

Attachment F
40 CFR Part 725

40 CFR Protection of Environment
CHAPTER I
ENVIRONMENTAL PROTECTION AGENCY (CONTINUED)

SUBCHAPTER R -- TOXIC SUBSTANCES CONTROL ACT

PART 725 -- REPORTING REQUIREMENTS AND REVIEW PROCESSES FOR
MICROORGANISMS

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Authority: 15 U.S.C. 2604, 2607, 2613, and 2625.

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Subpart A -- General Provisions and Applicability

§725.1 Scope and purpose.

(a) This part establishes all reporting requirements under section 5 of TSCA for manufacturers, importers, and processors of microorganisms subject to TSCA jurisdiction for commercial purposes, including research and development for commercial purposes. New microorganisms for which manufacturers and importers are required to report under section 5(a)(1)(A) of TSCA are those that are intergeneric. In addition, under section 5(a)(1)(B) of TSCA, manufacturers, importers, and processors may be required to report for any microorganism that EPA determines by rule is being manufactured, imported, or processed for a significant new use.

(b) Any manufacturer, importer, or processor required to report under section 5 of TSCA (see §725.100 for new microorganisms and §725.900 for significant new uses) must file a Microbial Commercial Activity Notice (MCAN) with EPA, unless the activity is eligible for a specific exemption as described in this part. The general procedures for filing MCANs are described in subpart D of this part. The exemptions from the requirement to file a MCAN are for certain kinds of contained activities (see §§725.424 and 725.428), test marketing activities (see §725.300), and research and development activities described in paragraph (c) of this section.

(c) Any manufacturer, importer, or processor required to file a MCAN for research and

development (R&D) activities may instead file a TSCA Experimental Release Application (TERA) for a specific test (see §725.250). A TERA is not required for certain R&D activities; however a TERA exemption does not extend beyond the research and development stage, to general commercial use of the microorganism, for which compliance with MCAN requirements is required. The TERA exemptions are for R&D activities subject to other Federal agencies or programs (see §725.232), certain kinds of contained R&D activities (see §725.234), and R&D activities using certain listed microorganisms (see §725.238).

(d) New microorganisms will be added to the Inventory established under section 8 of TSCA once a MCAN has been received, the MCAN review period has expired, and EPA receives a Notice of Commencement (NOC) indicating that manufacture or importation has actually begun. New microorganisms approved for use under a TERA will not be added to the Inventory until a MCAN has been received, the MCAN review period has expired, and EPA has received an NOC.

§725.3 Definitions.

Definitions in section 3 of the Act (15 U.S.C. 2602), as well as definitions contained in §§704.3, 720.3, and 721.3 of this chapter, apply to this part unless otherwise specified in this section. In addition, the following definitions apply to this part:

Consolidated microbial commercial activity notice or consolidated MCAN means any MCAN submitted to EPA that covers more than one microorganism (each being assigned a separate MCAN number by EPA) as a result of a prenotice agreement with EPA.

Containment and/or inactivation controls means any combination of engineering, mechanical, procedural, or biological controls designed and operated to restrict environmental release of viable microorganisms from a structure.

Director means the Director of the EPA Office of Pollution Prevention and Toxics.

Exemption request means any application submitted to EPA under subparts E, F, or G of this part. General commercial use means use for commercial purposes other than research and development.

Genome means the sum total of chromosomal and extrachromosomal genetic material of an isolate and any descendants derived under pure culture conditions from that isolate.

Health and safety study of a microorganism or health and safety study means any study of any effect of a microorganism or microbial mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a microorganism or microbial mixture, toxicological, clinical, and ecological, or other studies of a microorganism or microbial mixture, and any test performed under the Act. Microorganism identity is always part of a health and safety study of a microorganism.

(1) It is intended that the term "health and safety study of a microorganism" be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included,

but other information relating to the effects of a microorganism or microbial mixture on health or the environment is also included. Any data that bear on the effects of a microorganism on health or the environment would be included.

(2) Examples include:

(i) Tests for ecological or other environmental effects on invertebrates, fish, or other animals, and plants, including: Acute toxicity tests, chronic toxicity tests, critical life stage tests, behavioral tests, algal growth tests, seed germination tests, plant growth or damage tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies.

(ii) Long- and short-term tests of mutagenicity, carcinogenicity, or teratogenicity; dermatotoxicity; cumulative, additive, and synergistic effects; and acute, subchronic, and chronic effects.

(iii) Assessments of human and environmental exposure, including workplace exposure, and impacts of a particular microorganism or microbial mixture on the environment, including surveys, tests, and studies of: Survival and transport in air, water, and soil; ability to exchange genetic material with other microorganisms, ability to colonize human or animal guts, and ability to colonize plants.

(iv) Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a microorganism.

(v) Any assessments of risk to health and the environment resulting from the manufacture, processing, distribution in commerce, use, or disposal of the microorganism.

Inactivation means that living microorganisms are rendered nonviable.

Institutional Biosafety Committee means the committees described in the NIH Guidelines in section IV.B.2.

Intergeneric microorganism means a microorganism that is formed by the deliberate combination of genetic material originally isolated from organisms of different taxonomic genera.

(1) The term "intergeneric microorganism" includes a microorganism which contains a mobile genetic element which was first identified in a microorganism in a genus different from the recipient microorganism.

(2) The term "intergeneric microorganism" does not include a microorganism which contains introduced genetic material consisting of only well-characterized, non-coding regulatory regions from another genus.

Introduced genetic material means genetic material that is added to, and remains as a component of, the genome of the recipient.

Manufacture, import, or process for commercial purposes means:

(1) To import, produce, manufacture, or process with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, importer, or processor, and includes, among other things, "manufacture" or "processing" of any amount of a microorganism or

microbial mixture:

- (i) For commercial distribution, including for test marketing.
- (ii) For use by the manufacturer, including use for product research and development or as an intermediate.

(2) The term also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another microorganism or microbial mixture, including byproducts that are separated from that other microorganism or microbial mixture and impurities that remain in that microorganism or microbial mixture. Byproducts and impurities without separate commercial value are nonetheless produced for the purpose of obtaining a commercial advantage, since they are part of the manufacture or processing of a microorganism for commercial purposes.

Microbial commercial activity notice or MCAN means a notice for microorganisms submitted to EPA pursuant to section 5(a)(1) of the Act in accordance with subpart D of this part.

Microbial mixture means any combination of microorganisms or microorganisms and other chemical substances, if the combination does not occur in nature and is not an article.

Microorganism means an organism classified, using the 5-kingdom classification system of Whittaker, in the kingdoms Monera (or Procaryotae), Protista, Fungi, and the Chlorophyta and the Rhodophyta of the Plantae, and a virus or virus-like particle.

Mobile genetic element or MGE means an element of genetic material that has the ability to move genetic material within and between organisms. "Mobile genetic elements" include all plasmids, viruses, transposons, insertion sequences, and other classes of elements with these general properties.

New microorganism means a microorganism not included on the Inventory.

NIH Guidelines means the National Institutes of Health (NIH) "Guidelines for Research Involving Recombinant DNA Molecules" (July 5, 1994).

Non-coding regulatory region means a segment of introduced genetic material for which:

- (1) The regulatory region and any inserted flanking nucleotides do not code for protein, peptide, or functional ribonucleic acid molecules.
- (2) The regulatory region solely controls the activity of other regions that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein synthesis.

Small quantities solely for research and development (or "small quantities solely for purposes of scientific experimentation or analysis or research on, or analysis of, such substance or another substance, including such research or analysis for development of a product") means quantities of a microorganism manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that meet the requirements of

§725.234.

Structure means a building or vessel which effectively surrounds and encloses the microorganism and includes features designed to restrict the microorganism from leaving.

Submission means any MCAN or exemption request submitted to EPA under this part.

Technically qualified individual means a person or persons:

(1) Who, because of education, training, or experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the microorganism which is used under his or her supervision,

(2) Who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or microbiological research to minimize such risks, and

(3) Who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the microorganism as may be appropriate or required within the scope of conducting a research and development activity.

TSCA Experimental Release Application or TERA means an exemption request for a research and development activity, which is not eligible for a full exemption from reporting under §725.232, 725.234, or 725.238, submitted to EPA in accordance with subpart E of this part.

Well-characterized for introduced genetic material means that the following have been determined:

(1) The function of all of the products expressed from the structural gene(s).

(2) The function of sequences that participate in the regulation of expression of the structural gene(s).

(3) The presence or absence of associated nucleotide sequences and their associated functions, where associated nucleotide sequences are those sequences needed to move genetic material including linkers, homopolymers, adaptors, transposons, insertion sequences, and restriction enzyme sites.

§725.8 Coverage of this part.

(a) Microorganisms subject to this part. Only microorganisms which are manufactured, imported, or processed for commercial purposes, as defined in §725.3, are subject to the requirements of this part.

(b) Microorganisms automatically included on the Inventory. Microorganisms that are not intergeneric are automatically included on the Inventory.

(c) Microorganisms not subject to this part. The following microorganisms are not subject to this part, either because they are not subject to jurisdiction under the Act or are not subject to reporting under section 5 of the Act.

(1) Any microorganism which would be excluded from the definition of "chemical substance" in section 3 of the Act and §720.3(e) of this chapter.

(2) Any microbial mixture as defined in §725.3. This exclusion applies only to a microbial mixture as a whole and not to any microorganisms and other chemical substances which are part of the microbial mixture.

(3) Any microorganism that is manufactured and processed solely for export if the following conditions are met:

(i) The microorganism is labeled in accordance with section 12(a)(1)(B) of the Act, when the microorganism is distributed in commerce.

(ii) The manufacturer and processor can document at the commencement of manufacturing or processing that the person to whom the microorganism will be distributed intends to export it or process it solely for export as defined in §721.3 of this chapter.

§725.12 Identification of microorganisms for Inventory and other listing purposes.

To identify and list microorganisms on the Inventory, both taxonomic designations and supplemental information will be used. The supplemental information required in paragraph (b) of this section will be used to specifically describe an individual microorganism on the Inventory. Submitters must provide the supplemental information required by paragraph (b) of this section to the extent necessary to enable a microorganism to be accurately and unambiguously identified on the Inventory.

(a) Taxonomic designation. The taxonomic designation of a microorganism must be provided for the donor organism and the recipient microorganism to the level of strain, as appropriate. These designations must be substantiated by a letter from a culture collection, literature references, or the results of tests conducted for the purpose of taxonomic classification. Upon EPA's request to the submitter, data supporting the taxonomic designation must be provided to EPA. The genetic history of the recipient microorganism should be documented back to the isolate from which it was derived.

(b) Supplemental information. The supplemental information described in paragraphs (b)(1) and (b)(2) of this section is required to the extent that it enables a microorganism to be accurately and unambiguously identified.

(1) Phenotypic information. Phenotypic information means pertinent traits that result from the interaction of a microorganism's genotype and the environment in which it is intended to be used and may include intentionally added biochemical and physiological traits.

(2) Genotypic information. Genotypic information means the pertinent and distinguishing genotypic characteristics of a microorganism, such as the identity of the introduced genetic material and the methods used to construct the reported microorganism. This also may include information on the vector construct, the cellular location, and the number of copies of the

introduced genetic material.

§725.15 Determining applicability when microorganism identity or use is confidential or uncertain.

(a) Consulting EPA. Persons intending to conduct activities involving microorganisms may determine their obligations under this part by consulting the Inventory or the microorganisms and uses specified in §725.239 or in subpart M of this part. This section establishes procedures for EPA to assist persons in determining whether the microorganism or the use is listed on the Inventory, in §725.239 or in subpart M of this part.

(1) Confidential identity or use. In some cases it may not be possible to directly determine if a specific microorganism is listed, because portions of that entry may contain generic information to protect confidential business information (CBI). If any portion of the microorganism's identity or use has been claimed as CBI, that portion does not appear on the public version of the Inventory, in §725.239 or in subpart M of this part. Instead, it is contained in a confidential version held in EPA's Confidential Business Information Center (CBIC). The public versions contain generic information which masks the confidential business information. A person who intends to conduct an activity involving a microorganism or use whose entry is described with generic information will need to inquire of EPA whether the unreported microorganism or use is on the confidential version.

(2) Uncertain microorganism identity. The current state of scientific knowledge leads to some imprecision in describing a microorganism. As the state of knowledge increases, EPA will be developing policies to determine whether one microorganism is equivalent to another. Persons intending to conduct activities involving microorganisms may inquire of EPA whether the microorganisms they intend to manufacture, import, or process are equivalent to specific microorganisms described on the Inventory, in §725.239, or in subpart M of this part.

(b) Requirement of bona fide intent. (1) EPA will answer the inquiries described in paragraph (a) of this section only if the Agency determines that the person has a bona fide intent to conduct the activity for which reporting is required or for which any exemption may apply.

(2) To establish a bona fide intent to manufacture, import, or process a microorganism, the person who intends to manufacture, import, or process the microorganism must submit the following information in writing to the Office of Pollution Prevention and Toxics, Document Control Officer, 7407, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTN: BIOTECH bona fide submission.

(i) Taxonomic designations and supplemental information required by §725.12.

(ii) A signed statement certifying that the submitter intends to manufacture, import, or process the microorganism for commercial purposes.

(iii) A description of research and development activities conducted with the microorganism to date, demonstration of the submitter's ability to produce or obtain the microorganism from a foreign manufacturer, and the purpose for which the person will manufacture, import, or process the microorganism.

(iv) An indication of whether a related microorganism was previously reviewed by EPA to the

extent known by the submitter.

(v) A specific description of the major intended application or use of the microorganism.

(c) If an importer or processor cannot provide all the information required by paragraph (b) of this section, because it is claimed as confidential business information by its foreign manufacturer or supplier, the foreign manufacturer or supplier may supply the information directly to EPA.

(d) EPA will review the information submitted by the manufacturer, importer, or processor under this paragraph to determine whether that person has shown a bona fide intent to manufacture, import, or process the microorganism. If necessary, EPA will compare this information to the information requested for the confidential microorganism under §725.85(b)(3)(iii).

(e) In order for EPA to make a conclusive determination of the microorganism's status, the proposed manufacturer, importer, or processor must show a bona fide intent to manufacture, import, or process the microorganism and must provide sufficient information to establish identity unambiguously. After sufficient information has been provided, EPA will inform the manufacturer, importer, or processor whether the microorganism is subject to this part and if so, which sections of this part apply.

(f) If the microorganism is found on the confidential version of the Inventory, in §725.239 or in subpart M of this part, EPA will notify the person(s) who originally reported the microorganism that another person (whose identity will remain confidential, if so requested) has demonstrated a bona fide intent to manufacture, import, or process the microorganism and therefore was told that the microorganism is on the Inventory, in §725.239, or in subpart M of this part.

(g) A disclosure to a person with a bona fide intent to manufacture, import, or process a particular microorganism that the microorganism is on the Inventory, in §725.239, or in subpart M of this part will not be considered a public disclosure of confidential business information under section 14 of the Act.

(h) EPA will answer an inquiry on whether a particular microorganism is subject to this part within 30 days after receipt of a complete submission under paragraph (b) of this section.

§725.17 Consultation with EPA.

Persons may consult with EPA, either in writing or by telephone, about their obligations under this part. Written consultation is preferred. Written inquiries should be sent to the following address: Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTN: Biotechnology Notice Consultation. Persons wishing to consult with EPA by telephone should call (202) 554-1404; hearing impaired TDD (202) 554-0551 or e-mail: TSCA-Hotline@epamail.epa.gov.

Subpart B -- Administrative Procedures

§725.20 Scope and purpose.

This subpart describes general administrative procedures applicable to all persons who submit MCANs and exemption requests to EPA under section 5 of the Act for microorganisms.

§725.25 General administrative requirements.

(a) General. (1) Each person who is subject to the notification provisions of this part must complete, sign, and submit a MCAN or exemption request containing the information as required for the appropriate submission under this part. Except as otherwise provided, each submission must include all referenced attachments. All information in the submission (unless certain attachments appear in the open scientific literature) must be in English. All information submitted must be true and correct.

(2) In addition to specific information required, the submitter should submit all information known to or reasonably ascertainable by the submitter that would permit EPA to make a reasoned evaluation of the human health and environmental effects of the microorganism and any microbial mixture or article that may contain the microorganism.

(b) Certification. Persons submitting MCANs and exemption requests to EPA under this part, and material related to their reporting obligations under this part, must attach the following statement to any information submitted to EPA. This statement must be signed and dated by an authorized official of the submitter:

I certify that to the best of my knowledge and belief: The company named in this submission intends to manufacture, import, or process for a commercial purpose, other than in small quantities solely for research and development, the microorganism identified in this submission. All information provided in this submission is complete and truthful as of the date of submission. I am including with this submission all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by 40 CFR 725.160 or 725.260.

(c) Where to submit information under this part. Persons submitting MCANs and exemption requests to EPA under this part, and material related to their reporting obligations under this part, must send them to: TSCA Document Processing Center (7407), Rm. L-100, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(d) General requirements for submission of data. (1) Submissions under this part must include the information described in §725.155, 725.255, 725.355, or 725.455, as appropriate, to the extent such information is known to or reasonably ascertainable by the submitter.

(2) In accordance with §725.160 or 725.260, as appropriate, the submission must also include any test data in the submitter's possession or control and descriptions of other data which are known to or reasonably ascertainable by the submitter and which concern the health and environmental effects of the microorganism.

(e) Agency or joint submissions. (1) A manufacturer or importer may designate an agent to

submit the MCAN or exemption request. Both the manufacturer or importer and the agent must sign the certification required in paragraph (b) of this section.

(2) A manufacturer or importer may authorize another person (e.g., a foreign manufacturer or supplier, or a toll manufacturer) to report some of the information required in the MCAN or exemption request to EPA on its behalf. If separate portions of a joint submission are not submitted together, the submitter must indicate which information will be supplied by another person and identify that person. The manufacturer or importer and any other person supplying the information must sign the certification required by paragraph (b) of this section.

(3) If EPA receives a submission which does not include the information required, which the submitter indicates that it has authorized another person to provide, the review period will not begin until EPA receives all of the required information.

(f) Microorganisms subject to a section 4 test rule. (1) Except as provided in paragraph (f)(3) of this section, if a person intends to manufacture or import a new microorganism which is subject to the notification requirements of this part, and the microorganism is subject to a test rule promulgated under section 4 of the Act before the notice is submitted, section 5(b)(1) of the Act requires the person to submit the test data required by the testing rule with the notice. The person must submit the data in the form and manner specified in the test rule and in accordance with §725.160. If the person does not submit the test data, the submission is incomplete and EPA will follow the procedures in §725.33.

(2) If EPA has granted the submitter an exemption under section 4(c) of the Act from the requirement to conduct tests and submit data, the person may not file a MCAN or TERA until EPA receives the test data.

(3) If EPA has granted the submitter an exemption under section 4(c) of the Act and if another person previously has submitted the test data to EPA, the exempted person may either submit the test data or provide the following information as part of the notice:

- (i) The name, title, and address of the person who submitted the test data to EPA.
- (ii) The date the test data were submitted to EPA.
- (iii) A citation for the test rule.
- (iv) A description of the exemption and a reference identifying it.

(g) Microorganisms subject to a section 5(b)(4) rule. (1) If a person:

- (i) Intends to manufacture or import a microorganism which is subject to the notification requirements of this part and which is subject to a rule issued under section 5(b)(4) of the Act; and
- (ii) Is not required by a rule issued under section 4 of the Act to submit test data for the microorganism before the filing of a submission, the person must submit to EPA data described in paragraph (g)(2) of this section at the time the submission is filed.

(2) Data submitted under paragraph (g)(1) of this section must be data which the person submitting the notice believes show that the manufacture, processing, distribution in commerce,

use, and disposal of the microorganism, or any combination of such activities, will not present an unreasonable risk of injury to health or the environment.

(h) Data that need not be submitted. Specific data requirements are listed in subparts D, E, F, G, and L of this part. The following is a list of data that need not be submitted under this part:

(1) Data previously submitted to EPA. (i) A person need not submit any data previously submitted to EPA with no claims of confidentiality if the new submission includes: the office or person to whom the data were submitted; the date of submission; and, if appropriate, a standard literature citation as specified in §725.160(a)(3)(ii).

(ii) For data previously submitted to EPA with a claim of confidentiality, the person must resubmit the data with the new submission and any claim of confidentiality, under §725.80.

(2) Efficacy data. This part does not require submission of any data related solely to product efficacy. However, including efficacy data will improve EPA's ability to assess the benefits of the use of the microorganism. This does not exempt a person from submitting any of the data specified in §725.160 or 725.260.

(3) Non-U.S. exposure data. This part does not require submission of any data which relates only to exposure of humans or the environment outside the United States. This does not exclude nonexposure data such as data on health effects (including epidemiological studies), ecological effects, physical and chemical properties, or environmental fate characteristics.

§725.27 Submissions.

Each person who is required to submit information under this part must submit the information in the form and manner set forth in the appropriate subpart.

(a) Requirements specific to MCANs are described in §§725.150 through 725.160.

(b) Requirements specific to TERAs are described in §§725.250 through 725.260.

(c) Requirements specific to test marketing exemptions (TMEs) are described in §§725.350 and 725.355.

(d) Requirements specific to Tier I and Tier II exemptions for certain general commercial uses are described in §§725.424 through 725.470.

(e) Additional requirements specific to significant new uses for microorganisms are described at §725.950.

§725.28 Notice that submission is not required.

When EPA receives a MCAN or exemption request, EPA will review it to determine whether the microorganism is subject to the requirements of this part. If EPA determines that the microorganism is not subject to these requirements, EPA will notify the submitter that section 5 of the Act does not prevent the manufacture, import, or processing of the microorganism and that the submission is not needed.

§725.29 EPA acknowledgement of receipt of submission.

(a) EPA will acknowledge receipt of each submission by sending the submitter a letter that identifies the number assigned to each MCAN or exemption request and the date on which the review period begins. The review period will begin on the date the MCAN or exemption request is received by the Office of Pollution Prevention and Toxics Document Control Officer.

(b) The acknowledgement does not constitute a finding by EPA that the submission is in compliance with this part.

§725.32 Errors in the submission.

(a) Within 30 days of receipt of the submission, EPA may request that the submitter remedy errors in the submission. The following are examples of such errors:

- (1) Failure to date the submission.
- (2) Typographical errors that cause data to be misleading or answers to any questions to be unclear.
- (3) Contradictory information.
- (4) Ambiguous statements or information.

(b) In the request to correct the submission, EPA will explain the action which the submitter must take to correct the submission.

(c) If the submitter fails to correct the submission within 15 days of receipt of the request, EPA may extend the review period.

§725.33 Incomplete submissions.

(a) A submission under this part is not complete, and the review period does not begin, if:

- (1) The wrong person files the submission.
- (2) The submitter does not attach and sign the certification statement as required by §725.25(b).
- (3) Some or all of the information in the submission or any attachments are not in English, except for published scientific literature.
- (4) The submitter does not provide information that is required by sections 5(d)(1)(B) and (C) of the Act and §725.160 or 725.260, as appropriate.
- (5) The submitter does not provide information required by §725.25, 725.155, 725.255, 725.355, or 725.455, as appropriate, or indicate that it is not known to or reasonably ascertainable by the submitter.
- (6) The submitter has asserted confidentiality claims and has failed to:
 - (i) Submit a second copy of the submission with all confidential information deleted for the public file, as required by §725.80(b)(2).
 - (ii) Comply with the substantiation requirements as described in §725.94.
- (7) The submitter does not include any information required by section 5(b)(1) of the Act and pursuant to a rule promulgated under section 4 of the Act, as required by §725.25(f).
- (8) The submitter does not submit data which the submitter believes show that the microorganism will not present an unreasonable risk of injury to health or the environment, if EPA has listed the microorganism under section 5(b)(4) of the Act, as required in §725.25(g).
- (9) For MCANs, the submitter does not remit the fees required by §700.45(b)(1) or (b)(2)(vi) of this chapter.

(b)(1) If EPA receives an incomplete submission under this part, the Director, or a designee, will notify the submitter within 30 days of receipt that the submission is incomplete and that the review period will not begin until EPA receives a complete submission.

(2) If EPA obtains additional information during the review period for any submission that indicates the original submission was incomplete, the Director, or a designee, may declare the submission incomplete within 30 days after EPA obtains the additional information and so notify the submitter.

(c) The notification that a submission is incomplete under paragraph (b) of this section will include:

(1) A statement of the basis of EPA's determination that the submission is incomplete.

(2) The requirements for correcting the incomplete submission.

(3) Information on procedures under paragraph (d) of this section for filing objections to the determination or requesting modification of the requirements for completing the submission.

(d) Within 10 days after receipt of notification by EPA that a submission is incomplete, the submitter may file written objections requesting that EPA accept the submission as complete or modify the requirements necessary to complete the submission.

(e)(1) EPA will consider the objections filed by the submitter. The Director, or a designee, will determine whether the submission was complete or incomplete, or whether to modify the requirements for completing the submission. EPA will notify the submitter in writing of EPA's response within 10 days of receiving the objections.

(2) If the Director, or a designee, determines, in response to the objection, that the submission was complete, the review period will be deemed suspended on the date EPA declared the submission incomplete, and will resume on the date that the submission is declared complete. The submitter need not correct the submission as EPA originally requested. If EPA can complete its review within the review period beginning on the date of the submission, the Director, or a designee, may inform the submitter that the 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 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 this section, specific recordkeeping requirements included in certain subparts must also be followed.

(1) Additional recordkeeping requirements for activities conducted inside a structure are set forth in §725.235(h).

(2) Additional recordkeeping requirements for TERAs are set forth in §725.250(f).

(3) Additional recordkeeping requirements for TMEs are set forth in §725.350(c).

(4) Additional recordkeeping requirements for Tier I exemptions under subpart G of this part are set forth in §725.424(a)(5).

(5) Additional recordkeeping requirements for Tier II exemptions under subpart G of this part are set forth in §725.450(d).

(6) Additional recordkeeping requirements for significant new uses of microorganisms reported under subpart L of this part are set forth in §725.850. Recordkeeping requirements may also be included when a microorganism and significant new use are added to subpart M of this part.

§725.67 Applications to exempt new microorganisms from this part.

(a) Submission. (1) Any manufacturer or importer of a new microorganism may request, under section 5(h)(4) of the Act, an exemption, in whole or in part, from this part by sending a Letter of Application to the Chief, New Chemicals Branch, Chemical Control Division, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(2) General provisions. The Letter of Application should provide information to show that any activities affected by the requested exemption will not present an unreasonable risk of injury to health or the environment. This information should include data described in the following paragraphs.

(i) The effects of the new microorganism on health and the environment.

(ii) The magnitude of exposure of human beings and the environment to the new microorganism.

(iii) The benefits of the new microorganism for various uses and the availability of substitutes for such uses.

(iv) The reasonably ascertainable economic consequences of granting or denying the exemption, including effects on the national economy, small business, and technological innovation.

(3) Specific requirements. In addition to the requirements of paragraph (a)(2) of this section, the specific information requirements of the relevant subpart under which the exemption is sought should be met.

(i) Exemption from MCAN reporting under subpart D. Information requirements are set forth in §§725.155 and 725.160.

(ii) Exemption from TERA reporting under subpart E. Information requirements are set forth in §§725.255 and 725.260.

(iii) Listing a recipient microorganism as eligible for exemption under subpart G. Information regarding the following criteria should be addressed in an application to list a recipient microorganism under §725.420:

(A) Identification and classification of the microorganism using available genotypic and phenotypic information;

(B) Information to evaluate the relationship of the microorganism to any other closely related microorganisms which have a potential for adverse effects on health or the environment;

(C) A history of safe commercial use for the microorganism;

(D) Commercial uses indicating that the microorganism products might be subject to TSCA;

(E) Studies which indicate the potential for the microorganism to cause adverse effects to health or the environment; and

(F) Studies which indicate the survival characteristics of the microorganism in the environment.

(b) Processing of the Letter of Application by EPA -- (1) Grant of the Application. If, after consideration of the Letter of Application and any other relevant information available to EPA, the Assistant Administrator for Prevention, Pesticides and Toxic Substances makes a preliminary determination that the new microorganism will not present an unreasonable risk of injury to health or the environment, the Assistant Administrator will propose a rule to grant the exemption using the applicable procedures in part 750 of this chapter.

(2) Denial of the application. If the Assistant Administrator decides that the preliminary determination described in paragraph (b)(1) of this section cannot be made, the application will be denied by sending the applicant a written statement with the Assistant Administrator's reasons for denial.

(c) Processing of the exemption -- (1) Unreasonable risk standard. Granting a section 5(h)(4) exemption requires a determination that the activities will not present an unreasonable risk of injury to health or the environment.

(i) An unreasonable risk determination under the Act is an administrative judgment that requires balancing of the harm to health or the environment that a chemical substance may cause and the magnitude and severity of that harm, against the social and economic effects on society of EPA action to reduce that harm.

(ii) A determination of unreasonable risk under section 5(h)(4) of the Act will examine the

reasonably ascertainable economic and social consequences of granting or denying the exemption after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

(2) Grant of the exemption. The exemption will be granted if the Assistant Administrator determines, after consideration of all relevant evidence presented in the rulemaking proceeding described in paragraph (b)(1) of this section, that the new microorganism will not present an unreasonable risk of injury to health or the environment.

(3) Denial of the exemption. The exemption will be denied if the Assistant Administrator determines, after consideration of all relevant evidence presented in the rulemaking proceeding described in paragraph (b)(1) of this section, that the determination described in paragraph (c)(2) of this section cannot be made. A final decision terminating the rulemaking proceeding will be published in the FEDERAL REGISTER.

§725.70 Compliance.

(a) Failure to comply with any provision of this part is a violation of section 15 of the Act (15 U.S.C. 2614).

(b) A person who manufactures or imports a microorganism before a MCAN is submitted and the MCAN review period expires is in violation of section 15 of the Act even if that person was not required to submit the MCAN under §725.105.

(c) Using a microorganism which a person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 of the Act or this part is a violation of section 15 of the Act (15 U.S.C. 2614).

(d) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(e) Failure or refusal to permit entry or inspection as required by section 11 of the Act is a violation of section 15 of the Act (15 U.S.C. 2614).

(f) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. Persons who submit materially misleading or false information in connection with the requirements of any provision of this part may be subject to penalties calculated as if they never filed their submissions.

(g) EPA may seek to enjoin the manufacture or processing of a microorganism in violation of this part or act to seize any microorganism manufactured or processed in violation of this part or take other actions under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 2616).

§725.75 Inspections.

EPA will conduct inspections under section 11 of the Act to assure compliance with section 5 of the Act and this part, to verify that information required by EPA under this part is true and

correct, and to audit data submitted to EPA under this part.

Subpart C -- Confidentiality and Public Access to Information

§725.80 General provisions for confidentiality claims.

(a) A person may assert a claim of confidentiality for any information submitted to EPA under this part. However,

(1) Any person who asserts a claim of confidentiality for portions of the specific microorganism identity must provide the information as described in §725.85.

(2) Any person who asserts a claim of confidentiality for a use of a microorganism must provide the information as described in §725.88.

(3) Any person who asserts a claim of confidentiality for information contained in a health and safety study of a microorganism must provide the information described in §725.92.

(b) Any claim of confidentiality must accompany the information when it is submitted to EPA.

(1) When a person submits any information under this part, including any attachments, for which claims of confidentiality are made, the claim(s) must be asserted by circling the specific information which is claimed and marking the page on which that information appears with an appropriate designation such as "trade secret," "TSCA CBI," or "confidential business information."

(2) If any information is claimed confidential, the person must submit two copies of the document including the claimed information.

(i) One copy of the document must be complete. In that copy, the submitter must mark the information which is claimed as confidential in the manner prescribed in paragraph (b)(1) of this section.

(ii) The second copy must be complete except that all information claimed as confidential in the first copy must be deleted. EPA will place the second copy in the public file.

(iii) If the submitter does not provide the second copy, the submission is incomplete and the review period does not begin to run until EPA receives the second copy, in accordance with §725.33.

(iv) Any information contained within the copy submitted under paragraph (b)(2)(ii) of this section which has been in the public file for more than 30 days will be presumed to be in the public domain, notwithstanding any assertion of confidentiality made under this section.

(3) A person who submits information to EPA under this part must reassert a claim of confidentiality and substantiate the claim each time the information is submitted to EPA.

(c) Any person asserting a claim of confidentiality under this part must substantiate each claim in accordance with the requirements in §725.94.

(d) EPA will disclose information that is subject to a claim of confidentiality asserted under this section only to the extent permitted by the Act, this subpart, and part 2 of this title.

(e) If a submitter does not assert a claim of confidentiality for information at the time it is submitted to EPA, EPA may make the information public and place it in the public file without further notice to the submitter.

§725.85 Microorganism identity.

(a) Claims applicable to the period prior to commencement of manufacture or import for general commercial use -- (1) When to make a claim. (i) A person who submits information to EPA under this part may assert a claim of confidentiality for portions of the specific microorganism identity at the time of submission of the information. This claim will apply only to the period prior to the commencement of manufacture or import for general commercial use.

(ii) A person who submits information to EPA under this part must reassert a claim of confidentiality and substantiate the claim each time the information is submitted to EPA. For example, if a person claims certain information confidential in a TERA submission and wishes the same information to remain confidential in a subsequent TERA or MCAN submission, the person must reassert and resubstantiate the claim in the subsequent submission.

(2) Assertion of claim. (i) A submitter may assert a claim of confidentiality only if the submitter believes that public disclosure prior to commencement of manufacture or import for general commercial use of the fact that anyone is initiating research and development activities pertaining to the specific microorganism or intends to manufacture or import the specific microorganism for general commercial use would reveal confidential business information. Claims must be substantiated in accordance with the requirements of §725.94(a).

(ii) If the submission includes a health and safety study concerning the microorganism and if the claim for confidentiality with respect to the specific identity is denied in accordance with §725.92(c), EPA will deny a claim asserted under paragraph (a) of this section.

(3) Development of generic name. Any person who asserts a claim of confidentiality for portions of the specific microorganism identity under this paragraph must provide one of the following items at the time the submission is filed:

(i) The generic name which was accepted by EPA in the prenotice consultation conducted under paragraph (a)(4) of this section.

(ii) One generic name that is only as generic as necessary to protect the confidential identity of the particular microorganism. The name should reveal the specific identity to the maximum extent possible. The generic name will be subject to EPA review and approval.

(4) Determination by EPA. (i) Any person who intends to assert a claim of confidentiality for the specific identity of a new microorganism may seek a determination by EPA of an appropriate generic name for the microorganism before filing a submission. For this purpose, the person should submit to EPA:

(A) The specific identity of the microorganism.

(B) A proposed generic name(s) which is only as generic as necessary to protect the confidential identity of the new microorganism. The name(s) should reveal the specific identity of the microorganism to the maximum extent possible.

(ii) Within 30 days, EPA will inform the submitter either that one of the proposed generic names is adequate or that none is adequate and further consultation is necessary.

(5) Use of generic name. If a submitter claims microorganism identity as confidential under paragraph (a) of this section, and if the submitter complies with paragraph (a)(2) of this section, EPA will issue for publication in the FEDERAL REGISTER notice described in §725.40 the generic name proposed by the submitter or one agreed upon by EPA and the submitter.

(b) Claims applicable to the period after commencement of manufacture or import for general commercial use -- (1) Maintaining claim. Any claim of confidentiality under paragraph (a) of this section is applicable only until the microorganism is manufactured or imported for general commercial use and becomes eligible for inclusion on the Inventory. To maintain the confidential status of the microorganism identity when the microorganism is added to the Inventory, a submitter must reassert the confidentiality claim and substantiate the claim in the notice of commencement of manufacture required under §725.190.

(i) A submitter may not claim the microorganism identity confidential for the period after commencement of manufacture or import for general commercial use unless the submitter claimed the microorganism identity confidential under paragraph (a) of this section in the MCAN submitted for the microorganism.

(ii) A submitter may claim the microorganism identity confidential for the period after commencement of manufacture or import for general commercial use if the submitter did not claim the microorganism identity confidential under paragraph (a) of this section in any TERA submitted for the microorganism, but subsequently did claim microorganism identity confidential in the MCAN submitted for the microorganism.

(2) Assertion of claim. (i) A person who believes that public disclosure of the fact that anyone manufactures or imports the microorganism for general commercial use would reveal confidential business information may assert a claim of confidentiality under paragraph (b) of this section.

(ii) If the notice includes a health and safety study concerning the new microorganism, and if the claim for confidentiality with respect to the microorganism identity is denied in accordance with §725.92(c), EPA will deny a claim asserted under paragraph (b) of this section.

(3) Requirements for assertion. Any person who asserts a confidentiality claim for microorganism identity must: (i) Comply with the requirements of paragraph (a)(3) of this section regarding submission of a generic name.

(ii) Agree that EPA may disclose to a person with a bona fide intent to manufacture or import the microorganism the fact that the particular microorganism is included on the confidential Inventory for purposes of notification under section 5(a)(1)(A) of the Act.

(iii) Have available and agree to furnish to EPA upon request the taxonomic designations and supplemental information required by §725.12.

(iv) Provide a detailed written substantiation of the claim, in accordance with the requirements of §725.94(b).

(4) Denial of claim. If the submitter does not meet the requirements of paragraph (b) of this section, EPA will deny the claim of confidentiality.

(5) Acceptance of claim. (i) EPA will publish a generic name on the public Inventory if:

(A) The submitter asserts a claim of confidentiality in accordance with this paragraph.

(B) No claim for confidentiality of the microorganism identity as part of a health and safety study has been denied in accordance with part 2 of this title or §725.92.

(ii) Publication of a generic name on the public Inventory does not create a category for purposes of the Inventory. Any person who has a bona fide intent to manufacture or import a microorganism which is described by a generic name on the public Inventory may submit an

inquiry to EPA under §725.15(b) to determine whether the particular microorganism is included on the confidential Inventory.

(iii) Upon receipt of a request described in §725.15(b), EPA may require the submitter who originally asserted confidentiality for a microorganism to submit to EPA the information listed in paragraph (b)(3)(iii) of this section.

(iv) Failure to submit any of the information required under paragraph (b)(3)(iii) of this section within 10 calendar days of receipt of a request by EPA under paragraph (b) of this section will constitute a waiver of the original submitter's confidentiality claim. In this event, EPA may place the specific microorganism identity on the public Inventory without further notice to the original submitter.

(6) Use of generic name on the public Inventory. If a submitter asserts a claim of confidentiality under paragraph (b) of this section, EPA will examine the generic microorganism name proposed by the submitter. (i) If EPA determines that the generic name proposed by the submitter is only as generic as necessary to protect the confidential identity of the particular microorganism, EPA will place that generic name on the public Inventory.

(ii) If EPA determines that the generic name proposed by the submitter is more generic than necessary to protect the confidential identity, EPA will propose in writing, for review by the submitter, an alternative generic name that will reveal the identity of the microorganism to the maximum extent possible.

(iii) If the generic name proposed by EPA is acceptable to the submitter, EPA will place that generic name on the public Inventory.

(iv) If the generic name proposed by EPA is not acceptable to the submitter, the submitter must explain in detail why disclosure of that generic name would reveal confidential business information and propose another generic name which is only as generic as necessary to protect the confidential identity of the microorganism. If EPA does not receive a response from the submitter within 30 days after the submitter receives the proposed name, EPA will place EPA's chosen generic name on the public Inventory. If the submitter does provide the information requested, EPA will review the response. If the submitter's proposed generic name is acceptable, EPA will publish that generic name on the public Inventory. If the submitter's proposed generic name is not acceptable, EPA will notify the submitter of EPA's choice of a generic name. Thirty days after this notification, EPA will place the chosen generic name on the public Inventory.

§725.88 Uses of a microorganism.

(a) Assertion of claim. A person who submits information to EPA under this part on the categories or proposed categories of use of a microorganism may assert a claim of confidentiality for this information.

(b) Requirements for claim. A submitter that asserts such a claim must:

(1) Report the categories or proposed categories of use of the microorganism.

(2) Provide, in nonconfidential form, a description of the uses that is only as generic as necessary to protect the confidential business information. The generic use description will be included in the FEDERAL REGISTER notice described in §725.40.

(c) Generic use description. The person must submit the information required by paragraph (b) of this section by describing the uses as precisely as possible, without revealing the information

which is claimed confidential, to disclose as much as possible how the use may result in human exposure to the microorganism or its release to the environment.

§725.92 Data from health and safety studies of microorganisms.

(a) Information other than specific microorganism identity. Except as provided in paragraph (b) of this section, EPA will deny any claim of confidentiality with respect to information included in a health and safety study of a microorganism, unless the information would disclose confidential business information concerning:

- (1) Processes used in the manufacture or processing of a microorganism.
- (2) Information which is not in any way related to the effects of a microorganism on health or the environment, such as, the name of the submitting company, cost or other financial data, product development or marketing plans, and advertising plans, for which the person submits a claim of confidentiality in accordance with §725.80.

(b) Microorganism identity -- (1) Claims applicable to the period prior to commencement of manufacture or import for general commercial use. A claim of confidentiality for the period prior to commencement of manufacture or import for general commercial use for the specific identity of a microorganism for which a health and safety study was submitted must be asserted in conjunction with a claim asserted under §725.85(a). The submitter must substantiate each claim in accordance with the requirements of §725.94(a).

(2) Claims applicable to the period after commencement of manufacture or import for general commercial use. To maintain the confidential status of the specific identity of a microorganism for which a health and safety study was submitted after commencement of manufacture or import for general commercial use, the claim must be reasserted and substantiated in conjunction with a claim under §725.85(b). The submitter must substantiate each claim in accordance with the requirements of §725.94(b).

(c) Denial of confidentiality claim. EPA will deny a claim of confidentiality for microorganism identity under paragraph (b) of this section, unless:

- (1) The information would disclose processes used in the manufacture or processing of a microorganism.
- (2) The microorganism identity is not necessary to interpret a health and safety study.

(d) Use of generic names. When EPA discloses a health and safety study containing a microorganism identity, which the submitter has claimed confidential, and if the Agency has not denied the claim under paragraph (c) of this section, EPA will identify the microorganism by the generic name selected under §725.85.

§725.94 Substantiation requirements.

(a) Claims applicable to the period prior to commencement of manufacture or import for general commercial use – (1) MCAN, TME, Tier I certification, and Tier II exemption request requirements. Any person who submits a MCAN, TME, Tier I certification, or Tier II exemption

request should strictly limit confidentiality claims to that information which is confidential and proprietary to the business.

(i) If any information in the submission is claimed as confidential business information, the submitter must substantiate each claim by submitting written answers to the questions in paragraphs (c), (d), and (e) of this section at the time the person submits the information.

(ii) If the submitter does not provide written substantiation as required in paragraph (a)(1)(i) of this section, the submission will be considered incomplete and the review period will not begin in accordance with §725.33.

(2) TERA requirements. Any person who submits a TERA, should strictly limit confidentiality claims to that information which is confidential and proprietary to the business. If any information in such a submission is claimed as confidential business information, the submitter must have available for each of those claims, and agree to furnish to EPA upon request, written answers to the questions in paragraphs (d) and (e) of this section.

(b) Claims applicable to the period after commencement of manufacture or import for general commercial use. (1) If a submitter claimed portions of the microorganism identity confidential in the MCAN and wants the identity to be listed on the confidential Inventory, the claim must be reasserted and substantiated at the time the Notice of Commencement (NOC) is submitted under §725.190. Otherwise, EPA will list the specific microorganism identity on the public Inventory.

(2) The submitter must substantiate the claim for confidentiality of the microorganism identity by answering all of the questions in paragraphs (c), (d), and (e) in this section. In addition, the following questions must be answered:

(i) What harmful effects to the company's or institution's competitive position, if any, would result if EPA publishes on the Inventory the identity of the microorganism? How could a competitor use such information given the fact that the identity of the microorganism otherwise would appear on the TSCA Inventory with no link between the microorganism and the company or institution? How substantial would the harmful effects of disclosure be? What is the causal relationship between the disclosure and the harmful effects?

(ii) Has the identity of the microorganism been kept confidential to the extent that competitors do not know it is being manufactured or imported for general commercial use by anyone?

(c) General questions. The following questions must be answered in detail for each confidentiality claim:

(1) For what period of time is a claim of confidentiality being asserted? If the claim is to extend until a certain event or point in time, indicate that event or time period. Explain why the information should remain confidential until such point.

(2) Briefly describe any physical or procedural restrictions within the company or institution relating to the use and storage of the information claimed as confidential. What other steps, if any, apply to use or further disclosure of the information?

(3) Has the information claimed as confidential been disclosed to individuals outside of the company or institution? Will it be disclosed to such persons in the future? If so, what restrictions, if any, apply to use or further disclosure of the information?

(4) Does the information claimed as confidential appear, or is it referred to, in any of the following questions? If the answer is yes to any of these questions, indicate where the information appears and explain why it should nonetheless be treated as confidential.

(i) Advertising or promotional materials for the microorganism or the resulting end product?

(ii) Material safety data sheets or other similar materials for the microorganism or the resulting end product?

(iii) Professional or trade publications?

(iv) Any other media available to the public or to competitors?

(v) Patents?

(vi) Local, State, or Federal agency public files?

(5) Has EPA, another Federal agency, a Federal court, or a State made any confidentiality determination regarding the information claimed as confidential? If so, provide copies of such determinations.

(6) For each type of information claimed confidential, describe the harm to the company's or institution's competitive position that would result if this information were disclosed. Why would this harm be substantial? How could a competitor use such information? What is the causal connection between the disclosure and harm?

(7) If EPA disclosed to the public the information claimed as confidential, how difficult would it be for the competitor to enter the market for the resulting product? Consider such constraints as capital and marketing cost, specialized technical expertise, or unusual processes.

(d) Microorganism identity and production method. If confidentiality claims are asserted for the identity of the microorganism or information on how the microorganism is produced, the following questions must be answered:

(1) Has the microorganism or method of production been patented in the U.S. or elsewhere? If so, why is confidentiality necessary?

(2) Does the microorganism leave the site of production or testing in a form which is accessible to the public or to competitors? What is the cost to a competitor, in time and money, to develop appropriate use conditions? What factors facilitate or impede product analysis?

(3) For each additional type of information claimed as confidential, explain what harm would result from disclosure of each type of information if the identity of the microorganism were to remain confidential.

