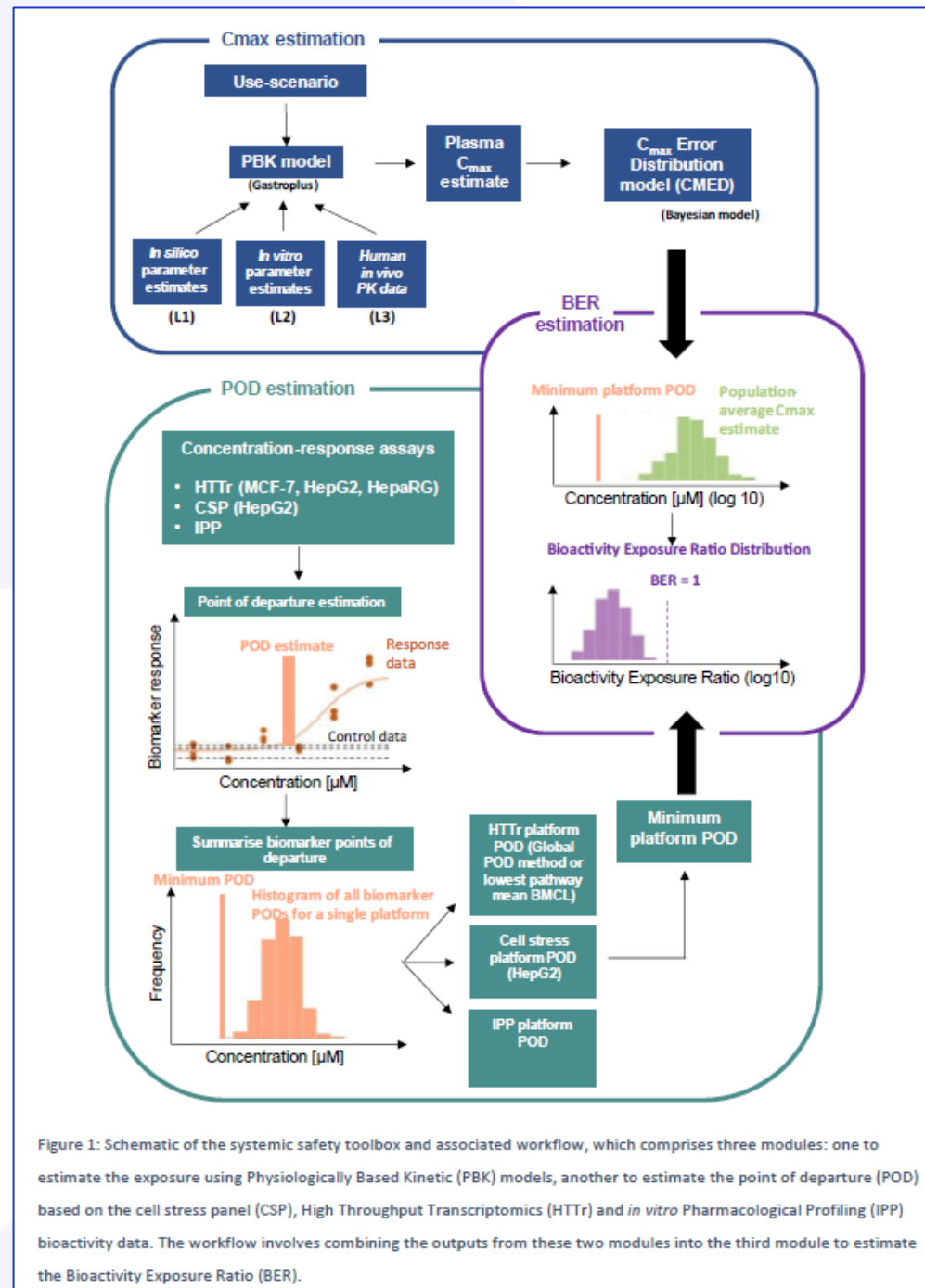


Figure 1: Schematic of the systemic safety toolbox and associated workflow, which comprises three modules: one to estimate the exposure using Physiologically Based Kinetic (PBK) models, another to estimate the point of departure (POD) based on the cell stress panel (CSP), High Throughput Transcriptomics (HTTr) and *in vitro* Pharmacological Profiling (IPP) bioactivity data. The workflow involves combining the outputs from these two modules into the third module to estimate the Bioactivity Exposure Ratio (BER).

