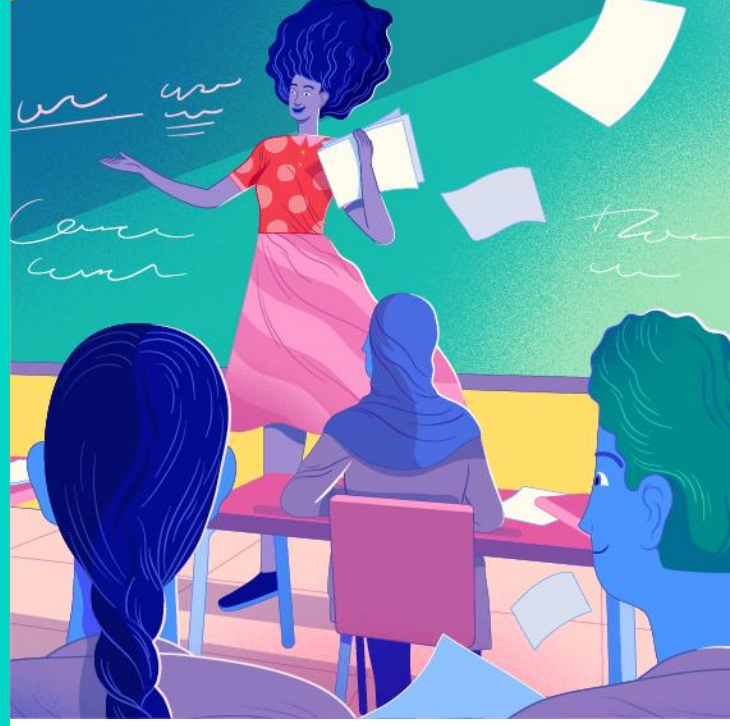
Industry Activities

Addressing the challenges



Unilever

The European Partnership for Alternative Approaches to Animal Testing

November 2021 Workshop: New Approach Methodologies (NAMs) in Regulatory Decisions for Chemical Safety

flash

EPAA Workshop

23 - 24 November 2021, virtual event

The European Partnership for Alternative Approaches to Animal Testing

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

On 23-24 November 2021, the EPAA held a virtual "Deep-Dive" Workshop on "Use of New Approach Methodologies (NAMs) in Regulatory Decisions for Chemical Safety". The workshop was opened by Sirpa Pietikäinen, MEP, and attended by more than 50 invited experts from industry, regulatory agencies and the European Commission. The use of NAMs has provided a clear impetus to move to a more human-relevant, innovative and greener process of chemical safety assessment, but has yet to gain widespread regulatory uptake. The Workshop was organised in the context of an on-going EPAA Project on NAMs with the specific aim to share information on the current use of NAMs, and stimulate discussion to help shape future activities of the EPAA project on the use of NAMs in regulatory decisions for chemical safety. The Workshop heard a number of case studies where NAMs have been applied successfully from different EPAA partners for a variety of endpoints and safety decisions. The NAMs currently being applied include in silico and in vitro methodologies, typically used as part of a strategy or tiered scheme, with the overall aim of providing information to make a decision relating to chemical safety. Discussion was based around the needs for NAMs to be acceptable for regulatory use including consideration of regulatory frameworks, evaluation and their application.

Key conclusions included:
- There is a strong desire to realise the benefits of NAMs, specifically to increase human relevance, accelerate innovation and for animal welfare, as well as to protect human health and the environment
- There is a continued need for case studies to build trust in the use of NAMs across a wide range of substances/ exposure situations
- Key areas for further development of NAMs were identified including the definition of applicability domains, better use of kinetic data (quantitative in vitro-in vivo extrapolations) and ensuring human-relevant Points of Departure are achieved
- Regulatory frameworks may need to be made more flexible to accommodate the use of NAMs
- There is a need to build trust through defining criteria for robust, reliable and reproducible use of NAMs and levels of acceptable variability
- Industry and regulators should explore opportunities to increase the use of NAM assessments in regulatory submissions to increase confidence in their use
- There is a need to raise awareness, training and expertise across all stakeholders
- Opportunities should be identified to leverage NAMs for the EU Chemicals Strategy for Sustainability

About EPAA

EPAA is a Public-Private Partnership across seven industry sectors and between European Commission and Industry stakeholders. Launched in 2005, it gathers 38 companies, 8 European trade federations and 5 Directorates-General of the European Commission.

Further information is available on https://ec.europa.eu/growth/sectors/chemicals/european-partnership-alternative-approaches-animal-testing_en

@EPAA3Rs

EPAA European Partnership for Alternatives

Understanding both the scientific and regulatory needs for change European and UK Chemicals Legislation

The EPAA includes 5 Directorates-General of the European Commission, 37 companies, and 8 European industry federations, each representing a separate industrial sector

[DocsRoom - European Commission (europa.eu)]

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AFSA
ANIMAL-FREE SAFETY ASSESSMENT COLLABORATION

Cosmetics Education and Training

Paul Russell

CTPA New Alternative Methods Workshop

17 March 2022

AFSA Cosmetics E&T

Why now?

- Increasing desire globally to perform chemical safety assessments without new animal testing
- Reflected in legislation restricting the use of animal testing for cosmetics
- Requires increasing reliance on new tools
- Focuses on improved exposure estimates coupled with hypothesis-led molecular characterization of a chemical's potential for bioactivity
- New approach to chemical safety assessment not yet reflected in formal regulatory guidance

AFSA
ANIMAL-FREE SAFETY ASSESSMENT COLLABORATION

AFSA Cosmetics E&T

A global training program in animal-free risk assessment

Scope

- Safety assessment of cosmetics and cosmetic ingredients without new animal data
- Covers all aspects of the process for internal and regulatory safety assessments
  - Consumer exposure: external and internal
  - Acute local effects to systemic repeat effects
- Covers the spectrum of available tools as well as some tools in development
- Focus on *understanding* the information generated from the tools and *how to use* this information vs. how to perform or build the individual methods

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ANIMAL-FREE SAFETY ASSESSMENT COLLABORATION

AFSA Cosmetics E&T

A global training program in animal-free risk assessment

Purpose

- Address the needs of regulatory & regulated communities, CROs & other stakeholders
- Support regional capacity-building to achieve long-term acceptance & implementation of non-animal approaches to safety assessment

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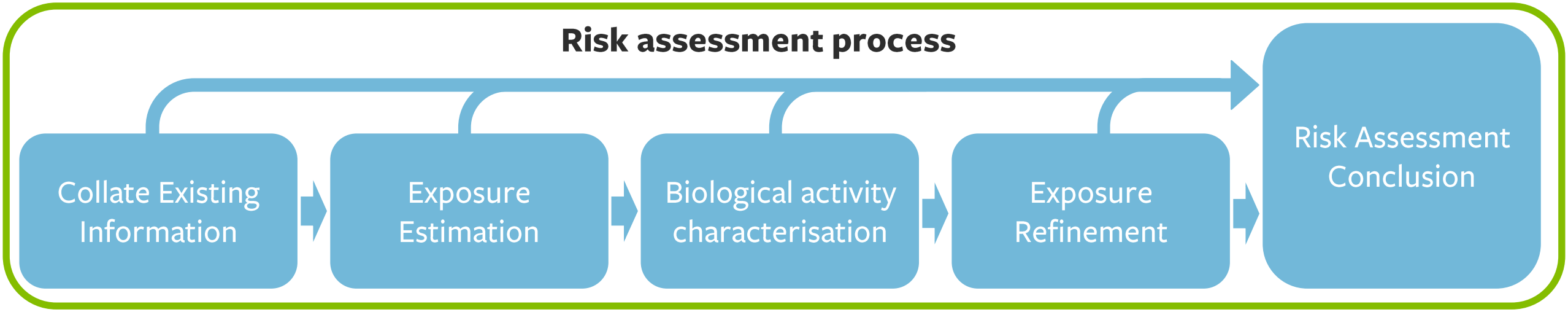
AFSA
COSMETICS

DISSEMINATION

- Webinars
- Videos
- 1-pagers
- AFSA website
- Continuing education sessions
- Symposia
- Academic lectures & collaborations

Animal Free Safety Assessment



- Hypothesis-driven
- Exposure-led
- Product & use-specific
- Iterative process of evaluation and information generation
- Risk-based safety decisions through integration of scientific evidence from multiple sources
- Goal is determining safe use

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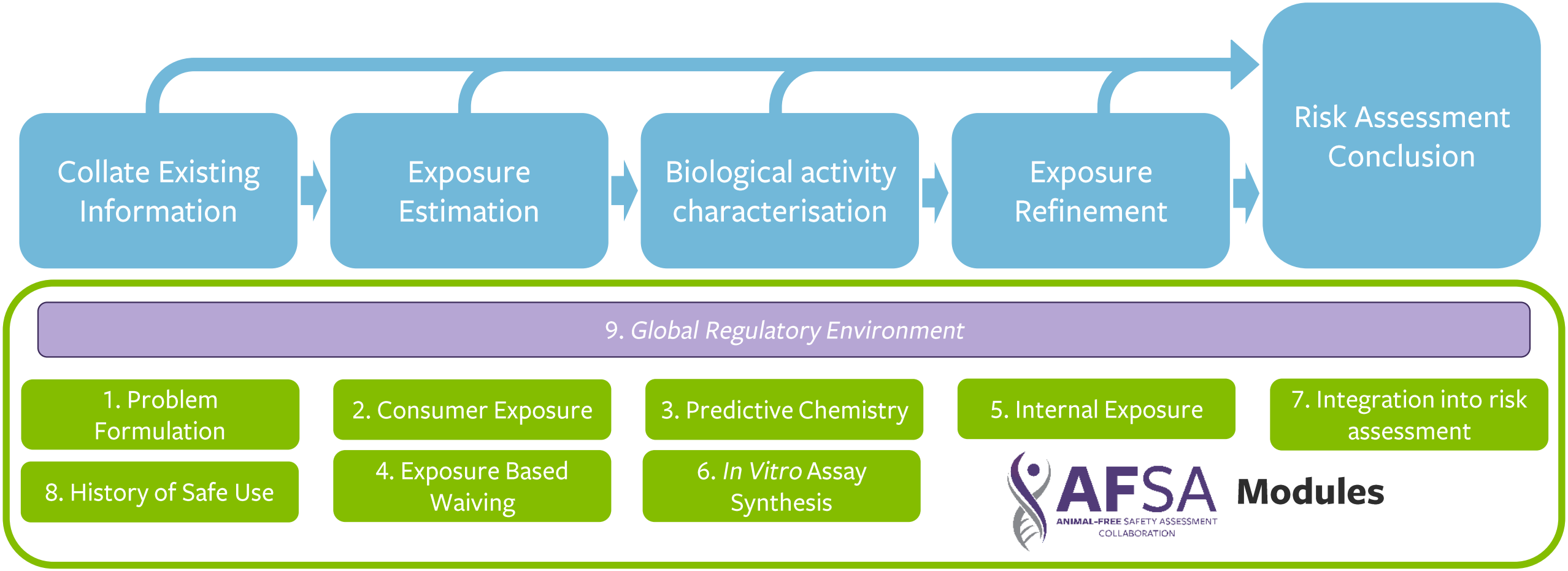
AFSA Cosmetics E&T program

Covering the NGRA from start to finish



AFSA ANIMAL-FREE SAFETY ASSESSMENT COLLABORATION

Animal-Free Safety Assessment Education and Training Program

Covering animal-free risk assessment from start to finish!

Virtual Introductory Series

Our program modules vary in length for the sake of completeness; this series offers an introduction to select modules to provide an overview of the topic and exemplify what is covered by the module in its entirety. Members of the module development team will be presenting.

Module 2: Consumer Exposure

Thursday, April 14, 13:00 – 14:30 GMT
(9 am EDT/2 pm UK/3 pm CET)
Christina Hickey, Firmenich
Catherine Barratt, Unilever

Module 3: Predictive Chemistry - In silico tools and Read-Across

Tuesday, April 26, 11:00 – 12:30 GMT
(7 am EDT/12 pm UK/1 pm CET)
Ann Detroyer, L'Oréal & Wendy Simpson, Unilever

Module 5: Dosimetry: internal exposure and IVIVE

Thursday, May 5, 13:00 – 14:30 GMT
(9 am EDT/2 pm UK/3 pm CET)
Rebecca Clewell, Tox Strategies
Allison Schafer, Proctor and Gamble

Module 9: Global Regulatory Landscape

Tuesday, May 10, 11:00 – 12:30 GMT
(7 am EDT/12 pm UK/1 pm CET)
Jay Ingram, Delphic HSE

All webinars will be on Zoom. Please register **here**. You will be able to register for each or all the sessions. Login information will be sent to registrants prior to each webinar.

AFSA COLLABORATION

For more information, visit: AFSACollaboration.org/Cosmetics/ capacity-building/

Or contact: Kate Willett, kwillett@hsi.org

AFSA COLLABORATION

Cosmetics Workstream Partners

HUMANE SOCIETY INTERNATIONAL

THE HUMANE SOCIETY OF THE UNITED STATES

Unilever

L'ORÉAL

P&G

Firmenich

AVON

iff

Givaudan

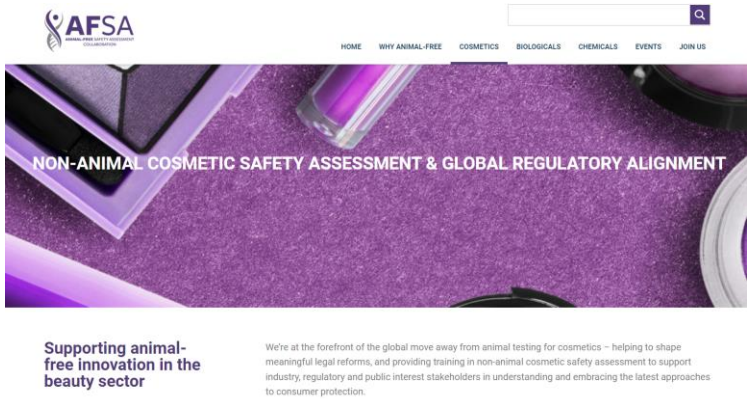
symrise

LUSH

Delphic HSE
SAFETY & REGULATORY SOLUTIONS

Lhasa Limited

IIVS
Institute for In Vitro Sciences



- **Companies** whose aims are aligned with those of AFSA are invited to join the collaboration

- **Authorities** are invited to provide input in terms of training content (priority modules, anything we've overlooked?) & discuss channels for dissemination

- **Companies** are invited to contribute existing training material for specific AFSA modules, or assist in the creation of new material

- **Partner companies** are invited to discuss legislative language with HSI & affiliates with a view to global harmonisation

AFSA ANIMAL-FREE SAFETY ASSESSMENT COLLABORATION

www.afsacollaboration.org/cosmetics