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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 712, 716, 720, 721, 723, 725, 766, 790, and 799

[EPA-HQ-OPPT-2011-0519; FRL-9394-6]

RIN 2070-AJ75

Electronic Reporting Under the Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending certain reporting requirements that were promulgated under the Toxic Substances Control Act (TSCA) to require the use electronic reporting. EPA is requiring the use of electronic reporting in order to minimize the paperwork burden associated with the underlying regulatory requirements and to minimize the cost to the Federal Government of the creation, collection, maintenance, use, dissemination, and disposition of information. This action will also improve the quality and use of information to strengthen decisionmaking, accountability, and openness in government and society, as well as provide for the timely dissemination of public information and in a manner that promotes the utility of the information to the public and makes effective use of information technology.

DATES: This final rule is effective [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2011-0519 is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics (OPPT) Docket, Environmental Protection

Agency (EPA) Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Katherine Sleasman, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-7716; email address: *sleasman.katherine@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture (including import), process, or distribute in commerce chemical substances and mixtures. Potentially affected entities may include, but are not limited to:

• Chemicals and Allied Products Manufacturers (NAICS code 32411).

• Petroleum Refining (NAICS codes 325 and 32411).

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.

II. Background

A. What Action is the Agency Taking?

EPA is promulgating amendments to reporting requirements under TSCA section 4 (including test rules and Enforceable Consent Agreements (ECAs)), TSCA section 5, TSCA section 8(a) Preliminary Analysis Information Rule (PAIR) at 40 CFR part 712, and TSCA section 8(d) Health and Safety Data Reporting Rules at 40 CFR part 716. EPA developed this action in accordance with its final plan for periodic retrospective reviews of existing regulations under Executive Order 13563, entitled "Improving Regulation and Regulatory Review." This final rule was proposed in the **Federal Register** issue of April 17, 2012 (Ref. 1). The purpose of the amendments is to manage and leverage EPA's information resources to reduce information collection burdens on the public; increase EPA program efficiency and effectiveness; and improve the integrity, quality, and utility of information to all users within and outside the Agency, including capabilities for ensuring dissemination of public information, public access to Federal Government information, and protections for privacy and security.

This final rule is part of broader government efforts to move to modern, electronic methods of information gathering. EPA's Chemical Information Submission System (CISS) Web-based reporting tool and e-PMN software enable more efficient data transmittal via the Central Data Exchange (CDX) and reduces errors with the built-in validation procedures. EPA believes the adoption of electronic reporting reduces the reporting burden for submitters by reducing the cost and time required to review, edit, and transmit data to the Agency. The resource and time requirements to review and

process data by the Agency will also be reduced and document storage and retrieval will require fewer resources. In addition, the final rule ensures the legal dependability of electronically submitted documents so that they meet the needs of the compliance and enforcement programs. The legal dependability of electronically submitted documents is ensured by valid electronic signatures that can be submitted into evidence, assurance that electronic documents can be authenticated to provide evidence of what an individual submitted and/or attested to, and assurance that electronic signatures resist repudiation by the signatory.

The Agency is extending the TSCA section 5 electronic reporting requirements to Notice of Commencements (NOCs) and support documents (e.g., correspondence, amendments, and test data) relating to TSCA section 5 notices submitted to EPA prior to April 6, 2010, the effective date of the TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting; Revisions to Notification Regulations (Ref. 2). Previously, follow-up submissions for TSCA section 5 notices submitted before this date were not subject to electronic reporting requirements.

Effective [*insert date 90 days after date of publication in the* **Federal Register**], EPA will only accept data, reports, and other information subject to these rules when submitted through CDX and the CISS tool for the submission of forms, reports, and other documents. TSCA section 5 submissions, however, must be submitted through CDX using e-PMN software downloaded from EPA's CDX website. Data, reports, and other information not submitted in the manner required will not be considered by EPA to have met the filing requirements of those rules. The CISS tool is also available for use in making voluntary submissions, such as those under Memoranda of Understanding

(MOUs), electronically, following the same procedures described in this final rule. Submitters should register through CDX and submit data, reports, and other documents through the CISS tool. The final rule amends the following regulations:

1. *TSCA section 4 test rules and ECAs.* Documents required under TSCA section 4 include letters of intent to conduct testing (40 CFR 790.45), extension requests (40 CFR 790.50), modification requests (40 CFR 790.55), exemption requests (40 CFR 790.80 and 40 CFR 790.82), hearing requests (40 CFR 790.90), data required to be developed under rules at 40 CFR part 799, and documents and correspondence related to ECAs negotiated pursuant to 40 CFR part 790. Affected sections include those relating to submission or modification of a study plan (40 CFR 790.62), and requests to modify the test schedule for any test required under an ECA (40 CFR 790.68). Electronic reporting requirements for TSCA section 4 rules and ECAs are added to 40 CFR 790.5 and 799.50. In addition, anyone who manufactures, imports, or processes a chemical substance under 40 CFR part 766, must test that chemical substance immediately upon manufacture, import, or processing for the presence of halogenated dibenzodioxins/halogenated dibenzofurans (HDDs/HDFs), and submit all test data to EPA. A requirement for electronic reporting is added to 40 CFR 766.35.

2. *TSCA section 5*. EPA is amending certain TSCA section 5 reporting requirements that extend electronic reporting requirements to NOCs and support documents (e.g., correspondence, amendments, and test data) relating to TSCA section 5 notices submitted to EPA before April 6, 2010. The e-PMN final rule (Ref. 2) required submitters of NOCs and support documents whose original notices were submitted to EPA prior to April 6, 2010 (legacy notices) to submit those NOCs and support documents

to EPA in hard copy. At the time the final e-PMN rule was published, EPA believed the hard copy submission of these documents was necessary because the Agency intended to operate two different databases; one for storing electronic TSCA section 5 notices submitted to EPA after April 6, 2010, and another for storing legacy notices. EPA originally intended to enter legacy notices only into EPA's "legacy database," i.e., the database used prior to April 6, 2010, and so would not have been able to link up a subsequent NOC or support document with its original or "parent" legacy notice if the subsequent document was entered into EPA's new database.

However, since publication of the e-PMN final rule, EPA's electronic reporting program has evolved and EPA now has the ability to house both legacy notices and notices submitted after April 6, 2010, in the same database. EPA is therefore amending 40 CFR parts 720, 721, 723, and 725 to require NOCs and support documents submitted after [*insert date 90 days after date of publication in the* **Federal Register**] for TSCA section 5 notices originally submitted prior to April 6, 2010, to be submitted electronically allowing them to be stored with their legacy TSCA section 5 notices in the new database.

In the e-PMN final rule, EPA phased-in electronic reporting of TSCA section 5 notices and their related NOCs and support documents over a 2-year period that ended April 6, 2012. In this final rule, EPA is removing the phase-in because the phase-in period is over and all TSCA section 5 notices, NOCs, and support documents are required to be submitted to EPA via CDX.

3. *TSCA section 8(a)*. Electronic reporting requirements for Form 7710-35, Manufacturer's Report--Preliminary Assessment Information (Manufacturer's Report),

are added to 40 CFR 712.28 and 712.30. In addition, electronic reporting requirements for Form 7710-51, Dioxins/Furans Report Form, are added to 40 CFR 766.35.

4. *TSCA section 8(d).* Electronic submission of data, reports, and other documents are now required under the TSCA section 8(d) Health and Safety Data Reporting Rule at 40 CFR part 716 and the Dibenzo-Para-Dioxins/Dibenzofurans Rule at 40 CFR part 766 (specifically 40 CFR 716.30, 716.35, 716.60, and 766.35). Additional affected sections of 40 CFR part 716 include the submission of underlying data, preliminary reports of ongoing studies, additional copies of studies (40 CFR 716.40), requests for extension of time (40 CFR 716.60), and requests for withdrawal of a chemical substance from a rule (40 CFR 716.105).

EPA also requires submission of allegations of significant adverse reactions to dibenzo-para-dioxins/dibenzofurans, pursuant to 40 CFR part 717. EPA has not received a large number of allegations of significant adverse reactions, and therefore is not implementing a mechanism for the electronic submission of these allegations of significant adverse reactions using the CISS tool at this time. Anyone subject to the applicable requirements of 40 CFR part 766 must continue to submit to EPA paper copies of allegations of significant adverse reactions.

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

TSCA gives EPA broad authority to regulate the manufacture (including import) and processing of chemical substances. The underlying requirements promulgated under this broad authority and amended by this final rule require manufacturers (including importers) and processors of chemical substances and mixtures to:

• Perform testing to generate data relevant to a determination whether the

manufacture, distribution in commerce, processing, use, or disposal of such chemicals or mixtures presents an unreasonable risk of injury to health or the environment (TSCA section 4).

• Report such data as EPA may reasonably require, including information that is necessary to facilitate the evaluation of the potential adverse human health and environmental effects from exposure to identified chemical substances, mixtures, or categories (TSCA section 8(a)).

• Submit lists and/or copies of ongoing and completed unpublished health and safety studies concerning identified chemical substances, mixtures, or categories (TSCA section 8(d)).

• Notify EPA at least 90 days before commencing the manufacture of a new chemical substance for commercial purposes (TSCA section 5(a)(1)(A)).

• Notify EPA at least 90 days before manufacturing or processing the chemical substance for any use of a chemical substance that EPA has determined, by rule, to be a "significant new use" (TSCA section 5(a)(2)).

In addition, the Paperwork Reduction Act (PRA) requires Federal agencies to manage information resources to reduce information collection burdens on the public; increase program efficiency and effectiveness; and improve the integrity, quality, and utility of information to all users within and outside an agency, including capabilities for ensuring dissemination of public information, public access to Federal Government information, and protections for privacy and security (44 U.S.C. 3506). Section 2 of TSCA expresses the intent of Congress that EPA carry out TSCA in a reasonable and prudent manner, and in consideration of the impacts that any action taken under TSCA

may have on the environment, the economy, and society (15 U.S.C. 2601). Electronic reporting was not available when TSCA was enacted nor when several underlying reporting requirements were subsequently promulgated by EPA. EPA believes that it is now reasonable and prudent to manage and leverage its information resources, including information technology (IT), to require the use of electronic reporting in the implementation of certain TSCA provisions. Electronic reporting can reduce burden and costs for the regulated entities by eliminating the costs associated with printing and mailing this information to EPA, while at the same time improving EPA's efficiency in reviewing submitted information, making decisions and disseminating information to the public.

III. Description of Changes to Reporting Procedures

This unit provides an overview of EPA's CDX, the Chemical Safety and Pesticide Program (CSPP), the CISS tool, and the e-PMN software for NOCs and support documents associated with legacy TSCA section 5 notices.

A. What is CDX?

CDX is EPA's centralized electronic submission receiving system. CDX also provides the capability for submitters to access their data through the use of web services. CDX enables EPA to work with stakeholders, including governments, regulated industries, and the public, to enable streamlined, electronic submission of data via the Internet. For more information about CDX, go to *http://epa.gov/cdx*.

B. What is CISS?

EPA developed the CISS tool for use in submitting data, reports, and other information under TSCA electronically to the Agency. In the proposed rule CISS was

referred to as e-TSCAweb. In this document only the term CISS is used. The CISS tool is available for use with Windows, Macs, Linux, and UNIX based computers, using "Extensible Markup Language" (XML) specifications for efficient data transmission across the Internet. The CISS tool provides user-friendly navigation, works with CDX to secure online communication, creates a completed Portable Document Format (PDF) for review prior to submission, and enables data, reports, and other information to be submitted easily as PDF attachments, or by other electronic standards, such as XML, and protects Confidential Business Information (CBI) as appropriate. Over time, there will be updates to CISS tool. The most recent version of CISS is available online at *http://epa.gov/cdx*.

C. What is the e-PMN Software for TSCA Section 5?

EPA has developed e-PMN software for use in preparing and submitting Premanufacture Notices (PMNs) and other TSCA section 5 notices and support documents electronically to the Agency. For further information on the software capabilities, visit the TSCA New Chemicals Program website available online at *http://www.epa.gov/oppt/newchems*. Also, see the e-PMN final rule (Ref. 2) for further guidance.

D. What are the Benefits of CDX Reporting and Use of the CISS Tool and the e-PMN Software?

The effort to eliminate paper-based submissions in favor of CDX reporting, including use of the CISS tool, is part of broader Federal Government efforts to move to modern, electronic methods of information gathering. The CISS tool and e-PMN software enable more efficient data transmittal and reduces errors with the built-in validation procedures. EPA believes the adoption of electronic reporting reduces the

reporting burden for submitters by reducing the cost and time required to review, edit, and transmit data to the Agency. It also allows submitters to share a draft submission within their organization, and more easily save a copy for their records or future use. The resource and time requirements to review and process data by the Agency will also be reduced and document storage and retrieval will require fewer resources. EPA expects to benefit from receiving electronic submissions and communicating back electronically with submitters. In addition, the use of CDX and the CISS tool ensures the legal dependability of electronic reports so that they meet the needs of the compliance and enforcement programs. The legal dependability of electronically submitted documents is ensured by valid electronic signatures that can be submitted into evidence, assurance that electronic documents can be authenticated to provide evidence of what an individual submitted and/or attested to, and assurance that electronic signatures resist repudiation by the signatory (Ref. 3).

E. How Do I Submit Data, Reports, and Other Documents Required Under TSCA Sections 4, 8(a), and 8(d) Using CDX?

This final rule requires submitters to register with EPA's CDX, request access to CSPP, and use the CISS tool to prepare a file for submission.

1. *Registering with CDX.* Registration enables CDX to authenticate each user's identity, and to verify each user's authorization to file official submissions to EPA on behalf of a company.

To submit electronically to EPA via CDX, individuals must first register in CDX through EPA's webpage at *http://cdx.epa.gov/epa_home.asp*.

To register in CDX, the CDX registrant (also referred to as "Electronic Signature Holder" or "Public/Private Key Holder") agrees to the terms and conditions, provides

information about the submitter and organization, selects a user name and password, selects a program and role, and follows the procedures outlined in the CDX user guide available on EPA's webpage at *http://www.epa.gov/cdr/tools/CDX_Registration_Guide_v0_02.pdf.*

Users, who have previously registered with CDX for TSCA section 5 submissions, or the Toxics Release Inventory TRI-ME web reporting, are able to add CSPP to their current registration, and use the CISS tool.