Worker Safety is ensured via prevention & protection

– exposure-based risk assessments specific for the activity / local operating set-up

The screenshot shows the 'Your Europe' website interface. At the top, there is a search bar and a language selector set to 'English EN'. The breadcrumb trail reads: 'Your Europe > Business > Human resources > Social security and health > Health and safety at work'. Below this is a navigation menu with categories: 'Running a business', 'Taxation', 'Selling in the EU', 'Human resources', 'Product requirements', 'Finance and funding', and 'Dealing with customers'. The main heading is 'Health and safety at work', with a note 'Last checked: 06/12/2021'. Under 'ON THIS PAGE', there are two highlighted items: 'ЄС підтримує Україну' and 'EU stands with Ukraine'. The section 'Risk assessment' is expanded, showing text about employer duties: 'As an employer, you must ensure the **health and safety** of your employees in every aspect related to work. This means you must evaluate all the **risks** your employees may be exposed to and put in place preventive, and protective measures, such as ensuring that each worker has received the necessary health and safety **information and training**. Sometimes, you might have to take additional measures, for example, to prevent dangerous situations occurring and provide training on **first aid, fire-fighting and evacuation of workers**. You should also appoint at least **one trained staff member** to ensure these measures are complied with.' Below this is a sub-section 'Risk assessment' with text: 'There are **no EU rules** that describe exactly how you should conduct **risk assessments**, however, in some countries, national rules may include more detailed requirements concerning the content and form of risk assessments.'

Under workplace legislation, it is the **employer's duty to carry out a risk assessment and ensure that the workers are protected and provided with information, guidance and training** on the safe use of chemicals in the workplace, based on information derived from the labels and the safety data sheet. The employer also has the right to demand further information from the supplier.

REACH continuously accumulates data on health and safety risks from the use of chemical substances. The **registrant** (the manufacturer or the importer), who has to provide this data to the ECHA, also has to **communicate** this information to the downstream user, by providing an extended safety data sheet with exposure scenarios containing operational conditions and risk management measures for safe use, meant to facilitate the training of workers and the risk assessment procedure. At the same time, the registrant has the right to be informed by the downstream users on the relevance of the proposed risk management measures, in particular if they are inappropriate.

