

Proposed Revisions to EPA’s Safer Choice Standard

Periodically, the U.S. EPA proposes revisions to its Safer Choice Standard. This revision renames the Standard as the Safer Choice and Design for the Environment (DfE) Standard (“the Standard”). The Standard establishes the minimum requirements that a product and its ingredients must meet to qualify to carry the Safer Choice label or DfE logo. EPA documents a company’s compliance with the Standard and commitment to manufacture Safer Choice- or DfE-certified products in a Partnership Agreement signed by EPA and company officials.

Revisions to the Standard serve multiple purposes; among them, they: keep the Standard current with the state of scientific and technological innovation; respond to stakeholder requests for clarity and added transparency; and expand the scope of the program as demand, capacity, and opportunity permit. While important, revisions to the Standard can be disruptive for partners and can make compliance with program requirements—and the verification process—more challenging. EPA therefore seeks to minimize the frequency of revisions and the difficulties associated with their implementation.

The proposed revisions to the Standard, presented below, will be the fourth set of revisions since the original Standard was posted on the EPA website in June 2009 (as the “Design for the Environment Standard for Safer Products”). As with the previous revisions, EPA publishes a notice of their availability for comment in a Federal Register Notice, notifies all current partners by email, and allows a 60-day period for comment. EPA will respond to comments, modify the proposal as appropriate, and issue a final version of the amended Standard and associated documents. If the comments indicate that no revisions are needed to a given section of the proposal, EPA expects to make the amendments effective when finalized. On the other hand, if the comments indicate that more discussion may be needed or more time is necessary to adapt to certain revisions, finalization for that subset of the revisions may be delayed or an implementation timeframe may be specified. The comment period will end on January 16, 2024. Please note that EPA welcomes comments on the Standard and any aspect of the certification programs at any time.

To comment on the current revisions, please submit comments to the docket ID # EPA-HQ-OPPT-2023-0520. Please identify the question(s) you are responding to by question number when submitting your comments. Note that you do not need to address every question and may focus on those where you have relevant expertise or experience. A version of the Standard with the proposed revisions in context and highlighted is available in the docket. Commenters can contact Melanie Adams at adams.melanie@epa.gov with questions.

Introduction to Key Revision Topics and Specific Requests for Comments

EPA has initiated this round of revisions to the Standard partly in response to comments and suggestions from a range of stakeholders. Key among the proposed changes is an update to the Safer Choice and DfE packaging criteria and the addition of a Safer Choice certification for cleaning service providers.

When adopted, following an opportunity for public comment and Agency response, the Agency

expects to make the revisions to the Standard effective upon the finalization and public notification. Candidate partners would need to comply with the newly enhanced standard prior to becoming program partners. Existing program partners would be expected to comply with the revisions within the year following their next partnership renewal, allowing them time to adapt to the changes and adjust their manufacturing and other processes, as necessary.

The proposed revisions to the Standard include changes to existing subject areas within the Standard. Many of these are in the nature of technical amendments. In some instances, EPA also deleted text from the Standard to avoid redundancy with program criteria as expressed elsewhere. Such changes are not discussed in this preamble, but EPA welcomes comment on all proposed changes. EPA is introducing the following topics to highlight their importance and to specifically request comments on them.

Entering or Exiting a Product Class (Section 3.4).

EPA has added detail to the Standard on its process for entering and exiting product classes (i.e., a category of products that have similar functions) under the Safer Choice program. EPA may solicit public input before entering or exiting a product class. For entering a new product class, EPA will consider various factors (e.g., product type, functionalities, and improvements to health and environment) and determine whether entering the new product class will advance the goals of the Safer Choice and DfE programs.

On rare occasions, newly available information about a class of products may indicate the products pose unanticipated serious adverse health or environmental effects. In such circumstances, EPA may find it necessary to end any partnerships and discontinue certification of products in the class, at least until EPA can understand the cause of the adverse effects and, if possible, develop criteria to address them. Currently, EPA does not have provisions in the Standard to address these situations and is proposing to add such provisions in *Section 3.4.2.1 Exceptional circumstances affecting health or the environment*. In general, if EPA decides to exit a product class, EPA will allow a period of time for partners to cease use of the product label or logo.

EPA requests comment on this proposed change.

On-Site Audit (Section 3.6.2).

On-site audits play an essential role in verifying product ingredients and good manufacturing practices and assuring consumers and other purchasers, especially governmental and other institutional purchasers, that products continue to meet EPA's requirements and conditions of partnership. Currently, EPA requires audits on a yearly basis throughout the partnership, including one on-site audit in the first or second year of the partnership cycle. To ensure that partners are formulating certified products in compliance with Safer Choice criteria, EPA is proposing, in *Section 3.6.2 On-site audit*, that the first audit for a new partner must be an on-site audit.

EPA requests comment on this proposed change.

Information to Help Reduce Carbon-Based Energy Consumption (Section 4.2.3.1).

Energy is an increasingly important sustainability issue for Safer Choice and DfE partners and stakeholders. EPA proposes to update the Standard to encourage and recognize product manufacturers' efforts to incorporate energy-saving technologies and approaches. This optional provision in *Section 4.2.3.1 Information to help reduce carbon-based energy consumption* lists actions manufacturers may implement. Partners may be recognized for demonstrating outstanding leadership and innovation in sustainable energy use.

Primary Packaging (Section 4.2.5).

In recent years, sustainable packaging has also become increasingly important for Safer Choice and DfE partners and stakeholders. To respond to increased demand for more sustainable practices, EPA is proposing to update its packaging criteria, originally added to the Standard in 2011 to ensure that certified products also use safer, more sustainable packaging. Practices and the state of the knowledge on sustainable packaging materials and technologies has evolved since 2011. Although the focus of the Safer Choice and DfE programs is safer product chemistry rather than packaging, EPA would like to ensure that the Standard sets a suitable and up-to-date bar for sustainable packaging and is proposing substantial changes to its primary packaging requirements. The revised requirements are informed by common themes across existing third-party packaging sustainability schemes. The specific recycled content levels that are proposed do not necessarily come from existing schemes but, based on research, are understood to be leadership but achievable levels. The revised requirements are intended as achievable targets reflecting best practices in industry.

EPA is proposing to add requirements to *Section 4.2.5 Primary packaging* on recyclability and recycled content, label compatibility, and primary packaging ingredients. Specifically, EPA is proposing to require that primary packaging be either recyclable and contain a minimum level of post-consumer recycled content or be designed to be reused. EPA understands that certain parts of product primary packaging (e.g., pump spray-heads) may not be recyclable. To account for this, EPA will allow partners whose primary packaging cannot meet the minimum recycled content levels and/or is not recyclable to request an exemption as described in the proposed Standard. Additionally, EPA is proposing to require that product labels associated with primary packaging not affect recyclability and that proper recycling method(s) be clearly indicated on the packaging.

EPA is also proposing to add per- and polyfluoroalkyl substances (PFAS) and all bisphenol-based chemicals (EPA previously added Bisphenol A) to its list of ingredients that may not be intentionally introduced into primary packaging material. EPA will explicitly list the four heavy metals (cadmium, lead, mercury, and hexavalent chromium) currently covered by the Standard as ingredients that may not be intentionally introduced into primary packaging material.

EPA is seeking stakeholder comment on all aspects of the primary packaging requirements, including, but not limited to:

Question 1: Are the proposed minimum post-consumer recycled content levels feasible for primary packaging made of plastic, glass, metal, fiber (e.g., paper or cardboard), or

other sustainable materials? If not, what levels would be feasible? How should EPA consider multi-material packaging?

Question 2: Is it reasonable for EPA to require that the entire product primary packaging be recyclable? If not, what is an appropriate minimum percent of recyclable material?

Question 3: Is it reasonable for EPA to require both a minimum recycled content and package recyclability? What are the challenges to achieving both simultaneously?

Question 4: In finalizing its criteria, should EPA consider concerns for contaminants that may be intentionally added and/or unintentionally introduced into recycled materials? At what point should testing occur?

Yellow Triangle Content Limit (Section 4.2.8).

To enhance transparency, EPA is updating the Standard to reflect the ongoing practice of allowing the use of yellow-triangle designated chemicals from the Safer Chemical Ingredients List (SCIL), when they do not cumulatively exceed 10% in the product as sold.

Ingredient Combinations Causing Adverse Effects (Section 4.5).

Certain ingredients, while independently meeting Safer Choice ingredient criteria, may cause adverse effects when combined. EPA does not allow ingredient combinations known to cause negative synergistic effects and is updating the Standard to reflect this ongoing practice in *Section 4.5 Ingredient Combinations Causing Adverse Effects*.

Products in Solid or Particulate-Generating Form (Section 4.6).

Solid products can be associated with particulates, which may be harmful to human health if inhaled. The bioavailability of such particulates, with respect to inhalation, is primarily determined based on their size. Particulates are generally considered to be inhalable when they have a diameter of 10 microns or less. Further, adverse effects are possible if the product produces byproducts that are of concern. EPA is proposing to add requirements to minimize the potential for adverse effects.

EPA is proposing to add *Section 4.6 Products in Solid or Particulate-Generating Form* to require certain information from manufacturers. EPA is proposing to require that, upon request, manufacturers of products in particulate-generating or solid form provide information to determine that the product does not contain or generate a substantial portion of particles that are respirable (10 microns or less).

Special Product Classes (Section 4.7).

Over the years, to extend the reach of the program into product categories where manufacturers sought to lead the market with safer ingredients, EPA has developed policy criteria and guidance as a supplement to the broader Standard. These policies have been distributed widely and posted on the Safer Choice website. EPA is now proposing to add links to the Safer Choice website, where criteria can be found, for the following product classes: *Section 4.7.1 Ice-melt products*, *Section 4.7.2 Inorganic- and mineral-based products*, *Section 4.7.3 Microorganism-based*

products, and *Section 4.7.6 Marine lubricants*. EPA is proposing to provide a brief description of each product class in the Standard and to refer readers to the Safer Choice website for the full criteria.

Products Intended for Use on Pets (Section 4.7.5).

EPA is adding a product class for non-pesticidal and non-drug pet care products in *Section 4.7.5 Products Intended for Use on Pets*. Specifically, EPA will evaluate chemicals used in products intended for use on pets for human and pet health in addition to environmental toxicity and fate. EPA will not allow ingredients in pet care products that are severely irritating or corrosive to skin or eyes unless whole product testing demonstrates low concern for irritation. EPA will also not allow Globally Harmonized System (GHS) listed sensitizers in certified pet care products (unless the manufacturer provides whole product testing demonstrating low concern for sensitization or a rationale based on functional necessity that also addresses sensitization) and will require that ingredients meet direct release criteria, with the exception of fragrance materials.

EPA requests comment on these proposed changes and the feasibility of the requirements for direct release, irritation, and sensitization for pet care products.

Direct Release Products (Section 4.8.1).

A number of stakeholders have approached Safer Choice to request the addition of a label that would distinguish products that meet Safer Choice direct release criteria.

Question 5: Would it be helpful to have a version of the Safer Choice label with text that distinguishes products that meet direct release criteria (similar to the Fragrance-Free Safer Choice label)?

Question 6: Would text such as “approved for outdoor use” better communicate the meaning of direct release to consumers and purchasers?

Question 7: Are there alternative phrases to “approved for outdoor use” that EPA should consider?

General Requirements (Section 5.2): Use of New Approach Methodologies (NAMs).

EPA continues to advance the use of NAMs to replace laboratory animal studies, and the program will continue to adopt NAMs as they are developed. The term NAMs refers to a wide range of technologies, approaches, and methodologies that do not require vertebrate animal testing. *In vitro* tests, those done in controlled experimental conditions on non-whole animal systems, are one type of NAMs. Since the Standard was last updated in 2015, EPA has approved several *in vitro* tests that may be used as part of evaluations in EPA programs that include Toxic Substances Control Act (TSCA) programs. NAMs are used as part of Safer Choice and DfE chemical evaluations.

The proposed revisions to the Standard include changes in the following sections to formalize the ongoing Safer Choice use of NAMs: *Section 5.2 General Requirements* and *Section 4.2.2 pH*.

Component-Specific Requirements (Sections 5.3, 5.11, and 5.17).

EPA is proposing several revisions and additions to *Section 5 Component-Specific Requirements*.

EPA requests comment on these changes to the Standard.

Surfactants (Section 5.3).

Under *Section 5.3 Surfactants*, EPA is proposing to require aquatic toxicity data for at least one trophic level for surfactants (or a close analog). EPA notes its ongoing practice that where data for human health are available, EPA will evaluate chemicals based on the thresholds in the Master Criteria.

Disposable Wipes (Section 5.11).

As the market for cleaning and other products in wipe form continues to grow, EPA would like to ensure that the Standard provides a high yet achievable bar for this product class. Currently, the Standard limits the composition of wipe materials to those that are readily compostable, citing cotton and bamboo as examples. EPA understands that it may not be possible to make wipe products that meet the program criteria and perform well for all uses. Wipes for some uses, like heavy-duty cleaning that requires abrasion, may need to be composed of a mixture of fibers (including synthetic fibers). Also, it is widely understood that flushing wipes and other substrates creates significant problems for households and wastewater treatment systems, including clogs, overflows, and damage to treatment infrastructure. As such, to reinforce current industry practice, EPA is proposing to require that all wipe-based products indicate they are not flushable to carry the Safer Choice label or DfE logo.

EPA is proposing to modify *Section 5.11 Disposable Wipes* to indicate that wipes made from both natural fibers and synthetic fibers from renewable sources are acceptable, provided they have similar biodegradability profiles (as demonstrated by one of the following or similar methods: EN13432, ASTM 6400, ASTM 5338, or ISO 14855). Wipes based products must also include “do not flush” logo and language on product labels to qualify for certification. Since fibers are often treated with processing chemicals to create the nonwoven substrates, EPA is also adding clarifying language on additive components (such as binders or coatings) in nonwoven substrates and how they must also meet program criteria.

EPA requests comment on the functionality and consumer acceptance of wipes that are composed of natural fibers and synthetic fibers from renewable sources.

Question 8: Should EPA only allow natural fibers in disposable wipes or also allow compostable synthetic fibers from renewable sources?

Odor Elimination Chemicals (Section 5.17).

Certain Safer Choice and DfE-certified products contain odor elimination chemicals, which function to reduce or eliminate odorous chemicals. For example, stain and odor removing products may contain odor elimination chemicals.

EPA is proposing to add *Section 5.17 Odor Elimination Chemicals* to formalize the evaluation criteria already used for these chemicals. Odor elimination chemicals would continue to be evaluated based on general requirements in Section 5.2 and based on requirements provided on the Safer Choice website.

EPA is requesting comment on the additional criteria for odor elimination chemicals.

Safer Chemical Ingredients List (Section 5.18).

The Safer Chemical Ingredients List (SCIL) is a list of chemical ingredients, arranged by functional-use class, that EPA has evaluated and determined to meet program criteria. While the current version of the Standard generally describes the SCIL, EPA believes that additional language further describing the relationship between the SCIL, the Standard, and Safer Choice and DfE-certified products would provide additional transparency. Specifically, EPA is proposing to describe the evaluation process for single Chemical Abstracts Service (CAS) Numbers that cover broad ranges of chemical structures.

Use of the Safer Choice Label by Raw Material Suppliers (Section 6.3).

While the Safer Choice label is generally intended for use on finished products, EPA is aware that raw material suppliers may wish to communicate that they supply ingredients that meet Safer Choice criteria. EPA is proposing to add language to the Standard that explains how the Safer Choice label should be used by material suppliers.

EPA proposes to add *Section 6.3 Use of the Safer Choice Label by Raw Material Suppliers* to document the ongoing practice under which raw material suppliers may use the Safer Choice label to indicate that certain raw materials meet Safer Choice criteria or that a specific supplier can formulate to meet Safer Choice criteria. For example, EPA currently allows this practice for raw material suppliers with chemical ingredients listed on CleanGredients (<https://cleangredients.org/>). EPA proposes to continue to work with interested raw material suppliers on a case-by-case basis.

Safer Choice Cleaning Service Certification (Section 7).

EPA requests comment on whether the Agency should establish a Safer Choice Cleaning Service Certification for cleaning service providers that use Safer Choice-certified products for cleaning and DfE-certified products for disinfecting. Residential and commercial cleaning service providers, as well as facility owners, managers, and government entities that provide in-house cleaning would be eligible for this certification. Entities that could be certified must be organizations and businesses that use cleaners, detergents, disinfectants, and related products as part of their primary operations. Program certification would require organizations and businesses to use exclusively Safer Choice-certified products for cleaning and DfE-certified products for disinfecting, in product categories with Safer Choice- and DfE-certified products, to the maximum extent practicable. Exceptions may be granted at EPA's discretion on a case-by-case basis. Certified entities will be directed to suggested trainings and educational resources,

including information about the Safer Choice and DfE programs, best cleaning practices, and guidance on how to find certified products. Educational resources will be available in English and Spanish and can be available in other languages upon request. Certified cleaning service providers will be permitted to display the Safer Choice Service Certification logo (outlined in Section 7.6), and their name and contact information will be listed on the Safer Choice website.

There are several potential benefits of this certification to cleaning service providers. First, use of cleaning products made with safer chemicals can improve environmental health and the health and safety of workers and the public who use products or may come in contact with them. Second, this certification will allow the cleaning service provider to project an image of sustainability in the marketplace, making their services more appealing to customers seeking out a green or safer cleaning or maintenance service. Third, this certification could help reduce costs to businesses by creating safer conditions for home cleaners and janitorial workers, often from underserved communities.

Candidates for Safer Choice Cleaning Service Certification must use a Safer Choice-qualified third-party profiler to prepare and submit applications, document exceptions, and conduct annual virtual audits. There is a cost associated with obtaining these services.

The proposal for the Safer Choice Cleaning Service Certification can be found in Section 7 of the Standard, with a template partnership agreement in Annex D. EPA requests comment on the following questions:

Question 9: Other than the exceptions outlined in Section 7.3.1.1, should other exceptions be included? Are these exceptions overly broad? Is granting the exceptions under this certification appropriate?

Question 10: Do you have a preference between the Safer Choice Service Certification logos in Section 7.6? Comments on the logo elements (e.g., tagline, color, and shape) would be especially valuable. Which do you think would best communicate the meaning of the certification?

Question 11: Should any of the locations for use of the Safer Choice Service Certification logo listed in Section 7.6.2 be removed or should additional locations be added?

Private Label, Licensee, and Toll Manufacture Products (Sections A.13 and B.13): Private Label Company Dilution.

Occasionally, private label companies purchase a concentrated form of a product and dilute to the final concentration at their own facility. To document the ongoing practice under which EPA explicitly allows for dilution by a private label company, EPA proposes to add language to the Safer Choice Partnership Agreement template in *Section A.13 Private Label, Licensee, and Toll Manufacture Products* and in the equivalent section (B.13) in the DfE Partnership Agreement template to allow dilution of a certified concentrate conducted by a private label company. EPA allows such “Ready To Use” private label products to be certified on a case-by-case basis. The partner must communicate that the concentrate is being diluted and the corresponding dilution rates to EPA.