(e) Health and safety studies of microorganisms. If confidentiality claims are asserted for information in a health or safety study of a microorganism, the following questions must be answered:

(1) Would the disclosure of the information claimed confidential reveal: confidential process information, or information unrelated to the effects of the microorganism on health and the environment. Describe the causal connection between the disclosure and harm.

(2) Does the company or institution assert that disclosure of the microorganism identity is not necessary to interpret any health and safety studies which have been submitted? If so, explain

how a less specific identity would be sufficient to interpret the studies.

§725.95 Public file.

All information submitted, including any health and safety study of a microorganism and other supporting documentation, will become part of the public file for that submission, unless such materials are claimed confidential. In addition, EPA may add materials to the public file, unless such materials are claimed confidential. Any of the nonconfidential material described in this subpart will be available for public inspection in the TSCA Public Docket Office, Rm. NE-B607, 401 M St., SW., Washington, DC, between the hours of noon to 4 p.m., Monday through Friday, excluding legal holidays.

Subpart D -- Microbial Commercial Activities Notification Requirements

§725.100 Scope and purpose.

(a) This subpart establishes procedures for submission of a notice to EPA under section 5(a) of the Act for persons who manufacture, import, or process microorganisms for commercial purposes. This notice is called a Microbial Commercial Activity Notice (MCAN). It is expected that MCANs will in general only be submitted for microorganisms intended for general commercial use. Persons who manufacture, import, or process a microorganism in small quantities solely for research and development as defined in §725.3 are not required to submit a notice to EPA. Persons who manufacture, import, or process a microorganism for research and development activities that do not fit the definition of small quantities solely for research and development may nonetheless qualify for more limited reporting requirements in Subpart E, including the TERA which can be used for review of research and development involving environmental release.

(b) Persons subject to MCAN submission are described in §725.105.

(c) Exclusions and exemptions specific to MCAN submissions are described in §725.110.

(d) Submission requirements applicable specifically to MCANs are described at §725.150.

(e) Data requirements for MCANs are set forth in §§725.155 and 725.160.

(f) EPA review procedures specific to MCANs are set forth in §725.170.

(g) Subparts A through C of this part apply to any MCAN submitted under this subpart.

§725.105 Persons who must report.

(a) Manufacturers of new microorganisms. (1) MCAN submission is required for any person who intends to manufacture for commercial purposes in the United States a new microorganism. Exclusions are described in §725.110.

(2) If a person contracts with a manufacturer to produce or process a new microorganism and the manufacturer produces or processes the microorganism exclusively for that person, and that person specifies the identity of the microorganism, and controls the total amount produced and the basic technology for the plant process, then that person must submit the MCAN. If it is unclear who must report, EPA should be contacted to determine who must submit the MCAN.

(3) Only manufacturers that are incorporated, licensed, or doing business in the United States

may submit a MCAN.

(b) Importers of new microorganisms. (1) MCAN submission is required for a person who intends to import into the United States for commercial purposes a new microorganism. Exclusions are described in §725.110.

(2) When several persons are involved in an import transaction, the MCAN must be submitted by the principal importer. If no one person fits the principal importer definition in a particular transaction, the importer should contact EPA to determine who must submit the MCAN for that transaction.

(3) Except as otherwise provided in paragraph (b)(4) of this section, the provisions of this subpart D apply to each person who submits a MCAN for a new microorganism which such person intends to import for a commercial purpose. In addition, each importer must comply with paragraph (b)(4) of this section.

(4) EPA will hold the principal importer, or the importer that EPA determines must submit the MCAN when there is no principal importer under paragraph (b)(2) of this section, liable for complying with this part, for completing the MCAN, and for the completeness and truthfulness of all information which it submits.

(c) Manufacturers, importers, or processors of microorganisms for a significant new use. MCAN submission is required for any person who intends to manufacture, import, or process for commercial purposes a microorganism identified as having one or more significant new uses in subpart M of this part, and who intends either to engage in a designated significant new use of the microorganism or intends to distribute it in commerce. Persons excluded from reporting on significant new uses of microorganisms and additional procedures for reporting are described in subpart L of this part.

§725.110 Persons not subject to this subpart.

Persons are not subject to the requirements of this subpart for the following activities:

- (a) Manufacturing, importing, or processing solely for research and development microorganisms that meet the requirements for an exemption under subpart E of this part.
- (b) Manufacturing, importing, or processing microorganisms for test marketing activities which have been granted an exemption under subpart F of this part.
- (c) Manufacturing or importing new microorganisms under the conditions of a Tier I or Tier II exemption under subpart G of this part.

§725.150 Procedural requirements for this subpart.

General requirements for all MCANs under this part are contained in subparts A through C of this part. In addition, the following requirements apply to MCANs submitted under this subpart:

- (a) When to submit a MCAN. A MCAN must be submitted at least 90 calendar days prior to manufacturing or importing a new microorganism and at least 90 calendar days prior to manufacturing, importing, or processing a microorganism for a significant new use.

(b) Section 5(b) of the Act. The submitter must comply with any applicable requirement of section 5(b) of the Act for the submission of test data.

(c) Contents of a MCAN. Each person who submits a MCAN under this subpart must provide the information and test data described in §§725.155 and 725.160.

(d) Recordkeeping. Each person who submits a MCAN under this subpart must comply with the recordkeeping requirements of §725.65.

§725.155 Information to be included in the MCAN.

(a) Each person who is required by this part to submit a MCAN must include the information specified in paragraphs (c) through (h) of this section, to the extent it is known to or reasonably ascertainable by that person. However, no person is required to include information which relates solely to exposure of humans or ecological populations outside of the United States.

(b) Each person should also submit, in writing, all other information known to or reasonably ascertainable by that person that would permit EPA to make a reasoned evaluation of the health and environmental effects of the microorganism, or any microbial mixture or article, including information on its effects on humans, animals, plants, and other microorganisms, and in the environment. The information to be submitted under this subpart includes the information listed in paragraphs (c) through (h) of this section relating to the manufacture, processing, distribution in commerce, use, and disposal of the new microorganism.

(c) Submitter identification. (1) The name and headquarters address of the submitter.

(2) The name, address, and office telephone number (including area code) of the principal technical contact representing the submitter.

(d) Microorganism identity information. Persons must submit sufficient information to allow the microorganism to be accurately and unambiguously identified for listing purposes as required by §725.12.

(1) Description of the recipient microorganism and the new microorganism. (i) Data substantiating the taxonomy of the recipient microorganism and the new microorganism to the level of strain, as appropriate. In lieu of data, EPA will accept a letter from a culture collection substantiating taxonomy, provided EPA, upon request to the submitter, may have access to the data supporting the taxonomic designation.

(ii) Information on the morphological and physiological features of the new microorganism.

(iii) Other specific data by which the new microorganism may be uniquely identified for Inventory purposes.

(2) Genetic construction of the new microorganism. (i) Data substantiating the taxonomy of the donor organism(s). In lieu of data, EPA will accept a letter from a culture collection substantiating taxonomy, provided EPA, upon request to the submitter, may have access to the data supporting the taxonomic designation.

(ii) Description of the traits for which the new microorganism has been selected or developed and other traits known to have been added or modified.

(iii) A detailed description of the genetic construction of the new microorganism, including the technique used to modify the microorganism (e.g., fusion of cells, injection of DNA,

electroporation or chemical poration, or methods used for induced mutation and selection). The description should include, for example, a description of the introduced genetic material, including any regulatory sequences and structural genes and the products of those genes; how the introduced genetic material is expected to affect behavior of the recipient; expression, alteration, and stability of the introduced genetic material; methods for vector construction and introduction; and a description of the regulatory and structural genes that are components of the introduced genetic material, including genetic maps of the introduced sequences.

(3) Phenotypic and ecological characteristics. (i) Habitat, geographical distribution, and source of the recipient microorganism.

(ii) Survival and dissemination under relevant environmental conditions including a description of methods for detecting the new or recipient microorganism(s) in the environment and the sensitivity limit of detection for these techniques.

(iii) A description of anticipated biological interactions with and effects on target organisms and other organisms such as competitors, prey, hosts, symbionts, parasites, and pathogens; a description of host range; a description of pathogenicity, infectivity, toxicity, virulence, or action as a vector of pathogens; and capacity for genetic transfer under laboratory and relevant environmental conditions.

(iv) A description of anticipated involvement in biogeochemical or biological cycling processes, involvement in rate limiting steps in mineral or nutrient cycling, or involvement in inorganic compounds cycling (such as possible sequestration or transformation of heavy metals).

(e) Byproducts. A description of the byproducts resulting from the manufacture, processing, use, and disposal of the new microorganism.

(f) Total production volume. The estimated maximum amount of the new microorganism intended to be manufactured or imported during the first year of production and the estimated maximum amount to be manufactured or imported during any consecutive 12-month period during the first 3 years of production. This estimate may be by weight or volume and should include an estimation of viability (i.e., viable cells per unit volume or colony forming units per unit dry weight).

(g) Use information. A description of intended categories of use by function and application, the estimated percent of production volume devoted to each category of use, and the percent of the new microorganism in the formulation for each commercial or consumer use.

(h) Worker exposure and environmental release. (1) For sites controlled by the submitter:

(i) The identity of sites where the new microorganism will be manufactured, processed, or used. For purposes of this section, the site for a person who imports a new microorganism is the site of the operating unit within the person's organization which is directly responsible for importing the new microorganism and which controls the import transaction. The import site may in some cases be the organization's headquarters office in the United States.

(ii) A process description of each manufacture, processing, and use operation, which includes a diagram of the major unit operations and conversions, the identity and entry point of all feedstocks, and the identity of any possible points of release of the new microorganism from the process, including a description of all controls, including engineering controls, used to prevent such releases.

- (iii) Worker exposure information, including worker activities, physical form of process streams which contain the new microorganism to which workers may be exposed, the number of workers, and the duration of activities.
- (iv) Information on release of the new microorganism to the environment, including the quantity and media of release and type of control technology used.
- (v) A narrative description of the intended transport of the new microorganism, including the means of transport, containment methods to be used during transport, and emergency containment procedures to be followed in case of accidental release.
- (vi) Procedures for disposal of any articles, waste, clothing, or other equipment involved in the activity, including procedures for inactivation of the new microorganism, containment, disinfection, and disposal of contaminated items.

(2) For sites not controlled by the submitter, a description of each type of processing and use operation involving the new microorganism, including identification of the estimated number of processing or use sites, situations in which worker exposure to and/or environmental release of the new microorganism will occur, the number of workers exposed and the duration of exposure; procedures for transport of the new microorganism and for disposal, including procedures for inactivation of the new microorganism; and control measures which limit worker exposure and environmental release.

§725.160 Submission of health and environmental effects data.

(a) Test data on the new microorganism in the possession or control of the submitter. (1) Except as provided in §725.25(h), and in addition to the information required by §725.155(d)(3), each MCAN must contain all test data in the submitter's possession or control which are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new microorganism or any microbial mixture or article containing the new microorganism, or any combination of such activities. This includes test data concerning the new microorganism in a pure culture or formulated form as used or as intended to be used in one of the activities listed above.

(2) A full report or standard literature citation must be submitted for the following types of test data: (i) Health effects data.

(ii) Ecological effects data.

(iii) Physical and chemical properties data.

(iv) Environmental fate characteristics.

(v) Monitoring data and other test data related to human exposure to or environmental release of the new microorganism.

(3)(i) If the data do not appear in the open scientific literature, the submitter must provide a full report. A full report includes the experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data.

(ii) If the data appear in the open scientific literature, the submitter need only provide a standard literature citation. A standard literature citation includes author, title, periodical name, date of publication, volume, and page numbers.

(4)(i) If a study, report, or test is incomplete when a person submits a MCAN, the submitter must identify the nature and purpose of the study; name and address of the laboratory developing the data; progress to date; types of data collected, significant preliminary results; and anticipated completion date.

(ii) If a test or experiment is completed before the MCAN review period ends, the person must submit the study, report, or test, as specified in paragraph (a)(3)(i) of this section, to the address listed in §725.25(c) within 10 days of receiving it, but no later than 5 days before the end of the review period. If the test or experiment is completed during the last 5 days of the review period, the submitter must immediately inform its EPA contact for that submission by telephone.

(5) For test data in the submitter's possession or control which are not listed in paragraph (a)(2) of this section, a person is not required to submit a complete report. The person must submit a summary of the data. If EPA so requests, the person must submit a full report within 10 days of the request, but no later than 5 days before the end of the review period.

(6) All test data described under paragraph (a) of this section are subject to these requirements, regardless of their age, quality, or results.

(b) Other data concerning the health and environmental effects of the new microorganism that are known to or reasonably ascertainable by the submitter. (1) Except as provided in §725.25(h), and in addition to the information required by §725.155(c)(3), any person who submits a MCAN must describe the following data, including any data from a health and safety study of a microorganism, if the data are related to effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the microorganism, of any microbial mixture or article containing the new microorganism, or of any combination of such activities:

(i) Any data, other than test data, in the submitter's possession or control.

(ii) Any data, including test data, which are not in the submitter's possession or control, but which are known to or reasonably ascertainable by the submitter. For the purposes of this section, data are known to or reasonably ascertainable by the submitter if the data are known to any of its employees or other agents who are associated with the research and development, test marketing, or commercial marketing of the microorganism.

(2) Data that must be described include data concerning the new microorganism in a pure culture or formulated form as used or as intended to be used in one of the activities listed in paragraph (b)(1) of this section.

(3) The description of data reported under paragraph (b) of this section must include:

(i) If the data appear in the open scientific literature, a standard literature citation, which includes the author, title, periodical name, date of publication, volume, and pages.

(ii) If the data are not available in the open scientific literature, a description of the type of data and summary of the results, if available, and the names and addresses of persons the submitter believes may have possession or control of the data.

(4) All data described in paragraph (b) of this section are subject to these requirements, regardless of their age, quality, or results; and regardless of whether they are complete at the time the MCAN is submitted.

§725.170 EPA review of the MCAN.

General procedures for review of all submissions under this part are contained in §§725.28 through 725.60. In addition, the following procedures apply to EPA review of MCANs submitted under this subpart:

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

(b) Notice of expiration of MCAN review period. (1) EPA will notify the submitter that the MCAN review period has expired or that EPA has completed its review of the MCAN. Expiration of the review period does not constitute EPA approval or certification of the new microorganism, and does not mean that EPA may not take regulatory action against the microorganism in the future.

(2) After expiration of the MCAN review period, in the absence of regulatory action by EPA under section 5(e), 5(f), or 6(a) of the Act, the submitter may manufacture or import the microorganism even if the submitter has not received notice of expiration.

(3) Early notification that EPA has completed its review does not permit commencement of manufacture or import prior to the expiration of the 90-day MCAN review period.

(c) No person submitting a MCAN in response to the requirements of this subpart may manufacture, import, or process a microorganism subject to this subpart until the review period, including all extensions and suspensions, has expired.

§725.190 Notice of commencement of manufacture or import.

(a) Applicability. Any person who commences the manufacture or import of a new microorganism for nonexempt, commercial purposes for which that person previously submitted a section 5(a) notice under this part must submit a notice of commencement (NOC) of manufacture or import.

(b) When to report. (1) If manufacture or import for nonexempt, commercial purposes begins on or after May 27, 1997, the submitter must submit the NOC to EPA no later than 30 calendar days after the first day of such manufacture or import.

(2) If manufacture or import for nonexempt, commercial purposes began or will begin before May 27, 1997, the submitter must submit the NOC by May 27, 1997.

(3) Submission of an NOC prior to the commencement of manufacture or import is a violation of section 15 of the Act.

(c) Information to be reported. The NOC must contain the following information: Specific microorganism identity, MCAN number, and the date when manufacture or import commences. If the person claimed microorganism identity confidential in the MCAN, and wants the identity

to be listed on the confidential Inventory, the claim must be reasserted and resubstantiated in accordance with §725.85(b). Otherwise, EPA will list the specific microorganism identity on the public Inventory.

(d) Where to submit. NOCs should be submitted to the address listed in §725.25(c).

Subpart E -- Exemptions for Research and Development Activities

§725.200 Scope and purpose.

- (a) This subpart describes exemptions from the reporting requirements under subpart D of this part for research and development activities involving microorganisms.
- (b) In lieu of complying with subpart D of this part, persons described in §725.205 may submit a TSCA Experimental Release Application (TERA) for research and development activities involving microorganisms or otherwise comply with this subpart.
- (c) Exemptions from part 725 are provided at §§725.232, 725.234, and 725.238.
- (d) Submission requirements specific for TERAs are described at §725.250.
- (e) Data requirements for TERAs are set forth in §§725.255 and 725.260.
- (f) EPA review procedures specific for TERAs are set forth in §§725.270 and 725.288.
- (g) Subparts A through C of this part apply to any submission under this subpart.

§725.205 Persons who may report under this subpart.

- (a) Commercial research and development activities involving new microorganisms or significant new uses of microorganisms are subject to reporting under this part unless they qualify for an exemption under this part.
- (b) Commercial purposes for research and development means that the activities are conducted with the purpose of obtaining an immediate or eventual commercial advantage for the researcher and would include:
 - (1) All research and development activities which are funded directly, in whole or in part, by a commercial entity regardless of who is actually conducting the research. Indications that the research and development activities are funded directly, in whole or in part, may include, but are not limited to:
 - (i) Situations in which a commercial entity contracts directly with a university or researcher; or
 - (ii) Situations in which a commercial entity gives a conditional grant where the commercial entity holds patent rights, or establishes a joint venture where the commercial entity holds patent or licensing rights; or
 - (iii) Any other situation in which the commercial entity intends to obtain an immediate or eventual commercial advantage for the commercial entity and/or the researcher.
 - (2) Research and development activities that are not funded directly by a commercial entity, if the researcher intends to obtain an immediate or eventual commercial advantage. Indications that the researcher intends to obtain an immediate or eventual commercial advantage may include, but are not limited to:
 - (i) The research is directed toward developing a commercially viable improvement of a product

already on the market; or

(ii) The researcher has sought or is seeking commercial funding for the purpose of developing a commercial application; or

(iii) The researcher or university has sought or is seeking a patent to protect a commercial application which the research is developing; or

(iv) Other evidence that the researcher is aware of a commercial application for the research and has directed the research toward developing that application.

(c) Certain research and development activities involving microorganisms subject to jurisdiction under the Act are exempt from reporting under this part. A person conducting research and development activities which meet the conditions for the exemptions described in §§725.232, 725.234, or 725.238 is exempt from TERA reporting under this subpart.

(d) A microorganism is not exempt from reporting under subpart D of this part if any amount of the microorganism, including as part of a mixture, is processed, distributed in commerce, or used, for any commercial purpose other than research and development.

(e) Quantities of the inactivated microorganism, or mixtures or articles containing the inactivated microorganism, remaining after completion of research and development activities may be disposed of as a waste in accordance with applicable Federal, State, and local regulations.

(f) A person who manufactures, imports, or processes a microorganism solely for research and development is not required to comply with the requirements of this section if:

(1) The person is manufacturing a microbial pesticide identified in §172.45(c), or

(2) The person is manufacturing a microbial pesticide for which an Experimental Use Permit is required, pursuant to §172.3; or

(3) The person is manufacturing a microbial pesticide for which a notification or an Experimental Use Permit is not required to be submitted.

§725.232 Activities subject to the jurisdiction of other Federal programs or agencies.

This part does not apply to any research and development activity that meets all of the following conditions.

(a) The microorganism is manufactured, imported, or processed solely for research and development activities.

(b) There is no intentional testing of a microorganism outside of a structure, as structure is defined in §725.3.

(c)(1) The person receives research funds from another Federal agency, and the funds are awarded on the condition that the research will be conducted in accordance with the relevant portions of the NIH Guidelines, or

(2) A Federal agency or program otherwise imposes the legally binding requirement that the research is to be conducted in accordance with relevant portions of the NIH Guidelines.

§725.234 Activities conducted inside a structure.

A person who manufactures, imports, or processes a microorganism is not subject to the reporting requirements under subpart D of this part if all of the following conditions are met:

- (a) The microorganism is manufactured, imported, or processed solely for research and development activities.
- (b) The microorganism is used by, or directly under the supervision of, a technically qualified individual, as defined in §725.3. The technically qualified individual must maintain documentation of the procedures selected to comply with paragraph (d) of this section and must ensure that the procedures are used.
- (c) There is no intentional testing of a microorganism outside of a structure, as structure is defined in §725.3.
- (d) Containment and/or inactivation controls. (1) Selection and use of containment and/or inactivation controls inside a structure for a particular microorganism shall take into account the following:
 - (i) Factors relevant to the organism's ability to survive in the environment.
 - (ii) Potential routes of release in air, solids and liquids; in or on waste materials and equipment; in or on people, including maintenance and custodial personnel; and in or on other organisms, such as insects and rodents.
 - (iii) Procedures for transfer of materials between facilities.
- (2) The technically qualified individual's selection of containment and/or inactivation controls shall be approved and certified by an authorized official (other than the TQI) of the institution that is conducting the test prior to the commencement of the test.
- (3) Records shall be developed and maintained describing the selection and use of containment and/or inactivation controls, as specified in §725.235(c). These records, which must be maintained at the location where the research and development activity is being conducted, shall be submitted to EPA upon written request and within the time frame specified in EPA's request.
- (4) Subsequent to EPA review of records in accordance with paragraph (d)(3) of this section, changes to the containment/inactivation controls selected under paragraph (d)(1) of this section must be made upon EPA order. Failure to comply with EPA's order shall result in automatic loss of eligibility for an exemption under this section.
- (e) The manufacturer, importer, or processor notifies all persons in its employ or to whom it directly distributes the microorganism, who are engaged in experimentation, research, or analysis on the microorganism, including the manufacture, processing, use, transport, storage, and disposal of the microorganism associated with research and development activities, of any risk to health, identified under §725.235(a), which may be associated with the microorganism. The notification must be made in accordance with §725.235(b).

§725.235 Conditions of exemption for activities conducted inside a structure.

- (a) Determination of risks. To determine whether notification under §725.234(e) is required, the manufacturer, importer, or processor must do one of the following:
 - (1) For research conducted in accordance with the NIH Guidelines, the manufacturer, importer, or processor must meet the conditions laid out at IV-B-4-d of the NIH Guidelines; or

(2) For all other research conducted in accordance with §725.234, the manufacturer, importer, or processor must review and evaluate the following information to determine whether there is reason to believe there is any risk to health which may be associated with the microorganism:

(i) Information in its possession or control concerning any significant adverse reaction of persons exposed to the microorganism which may reasonably be associated with such exposure.

(ii) Information provided to the manufacturer, importer, or processor by a supplier or any other person concerning a health risk believed to be associated with the microorganism.

(iii) Health and environmental effects data in its possession or control concerning the microorganism.

(iv) Information on health effects which accompanies any EPA rule or order issued under TSCA section 4, 5, or 6 of the Act that applies to the microorganism and of which the manufacturer, importer, or processor has knowledge.

(b) Notification to employees and others. (1) The manufacturer, importer, or processor must notify the persons identified in §725.234(e) by means of a container labeling system, conspicuous placement of notices in areas where exposure may occur, written notification to each person potentially exposed, or any other method of notification which adequately informs persons of health risks which the manufacturer, importer, or processor has reason to believe may be associated with the microorganism, as determined under paragraph (a) of this section.

(2) If the manufacturer, importer, or processor distributes a microorganism manufactured, imported, or processed under this section to persons not in its employ, the manufacturer, importer, or processor must in written form:

(i) Notify those persons that the microorganism is to be used only for research and development purposes and the requirements of §725.234 are to be met.

(ii) Provide the notice of health risks specified in paragraph (b)(1) of this section.

(3) The adequacy of any notification under this section is the responsibility of the manufacturer, importer, or processor.

(c) Recordkeeping. (1) For research conducted in accordance with the NIH Guidelines, a person who manufactures, imports, or processes a microorganism under this section must retain the following records: (i) Documentation that the NIH Guidelines have been adhered to. Such documentation shall include: (A) For experiments subject to Institutional Biosafety Committee review, or notification simultaneous with initiation of the experiment, the information submitted for review or notification, along with standard laboratory records, shall satisfy the recordkeeping requirements specified in §725.234(d)(3).

(B) For experiments exempt from Institutional Biosafety Committee review or notification simultaneous with initiation of the experiment, documentation of the exemption, along with standard laboratory records, shall satisfy the recordkeeping requirement specified in §725.234(d)(3).

(ii) Documentation of how the following requirements are satisfied under the NIH Guidelines:

(A) Copies or citations to information reviewed and evaluated to determine the need to make any notification of risk.

(B) Documentation of the nature and method of notification of risk, including copies of any labels or written notices used.

(C) The names and addresses of any persons other than the manufacturer, importer, or processor to whom the substance is distributed, the identity of the microorganism, the amount distributed, and copies of the notifications required.

(2) For all other research conducted in accordance with §725.234, a person who manufactures, imports, or processes a microorganism under this section, must maintain the following records:

(i) Records describing selection and use of containment and/or inactivation controls required by §725.234(d)(3) and certification by an authorized official required by §725.234(d)(2) for each microorganism.

(ii) Copies or citations to information reviewed and evaluated under paragraph (a) of this section to determine the need to make any notification of risk.

(iii) Documentation of the nature and method of notification under paragraph (b)(1) of this section, including copies of any labels or written notices used.

(iv) The names and addresses of any persons other than the manufacturer, importer, or processor to whom the substance is distributed, the identity of the microorganism, the amount distributed, and copies of the notifications required under paragraph (b)(2) of this section.

§725.238 Activities conducted outside a structure.

(a) Exemption. (1) Research and development activities involving intentional testing in the environment of certain microorganisms listed in §725.239 may be conducted without prior review by EPA if all of the conditions of this section and §725.239 are met.

(2) The research and development activity involving a microorganism listed in §725.239 must be conducted by, or directly under the supervision of, a technically qualified individual, as defined in §725.3.

(b) Certification. To be eligible for the exemption under this section, a manufacturer or importer must submit to EPA prior to initiation of the activity a document signed by an authorized official containing the following information:

(1) Name, address, and telephone number of the manufacturer or importer.

(2) Location, estimated duration, and planned start date of the test.

(3) Certification of the following: (i) Compliance with the conditions of the exemption specified for the microorganism in §725.239.

(ii) If state and/or local authorities have been notified of the activity, evidence of notification.

(c) Recordkeeping. Persons who conduct research and development activities under this section must comply with the recordkeeping requirements of §725.65 and retain documentation that supports their compliance with the requirements of this section and the specific requirements for the microorganism listed in §725.239.

§725.239 Use of specific microorganisms in activities conducted outside a structure.

(a) *Bradyrhizobium japonicum*. To qualify for an exemption under this section, all of the following conditions must be met for a test involving *Bradyrhizobium japonicum*:

(1) Characteristics of recipient microorganism. The recipient microorganism is limited to strains of *Bradyrhizobium japonicum*.

- (2) Modification of traits. (i) The introduced genetic material must meet the criteria for poorly mobilizable listed in §725.421(c).
- (ii) The introduced genetic material must consist only of the following components:
- (A) The structural gene(s) of interest, which have the following limitations:
- (1) For structural genes encoding marker sequences, the gene is limited to the *aadH* gene, which confers resistance to the antibiotics streptomycin and spectinomycin.
- (2) For traits other than antibiotic resistance, the structural gene must be limited to the genera *Bradyrhizobium* and *Rhizobium*.
- (B) The regulatory sequences permitting the expression of solely the gene(s) of interest.
- (C) Associated nucleotide sequences needed to move genetic material, including linkers, homopolymers, adaptors, transposons, insertion sequences, and restriction enzyme sites.
- (D) The vector nucleotide sequences needed for vector transfer.
- (E) The vector nucleotide sequences needed for vector maintenance.

- (3) Limitations on exposure. (i) The test site area must be no more than 10 terrestrial acres.
- (ii) The technically qualified individual must select appropriate methods to limit the dissemination of modified *Bradyrhizobium japonicum*.

(b) *Rhizobium meliloti*. To qualify for an exemption under this section, all of the following conditions must be met for a test involving *Rhizobium meliloti*:

- (1) Characteristics of recipient microorganism. The recipient microorganism is limited to strains of *Rhizobium meliloti*.
- (2) Modification of traits. (i) The introduced genetic material must meet the criteria for poorly mobilizable listed in §725.421(c) of this part.
- (ii) The introduced genetic material must consist only of the following components:
- (A) The structural gene(s) of interest, which have the following limitations:
- (1) For structural genes encoding marker sequences, the gene is limited to the *aadH* gene, which confers resistance to the antibiotics streptomycin and spectinomycin.
- (2) For traits other than antibiotic resistance, the structural gene must be limited to the genera *Bradyrhizobium* and *Rhizobium*.
- (B) The regulatory sequences permitting the expression of solely the gene(s) of interest.
- (C) Associated nucleotide sequences needed to move genetic material, including linkers, homopolymers, adaptors, transposons, insertion sequences, and restriction enzyme sites.
- (D) The vector nucleotide sequences needed for vector transfer.
- (E) The vector nucleotide sequences needed for vector maintenance.
- (3) Limitations on exposure. (i) The test site area must be no more than 10 terrestrial acres.
- (ii) The technically qualified individual must select appropriate methods to limit the dissemination of modified *Rhizobium meliloti*.

§725.250 Procedural requirements for the TERA.

General requirements for all submissions under this part are contained in subparts A through C of this part. In addition, the following requirements apply to TERAs submitted under this

subpart:

(a) When to submit the TERA. Each person who is eligible to submit a TERA under this subpart must submit the TERA at least 60 calendar days before the person intends to initiate the proposed research and development activity.

(b) Contents of the TERA. Each person who submits a TERA under this subpart must provide the information and test data described in §§725.255 and 725.260. In addition, the submitter must supply sufficient information to enable EPA to evaluate the effects of all activities for which approval is requested.

(c) A person may submit a TERA for one or more microorganisms and one or more research and development activities, including a research program.

(d) EPA will either approve the TERA, with or without conditions, or disapprove it under procedures established in this subpart.

(e) The manufacturer, importer, or processor who receives a TERA approval must comply with all terms of the approval, as well as conditions described in the TERA, and remains liable for compliance with all terms and conditions, regardless of who conducts the research and development activity. Any person conducting the research and development activity approved under the TERA must comply with all terms of the TERA approval, as well as the conditions described in the TERA.

(f) Recordkeeping. Persons submitting a TERA must comply with the recordkeeping requirements of §725.65. In addition, the following requirements apply to TERAs:

(1) Each person submitting a TERA under this part must retain documentation of information contained in the TERA for a period of 3 years from the date that the results of the study are submitted to the Agency.

(2) Summaries of all data, conclusions, and reports resulting from the conduct of the research and development activity under the TERA must be submitted to the EPA address identified in §725.25(c) within 1 year of the termination of the activity.

§725.255 Information to be included in the TERA.

(a) To review a TERA, EPA must have sufficient information to permit a reasoned evaluation of the health and environmental effects of the planned test in the environment. The person seeking EPA approval must submit all information known to or reasonably ascertainable by the submitter on the microorganism(s) and the research and development activity, including information not listed in paragraphs (c), (d), and (e) of this section that the person believes will be useful for EPA's risk assessment. The TERA must be in writing and must include at least the information described in the following paragraphs.

(b) When specific information is not submitted, an explanation of why such information is not available or not applicable must be included.

(c) Persons applying for a TERA, must include the submitter identification and microorganism identity information required for MCANs in §725.155(c), (d)(1), and (d)(2).

(d) Persons applying for a TERA must submit phenotypic and ecological characteristics information required in §725.155(d)(3) as it relates directly to the conditions of the proposed research and development activity.

(e) Persons applying for a TERA must also submit the following information about the proposed research and development activity:

(1) A detailed description of the proposed research and development activity. (i) The objectives and significance of the activity and a rationale for testing the microorganisms in the environment.

(ii) Number of microorganisms released (including viability per volume if applicable) and the method(s) of application or release.

(iii) Characteristics of the test site(s), including location, geographical, physical, chemical, and biological features, proximity to human habitation or activity, and description of site characteristics that would influence dispersal or confinement.

(iv) Target organisms (if the microorganism(s) to be tested has an intended target), including identification of each target organism and anticipated mechanism and result of interaction.

(v) Planned start date and duration of each activity.

(vi) If State and/or local authorities have been notified of the activity, evidence of notification.

(2) Information on monitoring, confinement, mitigation, and emergency termination procedures.

(i) Confinement procedures for the activity, access and security measures, and procedures for routine termination of the activity.

(ii) Mitigation and emergency procedures.

(iii) Measures to detect and control potential adverse effects.

(iv) Name of principal investigator and chief of site personnel responsible for emergency procedures.

(v) Personal protective equipment, engineering controls, and procedures to be followed to minimize dispersion of the microorganism(s) by people, machinery, or equipment.

(vi) Procedures for disposal of any articles, waste, clothing, machinery, or other equipment involved in the experimental release, including methods for inactivation of the microorganism(s), containment, disinfection, and disposal of contaminated items.

§725.260 Submission of health and environmental effects data.

Each TERA must contain all available data concerning actual or potential effects on health or the environment of the new microorganism that are in the possession or control of the submitter and a description of other data known to or reasonably ascertainable by the submitter that will permit a reasoned evaluation of the planned test in the environment. The data must be reported in the manner described in §725.160(a)(3) and (b)(3).

§725.270 EPA review of the TERA.

General procedures for review of all submissions under this part are contained in §§725.28

through 725.60. In addition, the following procedures apply to EPA review of applications submitted under this subpart:

(a) Length of the review period. (1) The review period for the TERA will be 60 days from the date the Document Control Officer for the Office of Pollution Prevention and Toxics receives a complete TERA, or the date EPA determines the TERA is complete under §725.33, unless EPA finds good cause for an extension under §725.56.

(2) A submitter shall not proceed with the research and development activity described in the TERA unless and until EPA provides written approval of the TERA. A submitter may receive early approval if a review is completed in less than 60 days.

(b) EPA decision regarding proposed TERA activity. (1) A decision concerning a TERA under this subpart will be made by the Administrator, or a designee.

(2) If EPA determines that the proposed research and development activity for the microorganism does not present an unreasonable risk of injury to health or the environment, EPA will notify the submitter that the TERA is approved and that the submitter can proceed with the proposed research and development activity described in the TERA.

(3) EPA may include requirements and conditions in its approval of the TERA that would be stated in the TERA approval under paragraph (c) of this section.

(4) If EPA concludes that it cannot determine that the proposed research and development activity described in the TERA will not present an unreasonable risk of injury to health or the environment, EPA will deny the TERA and will provide reasons for the denial in writing.

(c) TERA approval. (1) A TERA approval issued by EPA under this section is legally binding on the TERA submitter.

(2) When EPA approves a TERA, the submitter must conduct the research and development activity only as described in the TERA and in accordance with any requirements and conditions prescribed by EPA in its approval of the TERA.

(3) Any person who fails to conduct the research and development activity as described in the TERA and in accordance with any requirements and conditions prescribed by EPA in its approval of the TERA under this section, shall be in violation of sections 5 and 15 of the Act and be subject to civil and criminal penalties under section 16 of the Act.

§725.288 Revocation or modification of TERA approval.

(a) Significant questions about risk. (1) If, after approval of a TERA under this subpart, EPA receives information which raises significant questions about EPA's determination that the activity does not present an unreasonable risk of injury to health or the environment, EPA will notify the submitter in writing of those questions.

(2) The submitter may, within 10 days of receipt of EPA's notice, provide in writing additional

information or arguments concerning the significance of the questions and whether EPA should modify or revoke the approval of the TERA.

(3) After considering any such information and arguments, EPA will decide whether to change its determination regarding approval of the TERA.

(i) If EPA determines that the activity will not present an unreasonable risk of injury to health or the environment, it will notify the submitter in writing. To make this finding, EPA may prescribe additional conditions which must be followed by the submitter.

(ii) If EPA determines that it can no longer conclude that the activity will not present an unreasonable risk of injury to health or the environment, it will notify the submitter in writing that EPA is revoking its approval and state its reasons. In that event, the submitter must terminate the research and development activity within 48 hours of receipt of the notice in accordance with directions provided by EPA in the notice.

(b) Evidence of unreasonable risk. (1) If, after approval of a TERA under this subpart, EPA determines that the proposed research and development activity will present an unreasonable risk of injury to health or the environment, EPA will notify the submitter in writing and state its reasons.

(2) In the notice, EPA may prescribe additional safeguards to address or reduce the risk, or may instruct the submitter to suspend the research and development activities.

(3) Within 48 hours, the submitter must implement the instructions contained in the notice. The submitter may then submit additional information or arguments concerning the matters raised by EPA and whether EPA should modify or revoke the approval of the TERA in accordance with paragraph (a)(2) of this section.

(4) EPA will consider the information and arguments in accordance with paragraph (a)(3) of this section.

(5) Following consideration of the information and arguments under paragraph (a)(3) of this section, if EPA notifies the submitter that the R&D activity must be suspended or terminated, the submitter may resume the activity only upon written notice from EPA that EPA has approved resumption of the activity. In approving resumption of an activity, EPA may prescribe additional conditions which must be followed by the submitter.

(c) Modifications. If, after approval of a TERA under this subpart, the submitter concludes that it is necessary to alter the conduct of the research and development activity in a manner which would result in the activity being different from that described in the TERA agreement and any conditions EPA prescribed in its approval, the submitter must inform the EPA contact for the TERA and may not modify the activity without the approval of EPA.

Subpart F -- Exemptions for Test Marketing

§725.300 Scope and purpose.

(a) This subpart describes exemptions from the reporting requirements under subpart D of this

part for test marketing activities involving microorganisms.

(b) In lieu of complying with subpart D of this part, persons described in §725.305 may submit an application for a test marketing exemption (TME).

(c) Submission requirements specific for TME applications are described at §725.350.

(d) Data requirements for TME applications are set forth in §725.355.

(e) EPA review procedures specific for TMEs are set forth in §725.370.

(f) Subparts A through C of this part apply to any submission under this subpart.

§725.305 Persons who may apply under this subpart.

A person identified in this section may apply for a test marketing exemption. EPA may grant the exemption if the person demonstrates that the microorganism will not present an unreasonable risk of injury to health or the environment as a result of the test marketing. A person may apply under this subpart for the following test marketing activities:

(a) A person who intends to manufacture or import for commercial purposes a new microorganism.

(b) A person who intends to manufacture, import, or process for commercial purposes a microorganism identified in subpart M of this part for a significant new use.

§725.350 Procedural requirements for this subpart.

General requirements for all submissions under this part are contained in subparts A through C of this part. In addition, the following requirements apply to applications submitted under this subpart:

(a) Prenotice consultation. EPA strongly suggests that for a TME, the applicant contact EPA for a prenotice consultation regarding eligibility for a TME.

(b) When to submit a TME application. Each person who is eligible to apply for a TME under this subpart must submit the application at least 45 calendar days before the person intends to commence the test marketing activity.

(c) Recordkeeping. Each person who is granted a TME must comply with the recordkeeping requirements of §725.65. In addition, any person who obtains a TME must retain documentation of compliance with any restrictions imposed by EPA when it grants the TME. This information must be retained for 3 years from the final date of manufacture or import under the exemption.

§725.355 Information to be included in the TME application.

(a) To review a TME application, EPA must have sufficient information to permit a reasoned evaluation of the health and environmental effects of the planned test marketing activity. The person seeking EPA approval must submit all information known to or reasonably ascertainable by the person on the microorganism and the test marketing activity, including information not listed in paragraphs (c), (d), and (e) of this section that the person believes will demonstrate that the microorganism will not present an unreasonable risk of injury to health or the

environment as a result of the test marketing. The TME application must be in writing and must include at least the information described in paragraphs (b), (c), (d), and (e) of this section.

(b) When specific information is not submitted, an explanation of why such information is not available or not applicable must be included.

(c) Persons applying for a TME must submit the submitter identification and microorganism identity information required for MCANs in §725.155(c), (d)(1), and (d)(2).

(d) Persons applying for a TME must submit phenotypic and ecological characteristics information required in §725.155(d)(3) as it relates directly to the conditions of the proposed test marketing activity.

(e) Persons applying for a TME must also submit the following information about the proposed test marketing activity:

(1) Proposed test marketing activity. (i) The maximum quantity of the microorganism which the applicant will manufacture or import for test marketing.

(ii) The maximum number of persons who may be provided the microorganism during test marketing.

(iii) The maximum number of persons who may be exposed to the microorganism as a result of test marketing, including information regarding duration and route of such exposures.

(iv) A description of the test marketing activity, including its duration and how it can be distinguished from full-scale commercial production and research and development activities.

(2) Health and environmental effects data. All existing data regarding health and environmental effects of the microorganism must be reported in accordance with §725.160.

§725.370 EPA review of the TME application.

General procedures for review of all submissions under this part are contained in §§725.28 through 725.60. In addition, the following procedures apply to EPA review of TME applications submitted under this subpart:

(a) No later than 45 days after EPA receives a TME, the Agency will either approve or deny the application.

(b) A submitter may only proceed with test marketing activities after receipt of EPA approval.

(c) In approving a TME application, EPA may impose any restrictions necessary to ensure that the microorganism will not present an unreasonable risk of injury to health and the environment as a result of test marketing.

Subpart G -- General Exemptions for New Microorganisms

§725.400 Scope and purpose.

(a) This subpart describes exemptions from reporting under subpart D of this part, and from review under this part altogether, for manufacturing and importing of certain new microorganisms for commercial purposes.

- (b) Recipient microorganisms eligible for the tiered exemption from review under this part are listed in §725.420.
- (c) Criteria for the introduced genetic material contained in the new microorganisms are described in §725.421.
- (d) Physical containment and control technologies are described in §725.422.
- (e) The conditions for the Tier I exemption are listed in §725.424.
- (f) In lieu of complying with subpart D of this part, persons using recipient microorganisms eligible for the tiered exemption may submit a Tier II exemption request. The limited reporting requirements for the Tier II exemption, including data requirements, are described in §§725.450 and 725.455.
- (g) EPA review procedures for the Tier II exemption are set forth in §725.470.
- (h) Subparts A through C of this part apply to any submission under this subpart.

§725.420 Recipient microorganisms.

The following recipient microorganisms are eligible for either exemption under this subpart:

- (a) *Acetobacter aceti*.
- (b) *Aspergillus niger*.
- (c) *Aspergillus oryzae*.
- (d) *Bacillus licheniformis*.
- (e) *Bacillus subtilis*.
- (f) *Clostridium acetobutylicum*.
- (g) *Escherichia coli* K-12.
- (h) *Penicillium roqueforti*.
- (i) *Saccharomyces cerevisiae*.
- (j) *Saccharomyces uvarum*.

§725.421 Introduced genetic material.

For a new microorganism to qualify for either exemption under this subpart, introduced genetic material must meet all of the criteria listed in this section.

- (a) Limited in size. The introduced genetic material must consist only of the following:
 - (1) The structural gene(s) of interest.
 - (2) The regulatory sequences permitting the expression of solely the gene(s) of interest.
 - (3) Associated nucleotide sequences needed to move genetic material, including linkers, homopolymers, adaptors, transposons, insertion sequences, and restriction enzyme sites.
 - (4) The nucleotide sequences needed for vector transfer.
 - (5) The nucleotide sequences needed for vector maintenance.
- (b) Well-characterized. For introduced genetic material, well-characterized means that the following have been determined:
 - (1) The function of all of the products expressed from the structural gene(s).
 - (2) The function of sequences that participate in the regulation of expression of the structural

gene(s).

(3) The presence or absence of associated nucleotide sequences and their associated functions, where associated nucleotide sequences are those sequences needed to move genetic material including linkers, homopolymers, adaptors, transposons, insertion sequences, and restriction enzyme sites.

(c) Poorly mobilizable. The ability of the introduced genetic material to be transferred and mobilized is inactivated, with a resulting frequency of transfer of less than 10^{-8} transfer events per recipient.

(d) Free of certain sequences. (1) The introduced genetic material must not contain a functional portion of any of the toxin-encoding sequences described in this paragraph (d).

(i) For the purposes of this section, a functional portion of a toxin-encoding sequence means any sequence which codes for a polypeptide that has one of the following effects:

(A) It directly or indirectly contributes to toxic effects in humans. Directly contributes to toxic effects in humans means those sequences encoding polypeptides that have direct toxicity to target cells. An example of a sequence which directly contributes to toxic effects in humans is one which encodes the portion of diphtheria toxin, listed in paragraph (d)(2) of this section, capable of interacting with elongation factor 2, leading to inhibition of protein synthesis in target respiratory, heart, kidney, and nerve tissues. Indirectly contributes to toxic effects in humans means a sequence whose encoded polypeptide is not directly toxic to target cells, yet still adversely affects humans. An example of a sequence which indirectly contributes to toxic effects is the sequence which encodes the portion of the botulinum toxin, listed in paragraph (d)(3) of this section, capable of blocking the release of acetylcholine from gangliosides. Botulinum toxin affects neuromuscular junctions by its blockage of acetylcholine release, leading to irreversible relaxation of muscles and respiratory arrest.

(B) It binds a toxin or toxin precursor to target human cells.

(C) It facilitates intracellular transport of a toxin in target human cells.

(ii) While these toxins are listed (with synonyms in parentheses) in paragraphs (d)(2) through (d)(7) of this section according to the source organism, it is use of the nucleotide sequences that encode the toxins that is being restricted and not the use of the source organisms. The source organisms are listed to provide specificity in identification of sequences whose use is restricted. Although similar or identical sequences may be isolated from organisms other than those listed below in paragraphs (d)(2) through (d)(7) of this section, these comparable toxin sequences, regardless of the organism from which they are derived, must not be included in the introduced genetic material.

(2) Sequences for protein synthesis inhibitor.

Sequence Source	Toxin Name
Corynebacterium diphtheriae & C. ulcerans	Diphtheria toxin
Pseudomonas aeruginosa	Exotoxin A
Shigella dysenteriae	Shigella toxin (Shiga toxin, Shigella dysenteriae type I)

Abrus precatorius, seeds	toxin, Vero cell toxin)
Ricinus communis, seeds	Abrin
	Ricin

(3) Sequences for neurotoxins.

Sequence Source	Toxin Name
Clostridium botulinum	Neurotoxins A, B, C1, D, E, F, G (Botulinum toxins, botulinum toxins)
Clostridium tetani	Tetanus toxin (tetanospasmin)
Proteus mirabilis	Neurotoxin
Staphylococcus aureus	Alpha toxin (alpha lysin)
Yersinia pestis	Murine toxin
1 1 Snake toxins	
Bungarus caeruleus	Caeruleotoxin
Bungarus multicinctus	Beta-bungarotoxin (phospholipase)
Crotalus spp.	Crotoxin (phospholipase)
Dendroaspis viridis	Neurotoxin
Naja naja varieties	Neurotoxin
Notechia scutatus	Notexin (phospholipase)
Oxyuranus scutellatus	Taipoxin
Invertebrate toxins	
Chironex fleckeri	Neurotoxin
Androctonus australis	Neurotoxin
Centruroides sculpturatus	Neurotoxin

(4) Sequences for oxygen labile cytolysins.

Sequence Source	Toxin Name
Bacillus alve	Alveolysin
Bacillus cereus	Cereolysin
Bacillus laterosporus	Laterosporolysin
Bacillus thuringiensis	Thuringiolysin
Clostridium bifermentans	Lysin
Clostridium botulinum	Lysin
Clostridium caproicum	Lysin
Clostridium chauvoei	Delta-toxin
Clostridium histolyticum	Epsilon-toxin
Clostridium novyi	Gamma-toxin
Clostridium oedematiens	Delta-toxin
Clostridium perfringens	Theta-toxin (Perfringolysin)

Clostridium septicum	Delta-toxin
Clostridium sordellii	Lysin
Clostridium tetani	Tetanolysin
Listeria monocytogenes	Listeriolysin (A B)
Streptococcus pneumoniae	Pneumolysin
Streptococcus pyogenes	Streptolysin O (SLO)

(5) Sequences for toxins affecting membrane function.

Sequence Source	Toxin Name
Bacillus anthracis	Edema factor (Factors I II); Lethal factor (Factors II III)
Bacillus cereus	Enterotoxin (diarrheagenic toxin, mouse lethal factor)
Bordetella pertussis	Adenylate cyclase (Heat-labile factor); Pertussigen (pertussis toxin, islet activating factor, histamine sensitizing factor, lymphocytosis promoting factor)
Clostridium botulinum	C2 toxin
Clostridium difficile	Enterotoxin (toxin A)
Clostridium perfringens	Beta-toxin; Delta-toxin
Escherichia coli & other Enterobacteriaceae spp.	Heat-labile enterotoxins (LT); Heat-stable enterotoxins (STa, ST1 subtypes ST1a ST1b; also STb, STII)
Legionella pneumophila	Cytolysin
Vibrio cholerae & Vibrio mimicus	Cholera toxin (cholera toxin)

(6) Sequences that affect membrane integrity.

Sequence Source	Toxin Name
Clostridium bifermentans & other Clostridium spp	Lecithinase
Clostridium perfringens	Alpha-toxin (phospholipase C, lecithinase); Enterotoxin
Corynebacterium pyogenes & other Corynebacterium spp.	Cytolysin (phospholipase C), Ovis toxin (sphingomyelinase D)
Staphylococcus aureus	Beta-lysin (beta toxin)

(7) Sequences that are general cytotoxins.

Sequence Source	Toxin Name
Adenia digitata	Modeccin
Aeromonas hydrophila	Aerolysin (beta-lysin, cytotoxic lysin)
Clostridium difficile	Cytotoxin (toxin B)
Clostridium perfringens	Beta-toxin; Epsilon-toxin; Kappa-toxin
Escherichia coli & other Enterobacteriaceae spp.	Cytotoxin (Shiga-like toxin, Vero cell toxin)
Pseudomonas aeruginosa	Proteases

Staphylococcus aureus	Gamma lysin (Gamma toxin); Enterotoxins (SEA, SEB, SEC, SED SEE); Pyrogenic exotoxins A B; Toxic shock syndrome toxins (TSST-1)
Staphylococcus aureus & Pseudomonas aeruginosa	Leucocidin (leukocidin, cytotoxin)
Streptococcus pyogenes	Streptolysin S (SLS); Erythrogenic toxins (scarlet fever toxins, pyrogenic exotoxins)
Yersinia enterocolitica	Heat-stable enterotoxins (ST)

§725.422 Physical containment and control technologies.

The manufacturer must meet all of the following criteria for physical containment and control technologies for any facility in which the new microorganism will be used for a Tier I exemption; these criteria also serve as guidance for a Tier II exemption.

- (a) Use a structure that is designed and operated to contain the new microorganism.
- (b) Control access to the structure.
- (c) Provide written, published, and implemented procedures for the safety of personnel and control of hygiene.
- (d) Use inactivation procedures demonstrated and documented to be effective against the new microorganism contained in liquid and solid wastes prior to disposal of the wastes. The inactivation procedures must reduce viable microbial populations by at least 6 logs in liquid and solid wastes.
- (e) Use features known to be effective in minimizing viable microbial populations in aerosols and exhaust gases released from the structure, and document use of such features.
- (f) Use systems for controlling dissemination of the new microorganism through other routes, and document use of such features.
- (g) Have in place emergency clean-up procedures.

§725.424 Requirements for the Tier I exemption.

- (a) Conditions of exemption. The manufacture or import of a new microorganism for commercial purposes is not subject to review under this part if all of the following conditions are met for all activities involving the new microorganism:
 - (1) The recipient microorganism is listed in and meets any requirements specified in §725.420.
 - (2) The introduced genetic material meets the criteria under §725.421.
 - (3) The physical containment and control technologies of any facility in which the microorganism will be manufactured, processed, or used meet the criteria under §725.422.
 - (4) The manufacturer or importer submits a certification described in paragraph (b) of this section to EPA at least 10 days before commencing initial manufacture or import of a new microorganism derived from a recipient microorganism listed in §725.420.
 - (5) The manufacturer or importer complies with the recordkeeping requirements of §725.65 and maintains records for the initial and subsequent uses of the new microorganism that verify compliance with the following:
 - (i) The certifications made in paragraph (b) of this section.
 - (ii) All the eligibility criteria for the Tier I exemption including the criteria for the recipient

microorganism, the introduced genetic material, the physical containment and control technologies.

(b) Certification. To be eligible for the Tier I exemption under this subpart, the manufacturer or importer must submit to EPA a document signed by a responsible company official containing the information listed in this paragraph.

(1) Name and address of manufacturer or importer.

(2) Date when manufacture or import is expected to begin.

(3) The identification (genus, species) of the recipient microorganism listed in §725.420 which is being used to create the new microorganism which will be used under the conditions of the Tier I exemption.

(4) Certification of the following:

(i) Compliance with the introduced genetic material criteria described in §725.421.

(ii) Compliance with the containment requirements described in §725.422, including the provision in paragraph (a)(3) of this section.

(5) The site of waste disposal and the type of permits for disposal, the permit numbers and the institutions issuing the permits.

(6) The certification statement required in §725.25(b). Certification of submission of test data is not required for the Tier I exemption.

§725.426 Applicability of the Tier I exemption.

The Tier I exemption under §725.424 applies only to a manufacturer or importer of a new microorganism that certifies that the microorganism will be used in all cases in compliance with §§725.420, 725.421, and 725.422.

§725.428 Requirements for the Tier II exemption.

The manufacturer or importer of a new microorganism for commercial purposes may submit to EPA a Tier II exemption request in lieu of a MCAN under subpart D of this part if all of the following conditions are met:

(a) The recipient microorganism is listed in and meets any requirements specified in §725.420.

(b) The introduced genetic material meets the criteria under §725.421.

(c) Adequate physical containment and control technologies are used. The criteria listed under §725.422 for physical containment and control technologies of facilities should be used as guidance to satisfy the Tier II exemption request data requirements listed at §725.455(d). EPA will review proposed process and containment procedures as part of the submission for a Tier II exemption under this section.

§725.450 Procedural requirements for the Tier II exemption.

General requirements for all submissions under this part are contained in §725.25. In addition, the following requirements apply to requests submitted under this subpart:

(a) Prenotice consultation. EPA strongly suggests that for a Tier II exemption, the submitter

contact the Agency for a prenotice consultation regarding eligibility for the exemption.

(b) When to submit the Tier II exemption request. Each person who is eligible to submit a Tier II exemption request under this subpart must submit the request at least 45 calendar days before the person intends to commence manufacture or import.

(c) Contents of the Tier II exemption request. Each person who submits a request under this subpart must provide the information described in §§725.428 and 725.455, as well as information known to or reasonably ascertainable by the person that would permit EPA to determine that use of the microorganism, under the conditions specified in the request, will not present an unreasonable risk of injury to health or the environment.

(d) Recordkeeping. Each person who submits a request under this subpart must comply with the recordkeeping requirements of §725.65. In addition, the submitter should maintain records which contain information that verifies compliance with the following:

(1) The certifications made in the request.

(2) All the eligibility criteria for the Tier II exemption request including the criteria for the recipient microorganism, the introduced genetic material, the physical containment and control technologies.

§725.455 Information to be included in the Tier II exemption request.

The submitter must indicate clearly that the submission is a Tier II exemption request for a microorganism instead of the MCAN under subpart D of this part and must submit the following information:

(a) Submitter identification. (1) The name and headquarters address of the submitter.

(2) The name, address, and office telephone number (including area code) of the principal technical contact representing the submitter.

(b) Microorganism identity information. (1) Identification (genus, species, and strain) of the recipient microorganism. Genus, species designation should be substantiated by a letter from a culture collection or a brief summary of the results of tests conducted for taxonomic identification.

(2) Type of genetic modification and the function of the introduced genetic material.

(3) Site of insertion.

(4) Certification of compliance with the introduced genetic material criteria described in §725.421.

(c) Production volume. Production volume, including total liters per year, and the maximum cell concentration achieved during the production process.

(d) Process and containment information. (1) A description of the process including the following: (i) Identity and location of the manufacturing site(s).

(ii) Process flow diagram illustrating the production process, including downstream separations, and indicating the containment envelope around the appropriate equipment.

- (iii) Identities and quantities of feedstocks.
 - (iv) Sources and quantities of potential releases to both the workplace and environment, and a description of engineering controls, inactivation procedures, and other measures which will reduce worker exposure and environmental releases.
 - (v) A description of procedures which will be undertaken to prevent fugitive emissions, i.e. leak detection and repair program.
 - (vi) A description of procedures/safeguards to prevent and mitigate accidental releases to the workplace and the environment.
 - (2) Certification of those elements of the containment criteria described in §725.422 with which the manufacturer is in compliance, including stating by number the elements with which the manufacturer is in full compliance.
- (e) The site of waste disposal and the type of permits for disposal, the permit numbers and the institutions issuing the permits.
- (f) The certification statement required in §725.25(b). Certification of submission of test data is not required for the Tier II exemption.

§725.470 EPA review of the Tier II exemption request.

General procedures for review of all submissions under this part are contained in §§725.28 through 725.60. In addition, the following procedures apply to EPA review of Tier II exemption requests submitted under this subpart:

- (a) Length of the review period. The review period for the request will be 45 days from the date the Document Control Officer for the Office of Pollution Prevention and Toxics receives a complete request, or the date EPA determines the request is complete under §725.33, unless the Agency extends the review period for good cause under §725.56.
- (b) Criteria for review. EPA will review the request to determine that the new microorganism complies with §725.428 and that its manufacture, processing, use, and disposal as described in the request will not present an unreasonable risk of injury to health or the environment.
- (c) EPA decision regarding the Tier II exemption request. A decision concerning a request under this subpart will be made by the Administrator, or a designee.
- (d) Determination that the microorganism is ineligible for a Tier II review. (1) EPA may determine that the manufacturer or importer is not eligible for Tier II review, because the microorganism does not meet the criteria under §725.428 or the Administrator, or a designee, decides that there is insufficient information to determine that the conditions of manufacture, processing, use, or disposal of the microorganism as described in the request will not present an unreasonable risk to health or the environment.
 - (2) If the Agency makes this determination, the Administrator, or a designee will notify the manufacturer or importer by telephone, followed by a letter, that the request has been denied. The letter will explain reasons for the denial.
 - (3) If the request is denied, the manufacturer or importer may submit the information necessary

to constitute a MCAN under subpart D of this part.

(e) Approval or denial of the Tier II exemption request. (1) No later than 45 days after EPA receives a request, the Agency will either approve or deny the request.

(2) In approving a request, EPA may impose any restrictions necessary to ensure that the microorganism will not present an unreasonable risk of injury to health and the environment as a result of general commercial use.

(f) EPA may seek to enjoin the manufacture or import of a microorganism in violation of this subpart, or act to seize any microorganism manufactured or imported in violation of this section or take other actions under the authority of sections 7 or 17 of the Act.

(g) A manufacturer or importer may only proceed after receipt of EPA approval.

Subparts H-K [Reserved]

Subpart L -- Additional Procedures for Reporting on Significant New Uses of Microorganisms

§725.900 Scope and purpose.

(a) This subpart describes additional provisions governing submission of MCANs for microorganisms subject to significant new use rules identified in subpart M of this part.

(b) Manufacturers, importers, and processors described in §725.105(c) must submit a MCAN under subpart D of this part for significant new uses of microorganisms described in subpart M of this part, unless they are excluded under §§725.910 or 725.912.

(c) Section 725.920 discusses exports and imports.

(d) Additional recordkeeping requirements specific to significant new uses of microorganisms are described in §725.950.

(e) Section 725.975 describes how EPA will approve alternative means of complying with significant new use requirements designated in subpart M of this part.

(f) Expedited procedures for promulgating significant new use requirements under subpart M of this part for microorganisms subject to section 5(e) orders are discussed in §§725.980 and 725.984.

(g) This subpart L contains provisions governing submission and review of notices for the microorganisms and significant new uses identified in subpart M of this part. The provisions of this subpart L apply to the microorganisms and significant new uses identified in subpart M of this part, except to the extent that they are specifically modified or supplanted by specific requirements in subpart M of this part. In the event of a conflict between the provisions of this subpart L and the provisions of subpart M of this part, the provisions of subpart M of this part shall govern.

(h) The provisions of subparts A through F of this part also apply to subparts L and M of this part. For purposes of subparts L and M of this part, wherever the words "microorganism" or "new microorganism" appear in subparts A through F of this part, it shall mean the microorganism subject to subparts L and M of this part. In the event of a conflict between the provisions of subparts A through F and the provisions of subparts L and M of this part, the provisions of subparts L and M of this part shall govern.

§725.910 Persons excluded from reporting significant new uses.

(a) A person who intends to manufacture, import, or process a microorganism identified in subpart M of this part and who intends to distribute it in commerce is not required to submit a MCAN under subpart D of this part, if that person can document one or more of the following as to each recipient of the microorganism from that person:

(1) That the person has notified the recipient, in writing, of the specific section in subpart M of this part which identifies the microorganism and its designated significant new uses, or

(2) That the recipient has knowledge of the specific section in subpart M of this part which identifies the microorganism and its designated significant new uses, or

(3) That the recipient cannot undertake any significant new use described in the specific section in subpart M of this part.

(b) The manufacturer, importer, or processor described in paragraph (a) of this section must submit a MCAN under subpart D of this part, if such person has knowledge at the time of commercial distribution of the microorganism identified in the specific section in subpart M of this part that a recipient intends to engage in a designated significant new use of that microorganism without submitting a MCAN under this part.

(c) A person who processes a microorganism identified in a specific section in subpart M of this part for a significant new use of that microorganism is not required to submit a MCAN if that person can document each of the following:

(1) That the person does not know the specific microorganism identity of the microorganism being processed, and

(2) That the person is processing the microorganism without knowledge that the microorganism is identified in subpart M of this part.

(d)(1) If at any time after commencing distribution in commerce of a microorganism identified in a specific section in subpart M of this part, a person who manufactures, imports, or processes a microorganism described in subpart M of this part and distributes it in commerce has knowledge that a recipient of the microorganism is engaging in a significant new use of that microorganism designated in that section without submitting a MCAN under this part, the person is required to cease supplying the microorganism to that recipient and to submit a MCAN for that microorganism and significant new use, unless the person is able to document each of the following:

(i) That the person has notified the recipient and EPA enforcement authorities (at the address in

paragraph (d)(1)(iii) of this section), in writing within 15 working days of the time the person develops knowledge that the recipient is engaging in a significant new use, that the recipient is engaging in a significant new use without submitting a MCAN.

(ii) That, within 15 working days of notifying the recipient as described in paragraph (d)(1)(i) of this section, the person received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of the applicable section in subpart M of this part and will not engage in the significant new use.

(iii) That the person has promptly provided EPA enforcement authorities with a copy of the recipient's statement of assurance described in paragraph (d)(1)(ii) of this section. The copy must be sent to the Director, Office of Compliance (2221A), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(2) If EPA notifies the manufacturer, importer, or processor that the recipient is engaging in a significant new use after providing the statement of assurance described in paragraph (d)(1)(ii) of this section and without submitting a MCAN under this part, the manufacturer, importer, or processor shall immediately cease distribution to that recipient until the manufacturer, importer, or processor or the recipient has submitted a MCAN under this part and the MCAN review period has ended.

(3) If, after receiving a statement of assurance from a recipient under paragraph (d)(1)(ii) of this section, a manufacturer, importer, or processor has knowledge that the recipient is engaging in a significant new use without submitting a MCAN under this part, the manufacturer, importer, or processor must immediately cease distributing the microorganism to that recipient and notify EPA enforcement authorities at the address identified in paragraph (d)(1)(iii) of this section. The manufacturer, importer, or processor may not resume distribution to that recipient until any one of the following has occurred:

(i) The manufacturer, importer, or processor has submitted a MCAN under this part and the MCAN review period has ended.

(ii) The recipient has submitted a MCAN under this part and the MCAN review period has ended.

(iii) The manufacturer, importer, or processor has received notice from EPA enforcement authorities that it may resume distribution to that recipient.

§725.912 Exemptions.

Persons identified in §725.105(c) are not required to submit a MCAN under subpart D of this part for a microorganism identified in subpart M of this part, unless otherwise specified in a specific section in subpart M, if:

(a) The person submits a MCAN for the microorganism prior to the promulgation date of the section in subpart M of this part which identifies the microorganism, and the person receives written notification of compliance from EPA prior to the effective date of such section. The MCAN submitter must comply with any applicable requirement of section 5(b) of the Act. The MCAN must include the information and test data specified in section 5(d)(1) of the Act. For purposes of this exemption, the specific section in subpart M of this part which identifies the microorganism and §§725.3, 725.15, 725.65, 725.70, 725.75, 725.100, and 725.900 apply; after the effective date of the section in subpart M of this part which identifies the microorganism,

§§725.105 and 725.910 apply and §725.920 continues to apply. EPA will provide the MCAN submitter with written notification of compliance only if one of the following occurs:

(1) EPA is unable to make the finding that the activities described in the MCAN will or may present an unreasonable risk of injury to health or the environment under reasonably foreseeable circumstances, or

(2) EPA and the person negotiate a consent order under section 5(e) of the Act, such order to take effect on the effective date of the section in subpart M of this part which identifies the microorganism.

(b) The person is operating under the terms of a consent order issued under section 5(e) of the Act applicable to that person. If a provision of such section 5(e) order is inconsistent with a specific significant new use identified in subpart M of this part, abiding by the provision of the section 5(e) order exempts the person from submitting a MCAN for that specific significant new use.

§725.920 Exports and imports.

(a) Exports. Persons who intend to export a microorganism identified in subpart M of this part, or in any proposed rule which would amend subpart M of this part, are subject to the export notification provisions of section 12(b) of the Act. The regulations that interpret section 12(b) appear at part 707 of this chapter.

(b) Imports. Persons who import a substance identified in a specific section in subpart M of this part are subject to the import certification requirements under section 13 of the Act, which are codified at 19 CFR §§12.118 through 12.127 and 127.28(i). The EPA policy in support of the import certification requirements appears at part 707 of this chapter.

§725.950 Additional recordkeeping requirements.

Persons submitting a MCAN for a significant new use of a microorganism must comply with the recordkeeping requirements of §725.65. In addition, the following requirements apply:

(a) At the time EPA adds a microorganism to subpart M of this part, EPA may specify appropriate recordkeeping requirements. Each manufacturer, importer, and processor of the microorganism shall maintain the records for 3 years from the date of their creation.

(b) The records required to be maintained under this section may include the following:

(1) Records documenting the information contained in the MCAN submitted to EPA.

(2) Records documenting the manufacture and importation volume of the microorganism and the corresponding dates of manufacture and import.

(3) Records documenting volumes of the microorganism purchased domestically by processors of the microorganism, names and addresses of suppliers and corresponding dates of purchase.

(4) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the manufacturer, importer, or processor directly sells or transfers the microorganism, the date of each sale or transfer, and the quantity of the microorganism sold or transferred on such date.

§725.975 EPA approval of alternative control measures.

(a) In certain sections of subpart M of this part, significant new uses for the identified microorganisms are described as the failure to establish and implement programs providing for the use of either: specific measures to control worker exposure to or release of microorganisms which are identified in such sections, or alternative measures to control worker exposure or environmental release which EPA has determined provide substantially the same degree of protection as the specified control measures. Persons who manufacture, import, or process a microorganism identified in such sections and who intend to employ alternative measures to control worker exposure or environmental release must submit a request to EPA for a determination of equivalency before commencing manufacture, import, or processing involving the alternative control measures.

(b) A request for a determination of equivalency must be submitted in writing to the Office of Pollution Prevention and Toxics, Document Control Officer, 7407, 1200 Pennsylvania Ave., NW., Washington, DC 20460: ATTN: SNUR Equivalency Determination, and must contain:

(1) The name of the submitter.

(2) The specific identity of the microorganism.

(3) The citation for the specific section in subpart M of this part which pertains to the microorganism for which the request is being submitted.

(4) A detailed description of the activities involved.

(5) The specifications of the alternative worker exposure control measures or environmental release control measures.

(6) A detailed analysis explaining why such alternative control measures provide substantially the same degree of protection as the specific control measures identified in the specific section in subpart M of this part which pertains to the microorganism for which the request is being submitted.

(7) The data and information described in §§725.155 and 725.160. If such data and information have already been submitted to EPA's Office of Pollution Prevention and Toxics, the submitter need only document that it was previously submitted, to whom, and the date it was submitted.

(c) Requests for determinations of equivalency will be reviewed by EPA within 45 days. Determinations under this paragraph will be made by the Director, or a designee. Notice of the results of such determinations will be mailed to the submitter.

(d) If EPA notifies the submitter under paragraph (c) of this section that EPA has determined that the alternative control measures provide substantially the same degree of protection as the specified control measures identified in the specific section of subpart M of this part which pertains to the microorganism for which the request is being submitted, the submitter may commence manufacture, import, or processing in accordance with the specifications for

alternative worker exposure control measures or environmental release control measures identified in the submitter's request, and may alter any corresponding notification to workers to reflect such alternative controls. Deviations from the activities described in the EPA notification constitute a significant new use and are subject to the requirements of this part.

§725.980 Expedited procedures for issuing significant new use rules for microorganisms subject to section 5(e) orders.

(a) Selection of microorganisms. (1) In accordance with the expedited process specified in this section, EPA will issue significant new use notification requirements for each new microorganism that, after MCAN review under subpart D of this part, becomes subject to a final order issued under section 5(e) of the Act, except for an order that prohibits manufacture and import of the microorganism, unless EPA determines that significant new use notification requirements are not needed for the microorganism.

(2) If EPA determines that significant new use notifications requirements are not needed for a microorganism that is subject to a final order issued under section 5(e) of the Act, EPA will issue a notice in the FEDERAL REGISTER explaining why the significant new use requirements are not needed.

(b) Designation of requirements. (1) The significant new use notification and other specific requirements will be based on and be consistent with the provisions included in the final order issued for the microorganism under section 5(e) of the Act. EPA may also designate additional activities as significant new uses which will be subject to notification.

(2) Significant new use requirements and other specific requirements designated under this section will be listed in subpart M of this part. For each microorganism, subpart M of this part will identify:

(i) The microorganism name.

(ii) The activities designated as significant new uses.

(iii) Other specific requirements applicable to the microorganism, including recordkeeping requirements or any other requirements included in the final section 5(e) order.

(c) Procedures for issuing significant new use rules. (1) Possible processes. EPA will issue significant new use rules (SNURs) under this section by one of the following three processes: direct final rulemaking, interim final rulemaking, or notice and comment rulemaking. EPA will use the direct final rulemaking process to issue significant new use rules unless it determines that, in a particular case, one of the other processes is more appropriate.

(2) Notice in the FEDERAL REGISTER. FEDERAL REGISTER documents issued to propose or establish significant new uses under this section will contain the following:

(i) The microorganism identity or, if its specific identity is claimed confidential, an appropriate generic microorganism name and an accession number assigned by EPA.

(ii) The MCAN number.

(iii) A summary of EPA's findings under section 5(e)(1)(A) of the Act for the final order issued under section 5(e).

(iv) Designation of the significant new uses subject to, or proposed to be subject to, notification and any other applicable requirements.

(v) Any modification of subpart L of this part applicable to the specific microorganism and significant new uses.

(vi) If the FEDERAL REGISTER document establishes a final rule, or notifies the public that a final rule will not be issued after public comment has been received, the document will describe comments received and EPA's response.

(3) Direct final rulemaking. (i) EPA will use direct final rulemaking to issue a significant new use rule, when specific requirements will be based on and be consistent with the provisions included in the final order issued for the microorganism under section 5(e) of the Act. EPA will issue a final rule in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new microorganism.

(ii) The FEDERAL REGISTER document will state that, unless written notice is received by EPA within 30 days of publication that someone wishes to submit adverse or critical comments, the rule will be effective 60 days from the date of publication. The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the FEDERAL REGISTER, and a proposal will be published in the proposed rule section of the FEDERAL REGISTER. The proposal will establish a 30-day comment period.

(iii) If EPA, having considered any timely comments submitted in response to the proposal, decides to establish notification requirements under this section, EPA will issue a final rule adding the microorganism to subpart M of this part and designating the significant new uses subject to notification.

(4) Interim final rulemaking. (i) EPA will use the interim final rulemaking procedure to issue a significant new use rule, when specific requirements will be based on and be consistent with the provisions included in the final order issued for the microorganism under section 5(e) of the Act. The Agency will issue an interim final rule in the FEDERAL REGISTER following its decision to develop a significant new use rule for a specific new microorganism. The document will state EPA's reasons for using the interim final rulemaking procedure.

(A) The significant new use rule will take effect on the date of publication.

(B) Persons will be given 30 days from the date of publication to submit comments.

(ii) Interim final rules issued under this section shall cease to be in effect 180 days after publication unless, within the 180-day period, EPA issues a final rule in the FEDERAL REGISTER responding to any written comments received during the 30-day comment period specified in paragraph (c)(4)(i)(B) of this section and promulgating final significant new use notification requirements and other requirements for the microorganism.

(5) Notice and comment rulemaking. (i) EPA will use a notice and comment procedure to issue a significant new use rule, when EPA is designating additional activities which are not provisions included in the final order issued for the microorganism under section 5(e) of the Act as significant new uses which will be subject to notification. EPA will issue a proposal in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new microorganism. Persons will be given 30 days to comment on whether EPA should establish notification requirements for the microorganism under this part.

(ii) If EPA, having considered any timely comments, decides to establish notification requirements under this section, EPA will issue a final rule adding the microorganism to subpart

M of this part and designating the significant new uses subject to notification.

(d) Schedule for issuing significant new use rules. (1) Unless EPA determines that a significant new use rule should not be issued under this section, EPA will issue a proposed rule, a direct final rule, or an interim final rule within 180 days of receipt of a valid notice of commencement under §725.190.

(2) If EPA receives adverse or critical significant comments following publication of a proposed or interim final rule, EPA will either withdraw the rule or issue a final rule addressing the comments received.

§725.984 Modification or revocation of certain notification requirements.

(a) Criteria for modification or revocation. EPA may at any time modify or revoke significant new use notification requirements for a microorganism which has been added to subpart M of this part using the procedures of §725.980. Such action may be taken under this section if EPA makes one of the following determinations, unless other information shows that the requirements should be retained:

(1) Test data or other information obtained by EPA provide a reasonable basis for concluding that activities designated as significant new uses of the microorganism will not present an unreasonable risk of injury to health or the environment.

(2) EPA has promulgated a rule under section 4 or 6 of the Act, or EPA or another agency has taken action under another law, for the microorganism that eliminates the need for significant new use notification under section 5(a)(2) of the Act.

(3) EPA has received MCANs for some or all of the activities designated as significant new uses of the microorganism and, after reviewing such MCANs, concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities.

(4) EPA has examined new information, or has reexamined the test data or other information supporting its finding under section 5(e)(1)(A)(ii)(I) of the Act and has concluded that a rational basis no longer exists for the findings that activities involving the microorganism may present an unreasonable risk of injury to health or the environment required under section 5(e)(1)(A) of the Act.

(5) Certain activities involving the microorganism have been designated as significant new uses pending the completion of testing, and adequate test data developed in accordance with applicable procedures and criteria have been submitted to EPA.

(b) Procedures for limitation or revocation. Modification or revocation of significant new use notification requirements for a microorganism that has been added to subpart M of this part using the procedures described in §725.980 may occur either at EPA's initiative or in response to a written request.

(1) Any affected person may request modification or revocation of significant new use

notification requirements for a microorganism that has been added to subpart M of this part using the procedures described in §725.980 by writing to the Director, or a designee, and stating the basis for such request. The request must be accompanied by information sufficient to support the request. All requests should be sent to the TSCA Document Processing Center (7407), Room L-100, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTN: Request to amend SNUR.

(2) The Director, or a designee, will consider the request, make a determination whether to initiate rulemaking to modify the requirements, and notify the requester of that determination by certified letter. If the request is denied, the letter will explain why EPA has concluded that the significant new use notification requirements for that microorganism should remain in effect.

(3) If EPA concludes that significant new use notification requirements for a microorganism should be limited or revoked, EPA will propose the changes in a notice in the FEDERAL REGISTER, briefly describe the grounds for the action, and provide interested parties an opportunity to comment.

Subpart M -- Significant New Uses for Specific Microorganisms

§725.1000 Scope.

This subpart identifies uses of microorganisms which EPA has determined to be significant new uses under the authority of section 5(a)(2) of the Toxic Substances Control Act.

§725.1075 *Burkholderia cepacia* complex.

(a) Microorganism and significant new uses subject to reporting. (1) The microorganisms identified as the *Burkholderia cepacia* complex defined as containing the following nine species, *Burkholderia cepacia*, *Burkholderia multivorans*, *Burkholderia stabilis*, *Burkholderia vietnamiensis*, *Burkholderia ambifaria*, *Burkholderia pyrrocinia*, *Burkholderia cepacia* genomovar VIII (*Burkholderia anthina*), and *Burkholderia cepacia* genomovars III and VI are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new use is any use other than research and development in the degradation of chemicals via injection into subsurface groundwater.

(b) [Reserved]

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