

***Webinar:
Exposure-based screening tool for
contaminants in spices***

Exponent, Inc.

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Webinar Outline

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- Brief overview of the risk characterization framework and a dietary exposure assessment
- Description of screening tool
 - Objective
 - Approach
 - Framework
 - Data
- Tool Demo: Lead in cinnamon/cassia as a case study

Risk characterization framework

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- **Risk assessment is typically a four-step process**
 - Hazard identification
 - ✓ Hazard characterization (dose-response assessment)
 - ✓ Exposure assessment
 - ✓ Level of contaminant in food x consumption rate
 - ✓ Risk characterization
 - ✓ Comparison of exposure to dose-response

Dietary exposure assessment

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$$\begin{array}{|c|} \hline \text{Estimated daily exposure} \\ \text{to contaminant from} \\ \text{Food A} \\ \text{(ug/day or ug/kg bw/day)} \\ \hline \end{array}
 =
 \begin{array}{|c|} \hline \text{Level of contaminant} \\ \text{in Food A} \\ \text{(e.g., ug lead/g food)} \\ \hline \end{array}
 \times
 \begin{array}{|c|} \hline \text{Daily consumption of} \\ \text{Food A} \\ \text{(g food/day or} \\ \text{g food/kg bw/day)} \\ \hline \end{array}$$

- Typically, conservative assumptions are applied:
 - High-end consumer of Food “A” (e.g., 90th percentile consumer)
 - Assume 100% of the food item consumed by a consumer contains the contaminant
 - Often based on just two days of dietary recall to reflect long-term chronic consumption patterns
- Dietary exposure estimate is compared to regulatory threshold (i.e. “safe” exposure limit, e.g. ADI, IRL, TDI, RfD, etc.)

Proposition 65 exposure assessment

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$$\begin{array}{|c|} \hline \text{Estimated daily} \\ \text{exposure to} \\ \text{contaminant from} \\ \text{Food A (ug/day)} \\ \hline \end{array}
 =
 \begin{array}{|c|} \hline \text{Level of contaminant} \\ \text{in Food A} \\ \text{(e.g., ug lead/g food)} \\ \hline \end{array}
 \times
 \begin{array}{|c|} \hline \text{Daily} \\ \text{consumption of} \\ \text{Food A} \\ \text{(g food/day)} \\ \hline \end{array}$$

- Average consumer of Food A
- Assume 100% of the food item consumed by a consumer contains the contaminant
- Often incorporates a frequency component to reflect long-term chronic consumption patterns
- Dietary exposure estimate is compared to Proposition 65 Safe Harbor levels

Spice Screening Tool: Objective

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- Develop a dietary exposure screening tool for contaminants in dried spices
- Current tool incorporates:
 - 5 spices
 - 1 contaminant
- Allow risk assessors and managers to rapidly evaluate potential risks that may be associated with contaminants in select spices
 - Set aside detections that are not of public health concern or
 - Identify those that warrant further assessment with more refined data

Screening tool: Approach

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- Use readily available data and simple models
- Exposure-based
- Conservative assumptions are intentional and deliberate
- If exceedance, refined risk assessments are needed to support decision making process

Screening tool: Framework

Composed of three key elements of a dietary risk assessment:

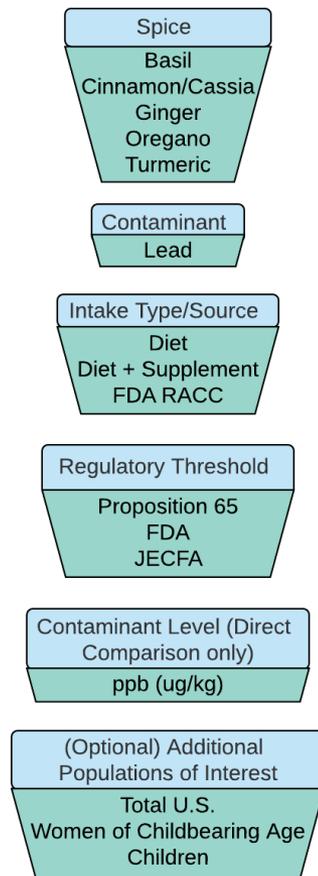
Step 1	Hazard characterization	Populated with default regulatory threshold limits for lead
Step 2	Dietary exposure assessment	Screening-level dietary exposure estimates based on a two parameter model: a) Contaminant level in spice of interest b) Amount of spice consumed (diet, diet + supplement)
Step 3	Risk characterization	Dietary exposure estimates are compared to regulatory thresholds

Screening tool: Data

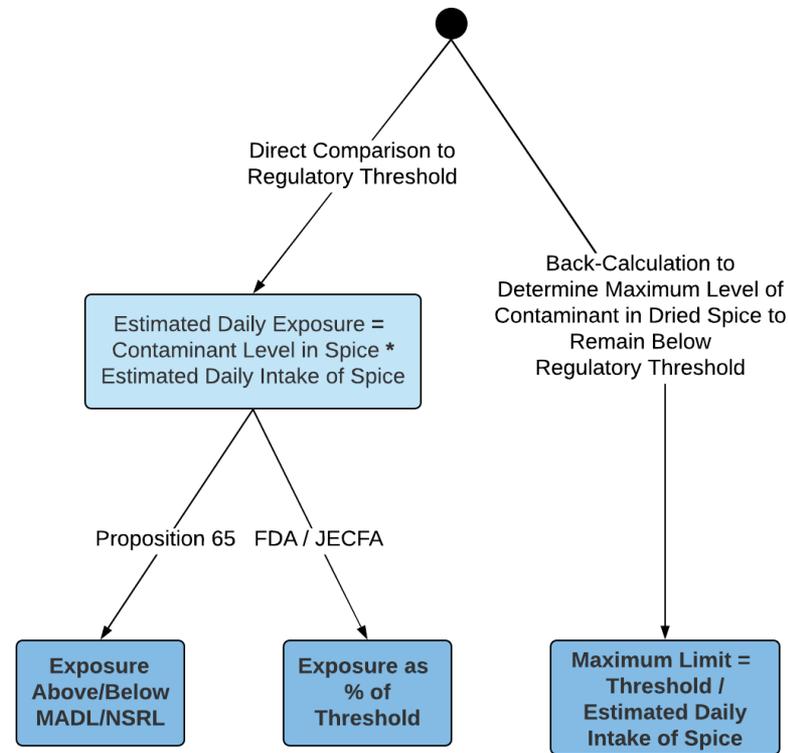
- Regulatory Thresholds
 - Based on review from authoritative bodies including FDA, EPA, JECFA, EFSA, OEHHA
- Spice consumption data
 - Estimated intakes: NHANES 2013-2016
 - Diet: utilizes recipes to estimate intake of spices within foods
 - Diet + Dietary supplement: includes reported use of dietary supplements containing select dried spices
 - Two-day average consumption (g/day) in 24-h dietary recalls
 - Per user mean, 90th, 95th, and 99th percentile intakes estimated for Total U.S. Population and select subpopulations
 - Default serving: FDA RACC (0.5 g RACC)
 - Consumption and threshold data are based on most current available data – should be updated over time.

Screening tool: Schematic

User-Specified Inputs:



Screening Evaluation:



Tool Demo

- Example: Lead in cinnamon/cassia
 1. Analytical results show there to be 1 ppm (1000 ppb) lead in ground cinnamon
 - Does this level exceed the Proposition 65 Safe Harbor threshold for lead in ground cinnamon?
 - What percentage of the Interim Reference Level (IRL) set by the US FDA is the estimated daily exposure to lead from consumption of ground cinnamon among children?
 2. What is the maximum lead level that could be in the dried spice and remain below the Proposition 65 MADL for lead?

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Regulatory thresholds for lead in food

Lead (CASRN 7439-92-1) Regulatory Threshold Table

<u>Authoritative Body</u>	<u>Threshold Type</u>	<u>Subpopulation of Interest</u>	<u>Threshold Level</u>	<u>Units</u>	<u>Regulatory Agency</u>
California's Proposition 65	MADL	Total population	0.5	µg/day	OEHHA
California's Proposition 65	NSRL	Total population	15	µg/day	OEHHA
US FDA	Interim Reference Level (IRL)	Children	3	µg/day	FDA
		Adults including pregnant women	12.5	µg/day	FDA
JECFA	PTWI (withdrawn)	Total Population	25	µg/kg bw/week	JECFA