

Changes to the Standard to Implement the Safer Choice Label
2/10/15

Implementation of a New Label for the DfE Safer Product Labeling Program and Supporting Modifications to the DfE Standard for Safer Products, now to be known as the “Safer Choice Standard,” including the Designation of a Fragrance-Free Label

This document explains several important changes to EPA’s Safer Product Labeling Program (SPLP), as well as a number of conforming changes to the program’s Standard for Safer Products, including: a new label¹ and name for the EPA SPLP; an associated fragrance-free label; and related changes to the standard that qualifies products for the label. With this document EPA is finalizing the new label for immediate use. While effective immediately, the Agency is requesting comment on the other changes described in this document, including a new, optional fragrance-free certification.

Redesigned Label

The EPA Design for the Environment (DfE) Safer Product Labeling Program has redesigned its label to better communicate the program’s human health and environmental protection goals, increase consumer and institutional/industrial purchaser understanding and recognition of products bearing the label, and encourage innovation and the development of safer chemicals and chemical-based products. The label’s new name “**Safer Choice**,” with the accompanying wording (or “tagline”) “**Meets U.S. EPA Safer Product Standards**” (which is part of the label), and design were developed over many months based on input and feedback from a diverse set of stakeholders and the general public.

This input and feedback included more than 1700 comments on EPA’s website, six consumer focus group sessions in three geographic markets, and a national online survey. EPA gave considerable weight to consumer and stakeholder feedback in tailoring and selecting the new label, to ensure that the Agency achieved, and continues to achieve, its redesign goals. (Summaries of the focus group sessions and online survey results are available at www.epa.gov/saferchoice/ [insert full link].)

As part of the newly named **Safer Choice Program**, the new label will be implemented through a small family of labels, with very similar content, design and color, but tailored for partnership types and product end-users. Presented here are: the primary label, intended for use on consumer products; the label for industrial and institutional products; and the new fragrance-free label.

¹ Because many stakeholders use the terms “label” and “logo” interchangeably, for the purposes of this document, EPA will use these two terms as synonyms. The DfE label means the certification provided to product manufacturers under the program’s standard and might refer to any of the three new logos described in this document.

Please note that EPA is not making any changes to the requirements that must be met to qualify for partnership and use of the new Safer Choice label.

For consumer products (primary mark):



For institutional and industrial products:



For fragrance-free products:



The Fragrance-free Label.

Health and environmental stakeholders have expressed the need for products that are certified to be fragrance-free products for individuals with fragrance allergies or sensitization concerns. In response to these needs, EPA developed an option for a fragrance-free label that would allow purchasers to identify fragrance-free products and know that the claim has been verified by a trusted source. When presented with a fragrance-free concept in the Agency’s focus group sessions on the label redesign, consumers clearly felt a fragrance-free label would be useful and thought it filled an important need in the marketplace. Product manufacturers also responded favorably, stating that it would help them serve a small but significant subset of consumers.

Manufacturers of fragrances indicated that fragrance-free products could serve those individuals with concerns for fragrances.

With this document, EPA is introducing a fragrance-free certification as a companion to the new Safer Choice label. EPA recognizes that consumers, institutional purchasers and product manufacturers care about the use of fragrances in cleaning, personal care and other products. At the same time, we know that many fragrance materials may be associated with sensitization and allergenic responses and lack toxicological data. Note that the term “fragrance” refers to a formulated product that contains multiple scent and other chemicals (e.g., carriers, stabilizers and preservatives), while “fragrance materials” are solely the scent and masking components in the fragrance.

If a product qualifies for the Safer Choice label and does not use any fragrance materials, as defined below, the program will allow the manufacturer to add a “fragrance-free” notation to the Safer Choice label. In the world of non-fragranced products, two descriptive terms are commonly used on labels: “Unscented” and “Fragrance-free.” Unscented generally means that, while fragrance materials are not used to impart a scent, a product may contain chemicals that neutralize or mask the odors of other ingredients. Fragrance-free means that neither fragrance materials nor masking scents are used in the product. EPA is using the broader “fragrance-free” designation with its Safer Choice label to help ensure that consumers and purchasers seeking to avoid exposure to fragrance chemicals can identify and select such products.

Fragrance-free certification. To qualify for the program’s fragrance-free label, a product must first meet all requirements in the Safer Choice Standard and safer ingredient criteria. EPA will review the product ingredients to ensure that the product contains no fragrance materials. The fragrance-free certification will mean that: 1) the product only contains ingredients on or eligible for the Safer Chemical Ingredients List (SCIL)—the program’s list of ingredients that meet our safer chemical criteria and are generally acceptable for use in Safer Choice labeled products—and 2) the product does not contain chemicals on the International Fragrances Association (IFRA) Transparency List of fragrance chemicals intended to impart or mask a scent². Product manufacturers and fragrance professionals regard the IFRA Transparency List as the comprehensive list of materials used by perfumers and the fragrance industry.

It is important to note that products that qualify for the DfE fragrance-free certification may still have an odor and not be on the IFRA Transparency List. Some product ingredients, such as surfactants or solvents, carry an odor. Only chemicals recognized as having dual functionality—e.g., that are intentionally used as a solvent and/or as a fragrance—would be ineligible for use in products seeking the fragrance-free certification. EPA will work with manufacturers on a case-by-case basis to determine whether a chemical has “dual functionality.”

Submission of Comments. If you have comments on the changes described in this document, please submit them to the EPA docket: EPA-HQ-OPPT-2015-0047. While your

² EPA is developing a list of fragrance chemicals that are acceptable for use in Safer Choice labeled products (that would not be certified as fragrance-free). The list will be a subset of the IFRA Transparency List.

comments are welcome on any aspect of the program addressed in this document, we ask that you especially consider commenting on the new fragrance-free label. All changes described in this document are effective immediately, but we will consider additional changes to the program based on your comments, as appropriate.

The Safer Choice Standard. As a result of the label redesign and recent program developments EPA is making a number of changes to the Standard, described below.

Changes to the Safer Choice Standard

Title page: To reflect the program’s new label, the title of the standards document will change from “EPA’s DfE Standard for Safer Products (DfE Standard)” to “**EPA’s Safer Choice Standard**” (formerly, the ‘DfE Standard for Safer Products’³).

Sec. 2.1 Definitions

To align the Standards with the [Interim Fragrances Criteria](#)⁴, the definition of “Fragrance 2.1.37” and “Fragrance raw material 2.1.38” will be deleted and replaced by a new definition for “Fragrance Materials 2.1.37.” The original definitions, dating from the first iteration of the Standard (2009), were overly broad. Since then, EPA has worked extensively on fragrances and with the fragrance industry to enhance its understanding of this industry. The revised definition will read as follows:

Sec. 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.)

³ For the purposes of institutional procurement requirements, state green purchasing specifications, etc., the Safer Choice label is equivalent to the DfE Safer Product label. Note that the logo for institutional products includes “DfE” in the web address to provide continuity with the previous name.

⁴ [DfE’s Interim Fragrances Criteria \(PDF\)](#) clarify which fragrance chemicals may be used in DfE products and provide a level and consistent set of requirements for DfE Formulator Partners and manufacturers of fragrances. 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 DfE functional class criteria (e.g., solvents).

Sec. 3 General Requirements:

A new section entitled “Fragrance-free Label” is being added, to read as follows:

Sec. 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 fragrances materials. Fragrance materials with dual functionality, including use as a fragrance, are not allowed in fragrance-free products.

Sec. 4.2.2.1 Concentrates in closed dilution-controlled systems

The program allows labeling of concentrated products that exceed the normal pH limits (2 to 11.5) if they otherwise comply with the Standard, are used in closed dilution-controlled systems, and meet the other safeguards in this provision. Without the dilution-controlled system and other safeguards, these products would represent a corrosivity and handling hazard. Using the safer choice label on the package of such products would be inappropriate and might confuse users regarding the proper handling practices. Consequently, a new subsection e) will be added to address label use, to read as follows:

e) the label is not used on the product (or packaging) when it is a concentrate (but may be used in promotional materials).

Sec. 4.5 Products Designed for Dermal Contact

Some products that meet EPA’s Safer Product Standard may also be subject to other agencies’ statutes and laws, such as those products designed for dermal contact. Two sentences, therefore, will be added to the end of the first paragraph to underscore the applicability of existing laws, to read as follows:

... 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.

Sec. 5.6 Fragrances

Introduced in the 2012 enhancements to the Standard, version 2.1 of the Criteria for Fragrances is not being implemented because of difficulties that have arisen in applying the criteria. Numerous attempts among manufacturer partners, manufacturers of fragrances, 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 Criteria⁵ and references to the version 2.1 criteria will be deleted from the 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 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.

Sec. 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 fragrance (or its ingredients) are:

- critical to the fragrance essence or product identity;
- otherwise in compliance with the fragrances criteria⁶;
- 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.

Sec. 6 Use of the Mark

This section contains multiple editorial changes, to conform to the new Safer Choice name and logo, as stated below. Sec. 6.2 contains illustrations of the three new logos, geared to product class: 1) consumer; 2) institutional and industrial; and 3) fragrance-free.

⁵ See footnote no. 4.

⁶ See footnote no. 4.

Sec. 6.1 Terms of Use

Sec. 6.1.1 The partner may use the Safer Choice logo, 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 logo use. The partner shall not use the logo 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.

Sec. 6.1.2 Use of the Safer Choice label must include the EPA web address, www.epa.gov/saferproducts, 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 logo 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 [the 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 [the company name’s] non-ingredient claims. EPA/Safer Choice provides its evaluation only as to the product’s human health and environmental characteristics, as specified in the Standard and based on currently available information and scientific understanding.

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

Sec. 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.

Sec. 6.1.5 The partner must discontinue use of the Safer Choice logo 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-on ingredients; on the termination of the partnership agreement; or, if so notified by EPA in writing.

Sec. 6.2 Illustrations of the EPA/Safer Choice Certification Mark

For consumer products (primary mark):



For institutional and industrial products:



For fragrance-free products:



The Partnership Agreement. Section 8 of the Agreement will be revised to read as follows:

[Company name] may use the appropriate Safer Choice logo, 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 logo or describe EPA/Safer Choice recognition on any general [Company name] materials, non-Qualifying Products or associated

literature, or advertising not specific 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 logo must be accompanied by the program web address-- www.epa.gov/dfe/saferproducts—in close proximity to the logo, as shown in Attachment A. Additionally, when advertising the qualifying products or informing consumers about them, [the Company name] must include the endorsement disclaimer, which appears below. [The 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. Insert disclaimer language and remaining provisions as they appear in sec. 6.2, above.

Miscellaneous

The words “Design for the Environment” or “DfE” have changed to “Safer Choice” or simply “the program.”

To better align the Standard with the program’s mission to facilitate the adoption of source reduction by businesses and improve the human health and environmental profile of a broad range of products, use of the word “cleaning” has been deleted, as appropriate, throughout the document. The term “cleaning,” as in “cleaning product,” is too narrow to represent the breadth of labeled products under the program.