

evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter;

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(5) For purposes of paragraph (f)(2) of this section, information will be considered newly acquired if it consists of data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events of a different type or greater severity or frequency than previously included in submissions to FDA, or new analyses of previously submitted data (e.g., meta-analyses).

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PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

6. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

7. Section 814.3 is amended by adding paragraph (o) to read as follows:

§ 814.3 Definitions.

* * * * *

(o) *Newly acquired information* means data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events of a different type or greater severity or frequency than previously included in submissions to FDA, or new analyses of previously submitted data (e.g., meta-analyses).

8. Section 814.39 is amended by revising paragraphs (d)(1) introductory text and (d)(2)(i) to read as follows:

§ 814.39 PMA supplements.

* * * * *

(d)(1) After FDA approves a PMA, any change described in paragraph (d)(2) of this section to reflect newly acquired information that enhances the safety of the device or the safety in the use of the device may be placed into effect by the applicant prior to the receipt under § 814.17 of a written FDA order approving the PMA supplement provided that:

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(2) * * *

(i) Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association.

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Dated: December 4, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–702 Filed 1–15–08; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 704, 720, 721, and 723

[EPA–HQ–OPPT–2007–0392; FRL–8131–8]

RIN 2070–AJ21

Proposed Clarification for Chemical Identification Describing Activated Phosphors for TSCA Inventory Purposes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed clarification.

SUMMARY: This document proposes a clarification under which activated phosphors that are not on the Toxic Substances Control Act (TSCA) section 8(b) Chemical Substance Inventory (TSCA Inventory) would be considered to be new chemical substances under TSCA section 5, thus would be subject to the notification requirements under TSCA section 5(a) new chemical notification requirements. In certain letters and other interpretations issued by EPA from 1978 to 2003, it appears that the Agency erroneously indicated that activated phosphors constitute solid mixtures for purposes of the TSCA Inventory, and thus that they were not separately reportable as chemical substances under TSCA section 5(a) new chemical notification requirements. This proposed clarification is necessary because EPA's interpretations in this area have not been consistent. Given this past inconsistency, EPA is seeking comment on its proposed clarification.

DATES: Comments must be received on or before March 17, 2008.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2007–0392, by one of the following methods:

• *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

• *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID

Number EPA–HQ–OPPT–2007–0392.

The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2007–0392. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the docket are listed in the docket index available in [regulations.gov](http://www.regulations.gov). To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) website to view the docket index or access available documents. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket

materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: For general information contact: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: David Schutz, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9262; e-mail address: schutz.david@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are, or may in the future be, a manufacturer or importer of an activated phosphor that requires submission of a premanufacture notification (PMN) or exemption request under TSCA section 5. Special procedures would apply to persons who manufactured these chemicals after the publication of the Initial TSCA Inventory and before a date 12 months following the publication of a final chemical identification clarification document in the **Federal Register**. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers or importers (NAICS codes 325, 3251), e.g., anyone who manufactures or imports, or who plans to manufacture or import, an activated phosphor for a non-exempt commercial purpose.

- Electric Lighting Equipment Manufacturing, Electric Lamp Bulb and Part Manufacturing (NAICS codes 3351, 33511), e.g., anyone who manufactures or imports, or who plans to manufacture or import, lighting equipment containing an activated phosphor for a non-exempt commercial purpose.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

This action proposes a clarification in the approach used for the chemical identification of activated (doped) phosphors for purposes of listing on the TSCA Inventory. A doped or activated phosphor is a substance resulting from the chemical combination of a mixture of metal oxides, carbonates, phosphates or acid phosphates, chlorides, and/or fluorides, most frequently by sintering, along with a small amount of one or more dopants. Dopants can include such chemical substances as antimony, europium, gallium, germanium, magnesium, manganese, strontium, or yttrium. When this material is electrically excited, it emits light. The color and electrical efficiency of light emission is a function of the parent phosphor and of the dopant which is present.

