

ANNUAL REPORT 2025



Accelerating Animal-Free
Safety Assessments, Together

ICCS

INTERNATIONAL
COLLABORATION ON
COSMETICS SAFETY



ACCOMPLISHMENTS ADVANCING COSMETICS SAFETY IN 2025

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CHAIR

FOREWORD



Stéphane Dhalluin PhD, DABT
Global Head
Human & Environmental Safety
Evaluation
L'Oréal

As Chair of the ICCS Board of Directors, I am proud to reflect on a year defined not only by progress, but by a world of possibility.

Across the globe, the conversation surrounding animal-free safety science is shifting. Regulators, scientists, and industry leaders are engaging with renewed openness and urgency.

There is growing recognition that scientific innovation has advanced to a point where a systemic and global transformation is both achievable and necessary. The time for progress is now.

In 2025, the Board endorsed a clear global strategy designed to position ICCS at the forefront of this international momentum. We refined our workplan to target areas of highest regulatory impact, strengthened coordination across our cross-border initiatives, and reinforced our commitment to scientific rigor and global collaboration.

ICCS' unique multi-stakeholder model enables

us to bridge international perspectives and build mutual confidence in practical, science-based frameworks. The discussions unfolding across all regions and continents signal a worldwide readiness for change.

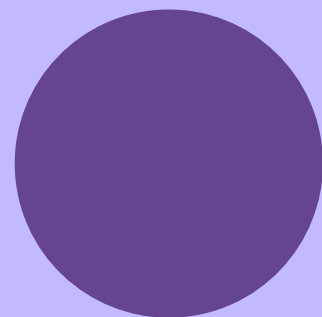
As we look ahead, I am optimistic about the path before us. The foundation has been laid, and ICCS is positioned to accelerate progress on a global scale – helping to ensure that animal-free safety science translates into universal global approaches for protecting both human and environmental health.

Together, we are not only advancing science, we are helping define its future on the world stage.



“The alignment between evolving science and modern regulatory expectations has never been stronger. The time for progress is now.”

THE TEAM



Dave Allen, PhD

Senior Director



Andreea Cuciureanu, MS

Program Manager
Human Health Sciences



Claire Fletcher

Director
Strategic Program Development



Ryan Heisler, MS

Program Manager
Environmental Sciences



Donna Macmillan, PhD

Director
Outreach and Capacity Building



Amelie Ott, PhD

Director
Environmental Sciences

PRESIDENT & CEO

ERIN HILL



If 2024 was about building foundations, 2025 was about delivery.

This year, ICCS translated strategy into action across our scientific portfolio and global engagement efforts. We advanced the New Approach Methodologies (NAMs) toolbox with practical outputs, including the release of our first Best Practice Guidance on Skin Sensitization, while continuing development of tools such as the Persistence Assessment Tool (PAT) and Models to Evaluate direct Release of Cosmetic Ingredients into natural waters (MERCi). These initiatives are designed to move beyond theory, providing structured, usable frameworks that regulators and safety assessors can apply with confidence.

We strengthened focus on scientific priorities, including systemic toxicity, aquatic safety, and more. Grounded in robust evidence and transparent methodologies, this work is essential to building regulatory confidence in next-generation risk assessments (NGRAs) that protect both human health and the environment.

Collaboration remained central to our progress. Through sustained dialogue with regulators, scientific experts, and partner organizations, we are helping build shared understanding around animal-free methodologies and their role in modern safety evaluation. What is increasingly clear is that confidence grows when science is transparent, data-driven, and developed collaboratively.

I am deeply grateful to our members and the ICCS team for their dedication and expertise. The work accomplished this year demonstrates what is possible when strategic vision is matched with disciplined execution. We enter 2026 energized and ready to build on this momentum.

Erin H. Hill

“By strengthening guidance, refining methodologies, and engaging regulators worldwide, ICCS demonstrated in 2025 that animal-free safety science is ready for broader adoption.”

AMOREPACIFIC GROUP

CRODA



OUR MEMBERS

A truly global, multi-stakeholder collaboration advancing animal-free cosmetics safety science.

A Global Community of Leaders

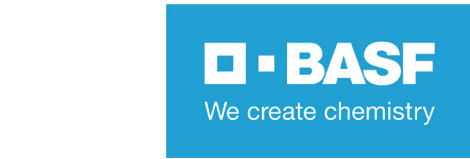
Our members represent NGOs, cosmetic and chemical trade and research associations, and leading cosmetic product and ingredient manufacturers worldwide.

Unmatched Depth of Expertise

Together, they bring scientific expertise, regulatory insight, advocacy leadership, and industry experience spanning the full cosmetics safety ecosystem.

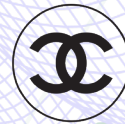
United to Advance a New Standard

This unique structure enables ICCS to bridge perspectives, align priorities, and accelerate credible, animal-free approaches for human and environmental protection globally.



Beiersdorf

L'ORÉAL



LVMH



ESTÉE LAUDER COMPANIES





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Amorepacific

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Ian Bartlett
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Camila Cortínez
Te Protejo

Gavin Maxwell
Unilever

Karma Fussell
Wella Company

With Appreciation to Our 2025 Board Members for Their Dedicated Service
and Commitment to Advancing the Mission of ICCS



Takao Ashikaga, PhD

*National Institute of Health Sciences
Japanese Center for Validation of Alternative
Methods*



Tara Barton-Maclaren, PhD

Health Canada



Scott E. Belanger, PhD

*Independent Senior Executive in
Environmental and Sustainability
Management of Chemicals*



Natalie Burden, PhD

*National Centre for the Replacement
Refinement & Reduction of Animals in
Research*



Marize Campos Valadares, PhD

*Universidade Federal de Goiás /
ANVISA*



Warren Casey, PhD

*National Institute of Environmental
Health Sciences*



Michelle Embry, PhD

*The Health and Environmental Sciences
Institute*



Prashiela Manga, PhD

U.S. Food and Drug Administration



Charlie Menzie, PhD

Independent



Katie Paul Friedman, PhD

Independent



Octavio Presgrave, PhD

*Brazilian Center for Validation of
Alternative Methods*



Kristin Schirmer, PhD

*Eawag - Swiss Federal Institute of
Aquatic Science and Technology*

SCIENCE ADVISORY COMMITTEE

The ICCS Science Advisory Committee (SAC) is a global group of experts in regulatory science, toxicology, and environmental safety. With leadership experience across regulatory authorities, research institutions, and validation organizations, the SAC plays a central role in guiding ICCS strategy.

By identifying emerging regulatory priorities, providing insight into evolving policy expectations, and advising on areas where scientific advancement is most needed, the SAC helps ensure ICCS initiatives remain aligned with regulatory needs. Their guidance supports the development of practical, regulator-informed frameworks to advance confidence in animal-free safety assessment approaches, including NAMs and NGRA.



Tomasz Sobański, PhD

European Chemicals Agency



Maurice Whelan, PhD

*European Commission Joint Research
Centre*



Carole Yauk, PhD

University of Ottawa

STRATEGIC PILLARS



ICCS was built on a clear and enduring foundation: three strategic pillars that together define who we are

— Science, Capacity Building, and Regulatory Engagement.

These pillars are not separate initiatives operating in parallel; they are interdependent commitments that have shaped ICCS from the beginning and continue to guide our path forward.

