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Subject: DfE Standard Requirements

1. See Section 7 for requirements/competency/qualification for DfE profilers
2. See Section A14 for audit requirements and Annex B

http://www.epa.gov/dfef/standard_for_safer_cleaning_products.pdf

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Section 7:

7 Profiler requirements

Candidates for DfE 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 shall have the skills, experience, and resources to perform chemical hazard assessments.

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

Recognized for Safer Chemistry www.epa.gov/dfef

17A profiler shall establish the ability to assess and interpret diverse toxicological and other health and environmental information. This shall include maintaining 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; 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 shall be indicated by involvement with EPA's Sustainable Futures Program; submission of Sustainable Futures Premanufacture Notices; 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 DfE Formulator review process and assessment methodology by having training and interacting with DfE and companies interested in DfE 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 DfE to be representative of those recognized by the program. DfE will review the results against the criteria in this section and determine whether the applicant has demonstrated competence.

Section A14

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»-DfE partnership comport with the DfE Standard and criteria documents, “Company_Name» agrees to participate in DfE’s surveillance and auditing program. The program will consist primarily of annual desk audits and triennial on-site audits, as described in the DfE Standard, section 3.6 and Annex B.

“Company_Name» will make its manufacturing facilities and recognized-product-related records available to DfE-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 DfE 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 DfE logo) 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 DfE

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 DfE, 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 DfE, the external verifier shall confirm that “Company_Name» has taken the remedial action necessary to assure DfE 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 DfE logo; 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.

Annex B Elements of Desk Audits and On-Site Audits

DfE partners will submit to the third-party verifier the following items, which are drawn from elements of the partnership agreement and DfE Criteria:

- List of all ingredients for each recognized product; • Statement that the ingredients have not changed since they were provided to DfE and referenced in the Partnership Agreement or in a DfE-approved amendment to the agreement; • Example of all product labels showing use of the DfE logo or mention of the DfE recognition; • Example of any product or company literature that use the DfE logo or mention the DfE recognition; • Any private or licensed product labels and literature that bear the DfE logo; • Summary of continuous improvement efforts as required by the Partnership Agreement; and • Documentation of education offered to end user.

B.2 On-site audits

The third-party verifier will seek the following information, based on the terms of the partnership agreement and DfE 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 complaint file; • Verification of end-user education; • Review

documentation of training offered to end users; • Confirm labeling requirements including safety matters, DfE logo requirements (use of the Mark) and verify no logo or mention of the DfE program is found on non-qualifying products; • Confirmation of appropriate product packaging; • 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 cleaning 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.