EPA is required under TSCA section 8(b), 15 U.S.C. 2607(b), to compile and keep current an inventory of chemical substances manufactured, imported, or processed for commercial purposes in the United States. This inventory is known as the TSCA Chemical Substances Inventory (TSCA Inventory). In 1977, EPA promulgated a rule published in the **Federal Register** issue of December 23, 1977 (42 FR 64572) under TSCA section 8(a), 15 U.S.C. 2607(a), to compile an inventory of chemical substances in commerce at that time. In 1983, and building on several earlier interim policies, EPA promulgated a rule published in the **Federal Register** issue of May 13, 1983 (48 FR 21722) under TSCA section 5, 15 U.S.C. 2604, to keep the TSCA Inventory up-to-date through a procedure for the submission, receipt, and health and safety review of PMNs covering chemical substances not yet in commerce from their intending manufacturers and importers.

Manufacturing, importing, or processing of a new chemical is illegal prior to the expiration of the PMN review period. Once EPA receives a PMN, the Agency has 90 days to review the notice (unless for good cause EPA extends the review period). During the review period, EPA may act under TSCA section 5(e) or 5(f) to regulate the

new chemical substance. If EPA has not prohibited manufacture or import of the chemical substance during the review period, these activities may begin subject to any restrictions or testing requirements imposed upon the submitter during the review period (these restrictions may be imposed upon others via a Significant New Use Rule (SNUR) and subsequent action under TSCA section 5(e) or 5(f) taken in follow-up to a significant new use notification (SNUN)). When manufacture or import begins, the notice submitter must provide a notice of commencement, after which EPA adds the chemical substance to the TSCA Inventory. If the Agency receives a PMN submission for a chemical substance which EPA determines is excluded from consideration as a chemical substance under TSCA (generally because it meets the criteria for one of the excepted categories at TSCA section 3(2)(B), which include mixtures, pesticides, tobacco, food, drugs, etc.) it will not accept the PMN. A similar practice was followed as well during the period 1978–1979, when the EPA was accepting submissions for the Initial TSCA Inventory, and during 1979–1983, prior to promulgation of the May 13, 1983 PMN rule.

Partly as a result of the Agency's incomplete information and understanding of the chemistry involved in manufacturing activated phosphors, from 1978 through 2003 EPA has been inconsistent in its interpretation to potential submitters and in its actions regarding whether activated phosphors are considered distinct chemical substances for purposes of the TSCA Inventory. During the period 1978–1979, when EPA received submissions for the Initial TSCA Inventory, it accepted a number of doped phosphors for listing, but in other cases it sent "problem letters" to the manufacturers of doped phosphors indicating that they were mixtures.

In October 1979, the Agency wrote to a lighting manufacturer and stated that such listings could be "unnecessary" and that their continued inclusion on the TSCA Inventory would be "closely examined." In January 1980, a lighting manufacturer wrote to the Agency to challenge problem letters it had received. The manufacturer stated that the materials it manufactured should be excluded from mixture status because they had characteristic crystal structures and that volatile reaction products given off during their manufacture showed that chemical synthesis was occurring. In March 1982, the Agency wrote to a lighting manufacturer and suggested that activated phosphors could be

regarded either as physically altered chlorophosphates or as mixtures, thus not subject to PMN. In August 1983, the Agency wrote to the lighting manufacturer which had challenged the problem letters and informed it that the materials had, in fact, been placed on the TSCA Inventory, and in addition that a PMN was appropriate for another activated phosphor but that "low levels" of an activator would not require separate PMN.

In January 1993, a lighting manufacturer submitted a Low Volume Exemption (LVE) Application for an activated phosphor with a letter referencing much of the history as described in this unit and asserting that, based on Agency positions, no submission should be necessary, but the Agency did accept the application and granted the LVE. After that LVE was granted, the manufacturer submitted a letter making the case that activated phosphors should, in fact, be considered to be mixtures and requesting that the Agency issue a clarifying statement. In response, the Agency met with the manufacturer on the issue and indicated that activated phosphors should be considered chemical substances instead of mixtures, but did not issue a written clarification.

