
Electronic Pre-manufacture Notice Users Guide

NOVEMBER 2002

INTRODUCTION

This document is intended to assist individuals using the electronic version of the Pre-manufacture Notice (PMN, form 7710-25) which is posted on the EPA's Central Data Exchange (CDX). Please read this guide for the step-by-step instructions for the PMN reporting process. There is a checklist of the steps included as a quick reference as Appendix A.

SUPPORT

EPA provides assistance for both technical and regulatory questions. The following are some of the mechanisms available to support PMN reporting.

Technical Issues: CDX Technical Support staff is available to respond to problems with the electronic form and clarifications of the steps to submit the form. Technical Support may be reached by telephone, fax, or email.

- ◆ *By telephone.* Person-to-person telephone support is available from 8:00 AM to 6:00 PM (EST/EDT). Call the toll-free line at 1-888-890-1995.
- ◆ *By fax.* You may request assistance 24 hours a day; support personnel will return calls from 8:00 AM to 6:00 PM (EST/EDT). The fax number is 703-917-7105.
- ◆ *By e-mail.* Send e-mail to EPACDX@csc.com with "PMN" in the subject line. Responses will be sent from 8:00 AM to 6:00 PM (EST/EDT).

Regulatory Issues: EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS) can answer questions of a regulatory nature. Examples might include questions of what information is required on the form, or when the form is to be submitted. Regulatory questions should be directed to David Schutz 202-564-9262, or alternatively Miriam Wiggins-Lewis 202-564-9373.

BACKGROUND

The electronic Pre-manufacture Notice is an enhanced version of the traditional paper form. It was developed in the Portable Document Format (PDF) developed by the Adobe Corporation. The form incorporates a look and feel similar to the paper version of the form, and includes the following capabilities:

- ◆ Creates a sanitized version of the PMN for submission based on the confidential business information (CBI) version,
- ◆ Generates extra pages to support the submission of a consolidated PMN
- ◆ Provides an electronic copy for record keeping, and
- ◆ Enables diagrams, in electronic form, to be incorporated into the PMN.

SUBMISSION PROCESS

This electronic form will be used, at least initially, to produce a paper submission, which will be sent to US EPA by mail or courier. The submitter will complete the form, print the CBI and non-CBI versions, sign the CBI version, and mail them both to the Agency.

As the Agency develops the internal procedures which will make it feasible, EPA intends to allow saving of the completed form and other supporting files to a write-only compact disk (CBI and Non-CBI versions on separate CDs). The submitter will then mail the CDs (along with a paper signature page) to the EPA. At the Agency, the data files will be uploaded into the PMN data repository and workflow process.

EPA would like to develop a completely electronic process. We want to enable filers to submit the forms to the Agency over the Internet and to verify them electronically (“electronic signature”). This will depend on consensus that transmission security is adequate and on Agency internal procedures

REQUIREMENTS

The electronic PMN is written for the Adobe Portable Data Format (PDF). In order to fill-in the electronic PMN, **you must use Adobe Acrobat software. To fill out and save the form, you must use either Acrobat Exchange 5.0 (or higher version) or Acrobat Approval.** It is also possible to fill in the blanks on the form and print it immediately using Adobe Acrobat Reader which is free; however, Reader does not permit the user to save the form for later use. With Adobe Acrobat Approval, you can fill in, sign, and save interactive Adobe

Portable Document Format (PDF) forms. With Acrobat *Approval 5.0*, users can easily complete and save the files to their desktops, fill them out offline, and send them later. This tool currently costs about 39 dollars and is available from Adobe site at <http://www.adobe.com>.

Adobe offers the Acrobat Reader for free download at <HTTP://WWW.ADOBE.COM/PRODUCTS/ACROBAT/READSTEP.HTML> (MS Windows version) and <HTTP://WWW.ADOBE.COM/SUPPORT/DOWNLOADS/ACRMAC.HTM> (Macintosh version). However, Acrobat Reader is not able to allow the user to store drafts or spawn additional pages. It is only recommended as a mechanism for printing a form for which you have already developed a complete draft.

STEPS TO COMPLETE THE FORM

1. Download the electronic PMN form, the Confidential Blank Page, the Blank Page (and for Reader users, the Continuation Page) to your computer's hard drive in a directory from either the OPPT web site at: <http://www.epa.gov/oppt/newchems/pmforms.htm> or from the CDX website at: <http://cdx.epa.gov/>. Also download the Electronic PMN User's Guide. All of the above are PDF files.
2. Open the electronic PMN form in Acrobat Exchange, Acrobat Approval, or Reader.
3. Print the basic form to assist with planning your submission.
4. You will need to assemble any required diagrams or pictures. You may either print the diagrams to paper and insert them as attachments once the PMN form is printed (for Reader users), or create PDFs of those images created in other software tools for insertion into the PMN form. (See Appendix B, items B-1 and B-2, for information on generating and incorporating diagrams as PDFs.)
5. Reader users will fill in the entire form and print it at this point. The following instructions apply generally to Exchange and Approval users.
6. If you are preparing a consolidated submission, complete part A of the Header sheet. Otherwise, skip to step #9.

NOTE: If your submission will be a consolidated submission, you must have prior approval from a pre-notice coordinator at the EPA, and a PC number for a consolidated submission.

6.1. Enter the Pre-notice Communication Number

- 6.2. Indicate if the consolidated PMN is for polymer or non-polymer substances. Based on your selection, a later step will generate the appropriate additions of pages 4 or 5 and pages 6 and 7.
 - 6.3 Indicate the number of substances approved for the consolidated PMN.
 - 6.4 Identify which, if any, of pages 8-11 and 13 should have additional pages generated (spawned) for your submission. Selecting a page will create one additional blank copy of that page for each of the substances even if the addition is not needed for all substances. Extras of page 8 and 9 can be requested in step 6 of the Header Sheet.
7. Identify how many additional copies of pages 8 and 9 will be needed. The default is zero additions with a maximum of five.

NOTE: If preparing a consolidated PMN, the number of pages selected is added for each substance even if the additional pages are not needed for all substances.

8. If you completed the Header Sheet Steps 1-4 for consolidated submissions or indicated additional copies of pages 8/9 in Step 5, then click on the **“Push here to spawn required pages”** icon to generate the additional pages. Otherwise, you may skip to the next step.
9. Start filling out the form. If you have a color monitor, CBI marked text will change to red when the CBI box is checked. **If at anytime you wish to save a draft of the form, go to page one of the PMN and click on the “Save Draft” button and name the file.** You can then open the saved file to startup from where you left off.
10. Where a diagram or picture is to be inserted directly in the electronic form, click on the **“Add Picture”** icon in the diagram box and select the PDF image. (See Appendix B, item B-2, for additional information on incorporating images.) (In the future when you are filing electronically, you can also include the file in its original (pre-PDF) format on the diskettes you mail to the EPA. EPA will encourage submitters using ISISDraw, ChemDraw, or CASDraw software in creating chemical structures to attach the native files for the Form or on the CD. This can speed the process of analyzing the chemical. If you plan to do so, identify the name of that file when prompted.)
11. If you insert a diagram and then want to replace it, override it with another diagram. If you want to clear the diagram from the page entirely, click on the **“Clear Picture”** icon. After being prompted by your browser, use the BlankPage.pdf file to override the original diagram.

12. If you need to create continuation pages, either click on the appropriate continuation sheet check box or insert your own continuation page (using the ContinuationPage.pdf file) in the paper submission. In either case be sure you identify the continuation page in Part III, “List of Attachments”. Appendix B, item B-3, explains the options for continuation sheets in greater detail.
13. Make sure you identify other documents to be included with the PMN as separate PDF files e.g. toxicity data on Part III, “List of Attachments.”
14. Once you are comfortable that the PMN is complete and the CBI boxes have been appropriately checked, click on the “Validate PMN” icon at the top of page one. (If you go back into the Form after validation to make changes, errors may occur.) Certain checks will be performed for common PMN problems, and warnings will be issued when appropriate (For example, if a PMN chemical’s CAS number appears to be incorrect on page 4 or 5, a warning will be issued.) Also, please review any “sticky notes” you may see on the form. They have important information regarding acceptable data types or formats for certain fields.
15. Save the file of the CBI version of the form in your directory and then print the form.
16. **Then sign all appropriate certifications on page 2 of the form.**
17. If the PMN contains CBI data, you will want to create a “sanitized” version of the CBI saved version of the PMN. Otherwise proceed to the next step for mailing the PMN.
 - 17.1 The first step in sanitizing the CBI version of the PMN is to go to the form’s page one and click on the “**Create Sanitized PMN**” icon.
 - 17.2 You will be prompted by an icon to replace diagrams marked confidential from spawned and unspawned pages using your browser. You will choose the ConfidentialBlankPage.pdf file to replace or override the diagram. If perchance you miss sanitizing a diagram during the prompting phase, you may perform the same operation by manually clicking on the “**Clear Picture**” icon and browsing to the ConfidentialBlankPage.pdf file. For the time being (eventually this will be fixed in the next version), disregard the “cancel” message that will pop up with the Browser (usually happens when sanitizing an unspawned page with a CBI marked diagram). Proceed to replace/override with a ConfidentialBlankPage.pdf file. Sanitization of confidential text will then take place. The form will freeze up for a while until the process is completed.

- 17.3 You will then be prompted to save the sanitized PMN under a new name, and we recommend that you save it to a separate directory.
- 17.4 Print the sanitized version of the PMN. All data in those sections marked CBI will be deleted from the print out or, in the case of those section(s) of text between braces ({ }), only the text between the braces will be “X’d” out with 5 X’s.
- 17.5 VISUALLY CHECK TO MAKE SURE CBI DATA HAVE BEEN REMOVED!**
18. Mail or send by courier to the EPA to the Document Control Officer in the Confidential Business Information Center (CBIC). US Mail goes to the EPA mailroom. Then it is distributed to the Program. Courier deliveries should come to our physical location.

Courier Submissions to the CBIC:

Submissions to the CBIC, in room 6428 in the EPA East Building, will only be accepted until 4 pm. If a courier service comes after that time, it will be turned away. The address for sending by courier is:

Document Control Officer TS-7407M
TSCA Data Processing Center – CBIC, Room 6428
1201 Constitution Ave., Washington, DC. zip: 20004-3302

The courier contact phone numbers are 202-564-8930 and -8940. Non-uniformed (bicycle, etc) couriers will be met at the 1201 Constitution Ave. entrance by CBIC personnel. Uniformed couriers are admitted to deliver directly to the CBIC.

US Mail Submissions:

Document Control Officer TS-7407M
TSCA Data Processing Center - CBIC
1200 Pennsylvania Ave., Washington, DC. zip: 20460

Helpful Hints

- ◆ The form is designed to have the appropriate number of pages spawned up front, and then it is recommended that it be filled out sequentially from beginning to end as much as possible. If you complete the form out of sequence, or if you change your mind and start deleting things, especially if you delete electronically generated continuation pages or spawned consolidated pages, the results may be unpredictable when you try to validate and/or save the form. If you keep the form as a draft, while jumping around (i.e. different people in different parts of a company

complete the form out of sequence), then it may not affect the form if the deletions mentioned above are not made. You will probably be more successful if you make a scratch version on paper beforehand, and work sequentially from that. If using the Reader, you will clearly need to work from a scratch version.

- ◆ Make sure the “hand” tool from the toolbar is enabled when you want to enter data. Adobe Exchange must be in this mode to enter data into the form fields.
- ◆ The CBI box at the bottom left of page 1 is read-only. If any CBI boxes are checked anywhere on the form, this box is checked automatically.
- ◆ Text is black unless you have checked a “CBI” box controlling that entry, in which case the text switches to red.
- ◆ While text boxes allow entry of numeric data, numeric fields do not allow letters. If a field does not allow data to be entered, you are probably trying to put alpha characters in a numeric field, or you have not made an entry in a previous field, which must have an entry for that field to be used.
- ◆ Use the mouse to check boxes and move between fields. Mouse clicks/movements key in some of the error checking.
- ◆ If you are prompted for the name of an attachment, you must also make sure you enter that attachment name on page 12 “List of Attachments.” Before completing the form, make sure you have listed all the attachments, whether PDF or native format.
- ◆ Because the form contains small type, it may help to “zoom” in to a magnification with which you are comfortable. Use the menu selections: “View,” “Zoom to...” option, or click on the toolbar’s magnifying glass. It may also help to print out a copy of the form to view while you are completing it on the computer.
- ◆ You can *copy and paste text* into any text field on the form.
- ◆ If you need additional pages, open the file and complete the questionnaire, which precedes the form (Header Sheet). Any needed additional pages will be spawned now. Fill out the Header Sheet to initiate page spawn. Then the appropriate number of additional pages 4 for chemicals or pages 5 for polymers, and additional pages 6 and 7 and (as appropriate) 8, 9, 10, 11, and 13 will be "spawned" and become part of the document. The Header Sheet does not count as part of the total pages in the form.
- ◆ The e-PMN form has kept the same pagination as in the existing paper form; however, it has added features that are not found in the existing form. The old pages have been lengthened to give submitters the

opportunity to include more information in certain fields. A small “a” following the page number delineates these pages, e.g. page 4 is followed by 4a. These numbers will be displayed across the top of each page followed by the running count of the total pages in the PMN form, and at the bottom of each page.

The pagination convention for spawned pages is a little more complicated. Below is an example of a consolidated PMN for 3 chemicals and additional copies of page 8:

Total pages go from the normal total of 18 to 31

The spawned pages are numbered as follows:

4, 4a, 4 1, 4a1, 4 2, 4a2

6, 6 1, 6 2

7, 7 1, 7 2

Appendix A PMN Procedural Checklist

The following table can be used as a checklist of following the steps towards completion of the PMN submission.

Table 1. Submission Check List

Step #	Description	Check if complete	Comment
1-2	Make sure you have the latest version of the electronic PMN and corresponding users guide. Download all necessary files from the Website to your computer's hard drive and open the form.		
3	Print a blank PMN form and prepare a mock-form. (Recommended for at least the first use.)		
4	All necessary illustrations and diagrams have been generated as PDF files for incorporation in the electronic form, or printed directly to paper with the appropriate information for attaching to the completed form.		
5-8	Prepare the electronic PMN for your submission by completing the Header Sheet and spawning additional pages as necessary.		
9	Complete all fields requiring data and mark CBI boxes.		
10	Insert PDF diagrams where necessary.		
11	If you make a mistake and want to replace a diagram, override it with another diagram by using the Browser. If you want to clear the diagram from the page entirely, override it by using the BlankPage.pdf file from your Browser.		
12	When using either Exchange or Approval, PDF continuation pages are automatically identified on the continuation page itself (and automatically incorporated at the end of the form); however, they must be listed on Part III, "List of Attachments." Reader users must identify each PDF continuation page and then incorporate the paper versions at the end of the file and on Part III, "List of Attachments."		
13	Make sure you identify other documents to be included with the PMN as separate PDF files, e. g. toxicity data in Part III, "List of Attachments."		
14	Use the validation feature to assist in reviewing the form.		
15	Save the file of the completed CBI version of the PMN form and then print it.		

16	Sign page 2 of the paper CBI version of the PMN form.		
17.1-4	Sanitize the CBI version of the PMN form according to directions in Step 17-1-17-5. Save the file under a new name and in a separate directory. Print the form.		
17.5	Review the sanitized form very carefully to assure that all CBI has been removed.		
18	Package the CBI and sanitized submissions, and mail to EPA		

Appendix B Additional Information

B-1. CREATING A PDF DOCUMENT

In order to attach files to the PMN form or insert illustrations into the PMN form, the attachment or illustration must be in PDF. PDF documents can be created either from electronic or hardcopy originals. Hardcopy documents must first be scanned using Acrobat Scan or other scanning software (most scanning software can create PDF documents). Electronic originals can be converted to PDF using one of the tools within the Acrobat suite such as PDF Writer or Distiller. The PDF Writer, for example, creates a PDF document through the “print” function on most programs. Instead of selecting a printer as the output device, the user selects PDF Writer.

B-2. INCORPORATING GRAPHICS AND DIAGRAMS

Many available graphics programs can be used to create diagrams and illustrations to accompany the PMN. The output of these programs is usually in a graphics format such as BMP, GIF, PC X, TIF, etc.

To add the graphic to the PMN as described item B-1, the graphic must first be converted to PDF. This generally requires Acrobat or some other converting software. If you have Acrobat, you can perform an “Import -> Image” from the File menu and the image will be converted to PDF for you. After you save the newly created PDF version of your original graphic, you can click on the “Add Picture” button on the PMN form and place the PDF type graphic directly on the electronic PMN form.

B-3. INSERTING PAGES INTO DOCUMENT

If you are using Exchange or Approval and you need to add continuation pages, you have two options:

- ◆ You can check the continuation box associated with that area of the form. A continuation page will be created and appended to the end of the document with the header information already completed. Then you can enter your continuation information, or
- ◆ You can develop the paper continuation sheets (for users of Reader) needed for your planned submission, and then packaged with your submission.

Do not delete a continuation page after you have generated it using the boxes in the form. Rather than delete a continuation page, you should delete the content and type in “**No longer applicable**” in text field.

B-4. BRINGING ATTACHMENTS INTO THE E-FORM

There is a feature in Adobe that allows you to bring all PDF attachments within the electronic PMN form so there is only one PDF file. The attachments then take on the pagination of the e-Form. This is possible using the insert feature of Adobe. You can find this feature under Document on the menu bar.