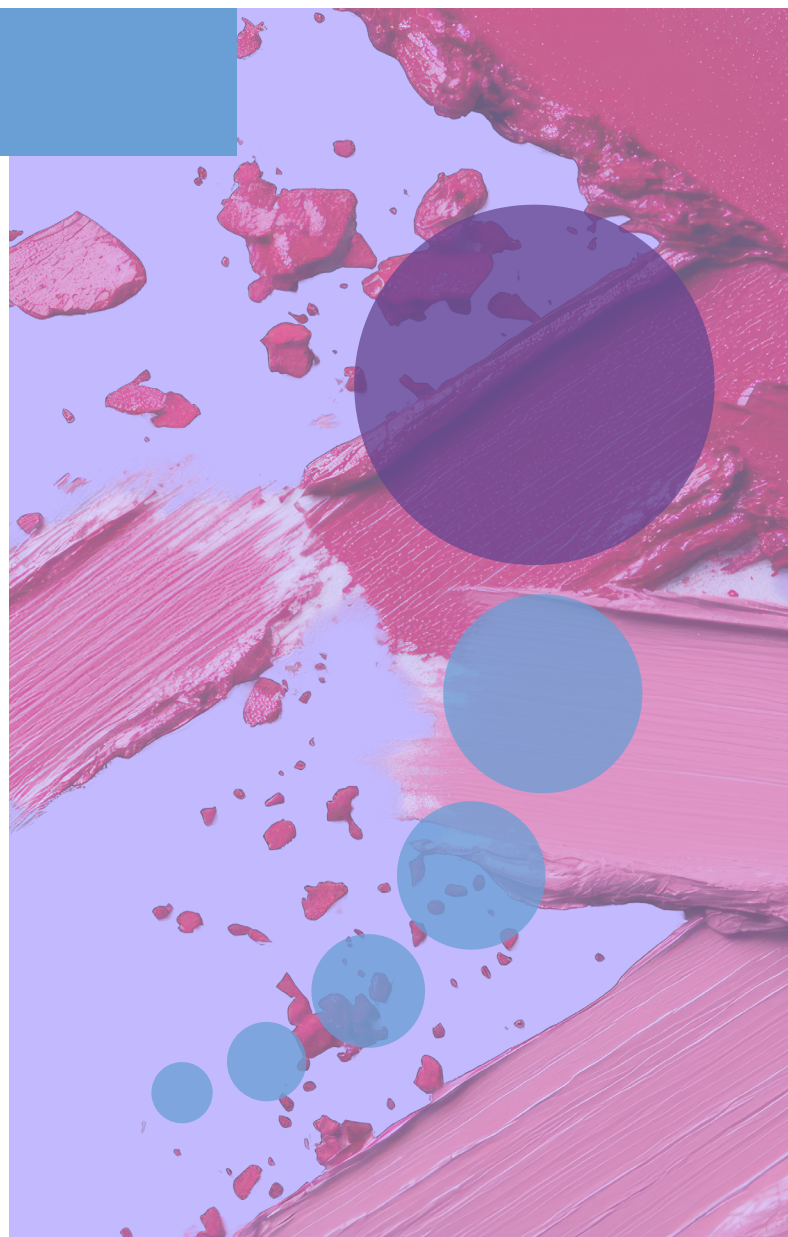
At the core is **Science**. ICCS was established to advance NAMs and NGRA frameworks for cosmetics and ingredient safety assessments that are protective of human and environmental health.

Our scientific projects provide the rigor, innovation, and credibility that underpin everything we do. They are focused on identifying, developing, and implementing emerging technologies that are robust, reproducible, and fit for purpose. Science remains the foundation of ICCS, the anchor that gives our work its strength and its voice.

Our second pillar, **Capacity Building**, translates science into practice. Building confidence in NAMs and NGRA requires more than generating data; it requires a community equipped to apply it thoughtfully and consistently. Through workshops, collaborative programs, and knowledge-sharing initiatives, ICCS fosters continuous learning and practical application to build the capacity necessary for uptake and implementation.

We support scientists, safety assessors, regulators, and industry professionals in strengthening their understanding of modern approaches to cosmetic safety evaluation. Education expands their collective expertise and ensures that innovation becomes embedded in everyday practice.

The third pillar, **Regulatory Engagement**, connects scientific advancement with real-world implementation. Advancing NAMs and NGRA frameworks involves ongoing dialogue with regulatory stakeholders, participation in validation and standardization activities, and support for greater global alignment in cosmetic regulatory approaches.



Engagement provides an avenue for shared understanding, transparency, and collaboration, helping ensure that evolving scientific methodologies are considered within appropriate regulatory contexts.

As ICCS continues to mature, these three pillars increasingly operate as a dynamic and reinforcing system.

Scientific advancement informs education. Education strengthens implementation. Implementation, supported by collaborative regulatory dialogue, builds broader confidence. In turn, regulatory perspectives help sharpen scientific priorities and training needs. This ongoing cycle strengthens the integrity and relevance of our work.

Our foundation remains firmly rooted in science, and that foundation continues to guide every initiative we undertake. At the same time, the evolution of modern safety assessment approaches naturally calls for thoughtful engagement beyond research and training environments.

As NAMs and NGRA frameworks continue to advance, there is growing opportunity to support their broader understanding and practical application.

The three pillars that define ICCS: **Science, Capacity Building, and Regulatory Engagement**, enable us to move forward with clarity of purpose.

Together, they position ICCS to **promote regulatory acceptance through engagement, build capacity for a sustainable shift, and increase cosmetic safety assessment capabilities worldwide.**

These are not new directions, but interconnected expressions of our mission.

Through this integrated approach, ICCS remains true to its foundation while continuing to contribute meaningfully to the evolving global landscape of cosmetic safety.



The Pillars That Power ICCS

- **Science**
Develop NAMs and NGRA frameworks for cosmetics and ingredient safety assessments that will be protective of human and environmental health.
- **Capacity Building**
Build a community to support continuous learning to establish confidence in, and application of, NAMs and NGRA for evaluating cosmetics.
- **Regulatory Engagement**
Accelerate the acceptance of NAMs and NGRA frameworks through standardization and validation activities, engagement with regulators, and supporting the global alignment of cosmetic regulatory requirements.

SCIENCE IN ACTION

In 2025, ICCS members advanced the scientific foundations necessary to support confident regulatory integration of NAMs. Across human health and environmental safety, member scientists translated mechanistic insight into structured frameworks, validated tools, peer-reviewed publications, and Best Practice Guidance designed for real-world decision contexts.

ICCS' impact this year is best understood not through individual activities, but through scientific outputs: guidance published, methodologies refined, case studies developed, tools operationalized, and manuscripts published in the peer reviewed literature.

The work reflects a core principle of ICCS: progress in animal-free safety assessments depends on rigorous science that includes transparent methodology and reproducible frameworks that regulators can apply with confidence.

At every stage, this work was led by ICCS members such as toxicologists, environmental scientists, computational biologists, and risk assessors, whose expertise drives the organization's technical agenda.

Public-Private Partnership ICCS to Collaborate with NICEATM on Landscape Analysis



In 2024, ICCS initiated a public-private collaboration with NIEHS and NICEATM to conduct a landscape analysis of non-animal methods for assessing systemic toxicity, including carcinogenicity (Carc) and developmental and reproductive toxicity (DART). Completed in 2025, it provides a strong scientific foundation to inform future priorities and advance cosmetic safety assessment capabilities.

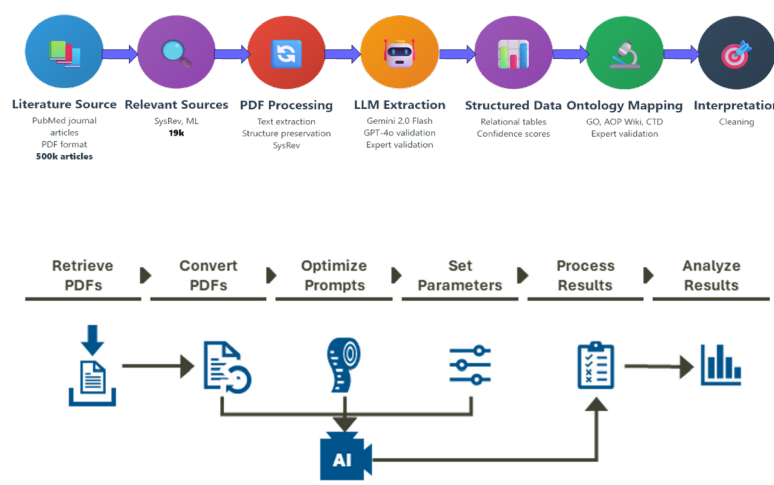
Human Health Using Expert-Guided Artificial Intelligence

Surveying the NAM Landscape

ICCS initiated a public-private collaboration with National Institute of Environmental Health Sciences (NIEHS) and the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) to conduct a landscape analysis of non-animal methods for assessing systemic toxicity, including carcinogenicity (Carc) and developmental and reproductive toxicity (DART). This work used a generative artificial intelligence (GenAI) approach, which decreased the time and improved efficiency of completing the analysis.

Utilizing this collaboration, the project surveyed and structured the scientific literature to identify opportunities for development, standardization, and implementation of modern NAMs. The analysis maps biological coverage and mechanistic connections, creating a knowledgebase of relevant molecular and cellular endpoints.

A central objective was mapping molecular and cellular endpoints to biological processes associated with systemic toxicity. By linking upstream mechanistic events to adverse outcome pathways, members created a knowledgebase that clarifies biological space coverage across NAM platforms. This effort supports more transparent hazard interpretation and provides a systematic foundation for identifying data gaps and prioritizing future method development.



Human Health Mapping Biological Space Coverage & Mechanistic Connections

Mechanistic Clarity as a Regulatory Imperative

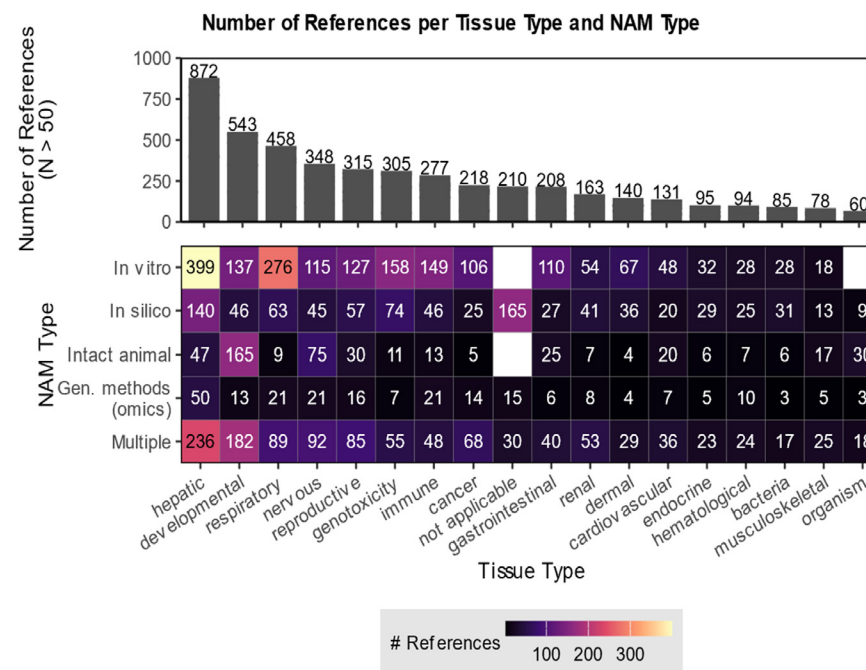
Systemic toxicity assessment requires more than isolated assay outputs. It requires coherent integration of mechanistic information across biological scales.

By explicitly mapping molecular targets and pathway perturbations, ICCS members are strengthening the interpretability of NAM datasets. The work enhances confidence in read-across, grouping, and weight-of-evidence evaluations, core components of next-generation risk assessment.

Mapping Biological Space Coverage and Mechanistic Connections

The project:

- Created a knowledgebase to inform the molecular and cellular targets relevant to systemic toxicity
- Informed the biological processes and their molecular targets and linked upstream mechanistic events to adverse outcome relationships



Human Health Advances in TTC Value for Botanical Extracts

ICCS members gathered in Brussels for a workshop on advances in Threshold of Toxicological Concern (TTC) values for botanical extracts. The meeting included external experts from academia and scientific organizations to support the application of TTC principles to botanical ingredients used in cosmetics.

Participants discussed proposed TTC values and a decision tree framework to promote consistent, science-based implementation across botanical substances.

Experts from three continents reviewed data-driven approaches to extending the COSMOS database to botanicals, including evaluation of repeat dose toxicity (RDT), DART, and genotoxicity datasets.



Project Discussion Continues
During SOT 2026

A machine learning approach for the development of a knowledgebase to identify systemic toxicity mechanistic targets and evaluate biological space coverage

[View session detail](#)

Author Block: M. Shobair¹, D. Allen², I. Ballone³, M. Brüll⁴, M. Burbank⁵, N. Choksi⁶, S. Fitch⁷, A. Irizar⁸, K. Josh⁹, S. Liu¹⁰, J. Tasaki¹¹, P. Kukic¹², T. Luechtefeld³, A. Najjar⁴, G. Ouedraogo⁵, K. Wolton¹¹, N. Yuko¹⁰, and C. Mahony¹². ¹Procter & Gamble, Mason, OH; ²International Collaboration on Cosmetics Safety, Raleigh, NC; ³Insilica LLC, Bethesda, MD; ⁴Beiersdorf, Hamburg, Germany; ⁵L'Oréal, Aulnay sous Bois, France; ⁶ToxStrategies LLC, Research Triangle Park, NC; ⁷ToxStrategies LLC, Houston, TX; ⁸The International Fragrance Association (IFRA), Geneva, Switzerland; ⁹Institute For Fragrance Materials (RIFM), Mahwah, NJ; ¹⁰R&D, Safety Science Research, Kao Corporation, Kanagawa, Japan; ¹¹Unilever, Bedford, United Kingdom; and ¹²Procter & Gamble Technical Centres Ltd, Reading, United Kingdom.

Background and Purpose: With increased reliance on New Approach Methods (NAMs) to support chemical risk assessment, mechanistic data modeling frameworks and knowledgebases are needed to facilitate hypothesis-based hazard evaluation.

Methods: A data discovery and enrichment approach was developed using natural language processing (NLP) and large-language models (LLMs), to extract key mechanistic relationships from unstructured research articles to build a knowledgebase of adverse-outcome pathways (AOPs) related to systemic toxicity. The workflow employs contextual learning and hierarchical data extraction to connect molecular targets and biological processes with downstream events relevant to systemic toxicity.

Results: Over 1000 mechanistic pathways for more than 9000 chemicals were identified using an integrated machine learning scheme that incorporates human input for model refinement, data confidence quantification, and ontology-based standardization. Expert curation, validation and interpretation with calibrated statistical confidence scoring achieved over 90% precision for chemical-target relationships and up to 100% precision for data cited in multiple studies.

Conclusions: The knowledgebase was validated with AOPWiki annotations and expert-curated pharmacological datasets, providing insights into systemic toxicity mechanistic pathways. This can inform on the systemic toxicity biological space coverage and mapping needed to identify downstream mechanistic events that can further the understanding of the bioactivity-to-adversity relationship and continuum.

Human Health

Toxicogenomics Web Tool

ICCS members continued development of the Toxicogenomics (TGx) Web Tool, a universal, intuitive platform designed to help operationalize TGx for regulatory application. This work progressed in parallel with broader framework initiatives, with the shared goal of strengthening the scientific foundation and practical usability of TGx in safety assessments.

Over the past decade, toxicogenomics has shown considerable promise for supporting chemical grouping and read-across, informing point-of-departure (POD) determinations, and contributing to mode-of-action (MoA) analyses. However, wider regulatory uptake has been constrained by variability in analytical approaches and the absence of harmonized, transparent workflows. The TGx Web Tool was developed to help address these challenges.

A Structured, Standardized TGx Workflow

The TGx Web Tool provides a structured workflow guiding users from raw transcriptomic data through to interpretable outputs suitable for regulatory consideration.

As described in the Society of Toxicology (SOT) poster, “A Universal Intuitive Tool for Toxicogenomics Applications”, the platform was designed to:

- Support chemical grouping and read-across
- Capture and organize MoA-relevant evidence
- Provide infrastructure for POD calculations
- Standardize data processing and reporting workflows

Alignment with OECD Frameworks

Regulatory alignment was a core consideration in the tool’s development. The TGx Web Tool incorporates the OECD Omics Reporting Framework (OORF), transforming the existing spreadsheet-based structure into a digital format that facilitates completion, automation, and integration into analysis workflows.

The platform also incorporates connectivity mapping (CMap) approaches to quantify biological similarity among chemicals, supporting grouping and read-across based on mechanistic transcriptomic data.

While current functionality emphasizes connectivity scores and related similarity metrics, the architecture was designed to be extensible, allowing additional analytical methods and databases to be incorporated in future iterations.

Transparency and Flexibility

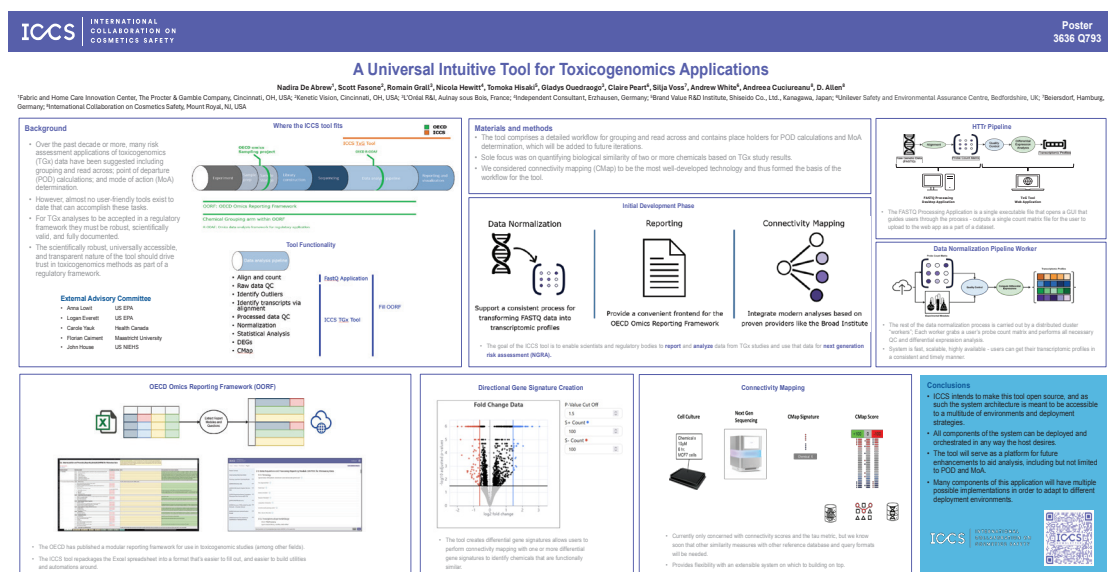
The TGx Web Tool was designed with transparency and adaptability in mind. ICCS intends for the platform to be open source, with modular architecture capable of deployment across a variety of environments and infrastructure configurations.

An External Advisory Committee, including representatives from regulatory agencies and academia, contributed input during development to help ensure scientific robustness and regulatory relevance.

Supporting Expert Judgment and Regulatory Confidence

Importantly, the TGx Web Tool does not replace expert judgment. Instead, it provides a structured framework within which mechanistic transcriptomic data can be generated, analyzed, and documented consistently. By harmonizing data normalization, gene signature creation, connectivity analyses, and OECD-aligned reporting, ICCS members are improving reproducibility and facilitating clearer interpretation of TGx results.

In 2025, continued refinement of the TGx Web Tool strengthened ICCS’ efforts to integrate toxicogenomics into NGRA. Through standardization, transparency, and regulatory alignment, the platform supports broader and more confident use of TGx data in safety decision-making.



Environmental Health

Chronic Fish Toxicity: Case Studies Toward Best Practice Guidance

Chronic fish toxicity remains one of the most technically challenging areas for integrating NAMs into environmental risk assessment. In 2025, ICCS initiated a structured case study program to address these challenges systematically and transparently.

The project follows a tiered strategy. Initial efforts focus on evaluating the applicability of NAMs to chronic fish toxicity using multiple cosmetic ingredient case studies. These case studies are designed not simply as demonstrations, but as practical tests of how, for example, mechanistic data, bioavailability considerations, and exposure context can be integrated within frameworks relevant to regulatory dossiers.

Across several case studies, the project will identify critical data gaps, assessing the strengths and limitations of available tools, and developing solutions that reduce reliance on vertebrate testing while maintaining environmental protection standards.

Work is being conducted in close exchange with partners including ECETOC and the Health and Environmental Sciences Institute (HESI), with shared learnings contributing to broader framework development and future OECD Integrated Approaches to Testing and Assessment (IATA) discussions. In addition, ICCS and its partners are also sharing the learnings with experts in the European Partnership for Alternative Approaches to Animal Testing (EPAA) group.

Ultimately, the objective is to consolidate insights into an ICCS Best Practice Guidance document, including structured decision criteria and flow charts, to support regulatory acceptance of NAM-based approaches for chronic fish toxicity and to advance environmentally relevant, animal-free assessment.



Environmental Health

Advanced Biodegradation Assessments

ICCS advanced several coordinated activities to strengthen the scientific basis and regulatory relevance of persistence and biodegradation assessments for small molecules and polymers, with particular focus on water-soluble and dispersible polymers.

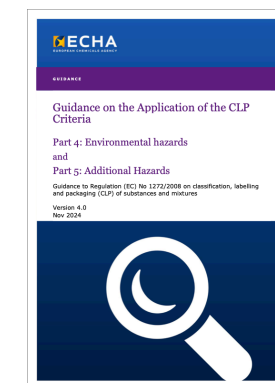
ICCS supported further recognition of the Persistence Assessment Tool (PAT), which is now referenced in the ECHA CLP guidance, helping to promote more consistent evaluation of degradation and persistence information.

In parallel, ICCS supported an expert presentation at the ECHA PBT Expert Group on environmental relevance and interpretation of screening biodegradation tests within regulatory contexts.

A new project was initiated to curate publicly available biodegradation and transformation pathway data for water-soluble and dispersible polymers. The initiative aims to provide standardized, structured data to support future *in silico* modeling tools and improved data reporting practices.



In addition, ICCS progressed planning for a multi-stakeholder symposium in 2026, to be convened under the SETAC umbrella, to develop a harmonized roadmap for advancing biodegradation assessments for water soluble polymers and fostering regulatory alignment.



ICCS members at SETAC Europe, May 11–15, 2025, Vienna, Austria

Environmental Health ICCS Co-Leads Landmark 2025 Innovate EcoSafety Summit



The 2025 Inaugural Innovate EcoSafety Summit in Reykjavík, Iceland marked a defining moment for advancing environmental NAMs globally.

Co-organized by ICCS alongside the Health and Environmental Sciences Institute (HESI), U.S. EPA, and UK NC3Rs, the Summit brought together nearly 60 experts from 10 countries

to accelerate the implementation of animal-free approaches in ecological risk and hazard assessment.

Across three intensive days—featuring 16 presentations, 12 posters, 10 “marketplace” proposals, and multiple breakout sessions—participants focused on two priority areas: replacing acute fish toxicity testing and advancing animal-free frameworks for evaluating endocrine activity in aquatic species.

Through structured case studies, experts examined where NAMs provide high confidence for regulatory decisions and where scientific gaps remain. Discussions underscored that confidence depends not only on data quality, but also on

clarity of framework, terminology, and regulatory context. For endocrine assessment, strong alignment emerged around tiered, mechanistic, weight-of-evidence frameworks integrating *in vitro* and computational data, while recognizing the need for improved assay coverage, exposure integration, and defined confidence criteria.

Importantly, the Summit translated dialogue into action. Short-term priorities include hands-on training, clearer applicability domains, regulatory guidance updates, and improved data transparency. Longer-term efforts will focus on developing reference datasets, linking NAM outputs with exposure models, and building harmonized frameworks to support global regulatory convergence.

Innovate was designed as a recurring global forum, convened every 2–3 years, to foster collaboration without duplicating existing efforts. ICCS is proud to have helped shape both the environmental NAM agenda and the Summit’s forward strategy.

The outcomes will inform case studies, regulatory engagement, SETAC outreach, and the formation of implementation groups to ensure tangible progress toward modern, protective, and animal-free ecological safety science.



Next Steps: Acute Fish

Short-term:

- Deliver training through scientific and regulatory forums leveraging hands-on case study demonstrations
- Clarify applicability domains and decision criteria for NAM-based acute assessments
- Initiate updates to key guidance (e.g., Fish Testing Framework, OECD 203)

Medium-to-long-term:

- Enable data transparency and access to avoid redundant testing
- Support regulatory convergence toward NAM-informed aquatic assessments



Patience Browne (OECD - OCDE) presenting



Left to Right: Natalie Burden (NC3Rs); Julie Krzykwa (HESI); Michelle Embry (HESI); Amelie Ott (ICCS); Amy Burden (NC3Rs)



Left to Right: Adriana Wigh (Henkel); Amelie Ott (ICCS); Véronique Poulsen (L'Oréal); Christopher Fassbender (PSCI); Donna Macmillan (ICCS)

Distribution of 2025 Science Initiatives by Delivery Status

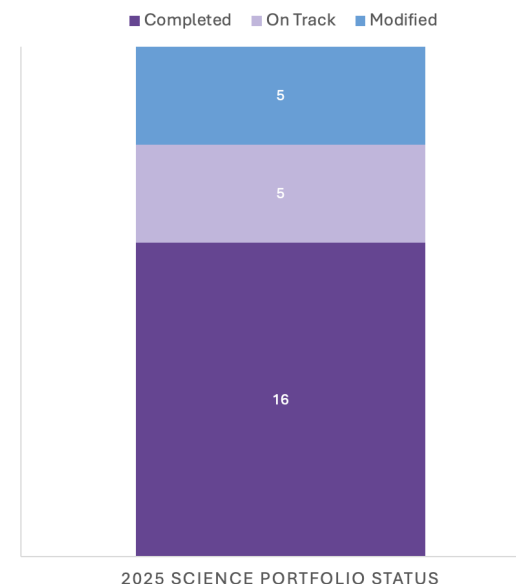


Figure 1. Distribution of 2025 Science Initiatives by Delivery Status

In 2025, ICCS advanced 26 major science initiatives across Human Health and Environmental Safety. Sixteen initiatives reached applicability or defined completion milestones, while ten additional initiatives remained actively progressing. Modified initiatives reflect strategic reprioritization or scope refinement rather than delay, demonstrating adaptive portfolio management aligned with regulatory priorities.

Distribution of 2025 Science Initiatives by Output Category

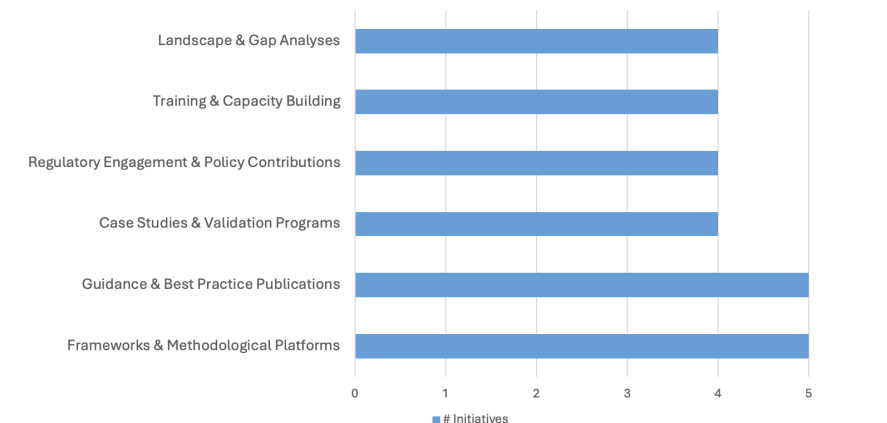


Figure 2. Distribution of 2025 Science Initiatives by Output Category

ICCS activities in 2025 spanned methodological framework development, regulatory guidance publication, validation case studies, global regulatory engagement, training programs, and landscape analyses. This distribution illustrates ICCS’ integrated model: advancing science, validating applicability, supporting regulatory integration, and building assessor capacity globally.

Completed 2025 Science Initiatives

- Landscape Analysis of Systemic Toxicity (NAMs and Mechanisms) with Gap Analysis
- Capacity Building for Safety Assessors via Training Courses (2 deliverables)
- Recommendations on Approaches for Systemic Toxicity + Case Study Examples
- Global EcoNAM Workshop for Acute AquaTox and Endocrine Disruption
- Case Study Results Brought to Regulators for Feedback and Next Steps
- Advanced MERCI Framework
- OECD Evaluation Framework Developed for Validating Identified Approaches for Regulatory Use
- Defined Approaches for Skin Sensitization Updated to Include Additional Key Event-Based Methods
- Establish ICCS as Partner of Choice for Scientific Exchange in EU and NA
- NAM-based Endocrine Disruption Framework
- Surfactants Incorporated into OECD Eye Irritation Defined Approach

GLOBAL CAPACITY BUILDING

ICCS continued to demonstrate strong leadership in global capacity building, equipping regulators, scientists, and industry stakeholders with the knowledge, tools, and partnerships needed to advance next-generation approaches for safety assessment. From high-profile international convenings to targeted technical trainings, ICCS strengthened scientific confidence in NAMs and fostered meaningful collaboration across regions.

Delivering the Mission at WC13 and EuroTox



3RS Integrating 3 Worlds
Human, Animal and Environmental Health
August 31 - September 4, 2025
Rio de Janeiro, Brazil

At the World Congress on Alternatives and Animal Use in the Life Sciences (WC13), ICCS delivered its mission on a global stage. With more than 85 attendees at its satellite event, and eight collaborative sessions, ICCS convened regulators, industry leaders, NGOs, and researchers to advance dialogue on animal-free safety assessments.

ICCS programming spanned seven sessions. Discussions addressed systemic toxicity assessment, validation

challenges, regulatory frameworks for complex endpoints, and emerging opportunities in Latin America.

ICCS also maintained a strong presence at EuroTox, further expanding engagement with the European toxicology community.



ICCS also maintained a strong presence at EuroTox, further expanding engagement with the European toxicology community.

Participation at EuroTox strengthened connections with regulators, academic experts, and industry scientists, helping ensure that advances in cosmetics safety are grounded in rigorous science and internationally relevant best practices.

Together, WC13 and EuroTox exemplified ICCS' role as a trusted convener and catalyst, accelerating animal-free safety assessments through collaboration and shared expertise.



Left to Right: Kaushal Joshi (RIFM); Karim Najjar (Beiersdorf); Gladys Ouedraogo (L'Oréal); Dave Allen (ICCS)



Gavin Maxwell (Unilever)



Left to Right: Erin Hill (ICCS); Octavio Presgrave (BraCVAM and ICCS SAC Member)



Left to Right: Andreas Schepky (Beiersdorf); Jochen Kühnl (Beiersdorf)

SOT Ancillary Meeting

A cornerstone of ICCS' 2025 capacity-building efforts was the Society of Toxicology (SOT) Ancillary Meeting, "Building Confidence in NGRAs for Cosmetics." The session created an important forum for collaboration, candid discussion, and forward-looking scientific exchange.

ICCS was honored to host Dr. Patience Browne, Principal Administrator of the Hazard & Exposure Assessment Programmes at OECD - OCDE. Dr. Browne shared critical updates on OECD activities related to validation



and systemic toxicity approaches, offering clarity on the evolving international landscape. Her insights reinforced the importance of scientific rigor, transparency, and regulatory engagement in advancing confidence in NAMs and NGRAs.

The ancillary meeting strengthened connections across sectors and ensured participants remained informed about key ICCS initiatives shaping modern cosmetics safety assessments. It also underscored ICCS' ongoing commitment to aligning innovation with regulatory expectations, an essential element of successful capacity building.



Expanding Reach in Latin America: NAMs Webinar Series

ICCS continued to expand its regional impact through the seven-part "Updates on New Approach Methodologies Applied to Human and Environmental Safety" webinar series, delivered in partnership with the Universidade Federal de Goiás (UFG) Faculty of Pharmacy and TOX IN.

Featuring leading experts from around the world and offered in Spanish and Portuguese, the series reached more than 440 registrants across 21 countries, representing 119 organizations, including regulatory agencies, academic institutions, industry stakeholders, and NGOs.



Strengthening Partnerships: CAFFCI MoU

ICCS signed a Memorandum of Understanding (MoU) with the China Association of Fragrance, Flavor and Cosmetic Industries (CAFFCI) in September 2025. This strategic partnership represents an important step forward in international collaboration for the cosmetics sector.



Under the MoU, ICCS and CAFFCI will focus on strengthening international integration, supporting deeper engagement in global cosmetics safety governance, and facilitating authorized translation and dissemination of ICCS Best Practice Guidance documents. The partnership also prioritizes expanding technical exchange across research, training, and innovation initiatives.

This collaboration enhances accessibility to internationally recognized best practices and supports locally actionable implementation, advancing regulatory alignment and scientific capacity in an important market. The MoU reflects ICCS' belief that global progress requires trusted

partnerships grounded in shared expertise and mutual commitment.



Left to Right: Chairwoman Yan Jiangying (CAFFCI) and Erin Hill (ICCS)

By delivering high-quality scientific content in multiple languages and engaging regional audiences directly, ICCS worked to strengthen capacity and foster inclusive dialogue. The series highlighted advancements in validation, ocular toxicity, and integrated human and environmental safety approaches, demonstrating ICCS' commitment to global accessibility and scientific excellence.



EUROTOX
ATHENS GREECE 14-17 September 2025

OUR Mission in Action

- WE INTRODUCED **3D-Nrf2** Reporter Epidermis Model
- WE SURVEYED **1000s** OF PUBLISHED PAPERS
- WE ARE DELIVERING CONSISTENT, REGULATORY-ALIGNED RESULTS: **OECD TG 467**
- WE INTRODUCED **3D-Nrf2** Reporter Epidermis Model
- ICCS members and collaborators introduced a 3D-Nrf2 reporter epidermis model designed to test challenging lipophilic compounds to overcome limitations in existing assays.
- OECD – OCDE has adopted Defined Approaches (DAs) under OECD TG 467 for classifying eye hazards to replace animal tests with human-relevant methods and strengthen global regulatory decisions. These DAs combine validated in vitro assays with defined data interpretation procedures to deliver consistent, regulatory-aligned results.
- 20 Member Sessions**
- Launch of the DIM Testing Project: Induction of Genomic Damage by Natural Plant Constituents Advancing Cardiotoxicity Risk Assessment
- An Emerging Toolbox for Botanical Risk Assessment: Alternative Testing Approaches in Ecotoxicology In vitro Approaches for Inhalation of Poorly Soluble and Insoluble Materials

Advancing Education Through Targeted Trainings

Targeted, in-depth trainings remain a principle of ICCS capacity-building efforts. ICCS contributed to several high-impact educational programs across Europe and beyond.

At Vrije Universiteit Brussel (VUB), ICCS participated in both the six-day “Safety Assessment of Cosmetics in the EU” training and the four-day “Introduction to the Environmental Safety of Cosmetics in the EU” course. ICCS staff delivered expert sessions on environmental risk assessments, emphasizing how innovative, animal-free methodologies can better protect ecosystems while aligning with regulatory frameworks. These courses brought together academic leaders, regulators, and industry scientists, fostering cross-sector exchange and practical application of emerging tools.

ICCS also engaged with industry and regulatory stakeholders at the IKW/ALB Workshop in Frankfurt, where discussions focused on promoting animal-free safety assessments through science, regulatory engagement, and education. Organized by IKW, the German association representing cosmetics and household product manufacturers, the workshop provided an important platform for strengthening dialogue between industry and authorities.

In addition, ICCS supported safety assessor training initiatives with CTFSA South Africa and IKW, as well as CTPA Training Courses, and others (see pages 21, 22, 24) helping integrate NAMs into regional and global safety assessment frameworks. These programs build assessor confidence, promote harmonization, and equip professionals with the expertise needed to implement next-generation approaches effectively.

A Sustained Commitment to Global Capacity Building

Across conferences including WC13, EuroTox, SOT, and the EcoSafety Summit, formal partnerships, regional webinars, and specialized trainings, ICCS has demonstrated sustained leadership in building scientific and regulatory capacity worldwide.

By convening experts, supporting training, strengthening partnerships, and expanding regional access to cutting-edge science, ICCS is not only advancing animal-free safety assessments, it is building the confidence, competence, and collaboration necessary to ensure the uptake of animal-free safety assessments.



Left to Right: Sascha Palowski (BASF); Heike Laue (Givaudan); Arnaud Boivin (L'Oréal); Marlies Bergheim (Henkel); Arianna Giusti (Cosmetics Europe); Vera Rogiers (VUB); Harald Streicher (Beiersdorf)



Aug 28, 2025
11:00 – 13:30 (SAST / CEST)



Left to Right: Fabienne Van Bamis (VUB), Tamara Van Haecke (VUB), Vera Rogiers (VUB), and Amelie Ott (ICCS)



Left to Right: Birgit Huber (IKW); Andrea Keck-Wilhelm (CVUA Karlsruhe); Danielle Botelho (RIFM); Amelie Ott (ICCS); Kelly Scherer (IKW)

chemical watch events & training

Emma Trogen (Cosmetics Europe), and Bridget Corridon (PCPC) shared regulatory and scientific perspectives on evolving global policy. Gavin Maxwell (Unilever) and Dave Allen (ICCS) shared the shift to animal-free approaches illustrating how NAMs and NGRA frameworks are advancing transparency, reproducibility, and regulatory confidence in modern safety science.



Matt Dent (Unilever) presenting at the CTPA Practical Training



Left to Right: Erin Hill (ICCS); Marc Pissavini (Coty, Vice Chair of Science at IFSCC); Amelie Ott (ICCS)



Donna Macmillan (ICCS) presenting at the CTPA International Seminar



Left to Right, Back to Front: Fabrice Nesslany (L'Oréal); Jay Ingram (Humane World for Animals); Jay Dawick (Innospec); Matt Dent (Unilever); Donna Macmillan (ICCS); Arianna Giusti (Cosmetics Europe); Caroline Rainsford (CTPA); Francesca Rapolla (CTPA); Lauren Kavanagh (Innospec); Carol Courage (Croda); Claire Fletcher (ICCS)

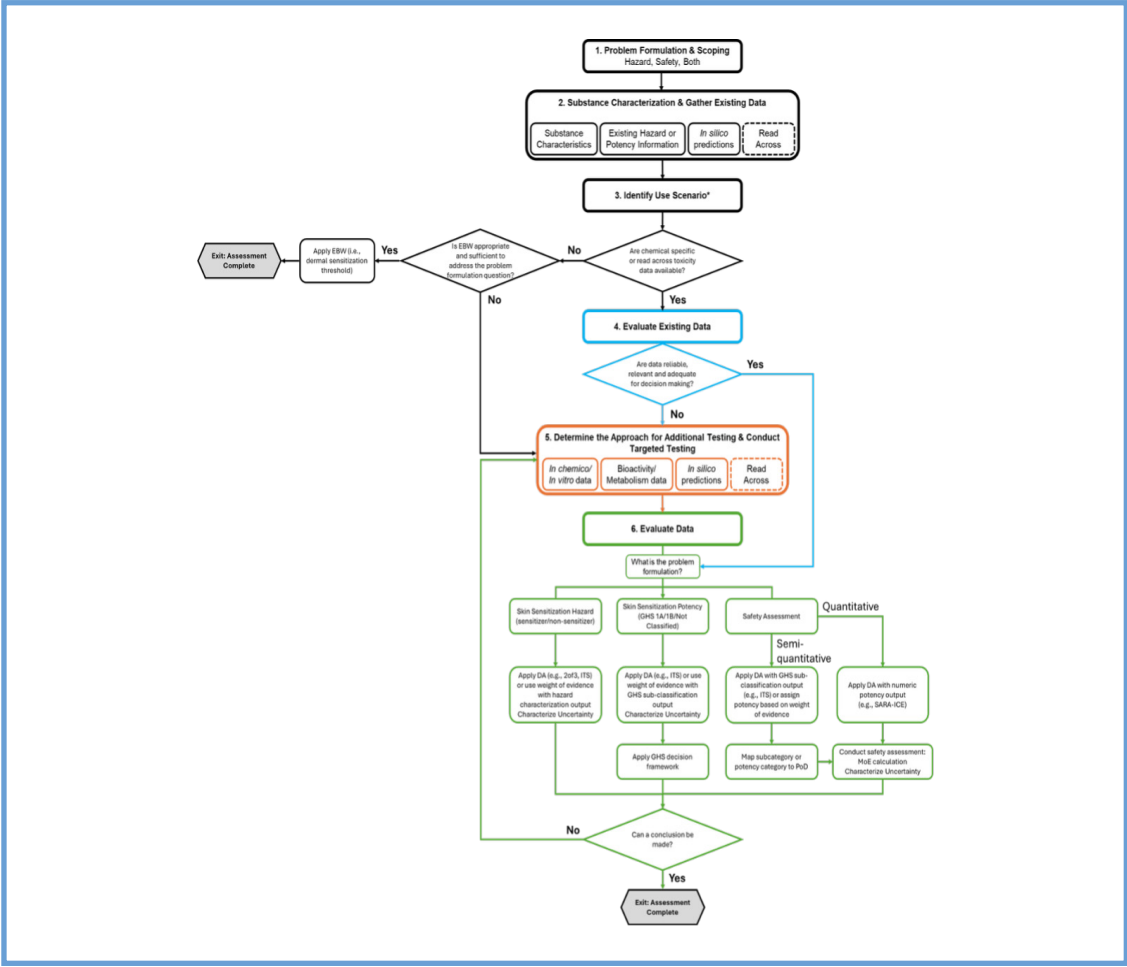


Left to Right: Amelie Ott (ICCS); Gerald Renner (Cosmetics Europe); Nico Forraz (CTIBIOTECH); Andrea Maltagliati (EFfCI)



THE SKIN SENSITIZATION BEST PRACTICE GUIDANCE DOCUMENT

Overview of Process to Evaluate Skin Sensitization Using Next Generation Risk Assessment



- Key Strengths Include:**
- A structured workflow guiding assessors through hazard and safety evaluations without new animal tests
 - Integration of OECD-aligned *in chemico* and *in vitro* assays within defined approaches
 - Clear guidance on exposure assessment, exposure-based waiving, and point-of-departure derivation
 - Emphasis on documentation, transparency, and uncertainty characterization

ICCS Best Practice Guidance (BPG) Document on Skin Sensitization: Advancing Confidence in Animal-Free Safety Assessments

ICCS released, on July 21, 2025, the BPG *Skin Sensitization Assessment: Using New Approach Methodologies for Substances in Cosmetics and Personal Care Products* representing a significant milestone in advancing practical, animal-free safety assessments.

Developed through the collaboration of ICCS working groups and external scientific partners, the guidance document provides a structured and transparent framework for integrating NAMs into regulatory-relevant safety decisions.

Grounded in NGRA principles, the BPG delivers a step-by-step workflow that supports both hazard identification and quantitative safety assessments without reliance on new animal testing. As outlined in the document's Executive Summary, its primary objective is to increase the use and acceptance of NAMs by providing assessors with a clear process, from problem formulation and substance characterization through exposure assessment, data integration, and uncertainty evaluation. By aligning

mechanistic data with the internationally recognized adverse outcome pathway (AOP) for skin sensitization, the guidance enables assessors to make informed, transparent, and defensible decisions.

What Makes the BPG Distinctive

The ICCS BPG consolidates existing international frameworks—including OECD Test Guidelines, defined approaches (DAs), and integrated approaches to testing and assessment (IATAs)—into an assessor-oriented workflow that is practical for real-world regulatory application. Rather than introducing new methods in isolation, it demonstrates how *in chemico*, *in vitro*, and *in silico* tools can be integrated cohesively to support decision-making.

The document is intended for safety assessors familiar with traditional approaches who are transitioning toward greater use of NAMs, helping to build both technical capability and regulatory confidence.

Engagement with Global Regulators: The ICCR Workshop

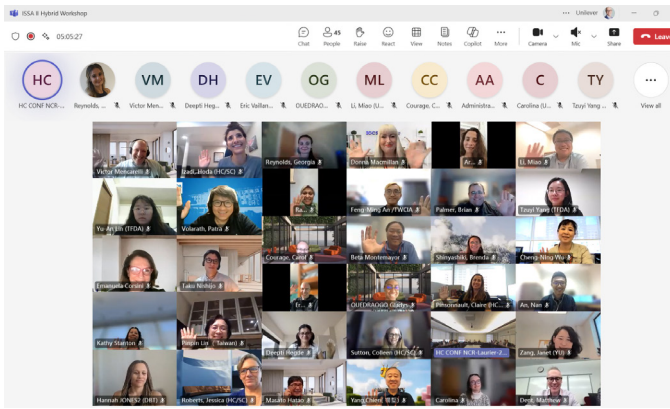
An important milestone in the launch of the BPG was its presentation at the Integrated Strategies for Safety Assessment of Cosmetics Joint Regulators–Industry Workshop hosted by the International Cooperation on Cosmetics Regulation (ICCR) on July 11, 2025.

At this hybrid workshop, regulators and cosmetics experts from more than 12 countries convened to advance NAMs in safety assessments.

ICCS was invited to present the workflow and scientific foundations of the BPG, providing a valuable opportunity to engage

directly with regulatory authorities on its application, clarity, and practical implementation.

The ICCR workshop proved instrumental in gathering feedback from regulators. Discussions centered on transparency in data interpretation, alignment with OECD defined approaches, and ensuring that NAM-based safety conclusions are clearly documented and reproducible. The input received during this forum strengthened confidence in the guidance and underscored the importance of continued dialogue between industry scientists and regulatory agencies as the global community advances animal-free science.





Strong Reception from the Regulatory and Scientific Community

Since its release, the Skin Sensitization BPG has been met with strong support from regulators and safety professionals across jurisdictions.

Eric Vaillancourt, Senior Toxicologist at Health Canada, reflected on the collaborative impact of the initiative:

“It was a privilege to join (and to learn from) such a dedicated group of subject-matter experts. This guidance is another important step in building confidence in the use of NAMs for regulatory decision-making... Kudos to the ICCS for being an agent of change! Looking forward to the upcoming BPGs!”

His remarks highlight a central achievement of the guidance: strengthening regulatory confidence in NAMs as credible tools for decision-making.

Anna Kotlowska, Regulatory Affairs Manager and Safety Assessor in the cosmetics industry, emphasized its practical value for professionals working at the interface of science and regulation:

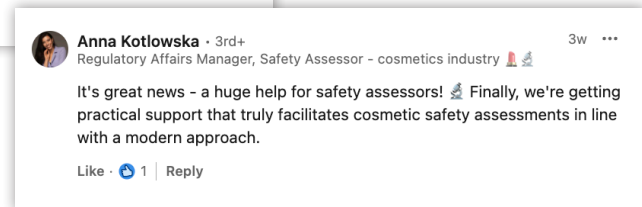
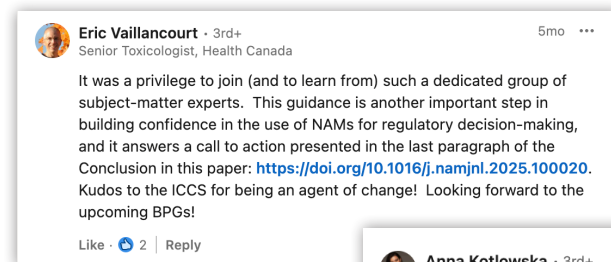
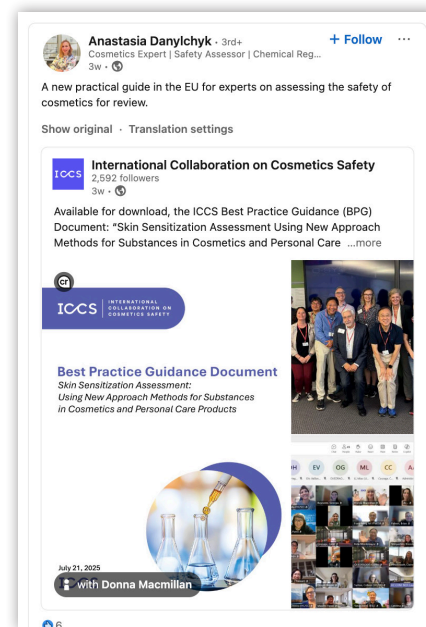
“It’s great news – a huge help for safety assessors! Finally, we’re getting practical support that truly facilitates cosmetic safety assessments in line with a modern approach.”

Her perspective reflects how the Skin Sensitization BPG fills a longstanding need for operational clarity—bridging high-level scientific principles and day-to-day regulatory assessment work.

Similarly, Anastasia Danylchuk, Cosmetics Expert and Safety Assessor in the EU, underscored the guidance’s significance for European safety review processes:

“A new practical guide in the EU for experts on assessing the safety of cosmetics for review.”

Together, these endorsements demonstrate that the Skin Sensitization BPG resonates across regulatory systems and professional communities.



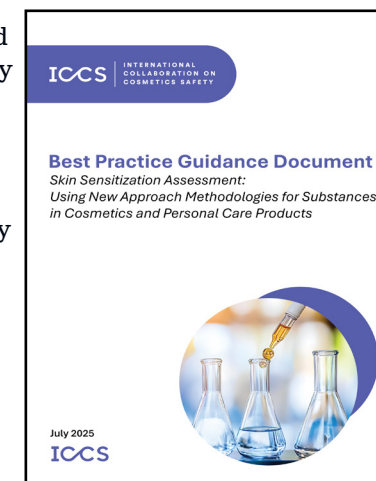
Building Confidence Through Collaboration

The Skin Sensitization BPG is the first in a growing series of ICCS Best Practice Guidance documents designed to support modern, NGRA-aligned safety assessments. Together, these documents aim to provide practical guidance across key endpoints and decision points in animal-free risk assessments.

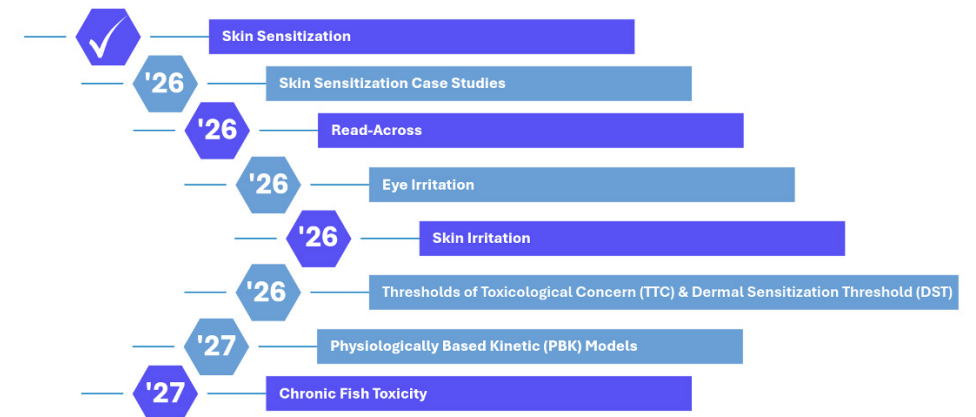
The next ICCS BPG, Read-Across, is expected in the coming months. Over the next two years, additional guidance documents are planned to cover areas such as eye irritation, skin irritation, thresholds of toxicological concern (TTC), physiologically based kinetic (PBK) modeling, and ecotoxicology endpoints.

As this suite of guidance expands, it will create a flexible framework that safety assessors and regulators can use to support transparent decision-making. In practice, multiple BPGs may be applied together—combining endpoint-specific NAM guidance with approaches such as read-across or TTC—to build robust, fit-for-purpose safety conclusions.

By developing these documents collaboratively with experts from regulatory agencies, industry, and NGOs, ICCS is working to ensure that the guidance reflects both scientific advances and real-world regulatory needs.



The ICCS BPG Portfolio



Looking Ahead

The release of the Skin Sensitization BPG marks the beginning of a broader effort to provide practical tools that support the global transition toward animal-free safety assessments.

With additional BPGs on the horizon, ICCS continues to build a shared framework that helps regulators and safety assessors apply next-generation methodologies with confidence.

REGULATORY ENGAGEMENT ACROSS FIVE CONTINENTS

In 2025, ICCS continued to expand its regulatory engagement, participating in more than 75 meetings, workshops, and scientific forums with regulators across five continents. These engagements reflect a steady effort to contribute technical expertise, share scientific advancements, and support the global transition toward animal-free safety assessments.

Through participation in multilateral workshops, scientific committees, international congresses, and formal correspondence with regulatory agencies, ICCS advanced dialogue on NAMs, NGRA, and IATAs. While regulatory transformation is complex and incremental, ICCS' growing presence in these forums demonstrates sustained commitment to constructive engagement.

Europe: Contributing to the Roadmap Toward Phasing Out Animal Testing

In response to the European Citizens' Initiative calling for a phase-out of animal testing for chemical safety assessments, the European Commission is developing a Roadmap outlining next steps. ICCS has participated in multiple consultations, roundtables, and workshops supporting this effort.

At the Animal-Free Chemical Safety Assessment Conference in Brussels, ICCS co-led breakout discussions focused on the application of NAMs to endocrine disruption and contributed to broader conversations on environmental safety. The conference convened approximately 250 experts from regulatory agencies, industry, and academia to identify potential actions for inclusion in the Commission's roadmap.

ICCS staff, Science Advisory Committee members, and member scientists also participated in the European Commission and ECHA's workshop in Helsinki. Across ten consultations and workshops over the past two years, ICCS has provided input on human health considerations, environmental safety, and implementation challenges associated with moving away from animal testing.

Engagement with the Scientific Committee on Consumer Safety (SCCS) Working Group on Methodologies further supported dialogue on NGRA for cosmetic ingredients. Discussions focused on standardization, criteria for acceptance, and practical application of NAMs—topics central to strengthening regulatory clarity.

OECD: Supporting International Framework Development

ICCS also continued to participate in the OECD Working Party on Hazard Assessment in Paris, contributing to a project aimed at developing a framework for evaluating multiple approaches

to systemic toxicity. Engagement in OECD activities supports alignment of scientific approaches across jurisdictions and reinforces the importance of harmonized evaluation strategies.

United States: Advancing Dialogue on Regulatory Modernization

In the United States, ICCS engaged both through scientific forums and direct agency correspondence.

ICCS submitted a letter to EPA Administrator Lee Zeldin highlighting the importance of the EPA Office of Research and Development, particularly the Center for Computational Toxicology and Exposure (CCTE), in advancing computational and animal-free safety tools. The letter emphasized the value of maintaining data resources and predictive tools that support efficient and human-relevant safety evaluations.

ICCS also wrote to FDA Commissioner Martin Makary requesting a meeting to discuss a proposed NGRA framework for over-the-counter (OTC) products, including sunscreens. The correspondence encouraged structured integration of computational toxicology, NAMs, and existing evidence into sunscreen safety evaluations and referenced recent statutory developments supporting modernization of nonclinical testing approaches. The meeting is scheduled for March 2026.

In parallel, ICCS members contributed to scientific exchange at the Florida Society of Cosmetic Chemists Sunscreen Symposium. Presentations addressed decades of UV filter research and highlighted how NAMs and NGRA can complement existing safety data and support innovation.

Asia and International Scientific Forums

At the 17th International Congress of Toxicology (IUTOX) in Beijing, ICCS members presented work on NAMs, NGRA, and *in silico* approaches in regulatory toxicology. Sessions addressed reproducibility, method standardization, and pathways to increasing confidence in NAMs. Chinese regulators attended IUTOX and it was an opportunity for open dialogue.

Participation in international scientific congresses provides the ability to exchange perspectives with regulators and researchers from multiple regions, supporting continued dialogue and collaboration.



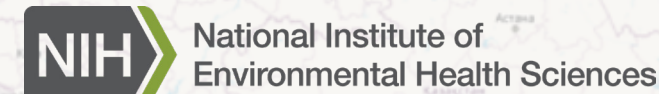
The European Partnership for Alternative Approaches to Animal Testing



Santé Canada Health Canada



Environment and Climate Change Canada
Environnement et Changement climatique Canada



A Measured but Meaningful Expansion

Across these 75+ engagements, ICCS maintained a consistent focus: contributing scientific expertise, encouraging regulatory clarity, and supporting practical pathways to animal-free safety assessments. While regulatory systems evolve at different paces across jurisdictions, 2025 demonstrated steady progress in engagement and dialogue. ICCS' participation in workshops, working groups, agency discussions, and formal submissions reflects an ongoing commitment to advancing science-based approaches that protect human and environmental health.

As NAMs and NGRA continue to mature, sustained engagement with regulators and international bodies remains essential. In 2025, ICCS contributed to conversations shaping the future of cosmetic and chemical safety assessments.

PUBLICATIONS

ICCS members have delivered peer-reviewed journal articles in leading outlets as well as scientific poster sessions advancing animal-free approaches.

- **Use of Alternatives to Animal Testing for Environmental Safety Assessment (ESA): Report from the 2023 EPAA Partners' Forum**

Regulatory Toxicology and Pharmacology

- **Highlighting Best Practices to Advance Next-Generation Risk Assessment of Cosmetic Ingredients**

NAM Journal

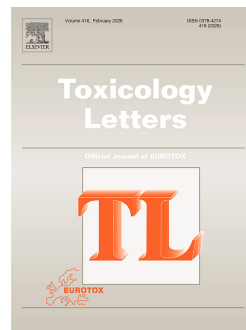
- **Broadening the Applicability Domain for Skin Sensitization Testing – Evaluation of a 3D-Nrf2 Reporter Epidermis Model to Test Lipophilic Compounds**

Toxicology Letters

- **Developing a Weight-of-Evidence Methodology for Persistence Assessment of Substances in the Environment**

Integrated Environmental Assessment and Management

Integrated Environmental Assessment and Management



POSTERS

- **A Universal Intuitive Tool for Toxicogenomics Applications**

- **Transpacific Eye Hazard Journey: Reproducibility of the STE^{0.5} for Surfactants**

- **The Persistence Assessment Tool (PAT): Implementing a Methodology for Data Quality Evaluation and Weight of Evidence in Persistence Assessments**

- **Exploring the Applicability of the OECD TG 249 Fish Cell Line Acute Toxicity Assay in Environmental Hazard and Risk Assessment of Cosmetic and Personal Care Product Ingredients**

- **In Vitro Pharmacologic Profiling Aids Systemic Toxicity Assessment of Chemicals, Current Status and Future Direction**

- **Biodegradation of Water-Soluble Polymers Reviewing In Silico Methods**

- **Between-Laboratory Reproducibility of the STE^{0.5} for Surfactants as a Prerequisite for Inclusion in OECD TG 491**

- **Mobility Assessment of Difficult-to-Test Substances - Addressing Instability in Soil**

- **Innovate EcoSafety Summit: A New Forum for Advancing Environmental Risk Assessment**

- **A Systematic Review of the Current State, Challenges, and Strategies for Broader Adoption of NAMs for Environmental Hazard Assessments of Chemicals**

- **Next Generation Risk Assessment (NGRA) of Skin Sensitization: Major Sources of Uncertainty and How to Assess Them, Exemplified with an In Chemico Test Method**



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