

Washington State PFAS in Food Packaging AA – Hazard Assessment Approach (03-18-2020)

Note: This Hazard Assessment Approach supersedes the approach dated October 2019

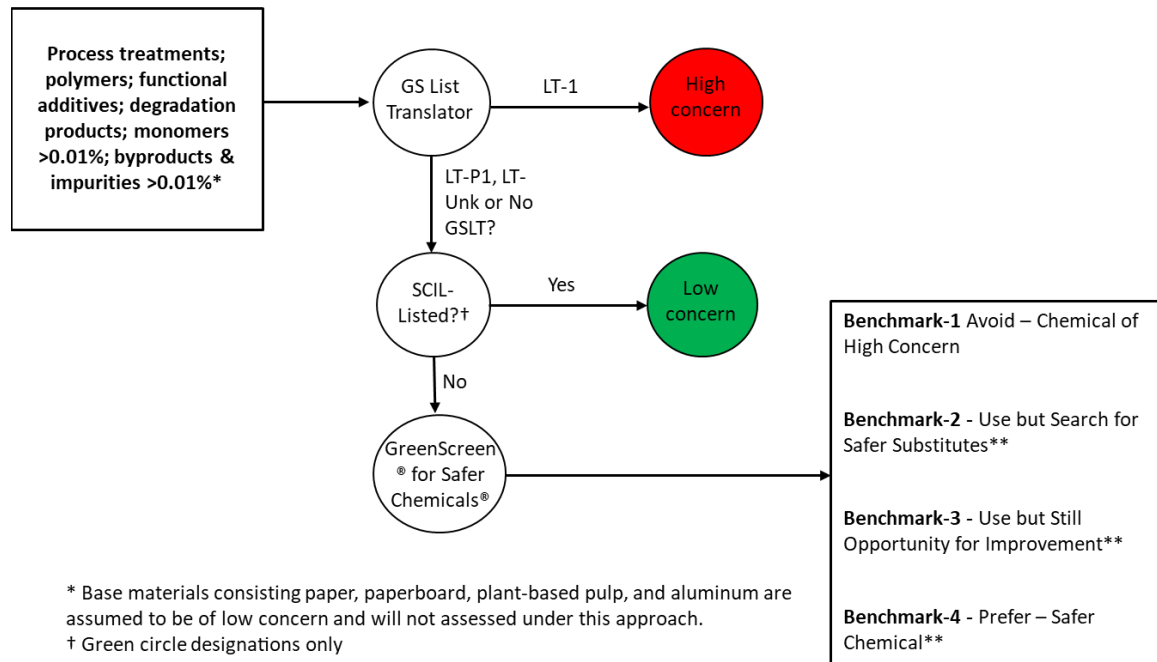
1. Tiered Approach to Hazard Assessment

As mentioned in the [May 2019 Stakeholder Webinar](#), alternatives can be roughly categorized into 3 groups: process treatments, base materials, system alternatives. For the purposes of this project, these are defined as:

- **Process treatments:** dry-end coatings or wet-end additives that are applied to the base material to provide oil and grease repellent properties to the product.
- **Base materials:** the primary substrate (paper, paperboard, fiber pulp, plastics, and aluminum), treated (including mechanical densification) or untreated.
- **System alternatives:** alternatives that provide the desired function but are not process treatments or base material alternatives. The primary system alternative for the PFAS in Food Packaging AA is reusable packaging and service ware.

SRC is recommending a tiered approach to assess these substances in a way that will ensure efficiency of project resources, reduction of redundancy, and consistency with IC2 Guidelines. This approach incorporates previous assessments and methods such as the [GreenScreen® List Translator](#), the [Safer Chemical Ingredients List \(SCIL\)](#), and other publicly available, high-quality assessments. This tiered assessment approach is outlined in Figure 1.

Figure 1. Tiered Hazard Assessment Approach for Substances Undergoing Hazard Evaluation



* Base materials consisting paper, paperboard, plant-based pulp, and aluminum are assumed to be of low concern and will not be assessed under this approach.

† Green circle designations only

** Benchmarks 2-4 are not automatically assumed to be safer alternatives. Ecology may further clarify safer alternatives based on the hazard information and how it compares to the PFAS base-case.

The [GreenScreen® List Translator](#) calculates a hazard score based on a set of authoritative lists that identify chemicals known to have human and ecological hazard concerns. These designations correspond to GreenScreen® criteria, and for the purposes of this assessment, any process treatment, base material, polymer, functional additive, and byproduct or monomer present at >0.01% with a List Translator score of “LT-1” will be designated a high concern and will not proceed to a Level 2 hazard assessment.

The Safer Chemical Ingredients List (SCIL) contains chemicals that meet the Safer Choice standard criteria, which is a hazard-based standard that is very similar to GreenScreen®. These designations are based on data-driven assessments that are verified by the U.S. EPA. To be conservative, only SCIL designations of “green circle” will be used in this assessment. SCIL chemicals designated as “half-green circle” or “yellow triangle,” having specified use-restrictions, or those listed under Specialized Industrial Products (SIP) *will not* be considered supportive of low concern designation and will be assessed via Level 2 hazard assessment methodology.

Base materials consisting of paper, paperboard, and pulp sourced from plant materials will not be evaluated under a Level 2 hazard characterization as these substances are cellulosic materials that are of generally low concern. Aluminum is another alternative base material that will not be evaluated under a Level 2 hazard characterization. Aluminum metal has been studied extensively in humans and animals and is generally considered to be of low concern to the general population. There has been a weak association of aluminum with Alzheimer’s disease, but this association is “highly controversial and there is little consensus regarding current evidence” (ATSDR, 2008). Gastrointestinal absorption is generally low, ranging of 0.1-0.4% in humans, although this varies depending on the chemical form (ATSDR, 2008).

2. Level 2 Hazard Assessment Methodology

The hazard assessment portion of this AA will comply with a Level 2 assessment under IC2 guidelines, which specifies a [GreenScreen® for Safer Chemicals®](#) (*herein GreenScreen®*). All target substances, including the chemical of concern and candidate alternatives, will be evaluated against the hazard assessment methodology, as well as residuals >0.01%, byproducts or impurities >0.01%, functional additives, and potential breakdown products. As per IC2 guidelines, the endpoints required for a Level 2 assessment include the following:

IC2 Level 2 Hazard Assessment & GreenScreen® Endpoints		
Group I Human health endpoints	Carcinogenicity	GreenScreen® for Safer Chemicals®
	Mutagenicity & Genotoxicity	
	Reproductive toxicity	
	Developmental toxicity (including developmental neurotoxicity)	
	Endocrine activity	
Group II Human health endpoints	Systemic toxicity (repeat dose toxicity, including immunotoxicity)	
	Neurotoxicity	
	Acute mammalian toxicity	

	Eye irritation	
	Skin Irritation	
	Skin sensitization	
	Respiratory sensitization	
Ecotoxicity	Acute aquatic toxicity	
	Chronic aquatic toxicity	
Environmental Fate	Persistence	
	Bioaccumulation	
Physical*	Flammability	
	Reactivity	

GreenScreen® has documented, transparent, and peer-reviewed methodologies for various types of substances including organic chemicals, inorganic chemicals, and polymeric substances. The GreenScreen® criteria helps to identify safer alternatives by evaluating the relevant hazard data related to human health, ecological health, environmental fate, and physical hazards. A method for interpreting data gaps is built into this method, including assigning a chemical a Benchmark U (unknown) if there are inadequate data to characterize the chemical under the benchmark criteria.

Ecology will compare the benchmark criteria under GreenScreen® to support the identification of a safer alternative to PFAS in food packaging. Ecology will also consider whether the hazard profile for the candidate alternatives ensures that the endpoints of concern for PFAS have been adequately addressed by reducing or alleviating the hazard concern for those endpoints. It's possible that an alternative with an improved benchmark score may not be selected as a safer alternative (Ecology and Health 2008). Ecology will provide rationale for any instances where an improved benchmark score does not equate to the designation of a safer alternative.

3. Data Needs (for Stakeholders)

To conduct a credible and defensible hazard assessments on substances that meets the goals of this project, additional information regarding the alternatives substances is required. Whenever possible, Ecology will utilize publicly available information. In order to fill gaps in the public dataset, Ecology may request voluntary disclosure from product manufacturers. Stakeholders may submit this information via a CBI disclosure. Please see the [PFAS AA CBI Request Template.docx](#) and [PFAS CBI Submission Process.docx](#) for further information.

1. Substance identification:
 - a. Product formulation disclosure, including:
 - i. Active ingredient (substance providing oil/grease-proofing function)
 - ii. Functional additives
 - iii. Known residual monomers or oligomers (>100 ppm or 0.01%)
 - iv. Known byproducts or impurities (>100 ppm or 0.01%)
 - b. Should include at a minimum a CAS RN and systematic chemical name for each formulation component.

- c. Chemical structure (SMILES, image). At the very least, one that could be easily derived from a CAS RN and chemical name.
- d. For polymeric substances, the following additional information are also required:
 - i. Representative structure
 - ii. Mole ratios of monomers
 - iii. Indication as to whether the monomers are blocked
 - iv. MW_n (molecular weight average)
 - v. Oligomer characterization:
 1. %MW <1000
 2. %MW <500
2. Experimental studies that address the endpoints for the hazard assessment (see table above Section 1).
 - a. The substance evaluated in these studies should be sufficiently characterized as per Section 3.1.
3. **A special note about Safety Data Sheets (SDS):** SDS's submitted by stakeholders will be reviewed for data adequacy and relevancy. These documents may be helpful in characterizing test substance identity, physical hazards associated with product handling, and accidental poisoning concerns. SDS's typically lack the necessary details to evaluate hazard endpoints in accord with IC2 Level 2 guidelines.

4. Data Reporting

The completed GreenScreen assessments will be publicly available. This includes the Benchmark score, Hazard Summary Table, and the summary of hazard classifications.

References:

ATSDR (2008) Toxicological profile for aluminum. Atlanta, GA. Agency for Toxic Substances and Disease Registry. Available at: <https://www.atsdr.cdc.gov/ToxProfiles/tp.asp?id=191&tid=34>

Ecology and Health (2008) Alternatives to Deca-BDE in Televisions and Computers and Residential Upholstered Furniture. Department of Ecology Publication No. 09-07-041. Department of Health Publication No. 334-181

GreenScreen® for Safer Chemicals®. Guidance and Resources. Available at:

<https://www.greenscreenchemicals.org/learn/guidance-and-method-documents-downloads>