2. *Communication through CDX*. Currently communication through CDX between the submitter and EPA is focused on transactional activities, meaning the submission of information to EPA and notification from EPA that the submission was received. EPA is mandating that all submissions of required materials be done through CDX but acknowledges that use of certified mail and email for correspondence related to the submissions is still necessary since the ability to do so within CDX is not yet available. EPA is in the process of enhancing the CDX correspondence functionality so the two-way emailing between submitters and EPA is offered in a secure environment.

3. *Preparing the submission.* All submitters are required to use the CISS tool to prepare their submissions. The CISS tool guides users through a "hands-on" process of creating an electronic submission. Once a user completes the relevant data fields, attaches appropriate PDF or other file types, such as XML files, and completes metadata information, the CISS tool validates the submission by performing a basic error check and makes sure all the required fields and attachments are provided and complete. Further instructions on submitting voluntary submissions, such as under MOUs and instructions for uploading PDF attachments or other file types, such as XML, and completing

metadata information are available through the CISS tool user guide.

4. *Completing the submission to EPA.* The CISS tool also allows the user to choose "Print," "Save," or "Transmit through CDX." When "Transmission through CDX" is selected, the user is asked to provide the user name and password that was created during the CDX registration process. The CISS tool then encrypts the file and submits it via CDX.

F. How Must TSCA Section 5 NOCs and Support Documents Relating to Legacy TSCA Section 5 Notices Be Submitted to EPA?

EPA is requiring that NOCs and support documents relating to legacy TSCA section 5 notices be submitted to EPA using the same process as described in 40 CFR 720.40(a)(2), see Unit II.A.3. All NOCs and support documents are required to be generated using e-PMN software and be completed through the finalization step of the software. See the e-PMN final rule (Ref. 2) for more detailed information on the process for submitting NOCs and support documents.

G. How Must CBI Be Submitted Using CISS?

All information sent by the submitter via CDX is transmitted securely to protect CBI. The CISS tool enables the user to submit CBI in an electronic format. The CISS tool also guides the user through the process of submitting CBI by prompting the submitter to check a CBI box if using an electronic form or by submitting a sanitized document containing CBI by bracketing, underlining, or otherwise marking the confidential information on the document to be submitted prior to scanning. The submitter must provide a sanitized non-CBI document and CBI document. Documents containing information claimed as CBI must be submitted in an electronic format, in accordance with the recordkeeping requirements (Ref. 3) and the following regulations:

1. *TSCA section 4 test rules and ECAs.* Documents required under TSCA section 4 that may contain information claimed as CBI include study plans submitted in accordance with test rules (40 CFR 790.50) and study plans submitted in accordance with an ECA (40 CFR 790.62). The CISS tool allows the submitter to indicate whether a study plan contains information claimed as CBI by checking the appropriate box. The submitter then is prompted to submit the study plan document in an electronic format. The submitter must indicate which information in the study plan contains information claimed as CBI by marking the specific information claimed as confidential and designating it with the words "confidential business information," "trade secret," or another appropriate phrase in the document prior to scanning. Subsequently, if CBI is claimed in either a study plan for test rules or an ECA, the submitter is prompted by the CISS tool to substantiate those claims by answering the substantiating questions pursuant to 40 CFR 790.7 in a document submitted in an electronic format.

2. *TSCA section 8(a).* The CISS tool includes areas for indicating CBI on Form 7710-35, Manufacturer's Report, (40 CFR 712.28 and 712.30). If CBI is indicated on Form 7710-35, Manufacturer's Report, the CISS tool requires the submitter to certify that the confidentially statements are true by prompting the submitter to select the "Confidentiality Certification Statement." The Dioxins/Furans Report Form (Form 7710-51) and instructions for downloading the form required under 40 CFR part 766 are available online at *http://www.epa.gov/oppt/chemtest/ereporting/index.html.*

3. *TSCA section 8(d).* Documents submitted under TSCA section 8(d) that contain information claimed as CBI must be indicated as such by using the CISS tool. The CISS tool allows the submitter to indicate if the document contains CBI by checking the

appropriate box. Then, the submitter is prompted to submit the document in an electronic format. In submitting a document that contains CBI, the CISS tool prompts the submitter to submit two copies of the document in an electronic format. The copy containing CBI must identify the confidential information by bracketing or underlining the information and labeling the copy "confidential," "proprietary," or "trade secret." The non-CBI second copy needs to have all confidential information deleted. Once CBI is claimed, the CISS tool prompts the submitter to substantiate their claims (40 CFR 716.55).

The CISS tool user guide also instructs users on how to submit and substantiate CBI information.

H. How Will the Agency Provide Opportunities for Potential Users to Become Familiar With the Reporting Tool?

The Agency will offer a webinar open to the public for potential users to become familiar with the CISS tool before its release following publication of this final rule. The webinar will be recorded and available at *http://www.epa.gov/oppt/chemtest/ereporting/index.html*. There will also be beta testing to allow submitters to become familiar with the CISS tool on their own and to provide comments to the Agency on its functionality and performance.

IV. Economic Analysis

The Agency's estimated economic impact of this final rule is presented in a document entitled "Economic Analysis for the Electronic Reporting under Toxic Substance Control Act (TSCA) Final Rule" (Economic Analysis) (Ref. 4) a copy of which is available in the docket and is briefly summarized in this unit.

EPA estimates that this final rule will result in cost savings to the affected companies because the time required to enter, review, edit, and submit their reports using

CDX will be reduced compared to the existing paper-based process.

EPA estimates that this final rule will result in total cost to the industry of approximately $14,061 in year 1 and a cost savings of $66,834 in each subsequent year. The cost savings in subsequent years are greater than those in year 1 because of the one-time CDX registration costs incurred at the initial submission. EPA assumes that industry will continue to realize cost savings each additional year.

EPA estimates that the Agency also will experience a reduction in the cost to administer submissions of data under TSCA in the long-run. Due to the one-time development cost of $200,000 for CDX in year 1 and an annual CDX Operations and Maintenance (O&M) cost of $57,353, EPA will incur a cost of $197,918 in year 1, after accounting for $59,435 in savings resulting from the burden reductions associated with electronic processing of submissions within the Agency. In subsequent years, EPA will incur the $57,353 annually in operations and maintenance costs, resulting in Agency savings of $2,082 a year in subsequent years.

EPA received 9,280 TSCA section 5 supporting documents between April 1, 2005 and June 22, 2011, with an average of 1,510 supporting documents each year. EPA assumed that the impact of this final rule relating to the submission of TSCA section 5 supporting documents would be very minimal given that industry has already undertaken electronic submission of such supplemental materials.

V. Response to Comments

The Agency received comments from two persons on the proposed rule for electronic reporting for TSCA submissions. One was an anonymous comment expressing support for electronic reporting and the other comment was from an industry trade

association. Copies of all comments received are available in the docket for this action. The comments received on the proposed rule did not result in EPA making significant changes to the final rule. A discussion of the comments germane to the rulemaking and the Agency's responses follow:

Comment 1: *Phased-in the electronic reporting requirements*. One commenter stated that EPA must phase-in the electronic reporting requirements. The commenter stated that EPA should conduct adequate beta testing, and then should accept paper submissions as well as electronic ones for at least a 2-year phase-in period. They said that it is essential to avoid excessive burden on submitters, as well as to avoid placing the regulated community in the position of potential late submission or noncompliance related to reporting system obstacles. In addition, the commenter asserted that EPA's logs of calls to its hotline for the Chemical Data Reporting Rule (CDR) reporting will demonstrate objectively the nature and level of problems that users have encountered in this electronic reporting system, which was mandatory and was not phased-in. They asserted that their member companies have spent time working through the new CDR electronic reporting system, consulting with EPA's help desk and other staff, and otherwise addressing the various issues presented by the mandatory electronic reporting under CDR.

The commenter stated that phasing-in is necessary to allow EPA to work with users to ensure that the system is practical, user-friendly, and free of errors. Based on the commenter's experience with developing CDR submissions, they noted that it is important that persons other than an Authorized Official (AO) are able to make submissions as appropriate in any electronic system, as they also do with paper

submissions.

The commenter strongly urged EPA to continue to allow submissions through alternative means for at least a phase-in period. The phase-in period should follow a thorough beta-testing period. Furthermore, they noted that EPA should consider allowing alternative means of submission on a case-by-case basis. It is possible that future rules under TSCA sections 4 and 8 will affect entities that have not done prior TSCA submissions or even used CDX. They noted that such entities should not be forced to use any electronic submission system (particularly in a short time frame) unless and until the system is proved to be foolproof, efficient, and user-friendly.

EPA Response: EPA is mandating certain electronic reporting under TSCA in this final rule because EPA believes that the benefits of filing submissions electronically are substantial, in terms of data quality and timeliness of processing and public data availability and for records management. The Agency also notes that paper submissions contain errors that can be caught with forms associated with electronic submissions thus increasing data reliability. Although EPA acknowledges the initial burdens incurred with registering submitters in CDX and in learning how to use the CISS tool, EPA has received very positive feedback from industry submitters for the CDR Rule. Submitters have conveyed that the electronic reporting tool for that program, eCDRweb, while experiencing some initial performance issues, is far superior to previous electronic reporting applications used by EPA. EPA believes that, as more TSCA submitters register with CDX and gain experience with the CISS tool, concerns with using the electronic reporting tool will diminish.

With regard to IT-related issues that arose during the CDR reporting, EPA

acknowledges that there were some issues in the registration process early in the reporting period, and that CDX registrants were unfamiliar with the registration process and how the reporting tool worked. EPA responded to issues reported through the CDX help desk, the CDR help desk and the TSCA hotline in a timely manner with patches to the system. Most of the issues involved delays in CDX registration, with the need to reset passwords in the system, and in some cases with issues related to using the XML schema provided by EPA.

The CDX system has been in operation for over 10 years and during that time, EPA has continued to improve the registration process so that it is more efficient for users. For example, EPA found that accepting the Electronic Signature Agreements of CDX registered submitters under Toxic Release Inventory for those registering in CDX as TSCA submitters significantly reduced the burden associated with the CDX registration process. EPA expects eventually to achieve a one-time registration process for all Agency submitters, not just for those under TSCA, in CDX and is exploring other ways to streamline the CDX registration process.

EPA strongly encourages TSCA submitters to register with CDX in advance so that they are in a position to report when the need arises. EPA also encourages that multiple submitters in each company register as AO with CDX so that an alternate AO will be able to make the submission in a timely manner in the event that one of the registered AO CDX users is unavailable. It is critical that AO be individuals who can make submissions on behalf of their company in order to comply with Cross-Media Electronic Reporting Regulation (Ref. 5).

EPA understands the commenter's interest in beta testing and agrees that

providing the regulated community with opportunities to learn how to use the CISS tool and provide feedback is beneficial. Through these opportunities, submitters will gain experience with its functionalities and operation, and EPA can make refinements as necessary. In response to this comment, EPA has established a 90-day time frame between the publication date and effective date of this final rule rather than a 30- or 60-day time frame, in order to facilitate compliance with the final rule's effective date. During the 90 days, EPA will offer webinars and training opportunities for submitters to gain experience with the reporting tool and CDX. EPA also conducted webinars for TSCA section 8(a) on September 18, 2012, and for TSCA section 8(d) on May 22, 2012, and September 20, 2012. During these webinars, industry representatives had the opportunity to familiarize themselves with both CDX and CISS and ask questions regarding their functionality. EPA is implementing best practices and procedures and adding technologies to closely monitor the performance of the CISS tool and accelerate resolution of any problems that may arise with the tool. Performance status and scheduled updates to the CDX registration process and the CISS tool will be made available on the EPA electronic reporting website available online at *http://www.epa.gov/oppt/chemtest/ereporting/index.html*. Use of a web-based reporting tool provides assurance that upgrades to the system are seamless to the user, minimizing downtime and disruptions to the reporting process. EPA is committed to ensuring that the gap between incident and response is minimal.

In light of the substantial disadvantages associated with paper submissions, and with the reporting tool improvements and training opportunities, EPA does not believe it is necessary to phase-in electronic reporting for TSCA sections 4 and 8. As a practical

matter, electronic reporting requirements covered under this final rule are invoked by individual rules that are not promulgated under a set schedule and may not have ongoing reporting requirements (e.g., annual reporting), so it would be difficult to phase-in electronic reporting requirements. Further, the phase-in period in place for TSCA section 5 notices is completed therefore the regulated community is familiar with the ePMN software and an additional phase-in period is not needed. In addition, EPA and many regulated entities have gained experience with electronic reporting under TSCA and EPA believes that phasing would accommodate only a small number of new reporters, while potentially confusing those submitters already filing electronically under other TSCA requirements. It would also impose burden on EPA to manage both paper and electronic systems. EPA believes that by providing additional time to register in CDX before this final rule becomes effective, continuing to improve registration and help desk functions, and by offering training opportunities to industry, both new and experienced submitters will be able to successfully report electronically to EPA and be aware of the status of submitted data, reports, and other documents.

Comment 2: *Information about EPA's plans for offering electronic reporting for TSCA sections 8(e) and 12(b)*. One commenter requested that EPA explain its plans for electronic reporting under TSCA section 8(e) and 12(b), particularly since EPA has been demonstrating its software for electronic reporting of TSCA section 8(e) submissions.

The commenter suggested that EPA establish voluntary electronic reporting options for submissions under TSCA section 8(e) and for export notifications under TSCA section 12(b). The commenter noted that electronic reporting should be voluntary, not mandatory, due to the short timeframes for reporting and the ongoing potential for

submissions to be made by first-time reporters. Also, the commenter noted that voluntary electronic reporting would allow companies to use any internal systems they may have already developed to accomplish export notification, at least until they are able to revise the systems to accommodate electronic reporting to EPA.

EPA Response: EPA will announce the availability of an electronic reporting option for use both by those who are required to submit a notification of substantial risk under TSCA section 8(e) and by those who wish to voluntarily submit related FYI notifications. EPA is also considering extending electronic reporting for TSCA section 12(b) export notifications but is not announcing the availability of such a reporting method at this time.

Comment 3: *Correspondence through CDX*. The commenter noted to EPA that such correspondence could be useful, depending on its format and method of delivery. However, the commenter noted that EPA should not rely solely on CDX as the sole means of communication, and requested that any material correspondence relating to submissions under TSCA sections 4 and 8(d) rules should be transmitted by traditional means (e.g., letter and/or email as appropriate) as well as through CDX. Finally, it was noted that it is very important that any reporting system include a clear mechanism for documented acknowledgement from EPA that a submission has been received.

EPA Response: EPA acknowledges that CDX correspondence with TSCA submitters is limited. EPA is considering options to enhance CDX correspondence functionalities, including offering the ability to conduct two-way emailing between submitters and EPA in a secure environment. EPA will continue to allow TSCA submitters to correspond with EPA about their electronically reported TSCA submissions

through email and certified mail after the submission and all related materials are electronically reported through CDX. CDX does create and store a Copy of Record of the original submission and any amendments made by the submitter. This functionality provides records management benefits for EPA as well as the regulated community and other stakeholders who make TSCA submissions.

VI. References

As indicated under **ADDRESSES**, a docket has been established for this final rule under docket ID number EPA-HQ-OPPT-2011-0519. The following is a listing of the documents that are specifically referenced in this action. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Electronic Reporting Under the Toxic Substances Control Act; Proposed Rule. **Federal Register** (77 FR 22707, April 17, 2012) (FRL-9337-5).

2. EPA. TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting; Revisions to Notification Regulations; Final Rule. **Federal Register** (75 FR 773, January 6, 2010) (FRL-8794-5).

3. Transfer of Records to the National Archives of the United States. 36 CFR part 1235.

4. EPA. Economic Analysis for the Electronic Reporting under Toxic Substances Control Act (TSCA) Final Rule. June 17, 2013.

5. EPA. Cross-Media Electronic Reporting; Final Rule. **Federal Register** (70 FR 59855, October 13, 2005) (FRL-7977-1).

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 by the Office of Management and Budget (OMB) under Executive Orders 12866 and 13563, entitled "Improving Regulation and Regulatory Review" (76 FR 3821, January 21, 2011).

EPA has prepared an Economic Analysis for this action, which is contained in a document entitled "Economic Analysis for the Electronic Reporting under Toxic Substances Control Act (TSCA) Final Rule" (Ref. 4). A copy of the Economic Analysis is available in the docket for this final rule and is summarized in Unit IV.

B. Paperwork Reduction Act

The information collection requirements (ICR) contained in this final 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. 2412.02 and OMB Control No. 2070-0183, is available in the docket for this final rule. The ICR addresses the incremental changes to the four currently approved ICR documents that cover the existing reporting and recordkeeping programs that are approved under OMB control numbers 2070-0004, 2070-0012, 2070-0033, and 2070-0054. 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 amended information collection activities

contained in this final rule are designed to assist the Agency in meeting its responsibility under TSCA to receive, process, and review reports, data, and other information. Thus, submissions in response to the collection of information covered by these ICRs are mandatory and respondents are required to use the CISS tool, except for TSCA section 5 submissions, which require the use of the existing electronic e-PMN software.

Burden is defined at 5 CFR 1320.3(b). The ICR document for this final rule provides a detailed presentation of the estimated burden and costs for the first year of the program. 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 1,228 hours per year for the first year of the final 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, and 0.8 hours for final rule familiarization.

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 final rule will not have a significant adverse economic impact on a substantial number of small entities.

Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this final rule 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 final rule is expected to reduce the existing regulatory burden. The factual basis for the Agency's certification is presented in the small entity impact analysis prepared as part of the Economic Analysis for this final rule, and is briefly summarized in Unit IV. EPA analyzed reporting data that identified individual companies submitting information under TSCA sections 4, 5, 8(a), or 8(d) and identified those companies potentially affected by this final rule that qualify for the small business status. EPA estimated the cost impact ratios for small parent entities potentially affected by this final rule and has determined that the estimated regulatory costs represent a small impact of less than 1% of their annual revenue. The estimated ratios range from less than 0.0001% to 0.014%, depending on the NAICS sector and employment size category, with an average of 0.001%. No small parent entities are expected to have a cost impact of greater than 1% of annual revenue. Since the estimated regulatory costs represent a small fraction of a typical parent entity's revenue (i.e., less than 1%), the impacts of this final rule are likely to be minimal.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531-1538, requires Federal agencies, unless otherwise prohibited by law, to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This final rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. EPA estimates that this final rule will result in total private sector cost of approximately $14,061 in year 1 and a cost savings of $66,834 in each subsequent year (Ref. 4). State, local, and tribal governments have not been affected by the TSCA sections 4, 5, 8(a), and 8(d) reporting requirements, and are not expected to be affected by this final rule. Thus, this final rule is not subject to the requirements of UMRA sections 202 or 205. This final rule is also not subject to the requirements of UMRA section 203 because it contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132

This action does not have a substantial direct effect on States, on the relationship between national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This final rule does not have tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This final rule does not significantly nor uniquely affect the communities of Indian Tribal governments nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to his final rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because this action is not an economically significant regulatory action as defined by E.O. 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This final 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 action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under E.O. 12866.

I. National Technology Transfer and Advancement Act

Since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), 15 U.S.C. 272 note, does not apply to this action.

J. Executive Order 12898

This final rule does not entail special consideration of environmental justice related issues as delineated by Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and the Comptroller General of the United States. EPA is submitting a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Parts 712, 716, 720, 721, 723, 725, 766, 790, and 799

Environmental protection, Administrative practice and procedure, Business and industry, Chemicals, Reporting and recordkeeping requirements.

Dated: November 19, 2013.

James Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR chapter I is amended as follows:

PART 712--[AMENDED]

1. The authority citation for part 712 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

2. In § 712.3, add new paragraphs (q) and (r) to read as follows:

§ 712.3 Definitions.

***** ***** ***** ***** *****

(q) *Central Data Exchange* or *CDX* means EPA's centralized electronic submission receiving system.

(r) *Chemical Information Submission System* or *CISS* means EPA's electronic, web-based reporting tool for the completion and submission of data, reports, and other information, or its successors.

3. In § 712.28, revise paragraphs (c) and (d) and add new paragraph (e) to read as follows:

§ 712.28 Form and instructions.

* * * * *

(c) Persons authorized to report information under this subpart must include the following information on Form 7710-35, Manufacturer's Report--Preliminary Assessment Information (Manufacturer's Report):

(1) A certification as to the truth and accuracy of the information reported signed and dated by an authorized person located at the plant site or corporate headquarters of the respondent company.

(2) A confidentiality statement signed and dated by an authorized person located at the plant site or corporate headquarters of the respondent company.

(3) The specific chemical name and Chemical Abstracts Service (CAS) Registry Number listed in 40 CFR 712.30.

(4) The name, company, address, city, State, ZIP code, and telephone number of a person who is submitting the form, which may be a person located at a plant site or corporate headquarters that will serve as the respondent, and will be able to answer questions about the information submitted by the company to EPA. A respondent to this

subpart must include the appropriate Dun and Bradstreet Number for each plant site reported.

(5) The plant site activities, such as the manufacturing of a chemical substance, including the total quantity of the chemical substance (in kilograms) imported in bulk during the reporting period.

(6) The total number of workers and total worker-hours in each process category, which includes enclosed process, controlled release process, and open process.

(7) The information related to chemical substance processing by customers, including customers' use in industrial and consumer products, the market names under which the chemical substance is manufactured or imported, and the customer's process categories that are sold to customers for further processing.

(d) Persons must use the CISS tool to complete and submit Form 7710-35, Manufacturer's Report, and accompanying letters, via CDX. Submission requires registration with CDX, and must be made only as set forth in this section.

