

**PFAS in Food Packaging AA  
Hazard Assessment Summary:  
Methodology & Decision Rules  
DRAFT**

October 3, 2019

# What will be assessed?

- PFAS Base-case
- Alternative process treatments providing OGR properties
- Polymers (barrier coatings and base materials)
- Functional additives (e.g. sizing agents, dispersants, etc.)
- Degradation products
- Monomers >0.01%
- Byproducts >0.01%
- Base materials consisting of paper, paperboard, plant-based pulp, and aluminum are assumed to be low concern and **will not** undergo Level 2 Hazard Assessment

# How will it be assessed?

- Tiered approach:
  - GreenScreen<sup>®</sup> List Translator scores of LT-1
    - High concern and **will not** undergo Level 2 Hazard Assessment
  - Substances on the U.S. EPA Safer Chemical Ingredients List (SCIL) (Green Circle only)
    - Low concern and **will not** undergo Level 2 Hazard Assessment
  - Substances not meeting the above will undergo Level 2 Hazard Assessment

# Level 2 Hazard Assessment Methodology

| IC2 Hazard Assessment Level 2 Endpoints |  |   |
|---|--|---|
| <b>Human Health</b>                     | Carcinogenicity  | <p><a href="#">DfE AA Criteria v2.0</a> (discrete substance and polymers MW&lt;1000; polymers MW&gt;1000 supplemented with <a href="#">SF Polymer Guidance</a>)</p> <p><u>Endpoints are categorized as:</u></p> <p>Very High</p> <p>High</p> <p>Moderate</p> <p>Low</p> <p>Very Low</p> |
|   | Mutagenicity & Genotoxicity  |   |
|   | Reproductive toxicity  |   |
|   | Developmental toxicity (including developmental neurotoxicity)     |   |
|   | Endocrine activity   |   |
|   | Acute mammalian toxicity   |   |
|   | Systemic toxicity (repeat dose toxicity, including immunotoxicity) |   |
|   | Neurotoxicity  |   |
|   | Skin sensitization   |   |
|   | Respiratory sensitization  |   |
| <b>Ecological</b>                       | Acute aquatic toxicity   |   |
|   | Chronic aquatic toxicity   |   |
| <b>Environmental Fate</b>               | Persistence  |   |
|   | Bioaccumulation  |   |
| <a href="#">Physical*</a>               | Flammability   |   |
|   | Reactivity   |   |

\*Corresponding to GHS hazards for explosives, self-reactive substances, substances which on contact with water emit flammable gases, oxidizing gases, oxidizing liquids & solids, organic peroxides, self-heating substances, and substances corrosive to metal.

# Hazard Assessment Decision Rules

## High Concern (Red):

- H or VH (CMR)
  - Carcinogenicity
  - Reproductive toxicity
  - Developmental toxicity (including developmental neurotoxicity)
  - Genotoxicity
- H or VH Acute toxicity, repeat dose toxicity, or neurotoxicity
- H – Endocrine activity
- VH Aquatic toxicity
- VH/H Persistence AND VH/H Bioaccumulation AND VH/H Aquatic toxicity
- VH Bioaccumulation AND VH Toxicity
- VH or H Physical hazard

## Moderate Concern (Orange):

- M (CMR)
  - Carcinogenicity
  - Reproductive toxicity
  - Developmental toxicity (including developmental neurotoxicity)
  - Genotoxicity
- M or L Acute toxicity, repeat dose toxicity, or neurotoxicity
- M – Endocrine activity
- H Aquatic toxicity AND M Persistence
- M Aquatic toxicity AND M Persistence
- VH Bioaccumulation AND VH Toxicity
- M Physical hazard

## Low Concern (Green):

- L (CMR)
  - Carcinogenicity
  - Reproductive toxicity
  - Developmental toxicity (including developmental neurotoxicity)
  - Genotoxicity
- L - Acute toxicity, repeat dose toxicity, or neurotoxicity
- Low – Endocrine activity
- H Aquatic toxicity AND VL/L Persistence
- M Aquatic toxicity AND VL/L Persistence
- L Bioaccumulation
- L Physical hazard

# Data Needs

- See Draft Hazard Assessment Methodology document, Section 4
- A stakeholder template covering the hazard and exposure data needs that can aid in the data sharing is under development. Please stay tuned!