EPA's Safer Choice Standard

(formerly, the 'DfE Standard for Safer Products')

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This document was developed with the purpose of making criteria for recognition under the EPA Safer Choice Program more transparent and accessible. A group convened under the Green Chemistry and Commerce Council provided guidance to Safer Choice for the development of this document to ensure that it would communicate well to its intended audience.

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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. Safer Choice 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. Safer Choice 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, Safer Choice offers unique technical tools, methodologies, expertise, and the potential for product recognition.

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 Safer Choice 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, Safer Choice 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 recognition is based on using the safest possible ingredients to make a high-performing product. Safer Choice considers whole product characteristics, like possible negative synergies between ingredients and pH level, as well as lifecycle factors, like energy efficiency and water savings.

Safer Choice's functional class approach screens for 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, Safer Choice 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.

Safer Choice 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 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 screened 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 class. For example, if a Safer Choice product contains a surfactant, then that surfactant will not be toxic to humans and will biodegrade readily to non-polluting degradation products. Many surfactants in conventional products biodegrade slowly or biodegrade to more toxic and persistent chemicals, which threaten aquatic life.

Product formulators who become Safer Choice partners, and earn the right to display the Safer Choice label on recognized 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.

Safer Choice uses a rigorous, in-depth approach to review products. By focusing at the ingredient level and on inherent characteristics, Safer Choice is able to carefully scrutinize formulations and make meaningful calls on potential concerns. Safer Choice 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. Safer Choice 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 Safer Choice in confidentiality).

> *Safer Choice reviews provide an extra measure of protection*. Safer Choice 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, Safer Choice 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.
>
> *Safer Choice 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. Safer Choice uses its knowledge of the structur-

al similarities between chemicals and its predictive models to flag ingredients with similar potential effects.

Safer Choice 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.

Safer Choice screens all ingredients for chemicals that may present serious health or environmental effects. This screening includes ingredients used in small percentages, like fragrances 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.

Safer Choice 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.

Safer Choice Standard

1 Purpose, Scope, and Normative References

1.1 Purpose

This document, the Safer Choice Standard, establishes minimum requirements for identifying products that meet the U.S. Environmental Protection Agency's Safer Choice Program (also know as the Formulator Program) criteria.

1.2 Scope

The Safer Choice Standard is intended to cover a wide range of 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, personal care, and floor care and other industrial products. While this document includes the review criteria for both the whole product and each product ingredient, the Safer Choice recognition 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/Safer Choice.

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.

AATCC Test Method 171-1995.

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

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

CSPA DCC-03 – Performance Test Methods and Guidelines – Rug Shampoo.

CSPA DCC-09 – Performance Test Methods and Guidelines – Glass Cleaners.

CSPA DCC-09A – Performance Test Methods and Guidelines – Standard Guide for Evaluating the Filming and Streaking of Glass Cleaners.

CSPA DCC-10 – Performance Test Methods and Guidelines – Foam Stability of Hand Dishwashing Detergents.

CSPA DCC-11 – Performance Test Methods and Guidelines – Home Laundering Pre-Wash Spotter Stain Removal.

CSPA DCC-12 – Performance Test Methods and Guidelines – Guidelines for Screening the Efficacy of Oven Cleaners.

CSPA DCC-13 – Performance Test Methods and Guidelines – Fabric Softeners.

CSPA DCC-14 – Guidelines for Anti-Redeposition Properties of Laundry Products.

CSPA DCC-16 – Guidelines for Evaluating the Efficacy of Bathroom Cleaners.

CSPA DCC-17 – Greasy Soil Test Method for Evaluating Spray-and-Wipe Cleaners Used on Hard, Non-Glossy Surfaces.

CAN/CGSB 2-GP-11, Method 20.3.

Globally Harmonized System of Classification and Labeling of Chemicals (GHS) http://www.unece.org/trans/danger/publi/ghs/ghs_rev02/02files_e.html.

Safer Choice Criteria for Chelating and Sequestering Agents – http://www2.epa.gov/saferchoice/safer-choice-criteria-chelating-and-sequestering-agents

Safer Choice Criteria for Environmental Toxicity and Fate for Chemicals in Direct Release Products – http://www2.epa.gov/saferchoice/standard#tab-3

Safer Choice Criteria for Fragrances – http://www2.epa.gov/saferchoice/safer-choice-criteria-fragrances

Safer Choice Master Criteria for Safer Ingredients – See http://www2.epa.gov/saferchoice/safer-choice-master-criteria-safer-chemical-ingredients

Safer Choice Criteria for Processing Aids and Additives – http://www2.epa.gov/saferchoice/safer-choice-criteria-processing-aids-and-additives

Safer Choice Criteria for Solvents -- http://www2.epa.gov/saferchoice/safer-choice-criteria-solvents

Safer Choice Criteria for Surfactants – http://www2.epa.gov/saferchoice/safer-choice-criteria-surfactants

Safer Choice Partnership Agreement – Annex A.

2 Reference Section

2.1 Definitions

Terms used in the Safer Choice 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 Amine: An organic compound containing a basic (alkaline) nitrogen atom. Amines may be primary (R-NH2), secondary (R2NH) or tertiary (R3N).

2.1.5 Analog: Closely-related chemical structures. (Reference: Analog Information Model)

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

2.1.7 Antioxidant: A chemical compound or substance that inhibits oxidation.

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

2.1.9 Association of Occupational and Environmental Clinics (AOEC) list of occupational asthmagens: A list of respiratory sensitizers and irritants found in occupational settings. For more information, please see http://www.aoec.org/.

2.1.10 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.

2.1.11 Asthmagen: An agent that causes asthma.

2.1.12 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.

2.1.13 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.

2.1.14 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.

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

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

2.1.17 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, to aid in keeping removed soil from re-depositing during washing. Builders for the purposes of this document include chelators, alkalinity boosters, pH adjusters, and buffering agents.

2.1.18 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 http://www.oehha.org/prop65.html

2.1.19 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.

2.1.20 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.

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

2.1.22 Component: A chemical as identified by its Chemical Abstract Service (CAS) number.

2.1.23 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.

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

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

2.1.26 Defoamer: Agent used to reduce foam.

2.1.27 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.

