Safer Products for Washington | Phase 3
Working Draft Criteria for Safer

Introduction

Revised Code of Washington (RCW) 70A.350[1] requires the Departments of Ecology and Health ("we") to identify safer alternatives to priority chemicals before proposing a restriction under the Safer Products for Washington program.[2]

Safer is defined in the law as "**less hazardous** to humans or the environment than the existing chemical or process." Risk is a combination of hazard and exposure. **To implement this law, we focus on reducing risk by reducing hazards.**

Once hazardous chemicals are in consumer products, reducing exposure is challenging. It is hard to predict how people will use consumer products and what they'll do with them when they're done. Contamination from hazardous chemicals in consumer products can result in those chemicals contaminating our communities, wildlife, and environmental resources.

If we can reduce the use of hazardous chemicals in consumer products by using safer alternatives, we have the opportunity to reduce exposure across the product lifecycle—from manufacturing to disposal or reuse. That means less exposure now and less cleanup later on.

To identify safer alternative chemicals, the Safer Products for Washington team proposes we use adaptable, hazard-based criteria outlined in this document. Safer alternatives may also be alternative products or processes. These criteria focus on how we identify safer alternative chemicals that function like priority chemicals. We will use the criteria to determine whether an alternative chemical is safer than the priority chemical class used in the priority product. The **minimum criteria for safer** is a baseline set of hazard criteria. In most cases, alternatives that meet the minimum criteria for safer are less hazardous than the priority chemical class. In certain cases, an alternative may need to meet **additional criteria** for us to ensure it is less hazardous than the priority chemical class.

This approach is based on the concept that "safer" is a spectrum and a continuous improvement process (Figure 1). Just because an alternative is safer than the priority chemical doesn't mean there isn't room for improvement.

Figure 1. The spectrum of safer showing progress from hazardous chemicals to optimal chemicals.

If you have questions about the criteria outlined here or about the Safer Products for Washington program, contact us at SaferProductsWA@ecy.wa.gov.

[1] https://app.leg.wa.gov/rcw/default.aspx?cite=70A.350
[2] https://www.ezview.wa.gov/site/alias__1962/37555/safer_products_for_washington.aspx

Outline

This document outlines how the Safer Products for Washington program will identify chemical alternatives that are safer than priority chemicals. First, we outline our approach for identifying safer chemical alternatives. We then review the process we used to develop our criteria, and detail the criteria for safer, including:

- Section 1.0 on data requirements.
- Section 1.1 overview of the criteria for safer, including minimum, additional, and within-class criteria.
- Section 1.2 describing the hazard endpoints scoring.

The four appendices include supplemental information to support the criteria:

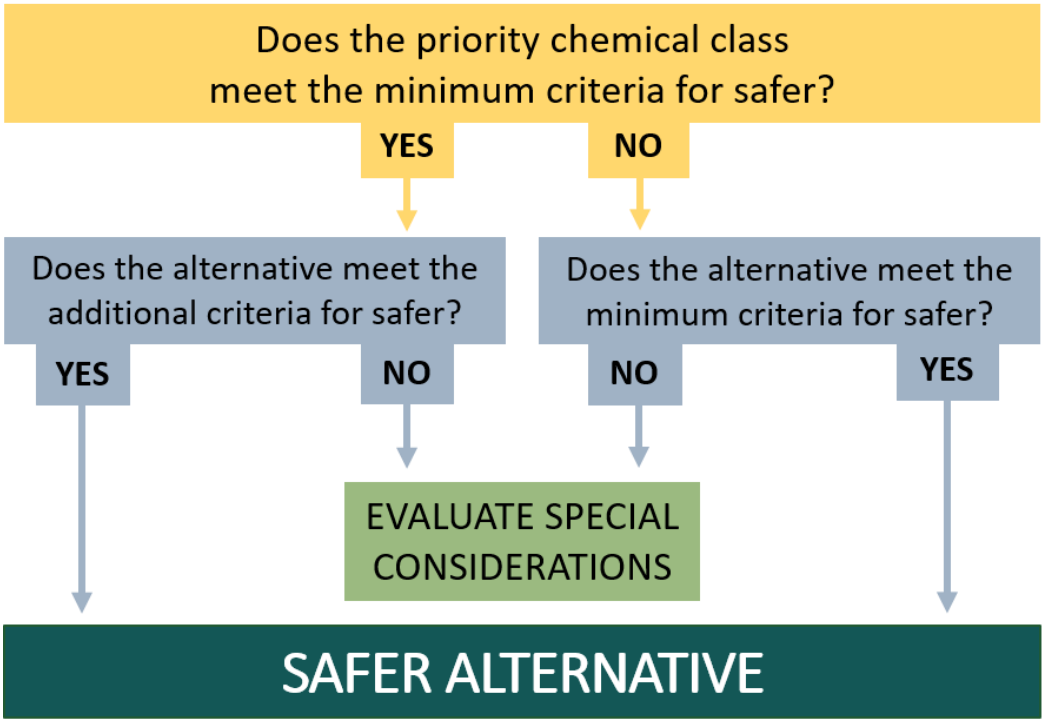
- Appendix 1 outlines the endpoint scoring approach in the GreenScreen® method.
- Appendix 2 includes the references we reviewed to develop our criteria.
- Appendix 3 includes a brief overview of each hazard assessment methodology we used to develop our criteria.

Approach for identifying safer chemical alternatives

We identify safer alternative chemicals to the priority chemical class based on whether they meet specific hazard criteria. Safer alternatives may also be **alternative products or processes**. This criteria focuses on how we identify safer **alternative chemicals**.

In this process, we evaluate the priority chemical class to determine whether the alternative chemical needs to meet the minimum or additional criteria for safer. If we identify an alternative chemical that meets the appropriate criteria for safer, it is a safer alternative. In some cases, alternative and priority chemical classes may have similar hazards levels, meaning we will include additional considerations in our evaluation. Figure 2 shows this process.

Figure 2. Overview of the general process we use to determine whether alternatives are safer than the priority chemical class. (This process assumes the priority chemical class does not meet the additional criteria for safer.)



Process overview: Does the alternative chemical need to meet the minimum or additional criteria for safer?

To safer alternatives, we need to determine whether the alternative chemical must meet the minimum or additional criteria for safer. To answer this question, we first determine if a priority chemical class meets or fails to meet our minimum criteria for safer. *See our explanation below for how we assess chemicals as a class.*

If a priority chemical class fails to meet our minimum criteria for safer, then the alternatives that do will be considered safer. Conversely, if a priority chemical class meets our minimum criteria for safer, then we must find alternative chemicals that meet the additional criteria to be considered safer.

This process can be broken down as follows:

- Does the priority chemical class meet the minimum criteria for safer?
    - If No, then we ask, Does the **alternative meet or exceed the minimum criteria** for safer?
        - If Yes, then it's safer.
        - If No, then we evaluate special considerations.
    - If Yes, then we ask, Does the **alternative chemical meet the additional criteria** for safer?
        - If Yes, then it's a safer alternative.
        - If No, then we evaluate special considerations.

This approach assumes priority chemical classes will not meet the additional criteria for safer. It is unlikely that a priority chemical class would both qualify as a priority chemical in the law and meet the additional criteria for safer.

How do we assess chemical classes?

Our process begins by determining whether the priority chemical class meets the minimum criteria for safer. We do this by considering hazard characteristics of chemicals within the priority chemical class to assess whether the class meets our minimum criteria for safer. The Washington State Legislature identified the priority chemical classes for our first Safer Products for Washington cycle, and included them in the statute.

There are many benefits to evaluating chemical classes as a whole. Evaluating chemicals by class avoids the problem of treating chemicals with insufficient data as not hazardous. A class approach can prevent regrettable substitutions of other chemicals in the class with equal hazard. It can also address cumulative impacts from chemicals in the class. The National Academy of Sciences (The Academy) describes these benefits further in its 2019 report on approaching flame retardants as a class (NAS, 2019).

The Academy (NAS, 2019) lays out four potential scenarios for assessing chemicals by class:

1. Data rich chemicals.
2. Data poor chemicals.
3. A mix of data rich and data poor chemicals.
4. Chemicals with variable or discordant data with response to biological activity.

It is unlikely that a class of data poor chemicals would meet the criteria to be priority chemicals under the Safer Products for Washington program. Therefore, scenarios 1, 3 and 4 are the most relevant to our work implementing this law.

- In scenario 1, taking a class-based approach to data rich chemicals is relatively straight forward.
- In scenario 3, there are sufficient data to assess one or two chemicals in the class, but no data on other chemicals. In this situation, the data available suggest that members of the class have similar biological activity. In this scenario, The Academy proposes an option for making a science-based policy decision to classify the class as potentially hazardous based on the data rich chemicals.
- In scenario 4, the data available suggest the class shows variable biological activity. Decision-making options in scenario 4 include making a policy decision based on the most conservative conclusion, or reclassifying the members in a less discordant way.

The NAS report (NAS, 2019) focuses on identifying chemical classes for a cumulative risk assessment. This often requires an understanding of whether the chemicals in the class impact the same biological pathways, which can make grouping these chemicals challenging. In contrast, our goal under Safer Products for Washington is to determine whether the chemical class meets or fails to meet our minimum criteria for safer.

We propose using, but slightly modifying, the NAS decision framework described above, to fit the hazard-based approach of Safer Products for Washington. We do not anticipate performing an

exhaustive review of all data from the priority chemical class. Instead, we will base our review on several chemicals with sufficient data in the class.

In some cases, the chemicals in the class are similar (NAS Scenario 3) in that they fail to meet our minimum criteria for safer, but some chemicals are poorly characterized. In these instances, we will make a science-based policy decision to classify the class as potentially hazardous based on the data rich chemicals, and to identify alternatives that meet the minimum criteria for safer.

In cases of wide variability (NAS Scenario 4) in the hazard within the class, where some chemicals in the class meet our minimum criteria for safer and other chemicals in the class do not, we will make one of the following determinations based on the Academy's approach for dealing with discordant data:

1. We will make a conservative decision to classify the class based on the data rich hazardous chemicals and seek alternatives that meet the minimum criteria.
2. We will make the determination that is best supported by data from chemicals in the class that have the potential to be found in the priority product.
3. We will use the within-class criteria (described below) to identify chemicals within the class that may be treated differently because they are safer.

This approach helps avoid the pitfalls of treating chemicals with no data as "not hazardous" and ensures the alternatives are safer than the priority chemical class.

Special considerations

Do we need to factor in exposure?

We only consider exposure if alternatives are not obviously safer based on hazard alone. When considering exposure, we ask whether the exposure routes or exposure potential could change the relevant hazards.

- If Yes, then it may be a safer alternative.
- If No, it's not a safer alternative.

We will seek alternatives with a significant reduction in hazard, but there may be some cases where the only alternative we identify has similar hazards to the priority chemical class. For example, both the priority chemical class and alternative meet the minimum criteria but fail to meet the additional criteria for safer. If the alternative is much less hazardous, we consider differences in exposure less important. However, if the alternative and priority chemical have similar hazards, exploring differences in exposure potential could help us determine whether the alternative is actually safer.

In these cases, we will evaluate potential exposure routes and chemical properties to determine whether specific hazards may be more or less relevant for a particular product-chemical combination. To determine which exposure routes (such as inhalation, dermal exposure, ingestion, aquatic contamination, etc.) are more or less relevant, we will consider both product attributes and the chemical properties. The chemical properties will be based on the IC2 Guide (IC2, 2017) and the Cradle to Cradle Certified™ Exposure Assessment methodology (Cradle to Cradle Certified™, 2020).

Considering which hazards are more or less relevant based on expected exposure routes will help us balance specific hazard trade-offs when an alternative and priority chemical show similar overall hazard

levels. If no specific exposure routes help distinguish between a priority chemical class and an alternative with similar hazards, we will consider potential differences in the magnitude of exposure potential.

Differences in exposure magnitude could result from an alternative being chemically bound or encapsulated, or from a functional barrier that prevents exposure. Differences in leaching, migration, or off-gassing between the priority chemical class and the alternative could also influence exposure (Cradle to Cradle Certified™, 2020). The concentration or amount of the chemical used in the product may also influence the magnitude of exposure potential. In these scenarios, we will still consider exposure potential to workers and the environment.

Do we consider chemical alternatives within the priority chemical class?

We will first seek alternatives outside the priority chemical class. If we do not identify safer alternatives outside the priority chemical class, and if considerable variability in toxicity suggests that some chemicals within the class may be safer alternatives, we will evaluate those chemicals using a set of "within-class" hazard criteria.

What is "within-class" hazard criteria?

To be considered a safer alternative within the priority chemical class, a chemical must meet the minimum or additional criteria for safer and within-class criteria. We will subject these chemicals and their known breakdown or transformation products to more protective requirements to ensure that in addition to meeting the minimum or additional criteria for safer, data show they do not have the same toxicity or environmental fate concerns associated with the priority chemical class.

The law allows for the identification of priority chemical classes based on the attributes of one or more members. Using a similar approach, we will ensure within-class alternatives do not share the same concerns as the priority chemical class. We will consider hazard endpoints associated with the priority class if one or more chemicals within the class scores high or very high according to the GreenScreen® scoring methodology. We will not accept within-class alternatives with data showing moderate endocrine disruption, carcinogenicity, mutagenicity, or reproductive or developmental toxicity if these endpoints are also associated with the priority chemical class.

For endocrine disruption, if data show that the class of priority chemicals is limited to a specific mechanism of action (such as anti-androgenicity or estrogenicity), data showing the alternative does not share this mechanism may be sufficient—even if it is not enough information to assign a score using GreenScreen®. Additionally, within-class alternatives may not be highly (or very highly) persistent or highly (or very highly) bioaccumulative according to the GreenScreen® scoring methodology.

Criteria development process

Ecology, in consultation with Health, developed the criteria for safer. To develop our criteria, we thoroughly reviewed existing methods for identifying safer chemicals and products that contain safer chemicals. In many cases, elements of existing criteria informed our process. Below is a summary of the existing methods we consulted.

We developed our criteria based on existing hazard assessment criteria from EPA's Safer Choice and Design for Environment (DfE) programs, and the GreenScreen® for Safer Chemicals Hazard Assessment Guidance (GreenScreen®). Learn more about these certification and labeling programs in Appendix 3.

All three frameworks rely on similar data sources—including the Global Harmonization System (GHS)—for classifying information using a weight of evidence approach. We chose to build on these methods for many reasons, but three are central:

- Each framework developed transparent criteria using a stakeholder process.
- Guidance documents for alternatives assessments recommend them.
- They are used in published alternatives assessments conducted by (or on behalf of) Washington state or the Federal government.

EPA's Safer Choice Program certifies chemicals and products that meet its Master Criteria (EPA, 2012, Appendix 2). EPA developed the Safer Chemical Ingredients List (SCIL) Master Criteria (adapted from Design for Environment, EPA 2015a) through an open stakeholder process. The criteria are publicly available, and the stakeholder process included a public comment period. Industry, NGOs, and government stakeholders participated and provided input on the project scope, helped identify functional alternatives, and helped develop the report (EPA, 2016).

GreenScreen® built on EPA's Design for Environment Criteria and developed a framework with input from a Scientific Advisory Committee, with representation from academia, businesses, and NGOs (GreenScreen®, 2020). The criteria and scoring system are publicly available. A number of businesses, governments, and NGOs use GreenScreen® to promote the use of safer alternatives (GreenScreen®, 2018).

Guidance documents for alternatives assessments identify the SCIL, DfE, and GreenScreen® methods. The Interstate Chemical Clearinghouse (IC2) Guide for Alternatives Assessments (IC2 Guide) recommends the GreenScreen® methodology for hazard comparison (IC2, 2017).

GreenScreen® categorizes chemicals into four "Benchmark" scores.

- The lowest, **Benchmark 1**, identifies chemicals that should be avoided.
- **Benchmark 2** chemicals are considered safer than Benchmark 1 chemicals, earning the designation "use, but continue to search for safer substitutes."
- **Benchmark 3** chemicals are safer than Benchmark 2 chemicals, and designated "use but still opportunity for improvement."
- **Benchmark 4** chemicals are preferred, safer chemicals.

Our minimum criteria for safer is based on the GreenScreen® Benchmark 2 criteria and our additional criteria for safer combines the SCIL master criteria and GreenScreen® Benchmark 3 criteria. Other government agencies use the approaches from which we derived our criteria to identify safer alternatives.

- California Department of Toxic Substances Control (DTSC)'s Safer Consumer Products Program Alternatives Analysis Guide lists GreenScreen® and SCIL for hazard evaluation (DTSC, 2017).

- The National Research Council identified both GreenScreen® and DfE as methods for comparing hazards in their 2014 review of alternatives assessment frameworks (NRC, 2014).
- EPA's alternatives assessment guidance recommends using the hazard criteria that formed the basis for the SCIL (EPA 2015a, DfE AA Criteria). Examples of published alternatives assessments using these criteria include BPA in thermal paper and flame retardants in flexible polyurethane foam, and printed circuit boards (EPA, 2011; 2015b; 2015c; 2015d).
- Ecology and others often use the GreenScreen® scoring system in alternatives assessments. Examples from Ecology include assessments of alternatives to Deca-BDE in electronics and furniture (Ecology, 2009), and copper in boat paint (NW Green Chemistry and TechLaw, 2017).

The criteria

Sections 1.0 and 1.1 define our data requirements and hazard criteria. Our minimum data requirements contain the endpoints generally recognized as most significant. We included exemptions to the data requirements based on chemical properties—either associated with exposure potential or tied to more protective hazard criteria.

The scoring of the hazard endpoints (very low, low, moderate, high, and very high) follows the process in the GreenScreen® methodology, which was adapted from EPA's DfE program and the GHS categorization (Appendix 3). In rare cases, we made minor modifications to the GreenScreen® scoring criteria, which we describe in Appendix 3.

1.0 Data requirements

1.0.1 Chemical hazard data requirements

In order to meet the minimum or additional criteria for safer, data must be present for the endpoints described in Table 1. We require data on carcinogenicity and mutagenicity. We require either reproductive or developmental toxicity. At least two of the following three endpoints are required: acute toxicity, systemic toxicity, and neurotoxicity. Skin or respiratory sensitization, acute aquatic toxicity or chronic aquatic toxicity, persistence, and bioaccumulation are required.

If an alternative is within the priority chemical class, we will not allow data gaps for hazard endpoints known to be associated with the priority chemical class. Find more details on how we identify hazards associated with priority chemicals in the section on within-class hazard criteria.

For each required endpoint, at least one of the following must be available:

- Sufficient measured data on the parent chemical.
- Measured data on a suitable analog.
- Estimated data on the parent chemical or a suitable analog chemical.

We will consider data from the primary literature, authoritative sources, and government reports. We will manage conflicting studies using a strength of evidence approach. We are basing our approach on the GreenScreen® methodology. Find more information on the amount of data needed for each endpoint in Appendix 1.

Table 1. Minimum data requirements and potential exemptions.

Hazard Endpoint	Requirement
Carcinogenicity	Required
Mutagenicity/Genotoxicity	Required
Reproductive or Developmental Toxicity	Required
Endocrine Disruption	Not required
Acute Toxicity	Not always required*
Single or Repeat Systemic Toxicity	Not always required*
Single or Repeat Neurotoxicity	Not always required*
Skin or Respiratory Sensitization	Required
Skin or Eye Irritation	Not required
Acute or Chronic Aquatic Toxicity	Required
Persistence	Required
Bioaccumulation	Required

Notes:

- * = Two out of these three endpoints require data.

1.0.2 Chemical concentration data requirements

This document describes our approach for evaluating intentionally added chemicals that serve the same function as priority chemicals. We are also concerned about residual monomers, known breakdown products, and impurities present in the product from chemicals that serve the function of priority chemicals. We describe our requirements for chemical concentration data below.

Current practices by SCIL and GreenScreen® inform the concentrations of alternatives we will consider. If we are evaluating a within-class alternative, we will consider concentrations of chemicals above a de minimis limit, which we will define for each product-chemical combination. We are considering potentially lower concentrations of priority chemicals, because we demonstrated that the presence of priority chemicals in priority products contributes to human and environmental exposure (Ecology, 2020).

When we evaluate chemical alternatives, we are evaluating the following:

- All chemicals intentionally added to serve the function of priority chemicals and their known breakdown/transformation products must meet our minimum or additional criteria for safer.
- Impurities and residual monomers of chemicals added to serve the function of priority chemicals present over 1,000 ppm must meet our minimum or additional criteria for safer.
- Impurities of chemicals added to serve the function of priority chemicals between 100 – 1,000 ppm must not score high for carcinogenicity, mutagenicity, reproductive or developmental toxicity, or endocrine disruption (if data are available).

If we evaluate a product that contains priority chemicals, we are evaluating the following:

- Priority chemicals present over de minimis concentrations must meet the minimum or additional criteria **and** the within-class hazard criteria.

- Known within-class breakdown products, impurities, and residual monomers present over de minimis concentrations must meet the minimum or additional criteria **and** the within-class hazard criteria.
- We will define unique de minimis concentrations for each product-chemical combination.

1.1 Criteria for safer

Moving toward safer chemicals is progressive. The criteria described below balance allowable persistence, bioaccumulation, and toxicity hazards with a goal of moving toward safer alternatives. If the priority chemical meets the minimum criteria for safer, then alternative chemicals must meet the additional criteria for safer.

The minimum criteria for safer

If the priority chemical class does not meet the minimum criteria for safer, alternative chemicals must meet the minimum criteria, described below, to be safer. The minimum criteria for safer is derived from GreenScreen™ Benchmark 2 criteria (Appendix 3). Data is not required for all endpoints described below. See Table 1 for data requirements. The criteria below describes the maximum allowable hazard traits.

- Carcinogenicity, mutagenicity, reproductive and developmental toxicity, and endocrine disruption must be moderate or lower.
- Persistence and bioaccumulation cannot both be very high.
- If any other human health or aquatic toxicity endpoints are very high, then persistence and bioaccumulation cannot both be high (Max Hazard Profiles 1 and 2, Table 2).
- If persistence is very high, then bioaccumulation cannot be very high and systemic toxicity (repeat exposure), neurotoxicity (repeat exposure), skin sensitization and respiratory sensitization must all be moderate or lower, and acute toxicity, systemic toxicity (single exposure), neurotoxicity (single exposure), eye irritation, skin irritation, and acute and chronic aquatic toxicity cannot be very high. (Max Hazard Profile 3, Table 2).
- If bioaccumulation is very high, then persistence cannot be very high and systemic toxicity (repeat exposure), neurotoxicity (repeat exposure), skin sensitization and respiratory sensitization must all be moderate or lower, and acute toxicity, systemic toxicity (single exposure), neurotoxicity (single exposure), eye irritation, skin irritation, and acute and chronic aquatic toxicity cannot be very high. (Max Hazard Profile 4, Table 2).

Table 2. The highest allowable hazard profiles in our minimum criteria for safer. The maximum allowable hazard for human health and ecotoxicity endpoints in profiles with different persistence and bioaccumulation. Data are not required for all endpoints. (The minimum data requirements from section 1.0 apply.)

	Carcinogenicity	Genotoxicity/ Mutagenicity	Reproductive Toxicity	Developmental Toxicity	Endocrine Activity	Acute Toxicity	Systemic Toxicity (single)	Systemic Toxicity (repeat)	Neurotoxicity (single)	Neurotoxicity (repeat)	Skin Sensitization	Respiratory Sensitization	Skin Irritation	Eye Irritation	Acute Aquatic Toxicity	Chronic Aquatic Toxicity	Persistence (P)	Bioaccumulation (B)
Max Hazard Profile 1	M	M	M	M	M	vH	vH	vH	vH	vH	vH	vH	vH	vH	vH	vH	M	H
Max Hazard Profile 2	M	M	M	M	M	vH	vH	vH	vH	vH	vH	vH	vH	vH	vH	vH	H	M
Max Hazard Profile 3	M	M	M	M	M	H	H	M	H	M	M	M	H	H	H	H	H	vH
Max Hazard Profile 4	M	M	M	M	M	H	H	M	H	M	M	M	H	H	H	H	vH	H

Notes:

- M = moderate.
- H = high.
- vH = very high.

Additional criteria for safer

If the priority chemical class meets our criteria for safer, alternative chemicals must meet the additional criteria, described below, to be safer. The additional criteria for safer is derived from GreenScreen™ Benchmark 3 criteria and the Safer Chemical Ingredients List Master Criteria (Appendix 3). Data is not required for all endpoints described below. See Table 1 for data requirements. The criteria below represents the maximum allowable hazards.

- Carcinogenicity, mutagenicity and reproductive and developmental toxicity must be low or likely low and endocrine disruption must be moderate or low.
- Neither persistence nor bioaccumulation can be very high.
- If acute aquatic toxicity is very high or systemic toxicity (repeat exposure), neurotoxicity (repeat exposure), skin sensitization or respiratory sensitization is high or acute toxicity, systemic toxicity (single exposure), neurotoxicity (single exposure), eye irritation, skin irritation or chronic aquatic toxicity is moderate, then persistence and bioaccumulation cannot both be moderate. (Max Hazard Profiles 1 and 2, Table 3).
- If either persistence or bioaccumulation is high, the other must be moderate or lower and systemic toxicity (repeat exposure), neurotoxicity (repeat exposure), skin sensitization, respiratory

sensitization, acute toxicity, systemic toxicity (single exposure), neurotoxicity (single exposure), eye irritation, skin irritation, and acute and chronic aquatic toxicity must be low or likely low (Max Hazard Profiles 3 and 4, Table 3).

Table 3. Additional hazard criteria that we will use to evaluate alternatives when priority chemicals meet the minimum criteria for safer. Data are not required for all endpoints. (The minimum data requirements from section 1.0 apply.)

	Carcinogenicity	Genotoxicity/ Mutagenicity	Reproductive Toxicity	Developmental Toxicity	Endocrine Activity	Acute Toxicity	Systemic Toxicity (single)	Systemic Toxicity (repeat)	Neurotoxicity (single)	Neurotoxicity (repeat)	Skin Sensitization	Respiratory Sensitization	Skin Irritation	Eye Irritation	Acute Aquatic Toxicity	Chronic Aquatic Toxicity	Persistence (P)	Bioaccumulation (B)
Max Hazard Profile 1	LL	L	L	L	M	H	H	M	H	M	M	M	H	H	vH	H	M	L
Max Hazard Profile 2	LL	L	L	L	M	H	H	M	H	M	M	M	H	H	vH	H	L	M
Max Hazard Profile 3	LL	L	L	L	M	L	L	L	L	L	L	L	L	L	L	L	H	M
Max Hazard Profile 4	LL	L	L	L	M	L	L	L	L	L	L	L	L	L	L	L	M	H

Notes:

- L = low.
- M = moderate.
- H = high.
- vH = very high.
- LL = indicates the chemical is likely low based on review of all available data (including chemical structure analogs) and that we identified no structural alerts.

Within-class criteria for safer

If the alternative is within the priority chemical class, it must meet the minimum or additional criteria, **and** the within-class criteria described below.

- Alternatives within the class cannot have data gaps for hazards associated with the priority chemical class (see details on endocrine disruption below).
- If carcinogenicity, mutagenicity, reproductive or developmental toxicity, or endocrine disruption are associated with the priority chemical class, alternatives within the class must score low on these endpoints (see details on endocrine disruption below).

- If endocrine disruption is associated with the priority chemical class, but limited to a specific mechanism of action (such as anti-androgenicity or estrogenicity), data showing the within-class alternative does not share this mechanism may be sufficient—even if it is still not enough information to assign a score GreenScreen® for endocrine disruption.
- Alternatives within the class cannot be highly persistent or highly bioaccumulative.

Hazard endpoints are associated with the priority class if one or more chemicals within the class scores high or very high according to the GreenScreen® scoring methodology.

1.2 Hazard endpoints scoring

GreenScreen® has defined criteria for Very High, High, Moderate, Low, or Very Low for 18 hazard endpoints, building on GHS and EPA's DfE criteria. GHS is a globally recognized method for classifying chemical hazards (United Nations, 2011). Our criteria uses the GreenScreen® method to determine endpoint scores for required and available data. Find more information about scoring for each endpoint in Appendix 1 and additional endpoints in GreenScreen®, Annex 1[3] (Appendix 3).

[3] https://www.greenscreenchemicals.org/images/ee_images/uploads/resources/GreeScreen1.4-Annex1-1.18.pdf

Appendix 1. Endpoint Scoring Methodology

Group I human health endpoints

Carcinogenicity

Moderate or lower carcinogenicity means that according to the GHS, the chemical is not a known or presumed carcinogen by any exposure route. We can identify known or presumed carcinogens by reviewing data or by presence on the lists specified in GreenScreen®, Annex 1 (Appendix 3). Moderate carcinogens, however, can be classified as a suspected carcinogen, or have limited or marginal data in animals. Chemicals can only score low if there is evidence of lack of carcinogenicity. In a modification from the GreenScreen® scoring system, we propose scoring chemicals as "likely low" in some scenarios. If sufficient data does not exist to assign a low carcinogenicity score, but there is no reason to suspect carcinogenicity after review of all available data, structural analogs, and structural alerts, we can accept the score as "likely low," rather than as a data gap.

Mutagenicity

Moderate or lower mutagenicity means that according to the GHS, the chemical is not a known or presumed mutagen by any exposure route. We can identify known or presumed mutagens by reviewing data or by presence on the lists specified in GreenScreen®, Annex 1 (Appendix 3). Moderate mutagens, however, can be classified as a suspected mutagen, or have limited or marginal data in animals. Chemicals can only score low if there is evidence that they do not cause chromosomal aberrations or gene mutations.

Reproductive toxicity

Moderate or lower reproductive toxicity means that according to the GHS, the chemical is not a known or presumed reproductive toxicant by any exposure route. We can identify known or presumed reproductive toxicants by reviewing data or by presence on the lists specified in GreenScreen®, Annex 1 (Appendix 3). Moderate reproductive toxicants, however, can be classified as a suspected reproductive toxicant, or have limited or marginal data in animals. Chemicals can only score low if there is evidence that they do not cause reproductive toxicity.

Developmental toxicity

Moderate or lower developmental toxicity means that according to the GHS, the chemical is not a known or presumed reproductive toxicant by any exposure route. We can identify known or presumed developmental toxicants by reviewing data or by presence on the lists specified in GreenScreen®, Annex 1 (Appendix 3). Moderate developmental toxicants, however, can be classified as a suspected developmental toxicant, or have limited or marginal data in animals. Chemicals can only score low if there is evidence that they do not cause developmental toxicity.

Endocrine disruption

When data are available for endocrine disruption, we will evaluate it to determine whether there is evidence of endocrine activity and related human health effects (high), evidence of endocrine activity (moderate), or adequate data available including negative studies (low). We can identify known and

suspected endocrine disruptors by reviewing data or by presence on the lists specified in GreenScreen®, Annex 1 (Appendix 3).

Group II human health endpoints

Acute mammalian toxicity

Acute mammalian toxicity can be very high. A very high score corresponds to the GHS Category 1 or 2 for any route of exposure. A high score corresponds to GHS Category 3 for any route of exposure. A moderate score corresponds to a GHS Category 4 for any route of exposure. In order to score low, the chemical must either:

- Correspond to a GHS Category 5.
- GHS must not classify the chemical and adequate data must be available, including negative studies.

Table 4. Acute toxicity LD/LC_{50} for oral, dermal, and inhalation exposure corresponding to GHS categories 1 through 5.

Classification Criteria	Category 1	Category 2	Category 3	Category 4	Category 5
Oral LD50	≤ 5 mg/kg bodyweight	>5 and ≤ 50 mg/kg bodyweight	>50 and ≤ 300 mg/kg bodyweight	>300 and ≤ 2000 mg/kg bodyweight	>2000 mg/kg bodyweight
Dermal LD50	≤ 50 mg/kg bodyweight	>50 and ≤ 200 mg/kg bodyweight	>200 and ≤ 1000 mg/kg bodyweight	>1000 and ≤ 2000 mg/kg bodyweight	>2000 mg/kg bodyweight
Inhalation LC50 (4-hr.) Gases	≤ 100 ppmV	>100 and ≤ 500 ppmV	>500 and ≤ 2500 ppmV	>2500 and ≤ 20000 ppmV	>20000 ppmV
Inhalation LC50 (4-hr.) Vapors	≤ 0.5 mg/	>0.5 and ≤ 2.0 mg/L	>2.0 and ≤ 10.0 mg/L	>10.0 and ≤ 20.0 mg/L	>20.0 mg/L
Inhalation LC50 (4-hr.) Dusts and Mists	≤ 0.05 mg/L	>0.05 and ≤ 0.5 mg/L	>0.5 and ≤ 1.0 mg/L	>1.0 and ≤ 5.0 mg/L	>5.0 mg/L

Systemic toxicity

Single exposure systemic toxicity can be very high and repeat exposure systemic toxicity can be high.

- **Single exposures**
    - A very high score corresponds to the GHS Category 1 for any route of exposure. GHS Category 1 means that there is either a) significant toxicity in humans, based on reliable, good quality human case studies or epidemiological studies, or b) that there is presumed significant toxicity in humans based on animal studies with significant and or severe toxic effects relevant to humans at generally low exposures.
    - For single exposure, a high score corresponds to GHS Category 2 for any route of exposure. GHS Category 2 means the chemical is presumed to be harmful to human health based on animal studies with significant toxic effects relevant to

humans at generally moderate exposure (or human evidence in exceptional cases).
    - A moderate score corresponds to a GHS Category 3 for any route of exposure. GHS Category 3 means that transient target organ effects occur.
    - In order to score low, GHS must not classify the chemical, and adequate data must be available, including negative studies.
- **Repeat exposure**
    - A high score for repeat exposure corresponds with a GHS Category 1. GHS Category 1 means that there is either a) significant toxicity in humans, from reliable, good quality human case studies or epidemiological studies, or b) that there is presumed significant toxicity in humans based on animal studies with significant and or severe toxic effects relevant to humans at generally low exposures.
    - A moderate score for repeat exposure corresponds to a GHS Category 2. GHS Category 2 means the chemical is presumed to be harmful to human health based on animal studies with significant toxic effects relevant to humans at generally moderate exposure (or human evidence in exceptional cases).
    - In order to score low, GHS must not classify the chemical, and it must have adequate data showing a lack of systemic toxicity. Table 5 shows Lowest Observable Effects Levels (LOELs) for repeat exposure toxicity studies by GHS category and corresponding score.

Table 5. Repeat Exposure Guidance Values from GHS and corresponding scores.

Classification Criteria	GHS Category 1 (High)	GHS Category 2 (Moderate)	Low
Oral Guidance Value (LOEL)	≤ 10 mg/kg bodyweight	>10 and ≤ 100 mg/kg bodyweight	>100 mg/kg bw/day
Dermal Guidance Value (LOEL)	≤ 20 mg/kg bodyweight	>20 and ≤ 200 mg/kg bodyweight	>200 mg/Kg-bw/day
Inhalation Vapors Guidance Value (LOEL)	≤ 0.2 mg/	>0.2 and ≤ 1.0 mg/L	>1.0 mg/L
Inhalation Dusts and Mists Guidance Value (LOEL)	≤ 0.02 mg/L	>0.02 and ≤ 0.2 mg/L	>0.2 mg/L

Neurotoxicity

Single exposure neurotoxicity can be very high and repeat exposure neurotoxicity can be high. A very high score corresponds to the GHS Category 1 for any route of exposure. GHS Category 1 means that there is either a) significant toxicity in humans, from reliable, good quality human case studies or epidemiological studies, or b) that there is presumed significant toxicity in humans based on animal studies with significant or severe toxic effects relevant to humans at generally low exposures. A high score corresponds to GHS Category 2 for any route of exposure. GHS classifies Category 2 as “presumed to be harmful to human health based on animal studies with significant toxic effects relevant to humans at generally moderate exposure (or human evidence in exceptional cases).” A moderate score corresponds to a GHS Category 3 for any route of exposure. GHS Category 3 means that transient target

organ effects occur. In order to score low, GHS must not classify the chemical, and adequate data must be available, including negative studies.

Skin and respiratory sensitization

Skin and respiratory sensitization can be high. High sensitization corresponds to a GHS Category 1A, meaning that there is high frequency of occurrence. A moderate score for sensitization corresponds to a GHS Category 1B, meaning there is low to moderate frequency of occurrence. In order for a chemical to score low, GHS must not classify the chemical, and adequate data and negative studies must be available.

Skin and eye irritation

Skin and eye irritation can be very high. Very high irritation corresponds to a GHS Category 1, meaning that there is irreversible damage. A high score for sensitization corresponds to a GHS Category 2A, meaning that the chemical is irritating. A moderate score corresponds to a GHS Category 2b, meaning that the chemical is mildly irritating. In order for a chemical to score low, GHS must not classify the chemical, and adequate data and negative studies must be available.

Environmental fate and transport

Acute aquatic toxicity

Acute aquatic toxicity can be very high, if persistence and bioaccumulation are also not high or very high. Very high acute aquatic toxicity corresponds to a GHS Category 1 (LC_{50} ≤1.00 mg/L). A high score for acute aquatic toxicity corresponds to a GHS Category 2 (LC_{50} between 1.00 and 10.0 mg/L). A moderate score corresponds to a GHS Category 3 (LC_{50} between 10.0 and 100 mg/L). In order for a chemical to receive a score of low, GHS must not classify the chemical, and adequate data and negative studies must be available.

Chronic aquatic toxicity

Chronic aquatic toxicity can be very high if persistence and bioaccumulation are also not high or very high. Very high chronic aquatic toxicity corresponds to an LC_{50} of less than 0.1 mg/L. A high score for chronic aquatic toxicity corresponds to a LC_{50} of 0.1 – 1.0 mg/L. A moderate score corresponds to a LC_{50} of 0.1 – 10 mg/L. In order for a chemical to score low, it must have a LC_{50} of greater than 10 mg/L.

Persistence

Moderate or lower persistence means that the half-life is less than 60 days in soil, 40 days in water, and 5 days in air. There can be suggestive evidence of long-range transport. For a chemical to have low persistence, it must have a half-life of less than 16 days in water and soil, and less than 2 days in air. For very low persistence, it must meet the 10-day window for the GHS rapid biodegradability test in water and soil.

Bioaccumulation

Bioaccumulation is based on the bioaccumulation factor (BAF), bioconcentration factor (BCF), log water octanol partitioning coefficient (Log Kow), and biomonitoring data. Table 6 shows the scoring from the GreenScreen® methodology (GreenScreen®, Annex 1[4] and Appendix 3).

Table 6. Bioaccumulation measurements and scoring criteria from the GreenScreen® methodology.

Criteria	Very High	High	Moderate	Low	Very Low
BCF or BAF	>5000	>1000-5000	>500-1000	>100-500	≤100
Log Kow	>5.0	>4.5-5.0	>4.0-4.5	__	≤4

Notes:

- BCF = bioconcentration factor.
- BAF = bioaccumulation factor.
- Log Kow = water octanol partition coefficient.

[4] https://www.greenscreenchemicals.org/images/ee_images/uploads/resources/GreeScreen1.4-Annex1-1.18.pdf

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Appendix 3. Existing Hazard Assessment Methodologies

We relied on the following hazard assessment methodologies to develop our own approach.

GreenScreen® for Safer Chemicals Hazard Assessment Guidance (GreenScreen®)

- GreenScreen® is a hazard assessment method[5] aimed at identifying safer alternatives. GreenScreen® categorizes chemicals into four benchmark scores. The lowest (Benchmark 1) identifies chemicals that should be avoided. Benchmark 2 chemicals are considered safer than Benchmark 1 chemicals, earning the designation "use, but continue to search for safer substitutes." Benchmark 3 chemicals are safer than Benchmark 2 chemicals—designated as "use but still opportunity for improvement" and Benchmark 4 chemicals are preferred, safer chemicals. We made a small modification to the carcinogenicity scoring described in GreenScreen® Appendix 1, but no other modifications.

EPA's Safer Choice program

- The general requirements listed in the Safer Choice Master Criteria[6], as applied by experts in the Safer Choice Program, are intended as a base set of criteria for all chemicals listed on the Safer Chemical Ingredient List (SCIL) and ingredients in Safer Choice recognized products. For some products, there are additional criteria that can be applied, depending on the chemical function and product lifecycle characteristics. These criteria make it possible for Safer Choice to ensure that chemicals in labeled products are among the safest in their functional classes and, without exception, cannot be listed carcinogens, mutagens or reproductive or developmental toxicants (CMRs), or persistent, bioaccumulative, and toxic chemicals (PBTs). Also, chemicals that release, degrade to, or form byproducts that are CMRs or PBTs will not be allowed.

Cradle to Cradle Certified™ (C2CC™)

- Cradle to Cradle Certified™ (C2CC™) is a globally recognized way to identify safer consumer products. In order to be certified, products undergo rigorous evaluation for material health and other concerns. The C2CC™ Material Health Standard Version 3.1 is the most relevant to the Safer Products for Washington program. C2CC™ developed the criteria through an open stakeholder process, and published the Material Health Certificate Standard.[7] Similar to the SCIL and GreenScreen® methodology, C2CC™ is grounded in the GHS, and includes additional information when available. The C2CC™ material health standard scores hazard endpoints as green (optimal chemicals), yellow (moderately problematic chemicals), and red (highly problematic chemicals-target for phase out). C2CC™ also developed exposure parameters[8] that can be helpful when hazards cannot be avoided or reduced.

[5] https://www.greenscreenchemicals.org/images/ee_images/uploads/resources/GreeScreen1.4-Annex1-1.18.pdf
[6] http://www2.epa.gov/saferchoice/safer-choice-master-criteria-safer-chemical-ingredients
[7] https://www.c2ccertified.org/resources/detail/material-health-certificate-standard
[8] https://www.c2ccertified.org/resources/detail/exposure-assessment-methodology