

Environmental Protection Agency

§ 725.54

running of the review period will resume on the date EPA originally declared it incomplete.

(3) If the Director, or a designee, modifies the requirements for completing the submission or concurs with EPA's original determination, the review period will begin when EPA receives a complete submission.

(f) If EPA discovers at any time that a person submitted materially false or misleading statements in information submitted under this part, EPA may find that the submission was incomplete from the date it was submitted, and take any other appropriate action.

§ 725.36 New information.

(a) During the review period, if a submitter possesses, controls, or knows of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the MCAN or exemption request, the submitter must send that information to the address listed in § 725.25(c) within 10 days of receiving the new information, but no later than 5 days before the end of the review period.

(b) The new submission must clearly identify the submitter, the MCAN or exemption request to which the new information is related, and the number assigned to that submission by EPA, if known to the submitter.

(c) If the new information becomes available during the last 5 days of the review period, the submitter must immediately inform the EPA contact for that submission by telephone of the new information.

§ 725.40 Notice in the Federal Register.

(a) *Filing of FEDERAL REGISTER notice.* After EPA receives a MCAN or an exemption request under this part, EPA will issue a notice in the FEDERAL REGISTER including the information specified in paragraph (b) of this section.

(b) *Contents of notice.* (1) In the public interest, the specific microorganism identity listed in the submission will be published in the FEDERAL REGISTER unless the submitter has claimed the microorganism identity confidential. If the submitter claims confidentiality, a

generic name will be published in accordance with § 725.85.

(2) The categories of use of the microorganism will be published as reported in the submission unless this information is claimed confidential. If confidentiality is claimed, the generic information which is submitted under § 725.88 will be published.

(3) A list of information submitted in accordance with § 725.160(a), 725.255, 725.260, 725.355, or 725.455, as appropriate, will be published.

(4) The submitter's identity will be published, unless the submitter has claimed it confidential.

(c) *Publication of exemption decisions.* Following the expiration of the appropriate review period for the exemption request, EPA will issue a notice in the FEDERAL REGISTER indicating whether the request has been approved or denied and the reasons for the decision.

§ 725.50 EPA review.

(a) *MCANs.* The review period specified in section 5(a) of the Act for MCANs runs for 90 days from the date the Document Control Officer receives a complete submission, or the date EPA determines the submission is complete under § 725.33, unless the Agency extends the review period under section 5(c) of the Act and § 725.56.

(b) *Exemption requests.* The review period starts on the date the Document Control Officer receives a complete exemption request, or the date EPA determines the request is complete under § 725.33, unless the Agency extends the review period under § 725.56. The review periods for exemption requests run as follows:

(1) *TERAs.* The review period for TERAs is 60 days.

(2) *TMEs.* The review period for TMEs is 45 days.

(3) *Tier II exemption requests.* The review period for Tier II exemption requests is 45 days.

§ 725.54 Suspension of the review period.

(a) A submitter may voluntarily suspend the running of the review period if the Director, or a designee, agrees. If the Director does not agree, the review period will continue to run, and EPA will notify the submitter. A submitter

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may request a suspension at any time during the review period. The suspension must be for a specified period of time.

(b) A request for suspension may be made in writing to the address listed in § 725.25(c). The suspension also may be made orally, including by telephone, to the submitter's EPA contact for that submission. EPA will send the submitter a written confirmation that the suspension has been granted.

(1) An oral request may be granted for no longer than 15 days. To obtain a longer suspension, the Document Control Officer for the Office of Pollution Prevention and Toxics must receive written confirmation of the oral request. The review period is suspended as of the date of the oral request.

(2) If the submitter has not made a previous oral request, the running of the review period is suspended as of the date of receipt of the written request by the Document Control Officer for the Office of Pollution Prevention and Toxics.

§ 725.56 Extension of the review period.

(a) At any time during the review period, EPA may unilaterally determine that good cause exists to extend the review period specified for MCANs, or the exemption requests.

(b) If EPA makes such a determination, EPA:

(1) Will notify the submitter that EPA is extending the review period for a specified length of time and state the reasons for the extension.

(2) For MCANs, EPA may issue a notice for publication in the FEDERAL REGISTER which states that EPA is extending the review period and gives the reasons for the extension.

(c) The total period of the extension may be for a period of up to the same length of time as specified for each type of submission in § 725.50. If the initial extension is for less than the total time allowed, EPA may make additional extensions. However, the sum of the extensions may not exceed the total allowed.

(d) The following are examples of situations in which EPA may find that good cause exists for extending the review period:

(1) EPA has reviewed the submission and is seeking additional information.

(2) EPA has received significant additional information during the review period.

(3) The submitter has failed to correct a submission after receiving EPA's request under § 725.32.

(4) EPA has reviewed the submission and determined that there is a significant possibility that the microorganism will be regulated under section 5(e) or section 5(f) of the Act, but EPA is unable to initiate regulatory action within the initial review period.

§ 725.60 Withdrawal of submission by the submitter.

(a) A submitter may withdraw a submission during the review period. A statement of withdrawal must be made in writing to the address listed in § 725.25(c). The withdrawal is effective upon receipt of the statement by the Document Control Officer.

(b) If a manufacturer, importer, or processor who withdrew a submission later resubmits a submission for the same microorganism, a new review period begins.

§ 725.65 Recordkeeping.

(a) *General provisions.* (1) Any person who submits a notice under this part must retain documentation of information in the submission, including:

(i) Any data in the submitter's possession or control; and

(ii) Records of production volume for the first 3 years of manufacture, import, or processing.

(2) Any person who submits a notice under this part must retain documentation of the date of commencement of testing, manufacture, import, or processing.

(3) Any person who is exempt from some or all of the reporting requirements of this part must retain documentation that supports the exemption.

(4) All information required by this section must be retained for 3 years from the date of commencement of each activity for which records are required under this part.

(b) *Specific requirements.* In addition to the requirements of paragraph (a) of