In 1995, EPA issued the publication entitled *Toxic Substances Control Act Inventory Representation for Products Containing Two or More Substances: Formulated and Statutory Mixtures (Formulated and Statutory Mixtures)*, available at <http://www.epa.gov/opptintr/newchems/pubs/mixtures.txt>, which interpreted the mixture definition given at 40 CFR 710.3(d) and 720.3(u):

Mixture means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except "mixture" does include (1) any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined, and if all of the chemical substances comprising the combination are not new chemical substances, and (2) hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water, so long as the nonhydrated form is itself not a new chemical substance.

Formulated and Statutory Mixtures discusses common examples of mixtures, including paints, blended fuels, and solvent combinations. "Mixture" can include, as well, solid solutions—homogeneous crystalline phases composed of several distinct chemical species. Alloys are solid

solutions, and are considered mixtures. For the purposes of TSCA, multi-component blends or formulations of chemical substances, or certain reaction product combinations which can be completely characterized as consistently formed sets of their constituent chemical substances, are considered to be mixtures of chemical substances. Mixtures are not reportable, although their constituent chemical substances are. Most important in the context of this clarification, a mixture can often provide its function over some range of constituent ratios, consequently it is unusual if the ratios of chemical substances which comprise a mixture are necessarily definite or stoichiometric, and if the mixture components are deliberately reacted together to manufacture a chemical substance, this reaction product cannot be considered a mixture for TSCA purposes except in very specialized circumstances which are not present in the case of the activated phosphors.

In June 1998, a lighting manufacturer wrote to the Agency and stated that, in the absence of any negative response by the Agency within 60 days of the letter, it intended to rely on the interpretation in *Formulated and Statutory Mixtures*, and that it believed that that interpretation precluded TSCA Inventory listing for activated phosphors. The Agency did not respond to that letter. Based on a 2003 request from a lighting manufacturer, and cognizant of the history described in this unit, EPA held a meeting with the manufacturer in September 2003 and as a result has reexamined some earlier assumptions—particularly about non-stoichiometry and non-reaction between chemical substances used to make activated phosphors—which may have led it to believe that activated phosphors could be considered mixtures.

The result of this reexamination is this clarification that individual activated phosphors should be considered to be distinct chemical substances under TSCA. EPA's clarification on the potential need to report activated phosphor materials is based on its updated understanding about reactions and stoichiometry in activated phosphors, as follows: Activated phosphors are in general synthesized by means of a solid state reaction at high temperature and using precise quantities of the precursor chemical substances, both for the base materials and for the dopants which control the quality of light emitted. Precise ratios of component materials are used to maintain strict stoichiometry in the end product, and component

materials are thoroughly blended before reaction for uniformity of the product. Heat may be absorbed or released by the reactant mixture at certain temperatures, typically by the release of water: This is generally an indication of chemical substance synthesis. During the manufacture of activated phosphors, other volatile reaction products are often emitted, another indication that chemical substances are being formed. The phosphor and the amount of dopant added need to be controlled with high precision, and during sintering the doped phosphor undergoes oxidation state changes. Consequently, EPA believes that activated phosphors cannot be manufactured for commercial purposes without chemical reaction. Additionally, activated phosphor products have a different function from the material which would be produced by the same synthetic process in the absence of dopant, and which would not emit the characteristic light, which is the primary property sought. Because dopants provide the primary property sought from these materials, small or even trace amounts of dopant must be considered to be reactants which must be included in the chemical identity. These factors preclude these materials from being considered as "mixtures."

B. What is the Agency's Authority for Taking this Action?

Section 5 of TSCA requires any person who intends to manufacture (defined by statute to include import) a new chemical substance (i.e., a chemical substance not on the TSCA Inventory) to notify EPA at least 90 days in advance and comply with the statutory provisions pertaining to the manufacture of new chemical substances for non-exempt commercial purposes. Section 8(b) of TSCA requires EPA to compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States (the TSCA Inventory). This requirement includes defining the scope of the listings on the TSCA Inventory.

C. Why is this Proposed Chemical Identity Clarification Necessary?

Because activated phosphors are precluded by the factors identified in the last paragraph of Unit II.A. from being considered to be formulated or statutory mixtures, some previous EPA interpretations that such materials need not be reviewed through the new chemicals process were incorrect. As a result of certain past EPA interpretations, some manufacturers of activated phosphors have not submitted new chemical notifications under TSCA

section 5 because those interpretations incorrectly indicated that activated phosphors were covered for TSCA purposes if the substances used in their manufacture were already on the TSCA Inventory. Other manufacturers have submitted notices for these materials, and they have been given TSCA Inventory listings in some cases. Several industry representatives have asked EPA to clarify the Agency's chemical identity policy for activated phosphors. EPA now agrees that it is necessary to add listings to the TSCA Inventory for activated phosphors which have been manufactured but not listed, and that it is possible that some existing listings should be altered to describe certain metal components as dopants. This document proposes a clarification to previous interpretations on chemical identity for activated phosphors. With this proposed clarification, activated phosphors that are not on the TSCA Inventory would be considered new chemical substances under TSCA section 5.

Because some of the interpretations provided by the agency prior to 2003 led some manufacturers to believe that the products they manufactured were already on the TSCA Inventory if their precursor substances were on the TSCA Inventory, some manufacturers of activated phosphor products have not submitted PMNs required under TSCA section 5. This chemical identification problem is similar to one involving monomer acid and its derivatives, which was resolved through Agency-industry dialog and a period for submission of new notices (Correction to Chemical Nomenclature for Monomer Acid and Derivatives for TSCA Inventory Purpose published in the **Federal Register** issue of June 27, 2001 (66 FR 34193) (FRL-6784-6). The Agency is proposing to address this activated phosphor situation in a similar manner.

III. Proposed TSCA New Chemicals Program Policy for Activated Phosphor Chemical Identity

EPA is proposing that the portion of EPA's earlier interpretations indicating that activated phosphors are mixtures rather than chemical substances in their own right was erroneous, and that TSCA Inventory listing would be required for these materials. Under this proposal, PMNs would be required for activated phosphors not on the TSCA Inventory (and for which a TSCA section 5(h)(4) exemption has not been granted) and which are manufactured on or after the effective date of the final clarification. In accordance with TSCA Inventory correction guidelines published in the

Federal Register issue of July 29, 1980 (45 FR 50544), activated phosphors that were never reported for the Initial TSCA Inventory are not eligible for TSCA Inventory correction as an alternative to PMN submission.

A. What is the Basis for and Scope of this Proposed Chemical Identification Clarification?

EPA no longer considers to be valid the chemical identity interpretation that activated phosphors are mixtures rather than chemical substances in their own right. Thus listing on the TSCA Inventory established at TSCA section 8(b) is required for these chemical substances. The proposed chemical identity clarification would affect anyone who manufactures or imports, or who plans to manufacture or import, an activated phosphor not now listed on the TSCA Inventory.

B. What Are the Key Dates and Provisions of this Proposed Chemical Identification Clarification?

The effective date for this proposed new chemical identity clarification, described in Unit II.B. would be 12 months following the date of publication of the final chemical identification clarification document in the **Federal Register**. Prior to this effective date, companies would be allowed to continue commercial production of non-TSCA Inventory listed activated phosphors under the old, incorrect chemical identity interpretation. After the effective date, any manufacturer making non-TSCA Inventory listed activated phosphors for non-exempt commercial purposes would no longer be in compliance with TSCA section 5. Therefore, companies would need to submit PMNs or exemption applications at least 90 days before the effective date to ensure that Agency review is completed before this chemical identification clarification takes effect. Continued commercial production prior to expiration of the applicable review period would be allowed if it were during the year following the date of publication of the final chemical identification clarification document in the **Federal Register** and applies only to activated phosphor materials already being made.