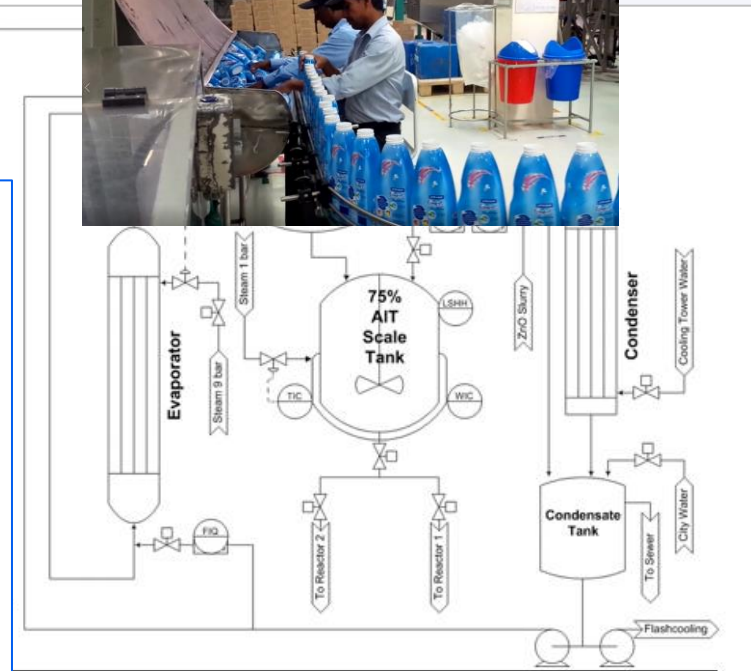
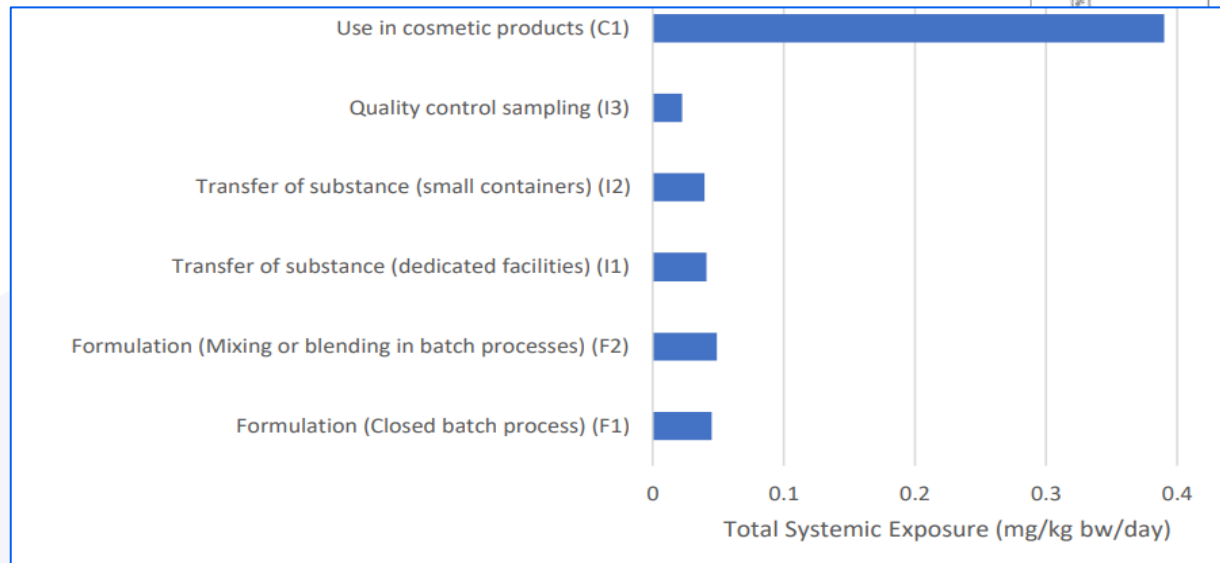
Can we change the types of data generated under REACH so they are based on advanced human-relevant science in place of animal testing?

NGRA approaches for Worker Safety decisions

- Understanding worker exposure
 - Routes
 - Levels
 - PPE*, engineering controls, ventilation, etc.
 - *PBK models for worker exposure*
- NGRA
 - *Bioactivity – Exposure Ratio (BER) approach for worker exposure*



* PPE = Personal Protective Equipment



Chemical Safety following environmental exposures – EU regulatory approach: protection from harm & use of non-animal tests



The screenshot shows the ECHA (European Chemicals Agency) website. The main navigation bar includes 'About Us', 'Contact', 'Jobs', and a search bar. Below this, there are three tabs: 'LEGISLATION', 'CONSULTATIONS', and 'INFORMATION ON CHEMICALS'. The 'LEGISLATION' tab is active, and the page title is 'ECHA > Legislation > REACH > Alternatives to animal testing under REACH'. On the left, there is a sidebar menu with categories like 'REACH', 'Understanding REACH', 'Substance Identification', 'Registration', 'Evaluation', 'Authorisation', 'Restriction', 'Communication in the supply chain', 'Candidate List substances in articles', 'Legislation', 'Alternatives to animal testing under REACH', and 'Enforcement'. The main content area is titled 'Alternatives to animal testing under REACH' and features an image of laboratory glassware. The text explains that chemicals can cause various health issues and that the European Parliament and Council have adopted legislation to protect people and the environment by promoting alternative test methods. It states that in practice, companies must test their chemicals for safety by using alternative methods or, as a last resort, testing on animals. The law requires companies to use alternative methods whenever possible.

EU REACH legislation has been in place for 15 years. It was introduced to protect people & the environment from harm and to promote alternative test methods.

