

Expert Models for Decision Makers TM

IDEA QRA Meeting

Cronan McNamara, CEO Creme Global March 2014



Creme Global - Services







Cloud Software

High Performance Technical Services Data Collection & Projects & Modelling

Expertise



Consumption Statistics	Expert Modelling	Food Safety	Flavourings & Fragrances
Nutrition Safety & Benefit	Additives	Packaging Migrants	Microbial Stability
Contaminants	Pesticides	Crop Science	Microbial Growth
Dose Response	Calories in vs. out	Cosmetics & Personal Care	High Performance Cloud Computing

Creme RIFM - Overview



- RIFM Creme Global
 - Partnership: Project Commenced in 2010
 - 3 Work Packages over Two Phases
- RIFM Creme Model
 - Aggregate Exposure Assessment
 - Fragrances and Flavorings
 - Dermal, Inhalation, Oral and Ingestion
 - Safety Factor Calculation



Creme RIFM Approach

Probabilistic NOT deterministic













World's Largest Survey











Online Consumption Diaries *Creme*



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

Personal Care Products



Body Lotion	Mass MarketPrestige
Deodorant	 Deodorant/Anti-Perspirant Spray Deodorant/Anti-Perspirant NonSpray Body Spray
Oral Care	ToothpasteMouthwash
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 MoisturizerHand Cream
Soaps	Liquid Hand SoapBar Soap
Air Care	Scented CandlesPlug-ins







Amount per use





Amount per Use



- Fitted / Empirical Distributions for Average Amount per Use
- Distributions can be matched back to main Consumption Diary based on Demographic

Study	Relevant Products
COLIPA	Body Lotion
(2005)	Deodorant (Spray)
	Deodorant (Non-Spray)
	Lipstick
	Face Moisturiser
	Shampoo
	Toothpaste
COLIPA	Hair Styling
(2009)	Hand Cream
	Liquid Foundation
	Mouthwash
	Shower Gel
Loretz, Api et al.	Lipstick
(2005)	Body Lotion
	Face Cream
Loretz, Api et al.	Spray Perfume
(2006)	Liquid Foundation
	Shampoo
	Bodywash
	Deodorant (Non-Spray)
	HairSpray
Loretz, Api et al.	Hair Conditioner
(2008)	
Private	LiquidHandSoap
	BarSoap





Fragrances and Mixtures Concentrations





RIFM Fragrances and Mixtures Concentrations



- Raw Data from Industry Partners
- Provides more realistic information on the ranges of Fragrance Concentrations







Dermal Retention Factors

- Retention Factors:
- Commonly used and are in SCCS Notes of Guidance
- Listed in Api et al. 2008
 "Dermal Sensitization QRA for Fragrance Materials"

Product	Retention Factor
BodyLotion (Mass, Prestige, Other)	100%
DeoSpray	100%
DeoRollOn	100%
BodySpray	100%
Toothpaste	10%
Mouthwash	1%
Lipstick	100%
LiquMakeupFoundation	100%
HairStyling	10%
EaudeToilette	100%
EaudeParfum	100%
AfterShave	100%
Showergel	1%
Shampoo	1%
RinseoffConditioner	1%
FaceMoisturizer	100%
HandCream	100%
HairSpray	10%
BarSoap	1%
LiquidHandSoap	1%





Anthropometric Data





Body Weight and Height



- Extract weight and height data from NHANES 07-08 survey:
- 8,861 US Subjects
- Build an empirical distribution for Body Weights and Heights for each Demographic Category separately.
- Use a scaling factor for European subjects.

Gender	Country	Age	Body Weight and Height
Male	France	18-24	Data(73.2, 181,)
Male	GB	18-24	Data(83.2, 170.2,)
Male	US	18-24	Data(81.3, 153.1,)

Surface Area of Body Parts



- EPA Exposure Factors Handbook Guidelines
- Dubois Formula:

SA = a x w^b x h^c w = bodyweight h = height a, b, c = constants (determined experimentally)

• EPA provide constants (a, b, c) for the following body parts:

Trunk	Head
Legs	Arms
Thighs	Upper Arms
Lower Legs	Forearms
Feet	Hands

Relative Body Surface Area



Make reasonable approximations based on known surface areas: e.g. Surface area of Scalp = $\frac{1}{2}$ Surface area of Head

Body Part	Surface Area	Reference
Scalp	1/2 Head	Shampoo (Api et al., 2008, Table 3)
Face	1/2 Head – (28.8cm ²)	Face washes, Eye Products, Lip Products (Api et al., 2008, Table 3)
Neck	1/10 Trunk	-
Chest	1/4 Trunk	-
Stomach	1/5 Trunk	-
Back	3/10 Trunk	-
Arms	Arms – (1/4 Hands)	-
Wrists	1/4 Hands	-
Palms	1/2 Hands	Shampoo (Api et al., 2008, Table 3)
IntimateParts	1/100 Total Body	Rule of Nines (O'Sullivan & Schmitz 2007, p. 1098, Fig 27.9)

Absolute Surface Areas



Body Part	Surface Area	Reference
Eyes	24cm ²	Eye Products (Bremmer et al., 2003)
Lips	4.8cm ²	Lip Products (Ferrario et al. 2000)
Mouth	212cm ²	Mouthwash, Lip Products (Collins and Dawes, 1987,
		Ferrario et al., 2000)
BehindEars	36cm ²	Discussion with project members
Underarms	200cm ²	(Bremmer 2006)



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











Creme







Daily Aggregate Exposure





Simulating the Total Population







Simulating the Total Population





Statistical Analyses




Statistical Analyses





Statistical Analyses





Acceptable and Actual Exposure



Based on the aggregate exposure for each body part, we can calculate the ratio a Acceptable Exposure Limit (AEL) and the aggregate Consumer Exposure Level (CEL) (Api et al., 2008). This ratio should be equal or greater than 1.

$$\frac{AEL_{BodyPart}}{CEL_{Aggregate}} \ge 1$$



Creme RIFM Fragrance Exposure Analysis





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Proxy setup

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6	bitset(12)	1	1_2007_2_0000095753	DeoRollOn	4		
7	bitset(7)	1	1_2007_2_0000095753	EaudeParfum	4		
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9	bitset(7)	2	1_2007_2_0000095753	EaudeParfum	4		
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18	bitset(15, 16)	3	1_2007_2_0000095753	BarSoap	2		
19	bitset(15, 16)	4	1_2007_2_0000095753	BarSoap	2		
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5	Product	RetentionFactorDermal	earrow RetentionFactorIngestion	RetentionFactorInhalation				
1	BodyLotionMass	1	0	0				
2	BodyLotionPrestige	1	0	0				
3	BodyLotionOther	1	0	0				
4	DeoSpray	0.235	0	0.2394				
5	DeoRollOn	1	0	0				
6	BodySpray	1	0	0				
7	Toothpaste	0.1	0.05	0				
8	Mouthwash	0.01	0.1	0				
9	Lipstick	1	0	0				
10	LiquMakeupFoundation	1	0	0				
11	HairStyling	0.1	0	0				
12	EaudeToilette	0.8	0	0.801258				
13	EaudeParfum	0.8	0	0.801258				
14	AfterShave	1	0	0				
15	Showergel	0.01	0	0				
16	Shampoo	0.01	0	0				
17	RinseoffConditioner	0.01	0	0				
18	FaceMoisturizer	1	0	0				
19	HandCream	1	0	0				
20	BarSoap	0.01	0	0				
21	LiquidHandSoap	0.01	0	0				
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2	50-64	EU	Female	1_2007_2_0000095761	France	11590.1	J
3	35-49	EU	Male	1_2007_2_0000096072	France	8094.98	
4	50-64	EU	Male	1_2007_2_0000096166	France	6174.76	
5	35-49	EU	Male	1_2007_2_0000096338	France	7758.51	
6	35-49	EU	Female	1_2007_2_0000096562	France	5413.56	
7	65+	EU	Male	1_2007_2_0000096760	France	13954.5	
8	50-64	EU	Male	1_2007_2_0000097248	France	6174.76	
9	50-64	EU	Male	1_2007_2_0000097413	France	6285.32	
10	35-49	EU	Male	1_2007_2_0000097435	France	8094.98	
11	50-64	EU	Male	1_2007_2_0000097446	France	6174.76	
12	25-34	EU	Male	1_2007_2_0000097603	France	6849.51	
13	35-49	EU	Male	1_2007_2_0000098089	France	7758.51	
14	18-24	EU	Female	1_2007_2_0000098397	France	2773.38	
15	50-64	EU	Male	1_2007_2_0000098682	France	12649.7	
16	35-49	EU	Male	1_2007_2_0000098686	France	7758.51	
17	25-34	EU	Male	1_2007_2_0000098814	France	6849.51	
18	25-34	EU	Female	1_2007_2_0000098998	France	6045.52	
19	65+	EU	Male	1_2007_2_0000099139	France	13954.5	
20	35-49	EU	Female	1_2007_2_0000099345	France	8893.99	
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New Assessment Wizard				23
	Select De	mographic		
Select Demographic	Region	Age Group		
Select Products	✓ EU	✓ 18 - 24		
Select Fragrances	✓ US	☑ 25 - 34		
Assessment Options	Gender	✓ 35 - 49		
Assessment Summary	🗹 Male	✓ 50 - 64		
	✓ Female	☑ 65+		

Number of Selected Subjects: 36446



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🍌 New Assessment Wizard

🖋 Select Demographic

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- ✓ Select Products
- Select Fragrances
 Select Body Parts
 Assessment Options
 Assessment Summary

Product Exposure Only (No Fragrances)				
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Select Fragrances

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Fragrance Name [CAS No.]	ĥ
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101-86-0	[101-86-0]	_
104-20-1	[104-20-1]	
🗌 104-54-1	[104-54-1]	
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🗆 115-95-7	[115-95-7]	
🗆 117-98-6	[117-98-6]	
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🗆 119-61-9	[119-61-9]	
121-32-4	[121-32-4]	
□ 121-33-5	[121-33-5]	
0 127-51-5	[127-51-5]	
138-86-3	[138-86-3]	
17511-60-3	[17511-60-3]	
18479-58-8	[18479-58-8]	
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Number of Fragrances Selected: 0

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- ✓ Select Products
- 💠 Select Fragrances Select Body Parts Assessment Options Assessment Summary

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Calculate Product Exposure

Number of Fragrances Selected: 3

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		119-61-9	[119-61-9]
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		121-33-5	[121-33-5]
		127-51-5	[127-51-5]
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		18479-58-8	[18479-58-8]
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		20298-69-5	[20298-69-5]
		23726-94-5	[23726-94-5]
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Number of Fragrances Selected: 3

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Number of Body Parts Selected: 18

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Advanced Options









Advanced Options

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🕂 Assessment Options			
Assessment Summary	► Choose cu	ustom Dermal Penetration and Retention tables	

▼ Advanced Options

Simulated population size:	36446	ĥ
Exposure types:	☑ Dermal Exposure (Absolute)	=
Exposure types:	☑ Dermal Exposure (Per Unit Surface Area)	-
	✓ Exposure (Absolute)	IU
	☑ Exposure (Per Unit Bodyweight)	
	✓ Ingestion Exposure (Absolute)	
	Ingestion Exposure (Per Unit Bodyweight)	
	✓ Inhalation Exposure (Absolute)	
	✓ Inhalation Exposure (Per Unit Bodyweight)	
Aggregation:	☑ Individual Products	~

🍌 New Assessment Wizard

	23

		Assessment Summary			
🖋 Select Demographic	Region:	EU. US		16	ì
V Select Products	Gender:	Male, Female			
🖋 Select Fragrances	Age Group:	18 - 24			
🖋 Select Body Parts		25 - 34 35 - 49			
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🕂 Assessment Summary		65+			
	Product(s):	Product Name	â		
		BodyLotionMass	U		
		BodyLotionPrestige			
		BodyLotionOther			
		DeoSpray			
	Fragrances source:	Default Fragrances			
	Fragrance(s):	Fragrance Name [CAS No.]			
		100-52-7 [100-52-7]			
		104-55-2 [104-55-2]		IU	J
		138-86-3 [138-86-3]			
	Rody part(s);				
	body part(s).	Body Part Name	â		
		Scalp	U		
		Face			
		Eyes			
		Lips	J		
	Retention source:	Default Retention Factors			
	Dermal Penetration source:	Default Dermal Penetration Factors			
	Name:	New Assessment			,

Your assessment has been submitted.

OK

Creme RIFM Fragrance Exposure Analysis					
<u>File E</u> dit <u>G</u> o <u>A</u> ctions <u>H</u> elp				Acco	unt Settings (user3)
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Body Part: Total Body V Fragrance / Product: 100-52-7 [100-52-7] V Calculation Type: Acute (Max Day) V Exposure Type: Total Body (Systemic, Per Unit Bodyweight) V

	Product	V Consumer Type	V Statistic	🛛 Value	Units	Standard Error
4539	BodyLotion	All Population	P95	0.0508	µg/kg	0.0060
2475	Deodorant	All Population	P95	0.0697	µg/kg	0.0055
2460	OralCare	All Population	P95	0.0167	µg/kg	0.0009
5664	CosmeticStyling	All Population	P95	0.0111	µg/kg	0.0013
1977	Hydroalcoholics	All Population	P95	0.3685	µg/kg	0.0179







Body Part: Total Body Inhalation ~

Fragrance / Product: 100-52-7 [100-52-7] V Calculation Type: Acute (Max Day) V Exposure Ty

Exposure Type: Total Body (Inhalation, Per Unit Bodyweight) 🗸

	Product	Y Consumer Type	Y Statistic	🛛 Value	Units	Standard Error		Select All			
1140	BodyLotionMass	All Population	P95	0.0000	µg/kg	0.0000		By Body Part (Dermal, Per Unit Surface Area)			â
1122	BodyLotionPrestige	All Population	P95	0.0000	µg/kg	0.0000		Total Body (Ingestion) Total Body (Ingestion, Per Unit Bodyweight)			J
1128	BodyLotionOther	All Population	P95	0.0000	µg/kg	0.0000		 Total Body (Inhelation) 	_		
5322	DeoSpray	All Population	P95	0.0013	µg/kg	0.0001		• Total Body (Inhalation, Per Unit Bodyweight)	=		
1116	DeoRollOn	All Population	P95	0.0000	µg/kg	0.0000		 Total Body (Systemic) 			Ŷ
							 Total Body (Systemic, Per Unit Bodyweight) 	Ŷ)	_	






Body Part: Face 🗸

Fragrance / Product: 100-52-7 [100-52-7] V Calculation Type: Acute (Max Day) V

Exposure Type: By Body Part (Dermal, Per Unit Surface Area) ~

Select <u>A</u> ll		ner Type	Y	Statistic	🍸 Value	Units	Standard Error	Select All	
🔾 Scalp	Â		005		0.0000		0.0000	O By Body Part (Dermal)	
⊙ Face	Ξ		-35		0.0000	µg/cm-	0.0000	 By Body Part (Dermal, Per Unit Surface Area) 	
O Eyes	U	n	P95		0.0000	µg/cm²	0.0000	O Total Body (Ingestion)	
O Lips		n	P95		0.0000	µg/cm ²	0.0000	○ Total Body (Ingestion, Per Unit Bodyweight)	
 Mouth 		n	P95		0.0000	µg/cm ²	0.0000	 Total Body (Inhalation) 	
O Neck		n	P95		0.0000	µg/cm ²	0.0000	 Total Body (Inhalation, Per Unit Bodyweight) 	J
 BehindEars 	v							 Total Body (Systemic))



Product: All Assessed Products V Fragrance / Product: 100-52-7 [100-52-7] V Calculation Type: Acute (Max Day) V Exposure Type: By Body Part (Dermal, Per Unit Surface Area) V

5	🛛 Body Part	Consumer Type		🍸 Value 1 🔨	Units	Standard Error							
2847	Underarms	All Population	P95	0.0173	µg/cm ²	0.0014		â					
5325	Palms	All Population	P95	0.0167	µg/cm ²	0.0006		U					
2343	Neck	All Population	P95	0.0104	µg/cm ²	0.0004							
5094	Hands	All Population	P95	0.0081	µg/cm ²	0.0005							
6702	Scalp	All Population	P95	0.0069	µg/cm ²	0.0002							
150/	RehindFare	All Dopulation	D05	0.0055	uniom2	0.0005		Ľ					

Example - Vanillin



*∢*Creme

Vanillin – Approximate relative contribution to P95 aggregate exposure



Example - PEA

PEA - All Population - P95 Total Body (Systemic, Per Unit Bodyweight)



Creme

Example - PEA



PEA – Approximate relative contribution to P95 aggregate exposure



Inhalation Exposure – Limonene^{Creme}



BaSo: BarSoap LHS: LiquidHandSoap HaSp: HairSpray AFA: AirFreshAerosol AFP: AirFreshPlugin SC: ScentedCandles BL: BodyLotion D: Decolorant OC: OralCare CS: CosmeticStyling H: Hydroalcoholics SP: ShowerProducts Moi: Moisturizers S: Soaps AC: AirCare All: All Assessed Products

Ingestion Exposure - Limonene *Creme





Dermal Exposure per Surface Area (BarSoap) - Limonene





Total Exposure (per unit BW) - Limonene





Total Exposure (per unit BW) - Limonene





Expert Models for Decision Makers TM

Thank you

Cronan McNamara CEO, Creme Global



Expert Models for Decision Makers TM

Thank you

Cronan McNamara CEO, Creme Global



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Thank you

Cronan McNamara CEO, Creme Global