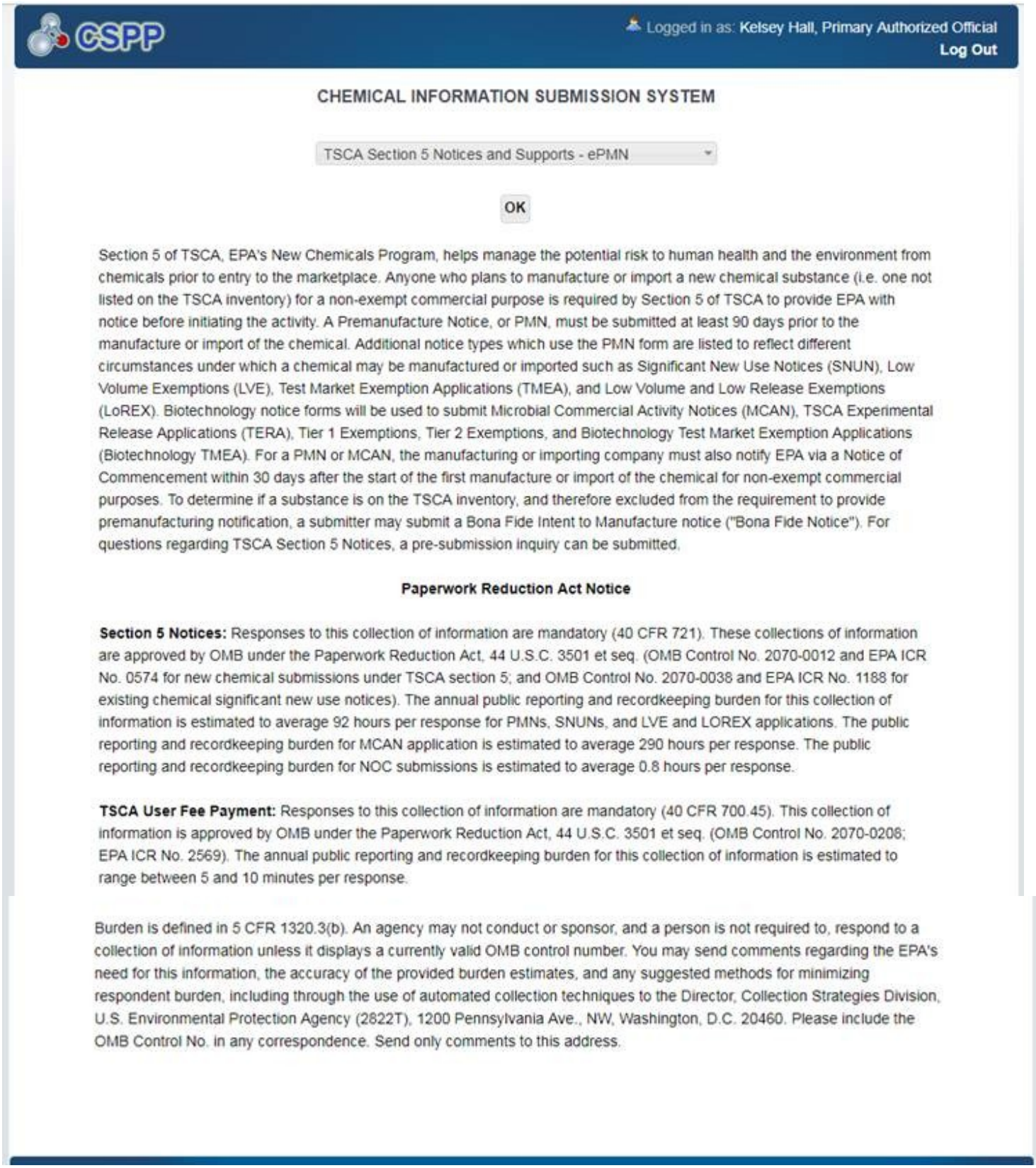
## CDX Landing Page for Section 5 Submissions:



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CHEMICAL INFORMATION SUBMISSION SYSTEM

