Expert Models for Decision Makers ™

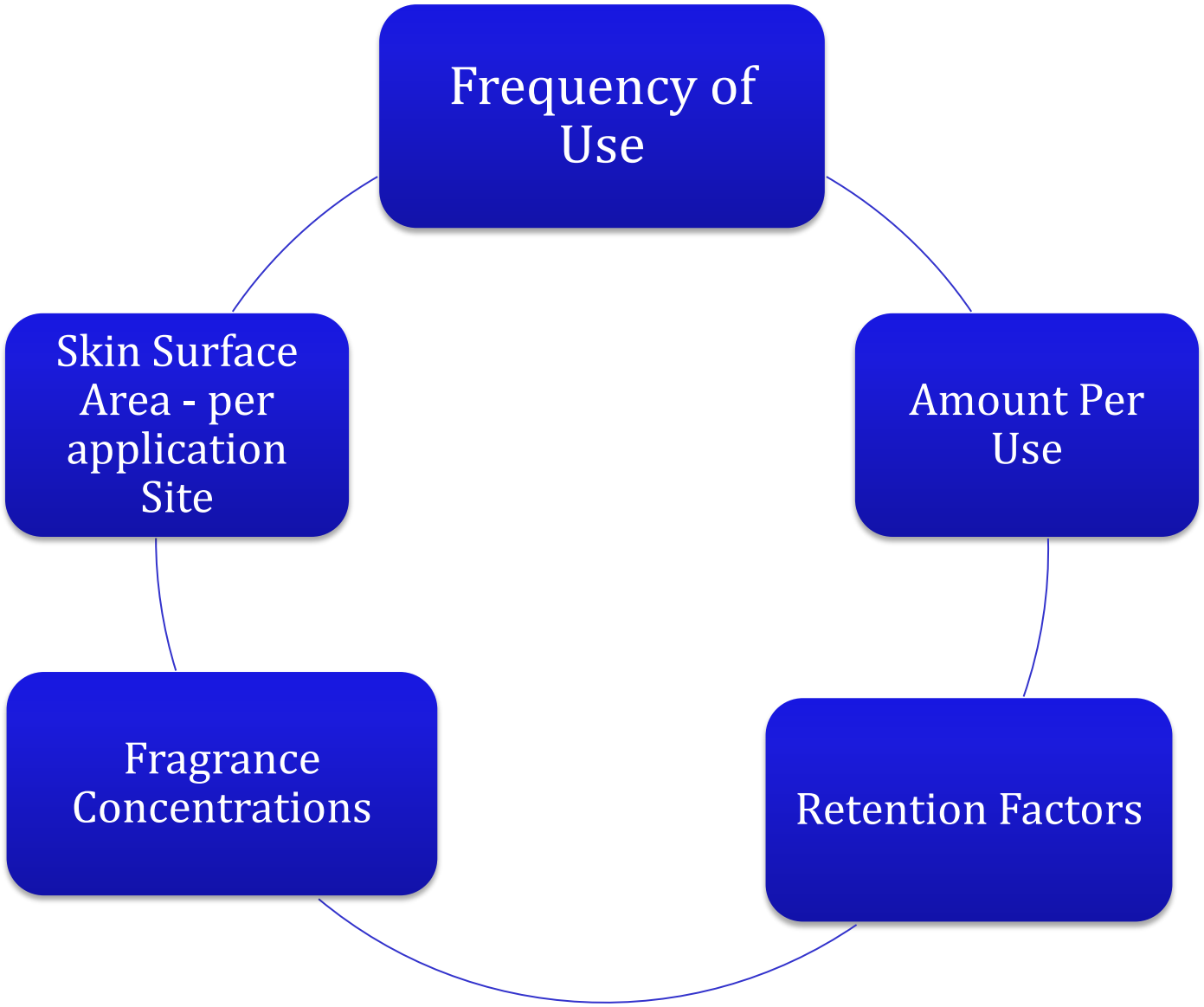
Summary of the aggregate exposure model and presentation of a proposal to incorporate aggregate exposure into the QRA categories

Cronan McNamara, CEO

Creme Global

14th May 2013

Required Data



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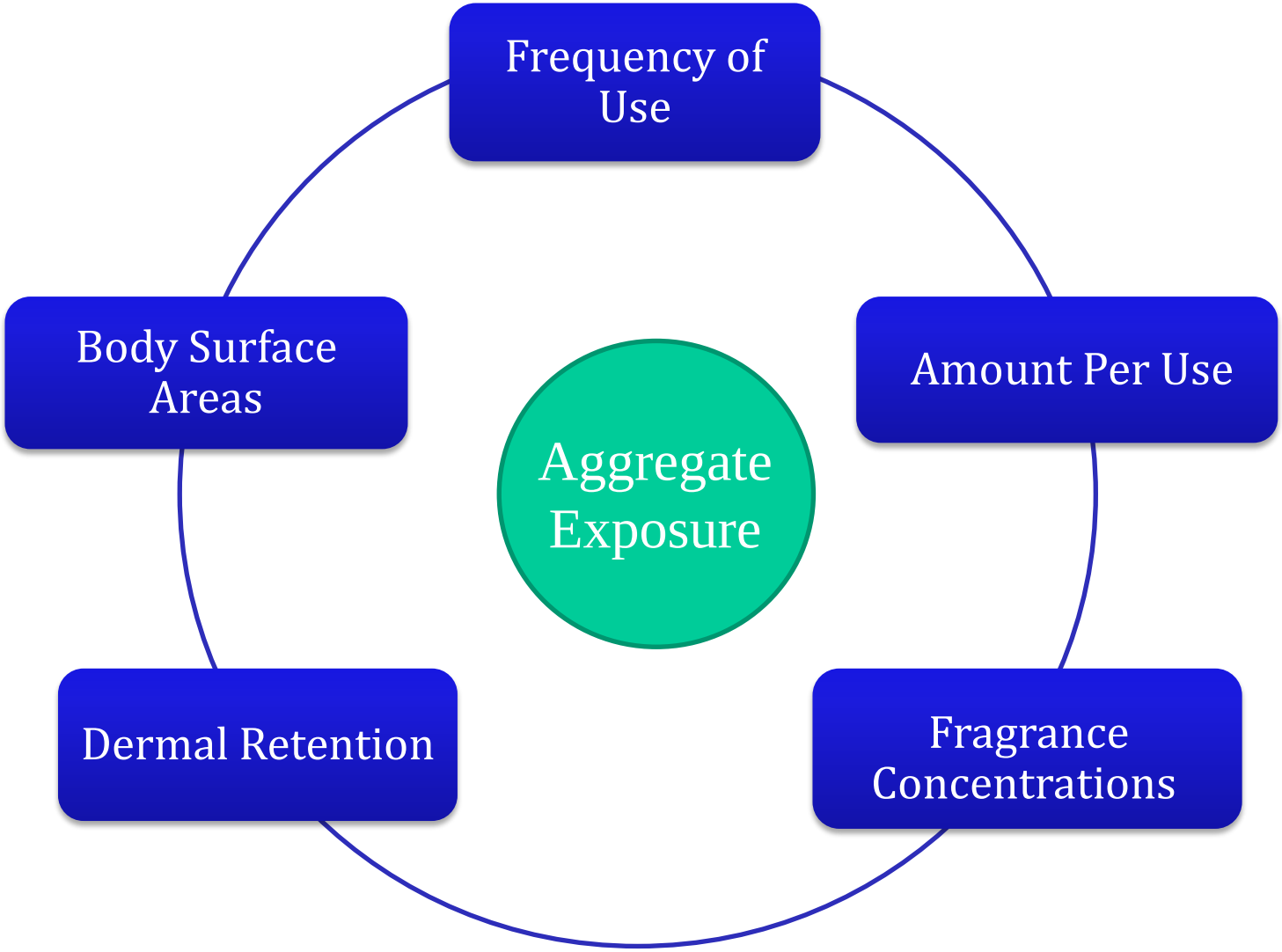

World's Largest Survey

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Online Consumption Diaries

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Online Consumption Diaries

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- Body Lotion
- Deodorant
- Oral Care
- Cosmetic Styling
- Hydro-alcoholics
- Shower Products
- Moisturizers
- Soaps
- Air Care

Personal Care Products

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Body Lotion	• Mass Market • Prestige
Deodorant	• Deodorant/Anti-Perspirant Spray • Deodorant/Anti-Perspirant NonSpray • Body Spray
Oral Care	• Toothpaste • Mouthwash
Cosmetic Styling	• Lipstick • Liquid/Makeup Foundation • Hair Styling Products (excl. Spray)
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
Air Care	• Scented Candles • Plug-ins

