Overview: AFSA Cosmetics Education and Training

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Humane Society International

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AFSA Cosmetics E&T

A Global Training Program in Non-Animal 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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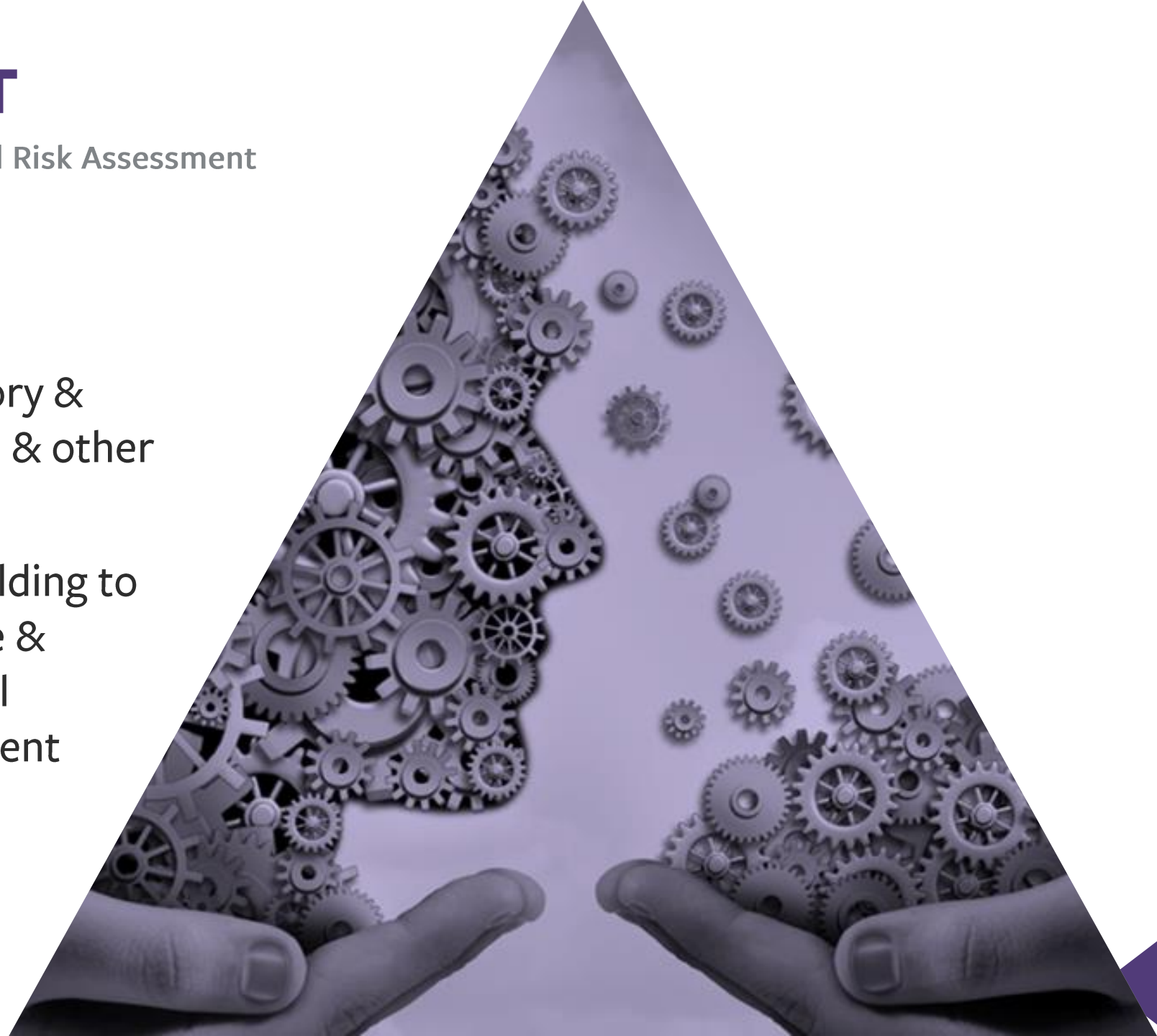
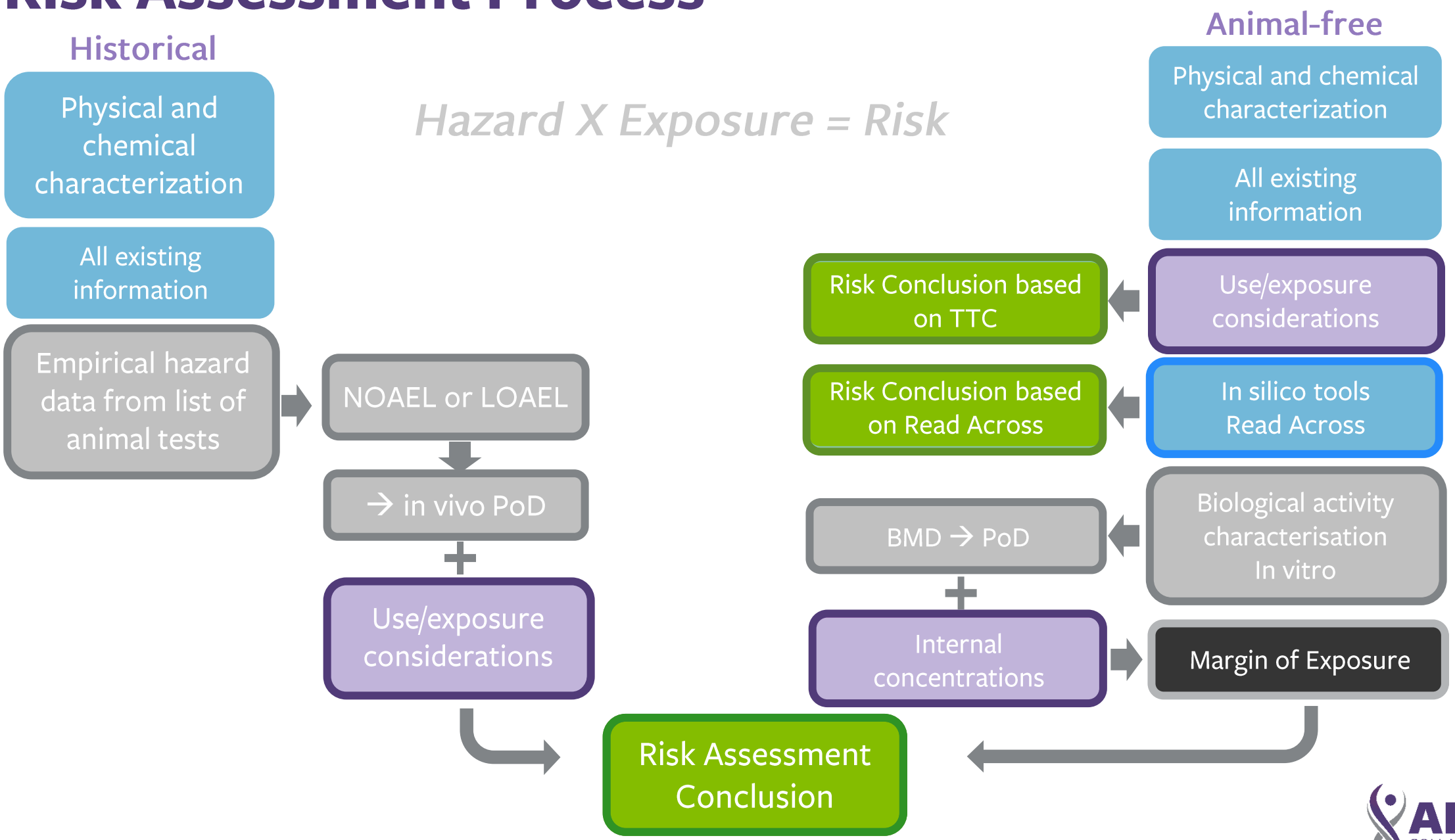
A Global Training Program in Non-Animal Risk Assessment

Purpose

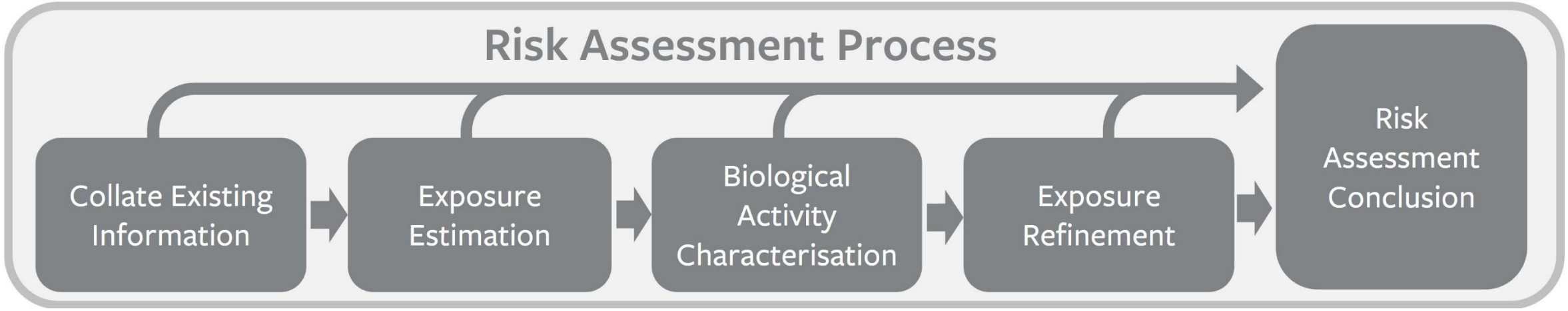
- Address the needs of regulatory & regulated communities, CROs & other stakeholders
- Support regional capacity-building to achieve long-term acceptance & implementation of non-animal approaches to safety assessment



Risk Assessment Process



International Cooperation on Cosmetics Regulation (ICCR) principles



Overarching

1. Human relevant
2. Exposure-led
3. Hypothesis driven
4. Designed to prevent harm

Risk Assessment Process

5. Following an appropriate appraisal of existing information
6. Using as tiered, iterative approach
7. Using robust and relevant methods and approaches

Documenting

8. Transparent and explicit about logic of overall approach
9. Identifying and characterizing sources of uncertainty

International Cooperation on Cosmetics Regulation (ICCR) Principles: Dent et al. 2018. Computational Toxicology 7:20-26.