Science & technology have advanced hugely since June 2007. Chemicals regulations need to catch up → framework for using best scientific data for safety decisions.

- Closing the Gap between Modern Safety Science & Regulatory Use of Next Gen Tools
- Building Confidence in the use of NAMs being Protective

Safety scientists are calling for paradigm shift & regulatory change - safe & sustainable ingredients without animal testing

Comment

Upholding the EU's Commitment to 'Animal Testing as a Last Resort' Under REACH Requires a Paradigm Shift in How We Assess Chemical Safety to Close the Gap Between Regulatory Testing and Modern Safety Science

Alternatives to Laboratory Animals
2021, Vol. 49(6) 123-132
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SAGE

Julia Fentem, Ian Malcomber, Gavin Maxwell and Carl Westmoreland

Archives of Toxicology
<https://doi.org/10.1007/s00204-021-03215-9>

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. Doe⁶ · Tatsiana Dudzina⁶ · Timothy W. Gant⁷ · Marcel Leist⁸ · Bennard van Ravenzwaay⁹

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Cosmetics
europa.europa.com

Unilever: EU needs 'paradigm shift' in chemical safety assessment methods

By Kacey Cullinney
23-Sep-2021 - Last updated on 23-Sep-2021 at 14:58 GMT

RELATED TAGS: Animal testing, Animal testing alternatives, non-animal testing methods, REACH, Chemicals, Regulation, next generation safety assessments, Unilever, safety assessment

Cosmetics
europa.europa.com

THE LONG READ: IN CONVERSATION WITH UNILEVER SAFETY & ENVIRONMENTAL ASSURANCE CENTRE (SEAC) EXECUTIVES

The future of animal-free chemical testing? There's a 'big frustration' in the scientific community, say Unilever execs

By Kacey Cullinney
20-Oct-2021 - Last updated on 20-Oct-2021 at 09:54 GMT

RELATED TAGS: Animal testing, Animal testing alternatives, cruelty-free, In vivo, Regulation, ECHA, REACH, Animal testing ban, Chemicals

Adoption of NGRA in cosmetic ingredient safety assessment ...



... use of similar approaches for chemicals registration purposes?

Computational Toxicology 7 (2018) 20–26

Contents lists available at ScienceDirect

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Computational Toxicology

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

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

Matthew Dent^{a,*}, Renata Teixeira Amaral^b, Pedro Amores Da Silva^b, Jay Ansell^c, Fanny Boislevé^d, Masato Hatae^e, Akihiko Hirose^f, Yutaka Kasai^g, Petra Kern^h, Reinhard Kreilingⁱ, Stanley Milstein^j, Beta Montemayor^k, Julcemara Oliveira^l, Andrea Richarz^m, Rob Taalmanⁿ, Eric Vaillancourt^o, Rajeshwar Verma^p, Nashira Vieira O'Reilly Cabral Posada^q, Craig Weiss^r, Hajime Kojima^s

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^e *Japan Cosmetic Industry Association (JCIA), Minami City Komiyacho 6F, 2-1-5, Toranomon, Minato-ku, Tokyo 105-0001 Japan*
^f *National Institute of Health Sciences, 1-18-1 Kamiyoga, Setagaya-ku, 158-8501 Tokyo, Japan*
^g *Kao Corporation, External Relations & Government Affairs, 2-1-3, Bunko, Saitama-ku, Tokyo 131-8501 Japan*
^h *Procter and Gamble Services Company NV, Tervelsteun 100, B 1853 Strombeek Bever, Belgium*
ⁱ *Chemical Products (CP) GmbH, Global Toxicology and Cosmetology, Am Dieckweg 7, 65843 Sobolush, Germany*
^j *US Food and Drug Administration (US FDA), Office of Cosmetics and Colors (OCCAC), Center for Food Safety and Applied Nutrition (CFSA), 5001 Campus Drive, College Park, MD 20740, USA*
^k *Cosmetics Alliance Canada, 420 Britannia Road East Suite 102, Mississauga, ON L4Z 3L5, Canada*
^l *Brazilian Health Regulatory Agency (ANVISA), Gerência de Produtos de Higiene, Perfumes, Cosméticos e Sabonetes, SIA Trecho 5, lote 200, Área Especial 57 - CEP 71205-050, Brazil*
^m *European Commission, Joint Research Centre (JRC), Directorate for Health, Consumers and Reference Materials, Chemical Safety and Alternative Methods Unit, Via E. Fermi 27/49, 21027 Bra, Italy*
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^o *Cosmetics Europe, Avenue Hermès Desobry 40, 1160 Auderghem, Belgium*
^p *Health Canada (HC), Consumer Product Safety Directorate, Health Environment and Consumer Safety Branch, 269 Laurier Ave. W., Ottawa, ON K1A 0R9, Canada*
^q *Independent Cosmetic Manufacturers and Distributors (ICMAD), 21552 Field Parkway, Suite 2015, Deer Park, IL 60016, USA*

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REGULATORY TOXICOLOGY

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ARTICLE INFO

ABSTRACT

Keywords: Consumer; New Generation Risk Assessment; New approach methodologies; Cosmetics risk assessment

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
 on Consumer Safety
 on Health, Environmental and Emerging Risks

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

EPA United States Environmental Protection Agency

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EPA New Approach Methods Work Plan: Reducing Use of Vertebrate Animals in Chemical Testing

CONTACT US

EPA United States Environmental Protection Agency

EPA 600/X-21/099 | December 2021 | www.epa.gov/research

New Approach Methods Work Plan

U.S. Environmental Protection Agency
 Office of Research and Development
 Office of Chemical Safety and Pollution Prevention
 December 2021

- Evaluate regulatory flexibility for accommodating NAMs
- Develop baselines and metrics for assessing progress
- Establish scientific confidence and demonstrate application
- Develop NAMs that fill critical information gaps
- Engage and communicate with stakeholders



International Cooperation on Cosmetics Regulation (2018)

Scientific Committee on Consumer Safety (2021)

Stakeholders engaging on use of NAMs for EU chemicals regulations

Comment

Upholding the EU's Commitment to 'Animal Testing as a Last Resort' Under REACH Requires a Paradigm Shift in How We Assess Chemical Safety to Close the Gap Between Regulatory Testing and Modern Safety Science

Alternatives to Laboratory Animals
2021, Vol. 49(4) 122-132
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Julia Fentem, Ian Malcomber, Gavin Maxwell and Carl Westmoreland

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Food for Thought ... Ready for Regulatory Use: NAMs and NGRA for Chemical Safety Assurance

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flash

EPAA Workshop

23 - 24 November 2021, virtual event



The European Partnership
for Alternative Approaches to Animal Testing

Deep-Dive Workshop on «Use of New Approach Methodologies (NAMs) in Regulatory Decisions for Chemical Safety»

How to accelerate the replacement of animal toxicity testing

Helsinki Chemicals
Forum 2022

8-9 June 2022
Stakeholder views on hot topics in chemicals safety

Context

It is agreed that we need to replace animal toxicity testing and many regulations encourage avoiding it. But the tests are still widely used. They can be time-consuming, costly and are not always accurate in predicting chemical effects in humans. While new approach methods (NAMs) are becoming available, implementing them has been a relatively slow process. Regulatory authorities are looking for assurance that these alternative test methods protect human health as efficiently/effectively as the animal models they replace. But how can confidence be achieved and how can we speed up their adoption by decision makers?

Moderator: Patience Browne, principal administrator, Hazard Assessment and Pesticides Programmes, Environmental Directorate, OECD

Panelists:

Gavin Maxwell, EPAA industry co-chair and safety science leader, Unilever Safety & Environmental Assurance Centre (SEAC)

Marina Pereira, senior strategist – regulatory policy, research and toxicology, Humane Society International

Ofelia Bercaru, director – prioritisation and integration, Echa

Maurice Whelan, head of Chemical Safety and Alternative Methods Unit, European Commission

Tara Barton-Maclaren, research manager, Healthy Environments and Consumer Safety Branch, Health Canada/ Government of Canada



PRESS RELEASE

Maisons-Alfort, 11 May 2022

Launch of the European research and innovation PARC programme to improve chemical risk assessment