(e) To access the CISS tool go to *https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx* and follow the appropriate links, and for further instructions to go *http://www.epa.gov/oppt/chemtest/ereporting/index.html*.

4. In § 712.30, revise paragraphs (a)(3)(i), (a)(3)(ii), and (c)(2) to read as follows:

§ 712.30 Chemical lists and reporting periods.

(a) * * *

(3) * * *

(i)(A) The respondent has previously and voluntarily provided EPA with a

Manufacturer's Report on a chemical substance or mixture subject to subpart B of this part, which contains data for a 1-year period ending no more than 3 years prior to the effective date described in paragraph (a)(2) of this section. Respondents meeting this condition must notify EPA by letter of their desire to have the voluntary submission used in lieu of a current data submission and must verify the completeness and current accuracy of the voluntarily submitted data. Such letters, sent in accordance with the method specified in § 712.28(d) to EPA, must contain the following language:

> I hereby certify that, to the best of my knowledge and belief, all information entered on this form is complete and accurate. I agree to permit access to, and the copying of records by, a duly authorized representative of the EPA Administrator, in accordance with the Toxic Substances Control Act, to document any information reported on the form.

(B) Notification letters must be submitted in accordance with the method specified in § 712.28(d) prior to the reporting deadline.

(ii)(A) The respondent has previously submitted a Manufacturer's Report on a chemical substance or mixture subject to subpart B of this part to the Interagency Testing Committee, but not to EPA, and that Manufacturer's Report contained data for a 1-year period ending less than 3 years prior to the effective date described in paragraph (a)(2) of this section. Respondents meeting this condition must submit a copy of the Manufacture’s Report, in accordance with the method specified in § 712.28(d) to EPA, and must submit an accompanying letter, also in accordance with the methods specified in § 712.28(d), notifying EPA of the respondent’s intent that the submission be used in lieu of a current Manufacturer’s Report. The notification letter must verify the completeness and current accuracy of the voluntarily submitted data. Such a letter must contain the following language:

I hereby certify that, to the best of my knowledge and belief, all information entered on this form is complete and accurate. I agree to permit access to, and the copying of records by, a duly authorized representative of the EPA Administrator, in accordance with the Toxic Substances Control Act, to document any information reported on the form.

(B) The submission must be made prior to the reporting deadline.

* * * * *

(c) * * *

(2) You must submit the information using the method specified in § 712.28(d).

* * * * *

Part 716--[AMENDED]

5. The authority citation for part 716 continues to read as follows:

Authority: 15 U.S.C. 2607(d).

6. In § 716.3, add the following definitions in alphabetical order to read as follows:

§ 716.3 Definitions.

* * * * *

Central Data Exchange or *CDX* means EPA's centralized electronic submission receiving system.

Chemical Information Submission System or *CISS* means EPA's electronic, web-based tool for the completion and submission of data, reports, and other information, or its successors.

* * * * *

7**.** In § 716.30, revise paragraph (c) and add new paragraph (d) to read as follows:

§ 716.30 Submission of copies of studies.

* * * * *

(c) Persons must use the CISS tool to complete and submit all data, reports, and other information required by 40 CFR part 716, via CDX. Submission requires registration with CDX, and must be made only as set forth in this section.

(d) To access the CISS tool go to *https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx* and follow the appropriate links and for further instructions to go *http://www.epa.gov/oppt/chemtest/ereporting/index.html*.

8. In § 716.35, revise paragraph (c) and add new paragraph (d) to read as follows:

§ 716.35 Submission of lists of studies.

* * * * *

(c) Persons must use the CISS tool to complete and submit all data, reports, and other information required by 40 CFR part 716, via CDX. Submission requires registration with CDX, and must be made only as set forth in this section.

(d) To access the CISS tool go to *https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx* and follow the appropriate links and for further instructions to go *http://www.epa.gov/oppt/chemtest/ereporting/index.html*.

9. In § 716.55, revise paragraph (b)(3) to read as follows:

§ 716.55 Confidentiality claims.

* * * * *

(b) * * *

(3) Failure to furnish a second copy when information is claimed as confidential in the first copy will be considered a presumptive waiver of the claim of confidentiality. EPA will notify the respondent by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The respondent will be given 30 days from the date of his or her receipt of this notification to submit the required second copy in accordance with the method specified in §716.30(d). If the respondent fails to submit the second copy within the 30 days, EPA will place the first copy in the docket.

* * * * *

10. In § 716.60, revise paragraphs (a), (b)(2), (c), and (d), and add new paragraph (e) to read as follows:

§ 716.60 Reporting schedule.

(a) *General requirements.* Except as provided in § 716.5 and paragraphs (b) and (c) of this section, submissions under §§ 716.30 and 716.35 must be submitted using the electronic method specified in §§ 716.30(c) and 716.35(c), on or before 60 days after the effective date of the listing of a substance or mixture in § 716.120 or within 60 days of proposing to manufacture (including import) or process a listed substance or listed mixture (including as a known byproduct) if first done after the effective date of the substance or mixture being listed in §716.120.

(b) * * *

(2) *Submission of copies of completed studies.* Persons must submit studies listed as ongoing or initiated under § 716.35(a)(1) and (2) within 30 days of completing the study, using the method specified in §§ 716.30(c) and 716.35(c).

(c) *Requests for extensions of time.* Respondents who cannot meet a deadline under this section may apply for a reasonable extension of time. Extension requests must be submitted on or before 40 days after the effective date of the listing of a substance or mixture in § 716.120, using the electronic method specified in §§ 716.30(c) and 716.35(c). The Director of EPA's Office of Pollution Prevention and Toxics will grant or deny extension requests.

(d) *Submission methods*. Persons must use the CISS tool to complete and submit all data, reports, and other information required by 40 CFR part 716, via CDX. Submission requires registration with CDX, and must be made only as set forth in this section.

(e) To access the CISS tool go to *https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx* and follow the appropriate links and for further instructions to go *http://www.epa.gov/oppt/chemtest/ereporting/index.html*.

11. In § 716.105, revise paragraph (d) and add new paragraph (e) to read as follows:

§ 716.105 Additions of substances and mixtures to which this subpart applies.

* * * * *

(d) Persons who wish to submit information that shows why a substance should be withdrawn must submit their comments by using the CISS tool to complete and submit all data, reports, and other information required by 40 CFR part 716, via CDX. Submission requires registration with CDX, and must be made only as set forth in this section.

(e) To access the CISS tool go to *https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx* and follow the appropriate links and for further instructions to go *http://www.epa.gov/oppt/chemtest/ereporting/index.html*.

Part 720--[AMENDED]

12. The authority citation for part 720 continues to read as follows:

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

13. In § 720.40:

a. Remove paragraphs (a)(2)(i) and (a)(2)(ii).

b. Redesignate paragraphs (a)(2)(iii) and (a)(2)(iv) as paragraphs (a)(2)(i) and (a)(2)(ii).

c. Revise newly redesignated paragraph (a)(2)(i).

d. Revise paragraph (c).

The amendments read as follows:

§ 720.40 General.

(a) * * *

(2) * * *

(i) *Submission via CDX.* TSCA section 5 notices and any related support documents must 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 software. To obtain a version of e-PMN software that contains an encryption module you must register with CDX. A version without encryption may be downloaded without registering with CDX.

* * * * *

(c) *Where to submit a notice or support documents*. For submitting notices or support documents via CDX, use the e-PMN software.

* * * * *

14. In § 720.75, revise paragraphs (b)(2) and (e)(1) 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. Requests for suspension may be submitted electronically to EPA via CDX. Such requests must be generated and completed using e-PMN software. See § 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

* * * * *

(e) *Withdrawal of a notice by the submitter.* (1)(i) 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 by EPA of the CDX submission.

(ii) *Submission of withdrawal notices.* EPA will accept statements of withdrawal only if submitted in accordance with this paragraph. Statements of withdrawal must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See § 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

* * * * *

15. In § 720.102:

a. Remove paragraph (d)(1).

b. Designate the introductory text of paragraph (d) as paragraph (d)(1).

c. Revise paragraph (d)(2).

The amendments read as follows:

§ 720.102 Notice of commencement of manufacture or import.

* * * * *

(d) * * *

(2) *Submission of notice of commencement.* EPA will accept notices of commencement only if submitted in accordance with this paragraph. All notices of commencement must 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 software. See § 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

Part 721--[AMENDED]

16. The authority citation for part 721 continues to read as follows:

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

17. In § 721.30, revise the introductory text of paragraph (b) 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 must submit the request to EPA via CDX using e-PMN software in the manner set forth in 40 CFR 720.40(a)(2)(i). See 40 CFR 720.40(a)(2)(ii) for information

on how to obtain e-PMN software. Support documents related to these requests must be submitted in the manner set forth in 40 CFR 720.40(c). A request for a determination of equivalency must contain:

* * * * *

18. In § 721.185, revise paragraph (b)(1) to read as follows:

§ 721.185 Limitation or revocation of certain notification requirements.

* * * * *

(b) * * *

(1) Any affected person may request modification or revocation of significant new use notification requirements for a chemical substance that has been added to subpart E of this part using the procedures described in §§ 721.160 or 721.170 by submitting a request that is accompanied by information sufficient to support the request. Persons submitting a request to EPA under this part must submit the request to EPA using e-PMN software in the manner set forth in 40 CFR 720.40(a)(2)(i). See 40 CFR 720.40(a)(2)(ii) for information on how to obtain the e-PMN software. Support documents related to these requests must also be submitted to EPA in the manner set forth in 40 CFR 720.40(c).

* * * * *

Part 723--[AMENDED]

19. The authority citation for part 723 continues to read as follows:

Authority: 15 U.S.C. 2604.

20. In § 723.50, revise paragraph (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 EPA at least 30 days before manufacture of the new chemical substance begins. Exemption notices and modifications must be submitted to EPA on EPA Form No. 7710-25 via CDX using e-PMN software in the manner set forth in this paragraph. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software. Notices and any related support documents, must be generated and completed (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

* * * * *

Part 725--[AMENDED]

21. The authority citation for part 725 continues to read as follows:

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

22. In § 725.25, revise paragraph (c) 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. MCANs and exemption requests, and any related support documents, must be generated, completed, and submitted to EPA (via CDX)

using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

* * * * *

23. In § 725.54, revise paragraphs (b) and (d) to read as follows:

§ 725.54 Suspension of the review period.

* * * * *

(b)(1) *Request for suspension.* 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.

(2) *Submission of suspension notices.* EPA will accept requests for suspension only if submitted in accordance with this paragraph. Requests for suspension, must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

* * * * *

(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 CDX submission by EPA.

24. In § 725.60, revise paragraph (a) to read as follows:

§ 725.60 Withdrawal of submission by the submitter.

(a)(1) *Withdrawal of notice by the submitter.* 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 CDX submission by EPA.

(2) *Submission of withdrawal notices.* EPA will accept statements of withdrawal only if submitted in accordance with this paragraph. Statements of withdrawal must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

* * * * *

25. In § 725.190, revise paragraph (d) to read as follows:

§ 725.190 Notice of commencement of manufacture or import.

* * * * *

(d) *How to submit*. All notices of commencement must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

26. In § 725.975, revise the introductory text of paragraph (b) 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 must submit the request to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software. Support documents related to these requests must also be submitted to EPA via CDX using e-PMN software. A request for a determination of equivalency must contain:

* * * * *

27. In § 725.984, revise paragraph (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. The request must be accompanied by information sufficient to support the request. Persons submitting a request to EPA under this part must submit the request to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software. Support documents related to these requests must also be submitted to EPA via CDX using e-PMN software.

* * * * *

PART 766--[AMENDED]

28. The authority citation for part 766 continues to read as follows:

Authority: 15 U.S.C. 2603 and 2607.

29. In § 766.3, add the following definitions in alphabetical order to read as follows:

§ 766.3 Definitions.

* * * * *

Central Data Exchange or *CDX* means EPA's centralized electronic submission receiving system.

Chemical Information Submission System or *CISS* means EPA's electronic, web-based reporting tool for the completion and submission of data, reports, and other information, or its successors.

* * * * *

30. Revise § 766.7 to read as follows:

§ 766.7 Submission of information.

(a) All information (including letters of intent, protocols, data, forms, studies, and allegations) submitted to EPA under this part must bear the applicable Code of Federal Regulations (CFR) section number (e.g., § 766.20).

(b) You must use the CISS tool to complete and submit all data, reports, and other information required under this part except for records and reports of allegations of significant adverse reactions, which must be submitted in accordance with paragraph (c) of this section.

(1) Submissions must be submitted to EPA via CDX.

(2) To access the CISS tool go to *https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx* and follow the appropriate links and for further instructions to go *http://www.epa.gov/oppt/chemtest/ereporting/index.html*.

(c) You must submit records and reports of allegations of significant adverse reactions and the accompanying cover letters by one of the following methods:

(1) Mail, preferably certified, to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, ATTN: Dioxin/Furan report part 766, Allegations of significant adverse reactions.

(2) Hand delivery to OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC, ATTN: Dioxin/Furan report part 766, Allegations of significant adverse reactions. 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.

31. In § 766.35, revise paragraph (c)(1)(i) to read as follows:

§ 766.35 Reporting requirements.

(c) * * *

(1) * * *

(i) A completed form (EPA 7710-51) for that chemical substance. The form and instructions are available online at *http://www.epa.gov/oppt/chemtest/ereporting/index.html*. One form must be submitted for each chemical substance for which a positive test result has been submitted.

* * * * *

PART 790--[AMENDED]

32. The authority citation for part 790 continues to read as follows:

Authority: 15 U.S.C. 2603.

33. In § 790.3, add the following definitions in alphabetical order to read as follows:

§ 790.3 Definitions.

* * * * *

Central Data Exchange or *CDX* means EPA’s centralized electronic submission receiving system.

* * * * *

Chemical Information Submission System or *CISS* means EPA's electronic, web-based tool for the completion and submission of data, reports, and other information, or its successors.

* * * * *

34. Revise § 790.5 to read as follows:

§ 790.5 Submission of information.

(a) All submissions and correspondence to EPA under this part must bear the Code of Federal Regulations (CFR) section number of the subject chemical test rule consent agreements.

(b) You must use the CISS tool to complete and submit via CDX all data, reports, other information, and correspondence required by rules promulgated under TSCA section 4, and for correspondence pertaining to consent agreements as required under this part. The submissions must be made only as set forth in this section.

(c) To access the CISS tool go to *https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx* and follow the appropriate links and for further instructions to go *http://www.epa.gov/oppt/chemtest/ereporting/index.html*.

35. In § 790.45, revise paragraph (a) to read as follows:

§ 790.45 Submission of letter of intent to conduct testing or exemption application.

(a) No later than 30 days after the effective date of a test rule described in § 790.40, each person subject to that test rule and required to comply with the requirements of that test rule as provided in § 790.42(a) must, for each test required, send his or her

notice of intent to conduct testing, or submit to EPA an application for exemption from testing by the method specified in § 790.5(b).

* * * * *

36. In § 790.48, revise paragraphs (b)(3), (b)(5), (c)(2), and (c)(3) to read as follows:

§ 790.48 Procedure if no one submits a letter of intent to conduct testing.

* * * * *

(b) * * *

(3) No later than 30 days after the date of publication of the **Federal Register** notice described in paragraph (b)(2) of this section, each person described in § 790.40(a)(4) and (a)(5) and each person processing the subject chemical as of the effective date of the test rule described in § 790.40 or by 30 days after the date of publication of the **Federal Register** notice described in paragraph (b)(2) of this section must, for each test specified in the **Federal Register** notice, either notify EPA of his or her intent to conduct testing, or submit to EPA an application for an exemption from testing requirements for the test. Each such notification to conduct testing or application for exemption from testing must be submitted to EPA by the method specified in § 790.5(b).

* * * * *

(5) If no manufacturer or processor submits a letter of intent to EPA through CDX within 30 days after either receipt of the certified letter or publication in the **Federal Register** notice described in (b)(4) of this section, all manufacturers and processors

subject to the test rule will be in violation of the test rule from the 31st day after receipt of the certified letter or publication in the **Federal Register.**

(c) * * *

(2) If no processor subject to the test rule has notified EPA through CDX of its intent to conduct one or more of the required tests within 30 days after the effective date of the test rule described in § 790.40, EPA will notify all the processors by certified mail or publish a notice in the **Federal Register** of this fact, specifying the tests for which no letter of intent has been submitted and to give the processors an opportunity to take corrective action.

(3) If no processor submits a letter of intent through CDX to conduct one or more of the required tests within 30 days after receipt of the certified letter or publication of the **Federal Register** notice described in paragraph (c)(2) of this section, all processors subject to the test rule will be in violation of the test rule from the 31st day after receipt of the certified letter or publication of the **Federal Register** notice described in paragraph (c)(2) of this section.

37. In § 790.50, revise paragraphs (b)(1) and (e) to read as follows:

§ 790.50 Submission of study plans.

* * * * *

(b) * * *

(1) EPA may grant requests for additional time for the development of study plans on a case-by-case basis. Requests for additional time for study plan development must be

submitted to EPA by the method specified in § 790.5(b). Any extension request must state why EPA should grant the extension.

* * * * *

(e) *Amendments to study plans.* Test sponsors must submit all amendments by the method specified in § 790.5(b).

38. In § 790.55, revise paragraph (a) to read as follows:

§ 790.55 Modification of test standards or schedules during conduct of test.

(a) *Application.* Any test sponsor who wishes to modify the test schedule for the mandatory testing conditions or requirements (i.e., "shall statements") in the test standard for any test required by a test rule must submit an application in accordance with this paragraph. Application for modification must be made by the method specified in § 790.5(b). Applications must include an appropriate explanation and rationale for the modification. Where a test sponsor requests EPA to provide guidance or to clarify a non-mandatory testing requirement (i.e., "should statements") in a test standard, the test sponsor must submit these requests to EPA by the method format specified in § 790.5(b).

* * * * *

39. In § 790.62, revise paragraph (c)(4) to read as follows:

§ 790.62 Submission of study plans and conduct of testing.

* * * * *

(c) * * *

(4) The test sponsor shall submit any amendments to study plans to EPA using the method specified in § 790.5(b).

* * * * *

40. In § 790.68, revise paragraph (b)(1) to read as follows:

§ 790.68 Modification of consent agreements.

* * * * *

(b) * * *

(1) Any test sponsor who wishes to modify the test schedule for any test required under a consent agreement must submit an application in accordance with this paragraph. Application for modification must be made using the method specified in § 790.5(b). Applications must include an appropriate explanation and rationale for the modification. EPA will consider only those applications that request modifications to mandatory testing conditions or requirements ("shall statements" in the consent agreement). Where a test sponsor requests EPA to provide guidance or to clarify a non-mandatory testing requirement (i.e., "should statements"), the test sponsor shall submit these requests to EPA using the method specified in § 790.5(b).

* * * * *

41. In § 790.87, revise paragraph (c) to read as follows:

§ 790.87 Approval of exemption applications.

* * * * *

(c)(1) EPA will give exemption applicants final notice that they have received a conditional exemption through one of the following ways:

(i) A final Phase II test rule that adopts the study plans in a two-phase rulemaking.

(ii) A separate **Federal Register** notice in a single-phase rulemaking.

(iii) A letter by certified mail will give exemption applicants final notice that they have received a conditional exemption.

(2) All conditional exemptions thus granted are contingent upon the test sponsors' successful completion of testing according to the specifications of the test rule.

42. In § 790.90, revise paragraph (c)(2) to read as follows:

§ 790.90 Appeal of denial of exemption application.

* * * * *

(c) * * *

(2) Hearing requests must be submitted using the method specified in § 790.5(b) and be received by EPA within 30 days of receipt of the Agency’s notification under § 790.88(b). Hearing requests must provide reasons why a hearing is necessary.

* * * * *

43. In § 790.93, revise paragraphs (c) and (d)(2) to read as follows:

§ 790.93 Termination of conditional exemption.

* * * * *

(c) Within 30 days after receipt of a letter notification or publication of a notice in the **Federal Register** that EPA intends to terminate a conditional exemption, the exemption holder may submit information using the method specified in § 790.5(b) either to rebut EPA's preliminary decision or notify EPA of its intent to conduct the required test pursuant to the test standard established in the test rule. Such a letter of intent shall contain all of the information required by § 790.45(c).

(d) * * *

(2) Hearing requests must be submitted using the method specified in § 790.5(b) and must be received by EPA within 30 days after receipt of the letter or publication in the **Federal Register** notice described in paragraph (b) of this section.

* * * * *

44. In § 790.97, revise paragraph (a) to read as follows:

§ 790.97 Hearing procedures.

(a) Hearing requests must be submitted using the method specified in § 790.5(b). Such requests must include the applicant's basis for appealing EPA's decision.

* * * * *

PART 799--[AMENDED]

45. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, and 2625.

46. Revise § 799.5 to read as follows:

§ 799.5 Submission of information.

(a) Information (e.g., letters, study plans, or reports) submitted to EPA must be submitted using the method specified in paragraph (b) of this section. All information submitted under this part must bear the Code of Federal Regulations (CFR) section number of the subject chemical test rule (e.g., § 799.1053 for trichlorobenzenes).

(b) You must use CISS to complete and submit all data, reports, and other information required under this part. Submissions must be submitted to EPA via the Central Data Exchange (CDX).

(c) To access CISS go to

https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx and follow the appropriate links and for further instructions to go *http://www.epa.gov/oppt/chemtest/ereporting/index.html*.

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