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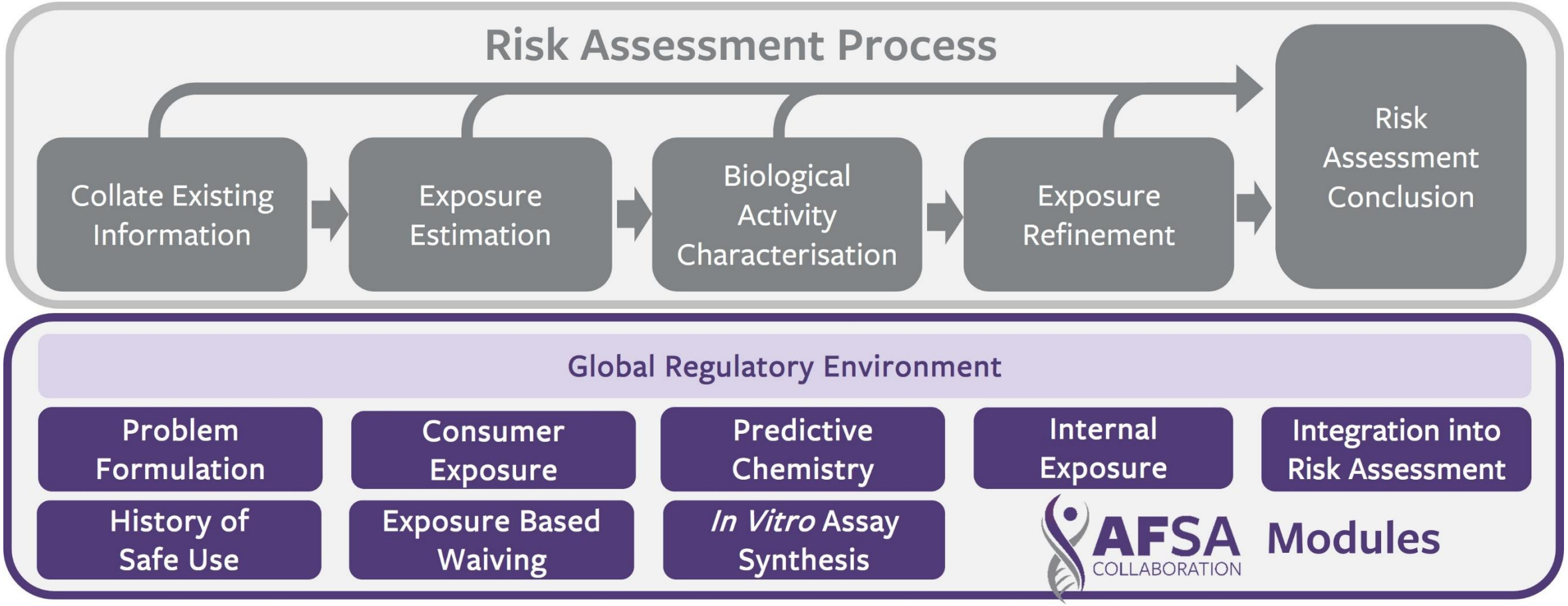
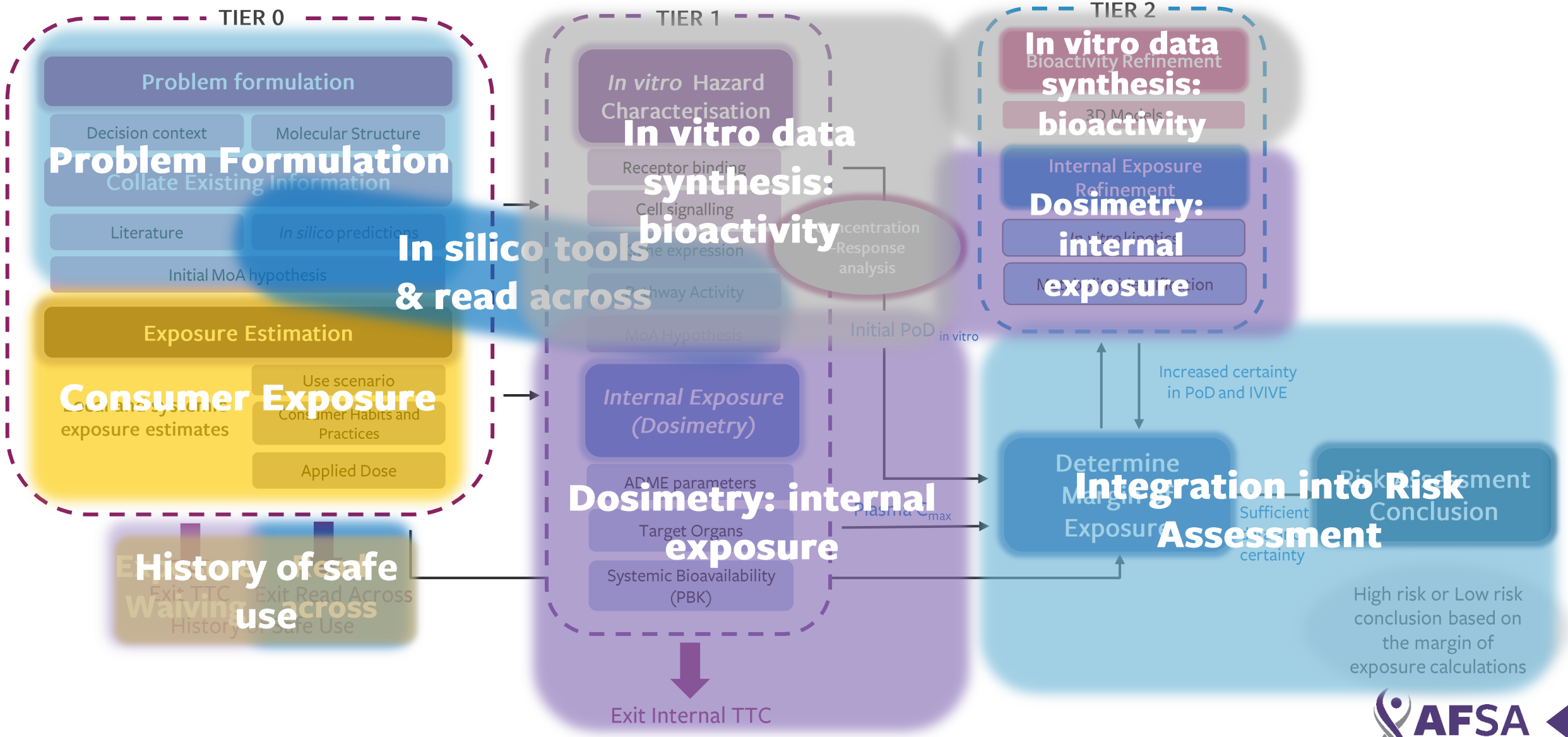
Covering Risk Assessment from start to finish



Next Generation Risk Assessment (NGRA) Framework



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Cosmetics Workstream Partners

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THE HUMANE SOCIETY OF THE UNITED STATES

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SAFETY & REGULATORY SOLUTIONS

Lhasa Limited

IIVS
Institute for In Vitro Sciences

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Consumer Exposure

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April 14, 2022

Outline

- Learning Objectives
- Initial Considerations
  - → Routes of Exposure
  - → Habits and Practices
- Tiered approach
- Deterministic modeling
- Probabilistic modeling
- Aggregate exposure

Learning Objectives

- Describe the factors involved in determining consumer exposure
  - → List habits and practices that can affect consumer exposure
  - → Identify routes of exposure for different product types
  - → List data sources for habits and practices information
- Describe the differences between deterministic and probabilistic modelling

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Initial Considerations

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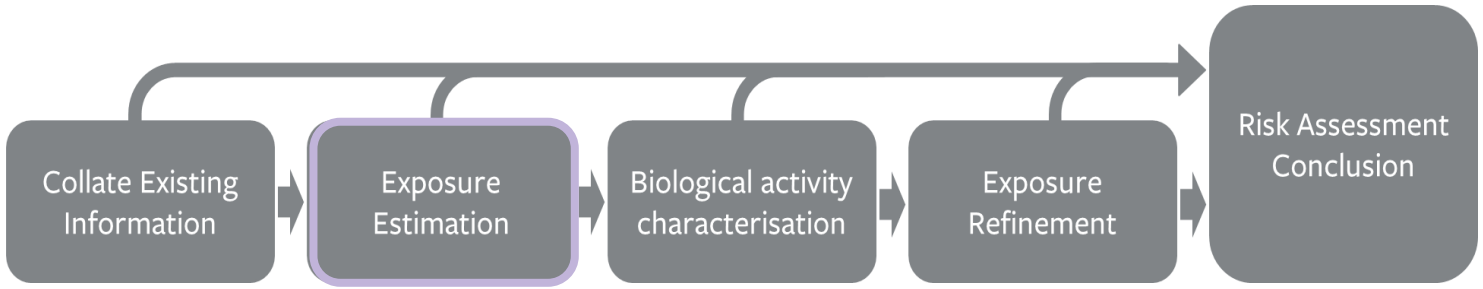
Context of Use

- NGRA safety assessments are led by exposure
- Exposure assessment includes:
  - → Understanding the consumer use scenario
  - → Characterizing the exposed population
  - → Identifying potential exposure routes, and
  - → Measuring or estimating the magnitude, duration and frequency of exposure
- Exposure data will define the hazard data needs and can be deterministic (point estimates) or probabilistic (data distributions)
- Consideration should be given to chemical characterization, including:
  - → Impurities
  - → Metabolism
- Aggregate exposure considers all sources of a chemical



Why is exposure assessment necessary?