TSCA Section 5 Notices and Supports - ePMN

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Section 5 of TSCA, EPA's New Chemicals Program, helps manage the potential risk to human health and the environment from chemicals prior to entry to the marketplace. Anyone who plans to manufacture or import a new chemical substance (i.e. one not listed on the TSCA inventory) for a non-exempt commercial purpose is required by Section 5 of TSCA to provide EPA with notice before initiating the activity. A Premanufacture Notice, or PMN, must be submitted at least 90 days prior to the manufacture or import of the chemical. Additional notice types which use the PMN form are listed to reflect different circumstances under which a chemical may be manufactured or imported such as Significant New Use Notices (SNUN), Low Volume Exemptions (LVE), Test Market Exemption Applications (TMEA), and Low Volume and Low Release Exemptions (LoREX). Biotechnology notice forms will be used to submit Microbial Commercial Activity Notices (MCAN), TSCA Experimental Release Applications (TERA), Tier 1 Exemptions, Tier 2 Exemptions, and Biotechnology Test Market Exemption Applications (Biotechnology TMEA). For a PMN or MCAN, the manufacturing or importing company must also notify EPA via a Notice of Commencement within 30 days after the start of the first manufacture or import of the chemical for non-exempt commercial purposes. To determine if a substance is on the TSCA inventory, and therefore excluded from the requirement to provide premanufacturing notification, a submitter may submit a Bona Fide Intent to Manufacture notice ("Bona Fide Notice"). For questions regarding TSCA Section 5 Notices, a pre-submission inquiry can be submitted.

