

**List of Subjects in 40 CFR Part 60**

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: December 12, 2008.

**Stephen L. Johnson,**  
Administrator.

For the reasons cited in the preamble, title 40, chapter I, part 60 of the Code of Federal Regulations is proposed to be amended as follows:

**PART 60—[AMENDED]**

1. The authority citation for part 60 continues to read as follows:

**Authority:** 42 U.S.C. 7401, *et seq.*

**§ 60.100a [AMENDED]**

2. In § 60.100a, paragraph (c) is stayed from February 24, 2009, until further notice.

**§ 60.101a [AMENDED]**

3. The definition of “flare” in § 60.101a is stayed from February 24, 2009, until further notice.

**§ 60.102a [AMENDED]**

4. In § 60.102a, paragraph (g) is stayed from February 24, 2009, until further notice.

**§ 60.107a [AMENDED]**

5. In § 60.107a, paragraphs (d) and (e) are stayed from February 24, 2009, until further notice.

[FR Doc. E8–29973 Filed 12–19–08; 8:45 am]

**BILLING CODE 6560–50–P**

**ENVIRONMENTAL PROTECTION  
AGENCY****40 CFR Parts 700, 720, 721, 723, and  
725**

**[EPA–HQ–OPPT–2008–0296; FRL–8395–8]**

**RIN 2070–AJ41**

**TSCA Section 5 Premanufacture and  
Significant New Use Notification  
Electronic Reporting; Revisions to  
Notification Regulations**

**AGENCY:** Environmental Protection  
Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing amendments to the Toxic Substances Control Act (TSCA) section 5 Premanufacture and Significant New Use Notification regulations to facilitate the introduction and use of electronic reporting. This action is intended to streamline and reduce the

administrative costs and burdens of TSCA section 5 notifications for both industry and EPA by establishing standards and requirements for the use of EPA’s Central Data Exchange (CDX) to electronically submit premanufacture notices (PMNs) and other TSCA section 5 notices and support documents to the Agency. EPA is also proposing to amend the TSCA section 5 User Fee regulations to add a new User Fee Payment Identity Number field to the PMN form, which would enable the Agency to match more easily a particular user fee with its notice submission. Lastly, EPA is proposing to remove the Agent signature block field on the PMN form, and thus the requirement for designated Agents to sign the form.

**DATES:** Comments must be received on or before February 20, 2009.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2008–0296, 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–2008–0296. 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–2008–0296. 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 [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.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 [www.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 at <http://www.regulations.gov>. 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: [TSCAHotline@epa.gov](mailto:TSCAHotline@epa.gov).

For technical information contact: Greg Schweer, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental

Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8469; e-mail address: [schweeer.greg@epa.gov](mailto:schweeer.greg@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

You may be affected by this action if you manufacture, import, or process chemicals for commercial purposes. Potentially affected entities may include, but are not limited to:

- Manufacturers, importers, and processors of chemical substances or mixtures (NAICS codes 325 and 324110, e.g., chemical manufacturing and processing and petroleum refineries).

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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR parts 700, 720, 721, 723, and 725 for TSCA section 5–related obligations. 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://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 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:

i. Identify the document by docket ID number and other identifying

information (subject heading, **Federal Register** date and page number).

ii. 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.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. 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?

EPA is proposing amendments to TSCA section 5 Premanufacture and Significant New Use Notification regulations and related provisions to facilitate the introduction and required use of a new electronic reporting mechanism.

The Government Paperwork Elimination Act (GPEA) (Public Law 105–277 (44 U.S.C. 3504)) requires that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (40 CFR part 3), published in the **Federal Register** of October 13, 2005 (70 FR 59848) (FRL–7977–1) provides that any requirement in title 40 of the CFR to submit a report directly to EPA can be satisfied with an electronic submission that meets certain conditions once the Agency publishes a notice that electronic document submission is available for that requirement. See Unit III.F. for more information on electronic signatures.

In light of GPEA and CROMERR, EPA is proposing these amendments to enable, and eventually require, manufacturers (including importers), and processors of TSCA chemical substances to use the Internet, through EPA's CDX, to submit TSCA section 5 notices to the Agency. These include PMNs (40 CFR part 720), Significant New Use Notices (SNUNs) (40 CFR part 721), Test Market Exemption Applications (TMEAs) (40 CFR part

720), Low Volume Exemption notices (LVEs) (40 CFR 723.50), Low Exposure/Low Release Exemption (LoRex) notices (40 CFR 723.50), biotechnology notices for genetically modified microorganisms (40 CFR part 725), Notices of Commencement of Manufacture or Import (NOCs) (40 CFR 720.102), and other support documents (e.g., correspondence, requests for suspensions of the notice review period, amendments, and test data).

The Agency is proposing to introduce CDX reporting in two phases over a 2–year period. During the first year following the effective date of the final rule, the Agency would allow submissions via CDX, optical disc, and paper. Regardless of the delivery method, EPA would require that all submissions be generated using the new electronic-PMN (e-PMN) software. One year after the final rule's effective date, paper submissions would no longer be accepted for any new notices and support documents (including NOCs). Two years after the final rule's effective date, disc-based submissions (e.g., CDs) for all new notices and support documents would no longer be accepted. In the third year after the final rule's effective date, all submitters would be required to submit all notices and support documents identified in Table 1 of Unit III.I. electronically via CDX using the e-PMN software. The Agency is proposing this phased approach because it would allow submitters to gain experience in using the e-PMN software and the submission delivery system.

EPA is also proposing to amend the TSCA section 5 User Fee regulations at 40 CFR 700.45 to add a new User Fee Payment Identity Number field to the PMN form. This would enable the Agency to match more easily a particular user fee with its notice submission. The second new information element on the amended PMN form would be optional and consist simply of the e-mail address for the authorized official submitting the notice listed on the “Submitter Identification” section on page three of the PMN form. EPA is also proposing to remove the required Agent signature block field on page two of the form.

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

Section 5(a)(1)(A) of TSCA requires persons to notify EPA at least 90 days before manufacturing (under TSCA manufacture includes import) a new chemical substance for commercial purposes. Section 3(9) of TSCA defines a “new chemical substance” as any substance that is not on the Inventory of

Chemical Substances compiled by EPA under section 8(b) of TSCA. Section 5(a)(2) of TSCA authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a notice to EPA at least 90 days before manufacturing or processing the chemical substance for that use. GPEA requires that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public.

*C. How are Premanufacture Notices and Other TSCA Section 5 Notices Currently Submitted and Processed by the Agency?*

Currently, TSCA section 5 submissions must be sent to EPA on paper through the U.S. mail or delivered by courier. Submitters are able to generate certain TSCA section 5 notices electronically using the PMN form available at the EPA New Chemicals Program website (<https://cdx.epa.gov/ssl/pmn/download.asp>). The form uses Adobe Acrobat Reader software, which allows submitters to complete the form electronically, and then print out and mail it to EPA as hard copy. The software is free and allows the user to complete the form and print it, but it does not allow the user to save the form. Approximately 35% of TSCA section 5 notices are currently generated using this software. Most of the remaining submissions are generated using other Agency-approved software that has been developed by industry trade groups or individual notice submitters. A very small percentage of submitters choose to fill out the PMN form by hand or typewriter, using a version of the form downloaded from EPA's TSCA New Chemicals Program website (See <http://www.epa.gov/opptintr/newchemicals/pubs/pmnpart1.pdf> and <http://www.epa.gov/opptintr/newchemicals/pubs/pmnpart2.pdf>).

If the submitter marks anything on the PMN form as CBI, then the submitter must submit a version of the form with the CBI and another version of the form without CBI. The latter version is referred to as the sanitized or non-CBI version and is required for the public docket.

Upon receipt at EPA, paper submissions are assigned a "mail received" number, which is used to identify the submission until an official

document control number (DCN) is generated, which does not occur until EPA verifies that the notice is complete. Once the mail information is captured, the submission is sent for prescreening. During prescreening, the submission is checked for completeness using criteria listed at 40 CFR 720.65. If the notice does not pass prescreening, EPA declares the original notice "Incomplete" and notifies the submitter that there is missing or incorrect information, and that the submitter must correct the package and provide a new submission to EPA. If a new notice is not submitted, EPA will return the user fee.

After a successful prescreening, EPA generates a DCN and barcode for the submission. EPA also generates a DCN and barcode for the non-CBI version of a CBI submission and places the non-CBI version in the public docket. The original CBI submission is then kept in a physical case file folder for reference. Any supporting documents for the submission are also assigned DCNs and placed in the physical case file folders.

**III. Description of Proposed Changes for TSCA Section 5 Reporting**

This unit provides a detailed description of EPA's electronic reporting software, the proposed changes to the reporting process, the benefits of electronic reporting to both industry and EPA, and how EPA is proposing to phase-in the electronic reporting.

*A. What is CDX?*

EPA's CDX is the point of entry on the Environmental Information Exchange Network (Exchange Network) for environmental data submissions to the Agency. CDX provides the capability for submitters to access their data through the use of web services. CDX enables EPA and participating program offices to work with stakeholders—including State, tribal, and local governments and regulated industries—to enable streamlined electronic submission of data via the Internet. For more information about CDX, go to <http://www.epa.gov/cdx>.

*B. What is the e-PMN Software?*

EPA has developed new e-PMN software for use in preparing and submitting PMNs and other TSCA section 5 notices and support documents electronically to the Agency. The e-PMN software would be available as a free Internet download from the Agency's website (<http://www.epa.gov/oppt/newchemicals>) or on optical discs provided by the Agency upon request. The e-PMN software works with

Windows, Macs, Linux, and UNIX-based computers, using XML (short for "Extensible Markup Language") specifications for more efficient data transmittal across the Internet. The e-PMN software operates using the Java 6 programming language, which can be downloaded free from <http://www.java.com>, if it is not already installed on your computer. The e-PMN software would provide user-friendly navigation, work with CDX to secure on-line communication, and create a completed Portable Document Format (PDF) file using the PMN form to accommodate internal company review prior to submission.

The e-PMN software includes features intended to be helpful for preparing PMNs and other notices using the PMN form, such as SNUNs. A validation mechanism would alert users when a field on the form, required by regulation, is either missing information or contains certain kinds of potentially incorrect information. For example, if "use" information is claimed CBI, then the e-PMN software would indicate that the form is not complete unless the submitter has provided both specific use information on the CBI version of the form and generic use information on the non-CBI version of the form. The e-PMN software includes header pages for biotechnology notices (i.e., Microbial Commercial Activity Notices (MCANs), TSCA Experimental Release Applications (TERAs), TMEAs, and Tier I or Tier II Exemption requests), support documents, and attachments—any document not submitted on the PMN form itself—that identify submitters and the nature of their communications.

Guidance documents developed by EPA for TSCA section 8(a) Inventory Update Rule (IUR) reporting via CDX are available at <http://www.epa.gov/opptintr/iur/pubs/factsheet.pdf> and [http://www.epa.gov/opptintr/iur/pubs/cdx\\_qanda.pdf](http://www.epa.gov/opptintr/iur/pubs/cdx_qanda.pdf). These documents provide background information on reporting via CDX that is relevant and useful for TSCA section 5 reporting as well. EPA would provide similar specific guidance for TSCA section 5 reporting via CDX, along with the e-PMN submission software, at the New Chemicals Program homepage (<http://www.epa.gov/oppt/newchemicals>) by the effective date of the final rule.

*C. What are the Benefits of CDX Reporting and Use of the e-PMN Software, Compared to the Existing Paper Method?*

The proposed change to phase-out paper-based submissions in favor of CDX reporting, including use of the e-PMN reporting software, for TSCA

section 5 notices and support documents is in concert with broader government efforts to move to modern, electronic methods of information gathering. The required use of CDX for submission of TSCA section 5 notices and support documents would be consistent with the GPEA requirement that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public.

The e-PMN software and electronic submission via CDX would change the way that companies interact with the Agency regarding many TSCA section 5 submissions. Companies would be registered with EPA to submit their data electronically to the Agency via CDX and the Agency in turn would benefit from receiving electronic submissions and being able to communicate back electronically with submitters. Data systems that once were populated manually would now be populated electronically reducing the potential for error that exists when data are entered by hand.

Agency personnel would also be able to communicate more efficiently with submitters electronically, compared to using U.S. mail. Two examples of routine communications from EPA that would go through CDX rather than the U.S. mail are the Acknowledgment Letter (acknowledging receipt of a notice), and the Incomplete Letter (stating why a notice has been declared incomplete). PMN electronic reporting software allows for more efficient data transmittal, and the software's validation mechanism should help industry users submit fewer incomplete notices, which ultimately would save EPA and industry processing resources and reduce transaction times. EPA believes the adoption of electronic communications would reduce the reporting burden on industry by reducing both the cost and the time required to review, edit, and transmit data to the Agency. It also would allow submitters to share a draft notice within the company during the creation of a notice and to save a copy of the final file for future use. A "Profiler," available in the software, would also allow for certain information to be kept on file by the submitter to avoid re-entering the same information into a new form.

All information sent by EPA or the submitter via CDX would be transmitted securely to protect CBI. Furthermore, if anything in the submission has been claimed CBI, a non-CBI copy of the notice must be provided by the submitter. The new e-PMN software would facilitate the creation of this non-

CBI version, eliminating the need for the submitter to do this manually.

#### *D. What are the Proposed Changes to the Existing PMN Form?*

EPA is proposing to amend the PMN form in order to collect two new information elements. First, 40 CFR part 700 requires submitters to pay a fee when they submit PMNs, MCANs, certain PMN exemption application notices, and SNUNs to the Agency. The amended PMN form would include a new User Fee Payment Identity Number field to enable the Agency to match more easily a particular user fee with a particular notice submission. A User Fee Payment Identity Number would be required and may be either a check number, a wire transfer number, or a "Pay.gov" transaction number used to transmit the user fee electronically. The second new information element on the amended PMN form would be optional and consist simply of the e-mail addresses for the authorized officials listed on the Submitter Identification section on page three of the PMN form. The e-mail address would enable the Agency to contact the submitter through e-mail, facilitating communications related to the submission.

EPA is also proposing to remove the required Agent signature block field on page two of the PMN form. On the existing PMN form, if a manufacturer/importer subject to the notice requirements in 40 CFR part 720 designates an Agent to submit the form pursuant to 40 CFR 720.40(e), both the manufacturer/importer and the Agent must sign the form. EPA is proposing to remove the requirement that Agents sign the PMN form because few Agents have submitted forms in the past, and the Agent signature block is rarely used by the Agency. Eliminating the second signature also simplifies development of the e-PMN form. Note that a form submitted by an Agent would still have to be signed by the manufacturer/importer's authorized company official, and the Agent's name and contact information would still be provided on page three of the PMN form. The authorized company official remains responsible for false or misleading statements in the notice.

The e-PMN software would allow users to print paper copies for internal company use. The printed version of the amended e-PMN form would have the same general look of the current paper PMN form, i.e., containing the same fields (with the modifications to the form discussed in Unit III.D.) and the same pagination. However, fields have been expanded to make more room for submitter information, resulting in a

larger total number of pages, and realigned to make the form easier to scan. Under this proposed rule, persons who choose to submit PMNs on paper during the first year after the effective date of the final rule would be required to use the new e-PMN software to generate the paper form for each PMN or other TSCA section 5 notice they submit. EPA is proposing this requirement because the Agency has incorporated into the form many scanning efficiencies for the electronic capturing of data that would be lost if a blank PMN form is printed, photocopied, and used for another submission.

#### *E. How Would PMNs be Submitted via the Internet Using CDX?*

The Internet submission of TSCA section 5 notices would require submitters to use the e-PMN software to prepare a data file and to register with EPA's CDX under "New Chemicals Submissions."

1. *Registering with CDX.* To register with CDX, the submitter would be directed to [http://cdx.epa.gov/epa\\_home.asp](http://cdx.epa.gov/epa_home.asp). The submitter would be asked to agree to Terms and Conditions, provide information about the submitter and his/her organization, select a user name and password, and download, complete and mail an electronic signature agreement to EPA (discussed further in Unit III.F.). The electronic signature agreement is needed to identify an authorized person and establish a method to electronically sign the submission. Once EPA receives the electronic signature agreement, the submitter's user name and password will be activated, and only then would the submitter be able to send a submission to EPA through CDX. For planning purposes, please allow up to 1 week for EPA to process the electronic signature agreement and activate the user name and password.

2. *Preparing the submission.* All submitters would be required to use the new e-PMN software to prepare their submissions of TSCA section 5 notices. The e-PMN software would be available for free as a download from EPA's New Chemicals Program website at <http://www.epa.gov/oppt/newchems> or mailed on an optical disc upon request. The e-PMN software guides users through the process of creating a PMN submission on their computers. Once a user completes the relevant data entry, the software would validate the submission by performing basic error checks and making sure all the required fields are completed, allow the user to create and save the submission for company

records, and prompt users to choose a submission method.

3. *Completing the submission to EPA.* During the 2-year phase-in period when paper and/or optical disc submission would still be allowed, the software would, as appropriate, also allow the user to choose "Print," "Save as a PDF," "Save as an XML file" for a submission on an optical disc, or "Transmission through CDX." While permitted, submissions made in paper or using an optical disc would need to be mailed or delivered to EPA in the same manner that they are currently. When "Transmission through CDX" is selected, the user would be asked to provide the user name and password that were created during the CDX registration process. The software would then encrypt the file and submit it via CDX to EPA's New Chemical System (NCS).

#### *F. What is the Electronic Signatures Agreement?*

In order to submit electronically to EPA via CDX, individuals acting on behalf of the submitter must first register with CDX. One must register either as:

1. An authorized official of a company who can send all types of TSCA section 5 documents to EPA via CDX, or
2. Someone authorized by the authorized official to send TSCA section 5 supporting documents to EPA via CDX. Note, however, that authorized company officials are the only persons allowed to send TSCA section 5 notices and Letters of Support to EPA via CDX.

There are two ways that joint submissions would be submitted to EPA via CDX. The first way is for each joint submitter to fill out his or her portion of the submission in separate notice forms. These forms are linked to each other within EPA via a common unique identifying number—a "TS" number (see proposed regulatory text language in 40 CFR 700.45(e)(3))—which both companies are required to develop together and put on their respective forms. The second way is for one of the joint submitters to provide supporting information in a Letter of Support. Both would require the authorized company officials of the joint submitting companies to register in order to submit to EPA via CDX.

To register in CDX, the CDX registrant (also referred to as "Electronic Signature Holder" or "Public/Private Key Holder") downloads two forms: The Electronic Signature Agreement and the Verification by Company Authorizing Official Form. Registration enables CDX to perform two important functions: Authentication of identity and

verification of authorization. For authentication of identity, the submitter completes the Electronic Signature Agreement form along with a signature and date, has the form notarized, and mails it back to EPA. The Verification by Company Authorizing Official Form requires the signatures of the authorized company official and anyone he/she authorizes to submit support documents for the company. There are separate designations for submitter in this form: The submitter is the authorized company official or the submitter is one of the following persons authorized by the authorized company official—a paid employee of the company, an outside consultant for the company, or an authorized representative agent for the company. When these forms are received, EPA activates the submitter's registration in CDX and sends him or her an e-mail notification. Submitters would need to complete and sign these forms only once.

#### *G. Would CBI be Protected When Submitting via CDX?*

Yes. EPA would ensure secure transmission of PMN data sent from the user's desktop through the Internet via the Transport Layer Security (TLS) 1.0 protocol. TLS 1.0 is a widely used approach for securing Internet transactions, and is endorsed by the National Institute of Standards and Technology (NIST) for protecting data sent over the Internet. See NIST Special Publication 800-52, *Guidelines for the Selection and Use of Transport Layer Security (TLS) Implementations*, <http://csrc.nist.gov/publications/nistpubs/800-52/SP800-52.pdf>.

In addition, e-PMN software supports EPA's CROMERR requirements, as described under 40 CFR part 3, by enabling the submitter to electronically sign, encrypt, and submit submissions which EPA subsequently provides back to the submitter as an unaltered copy of record. This assures the submitter that the Agency has received exactly what the submitter sent to EPA. The current version of e-PMN encrypts using a module based on the 128-bit Advanced Encryption Standard (AES) adopted by NIST. AES is implemented as part of the Sun Java Runtime Environment (JRE) 5, which is bundled as part of e-PMN installation. Details about AES can be found on the NIST website at <http://csrc.nist.gov/publications/fips/fips197/fips-197.pdf>, and information on Sun JRE implementation of AES can be found at [http://java.sun.com/developer/technicalArticles/Security/AES/AES\\_v1.html](http://java.sun.com/developer/technicalArticles/Security/AES/AES_v1.html). As appropriate, EPA may incorporate other encryption modules into future versions of e-PMN (such

versions might be developed before or after the final rule is to take effect) depending upon availability and suitability.

Information submitted via CDX is processed within EPA by secure systems certified for compliance with Federal Information Processing Standards.

EPA solicits comment on the security of transmission of e-PMN information via CDX.

#### *H. Would I be Required to Use the e-PMN Software for Any Paper or Optical Disc Submissions During the 2-Year Phase-In Period?*

Yes. Under this proposed rule, submitters would be required to use the e-PMN software to generate TSCA section 5 notices, NOCs, and support documents, regardless of whether they are submitted via CDX, on optical disc, or in paper form. EPA would not accept paper submissions that use either the old version of the paper PMN form or the amended form filled in by hand or typewriter. The Agency would make available free web downloads or, upon request, optical discs that contain the e-PMN software. All e-PMN software users, regardless of how a document is submitted, would need to undergo a "finalization" step in generating a document. During the finalization step, the e-PMN software checks that all required fields contain information and provides warnings for certain kinds of missing, incomplete, or incorrect data. Notices containing data which have not undergone finalization would be declared "Incomplete" by EPA. This step is necessary to allow for an accurate and efficient transfer of data from an optical disc or a paper form to the EPA data systems, and also enables the generation of a non-CBI version.

Anyone submitting the paper form that was generated using the e-PMN software would submit their notices to the Agency via U.S. mail or a courier service. The paper form would be signed on page 2. If the submitter makes any CBI claims, the original submission would need to include both the CBI version and a non-CBI version.

Optical discs would be submitted with an original signed hard copy of page 2 (Certification page) and a hard copy of page 3 (a copy of page 3 is needed for contact information in the event that the optical disc is not readable). Optical discs would need to be delivered only by courier service to avoid damage to the disk from the Agency's mail screening equipment.

*I. How Would Electronic Submission of TSCA Section 5 Notices that Currently Have No Required or Official Forms be Handled by CDX or the e-PMN Software?*

Certain TSCA section 5 notices such as LVE modifications, LoRex modifications, TMEAs, and biotechnology notices currently have no required or official forms. In order to allow for electronic and paper submission of these notices using the e-PMN software and CDX, the Agency is proposing the following:

1. For exemption modifications, submitters would use the e-PMN form by checking the "modification" box on page 1, filling in contact information on page 3, and including the previous exemption number and chemical identity information. A submitter may send a cover letter with the new revisions to the original exemption notice or the pertinent pages of the e-PMN form.

2. For a TMEA, the submitter would check the "TMEA" box on page 1 of the e-PMN form, and either fill out the form or attach a cover letter for the submission containing the information required by 40 CFR 720.38.

3. Biotechnology notices would have their own menu option. Instead of selecting "Premanufacture Notice," a submitter would select "Biotechnology," which would prompt the software to present a header page to the submitter with choices of biotechnology notices, and space to fill in contact information. The information required by 40 CFR part 725 would be submitted as an attachment(s).

The notices listed in Unit III.I.1. through 3. would need to undergo the "finalization" step (see Unit III.H.). An exemption submission on an optical disc would need to be accompanied by a complete signed hard copy of page 2 and a complete hard copy of page 3 of the e-PMN form for contact information in case the optical disc is not readable. The TMEA would only need a complete page 3. The optical discs for both types of submissions would need to be delivered by courier to the Agency to avoid damage to the disk from the Agency's mail screening equipment. If submitted by paper, the forms would need to be generated using the e-PMN software and sent to the Agency. For biotechnology notices, a signed hard copy of a biotechnology certification would need to accompany the optical disc. The printed form would follow the same procedures: Use the e-PMN software to generate a finalized "header" sheet with contact data, add

an attachment with notice information, and include a signature page.

The proposed submission process for completing the various notice and document types is summarized in Table 1 of this unit. After the effective date of the final rule, all of these notices would be prepared using the new e-PMN software.

**TABLE 1.—PROPOSED PROCESS FOR PREPARING TSCA SECTION 5 NOTICES AND SUPPORT DOCUMENTS**

TSCA Section 5 Documents	Proposed Process
PMNs and SNUNs	Form 7710–25 generated and finalized by e-PMN software.
LVE	Form 7710–25 generated and finalized by e-PMN software.
TMEA	e-PMN software to generate finalized submission either using Form 7710–25 or cover letter and attached information.
NOC	e-PMN software to generate finalized submission using Form 7710–56.
Biotechnology notices	e-PMN software to generate finalized "header" sheet with contact data, add attachment with notice information, include signature page.
Modifications to previous notices	Form 7710–25 generated and finalized by e-PMN software. Fill in pages 1, 2, and 3 of the Form, plus either applicable pages of Form, cover letter, or attachment.
Support documents	e-PMN software to generate finalized "header" sheet identifying reason for submission and contact data.

*J. How Would Delivery Methods to EPA Vary for Submissions via Paper, Optical Disc, or CDX?*

Depending upon how a notice is submitted, the following delivery methods would be used:

1. *Paper.* Printed, signed, and "header" sheets for attachments; delivered by mail or courier, allowed for the first year.

2. *Optical discs.* Data must be saved as XML files rather than as PDF files. Optical discs submitted with an original

signed hard copy of page 2 (Certification page) and a hard copy of page 3. Delivered by courier only. Allowed for the first 2 years only.

3. *CDX.* Document developed on-line; simply hit "send button" to deliver to EPA via CDX.

*K. Over What Time-Frame Would the Proposed Internet-Based CDX Reporting Requirement be Phased-In?*

The Agency is proposing to introduce electronic reporting in three phases. In the first phase, the Agency would allow the submission of TSCA section 5 notices and support documents via CDX, on optical disc, and on paper. All submissions (whether submitted via CDX, on optical disc, or on paper) would be required to be generated using the new e-PMN software.

In the second phase, occurring 1 year after the effective date of the final rule, paper submissions would no longer be accepted for any new notices and support documents (including NOCs). In the third phase, at the end of the second year after the effective date of the final rule, optical disc submissions for all new notices and support documents would no longer be accepted. Thereafter, EPA would accept only TSCA section 5 notices and support documents submitted through CDX. TSCA section 5 notices and support documents not submitted in the appropriate manner (and, for paper or optical disc submissions, during the time allowed for in the phase-in period) as described in this unit would be considered invalid by EPA and returned to the submitter. The Agency considers the proposed 2-year phase-in period to be enough time for submitters to gain experience using the CDX submission method and specifically seeks comments on this approach.

Note that NOCs and support documents whose original notices were submitted before the effective date of the final rule would still need to be mailed as hard copy to the Agency. This is necessary because, although the notices received after implementation of the new system will be entered into the newly created EPA database, notices submitted before promulgation of this rule will only exist in EPA's "legacy" database, i.e., the database used prior to promulgation of this rule, and so a subsequent support document would not be able to be linked up with its parent notice within EPA's new database. The proposed phase-in schedule for submissions is displayed in Table 2 of this unit.

TABLE 2.—PROPOSED E-PMN PHASE-IN SCHEDULE FOR TSCA SECTION 5 NOTICES AND SUPPORT DOCUMENTS<sup>1</sup>

Submission Method	Before Effective Date of Final Rule	First Year After Effective Date of Final Rule	Second Year After Effective Date of Final Rule	Third Year After Effective Date of the Final Rule, and Thereafter
Paper	Existing PMN form	Scanner-friendly paper form, generated and finalized using e-PMN software	Invalid	Invalid
Optical disc	Not applicable	Electronic submission generated and finalized using e-PMN software.	Electronic submission generated and finalized using e-PMN software.	Invalid
CDX/Internet	Not applicable	Available and optional	Available and optional	Mandatory

<sup>1</sup> NOCs and support documents for notices originally submitted on paper before the new system is implemented would still need to be mailed as hard copy.

#### *L. Would EPA Offer Any Exceptions to the Proposed Requirements?*

No. After careful consideration, the Agency has concluded that the overall benefits from everyone using the e-PMN software and submission through CDX exceed those associated with maintaining a multi-optioned reporting approach (Ref. 1). The Agency recognizes that there is the potential for costs and burden associated with predictable or unanticipated technical difficulties in electronic filing or with conversion to an electronic CDX reporting format. However, EPA expects that reduced reporting costs to submitters would ultimately exceed the transition costs and that any transition difficulties would be mitigated by:

1. The phase-in periods proposed.
2. EPA's planned outreach and training sessions prior to the effective date of the final rule. The Agency will allow ample time between the date of publication and the effective date of the final rule for submitters to install and become proficient with the e-PMN software.

3. EPA's planned technical support following the final rule's effective date.

#### *M. Will All Types of TSCA Section 5 Notices and Communications be Submitted via e-PMN Software?*

At this time, the Agency does not have electronic reporting capability for all TSCA section 5-related notices and support documents, due to the variability and infrequent nature of certain types of submissions. Examples are the Notice of *Bona Fide* Intent to Manufacture ("*bona fide*") and prenotice communications. EPA may consider offering electronic reporting of these and other submissions in the future.

#### **IV. Estimated Economic Impact**

The Agency's estimated economic impact of this proposal is present in a document entitled *Economic Analysis of*

*the Proposed Amendments to TSCA Section 5 Premanufacture and Significant New Use Notification Requirements* (Ref. 1), a copy of which is available in the docket and is briefly summarized in this unit. EPA estimates that the electronic submission option would reduce the burden and cost associated with reporting for PMNs and other TSCA section 5 notices and support documents. The burden estimation of 95 to 114 hours to complete the currently existing paper PMN form includes the time spent reading and becoming familiar with the form, gathering the required information and preparing the report, producing non-CBI responses for items claimed as CBI, and maintaining a file of the submission (Ref. 2).

In its economic analysis for the proposed rule (Ref. 1), EPA estimated cost and burden savings at the industry level, at the individual company level, and on a per-form basis. Estimates presented in this unit are for all TSCA section 5 notices; estimates for PMNs separately can be found in the economic analysis.

At the industry level for all TSCA section 5 notices, EPA estimates a net total burden decrease of 14,972 hours in the first year of the rule, 15,700 hours in the second year of the rule, and 16,178 hours in the third year of the rule. Industry savings are estimated at 16,187 hours per year for subsequent years of the rule. At the company level for all TSCA section 5 notices, EPA estimates an average net total burden decrease of 50.4 hours in the first year of the rule, 51.2 hours in the second and third years of the rule, and 50.4 hours per year for subsequent years of the rule.

At the industry level for all TSCA section 5 notices, EPA estimates a net cost savings of \$379,271 in the first year of the rule, \$424,863 in the second year of the rule, and \$457,066 in the third year of the rule. Industry savings are estimated at \$457,628 per year for

subsequent years of the rule. When taking into account the lower total number of notices expected during this 3-year ICR period in addition to savings attributable to the rule, the average annual reduction in industry costs is \$5.7 million. At the company level for all TSCA section 5 notices, EPA estimates an average cost savings of \$1,352 in the first year of the rule, \$1,396 in the second and third years of the rule, and \$1,352 in subsequent years of the rule.

EPA estimates that the Agency also will experience a reduction in both burden and cost to administer the TSCA section 5 notice program as a result of the proposed rule. Specifically, EPA expects to experience a net burden reduction of 4,521 hours in the first year of the rule, a reduction of 9,042 hours in the second year of the rule, and a reduction of 13,563 hours in the third and subsequent years of the rule. The Agency expects to experience a net savings of \$214,377 in the first year of the rule, a net savings of \$586,108 in the second year of the rule, and a net savings of \$1,057,838 in the third and subsequent years of the rule.

EPA recognizes that information and feedback received during the 2-year proposed phase-in period, along with experience gained during this phase-in period, can be used to further improve the use of the new Internet-based reporting mechanism. This information will also inform the Agency's estimates, which will be reflected in the Information Collection Request, which EPA must complete every 3 years under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*

#### **V. Request for Comment**

The Agency is making the e-PMN software available during the public comment period for this proposed rule. This will enable stakeholders to use the software on a test basis, which includes the ability to submit test notices via



CDX to EPA. The e-PMN software and guidance for CDX registration and submission is available at the Agency's website (<http://www.epa.gov/oppt/newchems>) or on optical discs provided by the Agency upon request. In addition, the following are two topics on which the Agency is specifically requesting public comment. EPA encourages all interested persons to submit comments on these two topics or other relevant topics, as well as on the use of the e-PMN software and submission of notices via CDX. This input will assist the Agency in developing a rule that successfully addresses information needs while minimizing potential reporting burdens associated with the rule. EPA requests that commenters making specific recommendations include supporting documentation where appropriate, including cost and burden estimates.

1. Based on the expected efficiency of electronic reporting via the Internet, EPA believes that companies would be supportive of the proposed rule and would quickly take advantage of the new Internet-based reporting system, moving away from paper or optical disc reporting. EPA specifically seeks comment on whether the proposed 2-year phase-in period following promulgation of the final rule, during which time paper and/or optical disc submissions would be accepted, is reasonable or necessary to allow sufficient time to transition to the new Internet-based method. Would enabling stakeholders to test the system prior to, and technical assistance after, the effective date of the final rule be sufficient to prepare industry for the new CDX submission method? Should there be no phase-in period, or a period shorter than 2 years? Does the proposed phase-in period approach overly complicate reporting?

2. EPA expects that electronic submission would reduce burden associated with reporting under TSCA section 5. EPA is seeking information that might further inform the Agency's burden estimates. Because use of CDX would be optional during the 2-year phase-in period, it is uncertain how many submitters would choose to take advantage of this submission method during that period. Therefore, estimated costs presented by EPA for submitters (reporting burden) and the Agency (time required for manual processing of data) may be overestimates of actual costs to the extent that submitters are able to use the electronic submission tool sooner. For example, do you intend to begin using CDX as soon as it is available? If not, when would you expect to begin using CDX and why? Are there

implementing factors that you expect to use in making your decisions that EPA should consider in evaluating the Agency's estimates? Are there any factors that would facilitate your earlier implementation of CDX? How much time does it take you to fill out and submit a notice via CDX, compared to the current paper method?

## VI. References

The public docket for this proposed rule has been established. The following is a listing of the documents referenced in this preamble that have been placed in the public docket for this proposed rule under docket ID number EPA-HQ-OPPT-2008-0296, which is available for inspection as specified under

### ADDRESSES.

1. EPA. Economic and Policy Analysis Branch, Office of Pollution Prevention and Toxics (OPPT). Economic Analysis of the Proposed Amendments to TSCA Section 5 Premanufacture and Significant New Use Notification Requirements. October 6, 2008.

2. EPA. Regulatory Impacts Branch, OPPT. Regulatory Impact Analysis of Amendments to Regulations for TSCA Section 5 Premanufacture Notifications. September 9, 1994.

3. EPA. Supporting Statement for a Request for OMB Review Under The Paperwork Reduction Act. Information Collection Request (ICR): New Information Collection Activities Related to Electronic Submission of Certain TSCA Section 5 Notices EPA ICR No. 2327.01. OMB Control No. 2070-NEW.

## VII. Statutory and Executive Order Reviews

### A. Executive Order 12866

This action is not a "significant regulatory action" under the terms of Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993) and is therefore not subject to review under the Executive Order.

### B. Paperwork Reduction Act

The information collection requirements contained in this proposed rule have been submitted for OMB approval under PRA, 44 U.S.C. 3501 *et seq.* The ICR document prepared by EPA, identified under EPA ICR No. 2327.01 and OMB control number 2070-NEW, is available in the docket for the proposed rule (Ref. 3). This ICR will amend the two currently approved ICR documents that cover the existing reporting and recordkeeping programs that are approved under OMB control number 2070-0012 and 2070-0038. 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. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

The amended information collection activities contained in this proposed rule are designed to assist the Agency in meeting its responsibility under TSCA to receive, process, and review PMNs and SNUNs in a timely manner and further the proper performance of the functions of the Agency. Information collection for review of PMNs and SNUNs is authorized by TSCA section 5 and confidentially of submitted information is protected under TSCA section 14.

The information collected under the two existing ICRs, as consolidated into the new ICR, would be modified by the addition of two new data elements:

1. A User Fee Payment Identity Number.

2. The submitter's (authorized official's) e-mail address(es).

The other revision to the information collection activities already approved by OMB, would be the change affecting how the submitter completes and submits the required form to EPA. As such, responses to the collection of information covered by this ICR would still be mandatory, but with the final rule, respondents would be required to use the e-PMN software to complete the form. The methods for submitting the completed form to EPA would change over a 2-year period following the effective date of the rule to allow for the new required submission through CDX to be fully implemented.

Burden is defined at 5 CFR 1320.3(b). The ICR document for this proposed rule provides a detailed presentation of the estimated burden and costs for 3 years of the program. The aggregate burden varies by year during the first 3 years of the rule because of the phase-in schedule of the proposed requirements. The rule-related burden and cost to chemical manufacturers, importers, and processors who would submit notices to the Agency for review is summarized here. The projected total burden to industry is 363 hours per year for the first 3 years of the rule. This includes an estimated average burden per response of 0.9 hours for CDX registration, 1.8 hours for requesting a CDX electronic signature, 0.1 hours for establishing an account for electronic fee payments, and 0.8 hours for rule familiarization.

Any comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any



suggested methods for minimizing respondent burden, should be directed to the docket for this proposed rule, under docket ID number EPA-HQ-OPPT-2008-0296. You may also submit a copy of your comments on the ICR to OMB. See **ADDRESSES** for submission of comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17<sup>th</sup> St., NW., Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after December 22, 2008, a comment to OMB is best assured of having its full effect if OMB receives it by January 21, 2009. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

#### C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, the Agency hereby certifies that this proposed rule, if promulgated as proposed, would not have a significant adverse economic impact on a substantial number of small entities, due to the burden-reducing nature of this action, which will benefit all submitters regardless of the size of the entity.

Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this document on small entities, small entity is defined as:

1. A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201.
2. A small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000.
3. A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

In determining whether a rule has a significant adverse economic impact on a substantial number of small entities, an agency may certify that a rule will not have a significant adverse economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. This proposed rule is expected to reduce the existing regulatory burden. The factual basis for the Agency's certification under the RFA is presented in the small entity impact analysis prepared as part of the Economic Analysis for this

proposed rule (Ref. 1), and is briefly summarized in Unit IV.

#### D. Unfunded Mandates Reform Act

Based on EPA's experience with past PMNs and SNUNs, State, local, and tribal governments have not been affected by these reporting requirements, and EPA does not have any reason to believe that any State, local, or tribal government will be affected by this rulemaking. As such, EPA has determined that this regulatory action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any affect 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).

#### E. Executive Order 13132

Under Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), EPA has determined that this proposed rule does not have "federalism implications" because it would not have substantial direct effects on the States, 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 the Executive Order. This proposed rule would establish electronic notification requirements that apply to manufacturers (including importers) and processors of certain chemicals. This proposed rule would not apply directly to States and localities and would not affect State and local governments. Thus, Executive Order 13132 does not apply to this proposed rule.

#### F. Executive Order 13175

Under Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), EPA has determined that this proposed rule does not have tribal implications because it would not have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in the Executive Order. EPA has no information to indicate that any tribal government manufactures or imports the chemical substances covered by this action. Thus, Executive Order 13175 does not apply to this proposed rule.

#### G. Executive Order 13045

This proposed rule would not require special consideration pursuant to the terms of Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because it is not likely to have an annual effect on the economy of \$100 million or more, nor does it establish an environmental standard, or otherwise have a disproportionate effect on children.

#### H. Executive Order 13211

This proposed rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this proposal does not have any significant adverse effect on the supply, distribution, or use of energy.

#### I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), 15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, etc.) that are developed or adopted by voluntary consensus standards bodies. This proposed rule would not impose any technical standards that would require EPA to consider any voluntary consensus standards.

#### J. Executive Order 12898

This proposed rule would 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 does not need to consider environmental justice-related issues.

#### List of Subjects in 40 CFR Parts 700, 720, 721, 723, and 725

Environmental protection, Chemicals, Electronic reporting, Hazardous substances, Reporting and recordkeeping requirements.

Dated: December 15, 2008.

**James B. Gulliford,**

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

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

## **PART 700—[AMENDED]**

1. The authority citation for part 700 is revised to read as follows:

**Authority:** 15 U.S.C 2625 and 2665, 44 U.S.C. 3504.

2. By revising § 700.45(e)(1); (e)(2); (e)(3); (e)(4)(i), (ii), and (iv); and (e)(5)(i), (ii), and (iv) to read as follows:

### **§ 700.45 Fee payments.**

\* \* \* \* \*

(e) \* \* \*

(1) Each remittance under this section shall be in United States currency and shall be paid by money order, bank draft, wire transfer, Pay.gov service provided through the Department of the Treasury, or check drawn to the order of the Environmental Protection Agency.

(2) Each paper remittance shall be sent to the Environmental Protection Agency, Washington Finance Center, Toxic Substances Control Act User Fees, P.O. Box 979073, St. Louis, MO 63197–9000.

(3) Persons who submit a TSCA section 5 notice shall place a unique identifying number and a payment identity number on the front page of each section 5 notice submitted. The unique identifying number must include the letters “TS” followed by a combination of 6 numbers (letters may be substituted for some numbers). The payment identity number may be a check number, a wire transfer number, or a “Pay.gov” transaction number used to transmit the user fee. The same TS number and the submitter’s name must appear on the corresponding fee remittance under this section. If a remittance applies to more than one section 5 notice, the person shall include the name of the submitter and a new TS number for each section 5 notice to which the remittance applies, and the amount of the remittance that applies to each notice. Any remittance not having the identifying name and numbers described in this paragraph will be returned to the remitter.

(4)(i) Each person who remits the fee identified in paragraph (b)(1) of this section for a PMN, consolidated PMN, intermediate PMN, or significant new use notice shall insert a check mark for the statement, “The company named in part 1, section A is a small business concern under 40 CFR 700.43 and has remitted a fee of \$100 in accordance with 40 CFR 700.45(b).” under

“CERTIFICATION” on page 2 of the Premanufacture Notice for New Chemical Substances (EPA Form 7710–25).

(ii) Each person who remits the fee identified in paragraph (b)(1) of this section for an exemption application under TSCA section 5(h)(2) shall insert a check mark for the statement, “The company named in part 1, section A is a small business concern under 40 CFR 700.43 and has remitted a fee of \$100 in accordance with 40 CFR 700.45(b).” in the exemption application.

\* \* \* \* \*

(iv) Each person who remits the fee identified in paragraph (b)(1) of this section for a MCAN for a microorganism shall insert a check mark for the statement, “The company named in part 1, section A is a small business concern under 40 CFR 700.43 and has remitted a fee of \$100 in accordance with 40 CFR 700.45(b).” in the certification required in § 725.25(b) of this chapter.

(5)(i) Each person who remits a fee identified in paragraph (b)(2) of this section for a PMN, consolidated PMN, intermediate PMN, or significant new use notice shall insert a check mark for the statement, “The company named in part 1, section A has remitted the fee specified in 40 CFR 700.45(b).” under “CERTIFICATION” on page 2 of the Premanufacture Notice for New Chemical Substances (EPA Form 7710–25).

(ii) Each person who remits a fee identified in paragraph (b)(2) of this section for an exemption application under TSCA section 5(h)(2) shall insert a check mark for the statement, “The company named in part 1, section A has remitted the fee specified in 40 CFR 700.45(b).” in the exemption application.

\* \* \* \* \*

(iv) Each person who remits the fee identified in paragraph (b)(1) of this section for a MCAN for a microorganism shall insert a check mark for the statement, “The company named in part 1, section A is a small business concern under 40 CFR 700.43 and has remitted a fee of \$100 in accordance with 40 CFR 700.45(b).” in the certification required in § 725.25(b) of this chapter.

\* \* \* \* \*

## **PART 720—[AMENDED]**

3. The authority citation for part 720 would continue to read as follows:

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

4. By adding paragraphs (ii), (jj), (kk), and (ll) to § 720.3 to read as follows:

### **§ 720.3 Definitions.**

\* \* \* \* \*

(ii) *e-PMN software* means electronic-PMN software, including associated instructions, created by EPA for use in preparing and submitting Premanufacture Notices (PMNs) and other TSCA section 5 notices and support documents electronically to the Agency.

(jj) *Central Data Exchange* or *CDX* means EPA’s centralized electronic document receiving system, or its successors, including associated instructions for registering to submit electronic documents.

(kk) *Optical disc* means compact disc (CD) or digital video disc (DVD).

(ll) *Support documents* means materials and information submitted to EPA in support of a TSCA section 5 notice, including but not limited to Letters of Support (see § 720.40(e)(2) and § 725.25(e)(2) of this chapter), correspondence, amendments, and test data. The term “support documents” does not include orders under TSCA section 5(e) (either consent orders or orders imposed pursuant to TSCA section 5(e)(2)(B)).

5. By revising § 720.40(a)(2), (c), (d)(2), (e)(1), and (e)(2) to read as follows:

### **§ 720.40 General.**

(a) \* \* \*

(2) All notices must be submitted on EPA Form 7710–25. Notices, and any support documents related to these notices, may only be submitted in a manner set forth in this paragraph.

(i) *Paper-based submissions.* Notices, and any support documents related to these notices, may be submitted on paper until [date 365 days after effective date of the final rule]. All paper-based notices must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print EPA Form 7710–25 for submission to EPA. Paper notices, and any support documents related to such notices, must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

(A) Support documents for notices that are submitted before [effective date of the final rule] must be submitted on paper to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

(B) [Reserved]

(ii) *Submissions on optical disc*—(A) Notices may be submitted as electronic files on optical disc until [date 731 days after effective date of the final rule]. All notices submitted as electronic files on optical disc must be generated using e-PMN reporting software and be completed through the finalization step of the software. Optical discs containing electronic notices must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(B) Persons submitting on optical disc must also complete and submit on paper the Certification and Submitter Identification sections of EPA Form 7710–25.

(iii) *Submissions via CDX*. Notices and any related support documents may be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices must be generated and completed on EPA Form 7710–25 using e-PMN reporting software.

(iv) You can obtain the e-PMN software and reporting instructions and CDX reporting instructions as follows:

(A) *Website*. Go to the EPA TSCA New Chemicals Program Internet homepage at <http://www.epa.gov/oppt/newchemicals> and follow the appropriate links.

(B) *By phone or e-mail*. Call the EPA CDX Call Center at (866) 411–4372 (4EPA).

(C) *E-mail*. [epacallcenter@epa.gov](mailto:epacallcenter@epa.gov).

(c) *Where to submit a notice or support documents*. For submitting notices or support documents via CDX, use the e-PMN software. Paper notices or support documents must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. Optical discs containing electronic notices or support documents must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004. Persons submitting on optical disc must also complete and submit on paper the Certification and Submitter Identification sections of EPA Form 7710–25.

(d) \* \* \*

(2) If information is claimed as confidential pursuant to § 720.80, a person who submits a notice to EPA in the manner set forth in § 720.40(a)(2)(i), (ii), or (iii) must also provide EPA with a sanitized copy.

(e) \* \* \*

(1) A manufacturer or importer may designate an agent to assist in submitting the notice. If so, only the manufacturer or importer, and not the agent, signs the certification on the form.

(2) A manufacturer or importer may authorize another person, (e.g., a supplier or a toll manufacturer) to report some of the information required in the notice to EPA on its behalf. The manufacturer or importer should indicate in a cover letter accompanying the notice which information will be supplied by another person and identify that other person as a joint submitter where indicated on their notice form. The other person supplying information (i.e., the joint submitter) may submit the information to EPA using either the notice form or a Letter of Support, except that if the joint submitter is not incorporated, licensed, or doing business in the United States, the joint submitter must submit the information to EPA in a Letter of Support only, not in a notice form. The joint submitter must indicate in the notice or Letter of Support the identity of the manufacturer or importer. Any person who submits a notice form or Letter of Support for a joint submission must sign and certify the notice form or Letter of Support.

\* \* \* \* \*

6. By revising paragraphs (a) and (c)(1)(iv) and adding paragraph (c)(x) to § 720.65 to read as follows:

**§ 720.65 Acknowledgment of receipt of a notice; errors in the notice; incomplete submissions; false and misleading statements.**

(a) *Notification to the submitter*. EPA will acknowledge receipt of each notice that has been submitted via CDX with a computer response via CDX that identifies the premanufacture notice number assigned to the new chemical substance and the date on which the review period begins. If the notice is submitted on paper or via optical disc, in accordance with § 720.40(a)(2)(i) or (ii), EPA will acknowledge receipt of the notice by sending the submitter a letter that identifies the premanufacture notice number assigned to the new chemical substance and the date on which the review period begins. After [date 731 days after effective date of the final rule], all acknowledgements will be made via CDX. The review period will begin on the date the notice is received by the Office of Pollution Prevention and Toxics Document Control Officer. The acknowledgment does not constitute a finding by EPA

that the notice, as submitted, is in compliance with this part.

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

(iv) The submitter does not submit the notice in the manner set forth in § 720.40(a)(2).

\* \* \* \* \*

(x) The submitter does not include a unique identifying number and a payment identity number as required by 40 CFR 700.45(e)(3).

\* \* \* \* \*

7. By revising paragraphs (b)(2) and (e)(1) and adding paragraphs (b)(3) and (b)(4) to § 720.75 to read as follows:

**§ 720.75 Notice review period.**

\* \* \* \* \*

(b) \* \* \*

(2) A request for suspension may only be submitted in a manner set forth in this paragraph. The request for suspension also may be made orally, including by telephone, to the submitter's EPA contact for that notice, subject to paragraph (b)(3) of this section.

(i) *Older notices*. Requests for suspension for premanufacture notices submitted before [effective date of the final rule] must be submitted on paper to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

(ii) *Newer notices*. For notices submitted on or after [effective date of the final rule], EPA will accept requests for suspension only if submitted in accordance with this paragraph:

(A) Requests for suspension may be submitted on paper until [date 365 days after effective date of the final rule]. All paper-based requests for suspension must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the request for suspension for submission to EPA. Paper requests for suspension must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

(B) Requests for suspension may be submitted as electronic files on optical disc until [date 731 days after effective date of the final rule]. All requests for suspension submitted as electronic files on optical disc generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be

used to print the request for suspension for submission to EPA. Paper requests for suspension must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(C) Requests for suspension may be submitted electronically to EPA via CDX. Such requests must be generated and completed using e-PMN reporting software. See § 720.40(a)(2)(iv) for instructions how to obtain e-PMN software and reporting instructions, and CDX reporting instructions.

(3) An oral request for suspension may be granted by EPA for a maximum of 15 days only. Requests for longer suspension must only be submitted in the manner set forth in this paragraph.

(4) If the submitter has not made a previous oral request, the running of the notice review period is suspended as of the date of receipt of the written paper request, electronic request on optical disc, or CDX submission by EPA.

\* \* \* \* \*

(e) \* \* \*

(1) A submitter may withdraw a notice during the notice review period by submitting a statement of withdrawal in a manner set forth in this paragraph. The withdrawal is effective upon receipt of the written paper request, electronic request on optical disc, or CDX submission by EPA.

(i) *Older notices.* Statements of withdrawal for premanufacture notices submitted before [effective date of the final rule] must be submitted on paper to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(ii) *Newer notices.* For notices submitted on or after [effective date of the final rule], EPA will accept statements of withdrawal only if submitted in accordance with this paragraph:

(A) Statements of withdrawal may be submitted on paper until [date 365 days after effective date of the final rule]. All paper-based statements of withdrawal must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the statement of withdrawal for submission to EPA. Paper statements of withdrawal must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(B) Statements of withdrawal may be submitted as electronic files on optical disc until [date 731 days after effective date of the final rule]. All statements of withdrawal submitted as electronic files on optical disc must be generated using e-PMN reporting software and be completed through the finalization step of the software. Optical discs containing electronic statements of withdrawal must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(C) Statements of withdrawal may be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such statements of withdrawal must be generated and completed using e-PMN reporting software. See § 720.40(a)(2)(iv) for instructions how to obtain e-PMN software and reporting instructions, and CDX reporting instructions.

\* \* \* \* \*

8. By revising § 720.80(b)(2)(i) to read as follows:

**§ 720.80 General provisions.**

\* \* \* \* \*

(b) \* \* \*

(2) \* \* \*

(i) The notice and attachments must be complete. The submitter must designate that information which is claimed as confidential in the manner prescribed on the notice form, via EPA's e-PMN software. See § 720.40(a)(2)(iv) for how to obtain e-PMN software and CDX reporting instructions.

\* \* \* \* \*

9. By revising § 720.102(c)(1) introductory text and (d) to read as follows:

**§ 720.102 Notice of commencement of manufacture or import.**

\* \* \* \* \*

(c) \* \* \*

(1) The notice must be submitted on EPA Form 7710-56, which is available as part of EPA's e-PMN software. See § 720.40(a)(2)(iv) for instructions how to obtain e-PMN software and reporting instructions, and CDX reporting instructions. The form must be signed and dated by an authorized official. All information specified on the form must be provided. The notice must contain the following information:

\* \* \* \* \*

(d) *Where to submit.* All notices of commencement must be submitted to EPA on EPA Form 7710-56. Notices may only be submitted in a manner set forth in this paragraph.

(1) *Older notices.* Notices of commencement for premanufacture

notices submitted before [effective date of the final rule] must be submitted on paper to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(2) *Newer notices.* For premanufacture notices submitted on or after [effective date of the final rule], EPA will accept notices of commencement only if submitted in accordance with this paragraph:

(i) Notices of commencement may be submitted on paper until [date 365 days after effective date of the final rule]. All paper-based notices of commencement must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the statement of withdrawal for submission to EPA. Paper notices of commencement must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(ii) Notices of commencement may be submitted as electronic files on optical disc until [date 731 days after effective date of the final rule]. All notices of commencement submitted as electronic files on optical disc must be generated using e-PMN reporting software and be completed through the finalization step of the software. Optical discs containing electronic notices of commencement must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(3) Notices of commencement may be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices of commencement must be generated and completed using e-PMN reporting software. See § 720.40(a)(2)(iv) for instructions how to obtain e-PMN software and reporting instructions, and CDX reporting instructions.

**PART 721—[AMENDED]**

10. The authority citation for part 721 would continue to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

11. By revising § 721.25(c) to read as follows:

**§ 721.25 Notice requirements and procedures.**

\* \* \* \* \*

(c) EPA will process the notice in accordance with the procedures of part 720 of this chapter except to the extent they are inconsistent with this part.

\* \* \* \* \*

12. By revising § 721.30(b) introductory text to read as follows:

**§ 721.30 EPA approval of alternative control measures.**

\* \* \* \* \*

(b) Persons submitting a request for a determination of equivalency to EPA under this part, unless allowed by 40 CFR 720.40(a)(2)(i), (ii), or (iii), must submit the request to EPA by direct computer-to-computer electronic transfer via EPA's Central Data Exchange (CDX) using EPA-provided e-PMN software in the manner set forth in 40 CFR 720.40(a)(2). See 40 CFR 720.40(a)(2)(v) for how to obtain e-PMN software, CDX reporting instructions, and other associated documents. Support documents related to these requests must be submitted in the manner set forth in 40 CFR 720.40(a)(2)(i), (ii), or (iii). If submitted by paper, requests must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; ATTN: SNUR Equivalency Determination. Optical discs containing electronic requests must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004; ATTN: SNUR Equivalency Determination. A request for a determination of equivalency must contain:

\* \* \* \* \*

**PART 723—[AMENDED]**

13. The authority citation for part 723 would continue to read as follows:

**Authority:** 15 U.S.C 2604.

14. By revising § 723.50(e)(1) to read as follows:

**§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.**

\* \* \* \* \*

(e) \* \* \*

(1) A manufacturer applying for an exemption under either paragraph (c)(1) or (c)(2) of this section must submit an exemption notice to the EPA at least 30 days before manufacture of the new chemical substance begins. Unless allowed as described by

§ 723.50(e)(1)(i), (e)(1)(ii), or (e)(1)(iii), exemption notices and modifications must be submitted to EPA on EPA Form No. 7710-25 by direct computer-to-computer electronic transfer via EPA's Central Data Exchange (CDX) using EPA-provided e-PMN reporting software in the manner set forth in this paragraph. Support documents related to these notices must also be submitted to EPA via CDX using e-PMN software in the manner set forth in this paragraph. See § 720.40(a)(2)(iv) of this chapter for how to obtain e-PMN software and reporting instructions, and CDX reporting instructions.

(i) *Paper-based submissions*—(A) Such notices, and any support documents related to these notices, submitted before [effective date of the final rule] must be submitted on paper to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(B) All other notices and related support documents may be submitted on paper until [date 365 days after effective date of the final rule]. All paper-based notices must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print EPA Form 7710-25 for submission to EPA. Paper notices must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(ii) *Submissions on optical disc*—(A) Notices may be submitted as electronic files on optical disc until [date 731 days after effective date of the final rule]. Notices submitted as electronic files on optical disc must be generated using e-PMN reporting software and be completed through the finalization step of the software. Optical discs containing electronic notices must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(B) Persons submitting on optical disc must still complete and submit on paper the Certification and Submitter Identification sections of EPA Form 7710-25 accompanying the optical disc.

(iii) *Submissions via CDX*—(A) As of [effective date of the final rule], notices, and any related support documents, may be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, notices must be generated and

completed on EPA Form 7710-25 using e-PMN reporting software.

(B) By [date 731 days after effective date of the final rule], all notices must be generated and completed on EPA Form 7710-25 using e-PMN reporting software and submitted electronically, along with any support documents related to these notices, to EPA via CDX.

(iv) Support documents for notices that are submitted before [effective date of the final rule] must be submitted on paper to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

\* \* \* \* \*

**PART 725—[AMENDED]**

15. The authority citation for part 725 would continue to read as follows:

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

16. By revising § 725.25(c), (e)(1), and (e)(2) to read as follows:

**§ 725.25 General administrative requirements.**

\* \* \* \* \*

(c) *Where to submit information under this part.* MCANs and exemption requests, and any support documents related to these submissions, may only be submitted in a manner set forth in this paragraph.

(1) *Paper-based submissions.* MCANs and exemption requests, and any support documents related to these submissions, may be submitted on paper until [date 365 days after effective date of the final rule]. All paper-based submissions must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the biotechnology notice submission to be sent to EPA. Paper notices must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(2) *Submissions on optical disc*—(i) MCANs and exemption requests may be submitted as electronic files on optical disc until [date 731 days after effective date of the final rule]. MCANs and exemption requests submitted as electronic files on optical disc must be generated using e-PMN reporting software and be completed through the finalization step of the software. Optical discs containing electronic notices must be submitted by courier to the Environmental Protection Agency,

OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(ii) Persons submitting on optical disc must still prepare, sign and submit on paper, the Certification statement in 40 CFR 725.25(b) along with submitter identification and contact information.

(iii) Support documents for MCANs or exemption requests that are submitted before [effective date of the final rule] must be submitted on paper to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(3) *Submissions via CDX.* MCANs and exemption requests, and any related support documents, may be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, notices must be generated and completed on EPA Form 6300.07 using e-PMN reporting software.

\* \* \* \* \*

(e) \* \* \*

(1) A manufacturer or importer may designate an agent to assist in submitting the MCAN. If so, only the manufacturer or importer, and not the agent, signs the certification on the form.

(2) A manufacturer or importer may authorize another person, (e.g., a supplier or a toll manufacturer) to report some of the information required in the MCAN to EPA on its behalf. The manufacturer or importer should indicate in a cover letter accompanying their MCAN which information will be supplied by another person and identify that other person as a joint submitter where indicated in their MCAN. The other person supplying information (i.e., the joint submitter) may submit the information to EPA either in the MCAN or a Letter of Support, except that if the joint submitter is not incorporated, licensed or doing business in the United States, the joint submitter must submit the information to EPA in a Letter of Support only, rather than the MCAN. The joint submitter must indicate in the MCAN or Letter of Support the identity of the manufacturer or importer. Any person who submits the MCAN or Letter of Support for a joint submission must sign and certify the MCAN or Letter of Support.

\* \* \* \* \*

17. By revising § 725.29(a) to read as follows:

**§ 725.29 EPA acknowledgement of receipt of submission.**

(a) EPA will acknowledge receipt of each submission via CDX with a computer response via CDX that

identifies the number assigned to each MCAN or exemption request and the date on which the review period begins.

If the notice or exemption request is submitted on paper or optical disc, in accordance with 40 CFR 725.25(c)(1) or (c)(2), EPA will acknowledge receipt of the notice by sending the submitter a letter that identifies the number assigned to the 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, if submitted via paper or optical disc.

\* \* \* \* \*

18. By adding paragraphs (a)(10) and (a)(11) to § 725.33 to read as follows:

**§ 725.33 Incomplete submissions.**

(a) \* \* \*

(10) The submitter does not include a unique identifying number and a payment identity number as required by § 700.45(e)(3) of this chapter.

(11) The submitter does not submit the notice in the manner set forth in § 725.25(c).

\* \* \* \* \*

19. By revising § 725.36(a) to read as follows:

**§ 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 within 10 days of receiving the new information, but no later than 5 days before the end of the review period. The new information must be sent in the same manner the original notice or exemption was sent, as described in § 725.25(c)(1), (c)(2), and (c)(3).

\* \* \* \* \*

20. By revising paragraph (b) and adding paragraphs (c) and (d) to § 725.54 to read as follows:

**§ 725.54 Suspension of the review period.**

\* \* \* \* \*

(b) A request for suspension may only be submitted in a manner set forth in this paragraph. The request for suspension also may be made orally, including by telephone, to the submitter's EPA contact for that notice, subject to paragraph (c) of this section.

(1) *Older notices.* Requests for suspension for notices submitted before [effective date of the final rule] must be submitted on paper to the Document Control Office (DCO) (7407M), Office of

Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(2) *Newer notices.* For notices submitted on or after [effective date of the final rule], EPA will accept requests for suspension only if submitted in accordance with this paragraph:

(i) Requests for suspension may be submitted on paper until [date 365 days after effective date of the final rule]. All paper-based requests for suspension must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the request for suspension for submission to EPA. Paper requests for suspension must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(ii) Requests for suspension may be submitted as electronic files on optical disc until [date 731 days after effective date of the final rule]. All requests for suspension submitted as electronic files on optical disc generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the request for suspension for submission to EPA. Paper requests for suspension must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(iii) Requests for suspension may be submitted electronically to EPA via CDX. Such requests must be generated and completed using e-PMN reporting software. See § 720.40(a)(2)(iv) of this chapter for instructions how to obtain e-PMN software and reporting instructions, and CDX reporting instructions.

(c) An oral request for suspension may be granted by EPA for a maximum of 15 days only. Requests for longer suspension must only be submitted in the manner set forth in this paragraph.

(d) If the submitter has not made a previous oral request, the running of the notice review period is suspended as of the date of receipt of the written paper request, electronic request on optical disc, or CDX submission by EPA.

21. By revising § 725.60(a) to read as follows:

**§ 725.60 Withdrawal of submission by the submitter.**

(a) A submitter may withdraw a notice during the notice review period

by submitting a statement of withdrawal in a manner set forth in this paragraph. The withdrawal is effective upon receipt of the written paper request, electronic request on optical disc, or CDX submission by EPA.

(1) *Older notices.* Statements of withdrawal for notices submitted before [effective date of the final rule] must be submitted on paper to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(2) *Newer notices.* For notices submitted on or after [effective date of the final rule], EPA will accept statements of withdrawal only if submitted in accordance with this paragraph:

(i) Statements of withdrawal may be submitted on paper until [date 365 days after effective date of the final rule]. All paper-based statements of withdrawal must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the statement of withdrawal for submission to EPA. Paper statements of withdrawal must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(ii) Statements of withdrawal be submitted as electronic files on optical disc until [date 731 days after effective date of the final rule]. All statements of withdrawal submitted as electronic files on optical disc must be generated using e-PMN reporting software and be completed through the finalization step of the software. Optical discs containing electronic statements of withdrawal must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(iii) Statements of withdrawal may be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such statements of withdrawal must be generated and completed using e-PMN reporting software. See § 720.40(a)(2)(iv) of this chapter for instructions how to obtain e-PMN software and reporting instructions, and CDX reporting instructions.

\* \* \* \* \*

22. By revising § 725.67(a)(1) to read as follows:

**§ 725.67 Applications to exempt new microorganisms from this part.**

(a) \* \* \*

(1) Any manufacturer or importer of a new microorganism may request, under TSCA section 5(h)(4), an exemption, in whole or in part, from this part by sending a Letter of Application in the manner set forth in § 725.25(c).

\* \* \* \* \*

23. By revising § 725.190(d) to read as follows:

**§ 725.190 Notice of commencement of manufacture or import.**

\* \* \* \* \*

(d) *Where to submit.* All notices of commencement must be submitted to EPA in a manner set forth in this paragraph.

(1) *Older notices.* Notices of commencement for a MCAN submitted before [effective date of the final rule] must be submitted on paper to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(2) *Newer notices.* For MCANs submitted on or after [effective date of the final rule], EPA will accept notices of commencement only if submitted in accordance with this paragraph:

(i) Notices of commencement may be submitted on paper until [date 365 days after effective date of the final rule]. All paper-based notices of commencement must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the statement of withdrawal for submission to EPA. Paper notices of commencement must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

(ii) Notices of commencement be submitted as electronic files on optical disc until [date 731 days after effective date of the final rule]. All notices of commencement submitted as electronic files on optical disc must be generated using e-PMN reporting software and be completed through the finalization step of the software. Optical discs containing electronic notices of commencement must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(3) Notices of commencement may be submitted electronically to EPA via CDX. Prior to submission to EPA via

CDX, such notices of commencement must be generated and completed using e-PMN reporting software. See § 725.25(c)(4) for instructions how to obtain e-PMN software and reporting instructions, and CDX reporting instructions.

24. By revising § 725.975(b) introductory text to read as follows:

**§ 725.975 EPA approval of alternative control measures.**

\* \* \* \* \*

(b) Persons submitting a request for a determination of equivalency to EPA under this part, unless allowed by § 725.25(c) (1), (2), or (3), must submit the request to EPA by direct computer-to-computer electronic transfer via EPA's Central Data Exchange (CDX) using EPA-provided e-PMN software in the manner set forth in § 725.25(c). See § 725.25(c)(4) for how to obtain e-PMN software and reporting instructions, and CDX reporting instructions. Support documents related to these requests must also be submitted to EPA via CDX using e-PMN software. If submitted on paper, requests must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; ATTN: SNUR Equivalency Determination. Optical discs containing electronic requests must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004; ATTN: SNUR Equivalency Determination. A request for a determination of equivalency must contain:

\* \* \* \* \*

25. By revising § 725.984(b)(1) to read as follows:

**§ 725.984 Modification or revocation of certain notification requirements.**

\* \* \* \* \*

(b) \* \* \*

(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. Persons submitting a request to EPA under this part, unless allowed by § 725.25(c)(1), (c)(2), or (c)(3), must submit the request to EPA by direct computer-to-computer electronic transfer via EPA's Central Data



Exchange (CDX) using EPA-provided e-PMN reporting software in the manner set forth in § 725.25(c). See § 725.25(c)(4) for how to obtain the e-PMN software, CDX reporting instructions, and other associated documents. Support documents related to these requests must also be submitted to EPA via CDX using e-PMN software. Paper requests must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; ATTN: Request to Amend SNUR. Optical discs containing electronic requests must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004; ATTN: Request to Amend SNUR.

\* \* \* \* \*

[FR Doc. E8-30379 Filed 12-19-08; 8:45 am]

BILLING CODE 6560-50-S

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 300

[Docket No. 0808061071-81575-01]

RIN 0648-AX17

#### Pacific Halibut Fisheries; Guided Sport Charter Vessel Fishery for Halibut

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Proposed rule; request for comments.

**SUMMARY:** NMFS proposes regulations that would limit the harvest of Pacific halibut by guided sport charter vessel anglers in International Pacific Halibut Commission Regulatory Area 2C (Area 2C) of Southeast Alaska to one halibut per day. This proposed regulatory change is necessary to reduce the halibut harvest in the charter vessel sector to approximately the guideline harvest level for Area 2C. The intended effect of this action is to manage the harvest of halibut consistent with an allocation strategy recommended by the North Pacific Management Council for the guided sport charter vessel fishery and the commercial fishery.

**DATES:** Comments must be received no later than January 21, 2009.

**ADDRESSES:** Send comments to Sue Salveson, Assistant Regional

Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Ellen Sebastian. You may submit comments, identified by “RIN 0648-AX17” by any one of the following methods:

- **Electronic Submissions:** Submit all electronic public comments via the Federal eRulemaking Portal website at <http://www.regulations.gov>.

- **Mail:** P. O. Box 21668, Juneau, AK 99802.

- **Fax:** (907) 586-7557.

- **Hand delivery to the Federal Building:** 709 West 9<sup>th</sup> Street, Room 420A, Juneau, AK.

All comments received are a part of the public record and will be posted to <http://www.regulations.gov> without change. All Personal Identifying Information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields if you wish to remain anonymous). Attachments to electronic comments must be in Microsoft Word, Excel, WordPerfect, or Adobe portable document file (pdf) formats to be accepted.

Copies of the Environmental Assessment (EA), Regulatory Impact Review (RIR), and Initial Regulatory Flexibility Analysis (IRFA) prepared for this action may be obtained from NMFS Alaska Region, P.O. Box 21668, Juneau, Alaska 99802, Attn: Ellen Sebastian, and on the NMFS Alaska Region website at <http://alaskafisheries.noaa.gov>.

**FOR FURTHER INFORMATION CONTACT:** Julie Scheurer, 907-586-7356.

**SUPPLEMENTARY INFORMATION:** The International Pacific Halibut Commission (IPHC) and NMFS manage fishing for Pacific halibut (*Hippoglossus stenolepis*) through regulations established under the authority of the Northern Pacific Halibut Act of 1982 (Halibut Act). The IPHC promulgates regulations governing the halibut fishery under the Convention between the United States and Canada for the Preservation of the Halibut Fishery of the Northern Pacific Ocean and Bering Sea (Convention). The IPHC(s) regulations are subject to approval by the Secretary of State with concurrence from the Secretary of Commerce (Secretary). After approval by the Secretaries of State and Commerce, the IPHC regulations are published in the **Federal Register** as annual management measures pursuant to 50 CFR 300.62 (March 7, 2008; 73 FR 12280).

The Halibut Act also provides regulatory authority to the North Pacific Fishery Management Council (Council) and the Secretary. The Council, under 16 U.S.C. 773c(c), may develop regulations applicable to U.S. nationals or vessels, which are in addition to, and not in conflict with regulations adopted by the IPHC. The regulations developed by the Council shall only be implemented with the approval of the Secretary, and must meet criteria outlined in section 773c(c), including consistency with 16 U.S.C. 1853(b)(6). The Secretary, under 16 U.S.C. 773c(a) and (b), has the general responsibility to carry out the Convention and Halibut Act. According to section 773c(b), “In fulfilling [the general responsibility to carry out the Convention and the Halibut Act], the Secretary shall, in consultation with the Secretary of the department in which the Coast Guard is operating, adopt such regulations as may be necessary to carry out the purposes and objectives of the Convention and [the Halibut Act].” The Secretary’s authority to take action under the Halibut Act has been delegated to NMFS.

NMFS takes this action under section 773c(b) to adopt such regulations as may be necessary to carry out the purposes and objectives of the Convention and the Halibut Act. This action would implement, among other measures, a one halibut daily bag limit on charter vessel anglers in IPHC Area 2C. This bag limit originally was recommended by the Council in June 2007, implemented by NMFS by final rule on May 28, 2008, with an effective date of June 1, 2008 (73 FR 30504). The May 28, 2008, final rule was enjoined by the U.S. District Court for the District of Columbia on June 10, 2008, (see Order Granting Plaintiffs’ Motion for a Temporary Restraining Order (TRO), dated June 11, 2008, and Order Granting Plaintiffs’ Motion for a Preliminary Injunction (PI), dated June 19, 2008, *Van Valin, et al. v. Gutierrez*, Civil Action No. 1:08-cv-941). NMFS has withdrawn the May 28, 2008, final rule that was challenged in the *Van Valin* lawsuit, and now takes action in a separate rulemaking to implement a one halibut daily bag limit, giving effect to the Council’s intent to keep the harvest of charter vessel anglers to approximately the established guideline harvest level (GHL).

In its Order Granting the Plaintiffs’ Motion for a Preliminary Injunction, dated June 19, 2007, the U.S. District Court determined that the Plaintiffs had met the burden for granting a preliminary injunction, including demonstrating a likelihood of success