

## ATTACHMENT D

### Safer Choice Program: Audit Process Guidance

To ensure that partnership products are in compliance with the Safer Choice Standard, and especially that the ingredients in certified products are identical to those disclosed to Safer Choice, Safer Choice conducts regular partner audits. Compliance with the Safer Choice program occurs on a three-year cycle. During the three-year partnership period, Safer Choice will conduct two audits via a third-party auditor: an on-site audit and a desk audit. Every three years, the partnership is renewed, and an audit is not required. It is the responsibility of the partner to schedule audits with the third-party auditor. It is advised that partners enroll in the Safer Choice Community cloud-based Salesforce system to receive automated reminders pertaining to compliance requirements.

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

(based on 11/2023 Proposed Safer Choice and Design for the Environment (DfE) Standard)

##### **1. Desk Audits**

Safer Choice partners will submit to the third-party auditor specified materials. The desk audit will focus on the partner's print and electronic materials and verify the authorized formula through a review of production records.

Elements of the desk audit include:

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

##### **2. On-Site Audits**

Safer Choice partners will allow the third-party auditor to visit their manufacturing facilities and conduct audits. The on-site audit will focus on the manufacturing process and the procedures in place to ensure that certified products comport with the Partnership Agreement. If a single facility produces a certified product, that facility will be subject to a site audit once per three-year partnership period. If multiple facilities produce a certified product, two sites will be selected for an audit once per three-year partnership period. Licensees and toll manufacturers are subject to the same rules as primary partners and their facilities will be considered separately from the facilities of the primary partner.

Elements of the on-site audit include:

- Verification that qualifying products are being manufactured using accepted ingredients and suppliers and at proper use levels. Authorized formula will be compared to manufactured product through review of production records, batch tickets, bills of lading, certificates of analysis and any other documentation necessary;
- Verification that any private label and licensed products packaged on-site are identical in formulation to the original certified product formulation, except as noted in the private label application (e.g., alternate dilution rate, alternate dyes or fragrances as specified in the partnership agreement);
- 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:
  - o Production walk-through;
  - o Review of practices for minimizing contamination of the Product during measuring, blending, packaging, and transport;
  - o Verification that bulk product containers, transfer equipment, and holding vessels for Certified Product are maintained in good repair;
  - o Review of records for cleaning, maintenance, and calibration of manufacturing equipment; and
  - o Review of supplier qualification records (including test data) for raw materials, packaging, and ingredients.

### **3. Audit Follow-up and Potential Noncompliance**

Upon completion of the audit, the third-party auditors will promptly notify Safer Choice of all noncompliance issues, highlighting any significant noncompliance, and will outline the steps partners need to take to address these issues (including an expedited review of any previously undisclosed product ingredients). Safer Choice will monitor for and, when necessary, manage significant noncompliance issues, such as:

- ingredient misuse, e.g., use of a non-reported or non-acceptable ingredient;
- label misuse or misrepresentation;
- failure to undergo an audit; and
- failure to complete audit corrective actions.