ATTACHMENT E

DfE Audit Process Guidance for the Safer Product Labeling Program

(DRAFT 8/9/12)

OMB Control No. 2070-0178

The public reporting and recordkeeping burden for this collection of information is estimated to average 27.2 hours per response for formulators of cleaning and non-cleaning products and 9.5 hours per response for partners wishing to add third-party partners and products, including the time for reviewing instructions, gathering information, and completing and reviewing the application. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed application to this address.

DfE has prepared this guidance to assist our qualified third parties in preparing for and conducting desk and on-site audits on DfE-labeled products and partners. For both desk and on-site audits, the guidance includes the following elements (in list format): Requisite audit materials, audit procedures, and audit follow-up.

Desk Audit Process

(based on 4/2011 Edition of the DfE Standard)

I. Materials Required in Advance of Audit

a. A statement that the ingredients and all claims made regarding the Agency's recognition (e.g., use of the DfE logo) comport with the Partnership Agreement or a DfE-approved amendment to the agreement; of note, this statement must confirm that the ingredients in labeled products are the same as those DfE has reviewed and referenced in the partnership agreement;
b. List of all ingredients for each recognized product;
c. Product labels showing use of the DfE logo or mention of DfE recognition;
d. Product or company literature that uses the DfE logo or mentions DfE recognition;
e. Private label (including licensed products) (PL) labels and literature that bear the DfE logo;
f. Summary of implementation activities for any continuous improvement efforts as required by the Partnership Agreement; and
g. Documentation of education offered to end users of Industrial/Institutional (I/I) products.

II. Audit Procedures

1. Request above-listed materials.
2. For each product, verify that the list of ingredients (including those from third-party suppliers) matches the formulation on record and formulation bills of material (e.g., batch tickets). Notify DfE of any discrepancies ASAP.
3. Verify correct use of the DfE logo / program name on labels, literature, and the partner company website.

4. Request updated PL forms to determine if PL products should be added / removed from list of labeled products. Verify correct use of the DfE logo / program name on PL labels, PL literature, and PL company website(s). Email any PL discrepancies to the attention of DfE and Dfesupport@abtassoc.com.
5. Verify that the "Summary of continuous improvement activities" addresses all ingredients identified as "target for improvement" in the partnership agreement and notify DfE of any unaddressed ingredients.
6. Verify that education is being offered to the end user of I/I products as described in Section 3.4 of the Standard.

III. Audit Follow-up and Potential Noncompliance

1. Send written notice to the partner and DfE with a deadline for addressing the audit issues or correcting the noncompliance, as applicable.
2. Verify corrective action and send an updated report to DfE (including the root-cause analysis, explanation of corrective action, and preventive action plan) within 30 days of notifying the client –OR-- Notify DfE that the partner company has not addressed the audit issues or not corrected the noncompliance within the allotted time.
3. Submit a "Desk Audit Report" that summarizes all items that DfE should be aware of concerning the partner company's audit, including all items that were acceptable as submitted and who performed the desk audit. Note: if there is a formula issue or problematic ingredient being used, please highlight this information in an email to DfE.

On-site Audit Process

(based on 4/2011 Edition of the DfE Standard)

I. Materials Required in Advance of Audit

a. Production records, batch tickets, bills of lading, certificates of analysis, and any other formulation documentation;
b. Customer and/or employee complaint file for any potential concerns associated with the manufacture or use of DfE products or ingredients;

c. Records for cleaning, maintenance, and calibration of manufacturing equipment; and
d. Supplier qualification records (including test data) for raw materials.

II. Audit Procedures

1. In advance of facility visit, request and review the above-listed items. For each product, verify that the list of ingredients (including those from third-party suppliers) matches the formulation on record and formulation bills of material (e.g., batch tickets). Notify DfE of any discrepancies ASAP.
2. On-site:
    a. Verify that labeled products are being manufactured with the ingredients agreed to under the partnership (and aligned with trade name/supplier), including at specified use levels, when appropriate;
    b. Verify records for cleaning, maintenance, and calibration of manufacturing equipment (if not done before visit);
    c. Verify that any PL products packaged on-site are identical in formulation to the original recognized product (i.e., no dilution, concentration, no added dyes or fragrances);
    d. Verify 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 to the product type, e.g., cleaning). Include:
        - Production walk-through;
        - Review practices for minimizing contamination during measuring, blending, and packaging; and
        - Verify bulk containers, transfer equipment, and holding vessels are in good repair.

III. Audit Follow-up and Potential Noncompliance

1. Send written notice to the partner and DfE with a deadline for addressing the audit issues or correcting the noncompliance, as applicable.

2. Verify corrective action and send an updated report to DfE (including the root-cause analysis, explanation of corrective action, and preventive action plan) within 30 days of notifying the client— OR— Notify DfE that the partner company has not addressed the audit issues or not corrected the noncompliance within the allotted time.
3. Submit an “On-site Audit Report” that summarizes all items that DfE should be aware of concerning the partner company’s audit, including all items that were acceptable and who performed the audit. Note: if there is a formula issue or a problematic ingredient being used, please highlight this information in an email to DfE.