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e-Index Builder Quick Tutorial

Version 1.0

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The e-Index Builder Quick Tutorial

This tutorial is designed to help applicants quickly understand how to compile electronic applications to the PMRA using the electronic Index Builder (EIB). For a full description of this program, download the EIB user guide at:

<http://www.pmra-arla.gc.ca/english/pdf/eprs/EIB-Guide-e.pdf>.

EIB is designed to help applicants and the PMRA electronically list and package files required for PMRA applications, in turn helping to designate Confidential Business Information, reduce application processing times and overall paper use. The EIB creates two files:

- 1) *The XML file*: a simple list of all the files included in an application, as well as several descriptors associated with those files.
- 2) *The PRZ file*: a zipped file containing all the files included in an application, as well as the associated XML file.

When sending an application, Applicants are required under DIR 2006-03 to submit the PRZ file using EIB. This tutorial is designed to aid Applicants in the creation of that file. Although this tutorial will help in using EIB to compile most applications, there will certainly be exceptions.

For support, contact the PMRA at 1-800-267-6315 within Canada, 1-613-736-3799 outside Canada, or via email at pmra_infoserv@hc-sc.gc.ca.

I. Downloading, Installing and Opening EIB.

- 1) Go to: <http://www.pmra-arla.gc.ca/english/appregis/e-indexbuilder-e.html>

▶ [Click here to download the latest version of the e-Index Builder](#)

2) Click

3) Click “Save”, and choose a destination on your computer for the .zip file.


3) Click “Open”, or double-click on the .zip file once it is saved. A window should open that has the file “eindexbuilder.jar” listed. Depending on the application you’re using, you will need to “extract” that file from the window. Normally, you can highlight the file, then drag and drop it onto your Desktop. From there, you can move it to any folder you wish.


4) Double click the “eindexbuilder.jar” file.

II. Using EIB

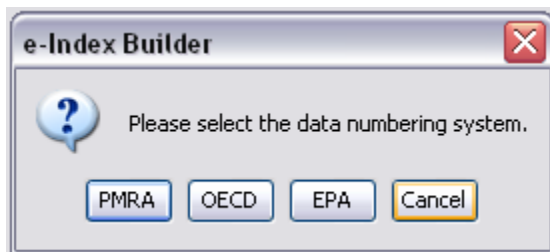
1) *Opening and Saving a File:*

a) If you are creating a new file, then click the  button.

b) If you are opening an existing .xml file, then click the  button.

c) At any time, click the following button to save your XML file: . It is a good idea to save your file often and to have back-ups to prevent the loss of data and time.

2) *Choosing a Numbering System:* If you are creating a new file, the following window then opens which gives you a choice of numbering systems (PMRA = Pest Management Regulatory Agency; OECD = Organization for Economic Cooperation and Development; EPA = Environmental Protection Agency):



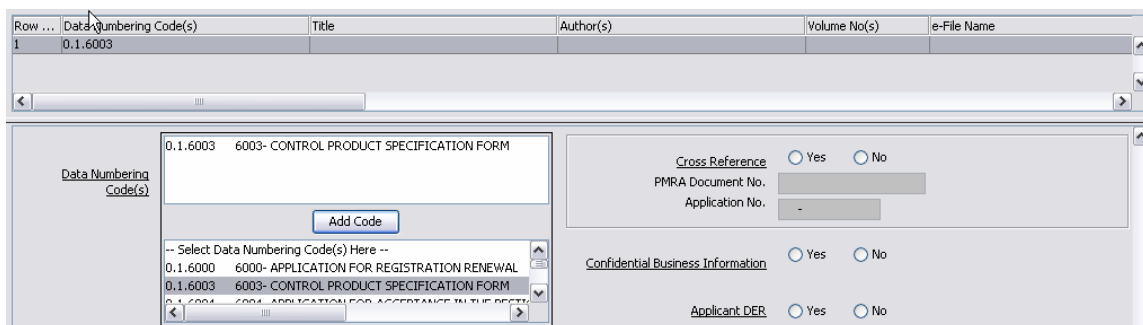
3) *The Main EIB interface:* After you’ve chosen the numbering system, you will be taken to the EIB interface. The main interface is made up of two components: the “List of Documents” Frame, which lists all the documents you have compiled for the application and the “Document Detail Frame”, which gives details on all the compiled documents.