- Human health safety
- Products with high, repeated exposure
- Route of exposure guides information needs
- For cosmetics and other personal care products, safety assessment is exposure-led

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Questions to answer when describing risk assessment context:

- **What type of exposure needs to be assessed?**
  - → Single ingredient in a single product type?
  - → Aggregate exposure from multiple products?
  - → New product – safety of single product?
  - → Systemic or topical?
- **What level of certainty is needed?**
  - → Depends on the nature of ingredient and the amount of estimated exposure
- **Is a tiered assessment necessary?**
  - → Depends on certainty needed; more complex estimate using more complex population data may be necessary

Consumer Product Type	Population	Activity/ Timeframe	Use Rates	Exposure Period
Cosmetics, hygiene, and baby care products	e.g. Both genders	Amount product used per application and frequency of use; per day	Product per application (grams); daily frequency of use	Chronic

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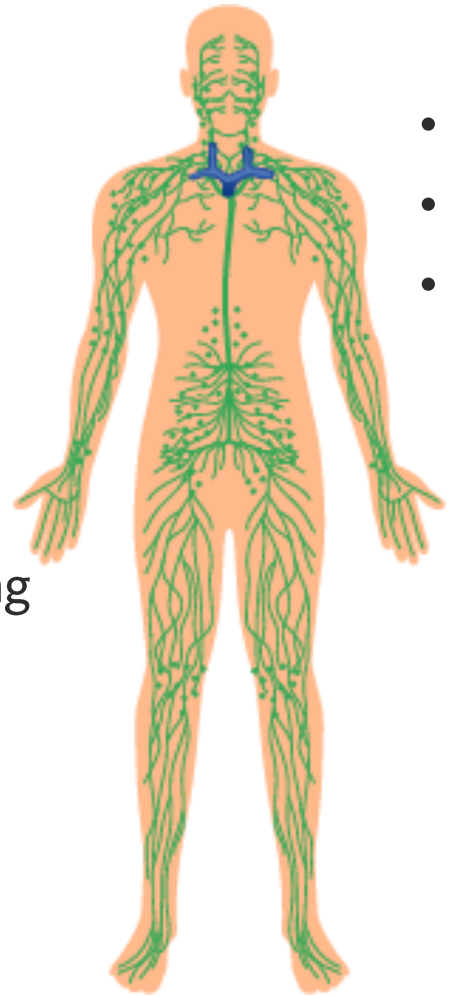
Use considerations: Routes of exposure

Skin

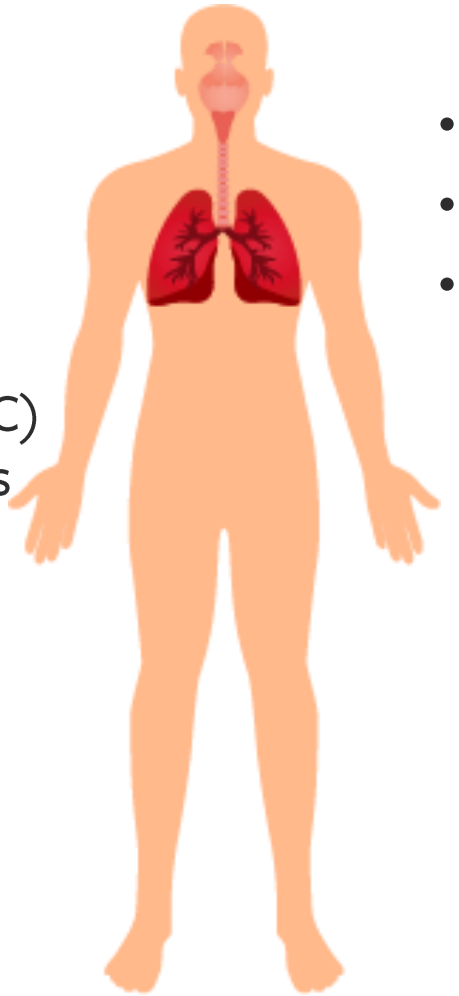
- Skin creams
- Deodorants
- Soap/cleansers
- Shampoo/ conditioner
- Shower gel
- Hand/dishwashing cleaners



Inhalation*

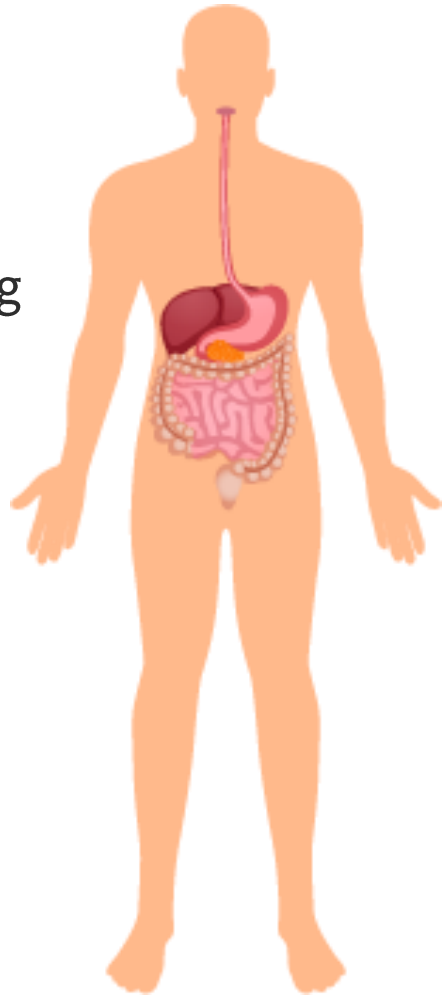
- Aerosols
- Pump sprays
- General purpose cleanser (GPC) trigger sprays

* Generally, depends on delivery system rather than product type.



Oral

- Toothpaste
- Lipsticks
- Dishwashing residues



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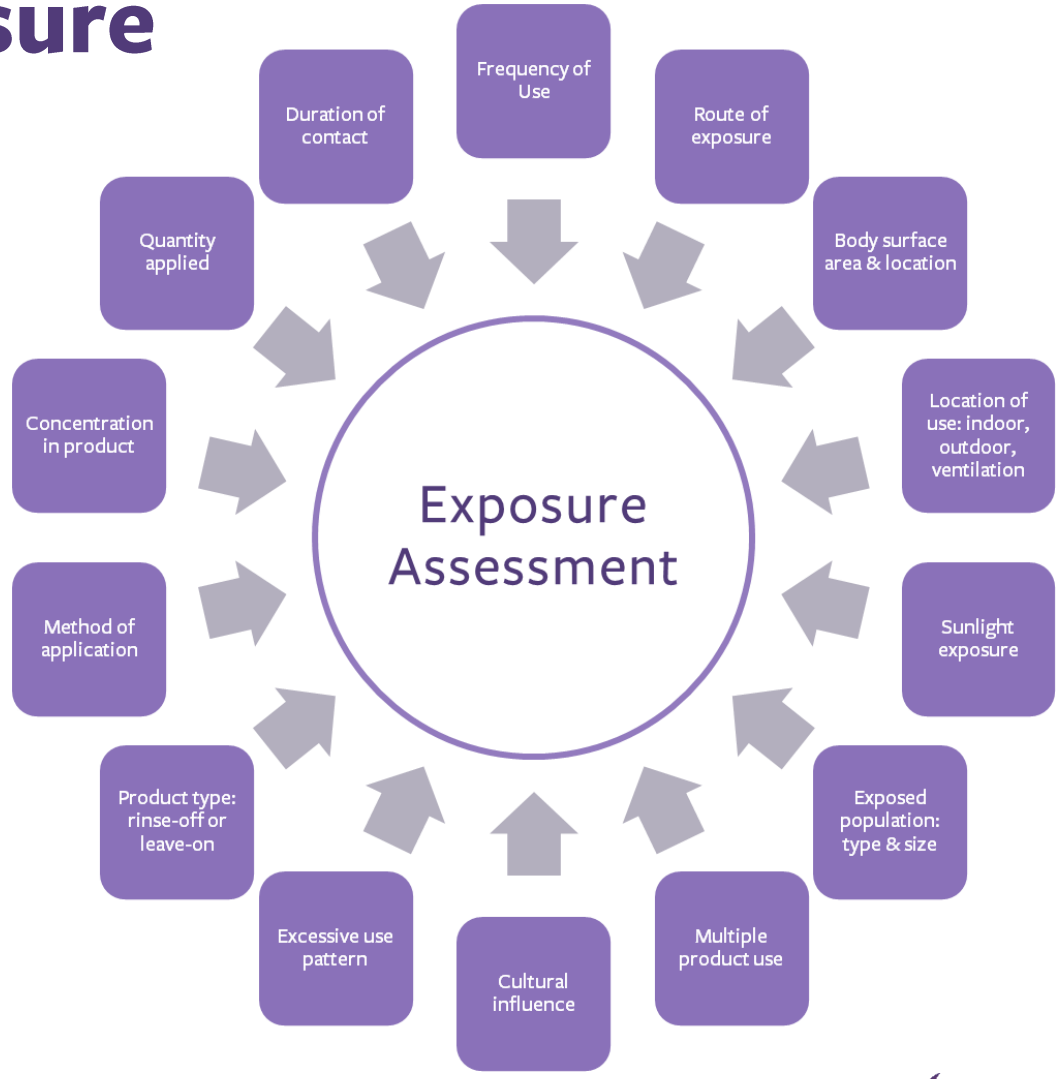
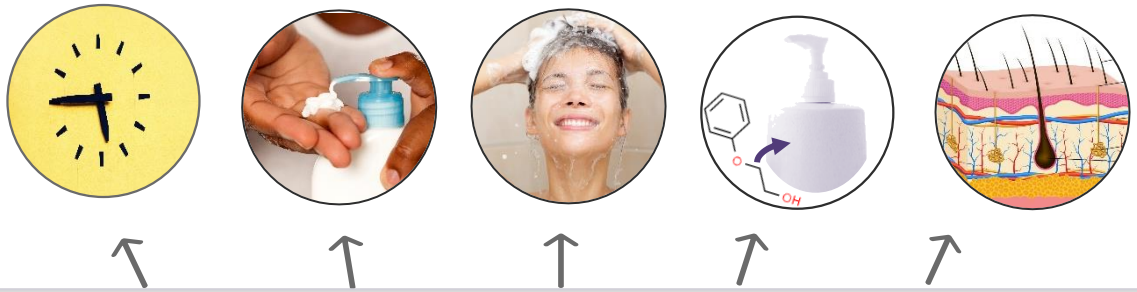
Habits and practices data are key to understanding exposure

Habits and Practices describe how consumers use the products and can vary across the globe for the same product type, based on a number of parameters.



Need to consider which exposure estimate is needed

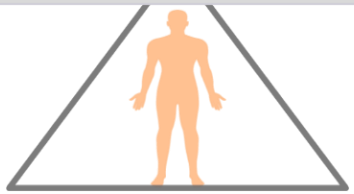
SYSTEMIC EXPOSURE
(mg/kg/day)



$$\text{Exp} = \frac{\text{Frequency x Amount x Retention x Concentration x Penetration}}{\text{BODYWEIGHT}}$$

LOCAL EXPOSURE
(ug/cm^2/day)

$$\text{Exp} = \frac{\text{Frequency x Amount x Retention x Concentration}}{\text{SURFACE AREA}}$$



Considering Local exposure: Quantitative Risk Assessment for Dermal Sensitization

Hazard Identification

- Does the ingredient have the potential to induce dermal sensitization?

Determine a WOE-NESIL

- Derive a no-expected-sensitization induction level (ug/cm^2/day)

Apply sensitization assessment factors

- Uncertainty factors: inter-individual variability, product composition, frequency/duration of product use, skin site considerations

Risk characterization

- Acceptable Exposure Level ≥ Consumer Exposure Level

$$AEL = \frac{WOE\ NESIL}{SAF}$$

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Tiered Assessment Approach For Systemic exposure

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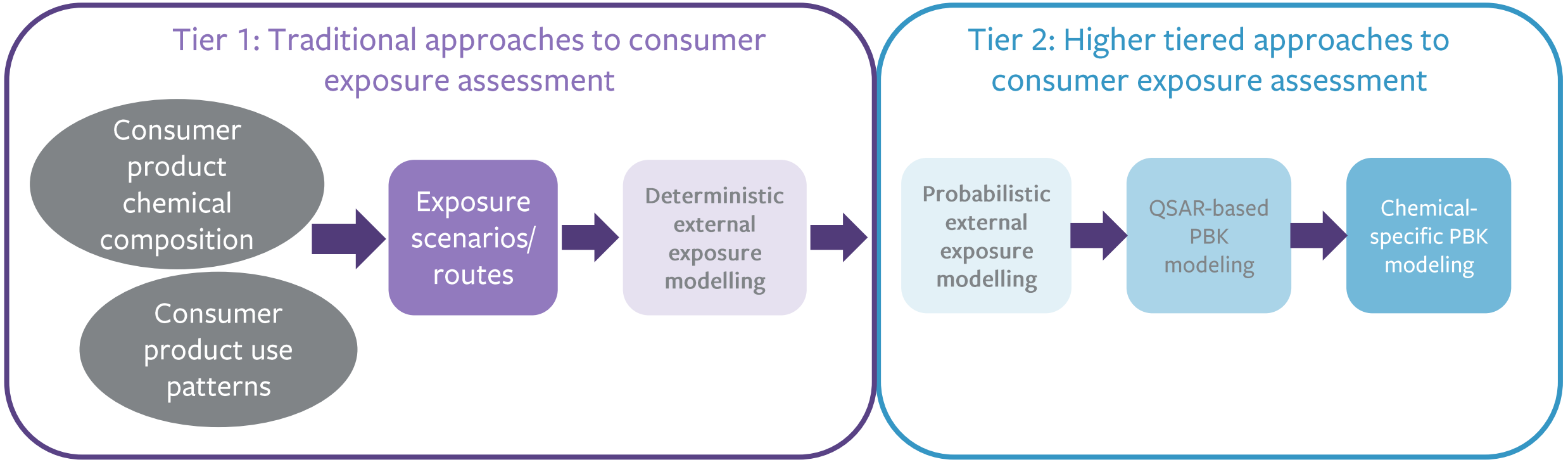
Tiered Exposure Assessment



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Tiered exposure assessment: reaching the level of certainty needed

- A first pass estimation can be made without a lot of data, based on standard assumptions about use and exposure
- If a more precise estimation is needed, a higher tier, probabilistic assessment is more appropriate

Assumptions for first pass estimation:

- The ingredient is present in the product at the maximum use concentration
- Using publicly available default assumptions or exposure modeling
- Systemic absorption can be based on general assumptions of absorption through skin, gut and lungs

Tier	1. Deterministic	2. Probabilistic
Input	Single number	Distribution
Outcome	Single number	Distribution, Uncertainty
Method	Algebra of single numbers	Monte Carlo Simulation using same equation as deterministic approach
Data Availability	Easy to access, modify or to generate	Difficult: database for each variable should be representative and pre-defined on distribution
Interpretation	Conservative with uncertainty	Realistic and Quantitative Uncertainty reduced

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Deterministic Modeling

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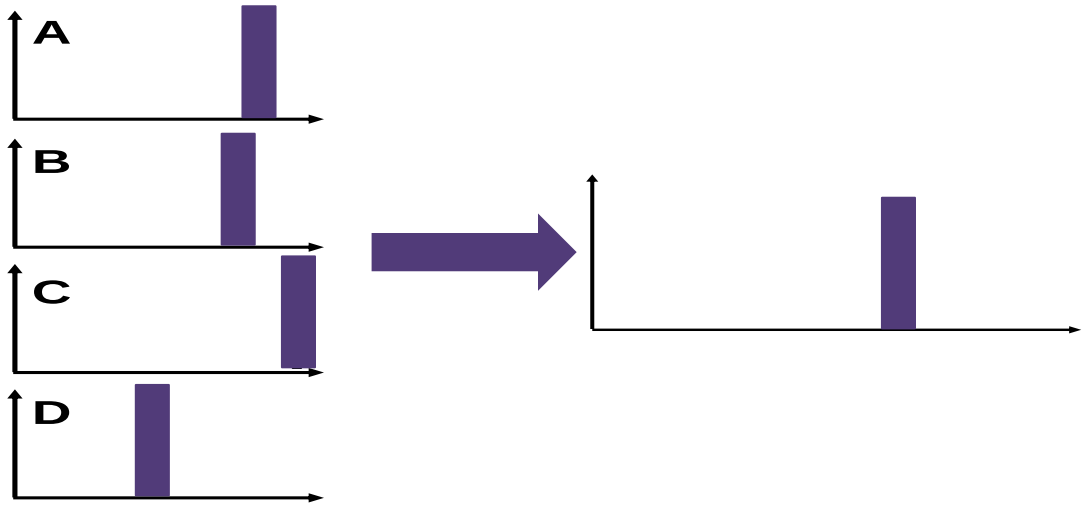
Deterministic Modeling

Generates a point estimate of exposure from simple models using readily available use and habits data

$$\text{Exp} = \frac{\text{Frequency x Amount x Retention x Concentration x Penetration}}{\text{Body weight}}$$



PROS	✓ Calculations are straightforward; not resource intensive
	✓ Uses established and default assumptions; widely accepted
	✓ Free tools are available
	✓ Easy to describe and communicate
CONS	× Single Point Estimate
	× Conservative (worst case over estimation) of exposure
	× Leaves out a lot of information

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Example Overview of Deterministic Assessment Approaches

Exposure = [Concentration of ingredient in product] X [amount applied] X [amount retained]

1. Dermal exposure Calculation:
   - Skin absorption starts with 100% default value
   - If this estimate results in an unfavorable outcome, take 50% as recommended by SCCS
   - If still not sufficient, estimate skin absorption with silico modelling
   - If still not sufficient, perform skin absorption study
2. Oral & Inhalation exposure Calculation:
   - Initial estimate oral or inhalation bioavailability 100% default value
   - refine with real values if data are available

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SCCS Notes of Guidance

Where existing data on product types is available, the following should be considered:

- Identify relevant exposure scenarios covering all functions and uses of the ingredient
- Include reasonably foreseeable exposure conditions

Product Type	Estimated daily amount applied q_x (g/d)	Relative daily amount applied q_x (mg/kg bw/d)	Retention factor Fret	Calculated daily exposure $E_{product}$ (g/d)	Calculated relative daily exposure[1] $E_{product}$ (mg/kg bw/d)
Bath, shower					
Shower gel	18.76	279.20	0.01	0.19	2.79
Hair care					
Shampoo	10.46	150.49	0.01	0.11	1.51
Skin care					
Body lotion	7.82	123.20	1.00	7.82	123.20
Face cream	1.54	24.14	1.00	1.54	24.14
Make-up					
Lipstick	0.057	0.90	1.00	0.057	0.90
Oral hygiene					
Toothpaste	2.75	43.29	0.05	0.138	2.16

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Example: ingredient in face cream at 1%

Dermal Exposure

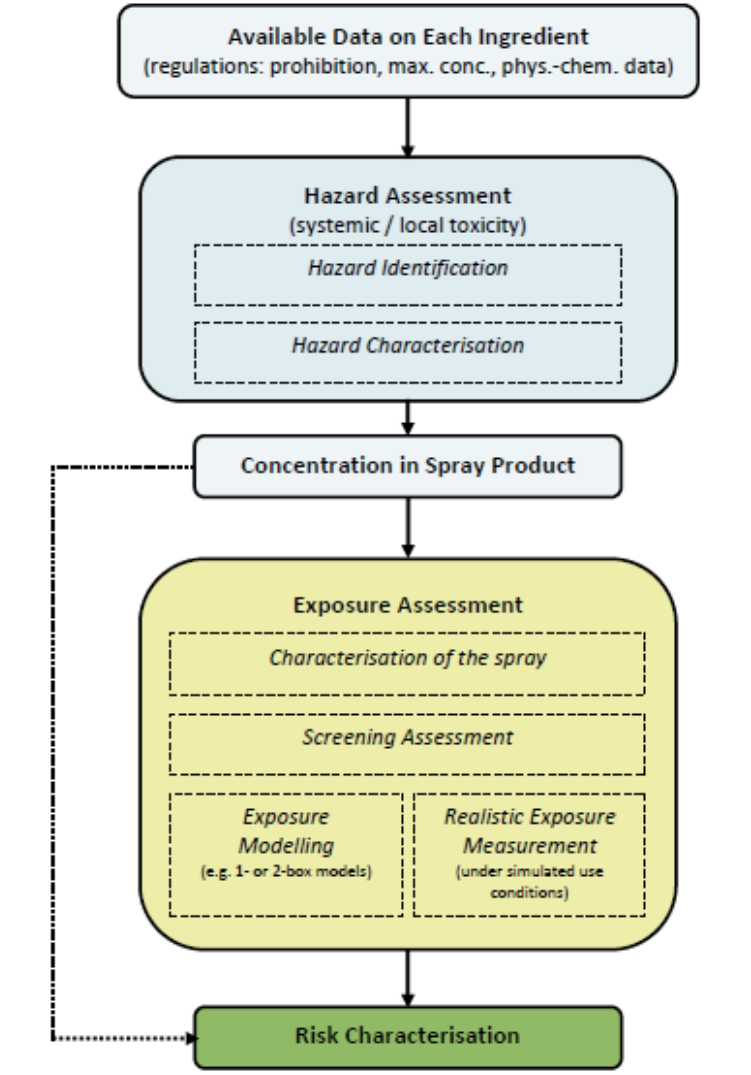
- **Product type:** Face cream
- **Frequency:** 1
- **Product amount:** 1.54 g (SCCS1628/21)
- **Retention factor:** 1 (SCCS1628/21)
- **Max % of ingredient to be used:** 1%
- **Dermal absorption:** 50%
- **Daily Exposure (DE)** = 1.54 g * 1% * 50% = 7.7 mg/day
- **Body weight:** 60 kg
- **Systemic exposure dose (SED):** = 0.128 mg/kg bw/day

$$\text{Exp} = \frac{\text{Frequency x Amount x Retention x Concentration x Penetration}}{\text{Body weight}}$$

$$\text{Daily exposure} = \frac{1 \text{ x } 1540 \text{ mg x } 1 \text{ x } 0.01 \text{ x } 0.5}{60}$$

SED = 0.128 mg/ kg bw/day

Inhalation Approaches



Colour code in boxes: Blue related to ingredients. Yellow related to product exposure.

Spray Characteristics

- Particle size distribution to understand whether particles are small enough to penetrate to the lung
- Define screening level approach for product format

Inhalation Exposure Assessment

EXPOSURE MODELLING

- Near field
- Products sprayed directly at body

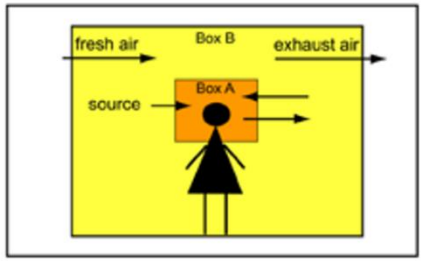


Figure 5: Assumption of a homogeneous distribution of whole quantity of sprayed product in Box A and Box B for a near field scenario

- Far field
- Products not sprayed directly at body

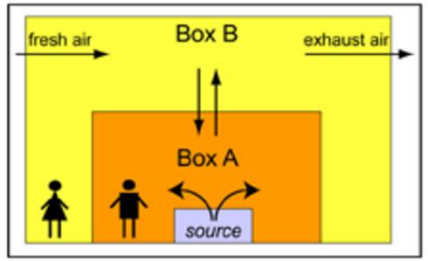


Figure 4: Assumption of a homogeneous distribution of whole quantity of sprayed produ in Box A and Box B for a far field scenario

FEA, 2013

EXPOSURE MEASUREMENTS

- Further refinement needed
- Simulated consumer exposure methods

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Probabilistic Modelling

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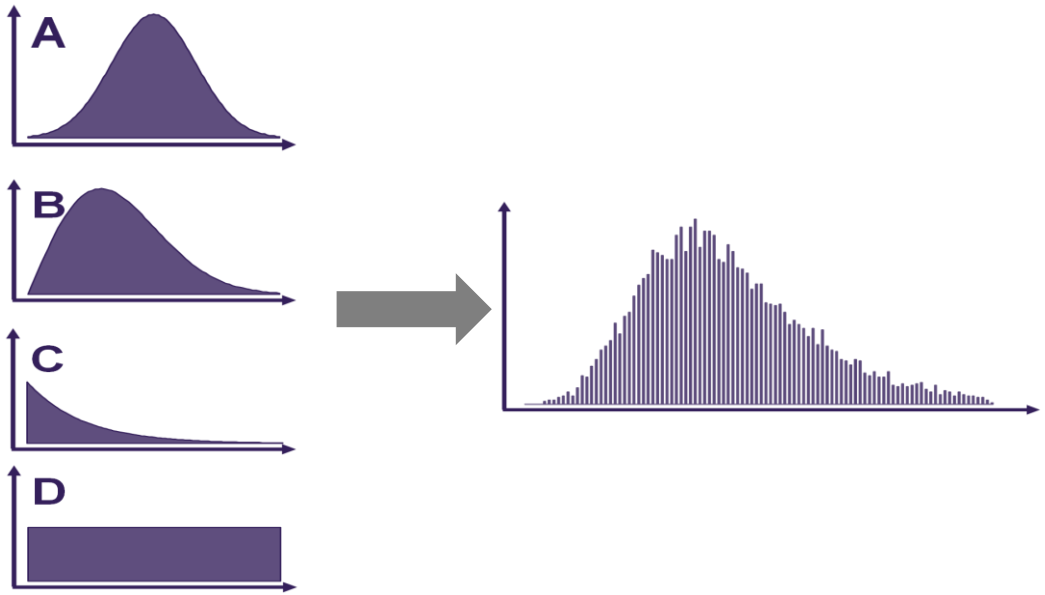
Probabilistic Modeling

Generates probability distributions as exposure estimates from complex models

$$\text{Exp} = \frac{\text{Frequency x Amount x Retention x Concentration x Penetration}}{\text{Body weight}}$$



PROS	✓ Probability distributions give more realistic outcomes
	✓ More Refined and avoids overestimation
	✓ Accounts for variability in the population
	✓ Provides more detailed understanding of variability of risks
CONS	× More complex and resource-intensive
	× Limited tools available
	× Not easy to transparently communicate

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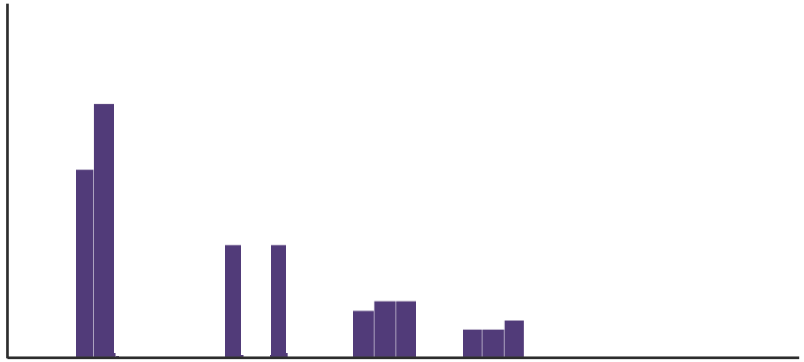
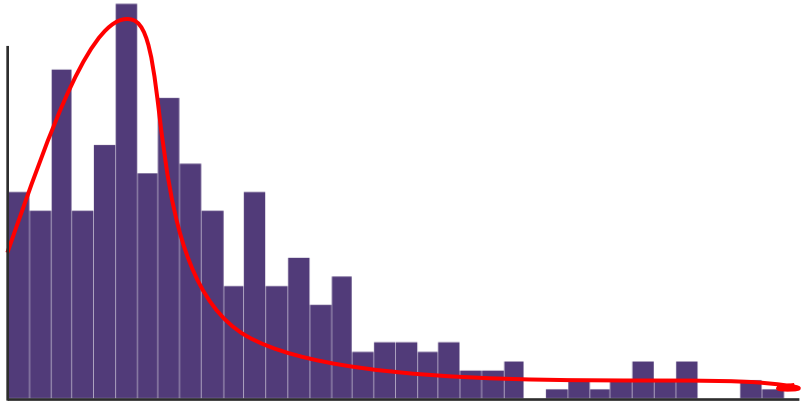
Monte Carlo Simulation

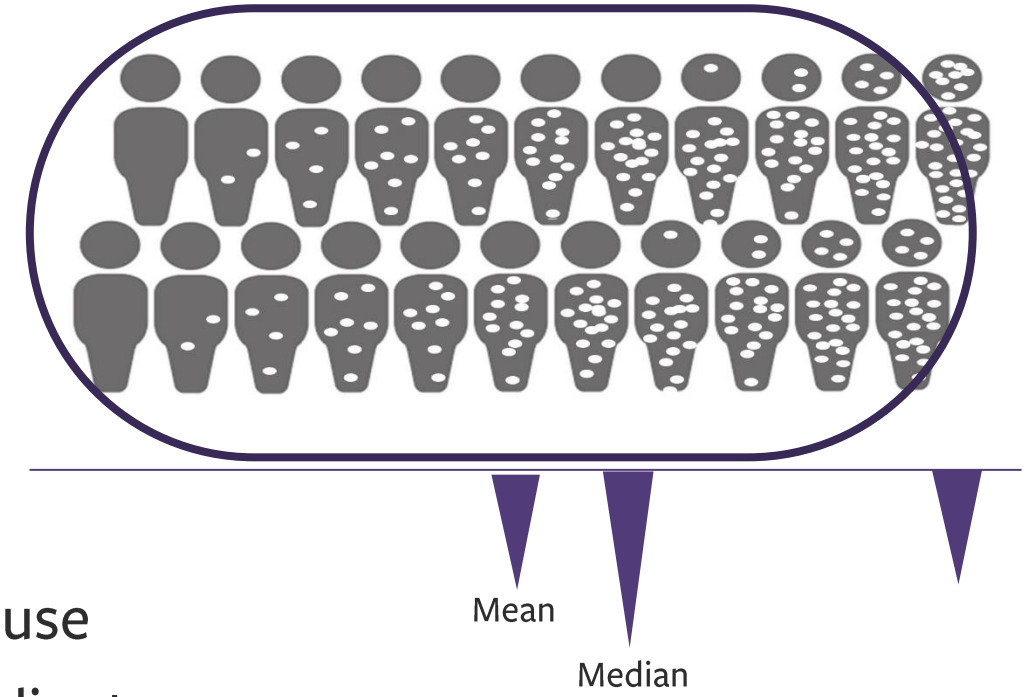
- Mathematical approach
- Simulates the equation numerous times
- Each time randomly selects different points from each of the input parameter distributions
- Generates a distribution of possible exposure estimates
- Gives better insight into what is going on in the general population





Concept of protecting to the 95th percentile of the population

- The 95th percentile of exposure is commonly considered when conducting risk assessments to protect more than typical consumer use
- '95th percentile' means that at most 5% of the population will exceed the estimated daily exposure



- This would provide protection for people who use
  - → a lot of one product that contains the ingredient
  - → few products with high concentrations of the ingredient
  - → use many different products that contain the ingredient

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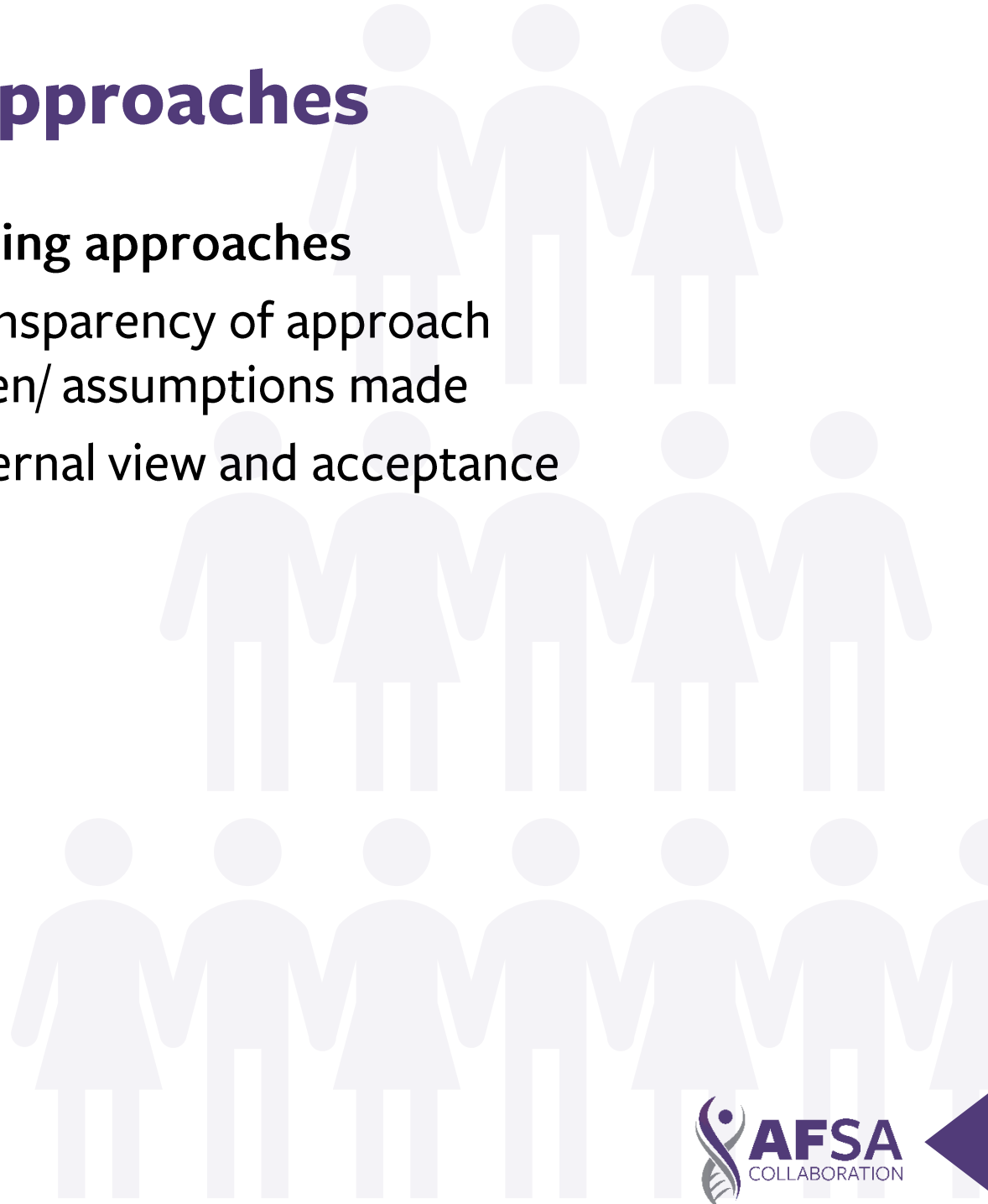
Challenges of Probabilistic Approaches

- **Extensive data requirements**
  - → Responding to industry surveys
    - Bespoke depending on ingredient/ refinement needed
  - → Product type mapping, raw data on ingredient use concentrations mapped to product tonnage
  - → Assumptions/ limitations
- **Modelling approaches**
  - → Transparency of approach taken/ assumptions made
  - → External view and acceptance



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Aggregate Exposure Modeling

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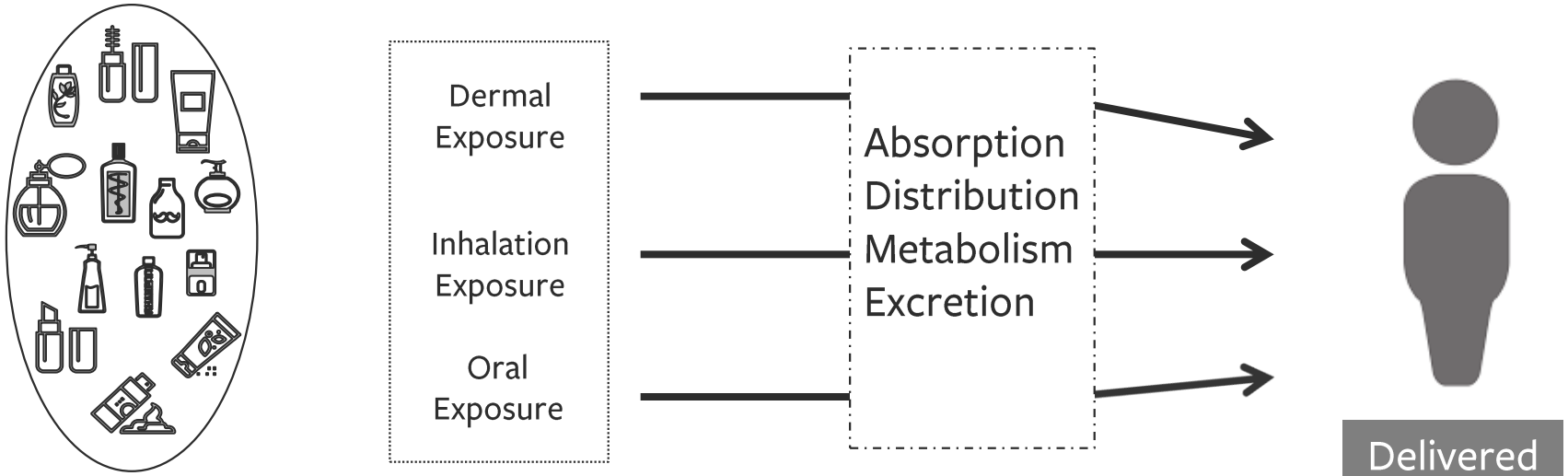
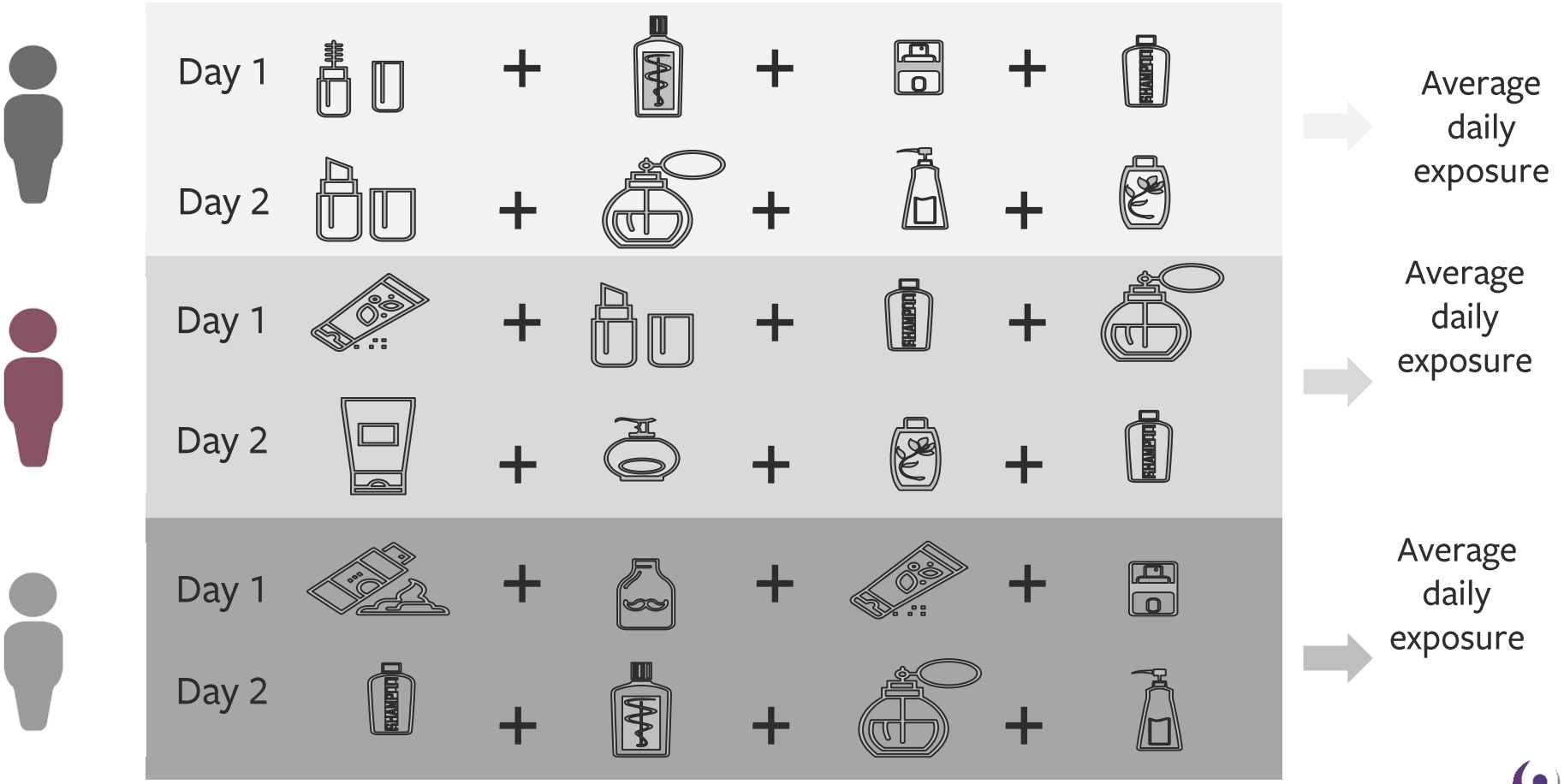
Aggregate Exposure

Considers all possible exposures, since a consumer may encounter an ingredient in different products on the same day



Use Patterns

- Differ day-to-day and person-to-person
- Need this data to create population distributions for probabilistic modeling



Person-based Probabilistic Models

- Model development funded by RIFM and developed by Creme Software
- Covers the following:
  - → Majority of PC products
  - → Air Care products
  - → Household care products
- Considers both systemic exposure (oral, dermal, inhalation) and local dermal endpoints

Body Lotion	• Mass Market • Prestige • Other
Deodorant	• Deodorant/Anti-Perspirant Spray • Deodorant/Anti-Perspirant NonSpray • Body Spray
Oral Care	• Toothpaste • Mouthwash
Cosmetic Styling	• Lipstick • Liquid/Makeup Foundation • Hair Styling Products • Hairspray
Hydroalcholics	• Eau de Toilette • Eau de Parfum • After Shave / Cologne (Splash-on)
Shower Products	• Showergel / Body Wash • Shampoo • Rinse-off Conditioner
Moisturizers	• Face Moisturizer • Hand Cream
Soaps	• Liquid hand soap • Bar Soap

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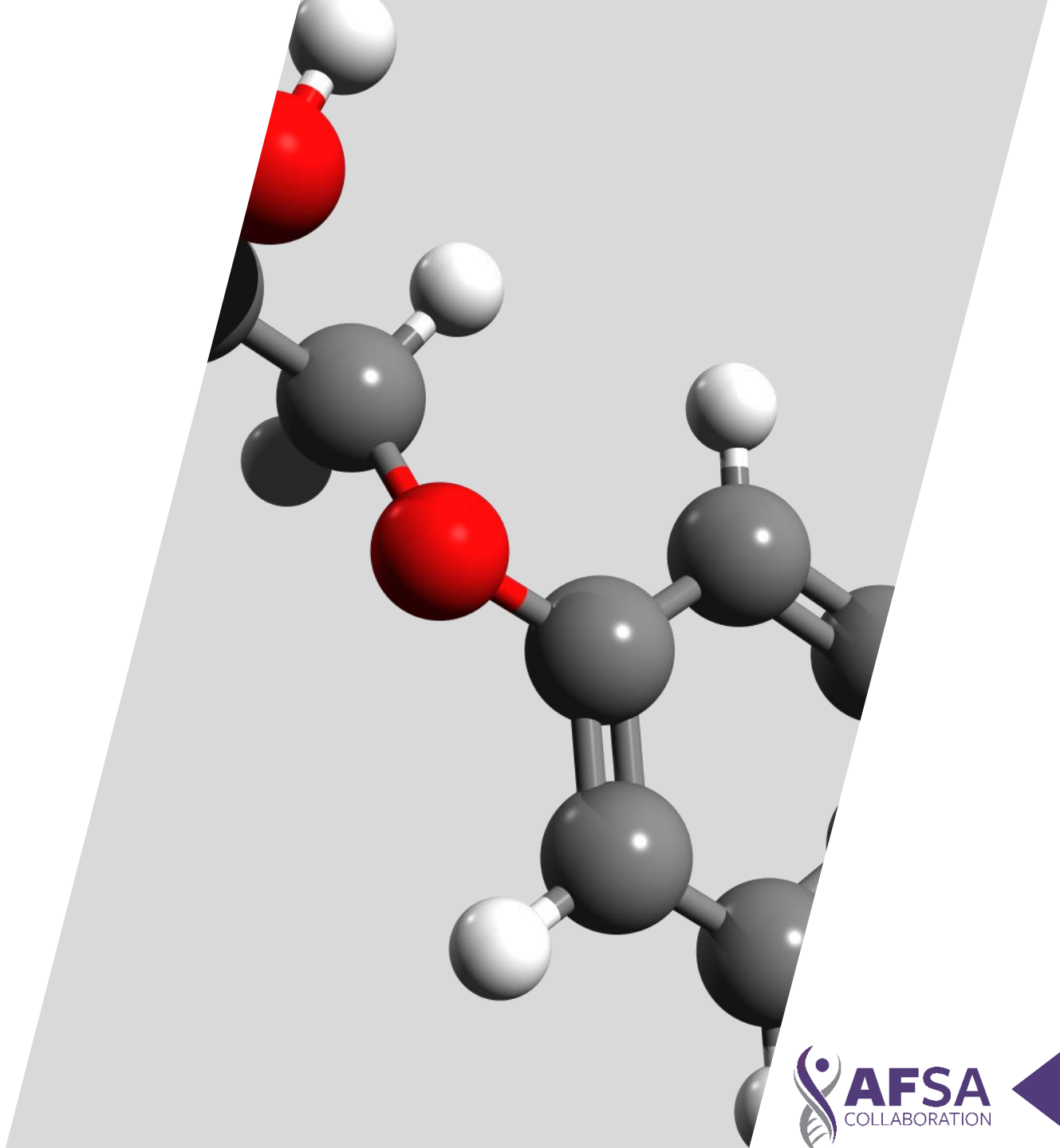
Case Study: Phenoxyethanol



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Deterministic Aggregate Exposure Assessment: phenoxyethanol in cosmetics

- Phenoxyethanol is a preservative, used in multiple product formats that can be used concurrently by consumers
- Phenoxyethanol has a regulatory use limit of 1% across cosmetic formats on EU cosmetics regulation
- SCCS Notes of Guidance used as a conservative starting point, contains 90th percentile of consumer use for a range of PC formats

$$\sum_{i} \frac{\text{Active level of preservative in product type } i \text{ (\%)} \times \text{Amount of product type } i \text{ used per day (g/day)} \times \text{Retention / Ingestion Factor} \times \text{Skin penetration for preservative in product type } i \text{ – dermal exposure products only (\%)} \times 1000}{\text{Body weight (kg)}}$$

Deterministic Aggregate Exposure Assessment: phenoxyethanol

- Assumes all products contain phenoxyethanol at 1% (regulated on EU cosmetics regulation) and a consumers uses all formats concurrently at the 90th percentile of use
- Skin penetration (80%) considered
- SCCS Notes of Guidance product use range

Product	Product use (g/day)	Retention Factor	Daily dose (mg/kg/day)
Shower gel	0.19	0.01	0.02
Hair conditioner	0.11	0.01	0.01
Shampoo	0.04	0.01	0.01
Hair styling	0.40		0.05
Liquid foundation	0.51	1.0	0.06
Makeup remover	0.50	0.1	0.07
Hand wash - soap	0.20	0.01	0.03
Body lotion	7.82	1.0	0.99
Face cream	1.54	1.0	0.19
Hand cream	2.16	1.0	0.26
Deodorant non-spray	1.50	1.0	0.18
Eye makeup	0.02	1.0	0.00
Mascara	0.03	1.0	0.00
Lipstick	0.06	1.0	0.01
Eyeliner	0.01	1.0	0.00
Toothpaste	0.14	0.05	0.02
Mouthwash	2.16	0.1	0.29
Total	17.38		2.19

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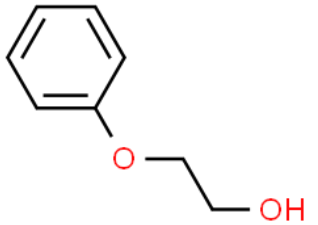
Probabilistic Aggregate Exposure Assessment: phenoxyethanol



- Two scenarios considered
  - →1% use in all product types
  - →Measured concentrations (from Danish EPA)
- Modelling approach for EU females only
- Crème PC model used
  - →Refinement of co-use data
  - →Variability in amount per use

Scenario	Statistic	Systemic Exposure Dose for Phenoxyethanol (mg/kg bw per day)
Phenoxyethanol present at 1% in all products	P95	1.14
Phenoxyethanol present at Danish EPA concentrations in all products	P95	0.78

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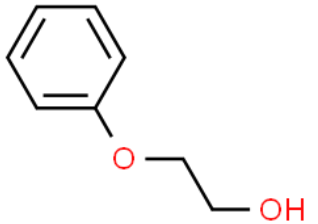
Tiered Aggregate Exposure Assessment Phenoxyethanol



Tier:	1. Deterministic	2. Probabilistic (a)	2. Probabilistic (b)
Product retention values	SCCS NoG 2012	SCCS NoG 2012	SCCS NoG 2012
Consumer habits and practices	Uses all products at high end use, every day	Adult EU and US female population; not all consumers use all products everyday	Adult EU and US female population; not all consumers use all products everyday
Concentration in product	Assumed 1% in all products	Assumed 1% in all products	Always present at measured concentrations in marketed products by Danish EPA
Absorption fractions	Skin penetration: 80% Oral absorption: 90% No inhaled formats	Skin penetration: 80% Oral absorption: 90% No inhaled formats	Skin penetration: 80% Oral absorption: 90% No inhaled formats
Aggregate systemic exposure (95^{th} percentile)	2.2 mg/kg bw/day	1.14 mg/kg bw/day	0.78 mg/kg bw/day

(ECETOC, 2016)

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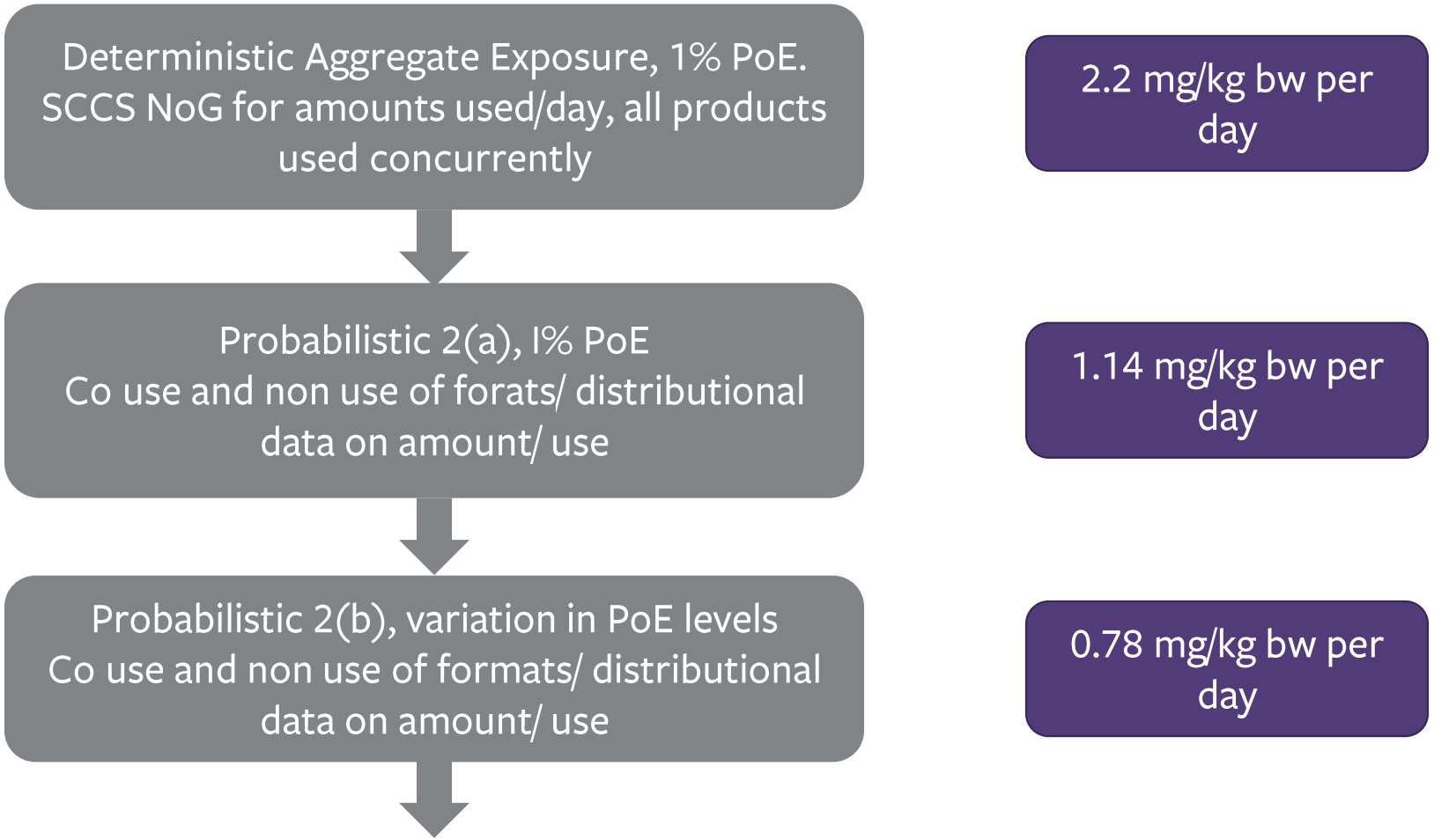
Summary: potential refinement options



Could refine further by incorporation of occurrence data

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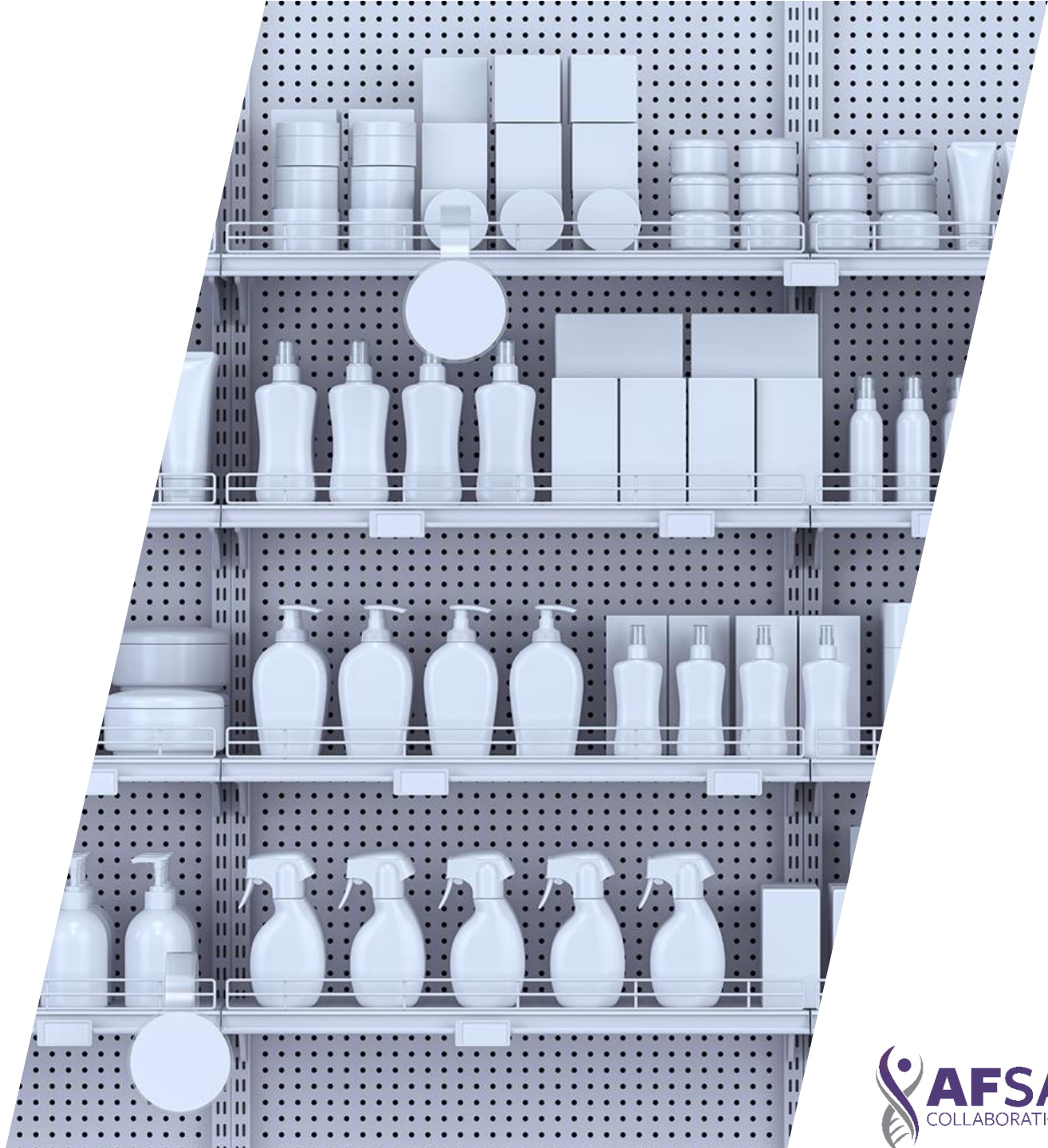
Next Steps



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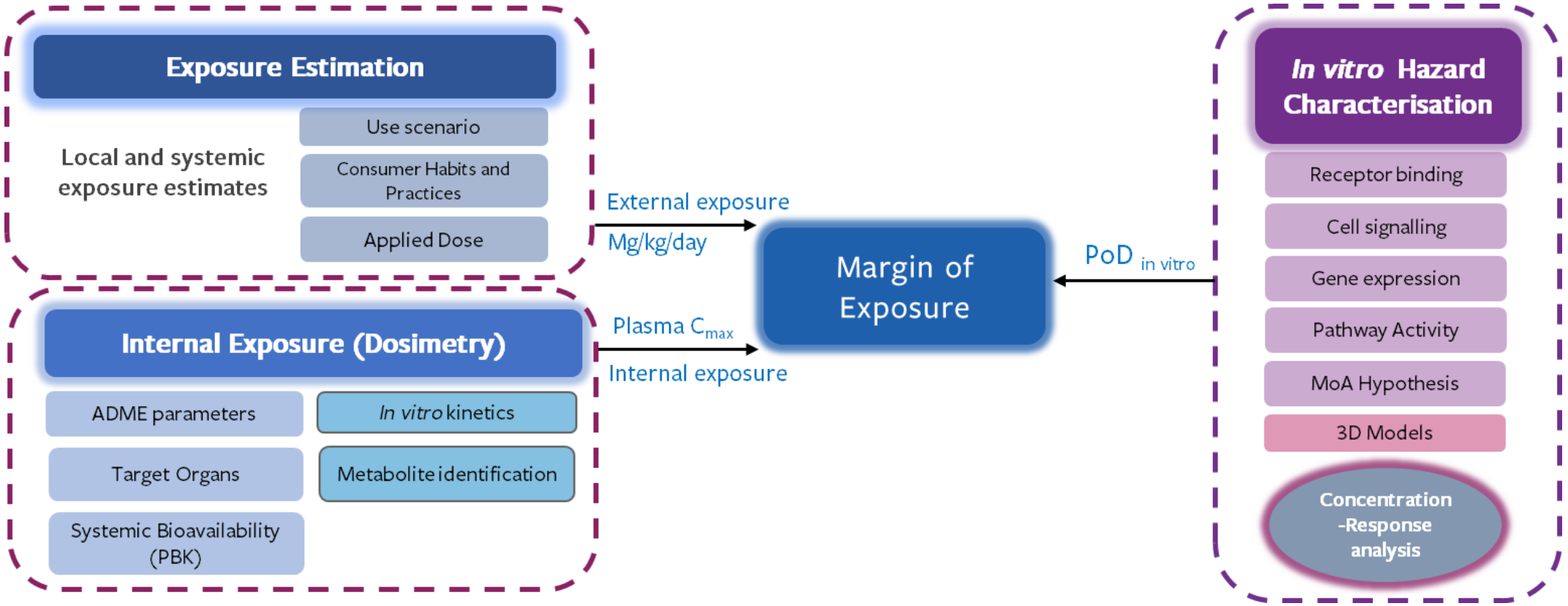
What do you do with an exposure estimate?

- Use in Margin of Exposure (MoE) estimation
- Use in “exposure-based waiving”
  - →threshold of toxicological concern (TTC)
  - →when exposure very low

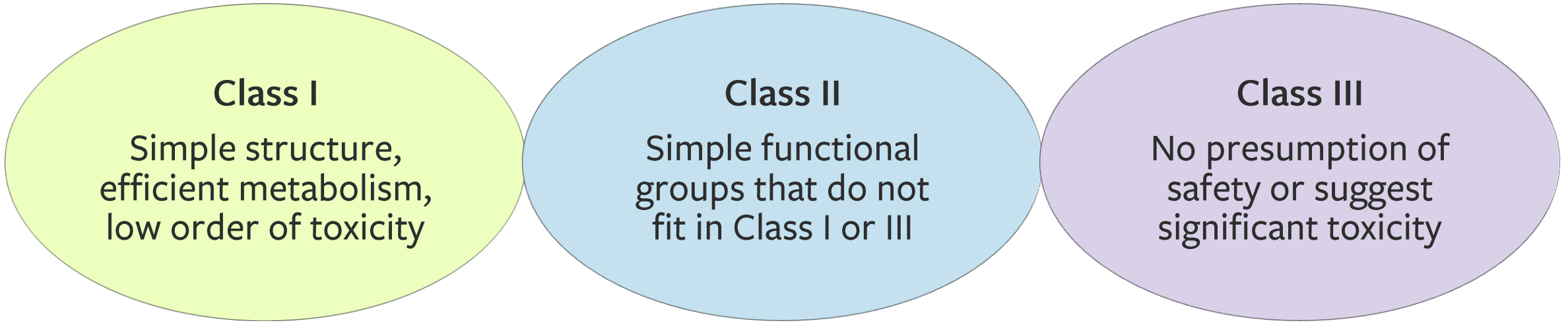
Margin of Exposure

$$\frac{\boldsymbol{Bioactivity}\ (mg/kg/day)}{\boldsymbol{Exposure}\ (mg/kg/day)} = \boldsymbol{MoE}$$



Threshold of Toxicological Concern

- Level of exposure below which there is no appreciable risk to human health
- Based on structure-activity relationships (SAR)
- Relies on the knowledge of distribution potencies for classes of chemicals which have existing toxicity data



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Summary and Conclusions

- External exposure assessment is a critical starting point to the risk assessment approach
- To calculate exposure estimates, we need to consider:
  - → Route(s) of exposure
  - → Consumer habits and practices data
    - Can be generated, or pulled from sources (e.g. the SCCS notes of guidance)
- Tiered approach is taken, typically simplest tier is sufficient
  - → Conservative deterministic approach
  - → Refined/realistic probabilistic approach
  - → Aggregate

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Summary and Conclusions

- Deterministic modeling
  - →Can be used as a first pass estimate with simple, available data and algebra
  - →Gives an estimate that is highly conservative with a fair amount of uncertainty
- Probabilistic modeling
  - →Uses more complicated population distribution data, often proprietary
  - →Applies more complex mathematics (e.g. Monte Carlo simulation)
  - →Estimate is more realistic and uncertainty is less and can be characterized

Either approach can be used to estimate aggregate exposure

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References and additional reading

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We value your feedback! As the AFSA Collaboration works to complete its free Master Class on Animal-Free Cosmetic Safety Assessment, we would appreciate your input on what we've developed so far and presented via this webinar preview series. Please take our FEEDBACK SURVEY

Thank You !

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