2.1.28 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.

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

2.1.30 Endocrine disruption list: European Commission list of substances prioritized for testing for endocrine disruption as identified in the June 2000 BKH report, "*Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption*" and its subsequent revisions.

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

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

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

2.1.34 Formulator: A company that designs and makes chemical choices for the manufacture of products. Safer Choice partners with formulator companies. Formulators may private label or license their Safer Choice-recognized formulas and thereby extend Safer Choice recognition to their licensees or private label customers. Key in Safer Choice's decision to extend recognition to private label or licensed products is a demonstration that the partner retains full control of the recognized formulation.

2.1.35 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.

2.1.36 Fluorosurfactant: Any organic substance which contains fluorine-based functional groups and has surface-active properties.

2.1.37 Fragrance materials: Discrete substances obtained by chemical synthesis or derived from a natural source and present in a fragrance at any level. 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 solvents and preservatives that do not function as a fragrance or to mask a scent.)

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

2.1.39 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 5.13 for information on residuals.

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

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

2.1.42 Manufacturer: A company that manufactures a finished product formulation. Safer Choice may partner with product manufacturers.

2.1.43 Mesophilic: A descriptive term for a phase in the composting process that occurs between temperatures of 20 to 45°C (68 to 113°F) and is characterized by the presence and activity of organisms capable of thriving at these temperatures.

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

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 Private label product: A product whose contents are identical to those in a Safer CHoice-recognized 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 partner for a third-party/private-label company or distributor.

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

2.1.53 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.

2.1.54 Residual of concern: A residual that fails to meet the criteria in the General 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 5.13 for more information.

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

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

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

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

2.1.59 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.

2.1.60 Small amines: Water-soluble compounds having a basic nitrogen functional group. The amine nitrogen atom may be mono- (primary amines), di- (secondary amines) or tri-substituted (tertiary amines). 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.

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

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

2.1.63 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.

2.1.64 Terpenes: Unsaturated hydrocarbons occurring in most essential oils and oleoresins of plants. Their structures are based on isoprene units, and may be cyclic or linear.

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

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

2.2 Abbreviations

AATCC – American Association of Textile Chemists and Colorists
ANSI – American National Standards Institute
AOEC – Association of Occupational and Environmental Clinics
ASTM – American Society for Testing and Materials
CAS – Chemical Abstract Service
CSPA – Consumer Specialty Products Association
DOT – Department of Transportation
EPA – US Environmental Protection Agency
FDA – Food and Drug Administration
FIFRA – Federal Insecticide, Fungicide, Rodenticide Act
GHS – Globally Harmonized System of Classification and Labeling of Chemicals
HAP – Hazardous Air Pollutant
IARC – International Agency for Research on Cancer
ISO – International Standards Organization
IUPAC – International Union of Pure and Applied Chemistry
MSDS – Material Safety Data Sheet
NTP – National Toxicology Program
OECD – Organisation for Economic Co-operation and Development
OSHA – Occupational Health and Safety Administration
PBT – Persistent, Bioaccumulative and Toxic
SIDS – Screening Information Data Set
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 Safer Choice Standard document shall be evaluated under the section having the most rigorous evaluation criteria.

3.1.3 To obtain Safer Choice recognition 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 Safer Choice 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 Safer Choice approval; the partner's commitment to continuous product improvement; limitations and responsibilities regarding use of the Safer Choice recognition and label; and partnership sunset and opportunity for renewal. A sample Partnership Agreement, containing all required elements, appears in Annex A.

3.2 Information and Formulation Requirements

3.2.1 The applicant shall submit, at a minimum, the complete product formulation information. All ingredients 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. Known residuals must be reported if present at greater than 0.01 percent by weight; see the discussion of residuals in Section 5.13. 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;
- A Chemical Abstract Service (CAS) number, functional name, trade designation, and supplier for each chemical present in the formulation;
- A Material Safety Data Sheet (MSDS) for the product and each ingredient, when available;
- The pH of the finished product, if applicable;
- 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 4.2.6);
- When available, a list of published and unpublished toxicological studies relevant to the chemicals and impurities present in the product, component, or material; and
- 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.

3.2.2 By reviewing the formulation information provided by the applicant, Safer Choice or its designate will determine any formulation-dependent contaminants to be evaluated in addition to the product-specific analytes identified in each product section.

3.3 Renewals

As described in Section A.15 of the Partnership Agreement, Safer Choice partners must renegotiate and renew the partnership prior to its expiration date (i.e., three years from the date of initiation). As part of the renegotiation, Safer Choice will consider the partner's performance under the partnership, including, but not limited to, its achievement of any continuous improvement targets specified in the agreement. Discussion of green chemistry innovations and opportunities for formulation improvements will be part of the renegotiations.

3.4 End-User Education

Formulators of Safer Choice-recognized products shall provide their end-user(s) with information on environmental, consumer, and worker safety matters. Safer Choice encourages partners to provide customers with a 16-section format MSDS as established by the American National Standards Institute (ANSI) standard for preparation of MSDSs (Z400.1). The partner or its distributor shall offer training on the proper use of the product (instructions on how to dilute, use and dispose of the product). OSHA, DOT, and other authorities require manufacturers to provide handling and other worker safety information.

3.5 Compliance

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

3.6 Verification of Partnership Compliance

3.6.1 Annual desk audit

Safer Choice partners will submit to the third-party verifier specified materials (elements of the desk audit are listed in Annex B.1). The desk audit will focus on the partner's print and electronic materials and verify the authorized formula through a review of production records.

3.6.2 On-site audit

Safer Choice partners will allow the third-party verifier to visit their manufacturing facilities and conduct audits (elements of the on-site audit are listed in Annex B.2). The on-site audit will focus on the manufacturing process and the procedures in place to ensure that recognized products comport with the Partnership Agreement.

If a single facility produces a recognized product, that facility will be subject to a site audit once per three-year partnership period. If multiple facilities produce a recognized 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.

3.6.3 External verifier

An external verifier—a person or body carrying out the verification—will conduct the site visits or paper audits. The external verifier must meet the criteria for qualified third parties in Section 7 of this document, as well as the competencies for external verifiers for products in ISO/IEC Guide 65: General criteria for bodies operating product certification systems. Competence criteria are specified in Sections 5.1.1, 5.1.2 and 5.2.1. An external verifier 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 external verifier 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 external verifier must confirm that the partner has taken the remedial action necessary to assure Safer Choice 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 partner may be asked to immediately cease use of the Safer Choice label; 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 and an estimate of the quantities of the currently labeled product(s).

3.7 Third-Party Manufacture of Safer Choice Products

3.7.1 Private label 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-recognized 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 recognition, the Safer Choice partner must inform and receive permission from Safer Choice, indicating the name of the private label product, the label owner, and the specific Safer Choice-recognized product to which it is identical or on which it is based. Private label products are subject to the audit provisions contained in Section 3.6.

3.7.2 Licensee products

A licensee product may carry the Safer Choice label provided that its contents are identical to those in a specified Safer Choice-recognized product. Before manufacture of the licensee product, the Safer Choice partner must inform and receive permission from Safer Choice, indicating the name of the licensee manufacturer and of the specific Safer Choice-recognized product to which the licensee product is identical. To assure quality, the licensee product must be manufactured under an agreement between the Safer Choice partner and the licensee and the agreement must be available to Safer Choice on request. Safer Choice 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 provided that its contents are identical to those in a specified Safer Choice-recognized product. Before toll manufacture of the Safer Choice-recognized product, the Safer Choice partner must inform and receive permission from Safer Choice, indicating the name of the toll manufacturer and of the specific Safer Choice-recognized 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 partner and the toll manufacturer and the agreement must be available to Safer Choice on request. Safer Choice 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 products and in the spirit of more complete communications on chemicals in common use, formulator-partners must disclose the contents of their Safer Choice-recognized products as described herein.

3.8.1 Scope

Except as provided below, manufacturers must disclose all intentionally added ingredients in their Safer Choice 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 CFR §701.3(l)).

3.8.2 Locus of disclosure

Ingredients must be disclosed in one of the following locations: on the product label; on the formulator’s Web site; at a toll-free number; or, on another media approved by Safer Choice. If disclosure does not occur on the product label, the formulator must provide the location of the ingredients on the label, e.g., the Web site address or toll-free number.

3.8.3 Ingredient descriptions

Except for ingredients protected as trade secrets (as defined in the Uniform Trade Secrets Act), formulators must use the Chemical Abstract Service (CAS) number, if available, and one or more of the following nomenclature systems to describe their ingredients: CAS name; Consumer Specialty Products Association (CSPA) Consumer Products 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 CSPA 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 categories of ingredients are commonly protected as trade secrets. When ingredients in these categories 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 Web site list, or subset of the list, of fragrance materials authored by the International Fragrance Association (IFRA) and available on IFRA's Web site (http://www.ifraorg.org/). Alternatively, if not a matter of trade secrets, the product formulator may state on its Web site 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 percent (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 percent, ingredients may be listed in any order.

3.9 Fragrance-free Label

For products that qualify for the Safer Choice label, manufacturers may request an additional certification—the Fragrance-free label—to indicate that a product contains no fragrance materials. To qualify as fragrance-free, a product must only contain ingredients on or eligible for the Agency's Safer Chemical Ingredients List (SCIL)—the list of ingredients that meet the Safer Choice safer chemical criteria and are acceptable for use in labeled products. The ingredients must not include fragrance materials. Chemicals with dual functionality, including use as a fragrance, are not allowed in fragrance-free products.

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 categories: 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 agreed upon by Safer Choice.

Performance testing requirements are product-category specific. Partners and candidate partners must consult Safer Choice or an authorized third-party profiler concerning product categories not specifically addressed below. For cleaning products, for example, each product shall effectively clean common soils and surfaces in its category 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 Safer Choice to test performance. The alternative method must be objective and scientifically validated, conducted under controlled and reproducible laboratory conditions, and Safer Choice must approve the acceptable performance level. Alternatively,

the product must perform comparably to a conventional, nationally recognized product in its category and at equivalent product-specific use directions.

Examples of performance requirements that are acceptable to Safer Choice include but are not limited to (note: the test methods listed in this section may have been revised; please ensure use of the latest versions):

4.2.1.1 Glass cleaners

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

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 Safer Choice.

4.2.1.2 Carpet cleaners/spot cleaners

The product must meet user requirements when tested according to CSPA DCC-03 and AATCC Test Method 171-1995. Alternatively, the product may be tested for cleaning efficacy and resoiling resistance using another equivalent method agreed upon by Safer Choice 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 Washroom cleaners

The product must remove at least 75% of soil using ASTM D5343-06, CSPA DCC-16 or equivalent method agreed upon by Safer Choice. 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 Safer Choice, 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, CSPA DCC-17 or an equivalent method agreed upon by Safer Choice.

4.2.1.6 Laundry and related products

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

A fabric softener must meet user requirements in CSPA DCC-13 or an equivalent method agreed upon by Safer Choice.

A laundry detergent must meet user requirements in CSPA DCC-14 or an equivalent method agreed upon by Safer Choice.

4.2.1.7 Oven cleaners

An oven cleaner must meet user requirements in CSPA DCC-12 or an equivalent method agreed upon by Safer Choice.

4.2.1.8 Hand dish soaps

A hand dish soap must meet user requirements in CSPA DCC-10 or an equivalent method agreed upon by Safer Choice.

4.2.2 pH

To minimize potential for dermal and eye irritation or injury, product pH must be ≥ 2 and ≤ 11.5. Products with pH < 2 or > 11.5 may be considered for recognition if *in vivo* assays prove 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:

a) the manufacturer can demonstrate that the product is designed for use only in a closed dilution-controlled dispensing system;
b) the system prevents backflow (see, e.g., American Society of Sanitary Engineering standard 1055B) and is designed to minimize waste and cross-contamination;
c) the pH at the most concentrated use dilution is within the acceptable range of 2 to 11.5;
d) the primary packaging is designed to minimize the potential for human exposures or environmental releases (e.g., through a drop test); and
e) the label 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 Energy

Safer Choice encourages the use of energy-saving technologies including the use of concentrates and detergents that work in cold water. Safer Choice considers energy efficiency by comparing product efficiency to that typical of the class, recognizing the importance of reducing energy use and generation of greenhouse gases. Safer Choice expects that energy-efficient products would continue to meet the hazard criteria in Section 5.

4.2.3.2 Ozone depleting substances

Safer Choice -recognized products must not contain ozone-depleting substances as defined by the 1987 Montreal Protocol. (http://www.epa.gov/ozone/science/ods/index.html)

4.2.5 Labeling requirements

The Safer Choice partner must provide its customers with information on environmental, consumer, and worker safety matters. The Safer Choice partner must also meet OSHA, DOT, and any other authority's requirements to provide safe handling and other worker safety information, as applicable.

4.2.6 Packaging

Safer Choice requires partners to implement sustainable packaging measures and to improve the packaging profile for their recognized products during the partnership. To qualify as a partner, a company must be at least at a 25 percent level with regard to its labeled products in one of the six sustainability

criteria listed below, developed by the Sustainable Packaging Coalition (http://www.sustainablepackaging.org). For example, to meet the minimum initial Safer Choice packaging requirement, a qualifying partner must be using 25 percent renewable or recycled source materials in its primary packaging. (This provision pertains to the primary packaging, i.e., the inner container or the material that comes in contact with the product ingredients.)

At each renewal of Safer Choice partnership agreements, partners must report on the status of their packaging practices in relation to each listed criterion and show progress in meeting their sustainability goals.

- Is sourced, manufactured, transported, and recycled using renewable energy;
- Optimizes the use of renewable or recycled source materials;
- Is manufactured using clean production technologies and best practices;
- Is made from materials healthful in all probable end-of-life scenarios;
- Is physically designed to optimize materials and energy; and
- Is effectively recovered and used in biological and/or industrial closed-loop cycles.

Note: Partners or candidates for partnership who have exceeded the 25% level and maximized their sustainable packaging opportunities need make no further showing.

Packaging materials may not contain heavy metals in accordance with Toxics and Packaging Clearinghouse (TPCH) model legislation. These criteria may be found at http://www.toxicsinpackaging.org/model_legislation.html. Additionally, other ingredients of potential concern may not be intentionally introduced into packaging material, including Bisphenol A (BPA) or the following phthalates: 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).

4.2.7 Volatile organic compounds (VOCs), hazardous air pollutants (HAPs), and Toxics Release Inventory (TRI) toxic chemicals

4.2.7.1 VOCs

In view of the contribution VOCs make to indoor air pollution and associated respiratory concerns, Safer Choice restricts product VOC-content based on the most stringent government criteria. Thus, pending revision to the EPA Office of Air and Radiation (OAR) regulations on product VOC content (at 40 CFR 59, Subpart C), Safer Choice will 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). When these criteria are not in agreement and a product may be used in an ozone-nonattainment area (as per OAR regulations at 40 CFR 50, 51 and 81), the more stringent standard will apply. (VOC criteria from OTC can be found under “Model Rule 2006 Consumer Products” at http://www.otcair.org/interest.asp?Fview=stationary#. VOC criteria from CARB can be found under “Regulation for Reducing VOC Emissions from Consumer Products” at http://www.arb.ca.gov/consprod/regs/gencpregs.htm.)

4.2.7.2 HAPs

Safer Choice does not allow 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 http://www.epa.gov/ttn/atw/188polls.html.

4.2.7.3 TRI

Safer Choice does not allow products containing chemicals included on EPA's Toxics Release Inventory chemical list, except those that meet the Safer Choice Criteria. The TRI list of chemicals can be found at http://www2.epa.gov/toxics-release-inventory-tri-program/tri-listed-chemicals.

4.2.8 Flammability

Labeled 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 flash point shall be determined by a closed-cup method, specifically, ASTM E502, or an equivalent method agreed to by EPA/Safer Choice.

4.2.8.1 Industrial laundry detergents

Manufacturers of laundry detergents formulated for industrial applications must have 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.

4.3 Cleaning Systems

A cleaning system, such as a laundry system, is not eligible for recognition unless every component meets the Safer Choice Criteria. The Safer Choice label may be used to indicate recognition 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

Safer Choice will consider for recognition 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. Recognition 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 recognized if they meet the following conditions:

1) Propellant. The system propellant 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).
2) 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 percent and below 3.5 microns (the deep-lung respirability threshold) must be at 0 percent, as demonstrated by the Malvern Mastersizers or other generally accepted method for measuring particle size of liquid sprays.
3) Packaging. a) Internal packaging. Any internal product packaging must not contain chemicals of concern per the Safer Choice Criteria; b) External packaging. The product container and other external packaging is made, to the extent feasible, of recycled materials and is itself recyclable.

4.5 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 http://www2.epa.gov/saferchoice/standard#tab-2 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. 4.5, it may need to carry a statement that indicates that FDA has not reviewed the product under this provision.

4.5.1 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.

4.5.2 pH

To further minimize the potential for dermal, eye or mucous membrane irritation, product pH must be greater than or equal to (≥) 4 and less than or equal to (≤) 9.5; products with a pH outside this range may be considered for recognition 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).

4.5.3 Allergens and sensitizers

No ingredients classified under GHS as skin or respiratory sensitizers are permitted in labeled 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 test methods listed in Master Criteria).

4.5.4 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.

4.5.5 Potential endocrine effects

Chemicals that are candidates for endocrine screening will be part of the review. Chemicals found to interact with or perturb the endocrine system, if associated with reproductive, developmental, carcinogenic, systemic, hormonal or other effects, will not be allowed.

4.5.6 Residuals of concern

Partnership candidates must submit to Safer Choice data from raw material suppliers on the percentage of residuals in their products. Residuals of concern (see definition at 2.1.55 and provision at 5.13) that cannot be eliminated must be restricted to the lowest possible levels.

4.5.7 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).

4.5.8 Fragrances

Fragrances must comply with the Safer Choice Criteria for Fragrances (at http://www2.epa.gov/saferchoice/safer-choice-criteria-fragrances); the criteria will apply to all fragrance components regardless of percentage in the fragrance.

4.5.9 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 http://www.cir-safety.org)—will not be acceptable in labeled products, as confirmed by their toxicological hazard and failure to pass the Criteria for Safer Chemical Ingredients.

4.6 Products Designed for Specialized Industrial Uses

Given the significant potential for safer formulation, Safer Choice will recognize products designed for specialized industrial and institutional applications. To qualify for recognition, candidate products must comply with the provisions in this standard, with the following limited exceptions and conditions:

1) All ingredients must comply with the general component-specific requirements in section 5, except for certain high-performance ingredients;
2) High-performance ingredients that do not meet the Safer Choice Master Criteria must:
    a. Serve a critical and specialized functional need in the formulation;
    b. Be selected from among the safest in their class, as measured against the Master Criteria;
    c. Exclude listed carcinogens, mutagens and reproductive or developmental toxicants, and persistent, toxic and bioaccumulative substances, as per the Master Criteria;
    d. Be limited in the finished product to the maximum extent possible, as appropriate to the product class, but never to exceed a total of 10% of finished product ingredients as sold;
    e. Be the subject of active continuous improvement efforts and a search for innovative alternatives, as verified during annual audits; and
    f. Be added to the Safer Choice Safer Chemical Ingredients List as a yellow-zone chemical and highlighted as a target for improvement/safer chemistry challenge.
3) In addition, manufacturers must design and market qualifying products for use only in industrial and institutional settings; and
4) Must monitor qualifying products for potential adverse health effects and report any occurrences to EPA's Safer Choice Program.

As product categories qualify under these provisions, EPA will specify on the Specialized Industrial Product page of its Safer Choice web site the ingredient limits and other conditions that are required policy for the sector. Companies may use the Safer Choice label on qualifying products, but must modify the tagline to read: "Recognized as a Safer Industrial Product."

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 Safer Choice Master Criteria (http://www2.epa.gov/saferchoice/safer-choice-master-criteria-safer-chemical-ingredients), as applied by experts in the Safer Choice Program, are intended as a base set of criteria all ingredients must meet to be acceptable for use in a Safer Choice-recognized product. These criteria make it possible for Safer Choice to ensure that chemicals in labeled 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 categories.

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 screen ingredients, where available and as noted in the criteria below. When an ingredient is not found on a list, raw data for each endpoint are preferred. Appropriate analog data, applied via predictive models, may also be used to fill data gaps.

5.2.1 Supplemental requirements for components that appear on certain lists of chemicals of potential concern

If a component appears on one of the following lists of chemicals of potential concern, it will be screened as described in Section 5.2: the California Proposition 65 list, which includes substances the state lists as causing cancer, birth defects, or other reproductive harm; the list of substances prioritized for testing for endocrine disruption by the European Commission; and the list of potential sensitizers published by the Association of Occupational and Environmental Clinics.

5.3 Surfactants

The criteria address environmental fate and toxicity as the distinguishing hazard endpoints for surfactants. Where Safer Choice is aware of concerns for other endpoints, Safer Choice may disallow a chemical based on the thresholds in its Master Criteria.

5.4 Direct-Release

Ingredients contained in products that are intended for use in applications that result in their immediate discharge to the environment, so that they bypass sewage treatment or septic systems, must meet the criteria in the Safer Choice Criteria for Environmental Toxicity and Fate for Chemicals in Direct Release Products at http://www2.epa.gov/saferchoice/standard#tab-3.

5.5 Solvents

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

5.5.1 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 Safer Solvents (phase I): the Solvent Screen (http://www2.epa.gov/saferchoice/safer-choice-criteria-solvents).

5.5.2 d-Limonene

As a solvent ingredient, d-limonene may only be used in a Safer Choice-recognized 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 percent 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 5.4).

5.5.3 Compliance with CARB limits

To be consistent with CARB VOC limits, as required by this standard (section 4.2.7.1), 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 exemption criteria). A chemical that meets the criteria except for potential concerns from inhalation exposures would not be allowed in aerosol-generating products.

5.6 Fragrances

Introduced in the 2012 enhancements to the Safer Choice Standard, version 2.1 of the Criteria for Fragrances is not being implemented because of the difficulties in applying the criteria. Numerous attempts among manufacturer partners, fragrance houses, and the program to implement the criteria revealed the likely root cause: the unavailability of human and environmental health information. Consequently, the program will leave in place the Interim Fragrances Criteria[1] and references to the version 2.1 criteria will be deleted from the Safer Choice Standard.

Also, to further unify our approach to the review of fragrances, the program is aligning across product types the requirements applied to labeled products that contain sensitizers that exceed the *de minimis* level (0.01%) in the end-use product. Specifically, we will apply the approach for consumer products, as it currently appears in the Safer Choice Standard, to all products, and most notably, requiring notice for sensitizers that exceed the *de minimis* level, preferably on the product label. As a result, sections 5.6.1 and 5.6.2 will be combined in a new section 5.6.1.

5.6.1 Sensitizers in Labeled Products

Each fragrance material that is a skin sensitizer is limited to no more than 0.01% 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 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 testing (see test methods listed in Master Criteria) and limit the amount of fragrance materials in the product to the level in the test sample.

5.7 Builders

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

5.7.1 Chelators

[1] The Interim Fragrances Criteria clarify which fragrance chemicals may be used in Safer Choice products and provide a level and consistent playing field for Safer Choice Formulator Partners and fragrance houses. Under the interim criteria, listed carcinogens, mutagens, or reproductive/developmental toxicants (CMRs); listed persistent, bioaccumulative, and toxic compounds (PBTs); and listed respiratory sensitizers are not allowed . To advance transparency, product manufacturers must disclose dermal sensitizers. Non-fragrance materials present in fragrance formulations will be evaluated under their appropriate Safer Choice functional class criteria (e.g., solvents).

Chelators must meet the criteria described in detail in the Safer Choice Criteria for Chelating Agents general requirements in Section 5.2. In addition, Safer Choice -recognized products must not contain inorganic phosphates that contribute to the process of eutrophication, nor NTA, a potential carcinogen. Chelators that have molecular weight (MW) above 1000 shall be evaluated under the polymer criteria.

5.8 Colorants, Polymers, Preservatives, and Related Chemicals

Colorants (including pigments and optical brighteners), polymers, certain preservatives (including antioxidants), and other chemicals referenced in section 5.14 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 endpoints, and the thresholds in section 5.8.3 will be used for environmental endpoints. Data on these chemicals will be required as per 5.8.3, unless noted otherwise.

5.8.1 Polymers

To be acceptable for labeled products, polymers must have low-concern characteristics.[2] Also, the requirements of this section apply to the low molecular weight components of polymers (typically less than 1,000 Daltons). Safer Choice 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 5.8.3, 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, except section 5.9, Environmental Toxicity and Fate, which must be addressed as per 5.8.3. Perfluoroalkyl polymers, allowed only in floor finishes, must, at a minimum, be limited to fluorinated carbon-chain lengths of less than eight atoms.

5.8.2 Preservatives

Preservatives have biocidal properties and time-sensitive functionality. Safer Choice 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.

5.8.3 Special requirements

For colorants, polymers, and preservatives, the toxicological endpoints in the Master Criteria will be addressed as follows:

1) *For Acute Mammalian Toxicity (section 5.1 of the Master Criteria), Neurotoxicity (5.4), Repeated Dose Toxicity (5.5), and Skin Sensitization (5.8), the following apply*:

   Data requirements: Chemicals evaluated individually against Authoritative Lists and GHS criteria.

2) *For Carcinogenicity (section 5.2 of the Master Criteria), Genetic Toxicity (5.3), and Reproductive and Developmental Toxicity (5.6), and Respiratory Sensitization (5.7), the following apply:*

   Data requirements: Screen specified R-Phrases and Authoritative Lists. Available data, measured and/or estimated, for the chemical and/or a suitable analog may be reviewed against the criteria using a weight-of-evidence approach.

[2] Described in the Sustainable Futures' Interpretive Assistance Document for Assessment of Polymers (http://www.epa.gov/oppt/sf/pubs/iad_polymers_june2013.pdf).

3) Environmental Toxicity and Fate

Limitation on Persistent, Bioaccumulative and Toxic chemicals: Acceptable chemicals must not be persistent (half-life $\geq$ 60 days), bioaccumulative (BCF/BAF $\geq$ 1,000), and aquatically toxic* (LC/EC50 $\leq$ 10 mg/L or NOEC/LOEC $\leq$ 1 mg/L).
Limitation on very Persistent and very Bioaccumulative chemicals: Acceptable chemicals must not be very persistent (half-life > 180 days or recalcitrant) and very bioaccumulative (> 5,000).
Limitation on very Persistent and very Toxic chemicals: Acceptable chemicals must not be very persistent (half-life > 180 days or recalcitrant) and very aquatically toxic* (LC/EC50 < 1.0 mg/L or NOEC/LOEC < 0.1 mg/L).

Data requirements: Screen Authoritative Lists. Available data, measured and/or estimated, for the chemical and/or a suitable analog may be reviewed against the criteria using a weight-of-evidence approach.

*Excludes the algal shading effects of colorants.

5.9 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.

5.10 Toxic Elements

Safer Choice-recognized products must not contain toxic elements such as heavy metals. Unavoidable de minimis levels may be present, e.g., from inorganic materials mined from the earth.

5.11 Enzymes and Enzyme Stabilizers

Enzymes and enzyme stabilizers shall meet the general requirements in Section 5.2, except as defined herein. (Products that contain live microbial cultures or viable spores are addressed in separate Safer Choice guidance.)

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 labeled 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 Safer Choice. 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 Safer Choice-acceptable protease enzymes. Safer Choice encourages the development of safer alternative stabilizers.

5.12 Disposable Wipes

Disposable wipes must be demonstrated to be compostable or flushable as formulated.

Safer Choice considers wipe composition and ability to decompose as key characteristics for disposable cleaning wipes when they are the intended method of application for a cleaning formulation. Qualifying wipes must be made of materials that are readily compostable (e.g., cotton, bamboo), as demonstrated through a certificate of analysis or similar means.

To be flushable, a disposable wipe must pass through the toilet and drainline system, be transported in wastewater conveyance systems, and be compatible with wastewater treatment systems where they exist, or in some regions, discharges of untreated wastewater. An example of an acceptable test protocol is the Guidance Document for Assessing the Flushability of Nonwoven Consumer Products, published by INDA, the U.S.-based association of nonwoven fabrics industry and EDANA, the European-based international association serving the nonwovens and related industries.

5.13 Residuals

Residuals of concern must be limited to less than 0.01 percent (by weight) or 100 ppm in the formulation. For ingredients known to contain residuals of concern, Safer Choice'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: Safer Choice is working to ascertain to extent to which the state of green chemistry can support the restrictions imposed by this section.]

5.14 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 5.8.2, Polymers)
- Solubility enhancers
    - Hydrotropes (see 5.3, Surfactants)
    - Small amines (see 4.6, Products Designed for Specialized Industrial Uses)
- Bleaching agents
- Rheology modifiers (see 5.8.2, Polymers)
- Plasticizers (see 4.6, Products Designed for Specialized Industrial Uses)
- Foam boosters, defoamers and antifoamers (see 5.3, Surfactants or 5.8.2, Polymers)
- Denaturants (see also 5.5, Solvents)
- Absorbents and adsorbents (see also 5.6.2 and 5.6.3, Sensitizers in Consumer and I/I Products)
- Corrosion inhibitors
- Antiredeposition agents (see 5.8.2, Polymers)
- Dispersing agent (see 5.3, Surfactants or 5.8.2, Polymers)
- Coalescing agent (see also 5.5, Solvents)

5.15 Potential Sensitizers and Irritants

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

5.16 Oxidant Stabilizers

As a general rule, phosphates are not allowed in Safer Choice 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. Safer Choice 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% in a labeled product.

5.17 Safer Ingredient List

To encourage the manufacture, use of and communications on safer chemicals, Safer Choice will list on its web site the chemicals that have met its safer ingredient criteria and are used in Safer Choice products. The list will contain chemicals used in or eligible for use in Safer Choice products. A chemical will be listed by common and specific name and CAS number under its primary functional-use class, and be accompanies by a symbol indicating its safer-chemical status. The listing will not disclose confidential or trade secret information.

5.18 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 http://www2.epa.gov/saferchoice/safer-choice-criteria-processing-aids-and-additives, and comply with the baseline requirements in section 5.2.

6 Use of the Mark

6.1 Terms of Use

6.1.1 The partner may use the Safer Choice label, as shown in sec. 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 use. The partner shall not use the label or describe EPA's recognition 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, as shown in sec. 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/Safer Choice recognition 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, contains ingredients with more positive human health and environmental characteristics than conventional products of the same type. EPA/Safer Choice relies solely on «Company_Name», its integrity and good faith, for information on the product's composition, ingredients and attributes. EPA/Safer Choice 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/Safer Choice provides its evaluation only as to the product's human health and environmental characteristics, as specified in the Safer Choice 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 pro-

motional 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/Safer Choice for review and approval any materials, including press releases, promotional materials, and advertisements the partner develops in connection with the partnership, and especially information that describes the Safer Choice Program or characterizes the program's position on issues related to a specific product sector.

6.1.5 The partner must discontinue use of the Safer Choice label or any other EPA/Safer Choice recognition within 30 days under the following circumstances: If the partner stops formulating the qualifying product(s) using the agreed-upon ingredients; on the termination of the partnership; or, if so notified by EPA in writing.

6.2 Examples of Appropriate Use of the Safer Choice Label

For consumer products (primary mark):

For institutional and industrial products:

For fragrance-free products:

7 Profiler Requirements

Candidates for Safer Choice recognition must use the services of a qualified third party profiler to prepare product recognition applications. To become a qualified third party profiler the candidate must submit a paper application to provide evidence of competency against the requirements in Sections 7.1 and 7.2, and undergo the pilot review described in Section 7.3.

7.1 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 Safer Choice Standard.

7.1.1 Staff

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

7.1.2 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 International Standards Organization (ISO) 65 to demonstrate a commitment to maintaining these capabilities.

7.1.3 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.

7.1.4 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.

7.1.5 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.

7.2 Elements of credibility and good standing

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

7.2.1 A profiler shall demonstrate a commitment to objectivity and due process approach by meeting the criteria of ISO 65.

7.2.3 A profiler shall demonstrate familiarity with the Safer Choice Program review process and assessment methodology by having training and interacting with Safer Choice and companies interested in Safer Choice recognition.

7.2.4 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.

7.3 Pilot review requirements

7.3.1 As the final step in the process the profiler shall demonstrate competency through a review of a formulation(s) judged by Safer Choice to be representative of those recognized by the program. Safer

Choice will review the results against the criteria in this section and determine whether the applicant has demonstrated competence.

Annex A

Sample 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» ("«Company_Name»") of «City_State_Zip_» and the U.S. Environmental Protection Agency ("EPA"). The partnership is part of the Safer Choice Program. 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 Standard and the associated Criteria for Safer Chemical Ingredients. For the purpose of this Agreement, these products include the following «Company_Name» products: *«Trade_Names»* (the "Qualifying Products"). The partnership will strive to promote and advance the environmental, technological, and efficiency benefits of these and future Qualifying Products.

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/Safer Choice 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.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/Safer Choice's recommendations and offer improved health and environmental characteristics. These Qualifying Products contain no (e.g. inorganic phosphates, hazardous solvents, or environmentally harmful surfactants). Instead, they use a proprietary blend of (e.g. surfactants, solvents, pH adjustors, and other in-

gredients), which exhibit more positive environmental and human health characteristics than conventional formulations.

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 fresh water 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/Safer Choice relies solely on «Company_Name», its integrity and good faith, for information on the composition, ingredients, and attributes of its Qualifying Products. EPA/Safer Choice 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/Safer Choice provides its evaluation 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/Safer Choice.

A.4 «Company_Name»'s Commitment to Formulate for the Environment

As part of the «Company_Name»–EPA/Safer Choice 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 key characteristics 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/Safer Choice 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/Safer Choice (see Section 11).

If any change is made to the agreed formulation, «Company_Name» agrees to notify EPA/Safer Choice of the change and provide the new formulation. EPA/Safer Choice 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.

The following is a non-confidential representation of the ingredients in the Qualifying Products, with their key characteristic (including green chemistry status or areas identified for future improvement), as evaluated by EPA/Safer Choice:

Ingredient	Key Evaluation Characteristic
«Product_Name»	
e.g., Surfactant	*Readily biodegradable, low concerns for byproducts. Meets Safer Choice Criteria for Surfactants.*
Solvent	*Low health and environmental concerns.*
Builder	*Low health and environmental concerns.*
Colorant	*Could be improved (see sec. 5)*

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/Safer Choice 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. Specifically, «Company_Name» agrees to consider use of an alternative preservative and colorants, as recommended by EPA/Safer Choice. «Company_Name» agrees to undertake this formulation review during the period of the Agreement

«Company_Name» may consult with EPA/Safer Choice about other products and, following EPA/Safer Choice review and assessment, may request that one or more new Qualifying Products be added to this Agreement. With EPA/Safer Choice's approval, this Agreement may be amended as set forth in Section 11 to include new Qualifying Products.

«Company_Name» and EPA/Safer Choice 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/Safer Choice, «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/Safer Choice, «Company_Name» agrees to share with EPA/Safer Choice 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 (http://www.epa.gov/oppt/existingchemicals/pubs/enhanchems.html) and the Screening Information Data Set (SIDS) Program of the Organization for Economic Co-operation and Development (OECD) (to learn more, visit http://webnet.oecd.org/hpv/ui/Default.aspx and the SIDS Test Guidelines at http://www.epa.gov/hpv/pubs/general/sidsappb.htm).

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; fragrances that have been screened for potential hazardous and persistent ingredients; 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/Safer Choice 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/Safer Choice contact to whom they may direct questions or comments on the partnership.

A.8 EPA Recognition 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/Safer Choice has reviewed and approved the intended use. «Company_Name» agrees to not use the label or describe EPA/Safer Choice recognition 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, the «Company_Name» must include the endorsement disclaimer, which appears below. «Company_Name» 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/Safer Choice recognition 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, contains ingredients with more positive human health and environmental characteristics than conventional products of the same type. EPA/Safer Choice relies solely on «Company_Name», its integrity and good faith, for information on the product's composition, ingredients and attributes. EPA/Safer Choice 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/Safer Choice provides its evaluation only as to the product's human health and environmental characteristics, as specified in the Safer Choice Standard and based on currently available information and scientific understanding.

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/Safer Choice 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/Safer Choice 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/Safer Choice'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/Safer Choice recognition, 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.

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/Safer Choice, 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/Safer Choice its best estimate of the production volume of the Qualifying Products (if possible, both in aggregate pounds or gallons and broken out by ingredient class).

At EPA's request, «Company_Name» agrees to make available to EPA/Safer Choice, 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/Safer Choice 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 recognition. «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/Safer Choice the performance of its Qualifying Products according to the guidelines provided by Safer Choice. «Company_Name» agrees to also share with EPA/Safer Choice 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» on the formulas of any «Company_Name» products is covered by the foregoing sentence.

EPA/Safer Choice agrees to only use the information provided by «Company_Name» for purposes related to the «Company_Name»-EPA/Safer Choice 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

As discussed in the Continuous Environmental Improvement section, «Company_Name» may request that EPA/Safer Choice add new Qualifying Products to this Agreement when reformulated. If EPA agrees to the addition, «Company_Name» may amend the Agreement by submitting a letter that addresses the essential elements from Sections 3, 4, 5 and 7 of the current Agreement. «Company_Name» and EPA/Safer Choice 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 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 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 product.

Before manufacture of any private label product that will carry Safer Choice recognition, “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 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 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 recognized 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 Safer Choice Standard and Criteria documents, “Company Name» agrees to participate in Safer Choice’s surveillance and auditing program. The program will consist primarily of annual desk audits and triennial on-site audits, as described in the Safer Choice Standard, Section 3.6 and Annex B.

“Company Name» will make its manufacturing facilities and recognized-product-related records available to Safer Choice-authorized third-party verifiers. On an annual basis, “Company Name» agrees to submit to the third-party verifier desk audit materials as specified in the Safer Choice Standard, Annex B.1. These materials will include a list of ingredients for each recognized product and a statement that the ingredients and all claims made regarding the Agency’s recognition (e.g. use of the Safer Choice la-

bel) comport with this agreement.

Approximately every three years, “Company Name» will allow a third-party verifier to visit its manufacturing facility and conduct an audit, which will include the elements listed the in the Safer Choice Standard, Annex B.2. The audit will focus on the manufacturing process and the procedures in place to ensure that recognized 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 external verifier 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 external verifier 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.

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 labeled 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 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 products as described herein and in the Safer Choice Standard, Section 3.8.

“Company Name” must disclose all intentionally added ingredients in their Safer Choice 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 Web site; 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 Web site address or toll-free number.

“Company Name” must use the Chemical Abstract Service (CAS) 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; Consumer Specialty Products Association (CSPA) Consumer Products 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 CSPA 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 Web site list, or subset of the list, of fragrance materials authored by the International Fragrance Association (IFRA) and available on IFRA's Web site (http://www.ifraorg.org/). Alternatively, “Company Name” may state on its Web site 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 percent (measured on a weight-weight percentage basis), ingredients must be listed in de-

scending order, with the ingredient at the highest percentage in formula listed first; for those present at or below 1.0 percent, ingredients may be listed in any order.

EPA Safer Chemical Ingredients List. To further EPA's goal of increasing the availability of information on safer chemicals and their use, Safer Choice maintains a list of safer ingredients in Safer Choice products on its website. Chemicals in the list are grouped by functionality and identified by common and specific name and CAS number. The list will be updated periodically to reflect new information, results of toxicity testing, and advances in safer chemistry. "Company_ Name" agrees to permit Safer Choice to list the ingredients in its labeled products, provided that no connection is made between "company name," the product name, and the product ingredients.

A.16 Packaging

In accordance with Section 4.2.6 of the Safer Choice Standard, "Company Name" agrees that, with respect to the inner container (i.e., the packaging material that comes into contact with its labeled product ingredients), it has achieved at least at a 25 percent level in one of the six sustainability criteria listed below, developed by the Sustainable Packaging Coalition (http://www.sustainablepackaging.org). "Company Name" further agrees that, if not already at a full performance level, it will improve the packaging profile of its labeled products during the partnership and that at each partnership renewal it will report on the status of its packaging practices in relation to the listed criteria and show progress in meeting its sustainability goals.

- Is sourced, manufactured, transported, and recycled using renewable energy;
- Optimizes the use of renewable or recycled source materials;
- Is manufactured using clean production technologies and best practices;
- Is made from materials healthful in all probable end-of-life scenarios;
- Is physically designed to optimize materials and energy; and
- Is effectively recovered and used in biological and/or industrial closed-loop cycles.

In addition, "Company_ Partner" agrees that its packaging materials will not contain toxic elements (as per Section 5.10 of the Safer Choice Standard), including heavy metals, as described in the Toxics and Packaging Clearinghouse model legislation (at www.toxicsinpackaging.org/model_legislation.html). "Company Partner" will also ensure that the following ingredients of concern are not used in its packaging: Bisphenol A (BPA) or the following phthalates: 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 terms and provisions in the Agreement will sunset three years from the date of signature, unless the parties renegotiate and renew a Partnership Agreement prior to the expiration date.

We agree to these terms and provisions:

For «Company»	For the U.S. Environmental Protection Agency
_____	_____
Signatory	David Widawsky
Title	Director, Chemistry, Economics, and Sustainable Strategies Division
Date _____	Date _____

Annex B

Elements of Desk Audits and On-Site Audits

B.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 recognition (e.g., use of the Safer Choice label) comport with the Partnership Agreement or a Safer Choice-approved amendment to the agreement; of note, this statement must confirm that the ingredients in labeled products are the same as those Safer Choice has reviewed and referenced in the partnership agreement;
- Product labels showing use of the Safer Choice label or mention of Safer Choice recognition;
- Product or company literature that uses the Safer Choice label or mentions Safer Choice recognition;
- Private label (including licensed product) labels and literature that bear the Safer Choice label;
- 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.

B.2 On-Site Audits

The third-party verifier will seek the following information, based on the terms of the Partnership Agreement and Safer Choice 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 recognized product (i.e., no dilution, concentration, no added dyes or fragrances);
- 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.