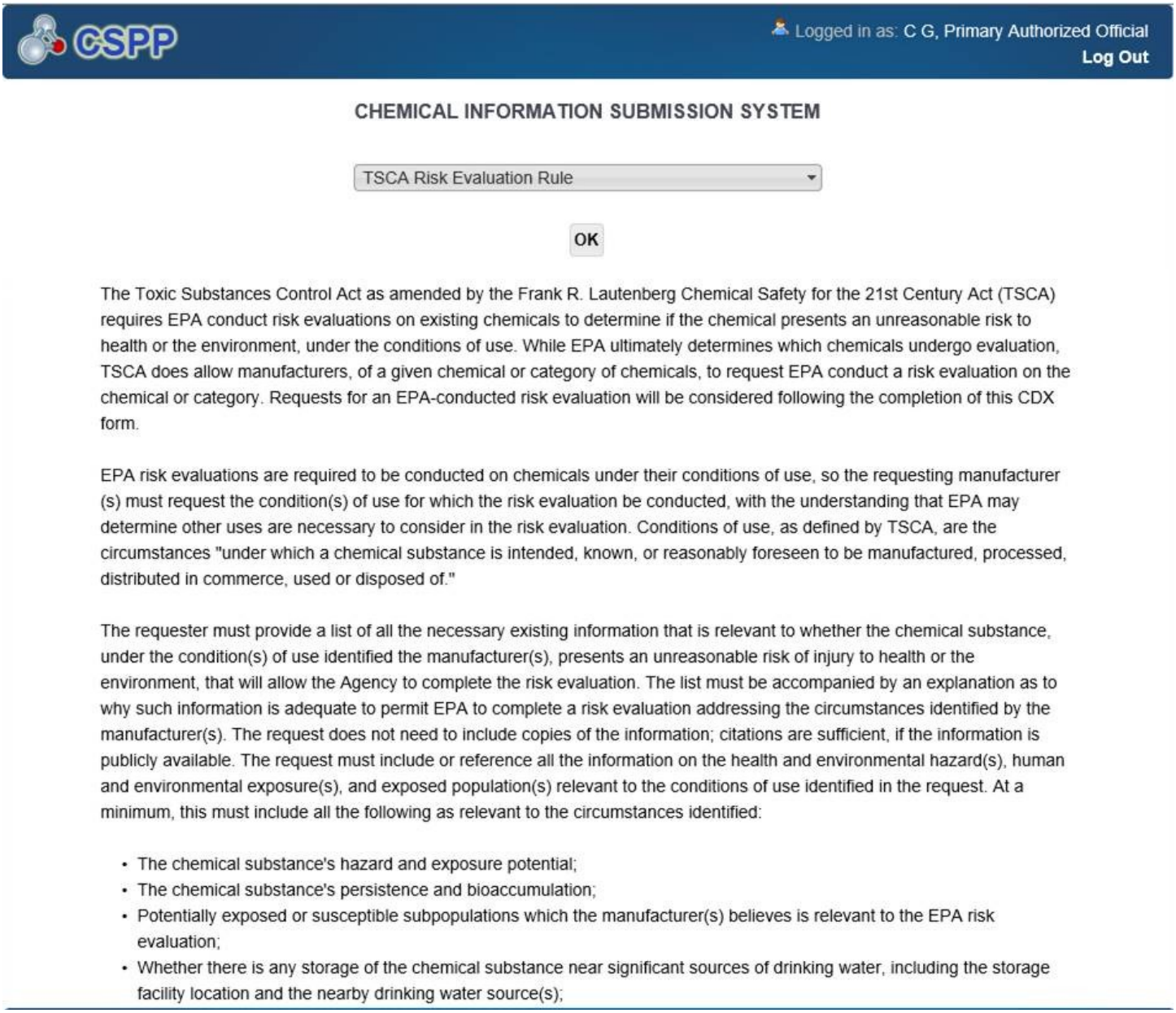
**Paperwork Reduction Act Notice**

**Section 5 Notices:** Responses to this collection of information are mandatory (40 CFR 721). These collections of information are approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0012 and EPA ICR No. 0574 for new chemical submissions under TSCA section 5; and OMB Control No. 2070-0038 and EPA ICR No. 1188 for existing chemical significant new use notices). The annual public reporting and recordkeeping burden for this collection of information is estimated to average 92 hours per response for PMNs, SNUNs, and LVE and LOREX applications. The public reporting and recordkeeping burden for MCAN application is estimated to average 290 hours per response. The public reporting and recordkeeping burden for NOC submissions is estimated to average 0.8 hours per response.

**TSCA User Fee Payment:** Responses to this collection of information are mandatory (40 CFR 700.45). This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0206; EPA ICR No. 2569). The annual public reporting and recordkeeping burden for this collection of information is estimated to range between 5 and 10 minutes per response.

Burden is defined in 5 CFR 1320.3(b). 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. You may send comments regarding the EPA's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Please include the OMB Control No. in any correspondence. Send only comments to this address.

## CDX Landing Page for Section 6 Submissions:



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TSCA Risk Evaluation Rule

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The Toxic Substances Control Act as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA) requires EPA conduct risk evaluations on existing chemicals to determine if the chemical presents an unreasonable risk to health or the environment, under the conditions of use. While EPA ultimately determines which chemicals undergo evaluation, TSCA does allow manufacturers, of a given chemical or category of chemicals, to request EPA conduct a risk evaluation on the chemical or category. Requests for an EPA-conducted risk evaluation will be considered following the completion of this CDX form.

EPA risk evaluations are required to be conducted on chemicals under their conditions of use, so the requesting manufacturer (s) must request the condition(s) of use for which the risk evaluation be conducted, with the understanding that EPA may determine other uses are necessary to consider in the risk evaluation. Conditions of use, as defined by TSCA, are the circumstances "under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of."

The requester must provide a list of all the necessary existing information that is relevant to whether the chemical substance, under the condition(s) of use identified the manufacturer(s), presents an unreasonable risk of injury to health or the environment, that will allow the Agency to complete the risk evaluation. The list must be accompanied by an explanation as to why such information is adequate to permit EPA to complete a risk evaluation addressing the circumstances identified by the manufacturer(s). The request does not need to include copies of the information; citations are sufficient, if the information is publicly available. The request must include or reference all the information on the health and environmental hazard(s), human and environmental exposure(s), and exposed population(s) relevant to the conditions of use identified in the request. At a minimum, this must include all the following as relevant to the circumstances identified:

- The chemical substance's hazard and exposure potential;
- The chemical substance's persistence and bioaccumulation;
- Potentially exposed or susceptible subpopulations which the manufacturer(s) believes is relevant to the EPA risk evaluation;
- Whether there is any storage of the chemical substance near significant sources of drinking water, including the storage facility location and the nearby drinking water source(s);

*Continued on next page (Scroll down on screen).*

- The chemical substance's production volume or significant changes in production volume; and
- Any other information relevant to the potential risks of the chemical substance under the circumstances identified in the request.

The request must include a commitment to provide to EPA any referenced information upon request. The request may also include any information that will inform EPA's determination as to whether restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment and that as a consequence, the request is entitled to be preferentially considered for a risk evaluation.

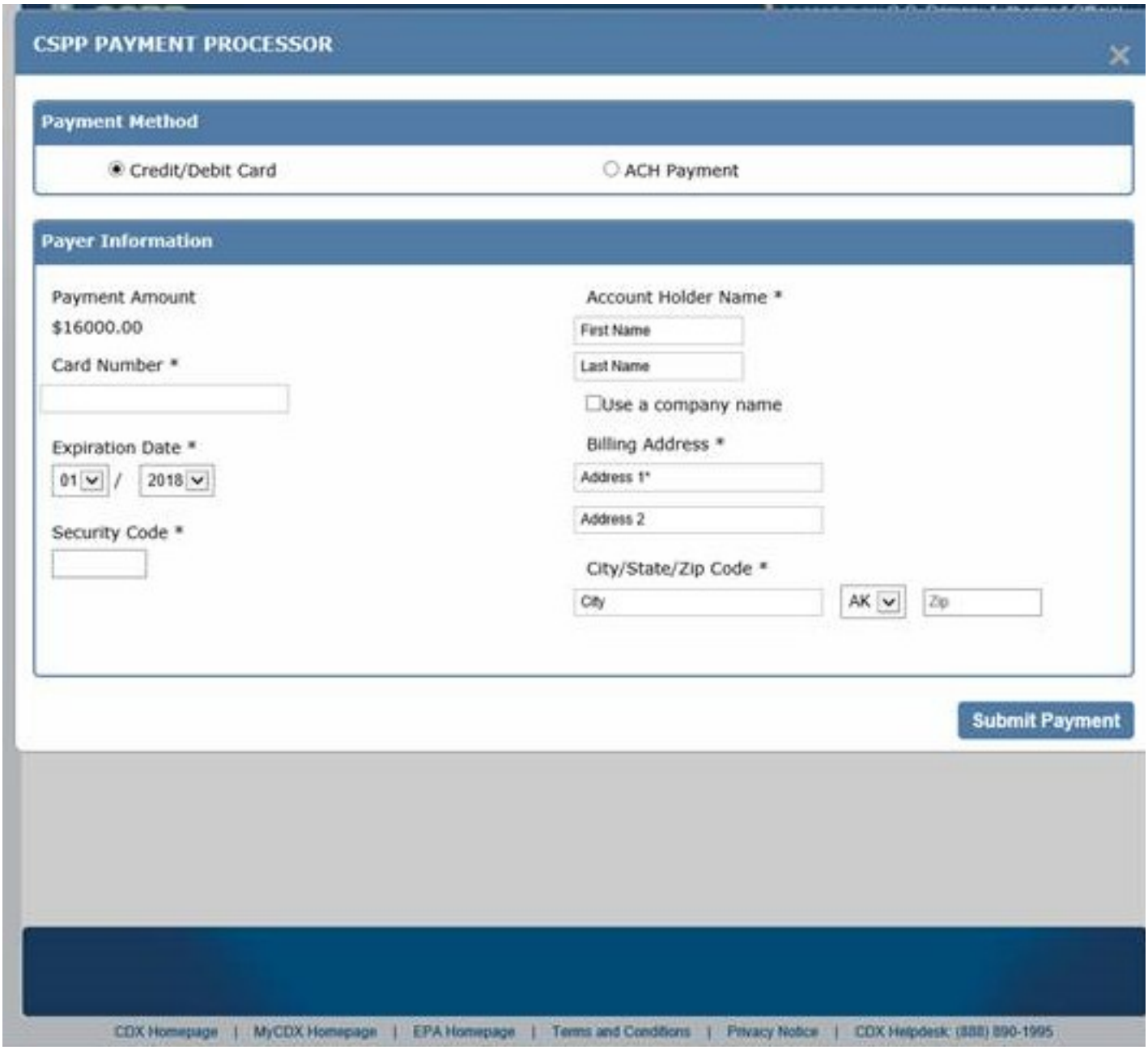
**Paperwork Reduction Act Notice**

**Request for Risk Evaluation:** Responses to this collection of information are voluntary but must comply with EPA's procedural requirements in order to be eligible for EPA consideration (40 CFR 702). This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0202; EPA ICR No. 2559). The annual public reporting and recordkeeping burden for this collection of information is estimated to average 96 hours per response.

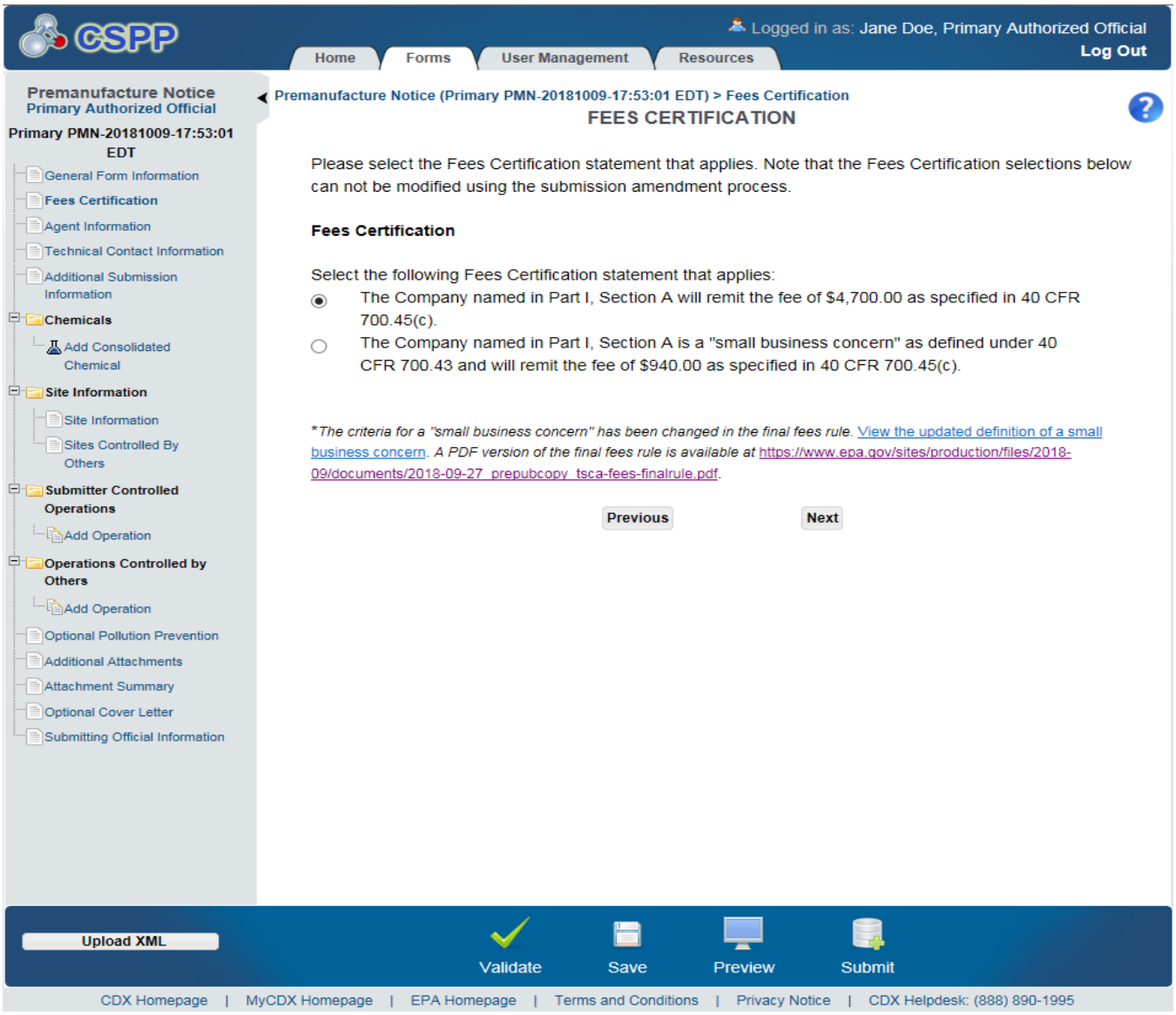
**TSCA User Fee Payment:** Responses to this collection of information are mandatory (40 CFR 700.45). This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0208; EPA ICR No. 2569). The annual public reporting and recordkeeping burden for this collection of information is estimated to range between 5 and 10 minutes per response.

Burden is defined in 5 CFR 1320.3(b). 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. You may send comments regarding the EPA's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Please include the OMB Control No. in any correspondence. Send only comments to this address.

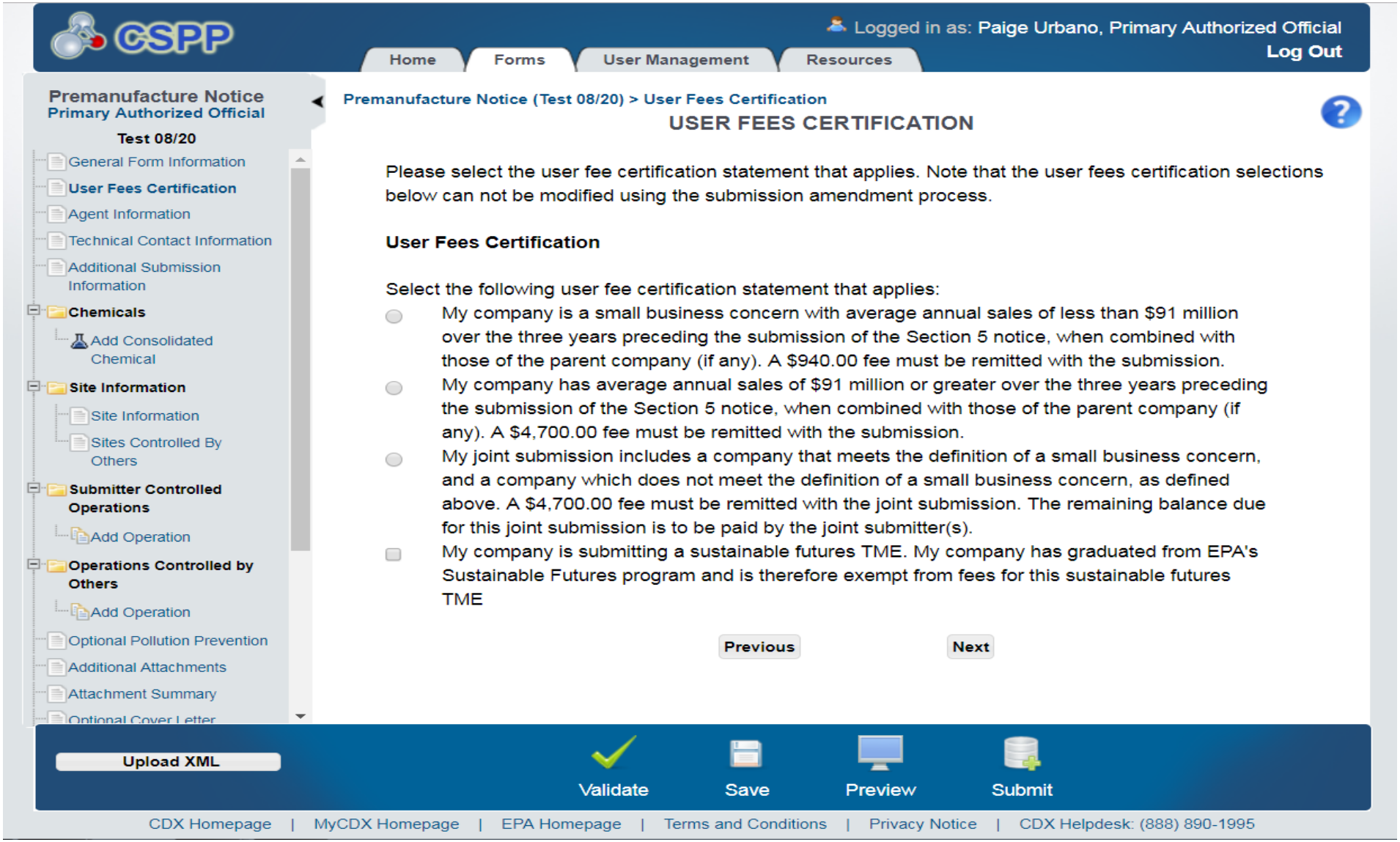
## CDX New Payment Widget for Section 5 and 6 Submissions:



## Section 5 Fees Certification Screen – New for Exemption Submissions:



## Section 5 Fees Certification Screen – New for TMEA Exemptions:



## Section 6 Fees Certification Screen – New for Manufacturer Requests: