# EPA's Safer Choice and Design for the Environment (DfE) Standard

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This document was developed with the purpose of making criteria for certification under the EPA Safer Choice and DfE programs more transparent and accessible.

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# Foreword

#### EPA's Safer Choice program

**Safer Choice partners to advance environmental protection.** The Safer Choice program is one of the U.S. Environmental Protection Agency's (EPA's) most valued partnership programs. The Safer Choice program works in partnership with a broad range of stakeholders to reduce risk to people and the environment by preventing pollution. The Safer Choice program focuses on industries that combine the potential for chemical risk reduction and improvements in energy efficiency with a strong motivation to make lasting, positive changes. The Safer Choice program convenes partners, including industry representatives and environmental groups, to develop goals and guide the work of the partnership. Partnership projects evaluate human health and environmental characteristics, performance, and other considerations of traditional and alternative technologies, materials, and processes. As incentives for participation and driving change, the Safer Choice program offers unique technical tools, methodologies, expertise, and the potential for product certification.

The Safer Choice program operates under authorities that include:

- Section 6604(b)(5) of the Pollution Prevention Act, 42 USC 13103(b)(5) which authorizes EPA to "facilitate the adoption of source reduction techniques by businesses." The term "source reduction" is defined at section 6603(5) of the PPA, 42 USC 13102(5).
- Section 102(2)(J) of the National Environmental Policy Act, 42 USC 4332(2)(J) to provide advice and information available to units of government, institutions and individuals that may be used to restore, maintain, and enhance the quality of the environment.

**Safer Choice enables the selection of safer alternatives through informed substitution.** Located in the Office of Pollution Prevention and Toxics, the Safer Choice program promotes safer product design and green chemistry alternatives through "informed substitution," the considered transition from a chemical of particular concern to safer chemicals or non-chemical alternatives. The goals of informed substitution are to minimize the likelihood of unintended consequences, which can result from a precautionary switch away from a chemical of concern without fully understanding the profile of potential alternatives, and to enable a course of action based on the best information—on the environment and human health—that is available or can be estimated. To be considered safer choices, potential alternatives should exhibit as many of the following characteristics as possible: they should be technically feasible; provide an improved profile for health and the environment; account for social considerations; and have the potential to result in lasting change.

**Safer Choice applies informed substitution to products.** The Safer Choice program applies informed substitution to critical areas of environmental and human health protection. The Safer Choice program partners with product manufacturers, or "formulators," environmentalists, and others, exchanging information and collaborating on the development of safer products. Formulators have been invaluable in helping the Safer Choice program understand the critical elements of product functionality and how to optimize product and health/environmental performance. Environmentalists have provided important insight on chemical characteristics, especially for defining the green end of the health/environmental spectrum, as well as identifying ways to ensure confidence in partnership environmental results.

To inform substitution, the Safer Choice program considers each ingredient in a product within its distinct functional class (e.g., surfactants, solvents, chelating agents, etc.) and compares the toxicity and fate profiles to identify the safest ingredients. Safer Choice certification is based on using the safest possible ingredients to make a high-performing product. The Safer Choice program considers whole product characteristics, like possible negative synergies between ingredients and pH level, as well as lifecycle factors, like energy efficiency and water savings.

The Safer Choice program's functional class approach makes it possible to compare similar chemicals and identify safer ingredients. Each ingredient in a formulation has a role to play in a

product. Whether it is to aid in cleaning by reducing surface tension (surfactants), dissolve or suspend materials (solvents), or reduce water hardness (chelating agents), each ingredient type has a function. Within these "functional classes," many ingredients share similar toxicological and environmental fate characteristics. As a result, the Safer Choice program focuses its review of formulation ingredients on the key environmental and human health characteristics of concern within a functional class. This approach allows formulators to use those ingredients with the lowest hazard in their functional class, while still formulating high-performing products.

The Safer Choice program uses the technical expertise of its workgroup of EPA scientists to compare ingredients in the same functional class and thereby identify those ingredients with the lowest hazard profile. The program has developed criteria for safer chemical ingredients to share this expertise and make it easier to formulate safer products. These criteria are used to identify safer chemical ingredients, particularly for use in products.

A Safer Choice-certified product contains the safest possible ingredients. The Safer Choice label offers a readily identifiable way to know that a product is as safe as possible for people and the environment. When you see the Safer Choice label on a product it means that the Safer Choice scientific review team has evaluated each ingredient for potential human health and environmental effects and that— based on the best available experimental data and EPA predictive models—the product contains only those ingredients that pose the least concern among chemicals in their functional class.

Product formulators who become Safer Choice partners, and earn the right to display the Safer Choice label on certified products, have invested heavily in research, development, and reformulation to ensure that their ingredients and finished product align at the green end of the health and environmental spectrum, while maintaining or improving product performance.

The Safer Choice program uses a rigorous, in-depth approach to review products. By focusing on the ingredient level and on inherent characteristics, the Safer Choice program is able to carefully scrutinize formulations and make meaningful calls on potential concerns. The Safer Choice program starts its product reviews with information that scientists already know about each chemical ingredient, such as how it works in a product and how it affects living things. When that information doesn't tell the full story, EPA looks at an ingredient's chemical structure—its components and shape—to understand how it could impact the environment and people.

A chemical's structure can tell a lot about how the chemical will behave and what types of effects it may have when it comes in contact with people or the environment. The Safer Choice program uses the special skills of the scientists at EPA who are experts in chemical analysis, hazard and risk assessment, and green chemistry.

**Safer Choice review is especially discriminating and protective.** The Safer Choice program is unique because of two defining characteristics: its assessment methodology and its technical review team. The Safer Choice technical review team has many years of experience and is highly skilled at assessing chemical hazards, applying predictive tools, and identifying safer substitutes for chemicals of concern. The review team applies the Safer Choice assessment methodology by carefully reviewing every product ingredient. (The review includes all chemicals, including those in proprietary raw material blends, which supplier companies share with the Safer Choice program in confidentiality).

Safer Choice reviews provide an extra measure of protection. The Safer Choice program uncovers chemicals of concern that can be masked by raw material blends or by dilution in water. By focusing at the ingredient level and on inherent characteristics, the Safer Choice program is able to carefully scrutinize formulations and make meaningful calls on potential concerns. For example, a surfactant that is acutely toxic to aquatic organisms and environmentally persistent can appear to pose a low concern when blended with other less toxic and less persistent surfactants. Similarly, water, typically the largest percentage ingredient even in concentrated products, can mask the toxicity of a hazardous chemical.

The Safer Choice program uses its expert knowledge and predictive tools to supplement lists of chemicals of concern. Few chemicals in commerce have been completely characterized, especially for chronic effects like cancer and developmental toxicity. For this reason, lists of chemicals with these effects can only be considered works in progress. The Safer Choice program uses its knowledge of the structural similarities between chemicals and its predictive models to flag ingredients with similar potential effects.

The Safer Choice program spots negative synergies between product components. These potentially dangerous chemical combinations, which occur with surprising frequency in products, pose concerns for both acute and longer-term effects. For example, mixing nitro-containing compounds with amines will create nitrosamines, potent carcinogens.

The Safer Choice program evaluates all ingredients to identify chemicals that may present serious health or environmental effects. This evaluation includes ingredients used in small percentages, like fragrance materials and dyes. Some of the chemicals of most potential concern in products are those used in small concentrations. Chemicals of concern include sensitizers, carcinogens, and environmentally toxic and persistent compounds. Small quantities don't necessarily mean small hazards: a person, once sensitized to a chemical, can have an allergic response even if exposed at minute levels.

The Safer Choice program recommends safer substitutes for chemicals of concern. Movement toward sustainability requires innovation and continuous improvement. The Safer Choice program works directly with EPA's green chemistry specialists to identify and recommend safer chemicals to its partners, continuously raising the bar and redefining the meaning of environmentally preferable products. Safer Choice helps partners by sharing information and guiding the development of safer products. This is a win for industry, families, and the environment.

**The Design for the Environment (DfE) logo is used for antimicrobial products.** DfE is a related program used by EPA for the purpose of helping consumers and commercial buyers identify antimicrobial products that meet this Standard and are registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). More information on the DfE program can be found at <u>https://www.epa.gov/pesticidelabels/learn-about-design-environment-dfe-certification</u>.

The Safer Choice program certifies cleaning services that use Safer Choice-certified products. Cleaning service providers using Safer Choice-certified products may want to project an image of sustainability in the marketplace and create safer conditions for workers. The Cleaning Service Certification logo is available for organizations and businesses that use cleaners, detergents, disinfectants, and related products as part of their primary operations. The logo distinguishes cleaning service providers who use Safer Choice-certified products for cleaning and DfE-certified products for disinfection either exclusively or to the maximum extent practicable.

# Safer Choice and Design for the Environment Standard

# 1 Purpose, Scope, and Normative References

# 1.1 Purpose

This document, the Safer Choice and Design for the Environment (DfE) Standard ("the Standard"), establishes minimum requirements for identifying products that meet the U.S. Environmental Protection Agency's (EPA's) Safer Choice and DfE program criteria. Products that meet these criteria and requirements are eligible for either the Safer Choice label or DfE logo, which are granted by EPA.

# 1.2 Scope

The Standard is intended to cover a broad scope of products including detergents, cleaners, and antimicrobial products. While this document includes the review criteria for both the whole product and each product ingredient, certification applies only to the finished product. A partner company's obligations under any federal, state or local laws or regulations governing the company or partnership products are in no way altered by the company's partnership with EPA.

Cleaning Service Certification is covered under Section 7 of this Standard.

# 1.2.1 Scope of Safer Choice label

The Safer Choice label is applied for products including but not limited to: glass cleaners, general purpose cleaners, washroom cleaners, carpet cleaners, laundry detergents, graffiti removers, boat and car care, drain cleaners, and floor care and other formulated chemical products.

# 1.2.2 Scope of DfE logo

The DfE logo is currently applied for EPA-registered antimicrobal products.

# 1.2.3 Scope of Cleaning Service Certification

Section 7 of this Standard allows use of a logo for cleaning service providers.

# 1.3 Normative References

The following documents are referenced in this text. The test methods and other references listed in this section may have been revised. Please ensure that you consult the latest version of any referenced documents.

# 21 CFR §701.3(I) – Designation of ingredients. <u>https://www.ecfr.gov/current/title-21/chapter-I/subchapter-G/part-701/subpart-A/section-701.3</u>

# 29 CFR §1910.1200 – Hazard communication. <u>https://www.ecfr.gov/current/title-29/subtitle-B/chapter-XVII/part-1910/subpart-Z/section-1910.1200</u>

AATCC Test Method 171-2019 - Test Method for Carpets: Cleaning of; Hot Water Extraction.

AMS 1526 – Cleaner for Aircraft Exterior Surfaces, Water-Miscible, Pressure-Spraying Type.

AMS 1530 – Cleaner for Aircraft Exterior Surfaces, Wipe-On, Wipe-Off.

Association of Occupational and Environmental Clinics (AOEC) - http://www.aoec.org/index.htm

ASTM D4488 – 95(2001)e1 Standard Guide for Testing Cleaning Performance of Products Intended for Use on Resilient Flooring and Washable Walls.

ASTM D5343 – 06 Standard Guide for Evaluating Cleaning Performance of Ceramic Tile Cleaners.

ASTM D6094 – 97 Standard Guide to Assess the Compostability of Environmentally Degradable Nonwoven Fabrics.

ASTM E502 – Standard Test Method for Selection and Use of ASTM Standards for the Determination of Flash Point of Chemicals by Closed Cup Methods.

ASTM G122 – 96(2002) Standard Test Method for Evaluating the Effectiveness of Cleaning Agents.

Boeing D6-17487 – Exterior and General Cleaners and Liquid Waxes, Polishes and Polishing Compounds.

California's Proposition 65 – Safe Drinking Water and Toxic Enforcement Act of 1986.

CAN/CGSB 2-GP-11, Method 20.3 – Methods of Testing and Analysis of Soaps and Detergents.

CRI TM-110 – Evaluation Procedures for CRI Carpet Spot Cleaning Product Certification.

DfE Partnership Agreement – Annex B.

ECHA Endocrine Disruptor Assessment List - https://echa.europa.eu/ed-assessment

EPA's Energy Star program partner resources – <u>https://www.energystar.gov/partner\_resources/join-en-ergy-star</u>

EPA's Energy Star Treasure Hunt program – <u>https://www.energystar.gov/buildings/save\_energy\_com-</u> mercial\_buildings/treasure\_hunts

EPA's List of Alternative Test Methods and Strategies or New Approach Methodologies (NAMs) per TSCA 4(h)(2)(C) – <u>https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/strategic-plan-reduce-use-vertebrate-animals-chemical</u>

EPA's SmartWay program - https://www.epa.gov/smartway

EPA's Strategic Plan to Promote Development and Implementation of Alternative Test Methods Within the TSCA Program – <u>https://www.epa.gov/sites/default/files/2018-06/documents/epa\_alt\_strat\_plan\_6-20-18\_clean\_final.pdf</u>

EPA's WaterSense Best Management Practices - https://www.epa.gov/watersense/commercial-buildings

EPA's WaterSense labeled products - https://www.epa.gov/watersense/watersense-products

Forest Service Specification 5100-304d – Long-Term Retardant, Wildland Firefighting.

FTC Green Guides – https://www.ftc.gov/news-events/topics/truth-advertising/green-guides

GreenBlue's Recycled Material Standard - https://www.rmscertified.com/

Globally Harmonized System of Classification and Labeling of Chemicals (GHS) – <u>https://unece.org/transport/dangerous-goods/ghs-rev10-2023</u>

HCPA DCC-03 – Cleaning Test Method – Rug Shampoo.

HCPA DCC-09 – Cleaning Test Method – Glass Cleaners.

HCPA DCC-09A – Cleaning Test Method – Standard Guide for Evaluating the Filming and Streaking of Glass Cleaners.

HCPA DCC-10 – Cleaning Test Method – Foam Stability of Hand Dishwashing Detergents.

HCPA DCC-11 - Cleaning Test Method - Pre-Wash Spotter Stain Removal.

HCPA DCC-12 – Cleaning Test Method – Guidelines for Screening the Efficacy of Oven Cleaners.

HCPA DCC-13 – Cleaning Test Method – Fabric Softeners.

HCPA DCC-14 – Cleaning Test Method – Guidelines for Anti-Redeposition Properties of Laundry Products.

HCPA DCC-16 – Cleaning Test Method – Lime Soap Removal.

HCPA DCC-17 - Cleaning Test Method - Greasy Soil.

HCPA DCC-18 – Cleaning Test Method – Method for Neat Hand Dish Washing.

HCPA DCC 19 – Cleaning Test Method – Biological Drain Maintenance.

ISO/IEC 17065: 2012 – Conformity assessment- requirements for bodies certifying products, processes, and services.

Safer Choice Cleaning Service Standard Partnership Agreement – Annex D.

Safer Choice Criteria for Chelating and Sequestering Agents – <u>https://www.epa.gov/saferchoice/safer-choice-criteria-chelating-and-sequestering-agents</u>

Safer Choice Criteria for Environmental Toxicity and Fate for Chemicals in Direct Release Products – <u>https://www.epa.gov/saferchoice/standard#directrelease</u>

Safer Choice Criteria for Fragrances – https://www.epa.gov/saferchoice/safer-choice-criteria-fragrances

Safer Choice Criteria for Processing Aids and Additives – <u>https://www.epa.gov/saferchoice/safer-choice-criteria-processing-aids-and-additives</u>

Safer Choice Criteria for Solvents - https://www.epa.gov/saferchoice/safer-choice-criteria-solvents

Safer Choice Criteria for Surfactants - https://www.epa.gov/saferchoice/safer-choice-criteria-surfactants

Safer Choice Master Criteria for Safer Ingredients – <u>https://www.epa.gov/saferchoice/safer-choice-mas-ter-criteria-safer-chemical-ingredients</u>

Safer Choice Partnership Agreement – Annex A.

Sustainable Packaging Coalition Guidance for Reusable Packaging – <u>https://sustainablepackag-ing.org/wp-content/uploads/2022/04/Guidance-for-Reusable-Packaging.pdf</u>

Toxics in Packaging Clearinghouse (TPCH) model legislation – <u>https://toxicsinpackaging.org/model-legis-</u> lation/

# 2 Reference Section

# 2.1 Definitions

Terms used in the Standard document that have a specific technical meaning are defined here.

2.1.1 Absorbent: A material with the tendency to take up another substance into the bulk of the material.

**2.1.2 Adsorbent:** A substance that attracts other substances to its surface, often for odor control purposes.

**2.1.3 Allergen:** An antigenic substance capable of producing immediate-type hypersensitivity. (See also skin and respiratory sensitizer)

2.1.4 Analog: Closely-related chemical structures.

**2.1.5 Antifoamer:** A material that prevents or minimizes the formation of foam.

**2.1.6 Antioxidant:** A chemical compound or substance that inhibits oxidation.

**2.1.7 Antiredeposition agent:** An ingredient used in detergents to help prevent loosened soil from resettling after it has been removed during washing.

**2.1.8 Asthma:** A chronic disorder of the airways that is complex and characterized by variable and recurring symptoms, airflow obstruction, bronchial hyperresponsiveness (bronchospasm), and an underlying inflammation. Asthma symptoms may be induced by a sensitizer (allergen) or an irritant.

2.1.9 Asthmagen: An agent that causes asthma.

**2.1.10 Bacteria, spore:** A refractile body formed within bacteria, especially genera of the family Bacillaceae, which is regarded as a resting stage during the life history of the cell, and is characterized by its resistance to environmental changes.

**2.1.11 Bacteria, vegetative:** Single-celled organisms belonging to kingdom Monera that possess a prokaryotic type of cell structure, which means their cells are non-compartmentalized, and their DNA is found throughout the cytoplasm rather than within a membrane-bound nucleus. Vegetative bacteria are in growth phase or reproductive phase; nutrients are not limited and the bacteria are not in spore form.

**2.1.12 Bioaccumulation:** The progressive increase in the amount of a substance in an organism or part of an organism, which occurs because the rate of intake exceeds the organism's ability to remove the substance from the body.

**2.1.13 Biodegradability:** The capability of organic matter to be decomposed by biological processes. Both the rate and the completeness of decomposition are factors in biodegradability.

2.1.14 Bleaching agent: A chemical that acts by oxidizing stains to break them down and remove color.

**2.1.15 Builder:** A broad category of materials that enhance or maintain the cleaning efficiency of the surfactant. Several types of compounds, with different performance capabilities, are used. Builders have a number of functions, principally to inactivate water hardness and to supply alkalinity. This is accomplished either by sequestration (i.e., holding hardness minerals in solution), by precipitation, or by ion exchange. Other functions of builders are to supply alkalinity to assist cleaning, especially of acid soils, to provide buffering so that alkalinity is maintained at an effective level, and to aid in keeping removed soil from re-depositing during washing. Builders for the purposes of this document include chelating agents, alkalinity boosters, pH adjusters, and buffering agents.

**2.1.16 California Proposition 65:** A California law that regulates substances the state lists as causing cancer, birth defects, or other reproductive harm. For more information, see <u>https://oehha.ca.gov/proposition-65</u>.

**2.1.17 Chelating agent:** An organic chemical that forms two or more coordination bonds with a central metal ion. Heterocyclic rings are formed with the central metal ion as part of each ring. Chelating agents can change the properties of metal ions, help to transport metal ions, and prevent scale formation.

**2.1.18 Coalescing agent:** A chemical that lowers the minimum film formation temperature of a polymer (typically in a floor finish) so that it will form a uniform film at normal indoor temperatures. These chemicals are typically solvents.

2.1.19 Colorant: Any substance, natural or synthetic, whose primary use is to color various materials.

**2.1.20 Commodity ingredient:** A chemical whose formulation does not vary between suppliers (e.g., sold free of auxiliary components, except for water).

**2.1.21 Component:** A chemical as identified by its Chemical Abstracts Service Registry Number (CAS Number).

**2.1.22 Compostable:** Capable of undergoing biological decomposition in a compost site as part of an available program, such that the material is not visually distinguishable and breaks down into carbon dioxide, water, inorganic compounds, and biomass, at a rate consistent with known compostable materials.

**2.1.23 Corrosion inhibitor:** A substance that prevents the disintegration of a material into its constituent atoms.

**2.1.24 Cross-linker:** A material that forms covalent bonds between polymer chains, either within or across chains.

2.1.25 Defoamer: Agent used to reduce foam.

**2.1.26 Denaturation:** 1. A process that renders a substance unfit to eat or drink without destroying its usefulness in other applications, for example adding methanol or a bittering agent to ethyl alcohol. 2. A change in molecular structure of proteins so that they cannot function normally, often caused by splitting of hydrogen bonds following exposure to reactive substances or heat.

**2.1.27 Direct release products:** Products that are intended for use in applications that result in their immediate release to the environment, so that they bypass sewage treatment or septic systems, shortening the time for degradation prior to entering sensitive environments. Home car washes, boat cleaners and graffiti removers are examples of direct-release products.

2.1.28 Dispersing agent: A material that increases the stability of particles in a liquid formulation.

**2.1.29 Enzyme:** A protein that acts as a catalyst in biochemical reactions. Each enzyme is specific to a particular reaction or group of similar reactions.

**2.1.30 Enzyme stabilizer:** A chemical that maintains the activity of enzymes in the formulation by preventing degradation and denaturation prior to use.

**2.1.31 Foam booster:** An additive used in detergents to increase suds production and stabilize lather.

**2.1.32 Formulator:** A company that designs and makes chemical choices for the manufacture of products. EPA partners with formulator companies. Formulators may private label or license their Safer Choice- or DfE-certified formulas and thereby extend Safer Choice or DfE certification to their licensees or

private label customers. Key in EPA's decision to extend certification to private label or licensed products is a demonstration that the partner retains full control of the certified formulation.

**2.1.33 Fluorescent whitening agent:** (optical brightener) Complex, organic molecules that adhere to fabrics as though they were dyes. Ultraviolet (UV) energy is absorbed, converted, and emitted as visible blue light to enhance fabric appearance and maintain whiteness or brightness.

**2.1.34 Fragrance:** A fragrance, as used in a product, is made up of fragrance materials and auxiliary materials including carriers (e.g., solvents) and preservatives.

**2.1.35 Fragrance materials:** Substances obtained by chemical synthesis or derived from a natural source and present in a fragrance at any level. Fragrance materials can be discrete substances or mixtures in natural complex substances. Natural complex substances are plant extracts and their physically modified derivatives that encompass a diverse family of substances. Fragrance materials are materials whose function is to impart or mask a scent and may include chemicals with dual functionality—scent and another function. This definition does not include auxiliary materials such as carriers (e.g., solvents) and preservatives that do not impart or mask a scent.

**2.1.36 Functional class:** A category of chemicals that have similar functions in a formulated product (e.g., surfactants, solvents).

**2.1.37 Hydrotrope:** A substance that increases the solubility in water of another material, which is only partially soluble.

**2.1.38 Ingredient:** One component or a blend of components that are intentionally added to make up a finished product. All ingredients are subject to this Standard, regardless of percentage in the formulation. See Section 5.12 for information on residuals.

**2.1.39 Irritant:** An agent that induces inflammation. Respiratory irritants may produce Reactive Airway Dysfunction Syndrome (RADS), also called irritant induced asthma.

**2.1.40 Licensee product:** A product whose contents are identical to those in a Safer Choice- or DfE-certified product that is manufactured by a third-party, non-Safer Choice or DfE partner under a contract between the Safer Choice or DfE partner/manufacturer and the third party/licensee.

**2.1.41 Manufacturer:** A company that manufactures a finished product formulation. EPA may partner with product manufacturers.

**2.1.42 New Approach Methodologies (NAMs):** NAMs are defined as any technology, methodology, approach, or combination thereof that can be used to provide information on chemical hazard and risk assessment that avoids the use of intact animals.

**2.1.43 Odor elimination chemical:** A chemical additive used to remove odorous chemicals. An odor elimination chemical is distinct from a fragrance or fragrance material, which would mask rather than remove an odor (see fragrances and fragrance materials). An odor eliminator can function by entrapping, encapsulating, neutralizing, or breaking down malodors.

2.1.44 Optical brightener: An alternate name for fluorescent whitening agent.

**2.1.45 Persistence:** The length of time the chemical can exist in the environment before being destroyed (i.e., transformed) by natural processes.

2.1.46 pH adjuster: Acids or bases that decrease or increase pH as needed in a formula.

**2.1.47 Photosensitizer:** A chemical which causes a photoallergy. Photoallergy is a form of allergic reaction due to a metabolite formed by the influence of light. The second and subsequent exposures produce photoallergic skin conditions, which are often eczematous.

**2.1.48 Plasticizer:** Plasticizers are additives that give hard plastics the desired flexibility, durability or other functional characteristics.

**2.1.49 Polymer:** A chemical substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and which consists of less than a simple weight majority of molecules of the same molecular weight.

**2.1.50 Preservative:** A substance that protects against the natural effects of aging, such as decay, discoloration, oxidation, and bacterial degradation.

**2.1.51 Primary noncompliance:** A failure to comply with the terms of the partnership agreement that is both intentional and material to the partnership (e.g., concerns the product formulation).

**2.1.52 Primary packaging:** A container or separable material component in direct contact with the formulated product.

**2.1.53 Private label product:** A product whose contents are identical to those in a Safer Choice- or DfEcertified product, or vary only as to minor components (reviewed by Safer Choice and specified in the Partnership Agreement), that is manufactured by a Safer Choice or DfE partner for a third-party/privatelabel company or distributor.

**2.1.54 Product class:** A category of products that have similar functions (e.g., glass cleaners, laundry detergents). Also referred to as **product category**.

**2.1.55 Protease:** An enzyme, also called a peptidase, which catalyzes the cleavage of internal peptide bonds in a polypeptide or protein.

**2.1.56 Recyclable:** Packaging that can be collected, separated, or otherwise recovered from the waste stream through an established recycling program for reuse or use in manufacturing or assembling another item. Recycling facilities that take the package must be available to consumers or communities where the item is sold.

**2.1.57 Recycled content:** Materials used in the manufacture of packaging that are recovered or otherwise diverted from the waste stream after consumer use (post-consumer).

**2.1.58 Residual:** Trace amounts of chemicals that are incidental to manufacturing. Residuals are not part of the intended chemical product but are present because of factors such as the nature of the synthesis and engineering pathways used to produce the chemical. Residuals include unintended by-products of chemical reactions that occur in product formulation and chemical synthesis, impurities in an ingredient that may arise from starting materials, incompletely reacted components, and degradation products.

**2.1.59 Residual of concern:** A residual that fails to meet the criteria in the Standard for carcinogenicity, mutagenicity, reproductive toxicity, and other human health effects, or fails to meet the criteria for persistence, bioaccumulation and toxicity, as defined by the Final PB&T Rule. See Section 5.12 for more information.

**2.1.60 Reusable:** Packaging that allows either the business or the consumer to put the same type of purchased product back into the original packaging, is designed to be returnable and/or refillable, and accomplishes a minimum number of reuses by being part of a system that enables reuse. See also <a href="https://www.ftc.gov/news-events/topics/truth-advertising/green-guides">https://www.ftc.gov/news-events/topics/truth-advertising/green-guides</a> (16 CFR 260.14).

2.1.61 Rheology modifier: A chemical that modifies the viscosity of a formulation.

**2.1.62 Sensitization:** The progressive amplification of a response following repeated administrations of a stimulus.

**2.1.63 Sensitizer, respiratory:** A substance that will lead to hypersensitivity of the airways and resultant effects following inhalation.

2.1.64 Sensitizer, skin: A substance that will induce an allergic response following skin contact.

**2.1.65 Solubility enhancer:** A chemical additive that prevents chemicals or materials from separating or falling out of solution. Solubility enhancers are often used in concentrated formulations. Solubility enhancers consist of subcategories such as hydrotropes and small amines.

**2.1.66 Small amines:** Water-soluble compounds having a basic (alkaline) nitrogen functional group. The amine nitrogen atom may be mono- (primary amines; R-NH2), di- (secondary amines; R2NH) or tri-substituted (tertiary amines; R3N). The organic aliphatic substituent(s) may include ether and/or hydroxyl functional groups. Small amines serve as pH adjustors and solubilizing agents. Typical small amines will have MW <200 and no more than 9 carbon atoms.

**2.1.67 Solvent:** A liquid that has the ability to dissolve, suspend, or extract other materials without causing chemical change to the material or solution.

**2.1.68 Supplier:** A manufacturer of a chemical component or ingredient, which is not an end-use product. A supplier furnishes raw materials to formulators.

**2.1.69 Surfactant:** Any organic substance and/or preparation which has surface-active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of reducing the surface tension of water, and of forming spreading or adsorption monolayers at the water-air interface, and of forming emulsions and/or microemulsions and/or micelles, and of adsorption at water-solid interfaces. Surfactants may also be used for purposes other than detergents such as emulsifiers, foaming agents, wetting agents, and stabilizers for dispersions.

**2.1.70** Third-party profiler (TPP): A person or body serving as an external verifier. See Section 8 for third-party profiler requirements.

**2.1.71 Toll manufacture product:** A product whose contents are identical to those in a Safer Choice- or DfE-certified product that is manufactured by a third-party, non-Safer Choice or DfE partner under an agreement between the Safer Choice or DfE partner and the third-party/toll manufacturer.

2.1.72 Vapor: The gaseous form of a substance or mixture released from its liquid or solid state.

# 2.2 Acronyms

AATCC - American Association of Textile Chemists and Colorists

ACI – American Cleaning Institute

AMS – Aerospace Material Specification

ANSI – American National Standards Institute

AOEC – Association of Occupational and Environmental Clinics

ASTM – American Society for Testing and Materials

CAS – Chemical Abstracts Service

CRI – The Carpet and Rug Institute

DfE – Design for the Environment

DOT – Department of Transportation

EPA – US Environmental Protection Agency

FDA – Food and Drug Administration FIFRA – Federal Insecticide, Fungicide, Rodenticide Act FTC – Federal Trade Commission GHS - Globally Harmonized System of Classification and Labeling of Chemicals HAP - Hazardous Air Pollutant HCPA – Household & Commercial Products Association HCS - Hazard Communication Standard I/I – Industrial and Institutional IARC - International Agency for Research on Cancer IFRA – International Fragrance Association ISO - International Standards Organization ISSA – The Worldwide Cleaning Industry Association IUPAC – International Union of Pure and Applied Chemistry NAM – New Approach Methodology NTP - National Toxicology Program OECD - Organisation for Economic Co-operation and Development OSHA – Occupational Health and Safety Administration PBT - Persistent, Bioaccumulative and Toxic ppm - parts per million SDS - Safety Data Sheet SIDS - Screening Information Data Set **TPCH – Toxics and Packaging Clearinghouse** TRI – Toxic Release Inventory TSCA – Toxic Substances Control Act VOC – Volatile Organic Compound

# **3** General Requirements

# 3.1 General

**3.1.1** Product and material information described in Section 3.2 shall be used to determine the specific section under which a product and its ingredients shall be evaluated.

**3.1.2** Products or ingredients whose intended uses fall under more than one section of the Standard document shall be evaluated under the section having the most rigorous evaluation criteria.

**3.1.3** To obtain Safer Choice or DfE certification for a product, the applicant must comply with the information requirements in Section 3.2 et seq. and must enter into a Partnership Agreement with EPA. The Partnership Agreement governs the relationship between EPA and its partner, the product formulator or manufacturer. It contains, among other elements, provisions covering the following: full ingredient disclosure; notification of changes in formula and the need for prior EPA approval; the partner's commitment to continuous product improvement; limitations and responsibilities regarding use of the Safer Choice label or DfE logo; and partnership sunset and opportunity for renewal. Sample Partnership Agreements for Safer Choice or DfE, containing all required elements, appear in Annexes A and B, respectively.

# 3.2 Information and Formulation Requirements

**3.2.1** The applicant shall submit, at a minimum, the complete product formulation information. All ingredients, including chemicals intentionally generated *in situ*, shall be reviewed to ensure that the potential environmental and human health effects of products and ingredients are accurately and adequately identified. Applicants must report all ingredients intentionally added to the formulation, regardless of percentage. The full composition of all intentionally added ingredients must be disclosed by all ingredient manufacturers to evaluate a product formulation; this may include disclosure by secondary and tertiary ingredient manufacturers. Additionally, known residuals must be reported if present at greater than 0.01% by weight; see the discussion of residuals in Section 5.12. Applicants must report:

• The intended function or end use of the product or the material;

- The composition of the formulation, including the percent or percent range of each ingredient in the formulation and its corresponding function as well as ingredient form when appropriate;
- A CAS Number, functional name, trade designation, and supplier for each intentionally added ingredient present in the formulation;
- A Safety Data Sheet (SDS) for the product and each ingredient, when available;
- The pH of the finished product, if applicable (see Section 4.2.2);
- The form of the finished product (e.g., liquid, trigger sprayer, aerosol, solid, foaming nozzle, wipe);
- Effective use concentrations;
- The expected yearly production volume of the end-use product;
- Product performance data (see Section 4.2.1);
- Information on environmental considerations in packaging (see Section 4.2.5);
- When available, a list of published and unpublished toxicological studies relevant to the chemicals and impurities present in the product, component, or material;
- Any other available supplemental product or ingredient environmental health and safety information, including biodegradation tests on individual ingredients; acute aquatic toxicity tests on product as a whole or individual ingredients; and human health and safety tests; and
- Information on the supplier(s) of each product ingredient (Note: partners must notify EPA of any change in or addition of a supplier).

**3.2.2** While reviewing the formulation information provided by the applicant, EPA will also determine any formulation-dependent contaminants to be evaluated in addition to product-specific requirements.

**3.2.3** EPA establishes implementation and compliance schedules, which may be on a case-by-case basis, to govern the time frames, following program changes or audits, by which partners must make changes to their formulations or operations to remain in good standing.

#### 3.3 Renewals

As described in Section A.17 of the Safer Choice Partnership Agreement and Section B.17 of the DfE Partnership Agreement, Safer Choice and DfE partners must renew the partnership prior to its expiration date. Failure to renew will result in termination of the Partnership three years from the date of signature.

#### 3.4 Entering or Exiting a Product Class

#### 3.4.1 Entering a product class

EPA reserves the right to enter or not enter product classes. EPA will consider on a case-by-case basis any manufacturer's request to open a product class to certification. EPA will weigh a number of factors in its decision, including the product type or chemical components, likely improvements to human health and environmental protection, and if the current program criteria adequately address all aspects of the new class.

EPA may solicit public input before entering into a new product class to determine whether the introduction of the Safer Choice label or DfE logo would advance the goals of the respective program. If EPA has not entered a product class, EPA will not certify a product in that product class, even if it would otherwise meet the Standard.

# 3.4.2 Exiting a product class

EPA reserves the right to exit a product class. For product classes that are currently active (i.e., classes with current partnership agreements that cover certified products in the relevant class), in the event that EPA decides to exit such a product class, EPA may notify and provide an opportunity for comment from any affected partners and stakeholders in that product class. If EPA decides to exit the product class, EPA will discontinue new product certification in the product class and not renew any existing partnerships at renewal, allowing a period of time for the partner to cease use of the label or logo.

# 3.4.2.1 Exceptional circumstances affecting health or the environment

Notwithstanding a partner's performance under the partnership agreement, if the Agency becomes aware of serious adverse health or environmental effects implicating a product class, EPA may end an existing partnership in that class during the partnership period and discontinue product certification in the class, as circumstances warrant. When such a circumstance arises, EPA will notify the affected partners and stakeholders of the situation and its intention to exit the class. EPA may provide an opportunity for comment. If EPA decides to end an existing partnership, EPA will allow a period of time for the partner to cease use of the label or logo. Sample Partnership Agreements for Safer Choice and DfE cover EPA's exit from a product class and appear in Annexes A and B, respectively.

# 3.5 End-User Education

Formulators of Safer Choice- and DfE-certified products shall provide their end-user(s) with information on environmental, consumer, and worker safety materials. EPA encourages partners to provide customers with a 16-section format SDS, as established by the Occupational Safety & Health Administration's (OSHA's) Hazard Communication Standard (HCS) for preparation of SDSs (29 CFR 1910.1200). The revised HCS adopts the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals to more uniformly and effectively communicate chemical hazards. When developing a product SDS, partners should comply with the HCS and also be attentive in calculating the percentage thresholds that require use of GHS hazard symbols and not automatically transfer symbols from supplier SDSs to their products.

# 3.6 Verification of Partnership Compliance

As described in Section A.10 of the Safer Choice Partnership Agreement and Section B.10 of the DfE Partnership Agreement, partners agree to make available to the EPA, on a confidential basis, formulation bills of material (e.g., batch tickets) to confirm that the certified products contain the ingredients as described in the Partnership Agreement.

# 3.6.1 On-site audit

Safer Choice and DfE partners will allow the third-party profiler to visit their manufacturing facilities and conduct audits (elements of the on-site audit are listed in Annex C.2). The on-site audit will focus on the manufacturing process and the procedures in place to ensure that certified products comport with the Partnership Agreement. Under newly established partnerships, an on-site audit must be the first audit conducted during the 3-year certification cycle.

If a single facility produces a certified product, that facility will be subject to a site audit once per threeyear partnership period. If multiple facilities produce a certified product, two sites will be selected for an audit once per three-year partnership period. Licensees and toll manufacturers are subject to the same rules as primary partners and their facilities will be considered separately from the facilities of the primary partner.

# 3.6.2 Desk audit

Safer Choice and DfE partners will submit to the third-party profiler specified materials (elements of the desk audit are listed in Annex C.1). The desk audit – occurring during year two of the 3-year certification cycle – will focus on the partner's print and electronic materials and verify the authorized formula through a review of production records.

# 3.6.3 Third-party profiler

A qualified third-party profiler will conduct the site visits or paper audits. The third-party profiler must meet the criteria for qualified third-party profilers in Section 8 of this document, as well as the competencies for third-party profilers for products in ISO/IEC Guide 17065: Conformity assessment – Requirements for bodies certifying products, processes, and services. Competence criteria are specified in ISO/IEC Guide 17065 Sections 6.1.1 and 6.1.2. A third-party profiler must be free of any potential conflicts of interest.

# 3.6.4 Results

If the audit reveals items of noncompliance, the partner must promptly correct the noncompliance. The noncompliant company must submit to the third-party profiler and to EPA, in writing and within 30 days of receiving written notice of noncompliance, the following: a root-cause analysis, an explanation of corrective action, and a preventive action plan. In collaboration with EPA, the third-party profiler must confirm that the partner has taken the remedial action necessary to assure EPA of the partner's ability to satisfy the terms of the Partnership Agreement. Unaddressed or egregious noncompliance may serve as grounds for terminating the partnership. In any case of serious noncompliance, the Safer Choice or DfE partner may be asked to immediately cease use of the Safer Choice label or DfE logo; procedures for handling existing stocks of products and labels will be determined on a case-by-case basis. The noncompliant partner must provide written confirmation that they have ceased using the Safer Choice label or DfE logo and an estimate of the quantities of the currently certified product(s). Primary noncompliance may serve as grounds for terminating the partnership.

# 3.7 Third-Party Manufacture of Safer Choice- and DfE-Certified Products

# 3.7.1 Private label products

A private label product may carry the Safer Choice label or DfE logo provided that its contents are either identical to those in a specified Safer Choice- or DfE-certified product, or very similar, and the ingredients that are different have been approved in the Partnership Agreement. Before manufacture of the private label product that will carry Safer Choice or DfE certification, the Safer Choice or DfE partner must inform and receive permission from EPA, indicating the name of the private label product, the label owner, and the specific Safer Choice- or DfE-certified product to which it is identical or on which it is based. Private label products carrying the DfE logo must possess a supplemental registration, provided by the Office of Pesticides Programs, that is linked to the primary registration of the label owner. Private label products are subject to the audit provisions contained in Section 3.6. Where the dilution of a certified concentrate is conducted by the private label company, the partner must communicate to Safer Choice the concentrate that is being diluted and verify the corresponding dilution rates.

# 3.7.2 Licensee products

A licensee product may carry the Safer Choice label or DfE logo provided that its contents are identical to those in a specified Safer Choice- or DfE-certified product. Before manufacture of the licensee product, the Safer Choice or DfE partner must inform and receive permission from EPA, indicating the name of the licensee manufacturer and of the specific Safer Choice- or DfE-certified product to which the licensee product is identical. To assure quality, the licensee product must be manufactured under an agreement

between the Safer Choice or DfE partner and the licensee and the agreement must be available to EPA on request. Safer Choice and DfE partners must ensure that their licensees submit to the audit provisions contained in Section 3.6.

# 3.7.3 Toll-manufactured products

A toll manufacture product may carry the Safer Choice label or DfE logo provided that its contents are identical to those in a specified Safer Choice- or DfE-certified product. Before toll manufacture of the Safer Choice- or DfE-certified product, the Safer Choice or DfE partner must inform and receive permission from EPA, indicating the name of the toll manufacturer and of the specific Safer Choice- or DfE-certified product to which the toll-manufactured product is identical. To assure quality and compliance with the Partnership Agreement, the toll-manufactured product must be manufactured under an agreement between the Safer Choice or DfE partner and the toll manufacturer and the agreement must be available to EPA on request. Safer Choice and DfE partners must ensure that their toll manufacturers submit to the audit provisions contained in Section 3.6.

# 3.8 Ingredient Communication

To enhance public awareness of the safer ingredients in Safer Choice- and DfE-certified products and in the spirit of more complete communications on chemicals in common use, formulator-partners must disclose the contents of their Safer Choice- and DfE-certified products as described herein.

# 3.8.1 Scope

Except as provided below, manufacturers must disclose all intentionally added ingredients in their Safer Choice- and DfE-certified products, except for "incidental ingredients." Incidental ingredients may be added to some product batches when needed (e.g., to adjust pH). As defined in 21 CFR §701.3(l), incidental ingredients are "present... at insignificant levels that have no technical or functional effect" (e.g., reagents, processing aids, and impurities) (<u>https://www.ecfr.gov/current/title-21/chapter-I/subchapter-G/part-701/subpart-A/section-701.3</u>). For the purposes of the Safer Choice program's ingredient disclosure requirement, EPA defines insignificant levels of incidental ingredients as <0.01% or <100 parts per million (ppm).

# 3.8.2 Locus of disclosure

Ingredients must be disclosed in one of the following locations: on the product label; on the formulator's website; at a toll-free number; or, on another media approved by EPA. If disclosure does not occur on the product label, the formulator must provide the location of the ingredients on the label, e.g., the website address or toll-free number. If disclosure occurs via a toll-free number, it must be available to the public at all times.

# 3.8.3 Ingredient descriptions

Except for ingredients protected as trade secrets (as defined in the Uniform Trade Secrets Act), formulators must use the CAS Number, if available, and one or more of the following nomenclature systems to describe their ingredients: CAS name; the Household & Commercial Products Association (HCPA) Ingredient Dictionary name; International Nomenclature of Cosmetic Ingredients (INCI) name; or, International Union of Pure and Applied Chemistry (IUPAC) name. Generally, for ingredients protected as trade secrets, a manufacturer may use chemical-descriptive name, for example, the EPA Premanufacture Notice generic name or the HCPA Dictionary name, in lieu of the specific chemical name; however, the name must be as specific as possible without revealing trade secret information.

The following class of ingredients are commonly protected as trade secrets. When ingredients in these classes are trade secrets, they should be disclosed as follows:

**Dyes and colorants**. Dyes and colorants should be listed by a chemical-descriptive name.

**Fragrances**. Scent ingredients may be listed as "Fragrance," on the label, but the formulator must indicate where detailed information can be found; for example, the website list, or subset of the list of fragrance materials authored by IFRA and available on IFRA's website (<u>https://ifrafra-grance.org/</u>). Alternatively, if not a matter of trade secret, the product formulator may state on its website the ingredients in the fragrance or the palette of fragrance materials used in its products, and may include, at the formulator's discretion, ingredients not used in the fragrance.

**Preservatives**. Preservatives in non-pesticidal products should be listed by a chemical-descriptive name. Pesticidal preservatives are subject to the US EPA Office of Pesticide Program regulations and guidance.

#### 3.8.4 Listing order

Formulators must use the following approach in listing ingredients: for those present at concentrations over 1.0% (measured on a weight-weight percentage basis), ingredients must be listed in descending order, with the ingredient at the highest percentage in formula listed first; for those present at or below 1.0%, ingredients may be listed in any order.

# 4 Product-Level Requirements

#### 4.1 Scope

The requirements in this section apply to finished products, including (but not limited to) those in the following classes: all-purpose, hard surface, glass, degreasers, kitchen and bath, hand dish, drain cleaning and maintenance, floor care, carpet care, car care, laundry, dish detergents, marine cleaning, graffiti removal, and odor removal.

#### 4.2 Criteria for All Products

#### 4.2.1 Performance

To ensure a baseline measure of performance, the applicant must make a good faith demonstration that their products perform effectively. Applicants must submit appropriate test results as specified below or provide equivalent performance tests or other demonstration of performance agreed upon by EPA.

Performance testing requirements are product-class specific. Partners and candidate partners must consult EPA or an authorized third-party profiler concerning product classes not specifically addressed below. For cleaning products, for example, each product shall effectively clean common soils and surfaces in its class at the most diluted/least concentrated manufacturer-recommended dilution level for routine cleaning, as measured by the following applicable standard test methods.

Manufacturers may use an alternative method approved by EPA to test performance. The alternative method must be objective and scientifically validated, conducted under controlled and reproducible laboratory conditions, include controls when appropriate, and produce quantitative results. EPA must approve the acceptable performance level. Alternatively, the product must perform comparably to a conventional, nationally recognized product in its class and at equivalent product-specific use directions.

Performance for DfE-certified products related to antimicrobial label claims should be demonstrated through the registration process. A company manufacturing a DfE-certified product with label claims for performance such as degreasing or cleaning – in addition to those regulated under FIFRA – must provide performance testing to the program to support those claims.

Examples of performance requirements that are acceptable to EPA include but are not limited to (note: Where updated versions of the tests listed below are available, use the latest versions):

# 4.2.1.1 Window/glass cleaners

The product must achieve at least a rating of three for cleaning, streaking and smearing when tested according to HCPA method DCC-09 and DCC-09A or equivalent method agreed upon by EPA.

#### 4.2.1.2 All-purpose cleaners

The product must remove at least 80% of the particulate or greasy soils, as appropriate, when tested according to ASTM G122, DCC-17, CAN/CGSB 2-GP-11 Method 20.3, ASTM 4488, or an equivalent method agreed upon by EPA.

#### 4.2.1.3 Carpet cleaners/spot removers

The product must meet user requirements when tested according to HCPA DCC-03 and AATCC Test Method 171-1995, and CRI TM-110. Alternatively, the product may be tested for cleaning efficacy and resoiling resistance using another equivalent method agreed upon by EPA as described in Section 4.2.1. Products that have WoolSafe certification or a Carpet and Rug Institute Cleaning Solutions Seal of Approval, or the equivalent, will be deemed to satisfy this provision.

#### 4.2.1.4 Tub/tile, toilet bowl cleaners

The product must remove at least 75% of soil using ASTM D5343-06, HCPA DCC-16, or equivalent method agreed upon by EPA. If the product is used for toilet bowl or urinal cleaning, it must also demonstrate efficacy under diverse water hardness conditions using an appropriate method agreed upon by EPA, as described in Section 4.2.1.

#### 4.2.1.5 Degreasers

The product must meet user requirements for soil removal on relevant substrates when tested according to ASTM method G122, CAN/CGSB 2-GP-11, Method 20.3, HCPA DCC-17, or an equivalent method agreed upon by EPA.

# 4.2.1.6 Laundry and related products

A consumer pre-wash spotter stain remover must meet user requirements in HCPA DCC-11 or an equivalent method agreed upon by EPA.

A fabric softener must meet user requirements in HCPA DCC-13 or an equivalent method agreed upon by EPA.

A laundry detergent must meet user requirements in HCPA DCC-14 or an equivalent method agreed upon by EPA.

#### 4.2.1.7 Oven cleaners

An oven cleaner must meet user requirements in HCPA DCC-12 or an equivalent method agreed upon by EPA.

#### 4.2.1.8 Hand dish soaps

A hand dish soap must meet user requirements in HCPA DCC-10 and DCC-18 or an equivalent method agreed upon by EPA.

# 4.2.1.9 Aircraft cleaners

An aircraft cleaner must meet user requirements in Boeing D6-17487 and AMS 1526 and 1530 or an equivalent method agreed upon by EPA.

# 4.2.1.10 Fire defense products

A fire defense product must meet requirements in Forest Service Specification 5100-304d or an equivalent method agreed upon by EPA.

# 4.2.1.11 Biological-based drain products

A biological-based drain maintainer must meet user requirements in HCPA DCC-19 or an equivalent method agreed upon by EPA.

# 4.2.2 pH

To minimize potential for dermal and eye irritation or injury, pH must be  $\geq 2$  and  $\leq 11.5$  for products as sold. Products with pH < 2 or > 11.5 may be considered for certification if *in vivo* assays or Agency-accepted *in vitro* studies (See List of Alternative Test Methods and Strategies or NAMs per TSCA Section 4(h)(2)(c); <u>https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/strategic-plan-reduce-use-vertebrate-animals-chemical</u>) demonstrate the product is not corrosive to the skin or to the eyes.

# 4.2.2.1 Concentrates in closed dilution-controlled systems

If a concentrated product complies with all other elements in this Standard, the pH may exceed the limits in 4.2.2, provided the following conditions are met:

- the manufacturer can demonstrate that the product is designed for use only in a closed dilutioncontrolled dispensing system;
- the system prevents backflow (see, e.g., American Society of Sanitary Engineering standard 1055B) and is designed to minimize waste and cross-contamination;
- the pH at the most concentrated use dilution is within the acceptable range of 2 to 11.5;
- the primary packaging is designed to minimize the potential for human exposures or environmental releases (e.g., through a drop test); and
- the label or logo is not used on the product (or packaging) when it is a concentrate (but may be used in promotional materials).

Further, if an ingredient in the concentrate does not meet Safer Choice criteria for acute mammalian toxicity (e.g., via estimation modeling), it may still be acceptable if the company provides experimental data that demonstrate a low concern.

# 4.2.3 Life-cycle considerations

# 4.2.3.1 Information to help reduce carbon-based energy consumption – voluntary provision

Safer Choice and DfE partners may wish to reduce carbon-based energy use. To support the work that partners are doing in this area, we are highlighting EPA programs that can help reduce energy use. Participation in these programs and other energy-saving efforts are optional and are not necessary for product certification, but partners may be recognized for demonstrating outstanding leadership and innovation in sustainable energy use.

EPA encourages partners to act on the voluntary criteria below. For each criterion met, the partner should describe how they have achieved that criterion (i.e., actions taken to meet the criterion). Some of

the following criteria may not be in the purview of each partner's business. Partners are encouraged to take action by:

- Using renewable energy in manufacturing, packaging, use, and/or distribution of products (e.g., participation in EPA's Green Power Partnership);
- Improving energy efficiency in transportation (e.g., participation in EPA's SmartWay program (<u>https://www.epa.gov/smartway</u>) or production of concentrates to reduce product volume/weight in transport);
- Improving energy efficiency in facility operations (e.g., use of EPA's Energy Star products, participation in the Energy Star program as a partner (<u>https://www.energystar.gov/partner\_resources/join-energy-star</u>) or as a certified building or facility, or use of the Energy Star Treasure Hunt program (<u>https://www.energystar.gov/buildings/save\_energy\_commercial\_buildings/treasure\_hunts</u>);
- Designing and developing products that lead to energy savings for the user (e.g., use of concentrates and detergents that work in cold water);
- Reducing water use and its direct and/or embedded energy use through the use of EPA Water-Sense labeled products (<u>https://www.epa.gov/watersense/watersense-products</u>) or implementation of commercial facility Best Management Practices (<u>https://www.epa.gov/watersense/commercial-buildings</u>);
- Selecting and using lower embodied-carbon materials (e.g., materials and products that have substantially lower levels of embodied greenhouse gas emissions associated with all relevant stages of production, use, and disposal, as compared to estimated industry averages of similar materials or products); and
- Pursuing other actions that lead to energy savings.

# 4.2.3.2 Ozone depleting substances

Safer Choice- and DfE-certified products must not contain ozone-depleting substances as defined by the 1987 Montreal Protocol (<u>https://www.epa.gov/ozone-layer-protection/ozone-depleting-substances</u>).

# 4.2.4 Labeling requirements from other agencies

The Safer Choice or DfE partner must provide its customers with information on environmental, consumer, and worker safety matters. The Safer Choice or DfE partner must also meet OSHA, DOT, FDA, and any other authority's requirements to provide safe handling and other worker safety information, as applicable. EPA may prohibit the certification of consumer products that require personal protective equipment, with the exception of gloves, for use.

For partners who would like to meet the Safer Choice and DfE Standard and also highlight biobased content of the packaging and/or the product, see USDA's BioPreferred program (<u>https://www.biopre-</u> ferred.gov/BioPreferred/).

# 4.2.5 Primary packaging

Primary packaging for certified products must meet the sustainable packaging criteria listed in Sections 4.2.5.1 through 4.2.5.3, including recyclability and post-consumer recycled content, label compatibility, and ingredient restrictions.

# 4.2.5.1 Recyclable and post-consumer recycled content

Packages must either be recyclable and be made of a certain percentage of post-consumer recycled content, or be designed to be reused. Packaging that is recyclable, made of a certain percentage of postconsumer recycled content, and designed to be reused would also meet this criterion. The minimum post-consumer recycled content (by weight) for various packaging is listed below. Multimaterial packaging will be considered on a case-by-case basis.

- Plastic packaging requires 15% minimum post-consumer recycled content.
- Glass packaging requires 25% minimum post-consumer recycled content.
- Fiber/cardboard/paper packaging requires 50% minimum post-consumer recycled content.
- Metal packaging requires 30% minimum post-consumer recycled content.

Post-consumer recycled content will be verified by requiring written statements from packaging suppliers. In certain circumstances, when primary packaging for a product cannot meet the requirements for recyclability and/or minimum post-consumer recycled content, partners may request an exemption to these criteria.

For example, EPA understands that certain parts of product packaging (e.g., pump spray-heads) may not be recyclable and that certain packaging may be compostable and therefore not recyclable or made of recycled content. Partners may also request an exemption if, for example, the total weight of the primary packaging cannot meet the recycled content level because of performance needs. Exemptions can also be requested for use of innovative source reduction (e.g., concentrates) and elimination of packaging. A partner requesting an exemption must provide a rationale and supporting documentation for the exemption.

# 4.2.5.2 Label compatibility and labeling instructions

Product labels associated with primary packaging must not affect recyclability. In addition, product manufacturers must include clear instructions or a link to online instructions on the packaging regarding how to recycle or reuse.

#### 4.2.5.3 Primary packaging ingredients

Primary packaging, including coatings, may not contain heavy metals – specifically cadmium, lead, mercury, and hexavalent chromium – in accordance with Toxics and Packaging Clearinghouse (TPCH) model legislation. These criteria may be found at <u>https://toxicsinpackaging.org/model-legislation/</u>. In addition, the following chemical ingredients may not be intentionally introduced into packaging materials, including coatings: per- and polyfluoroalkyl substances (PFAS); bisphenol-based chemicals such as Bisphenol A (BPA) and dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), butyl benzyl phthalate (BBP), di-n-pentyl phthalate (DnPP), di (2-ethylhexyl) phthalate (DEHP), di-n-octyl phthalate (DnOP), diisononyl phthalate (DINP), and diisodecyl phthalate (DIDP).

# 4.2.6 Volatile organic compounds (VOCs)

In view of the contribution VOCs make to indoor air pollution and associated respiratory concerns, EPA restricts product VOC-content based on the most stringent government criteria. Safer Choice- and DfE-certified products must adhere to VOC restrictions as prescribed by the Ozone Transport Commission (OTC) (see federal Clean Air Act, sections 176A and 184) and the California Air Resource Board (CARB). VOC criteria from OTC, "Regulatory & Technical Guideline for Consumer Products Phase V," can be found at <a href="https://otcair.org/upload/Documents/Reports/OTC\_RegAndTechGuidelineOnConsumerProducts\_Phase\_V\_Final\_11202018.pdf">https://otcair.org/upload/Documents/Reports/OTC\_RegAndTechGuidelineOnConsumerProducts\_Phase\_V\_Final\_11202018.pdf</a>. VOC criteria from CARB, "Regulation for Reducing Emissions from Consumer Products," can be found at <a href="https://www.arb.ca.gov/sites/default/files/2022-11/Consumer%20Products%20Reg%20Article%202\_11-30-22.pdf">https://www.arb.ca.gov/sites/default/files/2022-11/Consumer%20Products%20Reg%20Article%202\_11-30-22.pdf</a>. For products that are not accounted for in CARB's product categories, partners should demonstrate best efforts to minimize VOCs.

# 4.2.7 Flammability

Certified products must not exhibit the characteristic of ignitability, as defined at 40 CFR 261.21 (a)(1), and therefore must have a flash point at or above 60°C (140°F). The characteristic of ignitability includes an exception for aqueous solutions containing less than 24% alcohol by volume, for example, certain

disinfectants, as needed for product function. The flash point shall be determined by a closed-cup method, specifically, ASTM E502, or an equivalent method agreed to by EPA.

# 4.2.7.1 Industrial laundry detergents

Manufacturers of laundry detergents formulated for industrial applications must provide information on the product's potential to combust spontaneously, i.e., the temperature at which they would catch fire without an outside source of ignition.

# 4.2.8 Yellow triangle content limit

Chemicals on the Safer Chemical Ingredients List (Section 5.18) with a yellow-triangle designation must not cumulatively exceed 10% of a certified product as sold.

# 4.3 Cleaning Systems

A cleaning system, such as a laundry system, is not eligible for certification unless every component meets the Safer Choice criteria. The Safer Choice label or DfE logo may be used to indicate certification for the cleaning system, but not on individual components in the system unless they have independent, end-use applications.

# 4.4 Continuous Delivery Systems for Consumer Products

EPA will consider for certification consumer products in innovative continuous delivery systems (as distinct from products poured from a bottle or manual spray pumps) that reduce the potential for inhalation exposure and meet other environmental goals. Certification candidates must demonstrate significant innovation and environmental leadership. Product ingredients must satisfy the criteria set forth in this document and the Safer Choice criteria.

If ingredients satisfy Safer Choice criteria, products in continuous delivery systems may be certified if they meet the following conditions:

- Propellant. The system propellant will be evaluated against the general requirements in Section 5.2 and based on the Master Criteria and does not pose concerns for the environment and human health (e.g., compressed air; inert gas, like nitrogen; or CO2, if captured from combustion processes, with zero net increase in atmospheric CO2).
- Particle size distribution. Either a) the product contents from nozzle to the point of delivery are in a form that does not contain inhalable or respirable particles (e.g., foam); or, b) if the product contents are delivered in particle form, the distribution of particles below 10 microns (the inhalation threshold) must be less than 1% and below 3.5 microns (the deep-lung respirability threshold) must be at 0%, as demonstrated by generally accepted methods for measuring particle size of liquid sprays.
- Packaging. a) Internal packaging. Any internal product packaging must not contain chemicals of concern per the Safer Choice criteria; b) External packaging. In addition to the requirements in Section 4.2.5 on allowed materials, the product container and other external packaging should be made, to the extent feasible, of recycled materials and be itself recyclable.

# 4.5 Ingredient Combinations Causing Unintended Effects

As part of product review, EPA will evaluate the potential combined or synergistic effects of ingredients and, if such a combination would result in health or environmental effects that do not meet the program's safer ingredient criteria, EPA would not allow products with those ingredient combinations to carry the Safer Choice label or DfE logo.

# 4.6 Products in Solid or Particulate-Generating Form

Manufacturers of products in solid or particulate-generating form must provide, upon request, information (e.g., particle size distribution) that allows EPA to determine that the product: a) does not contain or generate a substantial portion of particles that are respirable (i.e.,10 microns or less); and, if appropriate, b) does not produce potential waste products of concern (candidate must submit an analysis of the byproducts generated). See also Section 5.16 on processing aids.

# 4.7 Special Product Classes

The following product classes have criteria, listed at <u>https://www.epa.gov/saferchoice/standard</u>. New product classes may be added in the future. Such additions will be included on the webpage but may not be listed in this section of the Standard.

# 4.7.1 Inorganic- and mineral-based products

The standard Safer Choice review is not oriented to evaluating a product composed solely of inorganic materials or minerals, which are typically inert and function via friction, for example, rather than chemical activity. EPA recognizes, however, that these products may substitute for chemical-based products that contain ingredients of potential concern and may generate significant direct and collateral human health and environmental benefits. EPA has therefore developed evaluation criteria that may make it possible to label these products (e.g., cleaners made of crushed glass or stones).

# 4.7.2 Microorganism-based products

Microorganism-based products are a distinct class and subject to tailored evaluation criteria available at <u>http://www.epa.gov/saferchoice/standard#microorganism</u>. In its review, EPA carefully considers the identity and potential hazards and risks of the microbial species in combination with other considerations like purity of strain, ingredient functionality, product performance, and manufacturing conditions.

# 4.7.3 Products designed for dermal contact

In addition to the criteria in this standard, products whose use will involve prolonged dermal contact must comply with the supplemental requirements listed below (the Safer Choice Criteria at <a href="http://www.epa.gov/saferchoice/standard#tab-2">http://www.epa.gov/saferchoice/standard#tab-2</a> contain guidance on appropriate testing). To the extent these products fall under the jurisdiction of the Food and Drug Administration (FDA), Safer Choice will consult with FDA prior to implementing this provision. (Safer Choice will be guided by FDA judgments, as expressed, for example, in official monographs, on the safety of products and ingredients.) It is important to note that compliance with the terms of this section does not alter a company's obligations under the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act, as applicable. If a product qualifies for the label under sec. 4.7.3, it may need to carry a statement that indicates that FDA has not reviewed the product under this provision.

# 4.7.3.1 Endocrine effects

Chemicals that are candidates for endocrine screening (see Section 5.2.1.5) will be assessed for health effects. Chemicals found to interact with or perturb the endocrine system, if associated with reproductive, developmental, carcinogenic, or other effects, will not be allowed.

# 4.7.3.2 Residuals of concern

EPA collects information from chemical manufacturers on known residuals and will limit the percentage of residuals of concern in products. Residuals of concern are limited to <0.01% (<100 ppm) in the formulation (Section 5.12). If other federal regulatory restrictions exist for a given chemical or product type, the more protective use limit will apply.

# 4.7.3.3 Colorants

Color additives, in any product type, must meet both FDA requirements and Safer Choice criteria for health and environmental safety. Any candidate colorant must appear on the FDA list for use in the United States and comply with FDA regulations on appropriate conditions for use (as per 21 CFR Parts 70-82).

#### 4.7.3.4 Ingredients on prohibited lists

Ingredients on authoritative lists of chemicals prohibited or restricted for use in cosmetics—notably, the FDA Cosmetics list (see 21 CFR 700.11 et seq.), the European Union Cosmetic Directive (Annex II), the Health Canada "Hotlist," and the Cosmetic Ingredient Review "Unsafe for Use" list (at <u>http://www.cir-safety.org</u>)—will not be acceptable in certified products, as confirmed by their toxicological hazard and failure to pass the criteria for safer chemical ingredients.

#### 4.7.3.5 Non-irritants

Only ingredients that are non-irritating to skin and eyes, as demonstrated by testing, clinical studies or consumer experience, will be acceptable. At a minimum, a product or its ingredients must not be categorized as an irritant under EPA Office of Pesticide Program regulations (i.e., must not require a precautionary statement) or GHS criteria.

#### 4.7.3.6 pH

To further minimize the potential for dermal, eye or mucous membrane irritation, product pH must be greater than or equal to ( $\geq$ ) 4 and less than or equal to ( $\leq$ ) 9.5; products with a pH outside this range may be considered for certification if *in vivo* testing or scientifically valid non-animal testing demonstrates they are non-irritating, or if they are known to be non-irritating based on their physical-chemical properties (e.g., buffering capacity).

# 4.7.3.7 Allergens and sensitizers

No ingredients classified under GHS as skin or respiratory sensitizers are permitted in certified products. The labeling of FDA food allergens (e.g., peanut, soy, dairy) must follow the requirements in the Food Allergen Labeling and Consumer Protection Act of 2004. Whole product testing may also be used to address concerns for sensitization potential (see text methods listed in Master Criteria).

#### 4.7.3.8 Dermal absorption

Where an ingredient may be dermally absorbed, the applicant must provide data, for example, repeated dose toxicity testing via the dermal route of exposure, on potential effects; these data must indicate that the ingredient presents a low hazard concern.

#### 4.7.3.9 Fragrances

Fragrances must comply with the Safer Choice Criteria for Fragrances (at <u>http://www.epa.gov/saf-erchoice/safer-choice-criteria-fragrances</u>); the criteria will apply to all fragrance components regardless of percentage in the fragrance.

#### 4.7.4 **Products intended for use on pets**

In addition to other requirements in the Standard (e.g., Section 4.7.3), EPA will make special efforts to evaluate data on effects that are particular to pets. Under this Standard, EPA would only label non-pesticidal and non-drug-pet-care products. Chemicals used in formulations intended for use on pets must be evaluated for human and pet health in addition to environmental toxicity and fate. Ingredients that are

severely irritating or corrosive to skin or eyes are not allowed in certified pet care products unless whole product testing demonstrates low concern for irritation. GHS listed sensitizers are not allowed in certified pet care products unless the manufacturer provides whole product testing demonstrating low concern for sensitization or a rationale based on functional necessity that also addresses sensitization. Additionally, with the exception of fragrance materials, ingredients in pet care products must meet direct release criteria (see Section 4.8.1).

# 4.7.5 Marine lubricants

Manufacturers of marine lubricants subject to the Office of Water Vessel General Permit (VGP) requirements for environmentally acceptable lubricants (EALs), who wish to qualify for the Safer Choice label, must comply with the Standard and criteria, with the limited exceptions and additional requirements specified in <u>https://www.epa.gov/saferchoice/standard#marine</u>.

# 4.7.6 Specialized industrial products

Specialized Industrial Products (SIPs) are a distinct subgroup of products that meet tailored criteria under the Safer Choice program. EPA is using the term "specialized" for this subset of Industrial and Institutional (I/I) products to distinguish them based on performance requirements from other, more common I/I products, like cleaners and detergents, and to indicate that they require certain ingredients with special, high-performance functionalities. Nevertheless, to earn the Safer Choice label, a candidate product and its ingredients must meet the general SIP criteria as well as the subclass-specific requirements specified in <a href="https://www.epa.gov/saferchoice/safer-choice-criteria-specialized-industrial-products">https://www.epa.gov/saferchoice/safer-choice-criteria-specialized-industrial-products</a>.

# 4.8 Special Product Classifications

# 4.8.1 Direct release products

Products intended for use outdoors (e.g., boat cleaners, graffiti removers) are likely to bypass sewage treatment, limiting the time for degradation prior to entering sensitive environments. All ingredients in these products must meet enhanced environmental criteria to address the potential for immediate contact with aquatic life (see <u>https://www.epa.gov/saferchoice/standard#directrelease</u>).

For products that qualify for the Safer Choice label or DfE logo, manufacturers may request an additional certification – the Certified for Outdoor Use label/logo – to indicate that a product meets the direct release criteria.

# 4.8.2 Fragrance-Free products

For products that qualify for the Safer Choice label or DfE logo, manufacturers may request an additional certification—the Fragrance-Free label/logo—to indicate that a product contains no fragrance materials. To qualify for the Fragrance-Free label, a product must first meet all requirements in the Standard. A product can qualify for the Fragrance-Free label/logo after an EPA review to confirm that the product contains no fragrance materials. Chemicals with dual functionality, including use as a fragrance, are not allowed in fragrance-free products.

# 4.8.3 Antimicrobial products

EPA's DfE program is administered jointly between EPA's Office of Pollution Prevention and Toxics (OPPT) and EPA's Office of Pesticide Programs (OPP). To obtain DfE certification, registrants must submit information to both offices (see <u>https://www.epa.gov/pesticide-labels/design-environment-dfe-certifica-tion-information-registrants</u>). In most cases, applicants should complete the OPPT review process before engaging with the OPP's Antimicrobials Division.

# 5 Component-Specific Requirements

# 5.1 Scope

The requirements of this section apply to the components of a finished product. The general requirements outlined in Section 5.2 will apply to all chemicals unless noted differently in the functional-class-specific criteria.

# 5.2 General Requirements

The general requirements listed in the Master Criteria (<u>https://www.epa.gov/saferchoice/safer-choice-master-criteria-safer-chemical-ingredients</u>), as applied by EPA experts, are intended as a base set of criteria all ingredients must meet to be acceptable for use in a Safer Choice- or DfE-certified product. These criteria make it possible for EPA to ensure that chemicals in certified products are from 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. The subsequent sections are additional requirements or exceptions to the Master Criteria requirements for specific functional-use ingredient classes.

For every chemical, ingredient data are required for each endpoint to confirm that the ingredient meets the Safer Choice criteria. Established lists from authoritative bodies, such as the IARC and NTP carcinogen lists, may be used to identify ineligible ingredients, where available and as noted in the criteria below. When an ingredient is not found on lists of hazardous chemicals, raw data for each endpoint are preferred. Appropriate analog data may also be used to fill data gaps. When possible, EPA encourages minimizing the use of new animal testing and instead encourages use of NAMs identified for use under TSCA (per TSCA Section 4(h)(2)(C)). The Safer Choice program may consider additional NAMs that meet EPA's criteria for scientific reliability and relevance on a case-by-case basis. The list and criteria can be found at <u>https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce</u>.

# 5.2.1 Lists of hazardous chemicals

Except as noted, EPA excludes from products that carry the Safer Choice label, or the DfE logo, chemicals on the authoritative lists below. Authoritative lists are one source of information EPA uses in its product evaluations, which also include empirical data, estimation models, and structure activity analysis.

# 5.2.1.1 Hazardous Air Pollutants (HAPs)

EPA does not allow certified products containing chemicals that are included on EPA's list of pollutants designated as hazardous air pollutants (HAPs) or air toxics, except those that meet the Safer Choice criteria. The list of HAPs can be found at <a href="https://www.epa.gov/haps/initial-list-hazardous-air-pollutants-mod-ifications">https://www.epa.gov/haps/initial-list-hazardous-air-pollutants-mod-ifications</a>.

# 5.2.1.2 Toxics Release Inventory (TRI)

EPA does not allow certified products containing chemicals included on EPA's Toxics Release Inventory chemical list, except those that meet the Safer Choice criteria. The list of TRI chemicals can be found at <a href="https://www.epa.gov/toxics-release-inventory-tri-program/tri-listed-chemicals">https://www.epa.gov/toxics-release-inventory-tri-program/tri-listed-chemicals</a>.

# 5.2.1.3 Lists of carcinogens, mutagens, and reproductive toxicants

Among other sources of information, EPA does not allow certified products to contain chemicals that are on the lists of potential carcinogens, mutagens, and reproductive/developmental toxicants from the following authoritative bodies, except as exempted based on properties that do not pertain to certified products (e.g., physical form (crystalline), extreme pH, etc.): the International Agency for Research on Cancer (IARC) (Groups 1, 2A, and 2B), the National Toxicology Program (NTP), the EPA Integrated Risk Information System (IRIS), National Institute for Occupational Safety and Health (NIOSH), European Commission (EC), and California's Proposition 65 (Prop 65). A full set of reference lists with prohibited chemicals appears in section 5.2 of the Master Criteria.

# 5.2.1.4 Lists of potential persistent bioaccumulative, and aquatic toxicants

EPA does not allow certified products containing chemicals, present on certain authoritative lists, that are a) persistent, bioaccumulative, and aquatically toxic (PBT), b) very persistent and very bioaccumulative, or c) very persistent and very aquatically toxic. Relevant lists include EU REACH Substances of Very High Concern; Stockholm Convention's Persistent Organic Pollutants (POPs); and OSPAR List of Substances of Possible Concern.

# 5.2.1.5 Additional lists of chemicals of potential concern

EPA will flag and evaluate chemicals for their impact on reproductive, developmental, carcinogenic, or other systemic effects if they appear on the following flagged lists: the Endocrine Disruptor Assessment list by the European Commission (<u>https://echa.europa.eu/ed-assessment</u>) and the US EPA Endocrine Disruptor Screening Program list of prioritized chemicals (<u>https://www.epa.gov/endocrine-disruption/endo-crine-disruptor-screening-program-chemical-screening-and-testing-progress</u>).

In addition to GHS classified skin and respiratory sensitizers, EPA considers additional information, such as the Association of Occupational and Environmental Clinics (AOEC) list of occupational asthmagens (<u>http://www.aoecdata.org/ExpCodeLookup.aspx</u>).

# 5.3 Surfactants

The criteria primarily address environmental fate and toxicity as the distinguishing hazard endpoints for surfactants. Where the Safer Choice program is aware of concerns for other endpoints (e.g., human health), the program may disallow a chemical based on the thresholds in its Master Criteria. The Safer Choice Criteria for Surfactants can be found at <u>https://www.epa.gov/saferchoice/safer-choice-criteria-surfactants</u>.

# 5.4 Solvents

Solvents must meet the general requirements in Section 5.2 unless otherwise noted below.

# 5.4.1 Alcohols, esters, ethylene glycol ethers, and propylene glycol ethers

Solvents classified as alcohols, esters, ethylene glycol ethers, or propylene glycol ethers must meet the solvent criteria described in detail in the Safer Choice Criteria for Solvents (phase I). The Safer Choice Criteria for Solvents can be found at <u>https://www.epa.gov/saferchoice/safer-choice-criteria-solvents</u>.

# 5.4.2 d-Limonene

As a solvent ingredient, d-limonene may only be used in a Safer Choice- or DfE-certified product in concentrations at which the potential oxidation products may be present at 20 millimoles per liter (mmol/L) or less (corresponding to a limonene concentration of 1.36% or less) in an overall formulation. Based on the potential to accelerate formation of oxidation products, d-limonene may not be used in combination with oxidizers, like H2O2; and based on its potential toxicity to aquatic organisms, d-limonene may not be used in direct-release products (see Section 4.8.1).

# 5.4.3 Compliance with CARB limits

To be consistent with CARB VOC limits, as required by this Standard (Section 4.2.6), and to enable the formulation of specialized industrial and other products, an exception to the solvents criteria will be made

for solvents that qualify as VOC-exempt or low-VOC, provided they comply, at a minimum, with the baseline requirements in Section 5.2 and are among the safest functional alternatives (see Safer Choice VOCexemption criteria: <u>https://www.epa.gov/sites/default/files/2014-02/documents/dfe\_criteria\_voc\_ex-</u> <u>empt\_solvents.pdf</u>). A chemical that meets the criteria except for potential concerns from inhalation exposures would not be allowed in aerosol-generating products.

# 5.5 Fragrances

Fragrance materials in Safer Choice- and DfE-certified products must meet the Safer Choice Criteria for Fragrances (<u>https://www.epa.gov/saferchoice/safer-choice-criteria-fragrances</u>).

# 5.5.1 Sensitizers in certified products

Each fragrance material that is a skin sensitizer is limited to no more than 0.01% (100 ppm) in the final product. EPA will allow manufacturers to use a skin sensitizer at a higher level in certain limited situations.

Notwithstanding the provisions in Section 3.8 on ingredient communication for fragrances, the final product may contain sensitizers if the manufacturer discloses on the product label each sensitizing ingredient present in the final product at greater than 0.01% (100 ppm) and provides evidence to EPA that the fragrances (or its ingredients) are:

- critical to the fragrance essence or product identity;
- otherwise in compliance with the fragrances criteria;
- the subject of good faith explorations of alternatives; and
- subject to a monitoring system that would alert the Agency if a user reports any adverse effects from the product.

Alternatively, the manufacturer may demonstrate that the formulated product does not cause a sensitization response through appropriate *in vivo* or *in vitro* testing and limit the amount of fragrance materials in the product to the level in the test sample.

# 5.6 Chelating and Sequestering Agents

Chelating and sequestering agents must meet the criteria described in detail in the Safer Choice Criteria for Chelating and Sequestering Agents (<u>https://www.epa.gov/saferchoice/safer-choice-criteria-chelating-and-sequestering-agents</u>) and general requirements in Section 5.2. In addition, Safer Choice- and DfE-certified products must not contain intentionally added phosphorous-containing chemistries that contribute to the process of eutrophication, nor nitriloacetic acid (NTA), a potential carcinogen. Chelating agents that have molecular weight (MW) above 1000 shall be evaluated under the polymer criteria.

# 5.7 Colorants, Polymers, Preservatives, and Related Chemicals

Colorants (including pigments and optical brighteners), polymers, certain preservatives (including antioxidants), and other chemicals referenced in Section 5.13 include as part of their functionality the ability to resist degradation and be effective over long periods. They also can be complex molecules and mixtures and often lack measured toxicity data. To identify the safest available chemicals in each class given their functional characteristics, the toxicity thresholds in the Master Criteria will be used to evaluate human health and environmental endpoints.

# 5.7.1 Polymers

To be acceptable for certified products, polymers must have low-concern characteristics.<sup>1</sup> Also, the requirements of this section apply to the low molecular weight components of polymers (typically less than

<sup>&</sup>lt;sup>1</sup> Described in the Sustainable Futures' Interpretive Assistance Document for Assessment of Polymers (<u>http://www.epa.gov/oppt/sf/pubs/iad\_polymers\_june2013.pdf</u>).

1,000 Daltons). EPA encourages the use of degradable polymers whenever possible; only those that do not degrade into CMRs or PBTs will be allowed.

Special conditions for certain categories of polymer: In addition to the requirements in 5.7.3, polymers that are respirable or water-absorbing must be in solution. Anionic polymers used as chelating agents must meet the requirements in the Safer Choice Criteria for Chelating Agents and Sequestering Agents, except Section 5.9, Environmental Toxicity and Fate, which must be addressed as per 5.7.3.

# 5.7.2 Preservatives

Preservatives have biocidal properties and time-sensitive functionality. EPA will allow use only at the lowest effective level. In addition to the CMR and PBT prohibitions in 5.2, preservatives that release CMRs or PBTs or whose reaction byproducts are CMRs or PBTs will not be allowed.

# 5.7.3 Special requirements

For colorants, polymers, and preservatives, the human health and environmental endpoints in the Master Criteria will be addressed as described in the Safer Choice Criteria for Colorants, Polymers, Preservatives, and Related Chemicals (<u>https://www.epa.gov/saferchoice/safer-choice-criteria-colorants-polymers-preservatives-and-related-chemicals</u>).

# 5.8 Bacteria (Spores & Vegetative)

Bacteria (spores & vegetative) strains shall be evaluated using complete human health and environmental risk assessments. These risk assessments shall include hazard assessments and exposure to workers, users and the environment during product use and end-of-life.

# 5.9 Toxic Elements

Safer Choice- and DfE-certified products must not contain toxic elements such as certain heavy metals, as indicated by their hazard profile. Unavoidable de minimis levels may be present, e.g., as components from inorganic materials mined from the earth.

# 5.10 Enzymes and Enzyme Stabilizers

Enzymes and enzyme stabilizers shall meet the general requirements in Section 5.2, except as defined herein. The Safer Choice Criteria for Enzymes and Enzyme Stabilizers can be found at <a href="https://www.epa.gov/saferchoice/safer-choice-criteria-enzymes-and-enzyme-stabilizers">https://www.epa.gov/saferchoice/safer-choice-criteria-enzyme Stabilizers</a>. Products that contain live microbial cultures or viable spores are addressed in separate guidance (see Section 4.7.2.)

Enzymes are not allowed under the following conditions of use: if they are spray-applied or, in products designed for indoor use, if residues may become airborne (e.g., carpet shampoo). Enzymes must be listed on the product label.

To help prevent inhalation of aerosolized enzymes, only liquid enzyme formulations or low-dust granulated enzyme formulations (i.e., encapsulated products with a minimum diameter of 0.15 mm) will be acceptable in certified products. If in a dry form, in addition to using only low-dust granulated enzymes, manufacturers must exercise and be able to demonstrate best efforts to ensure a safe workplace (for example, through dust control and allergy surveillance programs and the use of appropriate personal protective equipment, as needed).

The enzymes used in products must be well characterized, and their technical names and catalytic activities must be provided to EPA. Candidate partners must also submit the genus and species of the production organisms, including appropriate taxonomic data, as needed, and documentation of appropriate quality control measures. If present at appropriate levels, boric acid (and certain of its neutralized salts) may be used as a stabilizer in products containing protease enzymes allowed under this Standard. EPA encourages the development of safer alternative stabilizers.

# 5.11 Disposable Wipes

EPA considers substrate composition for disposable wipes when wipes are the intended method of application. Qualifying wipes must be made from natural fibers such as cotton or bamboo or synthetic fibers from renewable sources with the same biodegradability profile, which could be demonstrated through acceptable testing. Although many composting facilities do not accept disposable wipes, this requirement ensures the use of natural fibers from renewable materials. Acceptable tests may include EN13432, ASTM 6400, ASTM 5338, ISO 14855, or similar tests (preapproved by EPA). EPA may allow limited exceptions to these criteria for antimicrobial active products that demonstrate novel efficacy and are incompatible with wipe substrates that meet this Standard. All claims must comply with the FTC Green Guides.

Both the liquid formulation and additive components (like binders or coatings) of the substrates must meet program criteria. EPA also requires a "Do Not Flush" symbol and language to be prominently displayed on labels of all certified wipe-based products.

# 5.12 Residuals

EPA collects information from chemical manufacturers on known residuals and will limit the percentage of residuals of concern in products. Residuals of concern must be limited to less than 0.01% (by weight) or 100 ppm in the formulation. If there are other regulatory restrictions on residuals that apply to a given chemical or product type, the more health protective use limit will apply. For ingredients known to contain residuals of concern, EPA's goal will be to limit those residuals to the lowest practicable levels. Dilution will not be considered in calculating the percentage of residuals in concentrates. Formulators should understand that residuals may be present and should encourage chemical manufacturers to carefully monitor and control processes to limit residuals of concern. [Note: EPA is working to ascertain to extent to which the state of green chemistry can support the restrictions imposed by this section.]

For certain compounds, it may not be possible to synthesize the compound and meet this residuals limit. When these compounds are necessary for end-use product formulation, EPA will allow residuals to be present beyond the limit. The residuals must not be listed CMRs or PBTs. Manufacturers should show good faith efforts to limit the level of problematic residuals. EPA will identify, on a case-by-case basis, the compounds and residuals that will qualify for this exception.

# 5.13 Other Ingredients

The following types of ingredients will be reviewed based on the general requirements in Section 5.2 or as noted.

- Cross-linkers (see 5.7.1, Polymers)
- Solubility enhancers
  - Hydrotropes (see 5.3, Surfactants)
  - Small amines (see 4.7.6, Specialized industrial products)
- Bleaching agents
- Rheology modifiers (see 5.7.1, Polymers)
- Plasticizers (see 4.7.6, Specialized industrial products)
- Foam boosters, defoamers and antifoamers (see 5.3, Surfactants or 5.7.1, Polymers)
- Denaturants (see also 5.4, Solvents)
- Absorbents and adsorbents (see also 5.5.1, Sensitizers in certified products)
- Corrosion inhibitors
- Antiredeposition agents (see 5.7.1, Polymers)

- Dispersing agent (see 5.3, Surfactants or 5.7.1, Polymers)
- Coalescing agent (see also 5.4, Solvents)

# 5.14 Potential Sensitizers and Irritants

Whole product testing may be used to address concerns for sensitization potential (see test methods listed in Master Criteria).

# 5.15 Oxidant Stabilizers

As a general rule, phosphates are not allowed in Safer Choice- or DfE-certified products. We make one exception: for oxidant stabilizers, which are needed to prevent premature chemical reactions, because there are no safer alternatives. Oxidizers are typically purchased containing stabilizers. EPA encourages the development of safer oxidant stabilizers. Until those are available, we will allow use of phosphorus in very small quantities, not to exceed 0.5% (5,000 ppm) in a certified product.

# 5.16 Processing Aids and Additives

A large set of chemicals that play supporting roles in product formulations, processing aids (often considered commodity or generic ingredients) are diverse in structure and function but have in common that their chemical characteristics and long-standing safe use make them a low hazard concern. For example, physical-chemical properties (like simple acids, when controlled for product pH) or essential functionality in humans (like polysaccharides) can indicate low hazard. Processing aids are commonly used in cleaning and other products and often provide multiple functional attributes.

At a minimum, these chemicals must meet the parameters and conditions in Safer Choice's *Criteria for Processing Aids and Additives*, which has criteria tailored for each subgroup, at <u>https://www.epa.gov/saf-erchoice/safer-choice-criteria-processing-aids-and-additives</u>, and comply with the baseline requirements in Section 5.2.

# 5.17 Odor Elimination Chemicals

EPA reviews all ingredients in products qualified to carry the Safer Choice label or DfE logo, including odor elimination chemicals. Odor elimination chemicals will be evaluated against the general requirements in Section 5.2 and based on the Master Criteria.

# 5.18 Safer Chemical Ingredients List

To encourage the manufacture, use of and communications on safer chemicals, EPA lists on its website the chemicals that have met its safer ingredient criteria and are used in certified products. The Safer Chemical Ingredient List (SCIL) contains chemicals used in or eligible for use in certified products. Chemicals are listed by common and specific chemical name and CAS Number under functional-use class, accompanied by a symbol indicating its safer-chemical status. SCIL listings do not disclose confidential or trade secret information.

The CAS Number-level listing of ingredients on the SCIL is one tool that can help manufacturers as they formulate products with safer chemicals that may be eligible for Safer Choice certification. However, listing on the SCIL is not a stand-alone declaration that listed substances may be used in Safer Choice-certified products.

If a proposed formulation includes a SCIL-listed chemical with a CAS Number that covers a broad range of chemical structures, the structure(s) under the CAS Number associated with that chemical must be disclosed. EPA evaluates data associated with these structures and allows use of only chemicals with structures that meet the Standard and criteria.

# 6 Use of the Mark

# 6.1 Terms of Use

**6.1.1** The partner may use the Safer Choice label or DfE logo, as shown in Section 6.2, on containers or container packaging of products that qualify for the label ("qualifying products") or on advertising related solely to these products, provided that EPA has reviewed and approved the intended label or logo use. The partner shall not use the label or logo or describe EPA's certification on any general company materials, non-qualifying products or associated literature, or advertising not specific to the qualifying products. The partner is not permitted to use the EPA official seal or logo at any time.

**6.1.2** Use of the Safer Choice label must include the EPA web address, epa.gov/saferchoice and use of the DfE logo must include the EPA web address, epa.gov/dfe, as shown in Section 6.2. Additionally, when advertising the qualifying products or informing consumers about them, the partner must include the endorsement disclaimer, which appears below. The partner and EPA shall work to find an appropriate place to include the disclaimer (e.g., the company's web site) connected with advertising the qualifying products.

EPA certification does not constitute endorsement of this product. The Safer Choice label or Design for the Environment logo signifies that the product's formula, as [Company Name] has represented it to the EPA, contains ingredients that meet stringent EPA criteria for effects on human health and the environment. EPA relies solely on [Company Name], its integrity and good faith, for information on the product's composition, ingredients, and attributes. EPA has not independently identified, that is, via chemical analysis, the ingredients in the product formula, nor evaluated any of [Company Name] non-ingredient claims. EPA provides its evaluation only as to the product's human health and environmental characteristics, as specified in the Safer Choice and Design for the Environment Standard and based on currently available information and scientific understanding.

**6.1.3** The partner and EPA acknowledge that under 5 C.F.R. §2635.702(c), EPA will not endorse the purchase or sale of the partner's commercial products and services. The partner agrees to ensure that promotional materials describing or resulting from the partnership do not contain statements implying that EPA endorses the purchase or sale of commercial products or services.

**6.1.4** The partner shall make available to EPA for review and approval any materials, including press releases, promotional materials, and advertisements the partner develops in connection with the partner-ship, and especially information that describes the Safer Choice or DfE program or characterizes EPA's position on issues related to a specific product class.

**6.1.5** The partner must discontinue use of the Safer Choice label, DfE logo, or any other form of Safer Choice or DfE certification, within 30 days, under the following circumstances: if the partner stops formulating the Qualifying Product(s) using the agreed-upon ingredients; upon the termination of the partner-ship; or if so notified by EPA in writing. The partner must also discontinue use of the Safer Choice label or DfE logo if EPA determines that continuation of the partnership and certification of products in a certain class would adversely affect the value of the program's label and undermine its health-and-environmental-protection goals. The partner further agrees that it will use its best efforts to ensure that any merchants, distributors, or online vendors also cease use of the label or logo in association with the disqualified products (see also Section 3.4).

# 6.2 Examples of Appropriate Use of the Safer Choice Label and DfE Logo

# 6.2.1 Safer Choice label

For consumer products (primary mark):



For institutional and industrial products:



For fragrance-free products:



# 6.2.2 DfE logo

In addition to the requirements of this standard, any use of the DfE logo must also meet federal and state FIFRA labeling requirements.

For consumer products (primary mark):



For institutional and industrial products:



For fragrance-free products:



# 6.3 Use of the Safer Choice Label by Raw Material Suppliers

The Safer Choice label is primarily used on finished products. However, the Safer Choice label may be used to indicate certain raw materials meet Safer Choice criteria or that a supplier can formulate to meet Safer Choice criteria. Use of the label by chemical or raw material suppliers must be limited to these two purposes.

For example, with permission from the Safer Choice program, the Safer Choice label <u>may be used</u> to indicate that a chemical or raw material supplier's specific raw materials qualify for use in Safer Choice-certified products or to advertise a company's expertise in formulating or providing raw materials that qualify for use in Safer Choice-certified products. The Safer Choice label **may not be used** to indicate that a chemical or raw material supplier qualifies for Safer Choice certification or is Safer Choice-certified, or that all of their products/raw materials meet Safer Choice criteria.

Raw material suppliers interested in the use of the Safer Choice label should contact the Safer Choice program.

# 7 Safer Choice Cleaning Service Standard

This section describes the Safer Choice Cleaning Service Certification for cleaning service providers. The program's purpose is described in Section 7.1. The eligibility of applicants for certification is described in Section 7.2, and the certification criteria are discussed in Section 7.3. Application guidance is provided in Section 7.4. Compliance monitoring procedures are described in Section 7.5, and use of the logo is addressed in Section 7.6. Requirements for third-party profilers for the Safer Choice Cleaning Service Certification ("CSC Profilers") are included in Section 8.2.

# 7.1 Purpose

The purpose of this certification is to provide a safer and healthier environment for home cleaners and custodial workers, often from vulnerable communities, as well as for users and inhabitants of homes and buildings. The certification should improve the marketability for the services provided by cleaning service providers who hold the certification by helping the cleaning service provider project an image of sustainability in the marketplace.

### 7.2 Eligibility for Safer Choice Cleaning Service Certification

Cleaning service providers must provide cleaning services as part of their routine operations to be eligible for the Safer Choice certification for cleaning service providers. The eligible candidate is the entity that purchases products.

At the time of publication of this Standard, the following types of cleaning service providers are eligible to apply for a Safer Choice Cleaning Service Certification:

- Residential cleaners
- Commercial cleaners
- Facility managers, facility owners, or government entities with in-house cleaning services

# 7.3 Criteria for Safer Choice Cleaning Service Certification

### 7.3.1 Product use

The organization or business applying for certification must use Safer Choice-certified products for cleaning and DfE-certified products for disinfecting, in product classes with Safer Choice and DfE-certified products, to the maximum extent practicable. EPA may grant exceptions on a case-by-case basis if use of only products that meet the Safer Choice and DfE Standard is not practicable.

### 7.3.1.1 Exceptions to product use requirements

As stated in Section 7.3.1, organizations or businesses must use Safer Choice-certified products for cleaning and DfE-certified products for disinfecting, in product classes with Safer Choice and DfE-certified products, to the maximum extent practicable. Organizations or businesses may apply for an exception to this requirement for one year if no Safer Choice- and/or DfE-certified product is reasonably available (e.g., there are not a significant number of products that meet the Safer Choice and DfE Standard in a product class, supplier or retailer does not carry such products in their area, or procurement contracts restrict the use of specific products for certain uses). Exceptions will be limited and granted on a case-by-case basis. To obtain an exception, the organization or business should document the exception being used and the rationale as part of their application (Section 7.4) or audit (Section 7.5), or submit an out-of-cycle exception request at any time. These exceptions may be renewed yearly if the underlying reasons for the exception are still present.

### 7.4 Application

### 7.4.1 Application through a CSC Profiler

Applicants for the Safer Choice Cleaning Service Certification must use a Safer Choice-qualified CSC Profiler to prepare and submit applications. Once signed, the application becomes a partnership agreement with a term of one year. Applications may be made remotely.

# 7.4.2 Application materials

### 7.4.2.1 Required application materials

Applicants for certification must submit the following to a CSC Profiler:

- Most recent purchase invoices, including receipts or other equivalent documentation (e.g., photos), from the last year (i.e., 12 months prior to submitting the application) showing that the applicant for certification used Safer Choice-certified products for cleaning and DfE-certified products for disinfecting in product classes with Safer Choice- and DfE-certified products to the maximum extent practicable. An applicant may apply for an exception per Section 7.4.2.2.
- Attestation that applicant for certification uses Safer Choice-certified products for cleaning and DfE-certified products for disinfecting in product classes with Safer Choice- and DfE-certified products to the maximum extent practicable.

# 7.4.2.2 Reporting exceptions in application materials

If an applicant for certification cannot exclusively use Safer Choice-certified products for cleaning and DfE-certified products for disinfecting, in product classes with Safer Choice and DfE-certified products, in accordance with the exception provisions in 7.3.1.1, applicant should document the exception and explain the rationale as part of their application as described below.

- Documentation must be submitted to a CSC profiler. Examples of documentation of the exception may include copies of the procurement contract or supplier catalog.
- The rationale for the exception should reference the documentation and describe why exclusive use of Safer Choice-certified products for cleaning and DfE-certified products for disinfecting was determined to be not practicable. The rationale be submitted to a CSC Profiler.

# 7.5 Compliance Verification

# 7.5.1 Annual audit through a CSC Profiler

Certified organizations and businesses must use the services of a Safer Choice-qualified CSC Profiler to conduct annual audits. An approved audit extends the partnership agreement for a year. Audits may be conducted remotely.

# 7.5.1.1 Annual audit

Certified organizations and businesses must submit the following materials to a Safer Choice-qualified CSC Profiler:

- Most recent purchase invoices, including receipts or other equivalent documentation (e.g., photos), from the last year (i.e., 12 months prior to submitting the application) showing that the certified organization or business used Safer Choice-certified products for cleaning and DfE-certified products for disinfecting in product classes with Safer Choice- and DfE-certified products to the maximum extent practicable. Certified organizations and businesses may apply for an exception per Section 7.5.1.2.
- Attestation that the organization or business uses Safer Choice- and/or DfE-certified products in product classes with Safer Choice- and DfE-certified products to the maximum extent practicable.
- Attestation that organization or business supplies informational material and resources about Safer Choice- and DfE-certified products and best cleaning practices to their employees. Safer Choice will post information on its website that certified entities may find helpful.
- Materials, or images of material, that uses the Safer Choice Cleaning Service Certification logo or mentions the certification.

• Safer Choice questionnaire identifying the organization or business' primary customer and the number of households or businesses serviced.

# 7.5.1.2 Reporting exceptions for audit

If a certified organization or business cannot exclusively use Safer Choice-certified products for cleaning and DfE-certified products for disinfecting, in product classes with Safer Choice- and DfE-certified products, in accordance with the exception provisions in 7.3.1.1, the organization or business should document the exception and explain the rationale as described below.

- Documentation must be submitted to a CSC Profiler. Examples of documentation of the exception may include copies of the procurement contract or supplier catalog.
- The rationale for the exception should reference the documentation and describe why exclusive use of exclusively Safer Choice-certified products for cleaning and DfE-certified products for disinfecting was determined to be not practicable. The rationale should be submitted to a CSC Profiler.

# 7.6 Use of the Safer Choice Service Certification Logo

Certified service providers may use the Safer Choice Service Certification logo, as detailed in the subsections below.

### 7.6.1 Integrity of the Safer Choice Service Certification logo

The Safer Choice Service Certification logo should be used by certified service providers without modification.

### 7.6.2 Safer Choice Service Certification logo display

The Safer Choice Service Certification logo can be displayed in the following locations:

- Organization or business website
- Advertisements
- Uniforms
- Service provider equipment
- Facilities cleaned by service providers

### 7.6.3 Period of use

Cleaning service providers should only use and display the logo while actively certified as a Safer Choicecertified cleaning service. Actively certified cleaning service providers should have undergone an audit within one year or less.

#### 7.6.4 Entering or exiting a service sector

#### 7.6.4.1 Entering a service sector

EPA reserves the right to enter or not enter service sectors. EPA will consider on a case-by-case basis any provider's request to open a service sector to certification. EPA will weigh a number of factors in its decision, including the service type, likely improvements to human health (with a focus on worker health, environmental justice, and children's health) and environmental protection, and if the current criteria adequately address all aspects of the new sector.

EPA may solicit public input before entering into a new service sector to determine whether the introduction of the Safer Choice Service Certification logo would advance the goals of the respective

program. If EPA has not entered a service sector, EPA will not certify a service in that service sector, even if it would otherwise meet the Standard.

# 7.6.4.2 Termination of a service sector

EPA also reserves the right to exit a service sector. For service sectors that are currently active (i.e., sectors with current partnership agreements that cover certified services in the relevant sector), in the event that EPA decides to exit such a service sector, EPA may notify and provide an opportunity for comment from any affected partners and stakeholders in that service sector. If EPA decides to exit the service sector, EPA will discontinue new service certification in the service sector and not extend any existing partnerships, allowing a period of time for the partner to cease use of the logo.

# 8 **Profiler Requirements**

Candidates for Safer Choice or DfE certification must use the services of a qualified third-party profiler to prepare product certification applications. To become a qualified third-party profiler for Safer Choice and DfE product certification ("TPP"), the candidate must submit a paper application to provide evidence of competency against the requirements and undergo a pilot review as described in Section 8.1.

Similarly, candidates for the Safer Choice Cleaning Service Certification must use a qualified third-party profiler to prepare applications. To become a qualified CSC Profiler, the candidate must submit a paper application to provide evidence of competency against the requirements and undergo a pilot review as described in Section 8.2.

# 8.1 Safer Choice and DfE Certification

### 8.1.1 Elements of technical competence

The profiler must have the skills, experience, and resources to perform chemical hazard assessments, including the review of and updates to the Safer Choice Safer Chemical Ingredients List. The profiler must also be able to conduct partnership surveillance and audits on conformance with the Standard.

### 8.1.1.1 Staff

A profiler shall have the appropriate personnel to perform hazard assessments. Staff shall include chemists, biologists, toxicologists, or others with science/technical backgrounds.

### 8.1.1.2 Assessment and interpretation abilities

A profiler shall establish the ability to assess and interpret diverse toxicological and other health and environmental information. This shall include maintenance of appropriate staffing; a track record as a data reviewer; experience as a standards developer or certifier to standards or criteria. The profiler shall meet the criteria of ISO/IEC 17065 to demonstrate a commitment to maintaining these capabilities.

### 8.1.1.3 Access and management of hazard information

A profiler shall establish the ability to access and manage chemical, health and environmental hazard information, including fluency with chemicals at the structural level. This shall be indicated by appropriate staffing, with chemical and information technology expertise; protocol and equipment for data searching, storage and retrieval; and relevant experience and work products.

### 8.1.1.4 Use of estimation models and software

A profiler shall demonstrate skill at using EPA and other physical-chemical and environmental estimation models and software. This skill must be indicated by involvement with EPA's Sustainable Futures

Program or similar activity; submission of Sustainable Futures Premanufacture Notices or preparation of a like document; and relevant experience and work products.

# 8.1.1.5 Secure handling of proprietary business information

A profiler shall have the appropriate systems and procedures in place to ensure the protection of all proprietary business information obtained through the review process for this program.

### 8.1.2 Elements of credibility and good standing

The profiling organization must be able to establish neutrality, trustworthiness, and reliability.

**8.1.2.1** A profiler shall demonstrate a commitment to objectivity and due process approach by meeting the criteria of ISO/IEC 17065.

**8.1.2.2** A profiler shall demonstrate familiarity with the Safer Choice and DfE programs' review process and assessment methodology by having training and interacting with EPA and companies interested in Safer Choice or DfE certification.

**8.1.2.3** A profiler shall demonstrate a track record of high performance. This shall be supported by testimonials from clients and others in a position to evaluate performance.

### 8.1.3 Pilot review requirements

**8.1.3.1** As the final step in the process the profiler shall demonstrate competency through a review of a formulation(s) judged by EPA to be representative of those certified by the program. EPA will review the results against the criteria in this section and determine whether the applicant has demonstrated competence.

### 8.2 Safer Choice Cleaning Service Certification

### 8.2.1 Elements of technical competence

A CSC Profiler must have the skills, experience, and resources to competently perform reviews and assessments of – and otherwise comprehend and understand the import of business documents that relate to – the purchase and use of Safer Choice- and DfE-certified products and employee training related to the use of such products.

### 8.2.1.1 Staff

A CSC Profiler shall have the appropriate personnel with experience working with cleaning service providers related to their cleaning operations, including but not limited to training and education, consulting in support of cleaning practices, and sustainability.

### 8.2.1.2 Assessment and interpretation abilities

A CSC Profiler shall possess sufficient knowledge and familiarity with the Safer Choice program to enable it to readily identify Safer Choice- and DfE certified products. A CSC Profiler shall also possess sufficient knowledge and familiarity with product supply conditions, supplier limitations, pricing and other factors that are relevant in ascertaining whether the applicant for certification is using Safer Choice- and DfE-certified products to the maximum extent practicable.

### 8.2.2 Elements of credibility and good standing

The CSC Profiler must be able to establish neutrality, trustworthiness, and reliability.

**8.2.2.1** A CSC Profiler shall demonstrate a commitment to objectivity and due process approach by meeting the criteria of ISO/IEC 17065.

**8.2.2.2** A CSC Profiler shall demonstrate familiarity with the Safer Choice and DfE programs generally through appropriate interactions with EPA or other training and education, or by way of a demonstrated work history with companies in support of their interactions with the Safer Choice and DfE programs.

**8.2.2.3** A CSC Profiler shall demonstrate a track record of high performance. This shall be supported by testimonials from clients and others in a position to evaluate performance.

**8.2.2.4** A CSC Profiler shall have the appropriate systems and procedures in place to ensure the protection of all proprietary business information obtained through the review process for this program.

### 8.2.3 Pilot review requirements

**8.2.3.1** In regard to CSC Profilers, as the final step in the process, the CSC Profilers shall demonstrate their competency through a review of product invoices, Safer Choice- and DfE-certified products, and other information deemed appropriate by EPA to demonstrate competency in this subject matter. EPA will review the results against the criteria in Sections 7 and 8 and determine whether the applicant has demonstrated competence.

# Annex A

Sample Safer Choice Partnership Agreement [for cleaning product sector]

PARTNERSHIP AGREEMENT BETWEEN [COMPANY] AND U.S. ENVIRONMENTAL PROTECTION AGENCY SAFER CHOICE PROGRAM

#### A.1 Statement of Purpose

The purpose of this Partnership Agreement ("Agreement") is to set forth the basis, terms, and goals of the Safer Choice voluntary partnership between [Company] [Quoted Company Name] of [City, State] and the U.S. Environmental Protection Agency ("EPA"). The basic goal of the initiative is to seek and promote innovative chemical products, technologies, and practices that benefit human health and the environment.

A key purpose of the partnership program is to recognize and encourage the formulation of products with environmentally preferable chemistry and collateral benefits, as defined and described in the Safer Choice and Design for the Environment (DfE) Standard ("the Standard") and the associated Safer Choice component-class criteria. For the purpose of this Agreement, these products include the [Company Name] products as summarized in the Qualifying Products Table (the "Qualifying Products"). The partnership will strive to promote and advance the environmental, technological, and efficiency benefits of these and future Qualifying Products. As a precondition for partnership, [Quoted Company Name] agrees to work with a Safer Choice-qualified third-party profiler to develop the chemical and other information needed as the basis for this agreement and to have periodic audits of its Qualifying Product(s) (see Section 14).

This Agreement describes in general terms how [Company Name] formulates the Qualifying Products, their environmental and human health benefits, and how [Company Name] and EPA will work together to continually improve the health and environmental profile of the Qualifying Products and educate the consumer on these improvements and the Safer Choice program.

#### A.1.1 Qualifying products [Qualifying Products List: Name, Class, Sector 1, Partnership Agreement Date]

Product Name	Product Class	I/I or Consumer	Partnership Date
Example Product 1	Glass Cleaner	Both	Original: see Sec. 17

#### A.2 Statement of Context and Challenge

Each year, commercial formulators use billions of pounds of chemical ingredients to make a wide variety of general purpose and specialized products. EPA is concerned about the effect certain chemicals might have on environmental quality and on the health and safety of workers and the public who use products or may come in contact with them.

EPA believes that product formulators can improve the environmental and health profile of their products by using ingredients that are inherently less toxic, less environmentally persistent, less bioaccumulative, and that degrade to substances with similar desirable characteristics when compared to ingredients in some conventional formulations. Additional benefits can be derived through environmentally oriented reformulation. Energy efficiency, resource conservation, and sound management practices offer important additional components for measurable and sustainable improvement in products and programs.

EPA believes that conventional formulations, especially those for industrial/institutional ("I/I") use, may rely on certain ingredients whose environmental and human health profiles can be improved.

#### A.3 [Company Name]'s Improved Chemistries

In conjunction with the Safer Choice review process, [Company Name] has reformulated [a set of products for I/I cleaning and maintenance] that, according to [Company Name], meet EPA's recommendations and offer improved health and environmental characteristics. These Qualifying Products use ingredients that have been evaluated by EPA and are determined to be safer than traditional chemical ingredients, resulting in formulations with more positive environmental and human health characteristics than conventional formulations. These safer chemicals and ingredients are listed on the EPA Safer Chemical Ingredients List (SCIL), or are proprietary and qualify for listing but are withheld to protect intellectual property. The SCIL is a list that helps manufacturers find safer chemical alternatives that meet the criteria of the Safer Choice program (see <a href="https://www.epa.gov/saferchoice/safer-ingredients">https://www.epa.gov/saferchoice/safer-ingredients</a>).

In addition, these Qualifying Products only use surfactants that biodegrade readily to non-polluting substances, which helps relieve stress on the environment, especially threats to aquatic life. By not including environmentally harmful builders or extreme pH in these formulations, the environment-friendly profile and safety characteristics of these products is further enhanced. For example, an inorganic phosphate-free formula may promote a better balance of nutrients in the environment and healthier freshwater bodies. Safer sequestrants biodegrade readily to non-hazardous compounds and protect against environmental loading of metals. Mild pH formulas help protect workers, the environment, and building infrastructure. (For more information on the attributes and benefits of these products, see Section 7.)

Please Note: EPA relies solely on [Company Name], its integrity and good faith, for information on the composition, ingredients, and attributes of its Qualifying Products. EPA has not independently identified, i.e., via chemical analysis, the ingredients in the submitted formulas, nor evaluated any of [Company Name]'s non-ingredient claims. EPA expresses its judgment and professional opinion only as to the environmental and human health characteristics of the Qualifying Products, based on currently available information and scientific understanding. [Company Name]'s obligations under any federal, state, or local regulations governing the company or these products are in no way altered by its partnership with EPA.

#### A.4 [Company Name]'s Commitment to Formulate for the Environment

As part of the [Company Name]–EPA partnership, [Company Name] agrees to formulate and produce the Qualifying Products using agreed upon ingredients which have a more positive health and environmental profile than conventional formulations. To preserve the non-confidential nature of this document, a generic description of the ingredients in the Qualifying Products and their safer chemical status appears below.

As documentation of the Qualifying Products at the time of this Agreement, and to set a baseline for future improvements and formula changes, [Company Name] has provided to EPA the specific and complete chemical composition for these products. This section's ingredient-by-ingredient descriptions are intended to serve as surrogates for the actual formulas. [Company Name] reserves the right, however, to change ingredients, provided that their health/environmental profile is equal to or better than those in the current formulations and that any substitution occurs in consultation and agreement with EPA (see Section 12).

If any change is made to the agreed formulation, [Company Name] agrees to notify EPA of the change and provide the new formulation, unless the change is made to a commodity ingredient (i.e., changing ingredient supplier). Such changes include, to the best of [Company Name]'s knowledge, a change to any ingredient supplier in the supply chain for the qualifying products. EPA agrees to notify [Company Name] of the need for ingredient profiling and will make recommendations for changes to the

formulation as needed in order to remain a Qualifying Product. EPA will keep confidential all product formulas and other proprietary information that [Company Name] furnishes to the Agency (see confidentiality provisions in Section 11).

The following is a non-confidential representation of the ingredients in the Qualifying Products, with their safer chemical status or areas identified for future improvement, as evaluated and designated by EPA:

Ingredient [Example Product Name]	Safer Chemical Status
Ingredient 1	Low human health and environmental concern.
Ingredient 2	Expected to have low human health and environmental concerns.
Ingredient 3	Gray square (see Section 5).
Ingredient 4	Expected to have low human health and environmental concerns; contains auxiliary component(s) al- lowed for functionality.
Ingredient 5	Previous acceptable; not currently acceptable (see Sec- tion 5). [Language relevant for partnership agreement renewals only.]
Ingredient 6	Allowed for functionality.
Ingredient 7	Updated ingredient formulation not provided (see sec. 5). [Language relevant for partnership agree- ment renewals only.]
Fragrance	Meets Safer Choice Fragrances Criteria.

Adoption and use of the formulations described in this Agreement does not preclude, nor should it impede, [Company Name] in its efforts to further improve the health and environmental profile of the Qualifying Products. In fact, a main element of the [Company Name]–EPA partnership is to provide [Company Name] the opportunity to work with EPA chemists, environmental scientists, and risk reduction staff in investigating materials to further improve the health and environmental profile of its Qualifying Products.

### A.5 Continuous Environmental Improvement

[Company Name] agrees to make continuous environmental improvement an important element of its research and development activities related to its Qualifying Products. In addition to the environmentally oriented formulations set forth in Section 4, [Company Name] agrees to investigate the feasibility of making additional improvements in the environmental and health profile of the Qualifying Products.

Ingredients allowed for functionality. [Company Name] agrees to explore the use of and, if feasible, reformulate with safer alternatives to ingredients allowed for functionality, as detailed in Section 4, during the period of the Agreement. While these ingredients are best-in-class chemicals and among the safest available for a particular function, the function fulfilled by the chemical should be considered an area for safer chemistry innovation.

Additionally, [Company Name] agrees to:

- replace any [grey-squared ingredient(s)] within one year of notification of the SCIL status update
- replace any [previously acceptable ingredient(s)] within one year of the [month and year] agreement/amendment
- provide complete information for-or replace-any ingredient(s) with missing supplier information within one year of the [month and year] agreement/amendment

In addition, [Company Name] agrees to provide satisfactory [performance test results] and [revised labels] within one year of the [month and year] agreement/amendment date.

[Company Name] may consult with EPA about other products and, following EPA review and assessment, may request that one or more new Qualifying Products be added to this Agreement. With EPA's approval, this Agreement may be amended as set forth in Section 12 to include new Qualifying Products.

[Company Name] and EPA agree to discuss on a yearly basis the status of [Company Name]'s reformulation research and continuous improvement activities related to the Qualifying Products. [Company Name] may, at any time, request consultation and technical assistance from EPA in determining which chemical ingredients possess more positive health/environmental characteristics. [Company Name] may use informational materials from Safer Choice's website as general guides to environmentally desirable attributes for products.

#### A.6 Formulator Right to Know

Product formulators have a right to know the properties and potential risks – to their employees, customers, and communities – of the chemicals they use. Manufacturers of raw materials for detergents and other products should ascertain and communicate the properties and potential toxicity of their products, especially those made and sold in large quantities.

As part of its partnership with EPA, [Company Name] agrees to ask its raw material suppliers for test data on the chemicals they sell and that [Company Name] uses in its products. If the raw material suppliers do not have test data on their chemicals, [Company Name] agrees to encourage them to perform basic physico-chemical and toxicity testing. Upon request by EPA, [Company Name] agrees to share with EPA any available chemistry or toxicity information on its ingredients that it obtains from its suppliers.

To help ensure that any new testing serves to enhance the profile and general understanding of a particular chemical, all prospective studies should be considered in the context of the guidance offered in EPA's chemical evaluation programs (<u>https://www.epa.gov/chemicals-under-tsca</u>) and the Screening Information Data Set (SIDS) Program of the Organization for Economic Co-operation and Development (OECD) (to learn more, visit <u>http://webnet.oecd.org/hpv/ui/Default.aspx</u> and https://cfpub.epa.gov/si/si\_public\_record\_Report.cfm?Lab=&dirEntryID=2854).

#### A.7 User Benefits

[Company Name]'s Qualifying Products offer users the following set of benefits:

#### **Environmental Protection**

The Qualifying Products are formulated with the environment and human health strongly in mind and use the following types of ingredients: biodegradable surfactants, with byproducts that are less toxic than the parent compound; solvents that are not hazardous air pollutants and pose no threat to the Earth's ozone layer; and other components with a more positive environmental profile than in conventional products.

#### Worker/Consumer Safety

The Qualifying Products are also formulated to help ensure a safer workplace. Users of these products benefit from ingredients that include no components that pose serious hazards. This benefit is amplified for janitors, maintenance staff, housekeepers, and others who must use cleaning chemicals in confined spaces on a daily basis. Importantly, a safer health profile especially benefits children, who spend a large part of their day in indoor environments and can be particularly sensitive to the chemicals in some products. Also, the mild pH, low volatility, and low potential to catch fire enhance the safety profile of these products.

#### **Resource Conservation**

The Qualifying Products also have certain attributes that may significantly reduce wear and tear on substrates, fabrics, and other surfaces with which the products come in contact, thereby extending their usable life.

### **Customer Education**

[Company Name] acts as a product steward by providing its customers information on environmental and worker safety matters and trains its sales force on the benefits of formulations with improved environmental and health characteristics.

[Company Name] agrees to inform customers of Qualifying Products about the [Company Name]-EPA partnership, the meaning of the Safer Choice label, and the Safer Choice program's role in helping to protect human health and the environment. [Company Name] agrees to make available to its customers an EPA contact to whom they may direct questions or comments on the partnership.

### A.8 EPA Certification and Support

[Company Name] may use the appropriate Safer Choice label, shown on Attachment A to this Agreement, on containers or container packaging of Qualifying Products or on advertising related solely to these products, provided that EPA has reviewed and approved the intended use. [Company Name] agrees to not use the label or describe EPA certification on any general [Company Name] materials, non-Qualifying Products or associated literature, or advertising not related to the Qualifying Products. [Company Name] is not permitted to use the EPA official seal or logo at any time.

Use of the Safer Choice label must be accompanied by the program web address, epa.gov/saferchoice, as shown on Attachment A. Additionally, when advertising the qualifying products or informing consumers about them, [Company Name] must include the endorsement disclaimer, which appears below. [Company Name] and EPA agree to work to find an appropriate place (e.g., the company's web site) to include the disclaimer connected with advertising the qualifying products.

EPA certification does not constitute endorsement of this product. The Safer Choice label signifies that the product's formula, as [Company Name] has represented it to the EPA and as verified by audit, meets the requirements of the Safer Choice and Design for the Environment Standard. EPA relies solely on [Company Name] and its suppliers, their integrity and good faith, for information on the product's composition, ingredients and attributes. EPA has not independently verified – via chemical analysis – the ingredients in the product, nor evaluated any of [Company Name]'s non-ingredient claims. EPA provides its evaluation only as to the product's human health and environmental characteristics, as specified in the Safer Choice and Design for the Environment Standard.

The Parties acknowledge that under 5 C.F.R. §2635.702(c), EPA may not endorse the purchase or sale of commercial products and services provided by [Company Name]. The Parties agree to ensure that promotional materials describing or resulting from this Agreement do not contain statements implying that EPA endorses the purchase or sale of commercial products. This includes statements to the public in news releases, publications, on web sites or any other media.

[Company Name] agrees to make available to EPA for review and approval any materials, including press releases, promotional materials and advertisements that [Company Name] develops in connection with the partnership, and especially information that describes or characterizes the Safer Choice program or EPA's position on issues related to the specific product sector.

[Company Name] agrees to discontinue use of the Safer Choice label or any other form of EPA certification, within 30 days, under the following circumstances: If [Company Name] stops formulating the Qualifying Products using the agreed upon ingredients; upon the termination of this Agreement; or, if so notified by EPA in writing when, pursuant to Section 3.4 of the Standard, continuation of the partnership and certification of products in a certain class would adversely affect the value of the program's label and undermine its health-and-environmental-protection goals. [Company Name] further agrees that it will use its best efforts to ensure that any associated merchants, distributors, or online vendors also cease use of the label.

#### A.9 Limitations

All commitments made by EPA in this Agreement are subject to the availability of appropriated funds and budget priorities. Nothing in this Agreement, in and of itself, obligates EPA to expend appropriations or to enter into any contract, assistance agreement, interagency agreement, or incur other financial obligations. This Agreement does not exempt [Company Name] or any other organization from EPA policies for competition for financial assistance agreements or procurement contracts. [Company Name] agrees not to submit a claim for compensation for services rendered to EPA in connection with any activities it carries out in furtherance of this Agreement. Any endeavor involving reimbursement or contribution of funds between the parties to this Agreement will be handled in accordance with applicable laws, regulations, and procedures, and will be subject to separate agreements.

This Agreement does not create any right or benefit, substantive or procedural, enforceable by law or equity against [Company Name] or EPA, their officers or employees, or any other person. This Agreement does not direct or apply to any persons outside [Company Name] or EPA.

### A.10 Measures of Success

On an annual basis, [Company Name] agrees to provide to EPA its best estimate of the production volume of the Qualifying Products (if possible, in pounds per year or gallons per year).

At EPA's request, [Company Name] agrees to make available to EPA, on a confidential basis, formulation bills of materials that confirm that the Qualifying Products contain the ingredients agreed to in this Agreement or have been modified in accordance with its terms.

[Company Name] agrees to make reasonable attempts to monitor the product market and agrees to inform EPA about the Qualifying Products' influence on the market, including growth in sales and number of new customers, as well as the perceived value in Safer Choice certification. [Company Name] agrees to report on customer acceptance of and satisfaction with these products when this information is available.

As discussed in Section 5, [Company Name] agrees to furnish periodic updates to EPA on the continuous improvement component of its research and development activities and on its ongoing efforts to improve the health/environmental profile of the Qualifying Products. As a condition of partnership, [Company Name] has demonstrated to EPA the performance of its Qualifying Products according to the guidelines provided by Safer Choice (see <u>www.epa.gov/saferchoice/standard</u>). [Company Name] agrees to also share with EPA the results of any additional performance testing or verification when that information becomes available.

#### A.11 Confidentiality

In matters relating to this Safer Choice partnership and Agreement, EPA agrees to handle all information claimed by [Company Name] as confidential business information in accordance with EPA confidentiality procedures (see 40 CFR part 2, subpart B). EPA and [Company Name] agree that information supplied to EPA by [Company Name] regarding the formulas of any [Company Name] products or in connection with any audits required pursuant to Section 14 of this Agreement is covered by the foregoing sentence.

EPA agrees to only use the information provided by [Company Name] for purposes related to the [Company Name]-EPA partnership and disclose the information only to EPA employees and EPA contractors cleared for confidential information with a specific need to know.

#### A.12 Amendments to the Agreement

[Company Name] may request that EPA add new Qualifying Products to this Agreement when reformulated. If EPA agrees to the addition or change, the essential elements from Sections 3, 4, 5 and 7 of the current Agreement may be amended. [Company Name] and EPA agree to collaborate in developing the specific language for the amendment, which must be signed by an appropriate official for both parties. All other provisions of the Agreement shall be incorporated by reference.

#### A.13 Private Label, Licensee, and Toll Manufacture Products

[Company Name] acknowledges and agrees to the following roles, limitations, and responsibilities when third parties are involved in the manufacture of Safer Choice-certified products.

A private label product may carry the Safer Choice label provided that its contents are either identical to those in a specified Safer Choice-certified product, or very similar, and the ingredients that are different have been approved in the Partnership Agreement. A licensee or toll manufacture product may carry the Safer Choice label provided that its contents are identical to those in a specified Safer Choice-certified product.

Ready To Use private label products – where the dilution of a certified concentrate is conducted by the private label company – can be certified as a private label on a case-by-case basis. The partner must communicate to Safer Choice the concentrate that is being diluted and verify the corresponding dilution rates.

Before manufacture of any private label product that will carry Safer Choice certification, [Company Name] must inform and receive permission from Safer Choice, indicating the name of the private label product, the label owner, and the specific Safer Choice-certified product to which it is identical or on which it is based. Before manufacture of any licensee or toll manufacture product, [Company Name] must inform and receive permission from Safer Choice, indicating the name of the licensee or toll manufacturer and of the specific Safer Choice-certified product to which the licensee or toll manufacture product is identical. To assure quality, the licensee or toll manufacture product must be manufactured under an agreement between [Company Name] and the licensee or toll manufacturer and the agreement must be available to Safer Choice on request.

[Company Name] agrees to ensure that its private label, licensee, and toll manufacture products comply with the audit provisions in Section 14.

#### A.14 Partnership Surveillance and Audits

To ensure that the contents of certified products are as represented to the Agency under this agreement and that all other aspects of the [Company Name]-Safer Choice partnership comport with the Standard and criteria documents, [Company Name] agrees to participate in Safer Choice's surveillance and auditing program. The program will consist of annual audits: an on-site audit must take place within the first year of partnership formation, provided that the partnership products are being manufactured, and then once per three-year partnership period; and desk audits will occur in the non-site audit years, including a renewal in the year of partnership renewal, as appropriate.

[Company Name] will make its manufacturing facilities and certified-product-related records available to Safer Choice-authorized third-party profilers. On an annual basis, [Company Name] agrees to submit to the third-party profiler desk audit materials as specified in the Standard, Annex C.1. These materials will include a list of ingredients for each certified product and a statement that the ingredients and all claims made regarding the Agency's certification (e.g., use of the Safer Choice label) comport with this agreement.

Approximately every three years, [Company Name] will allow a third-party profiler to visit its manufacturing facility and conduct an audit, which will include the elements listed the in the Standard, Annex C.2. The audit will focus on the manufacturing process and the procedures in place to ensure that certified products comport with this agreement.

If the audit reveals items of noncompliance, [Company Name] will promptly correct the noncompliance. [Company Name] shall submit to the third-party profiler and to Safer Choice, in writing and within 30 days of receiving written notice of noncompliance, the following: a root-cause analysis, an explanation of corrective action, and a preventive action plan. In collaboration with Safer Choice, the third-party profiler shall confirm that [Company Name] has taken the remedial action necessary to assure Safer Choice of [Company Name]'s ability to satisfy the terms of this agreement. [Company Name] agrees to adhere to the implementation and compliance Schedules Safer Choice establishes and may revise from time to time (see Safer Choice Implementation and Compliance Schedules at <a href="https://www.epa.gov/saferchoice/safer-choice-implementation-and-compliance-schedules">https://www.epa.gov/saferchoice/safer-choice-implementation</a>.

Unaddressed or egregious noncompliance may serve as grounds for terminating the partnership. In any case of serious noncompliance, [Company Name] may be asked to do the following: immediately cease use of the Safer Choice label; estimate the quantities of currently certified product; and confirm the cessation and estimate in writing. Procedures for handling existing stocks of products and labels will be determined on a case-by-case basis.

#### A.15 Ingredient Communication

To enhance public awareness of the safer ingredients in Safer Choice-certified products and in the spirit of more complete communications on chemicals in common use, [Company Name] agrees to disclose the contents of their Safer Choice-certified products as described herein and in the Standard, Section 3.8.

[Company Name] must disclose all intentionally added ingredients in their Safer Choice-certified products, except for "incidental ingredients," that is, ingredients present at insignificant levels that have no technical or functional effect (e.g., reagents, processing aids, and impurities, as defined in 21 §701.3(l)).

[Company Name] agrees to disclose its ingredients in one of the following locations: on the product label; on their website; at a toll-free number; or, on another media approved by Safer Choice. If disclosure does not occur on the product label, [Company Name] must provide the location of the ingredients on the label, e.g., the website address or toll-free number. If disclosure occurs via a toll-free number, it must be available to the public at all times.

[Company Name] must use the Chemical Abstracts Service (CAS) Registry Number, if available and not trade secret information (as defined in the Uniform Trade Secrets Act), and one or more of the following nomenclature systems to describe their ingredients: CAS name; the Household & Commercial Products Association (HCPA) Ingredient Dictionary name; International Nomenclature of Cosmetic Ingredients (INCI) name; or, International Union of Pure and Applied Chemistry (IUPAC) name. Where needed to protect trade secret information, [Company Name] may, at a minimum, use a chemical-descriptive name, for example, the EPA Premanufacture Notice generic name or the HCPA Dictionary name, in lieu of the specific chemical name; however, the name must be as specific as possible without revealing trade secret information.

[Company Name] must list dyes, colorants, and preservatives by a chemical-descriptive name. [Company Name] may list scent ingredients as "Fragrance" on the label, but must also indicate where detailed information can be found; for example, the website list, or subset of the list, of fragrance materials authored by the International Fragrance Association (IFRA) and available on IFRA's website (<u>https://ifrafragrance.org/</u>). Alternatively, [Company Name] may state on its website the ingredients in the fragrance or the palette of fragrance materials used in its products and may also include the ingredients not used in the fragrance.

[Company Name] must use the following order in listing ingredients: for those present at concentrations over 1.0% (measured on a weight-weight percentage basis), ingredients must be listed in descending order, with the ingredient at the highest percentage in formula listed first; for those present at or below 1.0%, ingredients may be listed in any order.

### A.16 Primary Packaging

In accordance with Section 4.2.5 of the Standard, [Company Name] agrees that its primary packaging will either be recyclable and be made of a certain percentage of post-consumer recycled content (specified below), or be designed to be reused. For packaging that is recyclable, [Company Name] must also meet the minimum post-consumer recycled content (by weight) for various packaging material as listed below. Multi-material packaging will be considered on a case-by-case basis.

- Plastic packaging requires 15% minimum post-consumer recycled content.
- Glass packaging requires 25% minimum post-consumer recycled content.
- Fiber/cardboard/paper packaging requires 50% minimum post-consumer recycled content.
- Metal packaging requires 30% minimum post-consumer recycled content.

In certain circumstances, if [Company Name]'s primary packaging cannot meet the requirements for recyclability and/or minimum post-consumer recycled content, the partner may request an exemption to these criteria and provide a rationale and supporting documentation for the exemption.

[Company Name] further agrees that its product labels associated with primary packaging will not affect recyclability. [Company Name] will include clear instructions, or a link to online instructions, on the packaging regarding how to recycle.

In addition, [Company Name] agrees that the following chemical ingredients will not be intentionally introduced into packaging materials: cadmium, lead, mercury, hexavalent chromium, per- and polyfluoroalkyl substances (PFAS); bisphenol-based chemicals such as Bisphenol A (BPA); and dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), butyl benzyl phthalate (BBP), di-n-pentyl phthalate (DnPP), di (2-ethylhexyl) phthalate (DEHP), di-n-octyl phthalate (DnOP), diisononyl phthalate (DINP), and diisodecyl phthalate (DIDP).

### A.17 Termination or Renewal of the Agreement

Either party may, upon written notification, terminate this Agreement. In any event, the Partnership will terminate three years from the date of signature, unless the parties renew a Partnership Agreement prior to the expiration date. EPA will, upon request, provide additional time past the expiration date to complete the product renewal process, provided that [Company Name] is otherwise in compliance and pursuing product renewal; during this time, which must not exceed six months, all provisions in the Agreement will remain in effect.

If the Agency becomes aware of serious adverse health or environmental effects implicating a product class, EPA may end an existing partnership in that class during the partnership period and discontinue product certification in the class, as circumstances warrant. In such a case, EPA will notify the affected partners and stakeholders of the situation and its intention to exit the class. EPA may provide an opportunity for comment. If EPA decides to end an existing partnership, EPA will allow a period of time for the partner to cease use of the label.

We agree to these terms and provisions:

For	[Partner	Company]
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For the U.S. Environmental Protection Agency

[Signatory]	
[Signatory	Title]

[Signatory] [EPA Signatory Title]

Date \_\_\_\_\_

Date

# Annex B

Sample Design for the Environment Partnership Agreement [for cleaning product sector]

PARTNERSHIP AGREEMENT BETWEEN [COMPANY] AND U.S. ENVIRONMENTAL PROTECTION AGENCY DESIGN FOR THE ENVIRONMENT PROGRAM UNDER THE OFFICE OF PESTICIDE PROGRAMS-DfE ANTIMICROBIAL PESTICIDE PROGRAM

#### B.1 Statement of Purpose

The purpose of this Partnership Agreement ("Agreement") is to set forth the basis, terms, and goals of the Design for the Environment ("DfE") voluntary partnership between [Company] [Quoted Company Name] of [City, State] and the U.S. Environmental Protection Agency ("EPA"). The partnership is part of the Office of Pesticide Programs ("OPP")-DfE for Antimicrobial Pesticides Program ("OPP-DfE Program"). The program seeks to identify and label antimicrobial pesticides that are moving toward the green end of the pesticide spectrum. Please note that entry into partnership with DfE is one prerequisite in qualifying for the OPP-DfE Program. [Company Name] must also comply with OPP-specific program requirements. (Details on these requirements, as well as general information on the program, are available on the OPP web site at <a href="https://www.epa.gov/pesticide-labels/design-environment-logo-antimicrobial-pesticide-prod-ucts">https://www.epa.gov/pesticide-labels/design-environment-logo-antimicrobial-pesticide-prod-ucts.)</a>

A key purpose of the DfE partnership program is to recognize and encourage the formulation of products with environmentally preferable chemistry and collateral benefits, as defined and described in the Safer Choice and Design for the Environment (DfE) Standard ("the Standard") and the associated DfE component-class criteria. For the purpose of this Agreement, these products include the [Company Name] products as summarized in the Qualifying Products Table (the "Qualifying Products"). The partnership will strive to promote and advance the environmental, technological, and efficiency benefits of these and future Qualifying Products. As a precondition for partnership, [Quoted Company Name] agrees to work with a DfE-qualified third-party profiler to develop the chemical and other information needed as the basis for this Agreement and to have periodic audits of its Qualifying Product(s) (see Section 14).

This Agreement describes in general terms how [Company Name] formulates the Qualifying Products, their environmental and human health profiles, and how [Company Name] and EPA will work together to continually improve the health and environmental profile of the Qualifying Products and educate the consumer on these improvements, the DfE program and the OPP-DfE Program.

### Qualifying products [Qualifying Products List: Name, Class, Sector 1, Partnership Agreement Date]

Product Name	Reg. No.	Product Class	I/I or Consumer	Partnership Date
Example Prod- uct 1	12345-67	All-Purpose Cleaner	Both	Original: see Sec. 17

#### B.2 Statement of Context and Challenge

Each year, commercial formulators use billions of pounds of chemical ingredients to make a wide variety of general purpose and specialized cleaning/antimicrobial products. EPA is concerned about the effect certain chemicals might have on environmental quality and on the health and safety of workers and the public who use cleaning products or may come in contact with them.

EPA believes that cleaning product formulators can improve the environmental and health profile of their products by using ingredients that are inherently less toxic, less environmentally persistent, less bioaccumulative, and that degrade to substances with similar desirable characteristics when compared to ingredients in some conventional formulations. Additional benefits can be derived through environmentally oriented reformulation. Energy efficiency, resource conservation, and sound management practices offer important additional components for measurable and sustainable improvement in cleaning products and programs.

EPA believes that conventional formulations, especially those for industrial/institutional ("I/I") use, may rely on certain ingredients whose environmental and human health profiles can be improved.

### B.3 [Company Name]'s Improved Cleaning Chemistries

In conjunction with the DfE review process, [Company Name] has reformulated [a set of disinfectants for consumer and I/I cleaning and maintenance] that, according to [Company Name], meet EPA's recommendations and offer improved health and environmental characteristics. These Qualifying Products use ingredients that have been evaluated by EPA and meet a high standard for human health and the environment compared to conventional formulations. These chemicals and ingredients are listed on the EPA's Safer Chemical Ingredients List (SCIL) or are proprietary and qualify for listing but are withheld to protect intellectual property. The SCIL is a list that helps manufacturers find chemical alternatives that meet the criteria of the Safer Choice and DfE programs (see <a href="https://www.epa.gov/saferchoice/safer-ingredients">https://www.epa.gov/saferchoice/safer-ingredients</a>).

In addition, these Qualifying Products only use surfactants that biodegrade readily to low-concern substances, which helps relieve stress on the environment, especially threats to aquatic life. By not including environmentally harmful builders or extreme pH in these formulations, the environment-friendly profile and safety characteristics of these products are further enhanced. For example, an inorganic phosphate-free formula may promote a better balance of nutrients in the environment and healthier freshwater bodies. Alternative sequestrants biodegrade readily to non-hazardous compounds and protect against environmental loading of metals. Mild pH formulas help protect workers, the environment, and building infrastructure. (For more information on the attributes and benefits of this product, see Section 7.)

Note: EPA relies solely on [Company Name], its integrity and good faith, for information on the composition, ingredients, and attributes of its Qualifying Products. EPA has not independently identified, i.e., via chemical analysis, the ingredients in the submitted formulas, nor evaluated any of [Company Name]'s non-ingredient claims. If, at some time in the future, EPA has confirmation that the formulations of these products differ from the ingredient statement on the label or confidential statement of formula, the company would be in violation of FIFRA Section 12 and may face enforcement action. EPA expresses its judgment and professional opinion only as to the environmental and human health characteristics of the Qualifying Products, based on currently available information and scientific understanding. [Company Name]'s obligations under any federal, state, or local regulations governing the company or these products are in no way altered by its partnership with EPA.

#### B.4 [Company Name]'s Commitment to Formulate for the Environment

As part of [Company Name]–EPA partnership, [Company Name] agrees to formulate and produce the Qualifying Products using agreed-upon ingredients. To preserve the non-confidential nature of this document, a generic description of the ingredients in the Qualifying Products and their and their chemical status appears below.

As documentation of the Qualifying Products at the time of this Agreement, and to set a baseline for future improvements and formula changes, [Company Name] has provided to EPA the specific and

complete chemical composition for these products. This section's ingredient-by-ingredient descriptions are intended to serve as a surrogate for the actual formulas. [Company Name] reserves the right, however, to change ingredients, provided that their health/environmental profile is equal to or better than those in the current formulations and that any substitution occurs in consultation and agreement with EPA (see Section 12). In addition, to comply with FIFRA, [Company Name] would need to submit a formal request for formulation change to OPP, as well as any necessary associated confirmatory efficacy data.

If any change is made to the agreed formulation, [Company Name] agrees to notify EPA of the change and provide the new formulation, unless the change is made to a commodity ingredient (i.e., changing ingredient supplier). Such changes include, to the best of [Company Name]'s knowledge, a change to any ingredient supplier in the supply chain for the qualifying products. EPA/DfE agrees to no-tify [Company Name] of the need for ingredient profiling and will make recommendations for changes to the formulation as needed to remain a Qualifying Product. EPA will keep confidential all product formulas and other proprietary information that [Company Name] furnishes to the Agency (see confidentiality provisions in Section 11).

The following is a non-confidential representation of the ingredients in the Qualifying Products, with their chemical status or areas identified for future improvement, as evaluated and designated by EPA:

Ingredient [Example Product Name]	Chemical Status
Ingredient 1	Low human health and environmental concern.
Ingredient 2	Expected to have low human health and environmental concerns.
Ingredient 3	Gray square (see Section 5).
Ingredient 4	Expected to have low human health and environmental concerns; contains auxiliary component(s) allowed for functionality.
Ingredient 5	Previous acceptable; not currently acceptable (see Sec- tion 5). [Language relevant for partnership agreement renewals only.]
Ingredient 6	Allowed for functionality.
Ingredient 7	Updated ingredient formulation not provided (see sec. 5). [Language relevant for partnership agree- ment renewals only.]
Fragrance	Meets Safer Choice Fragrances Criteria.

Adoption and use of the formulations described in this Agreement does not preclude, nor should it impede, [Company Name] in its efforts to further improve the health and environmental profile of the Qualifying Products. In fact, a main element of [Company Name]–EPA partnership is to provide [Company Name] the opportunity to work with EPA chemists, environmental scientists, and risk reduction staff in investigating materials to further improve the health and environmental profile of the Qualifying Products.

#### B.5 Continuous Environmental Improvement

[Company Name] agrees to make continuous environmental improvement an important element of its research and development activities related to its Qualifying Products. In addition to the environmentally oriented formulations set forth in Section 4, [Company Name] agrees to investigate the feasibility of making additional improvements in the environmental and health profile of the Qualifying Products.

Ingredients allowed for functionality. [Company Name] agrees to explore the use of and, if feasible, reformulate with alternatives with an improved health and environmental profile compared to ingredients allowed for functionality, as detailed in Section 4, during the period of the Agreement. While these

ingredients are best-in-class chemicals for a particular function, the function fulfilled by the chemical should be considered an area for innovation.

Additionally, [Company Name] agrees to:

- replace any [grey-squared ingredient(s)] within one year of notification of the SCIL status update
- replace any [previously acceptable ingredient(s)] within one year of the [month and year] agreement/amendment
- provide complete information for-or replace-any ingredient(s) with missing supplier information within one year of the [month and year] agreement/amendment

In addition, [Company Name] agrees to provide satisfactory [performance test results] and [revised labels] within one year of the [month and year] agreement/amendment date.

[Company Name] may consult with EPA about other antimicrobial pesticide products and, following EPA review and assessment, may request that one or more new Qualifying Products be added to this Agreement, subject to the additional terms and conditions of the OPP-DfE Program. With EPA's approval, this Agreement may be amended as set forth in Section 12 to include new Qualifying Products.

[Company Name] and EPA agree to discuss the status of [Company Name]'s reformulation research and continuous improvement activities related to the Qualifying Products. [Company Name] may, at any time, request consultation and technical assistance from EPA in determining which chemical ingredients possess more positive health/environmental characteristics.

### B.6 Formulator Right to Know

Product formulators have a right to know the properties and potential risks – to their employees, customers, and communities – of the chemicals they use. Manufacturers of raw materials for detergents and other cleaning products should ascertain and communicate the properties and potential toxicity of their products, especially those made and sold in large quantities.

As part of its partnership with EPA, [Company Name] agrees to ask its raw material suppliers for test data on the chemicals they sell and that [Company Name] uses in its products. If the raw material suppliers do not have test data on their chemicals, [Company Name] agrees to encourage them to perform basic physicochemical and toxicity testing. Upon request by EPA, [Company Name] agrees to share with EPA any available chemistry or toxicity information on its ingredients that it obtains from its suppliers.

To help ensure that any new testing serves to enhance the profile and general understanding of a particular chemical, all prospective studies should be considered in the context of the guidance offered in EPA's chemical evaluation programs (<u>https://www.epa.gov/chemicals-under-tsca</u>) and the Screening Information Data Set (SIDS) Program of the Organization for Economic Co-operation and Development (OECD) (to learn more, visit <u>http://webnet.oecd.org/hpv/ui/default.aspx</u> and https://cfpub.epa.gov/si/si\_public\_record\_Report.cfm?Lab=&dirEntryID=2854).

### B.7 User Benefits

[Company Name]'s Qualifying Products offers users the following set of benefits:

#### Environmental Protection

The Qualifying Products are formulated with the environment and human health strongly in mind and uses the following types of ingredients: biodegradable surfactants, with byproducts that are less toxic than the parent compound; solvents that are not hazardous air pollutants and pose no threat to the Earth's ozone layer; and other components with an improved environmental profile than in conventional disinfecting products.

#### Worker/Consumer Safety

The Qualifying Products are also formulated to help ensure an improved workplace. Users of these products benefit from ingredients that include no components that pose serious hazards. This benefit is amplified for janitors, maintenance staff, housekeepers, and others who must use cleaning and pesticide chemicals in confined spaces on a daily basis. Importantly, an improved health profile especially benefits children, who spend a large part of their day in indoor environments and can be particularly sensitive to the chemicals in some cleaning and pesticide products. Also, the mild pH, low volatility, and low potential to catch fire enhance the profile of these products.

#### **Resource Conservation**

The Qualifying Products also have certain attributes that may significantly reduce wear and tear on substrates, fabrics, and other surfaces with which the products come in contact, thereby extending their usable life.

#### **Customer Education**

[Company Name] acts as a product steward by providing its customers information on environmental and worker safety matters and trains its sales force on the benefits of formulations with improved environmental and health characteristics.

[Company Name] agrees to inform customers of the Qualifying Products about the [Company Name]-EPA partnership, the meaning of the DfE logo, the OPP-DfE Program, and the DfE program's role in helping to protect human health and the environment. [Company Name] agrees to make available to its customers an EPA/DfE contact to who they may direct questions or comments on the partnership.

#### B.8 EPA Certification and Support

Upon successful completion of the OPP review, [Company Name] may use the DfE logo (shown on Attachment A to this Agreement)—subject to the conditions in this section and the OPP-DfE Program—on containers or container packaging of the Qualifying Products or on advertising related solely to these products, provided that EPA has reviewed and approved the intended use of the logo. [Company Name] agrees to not use the logo or describe EPA's certification on any general [Company Name] materials, non-Qualifying Products or associated literature, or advertising not related to the Qualifying Products. [Company Name] is not permitted to use the EPA official seal or logo at any time.

Use of the DfE logo must not be accompanied by an informational tagline, which is reserved for use in non-OPP-DfE-related partnerships, but must contain the OPP web address for the program. Additionally, [Company Name] agrees to include in advertising of the Qualifying Products an endorsement disclaimer and various educational information for the consumer regarding the DfE partnership. [Company Name] and EPA/DfE agree to work to find an appropriate place (e.g., company website) connected with advertising for the Qualifying Products to include the following language along with educational information:

EPA certification does not constitute endorsement of this product. The DfE logo signifies that the product's formula, as [Company Name] has represented it to the EPA and as verified by audit, meets the requirements of the Safer Choice and Design for the Environment Standard. EPA relies solely on [Company Name] and its suppliers, their integrity and good faith, for information on the product's composition, ingredients, and attributes. EPA has not independently verified – via chemical analysis – the ingredients in the product, nor evaluated any of [Company Name]'s non-ingredient claims. EPA provides its evaluation only as to the product's human health and environmental characteristics, as specified in the Safer Choice and Design for the Environment Standard.

The Parties acknowledge that under 5 C.F.R. §2635.702(c), EPA may not endorse the purchase or sale of commercial products and services provided by [Company Name]. The Parties agree to ensure

that promotional materials describing or resulting from this Agreement do not contain statements implying that EPA endorses the purchase or sale of commercial products. This includes statements to the public in news releases, publications, on web sites or any other media.

[Company Name] agrees to make available to EPA for review and approval any materials, including press releases, promotional materials and advertisements that [Company Name] develops in connection with the partnership, and especially information that describes or characterizes the DfE program or EPA/DfE's position on issues related to the specific product sector.

[Company Name] agrees to discontinue use of the DfE logo or any other form of EPA certification, within 30 days, under the following circumstances: If [Company Name] stops formulating the Qualifying Products using the agreed upon ingredients; upon the termination of this Agreement; or, if so notified by EPA in writing when, pursuant to Section 3.3.1 of the Standard, continuation of the partnership and certification of products in a certain class would adversely affect the value of the program's logo and undermine its health-and-environmental-protection goals. [Company Name] further agrees that it will use its best efforts to ensure that any associated merchants, distributors, or online vendors also cease use of the logo. In addition, [Company Name] agrees to voluntarily recall its DfE-certified products within the channels of trade, as per OPP program requirements.

### B.9 Limitations

All commitments made by EPA in this Agreement are subject to the availability of appropriated funds and budget priorities. Nothing in this Agreement, in and of itself, obligates EPA to expend appropriations or to enter into any contract, assistance agreement, interagency agreement, or incur other financial obligations. This Agreement does not exempt [Company Name] or any other organization from EPA policies for competition for financial assistance agreements or procurement contracts. [Company Name] agrees not to submit a claim for compensation for services rendered to EPA in connection with any activities it carries out in furtherance of this Agreement. Any endeavor involving reimbursement or contribution of funds between the parties to this Agreement will be handled in accordance with applicable laws, regulations, and procedures, and will be subject to separate agreements.

This Agreement does not create any right or benefit, substantive or procedural, enforceable by law or equity against [Company Name] or EPA/DfE, their officers or employees, or any other person. This Agreement does not direct or apply to any persons outside [Company Name] or EPA.

#### B.10 Measures of Success

On an annual basis, [Company Name] agrees to provide to EPA/DfE its best estimate of the production volume of the Qualifying Products (if possible, in pounds per year or gallons per year).

At EPA's request, [Company Name] agrees to make available to EPA, on a confidential basis, formulation bills of materials that confirm that the Qualifying Products contain the ingredients agreed to in this Agreement or have been modified in accordance with its terms.

[Company Name] agrees to make reasonable attempts to monitor the cleaning product market and agrees to inform EPA about the Qualifying Products' influence on the market, including growth in sales and number of new customers, as well as the perceived value in DfE certification. [Company Name] agrees to report on customer acceptance of and satisfaction with these products when this information is available.

As discussed in Section 5, [Company Name] agrees to furnish periodic updates to EPA on the continuous improvement component of its research and development activities and on its ongoing efforts to improve the health/environmental profile of the Qualifying Products. As a condition of partnership, [Company Name] has demonstrated to EPA the performance of its Qualifying Products according to the guidelines provided by DfE (see <u>www.epa.gov/saferchoice/standard</u>). [Company Name] agrees to also share with EPA the results of any additional performance testing or verification when that information becomes available.

### B.11 Confidentiality

In matters relating to this DfE partnership and Agreement, EPA agrees to handle all information claimed by [Company Name] as confidential business information in accordance with EPA confidentiality procedures (see 40 CFR part 2, subpart B). EPA and [Company Name] agree that information supplied to EPA by [Company Name] regarding the formulas of any [Company Name] products or in connection with any audits required pursuant to Section 14 of this Agreement is covered by the foregoing sentence.

EPA/DfE agrees to only use the information provided by [Company Name] for purposes related to the [Company Name]-EPA partnership and disclose the information only to EPA employees and EPA contractors cleared for confidential information with a specific need to know.

### B.12 Amendments to the Agreement

[Company Name] may request that EPA/DfE add new Qualifying Products or make other changes to this Agreement. If EPA agrees to the addition or change, the essential elements from Sections 3, 4, 5 and 7 of the current Agreement may be amended. [Company Name] and EPA agree to collaborate in developing the specific language for the amendment, which must be signed by an appropriate official for both parties. All other provisions of the Agreement shall be incorporated by reference.

### B.13 Private Label, Licensee, and Toll Manufacture Products

[Company Name] acknowledges and agrees to the following roles, limitations, and responsibilities when third parties are involved in the manufacture of DfE-certified products. [Company Name] must also comply with OPP-specific program requirements, and possess a supplemental registration that is linked to the primary registration of the label owner.

A private label product may carry the DfE logo provided that its contents are either identical to those in a specified DfE product, or very similar, and the ingredients that are different have been approved in the partnership agreement. A licensee or toll manufacture product may carry the DfE logo provided that its contents are identical to those in a specified DfE product.

Ready To Use private label products – where the dilution of a certified concentrate is conducted by the private label company – can be certified as a private label on a case-by-case basis. The partner must communicate to Safer Choice the concentrate that is being diluted and verify the corresponding dilution rates.

Before manufacture of any private label product that will carry DfE certification, [Company Name] must inform and receive permission from DfE, indicating the name of the private label product, the label owner, and the specific DfE product to which it is identical or on which it is based. Before manufacture of any licensee or toll manufacture product, [Company Name] must inform and receive permission from DfE, indicating the name of the licensee or toll manufacture and of the specific DfE product to which the licensee or toll manufacture product. To assure quality, the licensee or toll manufacture product must be manufactured under an agreement between [Company Name] and the licensee or toll manufacture and the agreement must be available to DfE on request.

[Company Name] agrees to ensure that its private label, licensee and toll manufacture products comply with the audit provisions in Section 14.

### B.14 Partnership Surveillance and Audits

To ensure that the contents of certified products are as represented to the Agency under this agreement and that all other aspects of the [Company Name]-DfE partnership comport with the Standard and criteria documents, [Company Name] agrees to participate in DfE's surveillance and auditing program. The program will consist of annual audits: an on-site audit must take place within the first year of partnership formation, provided that the partnership products are being manufactured, and then once per threeyear partnership period; and desk audits will occur in the non-site audit years, including a renewal in the year of partnership renewal, as appropriate.

[Company Name] will make its manufacturing facilities and certified-product-related records available to DfE-authorized third-party profilers. On an annual basis, [Company Name] agrees to submit to the third-party profiler desk audit materials as specified in the Standard, Annex C.1. These materials will include a list of ingredients for each certified product and a statement that the ingredients and all claims made regarding the Agency's certification (e.g., use of the DfE logo) comport with this agreement.

Approximately every three years, [Company Name] will allow a third-party profiler to visit its manufacturing facility and conduct an audit, which will include the elements listed in the Standard, Annex C.2. The audit will focus on the manufacturing process and the procedures in place to ensure that certified products comport with this agreement.

If the audit reveals items of noncompliance, [Company Name] will promptly correct the noncompliance. [Company Name] shall submit to the third-party profiler and to DfE, in writing and within 30 days of receiving written notice of noncompliance, the following: a root-cause analysis, an explanation of corrective action, and a preventive action plan. In collaboration with DfE, the third-party profiler shall confirm that [Company Name] has taken the remedial action necessary to assure DfE of [Company Name]'s ability to satisfy the terms of this agreement. [Company Name] agrees to adhere to the implementation and compliance schedules Safer Choice establishes and may revise from time to time (see Safer Choice Implementation and Compliance Schedules at <u>https://www.epa.gov/saferchoice/safer-choice-implementation-and-compliance-schedules</u>).

Unaddressed or egregious noncompliance may serve as grounds for terminating the partnership. In any case of serious noncompliance, [Company Name] would be asked to do the following: immediately cease use of the DfE logo; estimate the quantities of the currently certified product; and confirm the cessation and estimate in writing. Procedures for handling existing stocks of products and labels will be determined on a case-by-case basis.

Noncompliance that is also a violation of FIFRA may result in appropriate regulatory or enforcement action under FIFRA.

#### B.15 Ingredient Communication

To enhance public awareness of ingredients that meet a high standard for human health and the environment in DfE-certified products and in the spirit of more complete communications on chemicals in common use, [Company Name] agrees to disclose the contents of their DfE-certified products as described herein and in the Standard, Section 3.8.

[Company Name] must disclose all intentionally added ingredients in their DfE-certified products, except for "incidental ingredients," that is, ingredients present at insignificant levels that have no technical or functional effect (e.g., reagents, processing aids, and impurities, as defined in 21 §701.3(l)).

[Company Name] agrees to disclose its ingredients in one of the following locations: on the product label; on their website; at a toll-free number; or, on another media approved by DfE. If disclosure does not occur on the product label, [Company Name] must provide the location of the ingredients on the label, e.g., the website address or toll-free number. If disclosure occurs via a toll-free number, it must be available to the public at all times.

[Company Name] must use the Chemical Abstracts Service (CAS) Registry Number, if available and not trade secret information (as defined in the Uniform Trade Secrets Act), and one or more of the following nomenclature systems to describe their ingredients: CAS name; the Household & Commercial Products Association (HCPA) Ingredient Dictionary name; International Nomenclature of Cosmetic Ingredients (INCI) name; or, International Union of Pure and Applied Chemistry (IUPAC) name. Where needed to protect trade secret information, [Company Name] may, at a minimum, use a chemical-descriptive name, for example, the EPA Premanufacture Notice generic name or the HCPA Dictionary name, in lieu of the specific chemical name; however, the name must be as specific as possible without revealing trade secret information.

[Company Name] must list dyes, colorants, and preservatives by a chemical-descriptive name. [Company Name] may list scent ingredients as "Fragrance" on the label, but must also indicate where detailed information can be found; for example, the website list, or subset of the list, of fragrance materials authored by the International Fragrance Association (IFRA) and available on IFRA's website (<u>https://ifrafragrance.org/</u>). Alternatively, [Company Name] may state on its website the ingredients in the fragrance or the palette of fragrance materials used in its products, and may also include the ingredients not used in the fragrance.

[Company Name] must use the following order in listing ingredients: for those present at concentrations over 1.0% (measured on a weight-weight percentage basis), ingredients must be listed in descending order, with the ingredient at the highest percentage in formula listed first; for those present at or below 1.0%, ingredients may be listed in any order.

# B.16 Primary Packaging

In accordance with Section 4.2.5 of the Standard, [Company Name] agrees that its primary packaging will either be recyclable and be made of a certain percentage of post-consumer recycled content (specified below), or be designed to be reused. For packaging that is recyclable, [Company Name] must also meet the minimum post-consumer recycled content (by weight) for various packaging material is listed below. Multi-material packaging will be considered on a case-by-case basis.

- Plastic packaging requires 15% minimum post-consumer recycled content.
- Glass packaging requires 25% minimum post-consumer recycled content.
- Fiber/cardboard/paper packaging requires 50% minimum post-consumer recycled content.
- Metal packaging requires 30% minimum post-consumer recycled content.

In certain circumstances, if [Company Name]'s primary packaging cannot meet the requirements for recyclability and/or minimum post-consumer recycled content, the partner may request an exemption to these criteria and provide a rationale for the exemption.

[Company Name] further agrees that its product labels associated with primary packaging will not affect recyclability. [Company Name] will include clear instructions, or a link to online instructions, on the packaging regarding how to recycle.

In addition, [Company Name] agrees that the following chemical ingredients will not be intentionally introduced into packaging materials: cadmium, lead, mercury, hexavalent chromium, per- and polyfluoroalkyl substances (PFAS), bisphenol-based chemicals such as Bisphenol A (BPA), and dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), butyl benzyl phthalate (BBP), di-n-pentyl phthalate (DnPP), di (2ethylhexyl) phthalate (DEHP), di-n-octyl phthalate (DnOP), diisononyl phthalate (DINP), and diisodecyl phthalate (DIDP).

### B.17 Termination or Renewal of the Agreement

Either party may, upon written notification, terminate this Agreement. In any event, the Partnership will terminate three years from the date of signature, unless the parties renew a Partnership Agreement prior to the expiration date. EPA will, upon request, provide additional time past the expiration date to complete the product renewal process, provided that [Company Name] is otherwise in compliance and pursuing product renewal; during this time, which must not exceed six months, all provisions in the Agreement will remain in effect.

If the Agency becomes aware of serious adverse health or environmental effects implicating a product class, EPA may end an existing partnership in that class during the partnership period and discontinue product certification in the class, as circumstances warrant. In such a case, EPA will notify the affected partners and stakeholders of the situation and its intention to exit the class. EPA may provide an opportunity for comment. If EPA decides to end an existing partnership, EPA will allow a period of time for the partner to cease use of the logo.

We agree to these terms and provisions:

For [Partner Company]

For the U.S. Environmental Protection Agency

[Signatory] [Signatory Title] [Signatory] [EPA Signatory Title]

Date \_\_\_\_\_

Date \_\_\_\_\_

# Annex C

### Elements of Desk Audits and On-Site Audits

### C.1 Desk Audits

- Verification that qualifying products are being manufactured using approved ingredients. Authorized formulas will be compared to manufactured product through review of production records, batch tickets, bills of lading, certificates of analysis and any other documentation;
- Statement that the ingredients and all claims made regarding the Agency's certification (e.g., use of the Safer Choice label and/or DfE logo) comport with the Partnership Agreement or an approved amendment to the agreement; of note, this statement must confirm that the ingredients in certified products are the same as those EPA has reviewed and referenced in the partnership agreement;
- Product labels showing use of the Safer Choice label or DfE logo or mention of Safer Choice or DfE certification;
- Product or company literature that uses the Safer Choice label or DfE logo or mentions Safer Choice or DfE certification;
- Private label (including licensed product) labels and literature that bear the Safer Choice label or DfE logo;
- Summary of implementation activities for any continuous improvement efforts as required by the Partnership Agreement; and
- Documentation of education offered to end users of Industrial / Institutional (I/I) products.

# C.2 On-Site Audits

The third-party profiler will seek the following information, based on the terms of the Partnership Agreement and Standard and criteria, at subject facilities:

- Verification that qualifying products are being manufactured using accepted ingredients and suppliers and at proper use levels. Authorized formula will be compared to manufactured product through review of production records, batch tickets, bills of lading, certificates of analysis and any other documentation necessary;
- Verification that any private label and licensed products packaged on-site are identical in formulation to the original certified product formulation, except as noted in the private label application (e.g., alternate dilution rate, alternate dyes or fragrances as specified in the partnership agreement);
- Summary of implementation activities for any continuous improvement efforts as required by the Partnership Agreement;
- Review customer and/or employee complaint file;
- Review of Good Manufacturing Practices (i.e., manufacturing and packaging operations conducted within the scope of an effective quality system (e.g., ISO 9001) and in accordance with defined quality procedures appropriate for the manufacture of products). For this component the audit may include:
  - Production walk-through;
  - Review of practices for minimizing contamination of the Product during measuring, blending, packaging, and transport;
  - Verification that bulk product containers, transfer equipment, and holding vessels for Certified Product are maintained in good repair;
  - Review of records for cleaning, maintenance, and calibration of manufacturing equipment; and
  - Review of supplier qualification records (including test data) for raw materials, packaging, and ingredients.

# Annex D

Sample Partnership Agreement [for Cleaning Service Standard]

PARTNERSHIP AGREEMENT BETWEEN [COMPANY] AND U.S. ENVIRONMENTAL PROTECTION AGENCY SAFER CHOICE PROGRAM

### D.1 Statement of Purpose

The purpose of this Partnership Agreement ("Agreement") is to set forth the basis, terms, and goals of the Safer Choice voluntary partnership between [Company] [Quoted Company Name] of [City, State] and the U.S. Environmental Protection Agency ("EPA"). The partnership is part of the Safer Choice Program. The goal is to seek and promote the use of cleaning products that benefit human health and the environment.

A key purpose of the partnership program is to recognize and encourage the use of Safer Choicecertified products for cleaning and Design for the Environment (DfE)-certified products for disinfecting (the "Certified Products"). Safer Choice- and DfE-certified products can be found at <u>https://www.epa.gov/saferchoice/products</u> and at <u>https://www.epa.gov/pesticide-labels/dfe-certified-disinfectants</u>, respectively. As a precondition for partnership, [Company Name] agrees to work with a Safer Choice-qualified third-party profiler ("CSC Profiler") to provide the information needed as the basis for this agreement and to have annual audits (see Section 10).

This Agreement describes in general terms the use of Certified Products by [Company Name] and the expectations of a partnership between EPA and [Company Name].

#### D.2 Statement of Context and Challenge

Building and house cleaners are regularly exposed to cleaning chemicals which may cause adverse health impacts. According to the Bureau of Labor Statistics

(<u>https://www.bls.gov/iif/oshwc/osh/case/cd\_r100\_2020.htm</u>), cleaning workers are more likely to miss work because of exposure to harmful substances or environments than the general working population. Furthermore, populations who live, work, learn, play, and interact in buildings and facilities are affected by the chemicals and practices used to clean those buildings. Use of cleaning products made with safer chemicals can improve environmental health and the health and safety of workers and the public who use products or may come in contact with them.

The Safer Choice Cleaning Service Certification also responds to demand for use of safer products in homes and institutional spaces.

The potential benefits of this certification to cleaning service providers are twofold. First, this certification will allow the cleaning service provider to project an image of sustainability in the marketplace, making their services more appealing to customers seeking out more sustainable or safer cleaning services. Second, this certification could help reduce costs to businesses by creating safer conditions for home cleaners and janitorial workers, who often come from underserved communities, and who frequently use cleaning chemicals on the job.

### D.3 Use of Safer Choice- and DfE-Certified Products in Cleaning

[Company Name] must provide cleaning services as part of their routine operations to be eligible for the Safer Choice certification for cleaning service providers, as described in Section 7.2 of the Safer Choice and Design for the Environment Standard ("the Standard").

To meet certification criteria, [Company Name] must use Safer Choice- and DfE-certified products as indicated in Section 7.3.1 of the Standard, and they must include required attestation and documentation, outlined in Section 7.4.2.1 of the Standard.

#### D.4 Exceptions

If [Company Name] cannot attest to use of Safer Choice-certified products for cleaning and DfE-certified products for disinfecting, in product classes with Safer Choice- and DfE-certified products, to the maximum extent possible, in accordance with the exception provisions in Section 7.3.1.1 of the Standard, [Company Name] should document the exception and explain their rationale.

Documentation supporting the exception must be submitted to a CSC Profiler. Examples of documentation of the exception may include copies of the procurement contract or supplier catalog. Descriptions of reporting exceptions for the application and for continued compliance can be found in Section 7.4.2.2 and Section 7.5.1.2 of the Standard, respectively.

#### D.5 EPA Certification and Support

[Company Name] may use the Safer Choice Service Certification logo, shown on Attachment A to this Agreement, in the locations described in Section 7.6.2 of the Standard, provided that EPA has reviewed and approved the intended use. [Company Name] agrees to not use the label or describe EPA certification on any general [Company Name] materials not associated with the Cleaning Service Certification. [Company Name] is not permitted to use the EPA official seal or logo at any time.

Use of the Safer Choice Service Certification logo must be accompanied by the program web address, <u>www.epa.gov/saferchoice/cleaning</u>, as shown in Attachment A. Additionally, when advertising their cleaning services or informing consumers about them, [Company Name] must include the endorsement disclaimer, which appears below. [Company Name] and EPA agree to work to find an appropriate place (e.g., the company's web site) to include the disclaimer connected with advertising their cleaning services:

EPA/Safer Choice certification does not constitute endorsement of this cleaning service. The Safer Choice Service Certification logo signifies that [Company Name] uses Safer Choice-certified products for cleaning and DfE-certified products for disinfecting to the maximum extent practicable. EPA/Safer Choice relies solely on [Company Name], its integrity and good faith, for information on product use.

The Parties acknowledge that under 5 C.F.R. §2635.702(c), EPA may not endorse the services provided by [Company Name]. The Parties agree to ensure that promotional materials describing or resulting from this Agreement do not contain statements implying that EPA/Safer Choice endorses their cleaning services. This includes statements to the public in news releases, publications, on web sites, or any other media.

[Company Name] agrees to make available to EPA for review and approval any materials, including press releases, promotional materials, and advertisements that [Company Name] develops in connection with the partnership, and especially information that describes or characterizes the Safer Choice program or EPA's position on issues related to the cleaning industry sector.

[Company Name] agrees to discontinue use of the Safer Choice Service Certification logo or any other form of EPA certification, within 30 days, under the following circumstances: if [Company Name] stops using Safer Choice-certified products for cleaning and DfE-certified products for disinfecting to the maximum extent practicable; or upon the termination of this Agreement. [Company Name] further agrees that it will use its best efforts to ensure that any associated entities also cease use of the logo.

#### D.6 Limitations

All commitments made by EPA in this Agreement are subject to the availability of appropriated funds and budget priorities. Nothing in this Agreement, in and of itself, obligates EPA to expend appropriations or to enter into any contract, assistance agreement, interagency agreement, or incur other financial obligations. This Agreement does not exempt [Company Name] or any other organization from EPA policies for competition for financial assistance agreements or procurement contracts. [Company Name] agrees not to submit a claim for compensation for services rendered to EPA in connection with any activities it carries out in furtherance of this Agreement. Any endeavor involving reimbursement or contribution of funds between the parties to this Agreement will be handled in accordance with applicable laws, regulations, and procedures, and will be subject to separate agreements.

This Agreement does not create any right or benefit, substantive or procedural, enforceable by law or equity against [Company Name] or EPA, their officers or employees, or any other person. This Agreement does not direct or apply to any persons outside [Company Name] or EPA.

#### D.7 Confidentiality

In matters relating to this Safer Choice partnership and Agreement, EPA agrees to handle all information claimed by [Company Name] as confidential business information in accordance with EPA confidentiality procedures (see 40 CFR part 2, subpart B). EPA and [Company Name] agree that information supplied to EPA by [Company Name] and claimed as confidential business information is covered by the foregoing sentence.

EPA agrees to only use the information provided by [Company Name] for purposes related to the [Company Name]-EPA partnership and disclose the information only to EPA employees and EPA contractors cleared for confidential information with a specific need to know.

#### D.8 Partnership Audits

To ensure that all aspects of the [Company Name]-Safer Choice partnership comport with the Standard, [Company Name] agrees to participate in Safer Choice's auditing program. The program will consist of annual virtual audits.

On an annual basis, [Company Name] agrees to submit to the CSC Profiler audit materials as specified in the Standard, Section 7.5.1.

If the audit reveals items of noncompliance, [Company Name] will promptly correct the noncompliance. [Company Name] shall submit to the CSC Profiler and to Safer Choice, in writing and within 30 days of receiving written notice of noncompliance, the following: a root-cause analysis, an explanation of corrective action, and a preventive action plan. In collaboration with Safer Choice, the CSC Profiler shall confirm that [Company Name] has taken the remedial action necessary to assure Safer Choice of [Company Name]'s ability to satisfy the terms of this agreement. [Company Name] agrees to adhere to the implementation and compliance schedules Safer Choice establishes and may revise from time to time.

Unaddressed or egregious noncompliance may serve as grounds for terminating the partnership. In any case of serious noncompliance, [Company Name] may be asked to immediately cease use of the Cleaning Service Certification logo.

### D.9 Informational Material and Resources

To enhance awareness of the Safer Choice program and best cleaning practices, [Company Name] agrees to supply informational material and resources, provided by the Safer Choice program, about Safer Choice- and DfE-certified products and best cleaning practices to their employees as described in Section 7.5.1.1.

#### D.10 Termination or Renewal of the Agreement

Either party may, upon written notification, terminate this Agreement. In any event, the Partnership will terminate one year from the date of signature, unless the parties extend this Partnership Agreement prior to the expiration date. An approved audit extends this Partnership Agreement for a year. EPA will, upon request, provide additional time past the expiration date to complete the audit process, provided that [Company Name] is otherwise in compliance and pursuing an audit; during this time all provisions in the Agreement will remain in effect.

In the event that the Agency decides to exit a currently active service sector, EPA may notify and provide an opportunity for comment from any affected partners and stakeholders in that service sector. If EPA decides to exit the service sector, EPA will discontinue new service certification in the service sector and not extend any existing partnerships, allowing a period of time for the partner to cease use of the logo.

We agree to these terms and provisions:

For [Partner Company]

For the U.S. Environmental Protection Agency

[Signatory] [Signatory Title] [Signatory] [EPA Signatory Title]

Date \_\_\_\_\_

Date \_\_\_\_\_