4) *Adding a Document:* You may now begin compiling the documents needed for your application. Go to the following section:

a) From the list, choose a document that will become part of your package by *highlighting* that document.

b) Click “Add Selected”. The highlighted document will now appear in both the screen right above as well as in the List of Documents Frame. The following screenshot shows

what happens when “0.1.6003 6003- CONTROL PRODUCT SPECIFICATION FORM” is selected.

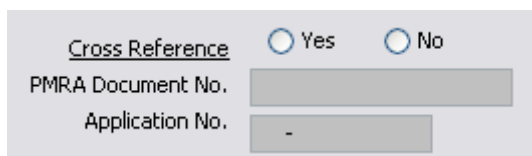


In this example, it is now indicated that one intends to include a Control Product Specification Form to the Application.

NOTE: You can insert as many DACOs as you wish per row. All you need to ensure is that all those DACOs correspond to the document you are describing in that row.

5) *Document Details:* The next step is to specify the details of the added document. Completing the following fields is *mandatory* for each added document:

a) Cross Reference: If you have previously submitted a document to the PMRA that can be used for the current application, the select ‘Yes’. If ‘Yes’ is selected, then you will need to supply either the PMRA Document No. of the previously submitted document or the Application No. of the application that document was associated with. **Please note that only test data may be cross-referenced.** If you are not cross-referencing a document, then simply select ‘No’.



b) Confidential Business Information (CBI): CBI refers to documents that are defined as CBI by the PCPA 2002. You may also refer to the following documents in determining how to designate CBI:

<http://www.pmr-arla.gc.ca/english/pdf/dir/dir2006-03-e.pdf>

<http://www.pmr-arla.gc.ca/english/pdf/dir/dir2006-04-e.pdf>



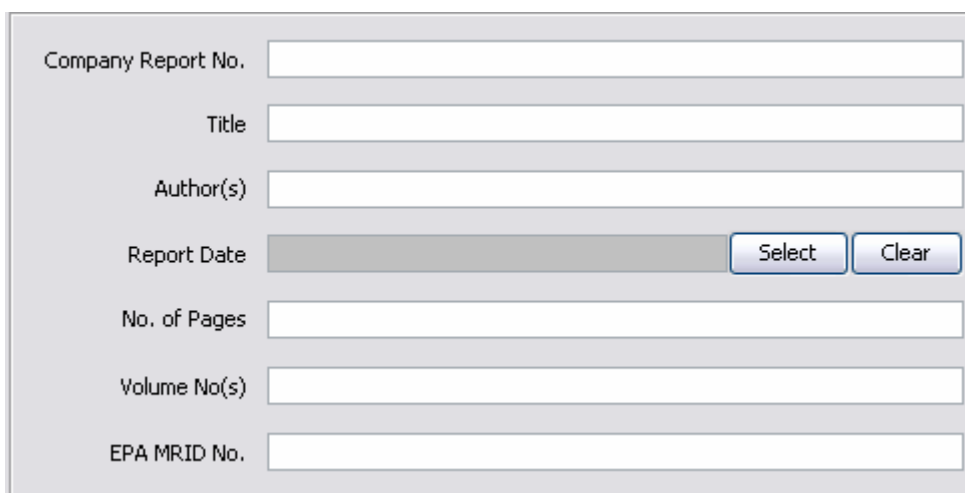
c) Applicant DER: An Applicant DER is an Applicant supplied Data Evaluation Report (DER). This is created by downloading and completing an Evaluation Template from the

PMRA website. The associated Yes/ No radio button should indicate whether the document being submitted is an Applicant DER. The Applicant DER and corresponding test data document must have identical values in the 'Document Group' field (this field will be described shortly).

Applicant DER Yes No

Every other field in the EIB in detailing documents are *optional*. However, please note that in most cases, these fields may actually be mandatory based on the type of application submitted or the choice selected in the 'Cross-Reference' field.

d) to j) are found in the following portion of the EIB screen, termed the *Report Information* portion of EIB:



Company Report No.	<input type="text"/>
Title	<input type="text"/>
Author(s)	<input type="text"/>
Report Date	<input type="text"/> <input type="button" value="Select"/> <input type="button" value="Clear"/>
No. of Pages	<input type="text"/>
Volume No(s)	<input type="text"/>
EPA MRID No.	<input type="text"/>

d) Company Report No.: The company report number of the attached document.

e) Title: The complete title of the report being submitted. This title can be the study title of the document, or when no formal title exists it may be a brief description of the document. The title may match the data numbering code description, e.g., "30 Day Rat Oncology Study".

f) Author(s): The names of the authors of the report being submitted.

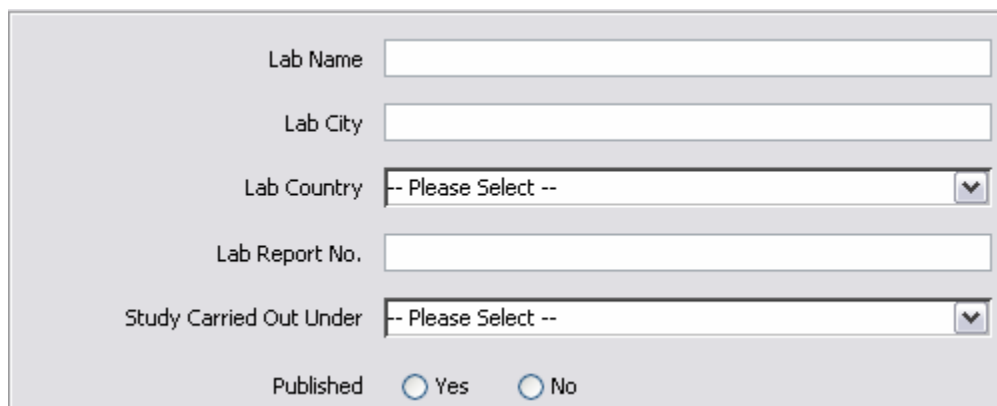
g) Report Date: The date which appears on the report. Choose a date by using the calendar opened by pressing the 'Select' button. If only the month and year is available then select the first day of that month and the corresponding year. If only the year is available then select January 1st of that particular year. To clear the date, click on the 'Clear' button next to the field.

h) No. Of Pages: The total number of pages included in the specific report that is included with this document record. This field is restricted to numeric characters.

i) Volume No(s): The specific volume number or the range of volume numbers covered by the report being submitted. The Parent document and CBI Reference document of a CBI document pair are NOT considered volumes of the same document, and do not require a value in this field. The format for citing volume numbers is <Number> of <Total>, e.g., 2 of 4.

j) EPA MRID No.: United States of America Environmental Protection Agency Master Record Identification Number.

k) to p) are found in the following portion of the EIB screen, termed the *Lab Information* portion of the screen:



k) Lab Name: The full legal name of the laboratory where the study was conducted. Abbreviations are not acceptable.

l) Lab City: The name of the city where the study was conducted.

m) Lab Country: From the drop down list select the name of the country where the lab is located.

n) Lab Report No.: The unique lab report number that is associated with each study. The test data and segregated Confidential Business Information (CBI) of a CBI reference pair must have identical Lab Report No. values.

o) Study Carried Under: The operational standards under which the study was performed. The acceptable values available in the drop-down list are:
- Not Applicable

- GAP - Good Agricultural Practice
- GEP - Good Engineering Practice
- GLP - Good Laboratory Practice

p) **Published:** Yes/ No indication of the document's publication status. If yes, provide the citation in the 'Comments' field. We recommend that you follow the Vancouver Style format for citing the document. For example:

In case of an Article:

Author(s). Title. Title of journal. Date of publication; volume(issue): page numbers

In case of a book:

Author(s). Title. Place: Publisher. Date of publication

q) **Document Group:** A free text field (any value may be provided) where a value may be entered to indicate related documents. The Applicant DER and corresponding test data document must have identical values in the Document Group field. The Document Group value is used to establish a relationship between documents in that group when entered into the PMRA document management system.

Document Group

r) **Comments:** This field can be used to include any extra information which needs to be submitted with the document in question. Additional cross reference information, relevant page number ranges and publication citations are examples of information that can be included in this space.

Comments

6) **Attaching Files:** Although the details of a file have been provided, the actual file itself has yet to be attached. Attaching files in EIB is very similar to attaching files using other programs.

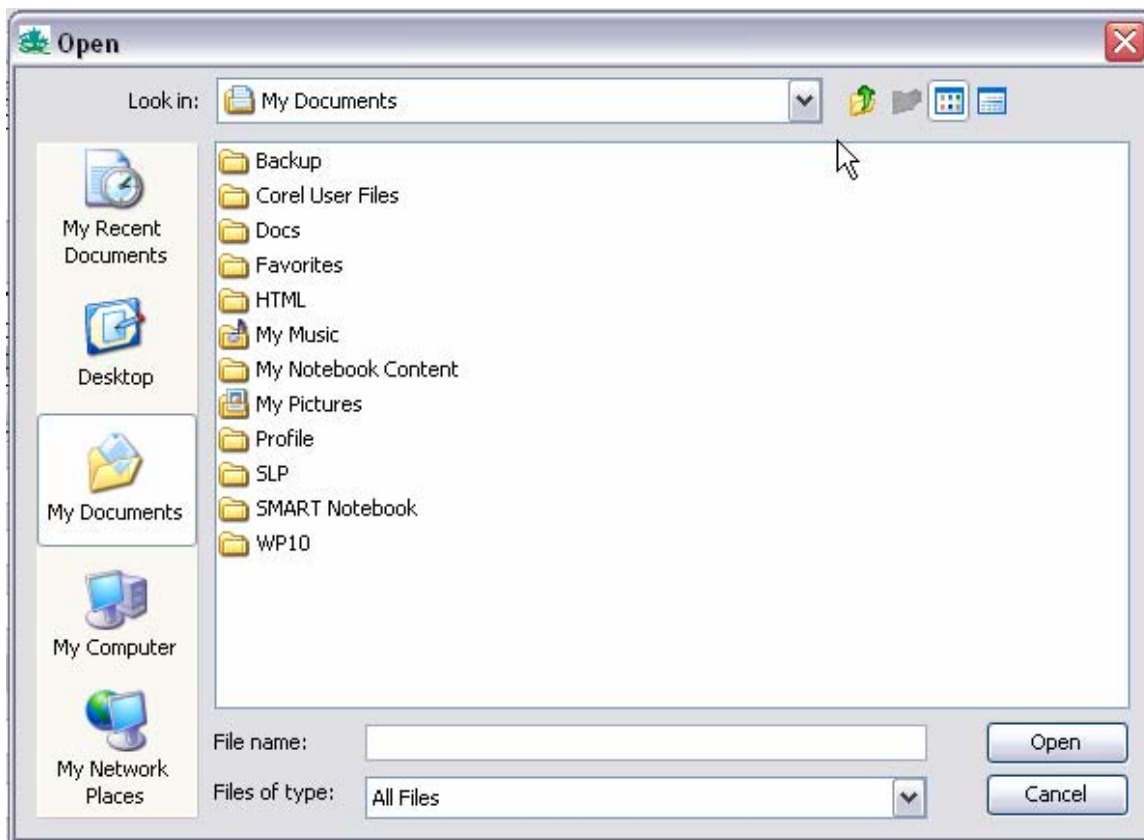
NOTE: Attaching a file is not mandatory. If you only have a paper copy of the file you are describing, then you do not need to perform this step.

At the bottom of the EIB screen, you will find the following section:

e-File Name

(The “Browse” button will only become usable when the ‘mandatory’ fields have been completed for a document.)

a) Click ‘Browse’. A file-folder window should appear on your screen, similar to the one found below:



b) Go to the folder that has the file which you have detailed up to this point. For example, if you have been detailing a Product Control Specification Form, you will be opening the folder that has that file.


c) Highlight the file then click ‘Open’ (or double-click on the file). The file is now attached. To be certain, the file name should now be listed in the ‘e-File Name’ window, similar to the graphic below:



Also, the name will be found in the ‘e-File Name’ column in the Document List, near the top of the EIB screen:


Row ...	Data Numbering Code(s)	Title	Author(s)	Volume No(s)	e-File Name
1	0.1.6003				0.1.6003_1281436.PDF

NOTE: You can only attach one file per row. If you attempt to attach another file to the same row, the new file will be attached and the old one will be removed from the EIB.


d) Once the file is attached, and all the file details have been provided, you are ready to add another file to the list. In order to do so, click the  button, found near the top of the EIB screen. This will add a new row in the List of Documents window, which will now look something like this:

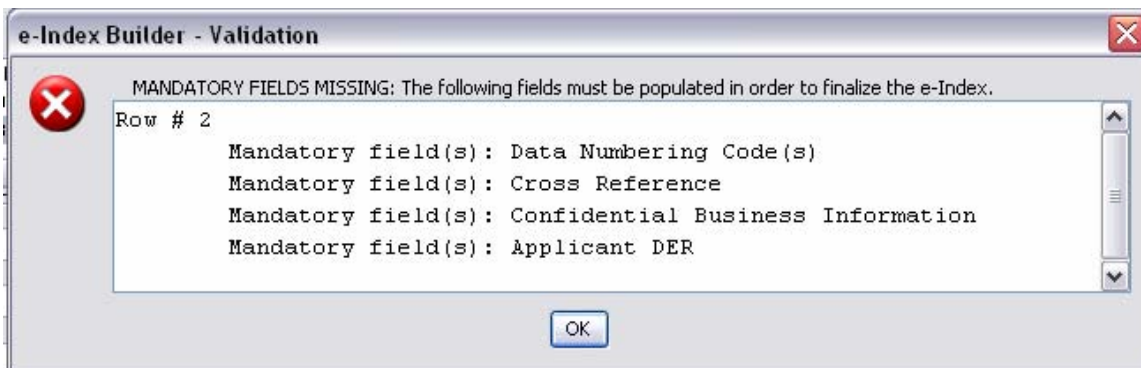
Row ...	Data Numbering Code(s)	Title	Author(s)	Volume No(s)	e-File Name
1	0.1.6003				0.1.6003_1281436.PDF
2					

With this new row, you can repeat the whole process of adding a document and giving the document details.

If you have mistakenly added a row, or wish to remove a row from the list, highlight the row and click the  button found near the top of the EIB screen.

7) *Creating the PRZ file:* By clicking the 'Save' button, one has not yet created all the files that need to be submitted to the PMRA. This button simply saves the XML file, which, as mentioned already, is only one of the files that need to be sent to the PMRA. The second file is the PRZ file, and it is created using the following process:

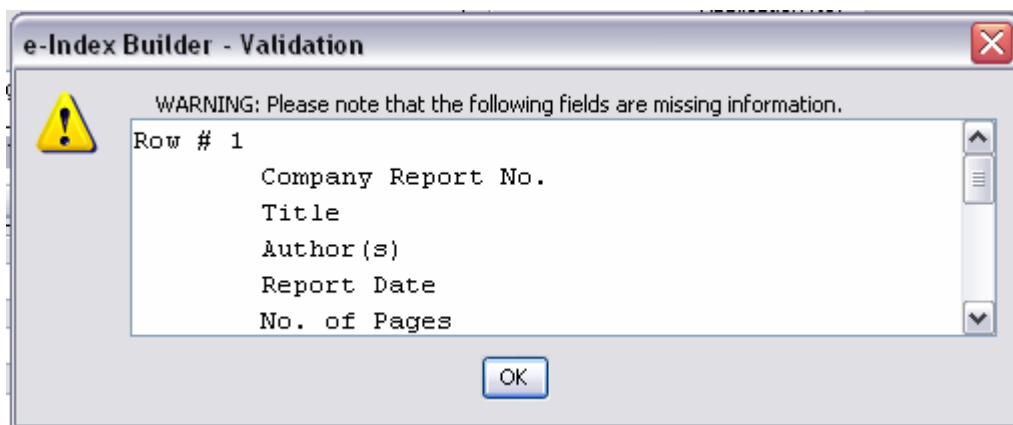
a) Click the  button to validate the XML file. Clicking this button performs a pass through the XML file to ensure that all the pieces of information have been provided by the Applicant. If you get a screen such as the following:




then there is *mandatory* information that is missing. You will need to address each of the issues before you can create the PRZ file.

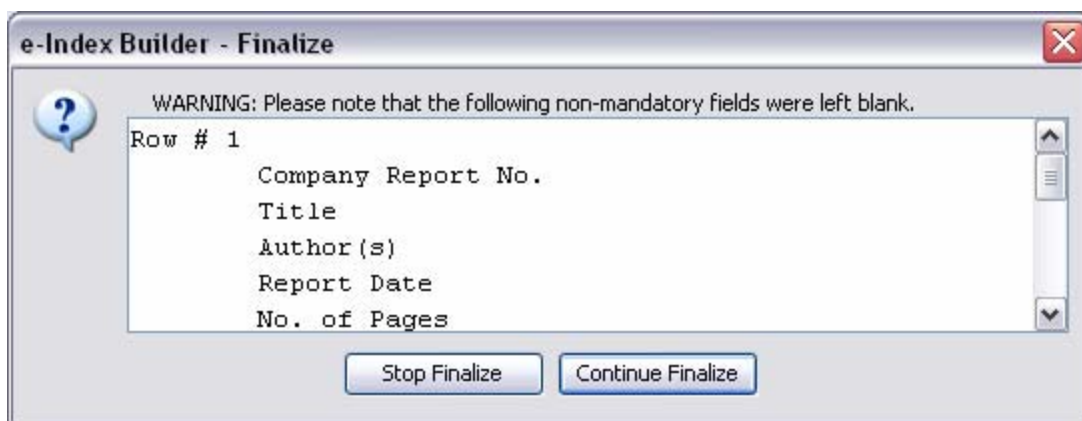
Note: if there is a lot of information missing, and you wish to have a record of this window before closing it, highlight the text inside the window, press 'Ctrl-C', and then paste the text in a text editor, such as Notepad.

If you have all the mandatory information completed, you may still get the following screen after pressing the 'VAL' button:

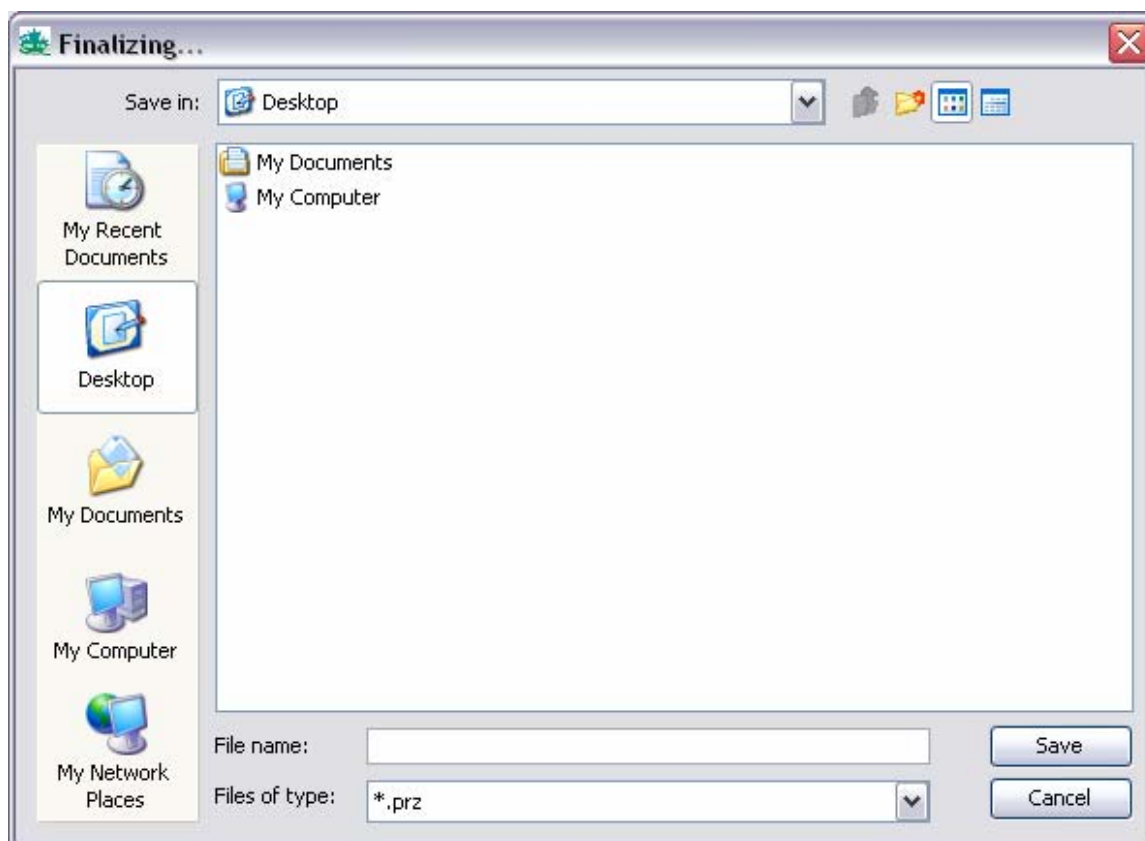


The EIB is simply telling you that there is information that is lacking which is not necessarily mandatory. You can choose to ignore this message and continue, but it may refer to information that would be important for your particular application.

b) After validating the XML file, click the  button, which prompts EIB to create the PRZ file. After clicking this button, you will get windows that are similar to the ones opened when you clicked the 'VAL' button. This is a final check before the PRZ file is created. If there are no mandatory fields missing, then you will get the following window:



Click 'Continue Finalize' to continue in the creation of the PRZ file. A window will then appear prompting you to name the file and allowing you to choose where to save the file.



Give the file an appropriate name, which may include the product name, the registration number, the date the file was created, etc. After naming the file and choosing the destination to save it, click 'Save'.

III. Submitting PRZ files

The PRZ file is all you need to submit to the PMRA. As mentioned already, it is a zipped file containing any of the electronic files included in an application, as well as the associated XML file. There are currently two methods for submitting PRZ files.

1) *E-mailing*: **E-mailing is not a secure avenue for sending files.** Attach the PRZ file to an e-mail and send it to PMRA-ARLA_DOCS@hc.sc.gc.ca. If the product has a PMRA Registration Number, include it in the subject header.

Before sending the PRZ file via e-mail, please ensure that it is less than 5MB. This can be done by right-clicking the PRZ file and selecting 'Properties'. The document size should be listed in the 'General' tab of the window that appears.

2) *Mail*: Burn the PRZ file to a CD or DVD and send the disk to:

Submission Coordination Division
Pest Control Management Agency
2720 Riverside Dr.
Ottawa, ON K1A 0K9

The size of the PRZ files that can be sent via CD and DVD is only limited by the memory capacities of these disks.

IV. Extra Functions

Near the top off the EIB screen, there are several buttons that have not yet been described in this tutorial. These buttons are not required for compiling PRZ files, but may help more experienced users in compiling their application files quicker.



: Close e-Index. This button may help when you have finished with a particular XML file and wish to work on another. To make sure you are working on the right file, use the close button to close the current file before starting or opening a new file.



: Hide/Show Document Details. For applications that have many documents listed in the List of Documents frame, a user may wish to hide the Document Details frame in order to better search through the list of documents. A user can also change the relative sizes of each frame by scrolling over the line dividing the two frames until a double-arrow scroll button appears. With this button, a user can adjust the sizes of the windows similar to how this operation is performed in other programs.



: Insert New Row. This button is different from the “Add New Row” button described in section II.6 d). While the “Add New Row” button adds a new row at the end of the list of documents, “Insert New Row” inserts a row right above any currently highlighted row in the List of Documents frame. This button would be helpful for a user to better organize their list of documents in the EIB.



: Copy Row. This button allows a user to create a new row in the List of Documents that has the same document details as a highlighted row. The only parts of the row that are not copied are the Cross Reference, Confidential Business Information, Applicant DER, e-file name sections. This button helps a user insert rows with information that is very similar to the one they copied, and allows a user to make any changes they wish. For example, if the user attached Volume 1 of a data package to one row, and wishes to create another row for Volume 2, all the user would need to do is copy the row with Volume 1, change some details in the Report Information section of the new row, and then attach Volume 2 to the new row.