Application Sites

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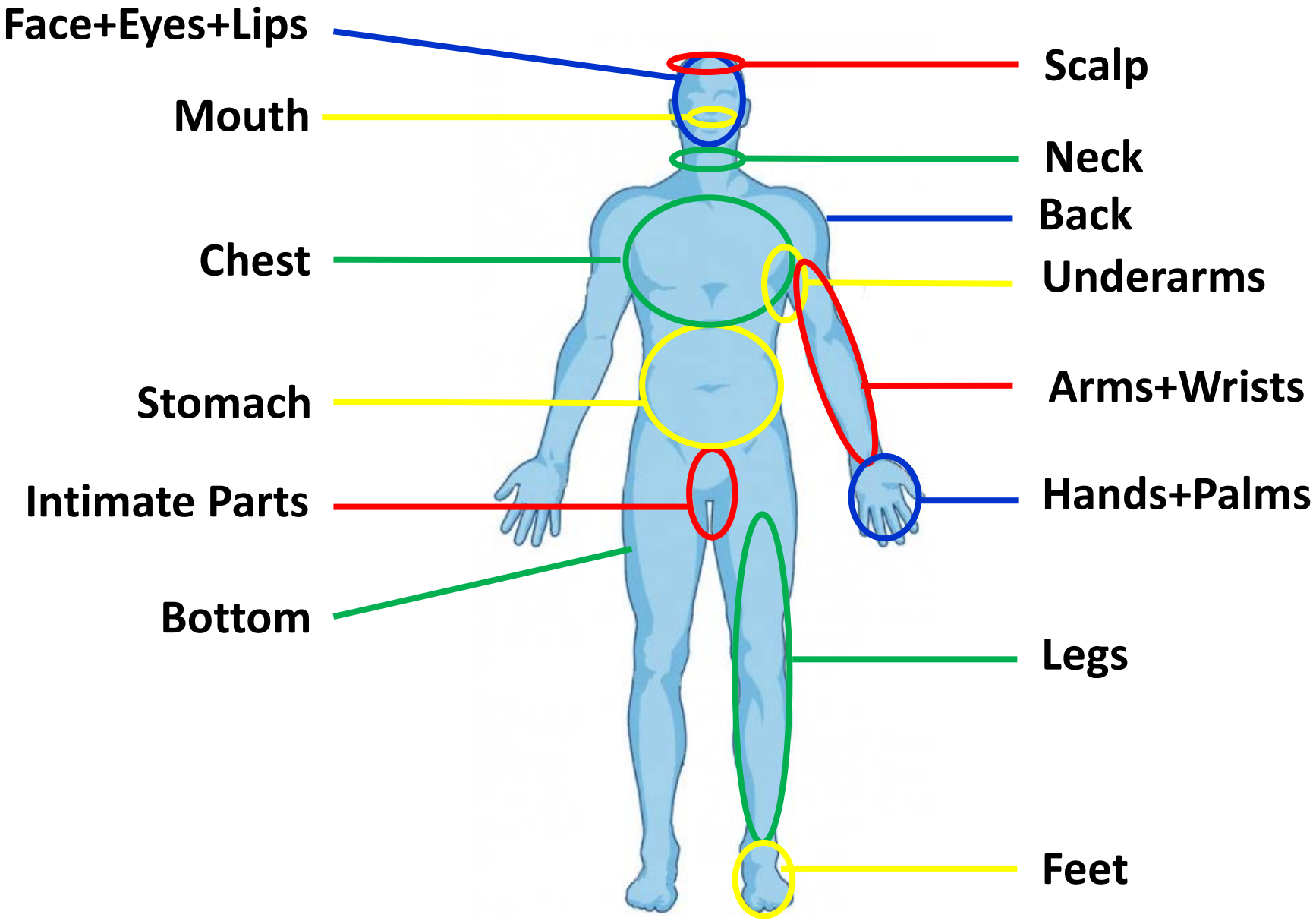

Consumer Exposure Level

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$$\text{Exposure} = \frac{Amount \times Retention \times Concentration}{Surface\ Area}$$

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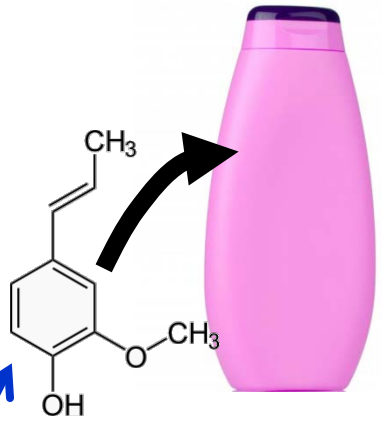
Consumer Exposure Level



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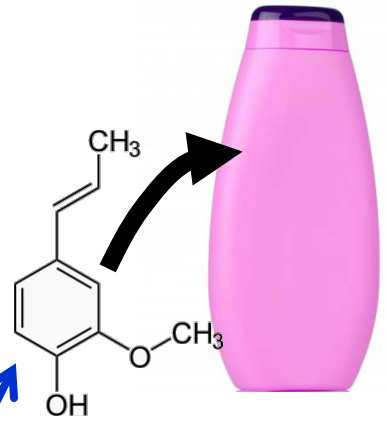

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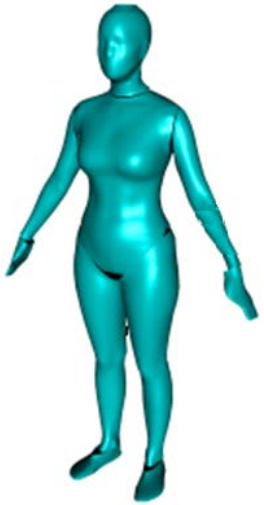

Daily Aggregate Exposure

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Simulating the Total Population

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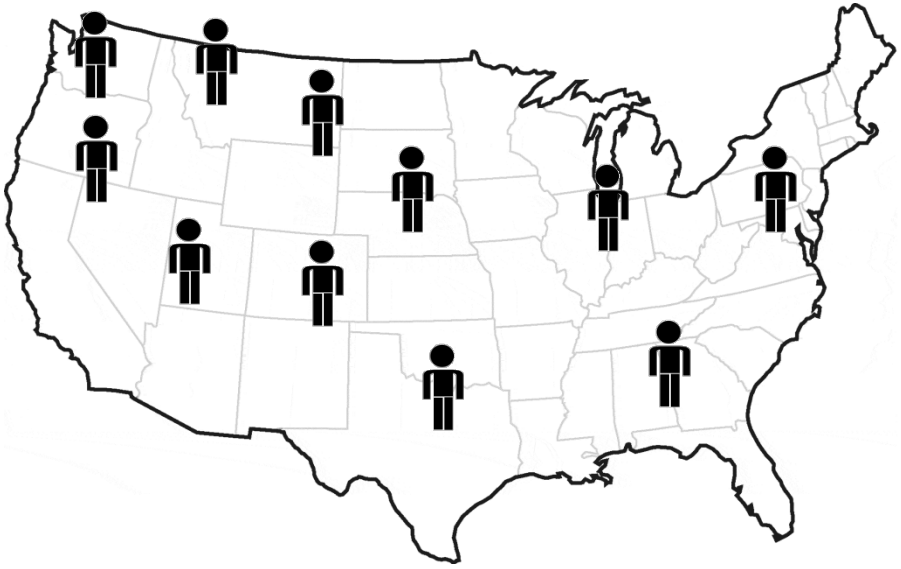
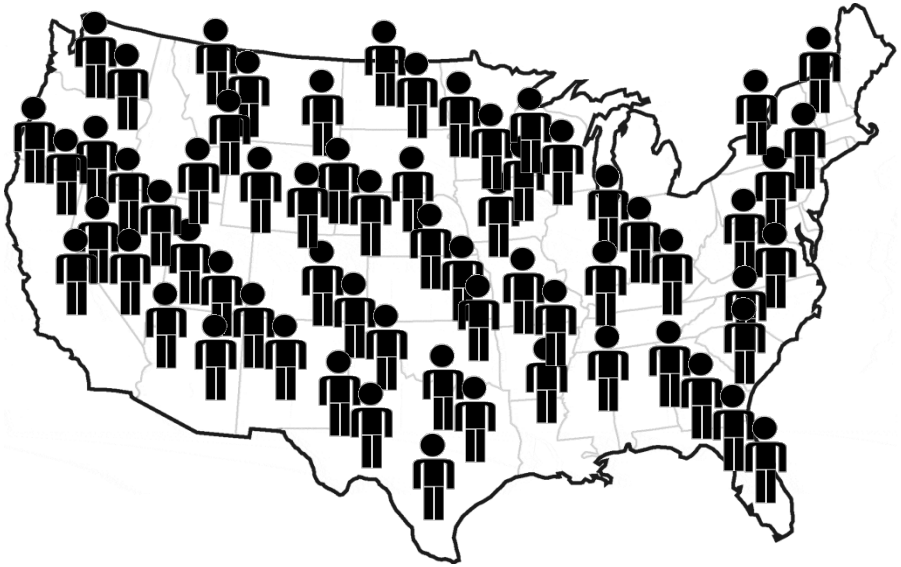


Simulating the Total Population

Creme



Calculating Exposure

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Dermal Exposure ($mg/cm^2/day$) =

$$\frac{Frequency \times Amount \times Concentration \times Rentention}{Surface\ Area}$$

Calculation repeated for:

- Each Day
- Each Subject
- Each Body Part
- Each Product

Dermal Exposure for Each Person for each Body Part

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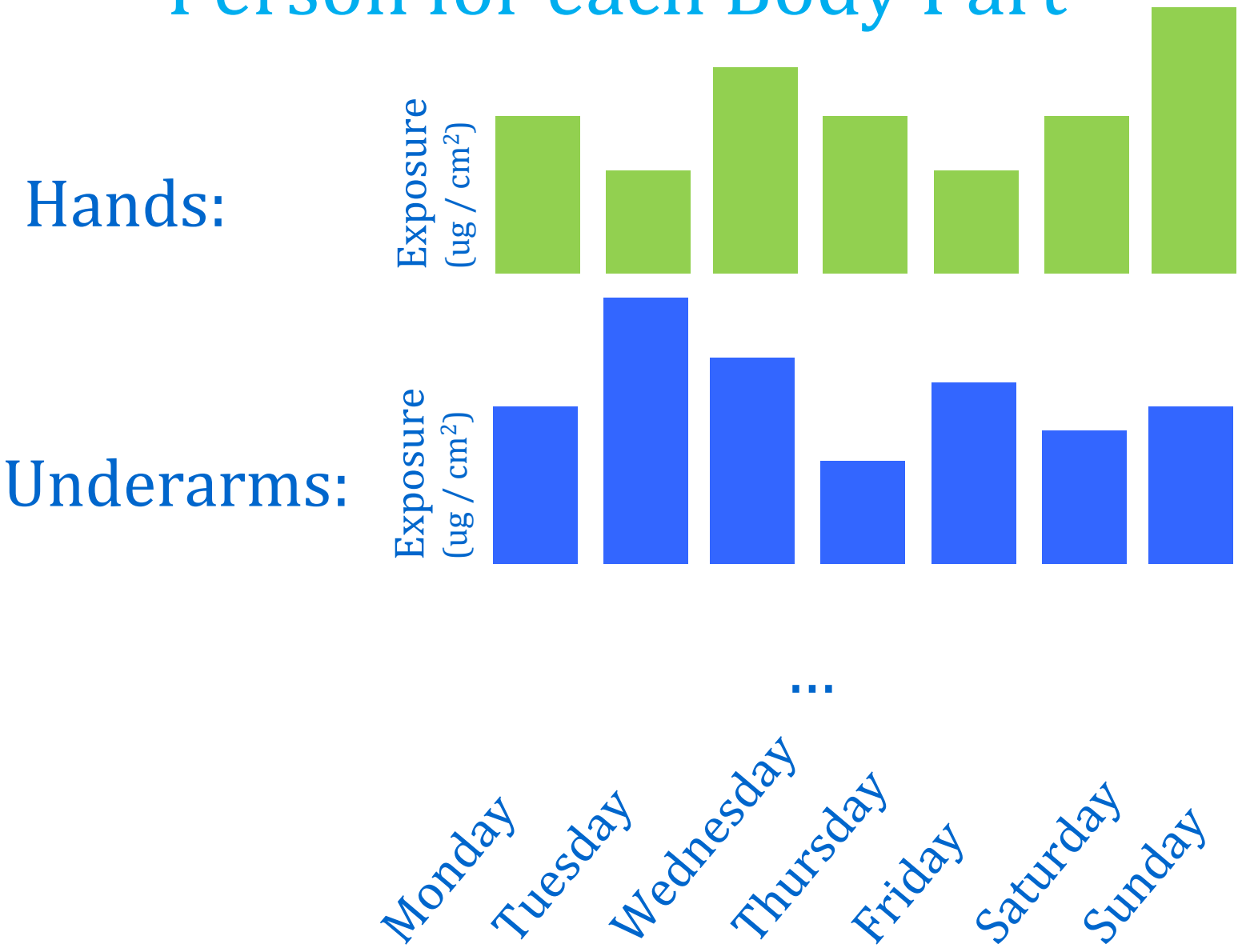

Dermal Exposure for Each Person for each Body Part

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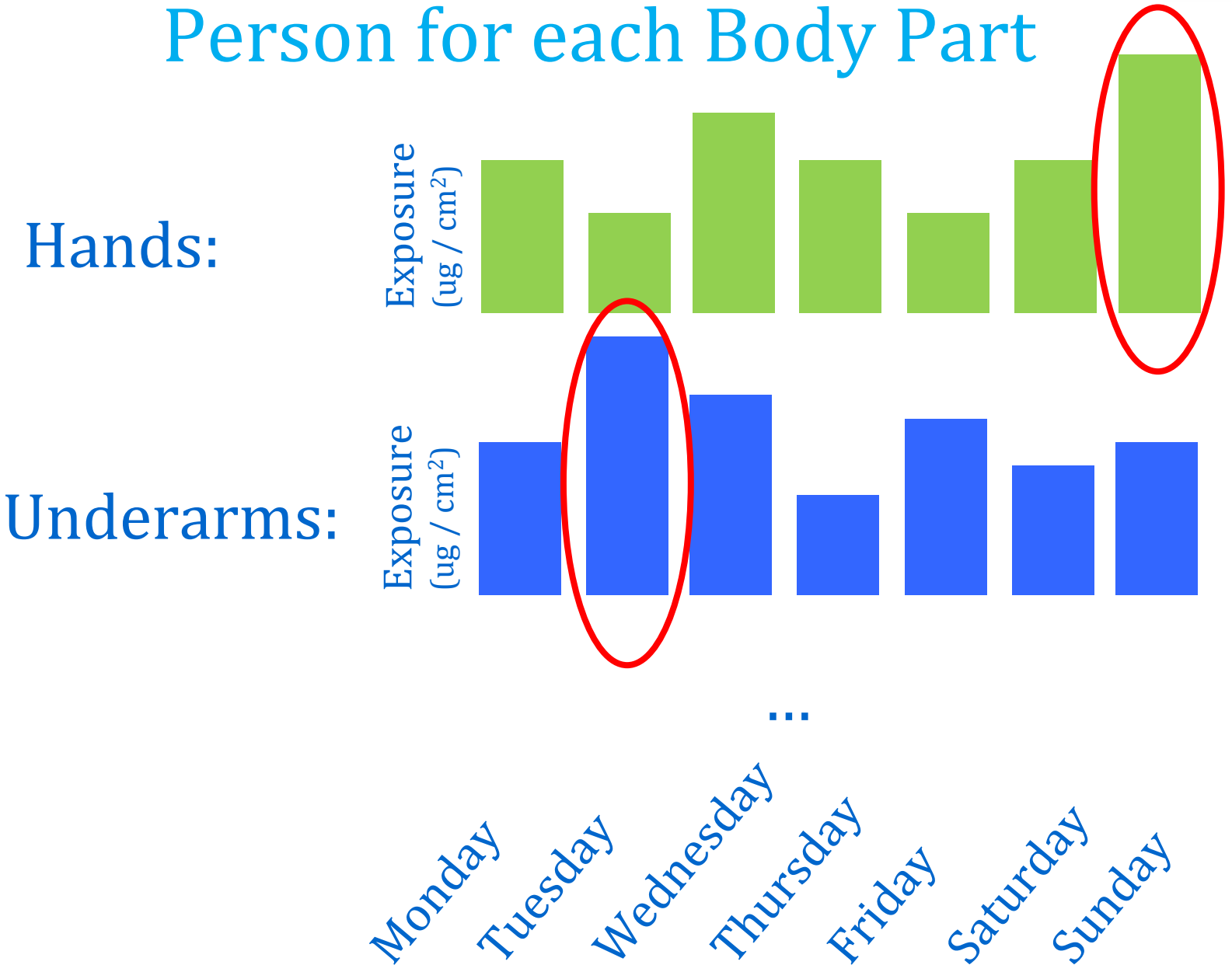

Dermal Exposure for Each Person for each Body Part

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Hands:

Underarms:

Worst day for each person for each application site

Dermal Exposure for Each Person for each Body Part

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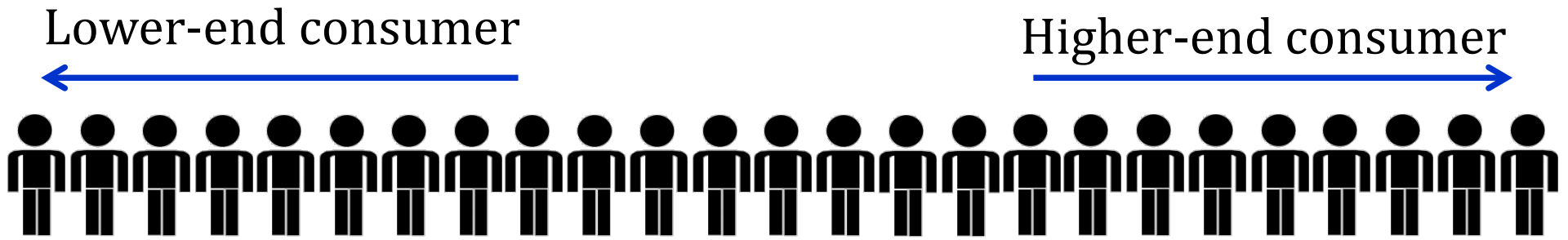

Dermal Exposure for Each Person for each Body Part

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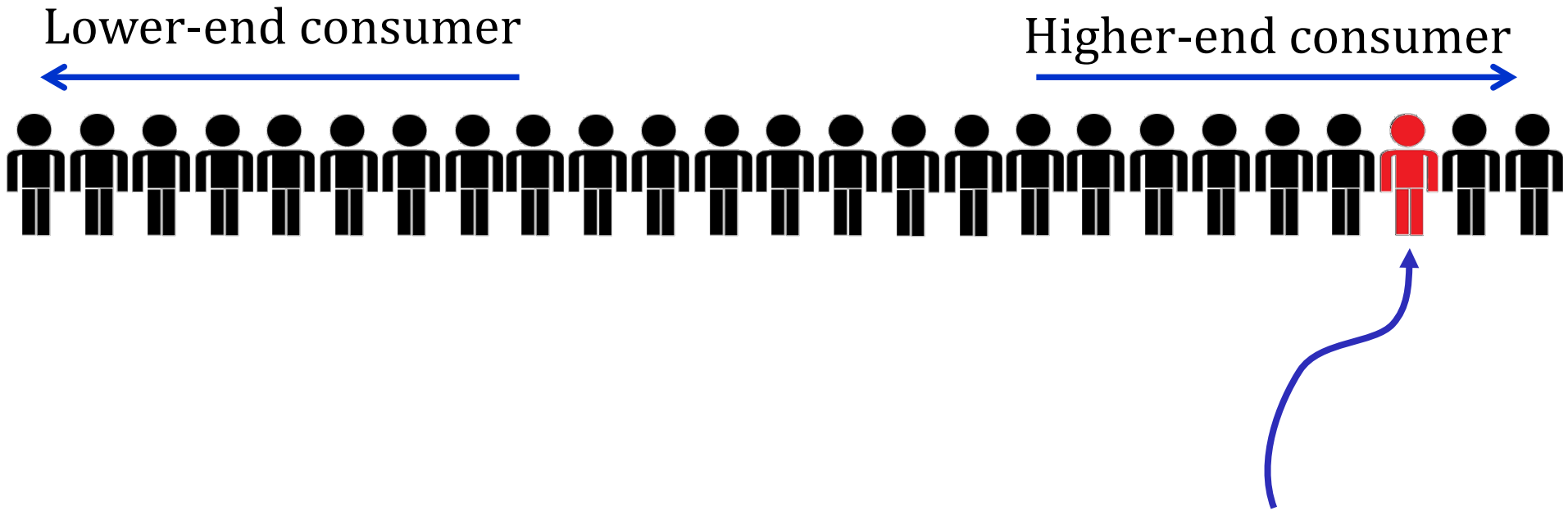

95th Percentile Consumer Exposure on **Worst Day** for each consumer for each **Application Site**

Incorporating SAFs into Aggregate Exposure Model

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- Each product has a Product SAF
- Each Body Site has a Site SAF

⇒Need to integrate Product SAFS into **aggregate exposure** model at each usage event

(i.e. before exposures are aggregated)

Incorporating SAFs into Aggregate Exposure Model

Creme

$$AEL_{Site} = \frac{NESIL}{Interindividual\ SAF\ \times Site\ SAF}$$

$$CEL_{\ Site} = \ Exposure_{Site} \times Product\ SAF \times Frequency\ SAF$$

$$\frac{AEL_{Site}}{P95\left(\ CEL_{Agg\ (Site)}\right)} > 1$$

Current IFRA Standards

- Run current IFRA standards concentrations through the aggregate exposure model

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Note: This assumes that every product on the market contains the fragrance at the maximum allowed concentration

Current IFRA Standards

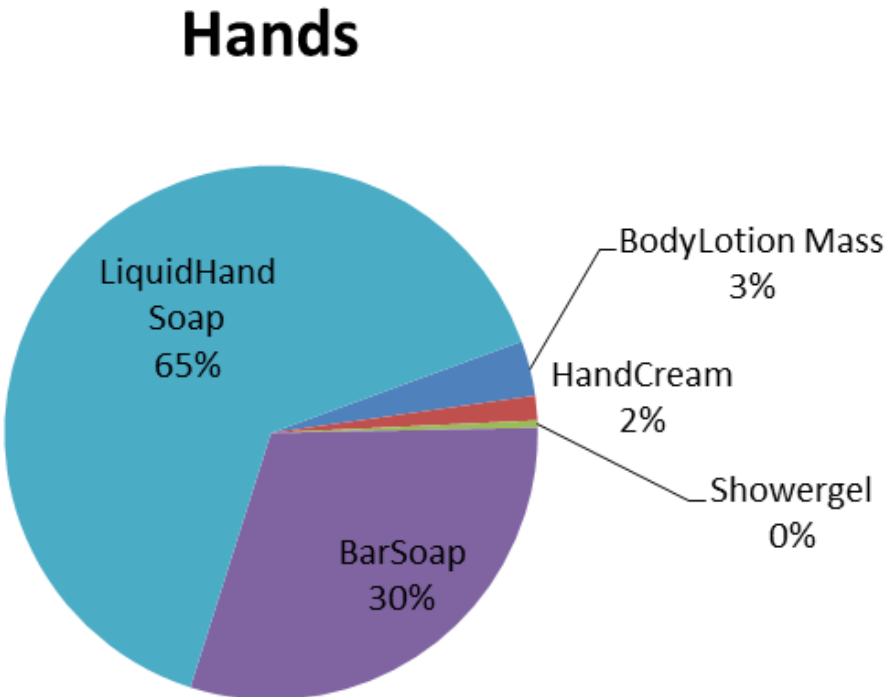
- Run current IFRA standards concentrations through the aggregate exposure model
- Apply new QRA SAFs
- Check $\frac{AEL_{Site}}{P95\left(CEL_{Agg\,(Site)}\right)} > 1$ for all application sites

Adjustment

- If the AEL/CEL < 1 for an application site

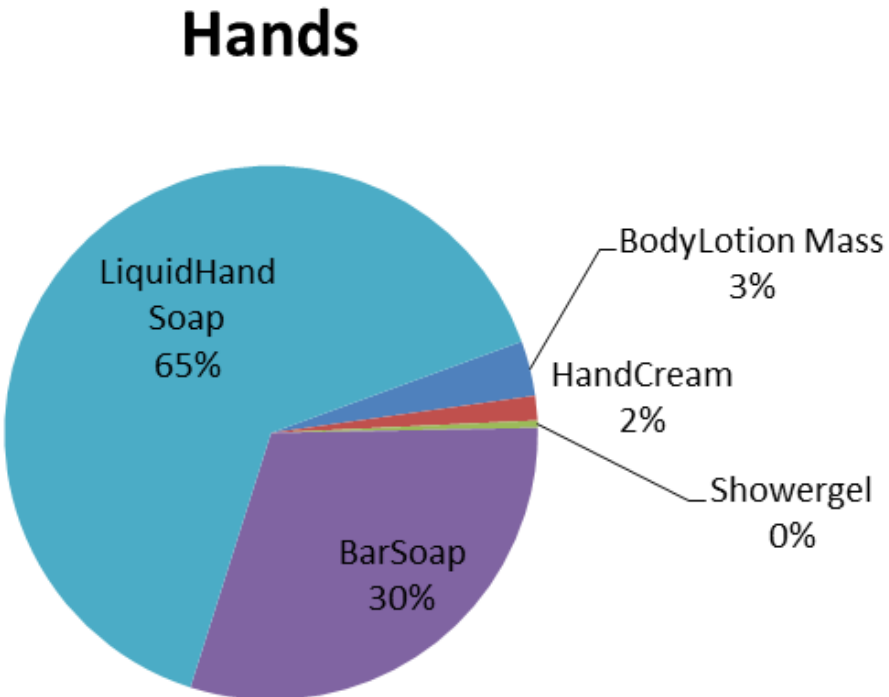
Adjustment

- If the AEL/CEL < 1 for an application site
- Analyse the products that contributed to aggregate exposure for that application site



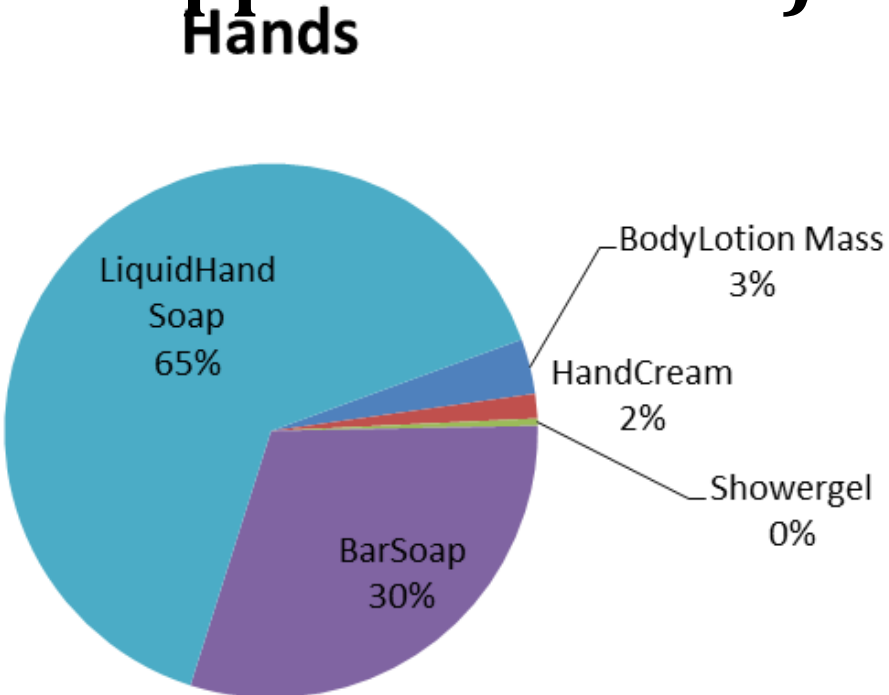
Adjustment

- Adjust (reduce) the concentration in those products with highest contribution to exposure for that application site



Adjustment

- Adjust (reduce) the concentration in those products with highest contribution to exposure for that application site
- **So that AEL/CEL > 1 for that site (and all application sites)**



In Summary

SAFs integrated into the Aggregate Exposure Model at the **Usage Event level**

$$AEL_{Site} = \frac{NESIL}{Interindividual\ SAF\ \times Site\ SAF}$$

$$CEL_{Site} = Exposure_{Site} \times Product\ SAF \times Frequency\ SAF$$

Ensure that:

$$\frac{AEL_{Site}}{P95\left(CEL_{Agg\ (Site)}\right)} > 1$$

For all application sites

(by adjusting concentrations in products if necessary)

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Ensure that:

$$\frac{AEL_{Site}}{P95\left(CEL_{Agg\ (Site)}\right)} > 1$$

For all application sites

(by adjusting concentrations in products if necessary)

There is more detailed data being put to work in the QRA II aggregate exposure and risk model.

These more detailed models and data will enable better decisions.

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14th May 2014