EPA will work closely with chemical manufacturers and importers to resolve chemical identity issues for any specific material for which the manufacturer believes the incorrect activated phosphor interpretations may still have applicability.

To facilitate the PMN process for activated phosphors currently using the incorrect chemical identification, EPA

would allow an exception to its TSCA new chemicals program policy of a limit of six chemical substances per consolidation notice for these chemical substances. However, consistent with the Agency's chemical identification requirements for consolidated notices, submitters must use the Chemical Abstracts Service (CAS) Inventory Expert Service to develop correct Chemical Abstracts (CA) names for all of their reported chemical substances, in accordance with Method 1 as described in the Premanufacture Notification regulations, 40 CFR 720.45(a)(3)(i). EPA encourages persons intending to manufacture activated phosphors to file PMNs using the proper chemical identity immediately instead of delaying their submissions to near the effective date of this proposed document.

PMNs filed in response to this chemical identification clarification should, as specified in 40 CFR 720.50, include all information normally included with a PMN submission, such as toxicity data on the PMN chemical substance that are in the possession or control of the PMN submitter, or known to or reasonably ascertainable by the PMN submitter.

C. What Are the Consequences of Not Submitting a PMN and Completing PMN Review on an Activated Phosphor Before the Effective Date of this Proposed Chemical Identification Clarification?

Starting on the effective date of the final chemical identification clarification document, anyone manufacturing (includes import) for a non-exempt commercial purpose an activated phosphor that is not specifically listed on the TSCA Inventory would be in violation of TSCA. Penalties of \$32,500 per violation per day are possible.

D. Would a PMN Be Required for Persons Who Did Not Submit One Due to an Incorrect EPA Interpretation, Regardless of Whether They Still Manufacture the Chemical Substance?

A PMN would have to be submitted by any person who intends to manufacture or import an activated phosphor not on the TSCA Inventory for a non-exempt commercial purpose on or after the effective date of the final chemical identification clarification document. If future manufacture is not intended, no PMN need be submitted. For example, if you manufactured such a phosphor in 1986 but are not currently manufacturing nor intending to resume manufacture, you would not be required to submit a PMN at this time. However, if you later form an intention to

manufacture the activated phosphor after the effective date of the final chemical identification clarification document, you would need to submit a PMN 90 days before commencing manufacture.

IV. Do Certain Statutory and Executive Order Reviews Apply to this Action?

No. This document presents the Agency's clarification of the TSCA Inventory chemical identification principles. This action is not a regulatory action or significant guidance document under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), as amended by Executive Order 13422 (72 FR 2763, January 23, 2007). As such, this action does not require review by the Office of Management and Budget (OMB) under Executive Order 12866. In addition, Executive Orders 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997) and 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), do not apply to this action because it is not "economically significant" as defined by section 3(f) of Executive Order 12866. Nor does this action establish an environmental standard that may have a negatively disproportionate effect on children, or otherwise have any significant adverse effect on the supply, distribution, or use of energy.

This document does not contain any new information collection requirements that would require additional review and approval by OMB under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*). The information collection activities related to the submission of information pursuant to TSCA section 5 are already approved by OMB under OMB Control No. 2070-0012 (EPA Information Collection Request [ICR] No. 574). The burden for that ICR is estimated to average 100 hours per respondent, including time for reading the regulations, processing, compiling, and reviewing the requested data, generating the request, storing, filing, and maintaining the data. Under PRA, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number, or is otherwise required to submit the specific information by a statute. The OMB control numbers for the EPA regulations that are codified in 40 CFR chapter I, after appearing in the preamble of the final rule, are further displayed either by publication in the

Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in a list at 40 CFR 9.1.

As indicated previously, this action is not subject to the notice-and-comment requirements under the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) or any other statute. As such, it is not subject to the provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*). Further, this action is expected to only have a limited impact because only entities which are now manufacturing such a chemical substance, and which have not already prepared and submitted a PMN to EPA, must submit a PMN as a result of this action if they intend to continue manufacturing it.

Based on EPA's experience with review of PMNs, State, local, and Tribal governments have not been impacted by these activities, and EPA does not have any reason to believe that any State, local, or Tribal government would be impacted by this action. As such, this action will not have substantial direct effects on the States or on the relationship between the national government and the States or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Nor does this action significantly or uniquely affect the communities of tribal governments as specified by Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000). In addition, EPA has determined that this regulatory action would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that require the Agency's consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

This action will not have an adverse impact on the environmental and health conditions in low-income and minority communities. Therefore, under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and*

Low-Income Populations (59 FR 7629, February 16, 1994), the Agency is not required to and has not considered environmental justice-related issues.

List of Subjects

40 CFR Part 704

Environmental protection, Chemicals, Confidential business information, Hazardous substances, Imports, Reporting and recordkeeping requirements.

40 CFR Part 720

Environmental protection, Chemicals, Hazardous substances, Imports, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Administrative practice and procedure, Chemicals, Hazardous substances, Imports, Labeling, Occupational safety and health, Reporting and recordkeeping requirements.

40 CFR Part 723

Environmental protection, Chemicals, Hazardous substances, Photographic industry, Reporting and recordkeeping requirements.

Dated: January 10, 2008.

James B. Gulliford,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

[FR Doc. E8-681 Filed 1-15-08; 8:45 am]

BILLING CODE 6560-50-S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket No. FEMA-B-7756]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed rule.

SUMMARY: Comments are requested on the proposed Base (1 percent annual-chance) Flood Elevations (BFEs) and proposed BFE modifications for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the proposed regulatory flood elevations for the reach described by the

downstream and upstream locations in the table below. The BFEs and modified BFEs are a part of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, these elevations, once finalized, will be used by insurance agents, and others to calculate appropriate flood insurance premium rates for new buildings and the contents in those buildings.

DATES: Comments are to be submitted on or before April 15, 2008.

ADDRESSES: The corresponding preliminary Flood Insurance Rate Map (FIRM) for the proposed BFEs for each community are available for inspection at the community's map repository. The respective addresses are listed in the table below.

You may submit comments, identified by Docket No. FEMA-B-7756, to William R. Blanton, Jr., Chief, Engineering Management Branch, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3151, or (e-mail) bill.blanton@dhs.gov.

FOR FURTHER INFORMATION CONTACT:

William R. Blanton, Jr., Chief, Engineering Management Branch, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3151 or (e-mail) bill.blanton@dhs.gov.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) proposes to make determinations of BFEs and modified BFEs for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed BFEs and modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new

buildings built after these elevations are made final, and for the contents in these buildings.

Comments on any aspect of the Flood Insurance Study and FIRM, other than the proposed BFEs, will be considered. A letter acknowledging receipt of any comments will not be sent.

Administrative Procedure Act Statement. This matter is not a rulemaking governed by the Administrative Procedure Act (APA), 5 U.S.C. 553. FEMA publishes flood elevation determinations for notice and comment; however, they are governed by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and the National Flood Insurance Act of 1968, 42 U.S.C. 4001, *et seq.*, and do not fall under the APA.

National Environmental Policy Act. This proposed rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601-612, a regulatory flexibility analysis is not required.

Executive Order 12866, Regulatory Planning and Review. This proposed rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866, as amended.

Executive Order 13132, Federalism. This proposed rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This proposed rule meets the applicable standards of Executive Order 12988.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is proposed to be amended as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001, *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.4 [Amended]

2. The tables published under the authority of § 67.4 are proposed to be amended as follows: