Paradigm Shift in Progress

Is it time for a global NGRA Roadmap?

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Safety, Environmental & Regulatory Sciences (SERS), Unilever

21st Oct 2025, ASCCT 2025

Next Generation Risk Assessment (NGRA) Paradigm Shift

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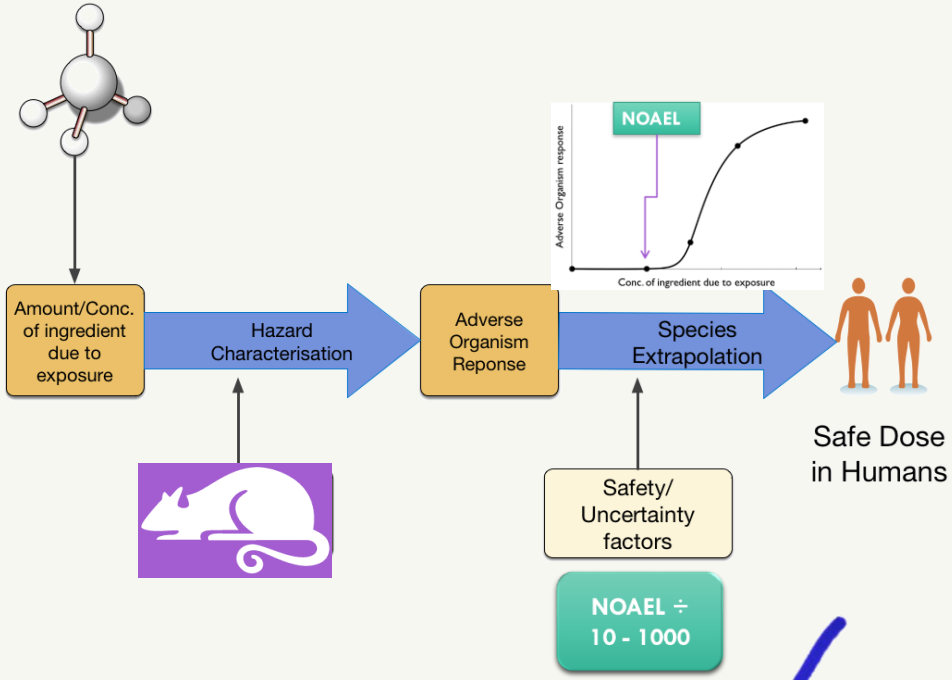
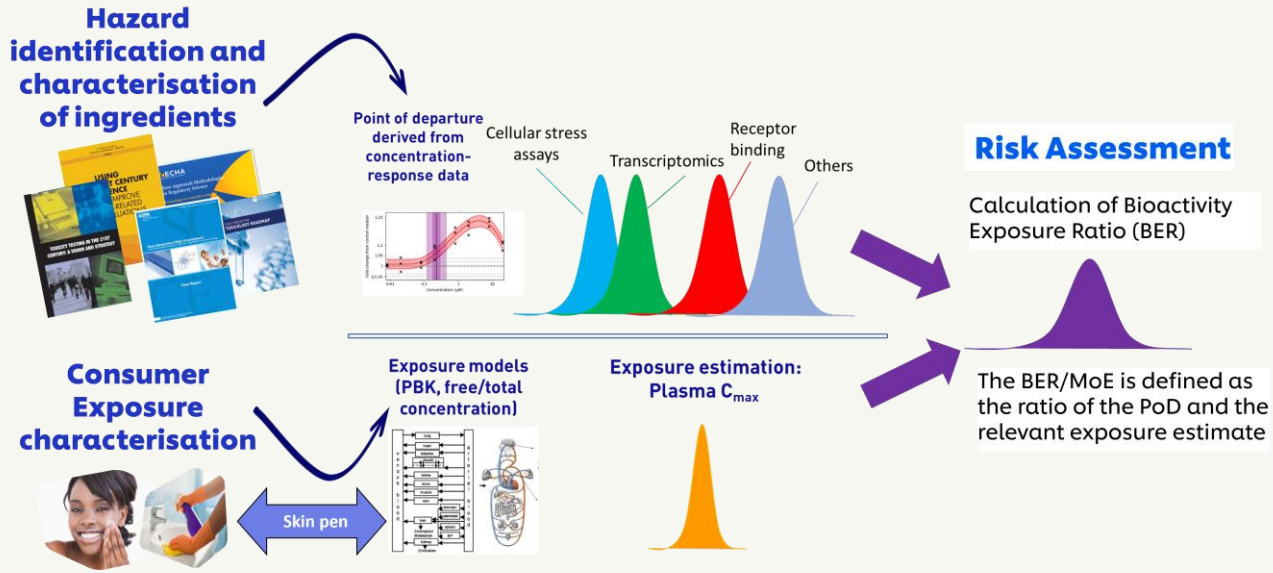
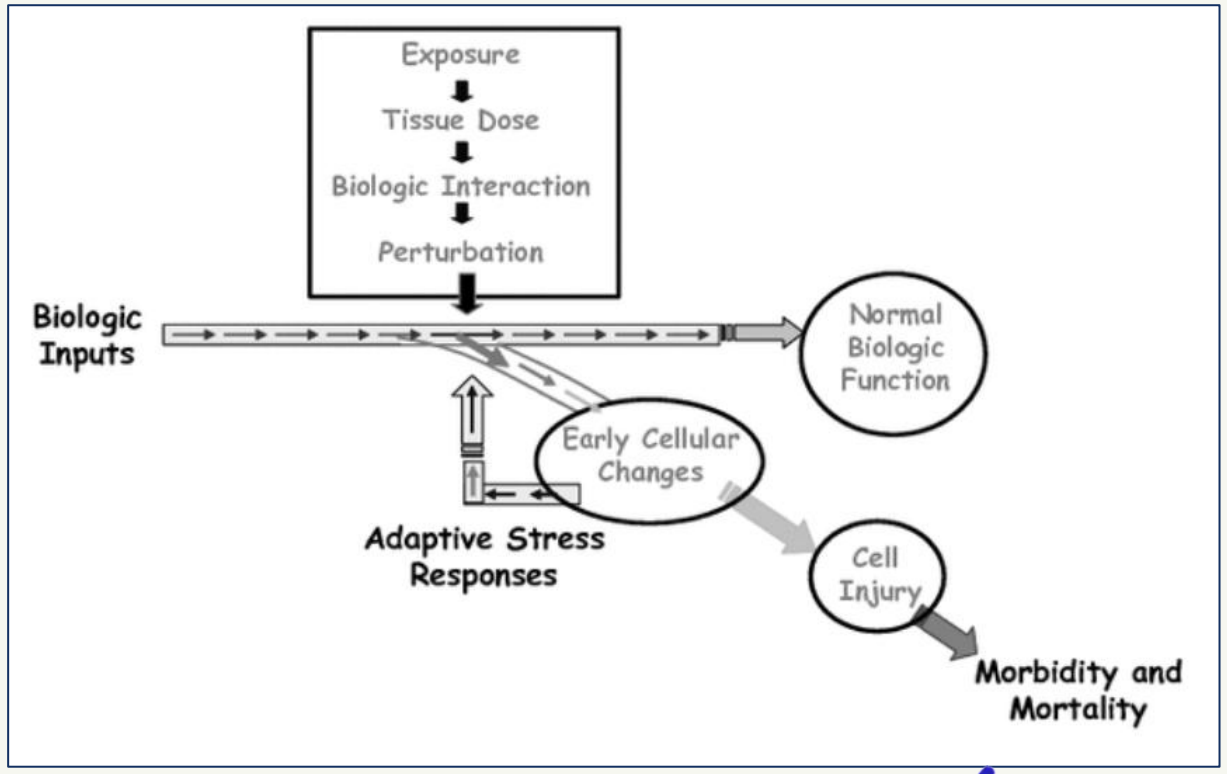
'Traditional' Risk Assessment

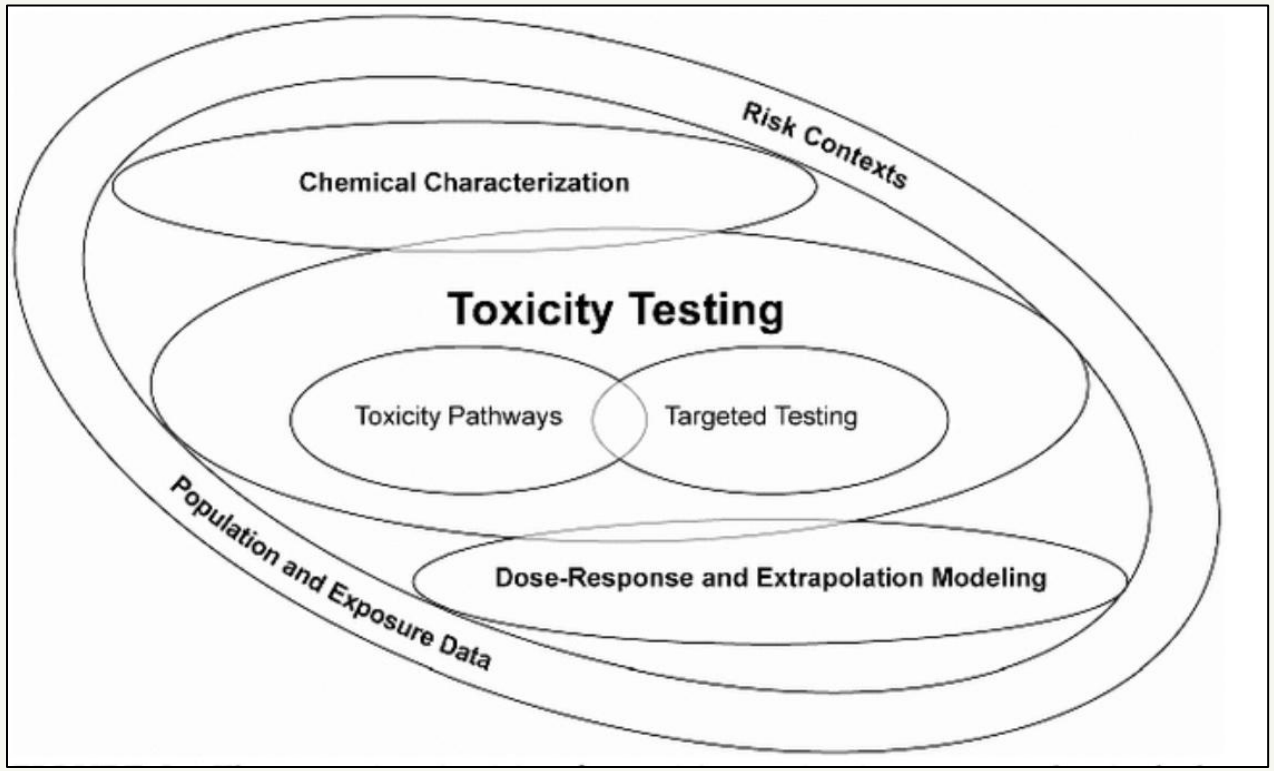


'Next Generation' Risk Assessment

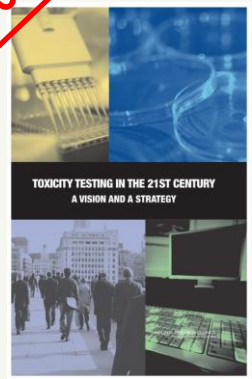


Next Generation Risk Assessment (NGRA) concepts





2007



[Toxicity Testing in the 21st Century: A Vision and a Strategy | The National Academies Press]

Next Generation Risk Assessment Conceptual Frameworks

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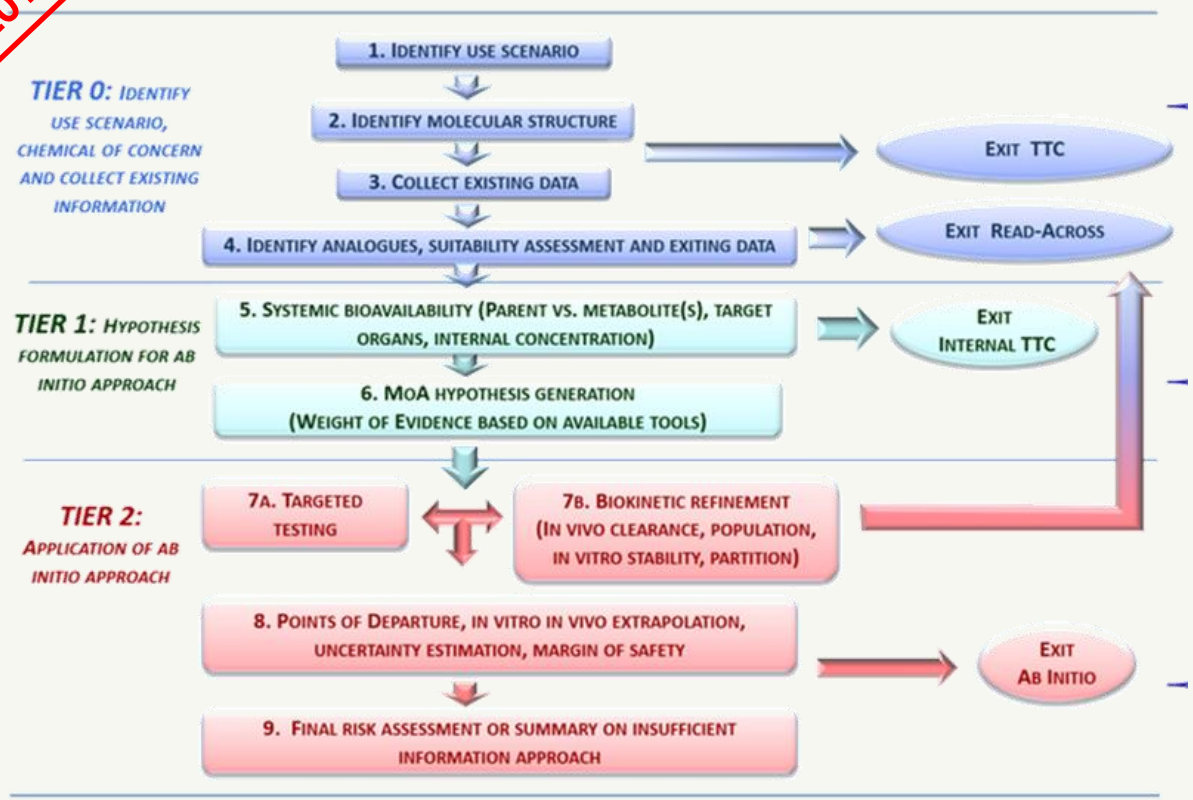
2017

SEURAT-1

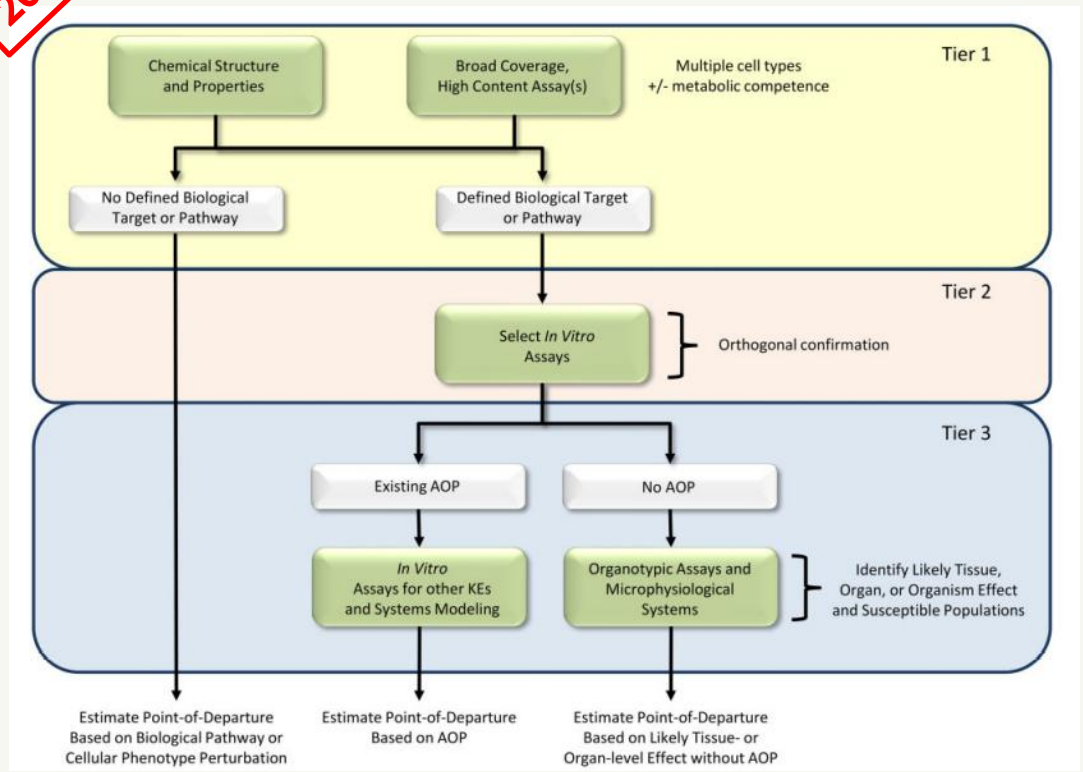


Ab initio chemical safety assessment: A workflow based on exposure considerations and non-animal methods

https://doi.org/10.1016/j.comtox.2017.10.001

2019

EPA United States Environmental Protection Agency



The Next Generation Blueprint of Computational Toxicology at the U.S. Environmental Protection Agency

https://pubmed.ncbi.nlm.nih.gov/30835285/

EU Scientific Committee on Consumer Safety (SCCS) created a 'safe space' to explore ab initio use of NGRA approaches for Cosmetics Safety

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2023

SCCS/1647/22
Corrigendum 2

Scientific Committee on Consumer Safety

SCCS

THE SCCS NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION 12TH REVISION

Scientific Committees

The SCCS adopted this guidance document by written procedure on 15 May 2023

The corrigendum 1 was adopted during plenary meeting on 26 October 2023, and the corrigendum 2 by written procedure on 21 December 2023

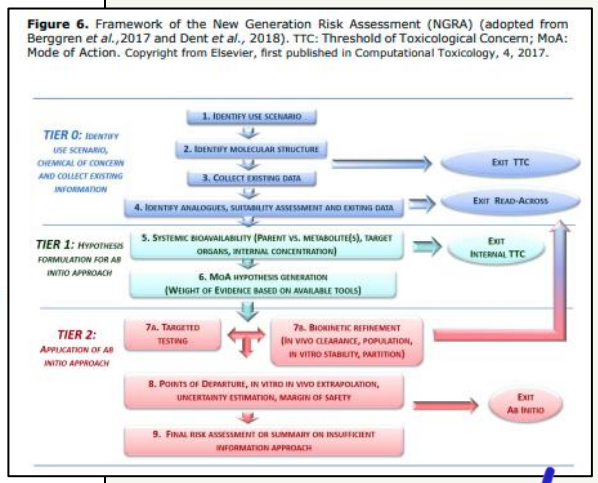

Figure 6. Framework of the New Generation Risk Assessment (NGRA) (adopted from Berggren *et al.*, 2017 and Dent *et al.*, 2018). TTC: Threshold of Toxicological Concern; MoA: Mode of Action. Copyright from Elsevier, first published in Computational Toxicology, 4, 2017.

2025

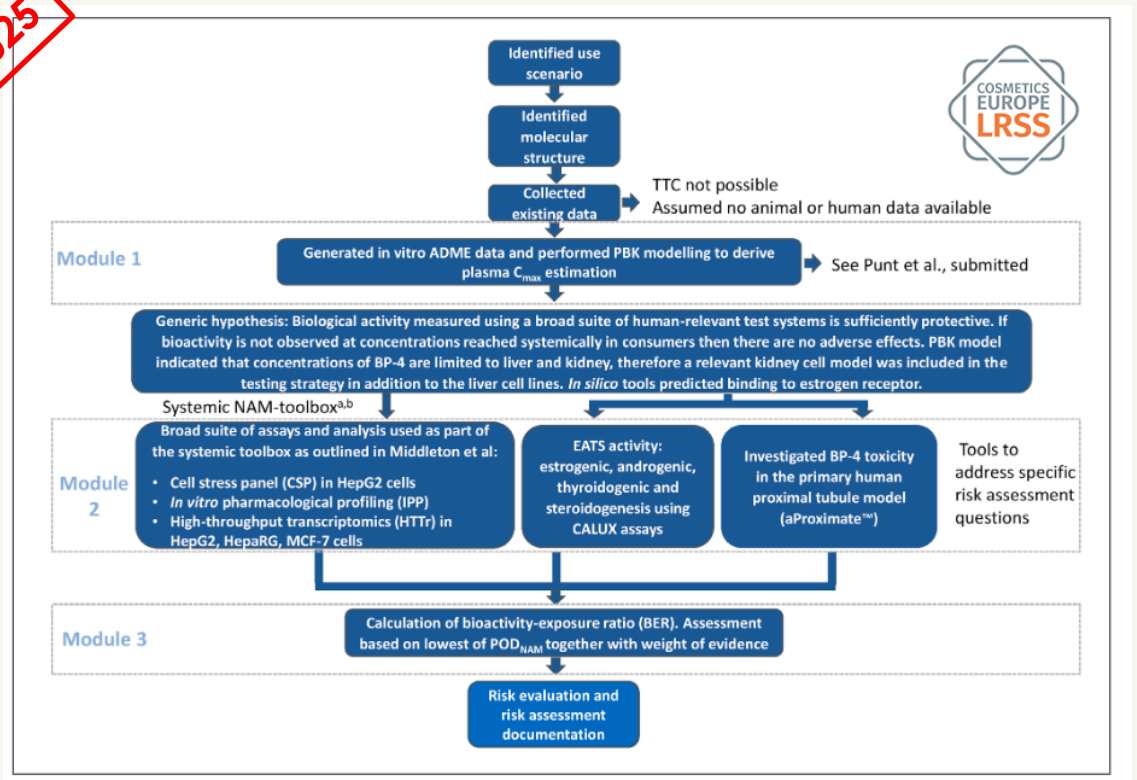

Fig. 1: NGRA case study workflow for 5% BP-4 in sunscreen body lotion
Adapted from Berggren et al. (2017) and Dent et al. (2021); [a] Middleton et al. (2022), [b] Cable et al. (2024).

SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 12th revision

SCCS 12th revision Notes of guidance

Making safety decisions for a sunscreen active ingredient using next-generation risk assessment: Benzophenone-4 case study

https://doi.org/10.14573/altex.2501201

International Cooperation of Cosmetics Regulators (ICCR) & International Collaboration on Cosmetics Safety (ICCS) are standardising global best practice for NGRA for Cosmetics Safety

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ICCR International Cooperation on Cosmetics Regulation

2018

https://doi.org/10.1016/j.comtox.2018.06.001

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

ICCR International Cooperation on Cosmetics Regulation

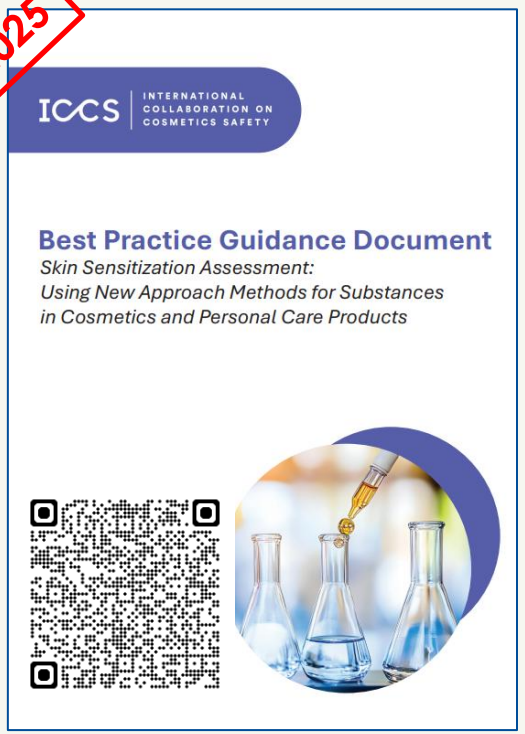
2021

https://doi.org/10.1016/j.yrtph.2021.105026

Paving the way for application of NGRA to safety decision-making for cosmetic ingredients

ICCS INTERNATIONAL COLLABORATION ON COSMETICS SAFETY

2025



Skin Sensitization Best Practice Guidance

Best Practice Guidance Document: Skin Sensitization: using NAMs for substances in Cosmetics

Ending animal testing of Cosmetic Products under China's Cosmetics Supervision and Administration Regulation (CSAR)

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1989–2014: First stage of cosmetics regulations

- ✓ Pre-market registration
- ✓ Safety responsibility lies largely with the authorities
- ✓ Mandatory AT for finished products

NATIONAL MEDICAL PRODUCTS ADMINISTRATION
国家药品监督管理局

https://english.nmpa.gov.cn/index.html

2014-2021: Adopting of non-animal approaches

- ✓ Ingredient-based risk assessment via safety assessment report
- ✓ No mandate AT for domestic non-special use cosmetics

2021-2024: CSAR in place

- ✓ No mandate AT for majority of cosmetics (domestic and imported "common" cosmetics)
- ✓ AT is required for special cosmetics and a few types of common cosmetics

2024-2025: Full CSAR implementation

- ✓ Mix mandate AT and non-animal approaches (e.g., TTC, QSAR/Read-across; IATA)
- ✓ For new cosmetic ingredient registration using NAMS (i.e., novel non-animal approaches that have been validated with 10 chemicals)

Accelerating the Pace of Chemical Risk Assessment (APCRA) case studies demonstrate the feasibility of NGRA approaches

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APCRA
ACCELERATING THE PACE OF CHEMICAL RISK ASSESSMENT

Led by: Health Canada Santé Canada ECHA EUROPEAN CHEMICALS AGENCY UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

https://apcra.net/case-studies/

2020

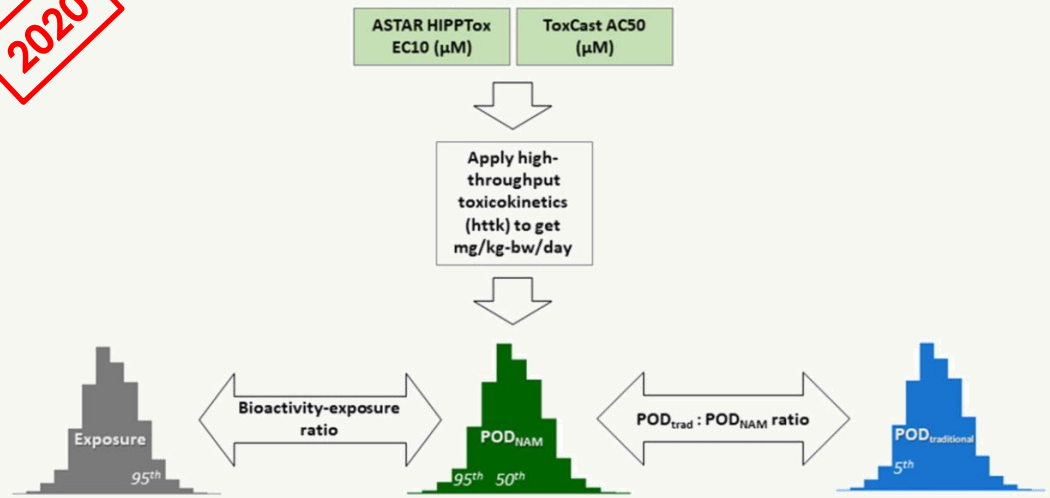

Figure 1. Overall workflow of the case study. This case study includes 448 substances with exposure predictions, *in vitro* assay data, HTTK information using the httk R package, and *in vivo* hazard information. The 50th and 95th percentile from the Monte Carlo simulation of interindividual toxicokinetic variability were used to estimate administered equivalent doses (AEDs), and the minimum of either the ToxCast or HIPPTox-based AEDs were selected as the $POD_{NAM,\ 50}$ or $POD_{NAM,\ 95}$. The POD_{NAM} estimates were compared with the fifth percentile from the distribution of the $POD_{traditional}$ values obtained from multiple sources to obtain the log_{10} POD ratio. The log_{10} bioactivity:exposure ratio (BER) was obtained by comparing the POD_{NAM} estimates to exposure predictions. All values used for computation were in log_{10}-mg/kg-bw/day units.

2025

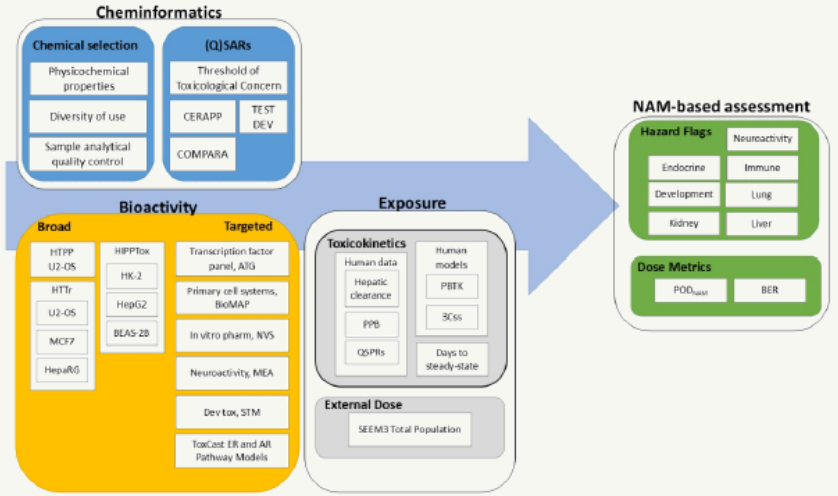

Figure 1. NAM-based assessment (NBA) workflow.
An overview of a NBA workflow that incorporates cheminformatics, broad and targeted bioactivity NAMs, via hazard flags, and exposure NAMs for internal and external exposures. The workflow culminates in a set of outputs for NBA, including hazard flags, POD¬NAM, and BER estimates.

Paul-Friedmann et al. 2020 APCRA 'retrospective' case study - To elucidate whether a "region of safety" , i.e. a threshold below which no bioactivity or toxicity would be anticipated, can be identified using NAMs for a list of chemicals with existing human health evaluations.

Paul-Friedmann et al. 2025 APCRA 'prospective' case study - To demonstrate how NAM data and classical toxicological studies can be used to inform the hazard and safety profile of chemicals with limited or unclear toxicological data

Regulatory Agencies are signalling their readiness to transition their organisations to enable regulatory use of NAMs/NGRA

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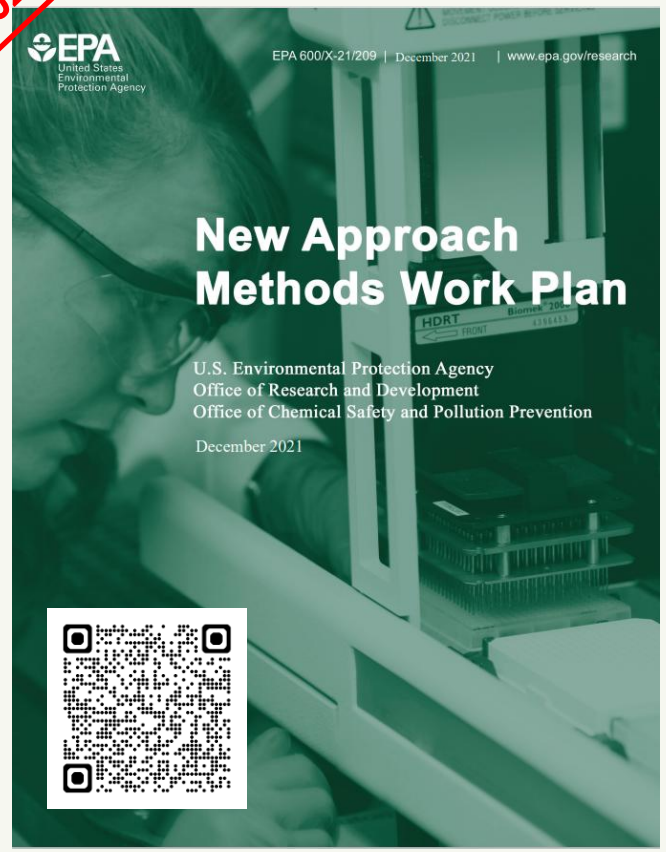
2021

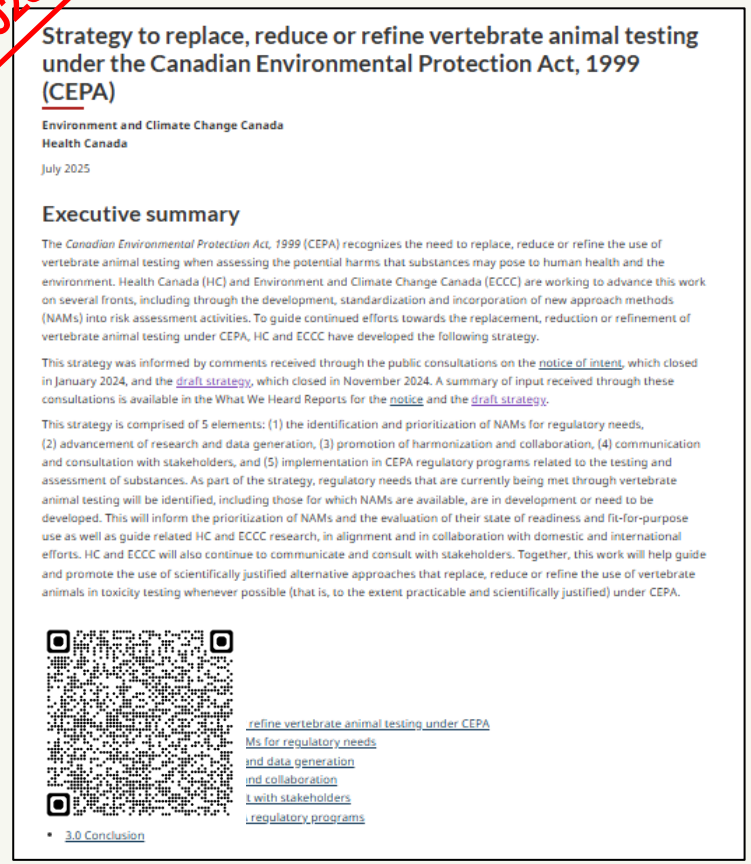


[New Approach Methods Work Plan (epa.gov)]

2023

[towards-an-animal-free-regulatory-system-for-industrial-chemicals]

2025



Strategy to replace, reduce or refine vertebrate animal testing under the Canadian Environmental Protection Act, 1999 (CEPA)

Environment and Climate Change Canada
Health Canada

July 2025

Executive summary

The *Canadian Environmental Protection Act, 1999* (CEPA) recognizes the need to replace, reduce or refine the use of vertebrate animal testing when assessing the potential harms that substances may pose to human health and the environment. Health Canada (HC) and Environment and Climate Change Canada (ECCC) are working to advance this work on several fronts, including through the development, standardization and incorporation of new approach methods (NAMs) into risk assessment activities. To guide continued efforts towards the replacement, reduction or refinement of vertebrate animal testing under CEPA, HC and ECCC have developed the following strategy.

This strategy was informed by comments received through the public consultations on the notice of intent, which closed in January 2024, and the draft strategy, which closed in November 2024. A summary of input received through these consultations is available in the What We Heard Reports for the notice and the draft strategy.

This strategy is comprised of 5 elements: (1) the identification and prioritization of NAMs for regulatory needs, (2) advancement of research and data generation, (3) promotion of harmonization and collaboration, (4) communication and consultation with stakeholders, and (5) implementation in CEPA regulatory programs related to the testing and assessment of substances. As part of the strategy, regulatory needs that are currently being met through vertebrate animal testing will be identified, including those for which NAMs are available, are in development or need to be developed. This will inform the prioritization of NAMs and the evaluation of their state of readiness and fit-for-purpose use as well as guide related HC and ECCC research, in alignment and in collaboration with domestic and international efforts. HC and ECCC will also continue to communicate and consult with stakeholders. Together, this work will help guide and promote the use of scientifically justified alternative approaches that replace, reduce or refine the use of vertebrate animals in toxicity testing whenever possible (that is, to the extent practicable and scientifically justified) under CEPA.

refine vertebrate animal testing under CEPA
Ms for regulatory needs
nd data generation
nd collaboration
l with stakeholders
regulatory programs
- 3.0 Conclusion

[Strategy to replace, reduce or refine vertebrate animal testing under CEPA]

Commission Roadmap to phase out Animal Testing for Chemical Safety will support a managed transition to NGRA in Europe

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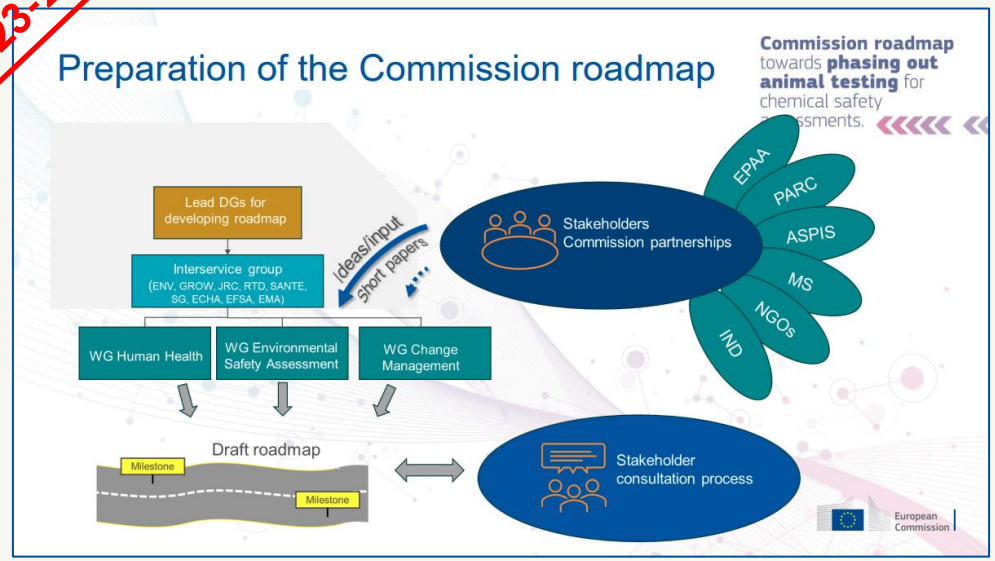
2023-26



Commission Roadmap will be published in Q1 2026

Roadmap proposal developed by Human Health, Environmental Safety & Change Management working groups, 3 open workshops & consultations

Stakeholders (incl. EPAA, PARC, ASPIS) involved throughout helping to build trust & foster collaboration

2025


Regulatory Toxicology and Pharmacology

Report of the European Commission workshop on "The roadmap towards phasing out animal testing for chemical safety assessments", Brussels, 11–12 December 2023

https://doi.org/10.1016/j.yrtph.2025.105818

Roadmap towards phasing out animal testing

European Partnership for Alternative Approaches to Animal Testing (EPAA) partnered with the Commission & other organisations to organise an **Animal-Free Chemical Safety Assessment conference** in March 2025

https://echa.europa.eu/documents/10162/127346428/AF-CSA_Conference+Report.pdf/d7994cf5-4b38-9a8a-9cbc-0c89da0dcad8?t=1749891499636

Commission Roadmap contains detailed cross-sector proposals for how to establish animal-free NGRA frameworks

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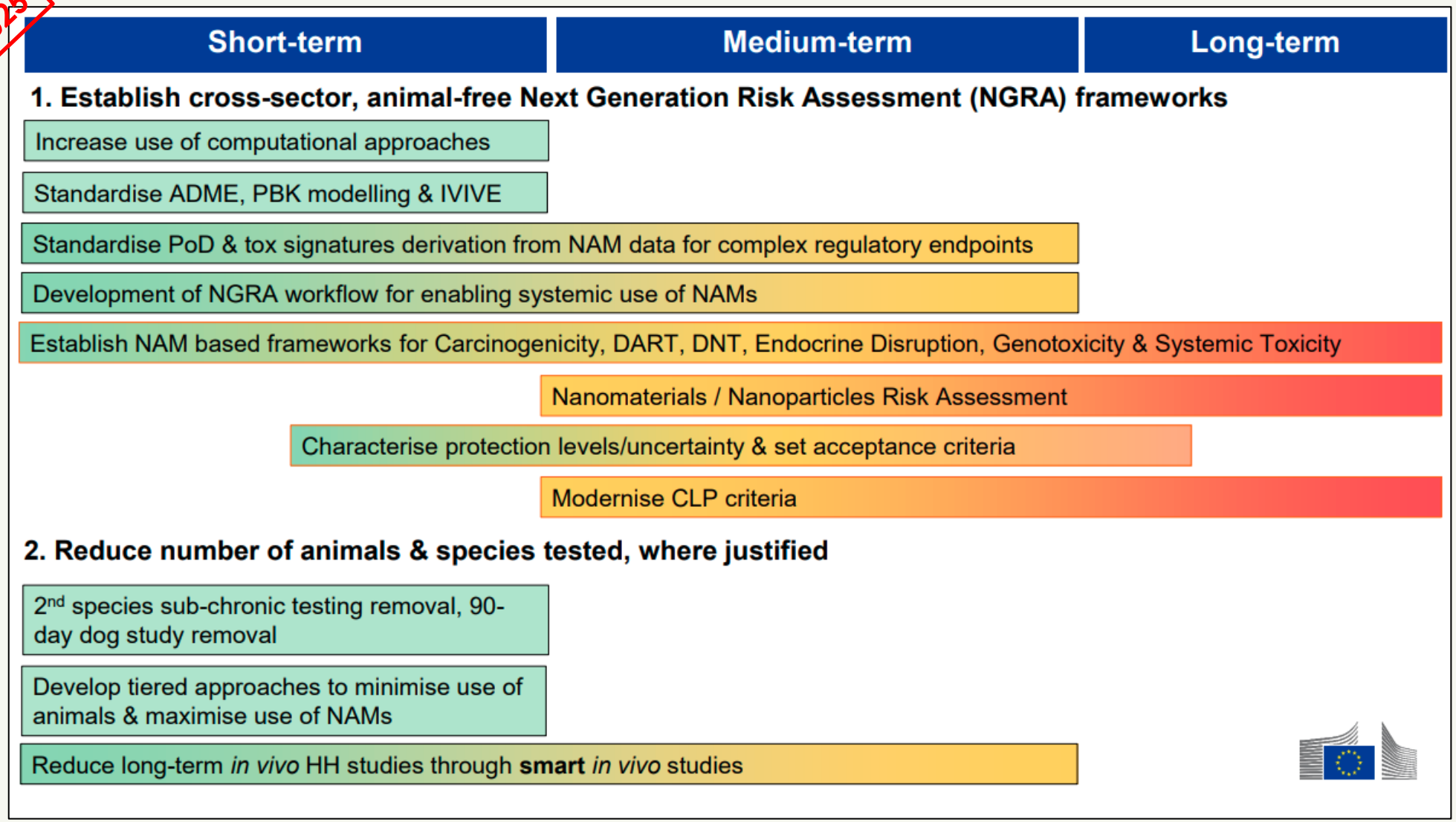
European Commission

2025



Commission Human Health working group overview of Roadmap proposals presented at 3rd workshop

OECD Integrated Approaches to Testing & Assessment (IATA) & guidance are driving global standardisation of NGRA for chemical safety

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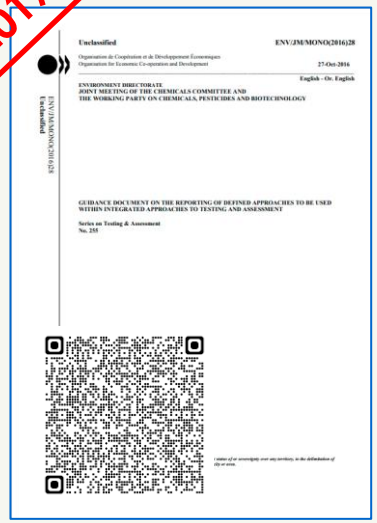
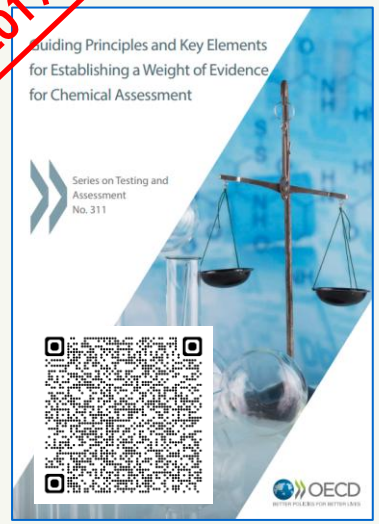
IATA combine multiple sources of information to conclude on the toxicity of chemicals and are developed to address a specific regulatory scenario or decision context.

2017



Guidance document on reporting of **Defined Approaches** for use in IATA

2019

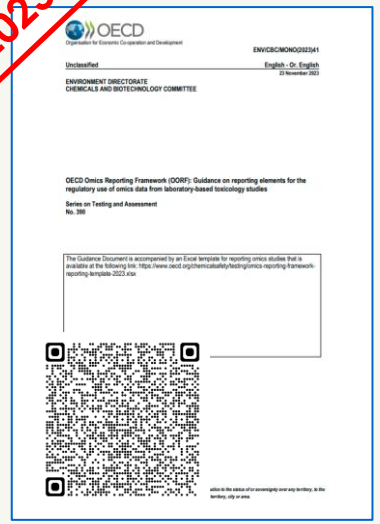


Guiding principles for establishing a **Weight of Evidence** for Chemical Assessment

2021

Guidance document on reporting of **Physiologically Based Kinetic (PBK) models**

2023



Omics Reporting Framework (OORF): Guidance on reporting elements for **omics data**

2023

(Q)SAR Assessment Framework: Guidance for **(Quantitative) Structure Activity Relationship models** and predictions

https://www.oecd.org/en/topics/sub-issues/assessment-of-chemicals/integrated-approaches-to-testing-and-assessment.html

New leaders are emerging, signalling their willingness to drive & shape the global transition to NGRA: South Korea

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✓ K-MOE

환경부
Ministry of Environment

Key Roles in NAMs Application

- Policy Vision
- Infrastructure Building
- Human Resources

K-MOE 2030 Vision:
60% chemical safety data with non-animal methods, advancing humane science and animal welfare

한국환경공단
Korea Environment Corporation

K-ECO NAMs Facility:
$25M investment, building a non-animal testing center (Organoid, organ-on-a-chip, omics), completion 2026.

✓ K-MFDS

식품의약품안전처
Ministry of Food and Drug Safety

Key Roles in NAMs Application

- Technology Validation
- Standardization
- Development of NAMs

Managing Various NAMs:
- Validation and regulatory adoption of non-animal methods (phototoxicity, skin/eye tests, KeraSkin™ ISO)
- KeraSkin™-based medical device skin irritation test adopted as ISO 10993-23, Korea's first NAMs method to become an ISO international standard in 2025.

Launching 2025 K-Organoid Consortium:
- Consisted of 27 Korean companies, 18 institutions
- Standardize organoid-based NAMs, register OECD TGs.

✓ K-MAFRA

농림축산식품부
Ministry of Agriculture, Food and Rural Affairs

Key Roles in NAMs Application

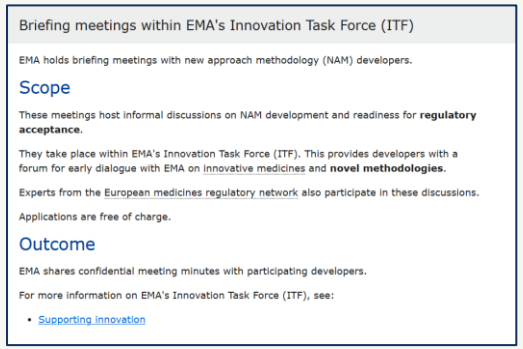
- Leading National Policy Task
- Animal Welfare

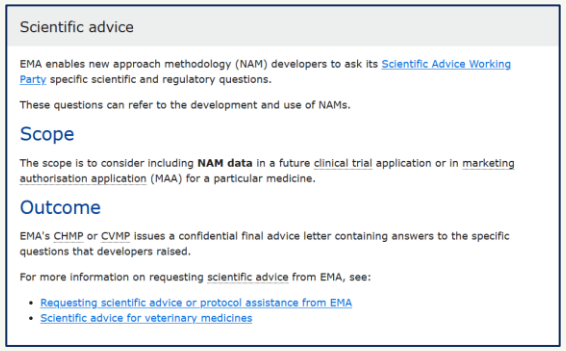
Promoting Alternative Testing as a National Policy:
Enactment of the *Animal Welfare Basic Act* (2027) and legislation of the *Animal Alternative Testing Promotion Act*

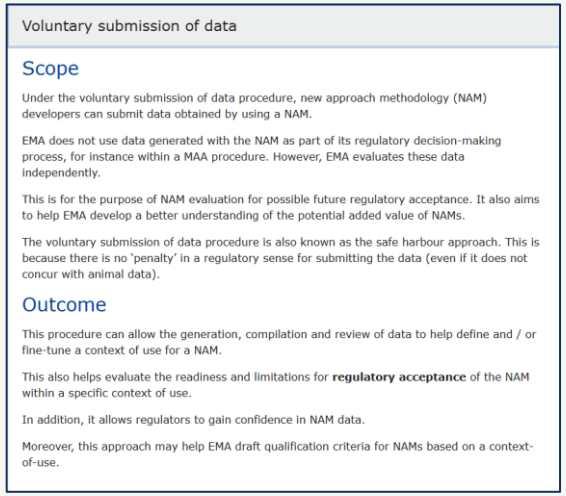
Animal Welfare in MAFRA:
3rd National Animal Welfare Plan (2025–2029): advancing welfare through regulation, support centers, and protection measure

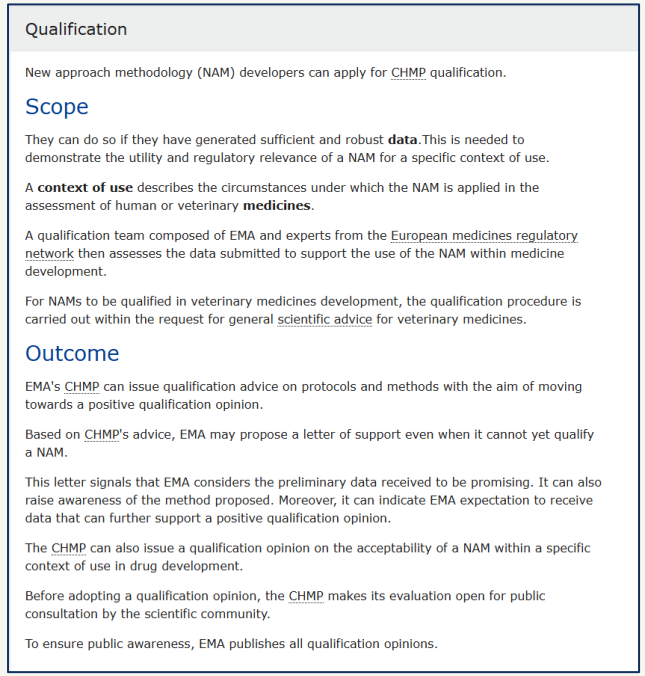
Acknowledgement: Prof. Jinhee Choi, Univ. Seoul

European Medicine Agency (EMA) has created ‘safe spaces’ & ‘regulatory sandboxes’ to support greater use of NAMs









Regulatory acceptance of new approach methodologies (NAMs) to reduce animal use testing | European Medicines Agency (EMA)

European Federation of Pharmaceutical Industries & Associations (EFPIA): commitment to 3Rs & Commission Roadmap engagement

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2022

PUTTING ANIMAL WELFARE PRINCIPLES AND 3Rs INTO ACTION – European Pharmaceutical Industry Report – 2022 Update

efpia
European Federation of Pharmaceutical Industries and Associations

Beyond Compliance: Practice | Science | Training
Leading by Example: Sharing | Enforcing
Open Communications: Dialogue | Reporting

EFPIA members support Phasing-In New Approach Methodologies

EFPIA members are committed to the science-based phase-in of methods to replace the use of animals for scientific purposes and the deletion of animal tests which are obsolete or redundant. EFPIA members aim to lead progress on this by engaging in a wide range of practical activities to help drive the development, uptake and promotion of non-animal technologies (NATs) and new approach methodologies (NAMs) so that these can be phased-in as soon as it is scientifically possible to do so.

The pharmaceutical industry members of EFPIA:

- Are fully committed to the principles of 3Rs;
- Continue to support the objectives of the Directive 2010/63/EU on the protection of animals used for scientific purposes which has enhanced animal welfare standards and mandated the application of replacement, reduction and refinement across the EU while ensuring Europe remains a world leader in biomedical research;
- Will continue to strive to go beyond what is legally required and work to develop and validate systems leading to improved 3Rs, animal welfare and high-quality science and technologies in every day practice and ultimately improve the lives of the people and animals that stand to benefit from the research. Training of staff will remain an essential element of good science and good welfare;
- Are committed to continue invest in collaborative research initiatives and projects to improve animal welfare and 3Rs, and support start-ups with expertise in new approaches as we transition from the Innovative Medicines Initiative (IMI – the largest health public private partnership) to the new Innovative Health Partnership (IHI);
- Will continue to work with regulators, the scientific community and civil society to improve implementation of the science and speed up regulatory acceptance of alternative methods in the EU and at a global level;
- Will strive to lead by example by disseminating beyond own department and own establishment to drive improvements in welfare and general quality of science;
- Will improve the systems in place working with academia, CROs, animal breeding and testing facilities to share good practices, new methodologies and lead by example by uptake of high 3Rs and animal welfare standards in the daily activities;
- Will be transparent in telling what we do and how we do it, to explain and justify where live animals are required and used and also inform on the work and commitment of companies to reduce the sectors reliance on animals;
- Will continue to identify, develop and implement their phase-in strategies and communicate on animal use through either dedicated webpages or CSR reports. Open communication and dialogue with the public are key to highlight our contribution to phasing-in replacement methods.

putting-animal-welfare-principles-and-3rs-into-action.pdf

2024-25

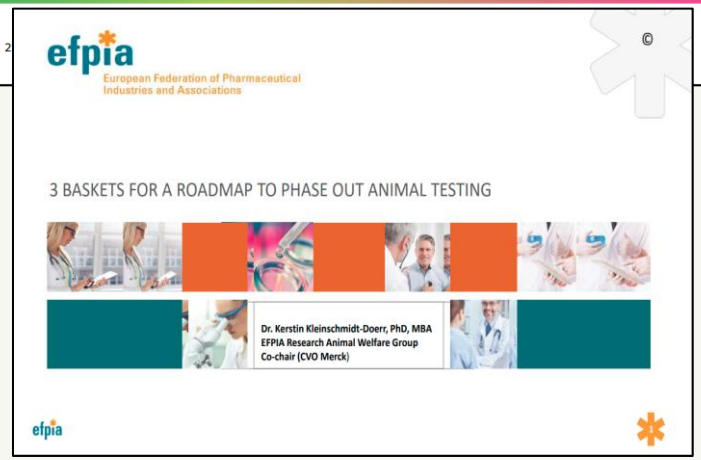
Basket 1
Animal experiments for which alternative technologies already exist or which are not scientifically necessary
Implementation plan with milestones

Basket 2
Animal testing purposes for which there are concrete ideas and hypotheses for the development of alternative methods
Prioritization of R&D investments

Basket 3
Animal testing, for which there is as yet no approach to replacing it with non-animal methods.
Evolution of Science Biggest Opportunity

Investment Prio: Refinement
Investment Prio: Replacement

efpia 2nd EC Roadmap Workshop | 2



EFPIA presentation at 2nd Commission Roadmap workshop

US FDA Roadmap to Reducing Animal Testing in Preclinical Safety Studies & NIH prioritization of human-based research technologies

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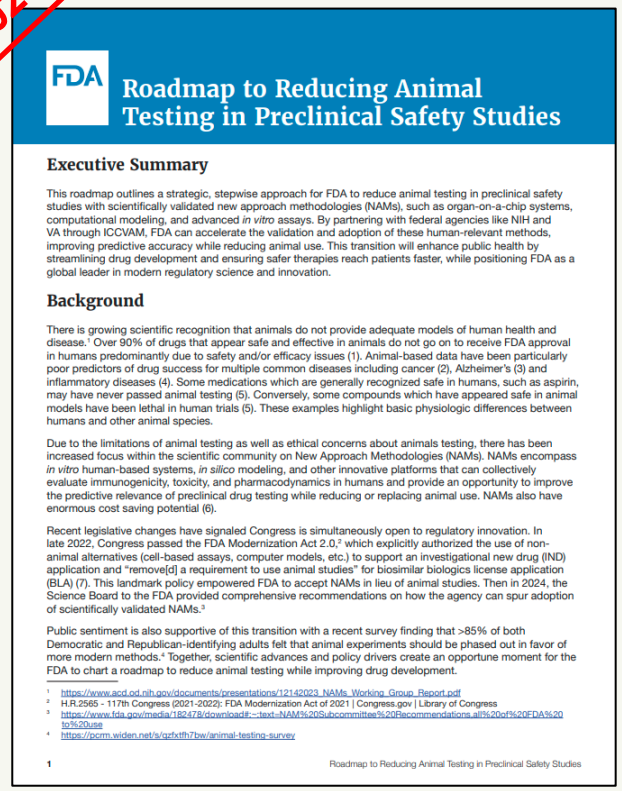
2025



FDA

Roadmap to Reducing Animal Testing in Preclinical Safety Studies

Executive Summary

This roadmap outlines a strategic, stepwise approach for FDA to reduce animal testing in preclinical safety studies with scientifically validated new approach methodologies (NAMs), such as organ-on-a-chip systems, computational modeling, and advanced *in vitro* assays. By partnering with federal agencies like NIH and VA through ICCVAM, FDA can accelerate the validation and adoption of these human-relevant methods, improving predictive accuracy while reducing animal use. This transition will enhance public health by streamlining drug development and ensuring safer therapies reach patients faster, while positioning FDA as a global leader in modern regulatory science and innovation.

Background

There is growing scientific recognition that animals do not provide adequate models of human health and disease.[1] Over 90% of drugs that appear safe and effective in animals do not go on to receive FDA approval in humans predominantly due to safety and/or efficacy issues (1). Animal-based data have been particularly poor predictors of drug success for multiple common diseases including cancer (2), Alzheimer's (3) and inflammatory diseases (4). Some medications which are generally recognized safe in humans, such as aspirin, may have never passed animal testing (5). Conversely, some compounds which have appeared safe in animal models have been lethal in human trials (5). These examples highlight basic physiologic differences between humans and other animal species.

Due to the limitations of animal testing as well as ethical concerns about animals testing, there has been increased focus within the scientific community on New Approach Methodologies (NAMs). NAMs encompass *in vitro* human-based systems, *in silico* modeling, and other innovative platforms that can collectively evaluate immunogenicity, toxicity, and pharmacodynamics in humans and provide an opportunity to improve the predictive relevance of preclinical drug testing while reducing or replacing animal use. NAMs also have enormous cost saving potential (6).

Recent legislative changes have signaled Congress is simultaneously open to regulatory innovation. In late 2022, Congress passed the FDA Modernization Act 2.0,[2] which explicitly authorized the use of non-animal alternatives (cell-based assays, computer models, etc.) to support an investigational new drug (IND) application and "remove[d] a requirement to use animal studies" for biosimilar biologics license application (BLA) (7). This landmark policy empowered FDA to accept NAMs in lieu of animal studies. Then in 2024, the Science Board to the FDA provided comprehensive recommendations on how the agency can spur adoption of scientifically validated NAMs.[3]

Public sentiment is also supportive of this transition with a recent survey finding that >85% of both Democratic and Republican-identifying adults felt that animal experiments should be phased out in favor of more modern methods.[4] Together, scientific advances and policy drivers create an opportune moment for the FDA to chart a roadmap to reduce animal testing while improving drug development.

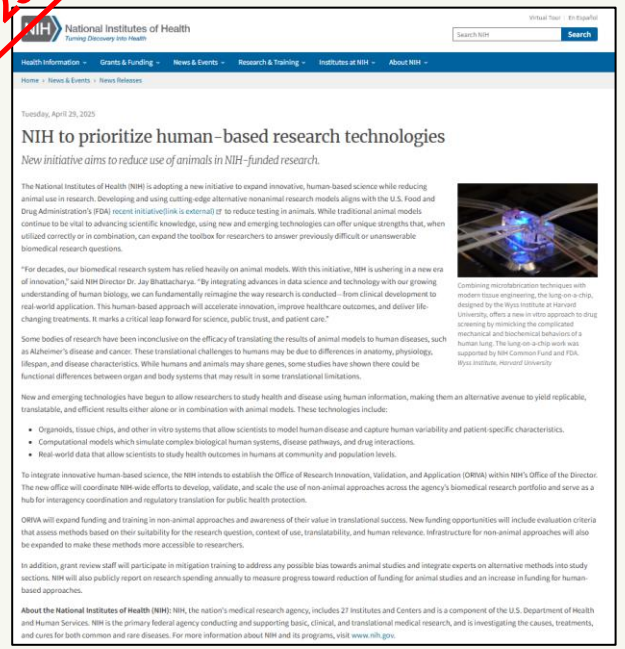
[1] https://www.acd.od.nih.gov/documents/presentations/12142023_NAMs_Working_Group_Report.pdf
[2] H.R.2565 - 117th Congress (2021-2022): FDA Modernization Act of 2021 | Congress.gov | Library of Congress
[3] https://www.fda.gov/media/182478/download#:~:text=NAM%20Subcommittee%20Recommendations,all%20of%20FDA%20to%20use
[4] https://pcrm.widen.net/s/qzfxtfh7bw/animal-testing-survey

1 Roadmap to Reducing Animal Testing in Preclinical Safety Studies

- **FDA Roadmap outlines strategic, approach to reduce animal testing in preclinical safety studies using New Approach Methodologies (NAMs)**:
  - organ-on-a-chip systems
  - computational modelling
  - advanced in vitro assays
- **FDA will accelerate the validation & adoption of NAMs by partnering with federal agencies like NIH & VA through ICCVAM**
- **The FDA roadmap seeks to:**
  - enhance public health
  - streamline drug development
  - ensuring safer therapies reach patients faster
  - position FDA as a global leader in modern regulatory science and innovation

[FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs | FDA]

2025



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Tuesday, April 29, 2025

NIH to prioritize human-based research technologies

New initiative aims to reduce use of animals in NIH-funded research.

The National Institutes of Health (NIH) is adopting a new initiative to expand innovative, human-based science while reducing animal use in research. Developing and using cutting-edge alternative nonanimal research models aligns with the U.S. Food and Drug Administration's (FDA) recent initiative(link is external) to reduce testing in animals. While traditional animal models continue to be vital to advancing scientific knowledge, using new and emerging technologies can offer unique strengths that, when utilized correctly or in combination, can expand the toolbox for researchers to answer previously difficult or unanswerable biomedical research questions.

"For decades, our biomedical research system has relied heavily on animal models. With this initiative, NIH is ushering in a new era of innovation," said NIH Director Dr. Jay Bhattacharya. "By integrating advances in data science and technology with our growing understanding of human biology, we can fundamentally reimagine the way research is conducted—from clinical development to real-world application. This human-based approach will accelerate innovation, improve healthcare outcomes, and deliver life-changing treatments. It marks a critical leap forward for science, public trust, and patient care."

Some bodies of research have been inconclusive on the efficacy of translating the results of animal models to human diseases, such as Alzheimer's disease and cancer. These translational challenges to humans may be due to differences in anatomy, physiology, lifespan, and disease characteristics. While humans and animals may share genes, some studies have shown there could be functional differences between organ and body systems that may result in some translational limitations.

New and emerging technologies have begun to allow researchers to study health and disease using human information, making them an alternative avenue to yield replicable, translatable, and efficient results either alone or in combination with animal models. These technologies include:

- Organoids, tissue chips, and other in vitro systems that allow scientists to model human disease and capture human variability and patient-specific characteristics.
- Computational models which simulate complex biological human systems, disease pathways, and drug interactions.
- Real-world data that allow scientists to study health outcomes in humans at community and population levels.

To integrate innovative human-based science, the NIH intends to establish the Office of Research Innovation, Validation, and Application (ORIVA) within NIH's Office of the Director. The new office will coordinate NIH-wide efforts to develop, validate, and scale the use of non-animal approaches across the agency's biomedical research portfolio and serve as a hub for interagency coordination and regulatory translation for public health protection.

ORIVA will expand funding and training in non-animal approaches and awareness of their value in translational success. New funding opportunities will include evaluation criteria that assess methods based on their suitability for the research question, context of use, translatability, and human relevance. Infrastructure for non-animal approaches will also be expanded to make these methods more accessible to researchers.

In addition, grant review staff will participate in mitigation training to address any possible bias towards animal studies and integrate experts on alternative methods into study sections. NIH will also publicly report on research spending annually to measure progress toward reduction of funding for animal studies and an increase in funding for human-based approaches.

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

Combining microfabrication techniques with modern tissue engineering, the lung-on-a-chip, designed by the Wyss Institute at Harvard University, offers a new in vitro approach to drug screening by mimicking the complicated mechanical and biochemical behaviors of a human lung. The lung-on-a-chip work was supported by NIH Common Fund and FDA. *Wyss Institute, Harvard University*

"For decades, our biomedical research system has relied heavily on animal models. With this initiative, NIH is ushering in a new era of innovation," said NIH Director Dr. Jay Bhattacharya. "

[NIH to prioritize human-based research technologies | National Institutes of Health (NIH)]

Have we reached a global tipping point in regulatory adoption of NGRA approaches?

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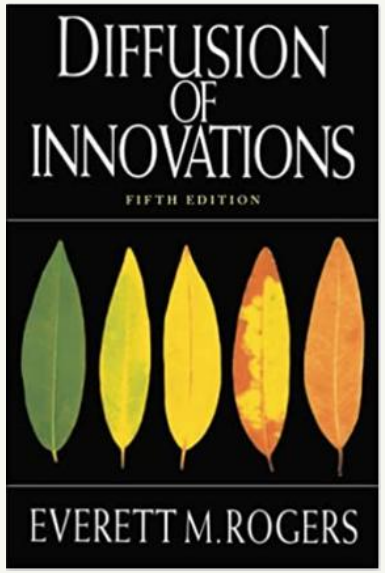
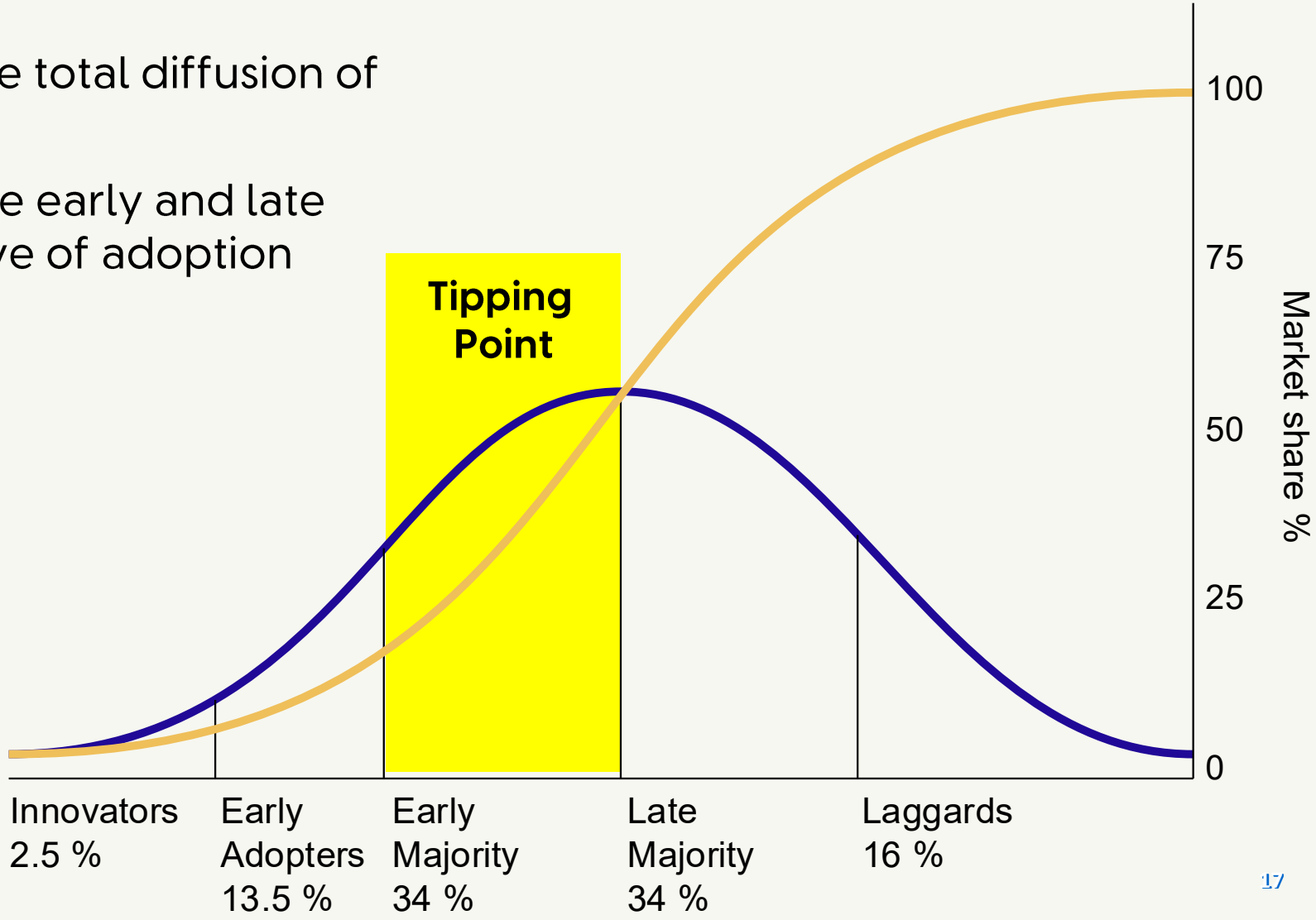
Tipping Point

- critical mass, after which the total diffusion of an innovation is likely
- inflection point between the early and late majority in the sigmoid curve of adoption



Diffusion of innovations - Wikipedia



What statement do you agree with the most? Please raise your hand to vote!

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1. We have passed the global tipping point for regulatory adoption of NGRA approaches

2. We are passing the global tipping point for regulatory adoption of NGRA approaches

3. We have not yet passed the tipping point for regulatory adoption of NGRA approaches

Is it time for a global NGRA roadmap?

Potential Global NGRA roadmap objectives:

- **Coordinate global transition** to actively manage the risks associated with the change
- **Accelerate knowledge exchange** to facilitate standardisation & AI automation of NGRA workflows
- **Rapidly scale education & training** to better enable upskilling of the global toxicology community
- **.....**

Acknowledgements:

Unilever Safety, Environmental & Regulatory Sciences (SERS) colleagues (sers.unilever.com)

In particular: Julia Fentem, Renato Ivan de Ávila, Bruno Campos, Predrag Kukic, Jin Li & Qinqin Liu who helped me prepare this presentation.

Thank you to Prof. Jinhee Choi, Univ. Seoul

All Unilever SERS collaborators: