

## Environmental Protection Agency

## § 82.180

to the SNAP Document Control Officer.

### § 82.180 Agency review of SNAP submissions.

(a) *Processing of SNAP notices.* (1) *90-day review process.* The 90-day review process will begin once EPA receives a submission and determines that such submission includes data on the substitute that are complete and adequate, as described in § 82.178. The Agency may suspend or extend the review period to allow for submission of additional data needed to complete the review of the notice.

(2) *Initial review of notice.* The SNAP Document Control Officer will review the notice to ensure that basic information necessary to process the submission is present (i.e., name of company, identification of substitute, etc.). The SNAP Document Control Officer will also review substantiation of any claim of confidentiality.

(3) *Determination of data adequacy.* Upon receipt of the SNAP submission, the Agency will review the completeness of the information supporting the application. If additional data are needed, the submitter will be contacted following completion of this review. The 90-day review period will not commence until EPA has received data it judges adequate to support analysis of the submission.

(4) *Letter of receipt.* The SNAP Document Control Officer will send a letter of receipt to the submitter to confirm the date of notification and the beginning of EPA's 90-day review period. The SNAP Document Control Officer will also assign the SNAP notice a tracking number, which will be identified in the letter of receipt.

(5) *Availability of new information during review period.* If critical new information becomes available during the review period that may influence the Agency's evaluation of a substitute, the submitter must notify the Agency about the existence of such information within 10 days of learning of such data. The submitter must also inform the Agency of new studies underway, even if the results will not be available within the 90-day review period. The Agency may contact the submitter to explore extending or suspending the re-

view period depending on the type of information received and the stage of review.

(6) *Completion of detailed review.* Once the initial data review, described in paragraphs (a)(2) and (3) of this section, has been completed, the Agency will complete a detailed evaluation of the notice. If during any time the Agency perceives a lack of information necessary to reach a SNAP determination, it will contact the submitter and request the missing data.

(7) *Criteria for review.* To determine whether a substitute is acceptable or unacceptable as a replacement for class I or II compounds, the Agency will evaluate:

(i) Atmospheric effects and related health and environmental impacts;

(ii) General population risks from ambient exposure to compounds with direct toxicity and to increased ground-level ozone;

(iii) Ecosystem risks;

(iv) Occupational risks;

(v) Consumer risks;

(vi) Flammability; and

(vii) Cost and availability of the substitute.

(8) *Communication of decision.* (i) *Communication of decision to the submitter.* Once the SNAP program review has been completed, the Agency will notify the submitter in writing of the decision. Sale or manufacture of new substitutes may commence after the initial 90-day notification period expires even if the Agency fails to reach a decision within the 90-day review period or fails to communicate that decision or the need for additional data to the submitter. Sale or manufacture of existing substitutes may continue throughout the Agency's 90-day review.

(ii) *Communication of decision to the public.* The Agency will publish in the FEDERAL REGISTER periodic updates to the list of the acceptable and unacceptable alternatives that have been reviewed to date. In the case of substitutes proposed as acceptable with use restrictions, proposed as unacceptable or proposed for removal from either list, a rulemaking process will ensue. Upon completion of such rulemaking, EPA will publish revised lists of substitutes acceptable subject to use conditions or narrowed use limits and

unacceptable substitutes to be incorporated into the Code of Federal Regulations. (See Appendices to this subpart.)

(b) *Types of listing decisions.* When reviewing substitutes, the Agency will list substitutes in one of five categories:

(1) *Acceptable.* Where the Agency has reviewed a substitute and found no reason to prohibit its use, it will list the alternative as acceptable for the end-uses listed in the notice.

(2) *Acceptable subject to use conditions.* After reviewing a notice, the Agency may make a determination that a substitute is acceptable only if conditions of use are met to minimize risks to human health and the environment. Where users intending to adopt a substitute acceptable subject to use conditions must make reasonable efforts to ascertain that other alternatives are not feasible due to safety, performance or technical reasons, documentation of this assessment must be retained on file for the purpose of demonstrating compliance. This documentation shall include descriptions of substitutes examined and rejected, processes or products in which the substitute is needed, reason for rejection of other alternatives, e.g., performance, technical or safety standards. Use of such substitutes in ways that are inconsistent with such use conditions renders them unacceptable.

(3) *Acceptable subject to narrowed use limits.* Even though the Agency can restrict the use of a substitute based on the potential for adverse effects, it may be necessary to permit a narrowed range of use within a sector end-use because of the lack of alternatives for specialized applications. Users intending to adopt a substitute acceptable with narrowed use limits must ascertain that other alternatives are not technically feasible. Companies must document the results of their evaluation, and retain the results on file for the purpose of demonstrating compliance. This documentation shall include descriptions of substitutes examined and rejected, processes or products in which the substitute is needed, reason for rejection of other alternatives, e.g., performance, technical or safety standards, and the anticipated date other

substitutes will be available and projected time for switching to other available substitutes. Use of such substitutes in applications and end-uses which are not specified as acceptable in the narrowed use limit renders them unacceptable.

(4) *Unacceptable.* This designation will apply to substitutes where the Agency's review indicates that the substitute poses risk of adverse effects to human health and the environment and that other alternatives exist that reduce overall risk.

(5) *Pending.* Submissions for which the Agency has not reached a determination will be described as pending. For all substitutes in this category, the Agency will work with the submitter to obtain any missing information and to determine a schedule for providing the missing information if the Agency wishes to extend the 90-day review period. EPA will use the authority under section 114 of the Clean Air Act to gather this information, if necessary. In some instances, the Agency may also explore using additional statutory provisions (e.g., section 5 of TSCA) to collect the needed data.

(c) *Joint processing under SNAP and TSCA.* The Agency will coordinate reviews of substitutes submitted for evaluation under both the TSCA PMN program and the CAA.

(d) *Joint processing under SNAP and FIFRA.* The Agency will coordinate reviews of substitutes submitted for evaluation under both FIFRA and the CAA.

[59 FR 13147, Mar. 18, 1994, as amended at 61 FR 25592, May 22, 1996; 61 FR 54039, Oct. 16, 1996]

#### § 82.182 Confidentiality of data.

(a) *Clean Air Act provisions.* Anyone submitting information must assert a claim of confidentiality at the time of submission for any data they wish to have treated as confidential business information (CBI) under 40 CFR part 2, subpart B. Failure to assert a claim of confidentiality at the time of submission may result in disclosure of the information by the Agency without further notice to the submitter. The submitter should also be aware that under section 114(c), emissions data may not be claimed as confidential.