Incident Report Form User Guide

Version 1.0

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Document Overview

The following document provides the Registrant and Application the functional and technical information needed in order to complete the Incident Report (IR) form and submit it to the Pest Management Regulatory Agency (PMRA).

Requests for assistance, including requests for technical assistance should be directed to 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.

Revision History

All aspects of this document, including diagrams, are under configuration control. Changes shall be reflected in the table below. A letter shall designate unofficially released versions. Each change shall result in a letter update (i.e. Version 1.0A to Version 1.0B).

A number shall designate all officially released versions. In addition, each minor change shall result in a version number update (i.e. Version 1.0 to Version 1.1) and each major change shall result in a new version (i.e. Version 1.0 to Version 2.0).

Version	Author	Change Description	Pages Affected	Release Date
1.0	Dana Bruce	SME. Provide content and editing.	All	July 27, 2007
1.0	Lisa Bambrick	Added to standard template, applied Style guide, added content, edited and formatted.	All	August 10, 2007

Table 1: Document Revision Table

1   Incident Report Form Introduction

Under section 13 of the *Pest Control Products Act* (PCPA), registrants and applicants for the registration of a pesticide, are required to report incidents of adverse effects that involve their pesticides. Incidents include effects on humans, domestic animals, the environment, packaging failures that could result in human exposure or injury, and excessive residues in food. The *Pest Control Products Incident Reporting Regulations* specify the actual reporting requirements, including the type of information to be reported and the time limits for reporting the information. The Regulations came into effect April 26, 2007.

Under section 13 of the PCPA, the Minister can direct the form and manner for reporting incidents. Consequently, registrants and applicants must use the Pest Management Regulatory Agency (PMRA) Incident Report form when submitting an incident to the PMRA. By answering the questions on the form, registrants are providing the prescribed information as described in the Regulations.

It is the legal responsibility of the registrant to complete the form accurately and with as much detail as possible based on the information they receive. Registrants are not required to prove or substantiate the information in order for it to be included in the report. Submitting an incident report to the PMRA in no way affirms causality between the pesticide and the effect. The report must be submitted electronically and can be downloaded from the PMRA website.

The Incident Report (IR) form has been developed by the PMRA as an electronic tool to capture all prescribed information for reporting an incident. The IR form is displayed in both English and French and divided into eight different subforms as listed below.

> ➢ Subform I: General Information
> ➢ Subform II: Human Incident Report
> ➢ Subform III: Domestic Animal Incident Report
> ➢ Subform IV: Environment (includes plants, insects and wildlife)
> ➢ Subform V: Residues in Food
> ➢ Subform VI: Packaging Failure
> ➢ Subform VII: Scientific Study
> ➢ Subform VIII: Reports Completed

For each incident reported, the registrants **must** complete **Subform I: General Information** and **Subform VIII**: **Reports Completed**. The registrant must also include at least one of the remaining six subforms. That is, the Human, Domestic Animal, Environment, Residue in Food, Packing Failure or the Scientific Study subform.

There are three phases to successfully completing an Incident Report Form.

1. **Download** the Incident Report PDF form from the PMRA website and save it to your local computer.

2. **Complete** at least three of the 8 subforms in the incident report: the General Information subform (subform I), the selected incident subform(s) (subform II - VII) and the Reports Completed subform (subform VIII) with as much detail as possible and save the form to your local computer. The Incident Report form is only to be submitted once the Reports Completed subform is dated, signed and saved. Saving the completed incident report to your local computer is necessary to create an e-index file for submission to the PMRA and to provide a status update on the incident after it has been submitted to the PMRA.

3. **Submit** to the PMRA the Incident Report form in a PRZ zip file format using the e-Index Builder to create and finalize the e-index file that describes the IR form. ONLY PRZ file formats are accepted. Paper copies of the form are NOT acceptable. For more information please refer to Section 9.3 How to Send the Incident Report Form.

Requests for assistance, including requests for technical assistance, should be directed to the Pest Management Information Service at 1-800-267-6315.

1.1 Who Can Submit Incident Reports

Reports must be submitted to the PMRA by the registrant or by an **officer** or **employee** of the registrant who is duly authorized to do so.

1.2   System Requirements

Version 7.0.7 or higher of Adobe Acrobat or Adobe Reader (the free Adobe Reader Plug-in, versions 7.0.9 or 8, are available from www.adobe.com) is required to electronically complete the Incident Report form.

The Incident Report form provides additional rights to allow users to save the form in Adobe Reader. Registrants will also require the ability to write to a CD or DVD on their existing computing environment. This is the preferred approach to submitting Incident Reports to the PMRA.

1.3   Definitions

Registrant: For the purpose of this document, the term 'registrant' refers to both a company in whose name a pesticide is registered and applicants for the registration of a pesticide.

Caller: The term 'caller' refers to the person who informed the registrant of the incident and provided the details.

Incident Report: In the regulations, the term 'incident report' is a report that contains the prescribed, or required, information that registrants must submit to the PMRA. The prescribed information is listed in section 3 of the *Pest Control Products Incident Reporting Regulations* and includes information such as the date the incident occurred, the location of the incident, the pesticide involved, and so on, and so forth.

1.3.1   Personal Information

Personal information, as defined in the Privacy Act, is any information that can be used either on its own or in combination with other information to identify an individual.

There are three questions in the Incident Report form that ask the registrant for information that could be considered personal information:

1. Contact information for a person within the registrant's organization who can be the point of reference for any questions that the PMRA may have about the specific incident.

2. City/town and province/state where the incident occurred. This information is not considered personal information on it's own, but could be used in conjunction with other information to identify an individual; and

3. Author's name(s) of scientific studies.

No other personal information should be provided to the PMRA, either in any of the text boxes, or in any attachments to the forms. Any unsolicited personal information provided by the registrant to the PMRA will be deleted from the PMRA's records. Make sure that no personal information (that is names, addresses, birth dates and so on) is present in any attachments or text boxes.

1.3.2 Confidential Test Data

Confidential Test Data (CTD) is defined in the *Pest Control Products Act* as scientific or technical information that may be protected under the *Access to Information and Privacy Act*. In the case of the IR form, all CTD must be placed in an attachment to the IR form. CTD must NOT be entered into the text fields of the form itself. All scientific studies provided by the registrant as an attachment will be considered CTD.

As with other applications made to the PMRA, CTD will not be posted to the public Registry, but will be available upon request for viewing in the Reading Room.

1.3.3 Confidential Business Information

Confidential Business Information (CBI) is protected from public access and may include:

➢ manufacturing and quality control processes;
➢ methods for determining composition;
➢ monetary value of sales; and
➢ identity and concentration of formulants.

All CBI must be placed in an attachment to the Incident Report form, NOT in the text fields of the form itself. As with other applications made to the PMRA, it is the registrant's responsibility to identify CBI.

2 Subform I: General Information

The Incident Report (IR) form is interactive therefore, selecting a category of incident(s) under Question 3 will display the corresponding subform(s) as well as the remaining questions under the General Information subform. For example, once an incident is selected, Question 8 from the General Information subform will prompt if the product was applied. If **No** is selected, no further application questions are asked but, if **Yes** is selected, more questions will need to be completed.

Most of the questions on the form are mandatory and must be completed before the user can proceed to the next subform. Any mandatory questions not completed will be highlighted in yellow when clicking the **Validate** button or the **>>** button. Almost all of the mandatory questions have an unknown option. Questions on the form that are greyed out cannot be answered. Typically, questions become inaccessible based on how you have responded to a previous question. There are also a few questions that are optional.

NOTE: Please ensure to scroll to the bottom of each subform in order to answer all questions displayed in the form.

2.1 Updating a Report

1. Select the **Update the report – Mise à jour d'une déclaration précédente** radio button.

When submitting an update to a previously submitted report, the incident report number is required. This number is generated by the PMRA and will be emailed to the registrant contact person identified on the form after the incident has been submitted to the PMRA. The incident report number can also be found on the public registry. Report updates are to be made to the **original report** and then re-submitted to the Pest Management Regulatory Agency (PMRA).

To provide a status update to a report, open the original report that was saved to your local computer (as indicated in Section 1) and select **Update the report – Mise à jour d'une déclaration précédente** in question 1 of subform I.

When the **Update the report – Mise à jour d'une déclaration précédente** radio button is selected, all the fields in the original report are greyed and therefore can not be edited.

Each subform will display a **Status Update** text box to provide information updates for the subform. The option to attach a report for the update is available for the **Environment**, **Residues in Food** and **Scientific Study** subforms.

Once the updates are completed, the **Reports Completed** subform must be signed and dated again before submitting it to the PMRA.

2.2 Creating a New Report

1. Report Type - Type de rapport

( ) New incident report - Nouvelle déclaration d'incident   ( ) Update the report - Mise à jour d'une déclaration précédente

Incident Report No. - N^o de la demande _____

1. Select the **New Incident Report – Nouvelle déclaration d'incident** radio button. Please refer to Question 2 to begin completing the subform.

2. Registrant Information - Renseignements concernant le titulaire

Registrant Reference Number - Numéro de référence du titulaire d'homologation _____

Registrant Name (Full Legal Name, no abbreviations)
Nom du titulaire (nom légal complet, aucune abbréviation) _____

Address
Adresse _____

City - Ville _____   Prov / State - État _____

Country - Pays _____   Postal Code - Code postal /Zip _____

Registrant Contact Person - Personne ressource du titulaire _____

Telephone - Téléphone _____   Fax - Télécopieur _____

Email - Courriel _____

2. A registrant reference number is unique number that can be used by the registrant to track and identify the Incident Report. Although this field is optional, it is strongly recommended that the registrants complete it. The registrant reference number can be provided in order to track the IR form internally within your organization. Provide the full registrant name and address. Then provide the registrant contact information of the person within your organization that the PMRA can contact about this specific incident.

The information provided about the registrant contact person will also be used by the PMRA to acknowledge receipt of an IR form. This information will not be posted to the Public Registry.

3. Select the appropriate subform(s) for the incident - Choisir le (les) sous-formulaire(s) correspondant à l'incident

☐ Human - Incident chez l'humain

☐ Domestic Animal - Incident chez un animal domestique

☐ Environment - Environnement

☐ Residues in Food - Résidus dans les aliments

☐ Packaging Failure - Défaillance de l'emballage

☐ Scientific Study - Étude scientifique

3. Select the appropriate subform(s) for the incident that is being reported. Multiple selections can be made, however the **Residues in Food** and the **Scientific Study** subforms are completed separately and cannot be included with other subforms.

Questions 4 to 6 and 8 only appear if the Human, Domestic Animal or Environment subforms have been selected. Question 7a will be displayed for the above subforms only when Questions 5 has been answered.

Selecting the Residues in Food subform will display Questions 4 to 8. If Packaging Failure is selected, only Questions 4 to 7a will appear. Only Question 7a is displayed when selecting the Scientific Study subform.

4. Date registrant was first informed of the incident
Date à laquelle le titulaire d'homologation a été informé pour la première fois de l'incident

4. Click in the response field, and then click the down arrow to display the calendar. Select the date the registrant was first made aware of the incident. The date selected must be the current date or in the past.

5. Location of incident - Lieu de l'incident

Country - Pays [▾]   Prov / State - État [▾]   City - Ville [   ]

5. Select the country, province or state and enter the city (if known) of where the incident occurred. When selecting the Residue in Food or Packaging checkbox, Canada is selected by default under the Country drop-down list.

6. Date incident was first observed
Date de la première observation de l'incident   ☐ Unknown - Inconnu

6. Click in the response field, and then click the down arrow to display the calendar. Select the date when the caller first became aware of the incident. If the date is not known, select the **Unknown - Inconnu** checkbox.

Product Description - Description du produit

7. a) Provide the active ingredient and, if available, the registration number and product name (include all tank mixes). If the product is not registered provide a submission number
Donner le nom de la matière active et, si disponibles, le numéro d'homologation et le nom du produit (incluant tous les mélanges).
Si le produit n'est pas homologué, donner le numéro de la demande d'homologation

| Active Matière(s) active(s): | Add Active(s) - Ajouter matière(s) active(s) | Registration No. Nᴼ d'homologation | | Submission No. Nᴼ de la demande d'homologation | |
| Product Name Nom du produit | | | | | |

7.a. Provide the active ingredient, product name, and registration number (include all tank mixes). If the product is not registered, provide a submission number. If more than one product was reported to be involved in the incident, click the **+** button located at the top left-hand corner of Question 7 a) to add another field. To remove a product name field click the **–** button.

NOTE: For U.S products, the EPA registration number cannot be entered into the **Registration No**. field. The hyphen will not be accepted. As such, for U.S products please enter the registration number in the **Product Name** field in addition to the name of the product.

Adding an Active Ingredient:

1. Click the **Add Active(s) – Ajouter matière(s) active(s)** button. A separate screen will become available. Active ingredients can also be listed in French by selecting the **French Names** – **Noms français** checkbox.

2. Select the active ingredient from the list, and then click the **Add - Ajouter** button. The selected active ingredient will be listed in the **Selected Active Ingredients** window box. To remove the added active ingredient, select it, and then click the **Remove** – **Effacer** button. Clicking the **Clear** – **Enlever** button will remove *all* the active ingredients listed in the **Selected Active Ingredients** box.

3. When finished, click the **OK** button to return to the **General Information** subform or click the **Cancel** button to remove the selected active ingredient and return to the previous screen.

NOTE: If the active ingredient is not available from the list, click the **Add** "**Other"** – **Ajouter "Autre"** button, and then click **OK**. Question 7a) will be displayed with an additional active ingredient field in order to enter the active ingredient manually. Click the **–** button to remove the Active Ingredient entry or the **+** button to insert another active ingredient field.

7. b) Type of formulation (select all that apply) - Type de formulation (cocher tout ce qui s'applique)

- Liquid - Liquide
- Dust - Poudre
- Bait - Appât
- Unknown - Inconnu
- Tablet - Comprimé
- Granular - Granulé
- Other (specify) - Autre (préciser)
- Dry Flowable (water dispersible granules) - Pâte granulée (granulés dispersables dans l'eau)
- Wettable or soluble powder - Poudre mouillable ou soluble

> 7. b) This question only appears when **United States** is selected as the country where the incident occurred under Question 5. Multiple selections of formulation types can be selected.

Application Information - Renseignments sur l'application

8. Product was applied? - Est-ce que le produit a été appliqué?   ○ Yes - Oui ○ No - Non ● Unknown - Inconnu

> 8. If **Yes - Oui** is selected, Questions 9-12 become available. If **No - Non** or **Unknown - Inconnu** is selected, the **General Information** subform is completed. Click the **>>** button to complete the following subform(s) or the **Validate - Valider** button to ensure all mandatory questions have been answered. If all the mandatory information has not been completed, the remaining fields will be highlighted in yellow. Once the mandatory questions are completed, click the **Validate – Valider** button to ensure the questions are no longer highlighted in yellow, and then click the **>>** button to move to the next subform.

NOTE: The **>>, <<** and **Validate** buttons are located at the top and bottom right-hand corners of each subform and are used to navigate between subforms. You can only move forward to a newly created subform after all mandatory fields in the current subform have been answered.

9. Application Rate
Dose d'application   Units / Unités   Other Units / Autres unités   ☐ Unknown - Inconnu

> 9. Provide the application rate and units. If the units are not one of the options in the drop-down list, manually enter the units in the **Other Units** field. If you do not know the application rate select the **Unknown – Inconnu** checkbox.

10. Site pesticide was applied to (select all that apply) - Site d'application (choisir tout ce qui s'applique)
- Site
- Site

> 10. Select the site where the pesticide was applied from the drop-down list. If Agricultural Indoor/Outdoor, Industrial or Other is selected, specify the type that was treated.

11. Provide any additional information regarding application (how it was applied, amount applied, the size of the area treated etc)
Donner tout renseignement additionnel concernant l'application (comment le produit a été appliqué, la quantité utilisée, la superficie de la zone traitée, etc.)

11. Describe the application in detail.

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12. In your opinion, was the product used according to the label instructions?
Selon vous, le produit a-t-il été utilisé en conformité avec le mode d'emploi de l'étiquette?

○ Yes - Oui   ○ No - Non   ⦿ Unknown - Inconnu

12. This question is to be answered by the registrant, not the caller. It is not a mandatory question and may be left blank. It will be posted to the Public Registry.

Public Registry

The Public Registry is a collection of non-confidential information on pesticides or the pesticide regulatory system, and includes product information, such as incident reports and regulatory and policy documents.

All prescribed information provided in the IR form will be posted to the Public Registry, except for personal information, confidential test data or confidential business information. Supplemental information, which is opinion or commentary provided by the registrant, will be posted to the Public Registry.

3   Subform II: Human

A separate Human subform must be completed for each human affected by an incident. For example, if two people have been affected in one incident, two separate Human subforms are required to be completed. Subforms are numbered at top right-hand corner. Additional Human or other subforms can be added by clicking the **+** button located at the top right-hand corner of the subform. To delete a subform simply click the **–** button.

3.1   Completing the Human subform

1. Source of Report - Source de la déclaration

◯ Data Subject - Personne affectée   ◯ Medical Professional - Professionnel de la santé   ◯ Other - Autre

1.   Who informed the registrant of the incident? Was it the data subject, (the person affected by the incident) a medical professional (a third party from the medical profession, such as a nurse or physician) or other source.

2. Demographic information of data subject - Renseignement démographique sur la personne affectée

Sex - Sexe: ◯ M   ◯ F   ◯ Unknown - Inconnu   Age - Âge [_____ ▾]

2.   Provide information on the person who was affected in this incident.

3. List all symptoms, using the selections below.
    Énumérez tous les symptômes, au moyen des choix suivants.

☐ French Lists for question 3 --Listes françaises pour la question 3

System - Système	Symptom - Symptôme
[+][-] [____ ▾]	[____ ▾]
specify - préciser [_____]	

3.   The list of symptoms is unique for each system and contains synonyms for many of the symptoms. For example, under the system *eye*, *miosis* and *pinpoint pupils* are included in the list. Select the symptom that best represents what was reported to you. First, choose the system, and then select the symptom. Additional symptoms may be reported by clicking the **+** button located in the left hand corner or deleted by clicking the **-** button.

If a symptom is not included in the drop-down list;
> a.   Choose the appropriate system, and then select **Other** from the **Symptom - Symptôme** list.
> b.   Enter the symptom manually in the **specify - préciser** text field.

If you are uncertain of the system to which a symptom belongs to;
> a.   Select **Unknown** from the **System - Système** drop-down list. The symptom will automatically be **Other.**
> b.   Enter the symptom manually in the **specify - préciser** text field.

NOTE: The available symptoms are a subset of the list from the Guidance Document for the Pest Control Products Incident Reporting Regulations. Please refer to Appendix A for

the list of symptoms, organized by system and Appendix B for the alphabetical listing of the symptoms.

4. How long did the symptoms last? - Quelle a été la durée des symptômes?	▾

4. Select the time range that represents the length to which the symptom lasted. If more than one symptom is being reported, select the time frame that represents the longest period.

5. Was medical treatment provided? Provide details in question 13. La personne affectée a-t-elle reçu des soins médicaux? Donner les détails à la question 13.	○ Yes - Oui ○ No - Non ○ Unknown - Inconnu

5. Medical treatment includes any treatment **prescribed** by a medical professional including prescription drugs, over the counter medication, physiotherapy, and so on. If a data subject visits a medical professional, but does not receive any form of treatment, select the **No** radio button. Describe in detail what the treatment consisted of under Question 13. Include results from medical tests, if available.

6. a) Was the person hospitalized? - Est-ce que la personne a été hospitalisée?	○ Yes - Oui ○ No - Non ⦿ Unknown - Inconnu

6. a) A person would be considered hospitalized if he or she had been admitted to a hospital for treatment of the symptoms related to this incident. If a data subject goes to the hospital, but is not admitted, then they have not been hospitalized.

6. b) For how long? - Pendant combien de temps?		▾	☐ Unknown - Inconnu

6. b) Indicate the length of time that the data subject was hospitalized, beginning with admission to the hospital.

7. Exposure scenario - Scénario d'exposition

○ Occupational - Professionnel   ○ Non-occupational - Non professionnel   ⦿ Unknown -Inconnu

7. Occupational exposure signifies that exposure to the pesticide occurred at the workplace. If the exposure did not occur at the workplace, it would be considered non-occupational.

8. Select all options that describe how the data subject was exposed to the pesticide involved in this incident.

   Application: any activity that occurred during the use of the product, such as mixing and loading the pesticide, applying the pesticide, cleaning of machinery after the use and so on.

   Contact with treated area: examples include walking across a lawn that had been sprayed with an herbicide, petting a dog that was treated for fleas, harvesting vegetables that had been sprayed with a pesticide and so on.

   Drift from the application site: the movement of pesticide by wind away from the intended area of application. As a pesticide is applied, it may drift or move from the site of application to another unintended site.

   Pesticide spill: the accidental release of a pesticide onto or into the land or water.

   Poisoning from ingestion of the pesticide: indicate if the consumption was **Intentional** or **Accidental**. Although an incident involving intentional poisoning with a pesticide is not required to be reported to the PMRA (incidents that would constitute an offence under the Criminal Code are not required), some registrants may choose to submit them voluntarily. These IRs will not be posted to the public registry.

   Other: select this checkbox if the method of exposure is unknown.

9. Select all options that apply.

10. Route(s) of exposure - Voie(s) d'exposition

☐ Skin - Peau ☐ Eye - Yeux ☐ Oral - Orale ☐ Respiratory - Respiratoire ☐ Unknown - Inconnu

10. By selecting the route of exposure, you are identifying the physical area of contact by which the data subject was introduced to the pesticide. Select all options that apply. The option **Oral** includes ingestion. The respiratory route of exposure means contacting the pesticide by breathing it in.

11. What was the length of exposure? Durée de l'exposition?

11. The length of exposure should be measured from the first moment that the data subject came into contact with the pesticide to the last moment that there was contact.

12. Time between exposure and onset of symptoms Temps écoulé entre l'exposition et l'apparition des symptômes

12. The onset of symptoms refers to when the first signs of the symptoms were observed.

13. Provide any additional details about the incident (eg. description of the frequency and severity of the symptoms, type of medical treatment, results from medical tests, outcome of the incident, amount of pesticide exposed to, etc.)

Donner tout détail additionnel au sujet de l'incident (p.ex. description des symptômes tels que la fréquence et la gravité, type de soins médicaux, résultats des tests médicaux, quantité de pesticide à laquelle la personne a été exposée, etc.)

13. Include as much detail about the incident as possible.

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14. Severity classification - Classification selon la gravité

○ Death - Mort   ○ Major - Majeure   ○ Moderate - Modérée   ○ Minor - Mineure

14. Determine the severity classification by using the Decision Tree for the Classification of Incidents Involving Humans or Domestic Animals located in the Guidance Document for the Pest Control Products Incident Reporting Regulations. Use the level of severity to determine when the report must be submitted to the PMRA.

Health Canada   Santé Canada

15. Provide supplemental information here - Donner des renseignements additionnels ici

15. This question provides the registrant an opportunity to submit their opinions and comments about the incident. This question is not mandatory and may be left blank. It will be posted to the Public Registry.

4 Subform III: Domestic Animal

A separate Domestic Animal subform must be completed for each type of domestic animal affected by an incident. If an incident involves multiple animals of the same type and with the same symptoms, a single form can be used.

4.1 Completing the Domestic Animal subform

1. Source of Report - Source de la déclaration

○ Animal's Owner - Propriétaire de l'animal   ○ Medical Professional - Professionnel de la santé   ○ Other - Autre

1. Who informed the registrant of the incident? A medical professional may include a veterinarian, veterinary technician or other source.

2. Type of animal affected
Type d'animal touché   [▼]   specify / préciser [   ]

2. Select the type of animal affected from the drop-down list. If the type of animal is not included in the drop-down list, select **Other**, and then manually enter the type of animal in the **specify** text field.

3. Breed
Race   [   ]

3. Enter the breed of animal, if known. If you do not know the breed of animal enter *unknown* in the text field as this is a mandatory question.

4. Number of animals affected
Nombre d'animaux touchés   [   ]

4. Enter the number of animals affected.

5. Sex - Sexe: ☐ M   ☐ F   ☐ Unknown - Inconnu

5. Select if the animal is female or male.

6. Age (provide a range if necessary)
Âge (fournir un ordre de grandeur si nécessaire)   [   ]   ☐ Unknown - Inconnu

6. Enter the age of the animal or select the **Unknown** checkbox.

7. Weight (provide a range if necessary)
Poids (fournir un ordre de grandeur si nécessaire)   ☐ Unknown - Inconnu

7.   Enter the weight of the animal.

8. Route(s) of exposure - Voie(s) d'exposition:

☐ Skin - Cutanée   ☐ Eye - Oculaire   ☐ Oral - Orale   ☐ Respiratory - Respiratoire   ☐ Unknown - Inconnu

8.   Selecting the route of exposure identifies the physical area of contact by which the animal was introduced to the pesticide. Select all options that apply. The option **Oral** includes ingestion. The respiratory route of exposure means contacting the pesticide by breathing it in.

9. What was the length of exposure? - Durée de l'exposition?

9.   The length of exposure should be measured from the first moment that the animal came into contact with the pesticide to the last moment that there was contact.

10. Time between exposure and onset of symptoms
Temps écoulé entre l'exposition et l'apparition des symptômes

10.   The onset of symptoms refers to when the first signs of the symptoms were observed.

11. List all symptoms, using the selections below - Énumérer tous les symptômes, au moyen des choix suivants

☐ French Lists for question 11 - Listes françaises pour la question 11

        System - Système   **Symptom - Symptôme**

☐ ⊞☐ ─   [▼]   [▼]
        specify - préciser [   ]

11.   The list of symptoms is unique for each system and contains synonyms for many of the symptoms. For example, under the system *respiratory*, e*pistaxis* and *nose bleed* are listed and mean the same thing. Please note that euthanasia is not a symptom. If the animal was euthanised, this should be indicated in Question 15 as an outcome of the incident. First, choose the system, and then select the symptom. Additional symptoms may be reported by clicking the **+** button located in the left hand corner or deleted by clicking the **-** button.

If a symptom is not included in the drop-down list;
    a.   Choose the appropriate system, and then select **Other** from the **Symptom - Symptôme** list.
    b.   Enter the symptom manually in the **specify - préciser** text field.

If you are uncertain of the system to which a symptom belongs to;
    c.   Select **Unknown** from the **System - Système** drop-down list. The symptom will automatically be **Other.**
    d.   Enter the symptom manually in the **specify - préciser** text field.

NOTE: The available symptoms are a subset of the list from the Guidance Document for the Pest Control Products Incident Reporting Regulations. Please refer to Appendix A for the list of symptoms, organized by system and Appendix B for the alphabetical listing of the symptoms.

12. How long did the symptoms last? - Quelle a été la durée des symptômes?	⌄

12. Select a time range that represents the length that the symptom lasted. If more than one symptom is being reported, select the time frame that represents the longest period.

13. Was medical treatment provided? Provide details in question 17. Des soins médicaux ont-ils été prodigués? Donner les détails à la question 17.	○ Yes - Oui ○ No - Non ○ Unknown - Inconnu

13. Medical treatment includes any treatment **prescribed** by a medical professional including prescription drugs, over the counter medication, physiotherapy, and so on. If an animal was taken to a veterinarian but did not receive any form of treatment, click the **No** radio button. Describe in detail what the treatment consisted of under Question 17. Include results from medical tests, if available.

14. a) Was the animal hospitalized? - Est-ce que l'animal a été hospitalisé?	○ Yes - Oui ○ No - Non ○ Unknown - Inconnu

14. a) An animal would be considered hospitalized if it had been admitted to a veterinary clinic or animal hospital for treatment of the symptoms related to this incident. If the animal is taken to the veterinary clinic but not admitted, then they have not been hospitalized.

14. b) How long was the animal hospitalized? Combien de temps l'animal a été hospitalisé?		⌄	☐ Unknown - Inconnu

14 b) Indicate the length of time that the animal was hospitalized, beginning with admission to the clinic or hospital.

15. Outcome of the incident - Issue de l'incident	⌄

15. Choose from the drop-down list the option that best describes how the incident was resolved. If the animal recovers, but has some symptoms remaining, for example partial blindness, then select **Recovered with residual effects**. Euthanasia is an option for the outcome of the incident.

16. How was the animal exposed? De quelle manière l'animal a-t-il été exposé?	⌄
specify - préciser	

16. Choose from the drop-down list the process by which the animal was exposed. If **Other** is selected from the list, specify how the animal was exposed in the **specify - préciser** field.

17. Provide any additional details about the incident
(eg. description of the frequency and severity of the symptoms, type of medical treatment, results from medical tests, amount of pesticide exposed to, etc.)
Donnez tout détail additionnel au sujet de l'incident
(p.ex. description des symptômes tels que la fréquence et la gravité, type de soins médicaux, résultats des tests médicaux, quantité de pesticide à laquelle l'animal a été exposée, etc.)

17. Provide as much information as possible about the incident.

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18. Severity classification (if there is more than 1 possible classification, select the most severe)
Classification selon la gravité (s'il y a plus d'une catégorie possible, veuillez choisir la plus grave)

◯ Death - Mort   ◯ Major - Majeure   ◯ Moderate - Modérée   ◯ Minor - Mineure

18. Determine the severity classification by using the Decision Tree for the Classification of Incidents Involving Humans or Domestic Animals located in the Guidance Document for the Pest Control Products Incident Reporting Regulations. Use the level of severity to determine when the report needs to be submitted to the PMRA.

19. Provide supplemental information here - Donner des renseignements additionnels ici

19. This question provides the registrant an opportunity to submit their opinions and comments about the incident. This question is not mandatory and may be left blank. It will be posted to the Public Registry.

5   Subform IV: Environment

A separate Environment Subform must be completed for each type of organism affected by an incident. Types of organisms are listed under Question 1 of the Environment subform.

5.1   Completing the Environment subform

1. Type of organism affected - Type d'organisme touché		▾

1. Choose the type of organism that was affected by the incident from the drop-down list. Types of organisms are based on the Schedule from the *Pest Control Products Incident Reporting Regulations*. Note that the list of symptoms under Question 6 will be different when selecting an animal versus plant.

2. Common name(s) Nom(s) commun(s)		☐ Unknown - Inconnu

2. Enter the common name of the organism, if known.

3. Scientific name(s) Nom(s) scientifique(s)		☐ Unknown - Inconnu

3. Enter the scientific name of the organism, if known.

4. Number of organisms affected - Nombre d'organismes touchés		☐ Unknown -Inconnu

4. Enter the number of organisms affected. A range or percentage is acceptable.

5. Description of site where incident was observed - Description du lieu où l'incident a été observé:

Terrestrial - Terrestre	Fresh water - Eau douce	Salt Water - Eau salée
☐ Residential - Résidentiel	☐ Pond - Étang	☐ Estuary - Estuaire
☐ Agricultural - Agricole	☐ Stream - Ruisseau	☐ Bay -Baie
☐ Roadside - Bord de chemin	☐ River - Rivière	☐ Ocean -Océan
☐ Forest - Forêt	☐ Lake -Lac	☐ Sediments - Sédiments
☐ Other - Autre	☐ Sediments - Sédiments	☐ Other - Autre
	☐ Wetland -Terre humide	
	☐ Other - Autre	

5. Select the site(s) where the incident was observed. Select all that apply. The site options have been subdivided into three categories: Terrestrial (land based), Fresh Water and Salt Water.

In the Terrestrial category:
- A residential site is one that is based on or connected to a residence, and may include a residential neighbourhood or a single residential property.
- An agricultural site includes any place where agriculture occurs, including greenhouses.
- Roadside refers to the strip of land beside a road.
- Forest may include any wooded area.

In the Fresh Water category:
- A pond is a small body of still water, formed either naturally or artificially.
- A stream is a flowing body of water, smaller than a river.
- A river is a large flowing body of water that flows in a channel to the ocean or a lake.
- Sediment is matter that settles to the bottom of a body of water, or that is carried by water and deposited elsewhere.
- A wetland is a marsh, swamp or other stretch of land that is frequently saturated with water.

In the Salt Water category:
- An estuary is the tidal mouth of a large river, where the salt water (tide) meets fresh water.
- A bay is a body of water where the coastline curves inwards.
- Sediment is matter that settles to the bottom of a body of water, or that is carried by water and deposited elsewhere.

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6. Check all symptoms that apply - Cocher tous les symptômes qui s'appliquent à:

☐ Abnormal behavioural effects - Anomalies du comportement
☐ Congenital anomalies - Malformation
☐ Death - Mort

☐ Impairment of health - Détérioration de la santé
☐ Reproductive impairment - Troubles de la reproduction

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6. Check all symptoms that apply - Cocher tous les symptômes qui s'appliquent à:

☐ Abnormal abscission - Abscission anormale
☐ Abnormal flower quality or number - Qualité ou quantité anormale de fleurs
☐ Abnormal leaf discoloration - Décoloration anormale des feuilles
☐ Abnormal plant stance - Port anormal de la plante
☐ Death - Mort
☐ Deformities - Malformation
☐ Visible injury (eg. chlorosis, necrosis, bleaching)
Lésions visibles à l'oeil nu (p. ex. chlorose [jaunissement], nécrose, décoloration)

☐ Epinasty (leaf wilt) - Épinastie (flétrissement des feuilles)
☐ Reduced emergence - Levée réduite des semis
☐ Reduction in seed or fruit yield
Réduction de la production de semences et de fruits
☐ Stunted vegetative growth - Rabougrissement
☐ Terminal bud death - Mort des bourgeons terminaux

6. Select all that apply.

There are two different symptom boxes available depending on the type of organism selected under Question 1. The first symptom box is displayed if birds, amphibian, mammal, reptile, fish, aquatic or terrestrial Invertebrate is selected in Question 1. The second symptom box is displayed if trees or shrubs, herbaceous plants, or aquatic plants is selected.

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7. Describe symptoms and outcome (died, recovered, etc.).
Provide additional details about the incident (e.g. amount of rainfall, distance from treatment site, etc.).

Décrire les symptômes et issue (mort, rétablissement, etc.).
Donner tout détail additionnel au sujet de l'incident (p.ex. quantité de pluie, distance du site d'application, etc.).

7. Provide as much detail as possible about the incident.

8. a) Was the incident a result of (select all that apply) - Est-ce que l'incident a été causé par (coucher tout ce qui s'applique) :

☐ Application - Application ☐ Spill - Déversement ☐ Disposal - Élimination ☐ Run-off - Ruissellement ☐ Drift - Dérive de pulvérisation

☐ Wash-off - Lessivage ☐ Other - Autre ☐ Unknown - Inconnu

8. Select all options that describe what the incident was a result of.

Application: any activity that occurred during the use of the product, such as mixing and loading the pesticide, use of the pesticide, or cleaning of machinery after the use.

Spill: the accidental release of a pesticide onto or into the land or water

Disposal: the disposal of a pesticide relates to any activity involved with getting rid of the pesticide or the pesticide container.

Run-off: that part of precipitation which flows towards a river on the ground   surface or within the soil and can transport a pesticide.

Drift: the movement of pesticide by wind away from the intended area of application.

Wash-off: the run-off produced when cleaning pesticide application equipment.

8. b) i) How many times has the product been applied this year?
Combien de fois le produit a-t-il été appliqué cette année? ☐ Unknown - Inconnu

8. b) ii) What was the date of the last application?
Date de la dernière application ☐ Unknown - Inconnu

8. b) i) If the product was applied, indicate the number of times that it has been applied in the past calendar year. If it has not been previously applied, enter **0** in the field.

b) ii) If the product has been previously applied, indicate the date of the last application. If the caller does not know the exact date, an approximation is appropriate.

8. c) Please provide details of the spill such as when, where, how much and any other applicable details
Veuillez indiquer notamment le moment, le lieu et la quantité du déversement ainsi que toute autre circonstance

8. c) If the incident occurred as a result of a spill; provide as much detail as possible about the spill.

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9. Did it rain - Est-ce qu'il a plu

9. a) During application? - Pendant l'application?   ○ Yes - Oui ○ No - Non ◉ Unknown - Inconnu

9. b) Up to 3 days after application? - Jusqu'à 3 jours après l'application? ○ Yes - Oui ○ No - Non ◉ Unknown - Inconnu

9. a) If the product was applied, indicate whether it rained during the application of the product. Application includes mixing/loading.

b) Indicate whether it rained during the three days following the application of the product.

10. a) Was there a buffer zone? - Y avait-il une zone tampon?   ◉ Yes - Oui ○ No - Non ○ Unknown - Inconnu

10. b) What type? - De quel genre?   ○ Aquatic - Aquatique ○ Terrestrial - Terrestre

10. c) What was the size of the buffer zone? Quelle était la taille de la zone tampon? [   ] Units Unités [▾] ☐ Unknown - Inconnu

10. a) Indicate if a buffer zone was incorporated into the application of the product.

b) A buffer zone may be aquatic or terrestrial.

c) If a buffer zone was used during the application, indicate the size of the buffer zone.

11. a) Were environmental samples collected and analysed? Est-ce que des échantillons ont été recueillis dans l'environnement et analysés? ○ Yes - Oui ○ No - Non ○ Unknown - Inconnu

11. a) Indicate whether environmental samples were collected and analysed. If the samples were collected, but not analysed, click the **No** button.

11. b) Please provide an analytical report, including methodology, as an electronic attachment. Fournir le rapport d'analyse, y compris la méthodologie, en pièce électronique jointe.

11. c) Is an extension needed to submit the report? - Une extension est-elle requise pour soumettre un rapport? ◉ Yes - Oui ○ No - Non

11. d) When will the report be submitted? Quand le rapport sera-t-il soumis? [   ]

11.   b) If environmental samples were analysed, provide the report as an attachment.

c) Indicate whether more time is needed to complete the analysis.

d) When do you anticipate the analysis to be complete and ready for submission to the PMRA?

11. e) File attachment information - Renseignments sur la pièce jointe

11. e) To attach more then one report click the **+** button located at the top left-hand corner. To remove a report, simply click the **–** button. The Data Numbering Code(s) can also be listed in French by selecting the **French Lists – Listes françaises** checkbox.

Indicate whether the attachment contains Confidential Business Information (CBI) by selecting the corresponding radio button. The Confidential Business Information radio button indicates if the entire document is CBI as defined in the PCPA 2002. If two documents are being submitted as the non-CBI (parent document) and CBI (CBI reference document) components of a document pair, all of the Document data must be identical except for the CBI Yes / No value. That is, the Parent Document should be marked CBI **No** and the CBI Reference Document should be marked CBI **Yes**.

Is the attachment a cross reference to information that the PMRA already received? If **No** is selected complete the information, and then click the **Browse – Parcourir** button to attach the file. If **Yes** is selected the file attachment option will be removed and the Confidential Business Information radio buttons will be greyed out. The Application number and PMRA Document No. fields are visible to provide information about the source of the cross referenced information.

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12. Severity classification (if there is more than one possible classification, select the most severe)
Classification selon la gravité (s'il y a plus d'une catégorie possible, veuillez choisir la plus grave)

○ Major - Majeure   ○ Moderate - Modérée   ○ Minor - Mineure

12. Select the severity classification based on the Schedule included in the *Pest Control Products Incident Reporting Regulations*. Use the level of severity to determine when the report needs to be submitted to the PMRA.

13. Please provide supplemental information here
Donner des renseignements additionnels ici

13. This question provides the registrant an opportunity to submit their opinions and comments about the incident. This question is not mandatory and may be left blank. It will be posted to the Public Registry.

6 Subform V: Residues in Food

This subform cannot be used with other subforms.

6.1 Completing the Residues in Food subform

1. Pesticide(s) and degradate(s) analysed for Pesticide(s) et produit(s) de dégradation	

1. If there is more than one pesticide(s) or degradate(s) to be entered, place a comma (,) between them.

2. Concentration of pesticide/degradate in food Concentration de pesticide/produit de dégradation dans l'aliment		Units Unité(s)		Other Units Autre(s) unité(s)	

2. Enter the concentration of the residue(s) in question that was found in the food sample(s).

3. Corresponding limit of detection Limite de détection correspondante		Units Unité(s)		Other Units Autre(s) unité(s)	

3. Enter the limit of detection for the residue(s) in question.

4. Sample Type - Type d'échantillon

- ○ Raw Agricultural commodity - Produit agricole à l'état brut
- ○ Prepared or processed food - Aliment préparé ou transformé
- ○ Other - Autre
- ○ Unknown - Inconnu

4. Indicate the type of sample was analysed.

   Raw Agricultural commodity is one that has not been processed or prepared in another food type.

   Prepared or processed food includes all food that is not in its original shape that has been changed into another type of food.

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5. Method of analysis (include if a confirmatory method was used in addition to the screening method)
   Méthode d'analyse (préciser si l'on a eu recours à une méthode de confirmation en plus de la méthode d'échantillonnage)

5. Describe in detail the method of analysis and include the confirmatory method, if one was used.

Sample Information - Renseignements concernant l'échantillon:

6. What is the reason the sample was collected (e.g. complaint, inspection, process monitoring)?
   Pourquoi a-t-on prélevé un échantillon (p. ex. plainte, inspection, contrôle de procédé)?

☐ Unknown - Inconnu

6. Explain in detail why the sample was collected.

7. What organization collected the sample? - Quel organisme a prélevé l'échantillon?

○ Provincial - Provincial

○ Canadian Food Inspection Agency - Agence canadienne d'inspection des aliments

○ Canadian Grain Commission - Commission canadienne des grains

○ Other - Autre

○ Unknown - Inconnu

specify agency
préciser l'agence

7. Indicate which organization was responsible for collecting the sample by selecting the corresponding radio button.

8. From what point in the distribution channel was the sample taken? - À quel point du canal de distribution l'échantillon a-t-il été prélevé?

☐ Farm - Ferme   ☐ Warehouse - Entrepôt   ☐ In Transit - Expédition   ☐ Retail - Commerce   ☐ Other - Autre   ☐ Unknown - Inconnu

8. Indicate where in the process of production the food sample was taken.

9. How large was the food commodity from which the sample was taken?
   Quelle était la taille du lot dans lequel l'échantillon a été prélevé?

☐ Unknown - Inconnu

9. Enter how large the food commodity was from which the food sample was taken. Note that this does not represent the size of the sample analysed.

10. How many samples were taken?
    Combien d'échantillons ont été prélevés?

☐ Unknown - Inconnu

10. Enter how many samples were taken. Note that this does not represent how many samples were analysed.

11. How large was the sample size? Quelle était la taille de l'échantillon?		☐ Unknown - Inconnu

11. Enter the size of the sample that was analysed.

12. What action was taken based on the violative residue? - Quelle mesure a été prise en fonction de ces résidus?

○ No action - Aucune mesure ○ Shipment rejected - Rejet du lot ○ Shipment destroyed - Destruction du lot

○ Other - Autre ○ Unknown - Inconnu

12. Indicate whether any action was taken, based on the fact that the residue in the food was above the accepted level by selecting the corresponding radio button.

13. a) Provide analytical report, including methodology, as an electronic attachment.
Fournir le rapport d'analyse, y compris la méthodologie, en fichier électronique joint.

13. b) Is an extension needed to submit the analytical report? - A-t-on besoin d'un délai? ⦿ Yes - Oui ○ No - Non

13. c) When will the report be submitted? Quand le rapport sera-t-il soumis?

13. a) Provide the analytical report as an attachment. Ensure that a description of the methodology is included.

b) Indicate whether more time is needed to complete the analysis.

c) When do you anticipate the analysis to be complete and ready for submission to the PMRA?

d) To attach more than one report click the **+** button located at the top left-hand corner. To remove a report, simply click the **–** button. The Data Numbering Code(s) can also be listed in French by selecting the **French Lists – Listes françaises** button.

Indicate whether the attachment contains Confidential Business Information (CBI) by selecting the corresponding radio button. The Confidential Business Information radio button indicates if the entire document is CBI as defined in the PCPA 2002. If two documents are being submitted as the non-CBI (parent document) and CBI (CBI reference document) components of a document pair, all of the Document data must be identical except for the CBI Yes / No value. That is, the Parent Document should be marked CBI **No** and the CBI Reference Document should be marked CBI **Yes**.

Is the attachment a cross reference to information that the PMRA already received? If **No** is selected complete the information, and then click the **Browse – Parcourir** button to attach the file. If **Yes** is selected the file attachment option will be removed and the Confidential Business Information radio buttons will be greyed out. The **Application Number** and **PMRA Document No**. fields are visible to provide information about the source of the cross referenced information.

14. Provide supplemental information here
    Donner des renseignements additionnels ici

14. This question provides the registrant an opportunity to submit their opinions and comments about the incident. This question is not mandatory and may be left blank. It will be posted to the Public Registry.

7 Subform VI: Packaging Failure

This subform can be used separately or combination with the Human, Domestic Animal and Environment subforms.

If the packaging fails and another incident occurred, then both the Packaging Failure subform and the other relevant subform must be completed. For example, if a package fails and as a result a person suffers from a rash, then the Packaging Failure subform and the Human subform must be completed.

7.1 Completing the Packaging Failure

1. What is the type of packaging that failed? - Type d'emballage défaillant?

	specify préciser	

1. Indicate the type of packaging that failed. If more than one type of packaging failed, click the **+** button to add additional types. Click the **-** button to remove additional types of packaging.

2. Did packaging failure occur during - La défaillance de l'emballage est apparue pendant

○ Use of Product - L'utilisation du produit   ○ Storage - L'entreposage   ○ Transportation - Le transport   ○ Other - Autre

specify préciser

2. Indicate the activity during which the packaging failed. If it did not occur during the use of the product, storage, or transportation, select **Other - Autre** and enter the details in the **specify - préciser** field.

Use of Product: includes activities such as mixing and loading the pesticide, application of the pesticide and cleaning of machinery after the use.

Storage: the failure occurred during the storage of the pesticide.

Transportation: pesticide failure only needs to be reported for those incidents that occur during normal transportation. For example, a case that breaks after falling off a truck during transport is not considered packaging failure.

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3. Did packaging failure result in - La défaillance de l'emballage a donné lieu à :

☐ potential injury - une blessure potentielle   ☐ potential exposure - une exposition potentielle

3. Indicate whether the packaging failure resulted in potential injury or potential exposure.

   Potential injury: is any possible injury that may occur as a result of a failure in the packaging only, not in the escape of the pesticide itself. For example, if a pressurized can exploded, the potential outcome would be injury due to the can itself, not the pesticide being released.

   Potential exposure: refers to any possible exposure and symptoms based on the unintentional release of the pesticide itself. If a package fails and another incident occurs, both subforms must be completed.

4. Describe how the packaging failed and the surrounding circumstances, including a description of the potential injury or exposure
   Décrire pourquoi l'emballage a été défaillant et dans quelles circonstances, décrire notamment la blessure ou l'exposition potentielle

4. Describe in detail how the packaging failed. Include a description of the potential injury, if appropriate.

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5. Provide supplemental information here - Donner des renseignements additionnels ici

5. This question provides the registrant an opportunity to submit their opinions and comments about the incident. This question is not mandatory and may be left blank. It will be posted to the Public Registry.

8   Subform VII: Scientific Study

This subform cannot be used with other subforms.

8.1   Completing the Scientific Study subform

1. Study Reference - Renseignements concernant l'étude	
Author(s) Auteur(s)	
Title Titre	
Date	

1.   Provide details on the scientific study such as the Author name(s), the title of the study and the date of the study.

2. a) Is an extension needed to translate the document? - Si une traduction est requise, a-t-on besoin d'un délai? ⦿ Yes - Oui ○ No - Non
2. b) When will the document be submitted? Quand le rapport sera-t-il soumis?
2. c) Attach a summary of the study in English or French - Joindre un résumé de l'étude en anglais ou en français

2.   a) Identify whether more time is required in order to translate the study into either English or French.

   b) If more time is required in order to translate the study, provide an estimate as to how long will be required for the translation.

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d) To attach more than one report click the **+** button located at the top left-hand corner. To remove a report, simply click the **–** button. The Data Numbering Code(s) can also be listed in French by selecting the **French Lists – Listes françaises** button.

Indicate whether the attachment contains Confidential Business Information (CBI) by selecting the corresponding radio button. The Confidential Business Information radio button indicates if the entire document is CBI as defined in the PCPA 2002. If two documents are being submitted as the non-CBI (parent document) and CBI (CBI reference document) components of a document pair, all of the Document data must be identical except for the CBI Yes / No value. That is, the Parent Document should be marked CBI **No** and the CBI Reference Document should be marked CBI **Yes**.

Is the attachment a cross reference to information that the PMRA already received? If **No** is selected complete the information, and then click the **Browse – Parcourir** button to attach the file. If **Yes** is selected the file attachment option will be removed and the Confidential Business Information radio buttons will be greyed out. The **Application Number** and **PMRA Document No**. fields are visible to provide information about the source of the cross referenced information.

3. Type of incident identified in the study - Type d'incident indiqué dans l'étude:

☐ New health or environmental hazard - Nouveau danger pour la santé ou pour l'environnement

☐ Increased health or environmental risk - Augmentation du risque sanitaire ou environnemental

☐ Presence of a component or derivitive - Présence d'un composant ou d'un dérivé

3. Select the reason that the scientific study is being submitted to the PMRA. The type of incident relates to the data that was available during the last registration of the product. For example, **Increased health or environmental risk** is relative to the health or environmental risks identified when the product was registered, or when the product was re-evaluated.

4. Describe the incident identified in the study (e.g. study demonstrates an increased risk to non-Hodgkin's lymphoma after exposure to pesticide X)
Décrire l'incident indiqué dans l'étude (p. ex. l'étude indique un risque accru de lymphome non hodgkinien des suites d'une exposition au produit)

4. Provide a detailed description of the incident (new or increased health or environmental risk or presence of a component or derivative) that was identified in the study.

5. a) Was the study discontinued before completion?
L'étude a-t-elle été abandonnée avant son d'achèvement?   ◉ Yes - Oui   ○ No - Non

5. b) Provide the reason for discontinuation - Préciser la raison de l'abandon

5. a) Indicate whether the study was discontinued before it was completed.

    b) If the study was discontinued before it was completed, explain clearly why.

6. If the study is ongoing, what is the expected completion date?
Si l'étude est en cours, quelle est la date d'achèvement prévue?   ☐ Unknown - Inconnu

6. If the study has not yet been completed, indicate when the study is expected to be finished.

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7. Provide supplemental information here - Donner des renseignements additionnels ici

7. This question provides the registrant an opportunity to submit their opinions and comments about the incident. This question is not mandatory and may be left blank. It will be posted to the Public Registry.

9 Subform VIII: Reports Completed

Once the General Information and all the selected subforms are completed, the following dialog box will be displayed. Enter the current date and your name. The option to add an electronic signature is available. However, a text signature is still required.

NOTE: When choosing the electronic signature, do not select security options on the signature that prevent the form from being opened, printed or modified.

9.1 Printing the Incident Report Form

The full IR form can only be printed once the **General Information**, the selected incident report subform(s) and the **Reports Completed** subform have been completely filled out. If you select the print button available at the top of each subform before the information is completed, it will only print what is currently displayed on the screen. The same is true when selecting to print from the file menu. The behaviour of Adobe Acrobat changes slightly with the versions therefore, when selecting to print you may have to ensure to select to print all the pages, as it may not automatically be selected.

To print the complete report:

1. Click the **Print - Imprimer** button located at the top of each subform. The **Print** dialog box is displayed.

2. Ensure **All** is selected under the **Print Range** option.

3. Click **OK**.

To print the current subform displayed on the screen:

1. Select the **File** menu, and then click **Print**.

2. Ensure **Current view** is selected under the **Print Range** option.

3. Click **OK**.

9.2 Saving the Incident Report

1. From the **File** menu, click **Save As**. Browse to the location you wish to save the file, and then click the **Save** button.

NOTE: Do not use special characters or spaces when naming your file. Only use letters and numbers.

9.3 How to Send the Incident Report Form

The Incident Report form being submitted to the PMRA must be in a PRZ zip file format. The e-Index Builder can be downloaded from the PMRA website and is used to create the PRZ files. Please refer to the e-Index Builder User Guide for instructions on creating an electronic index. The data numbering code for incident reports is **0.1.7003**.

You have the option to send the Incident Report form to the PMRA by mail or email. Email is not considered a secure method.

9.3.1 Mail

Please ensure the CD or DVD is labelled and clearly indicates that it is an incident report.

The PMRA mailing address is:

Pest Management Regulatory Agency
Incident Report
2720 Riverside Drive
Ottawa, Ontario
A.L. 6606D2
K1A 0K9

9.3.2 Email

Email incident reports to PMRA-ARLA_DOCS@hc-sc.gc.ca

Instructions for submitting incident reports by email:

1. **Subject Line**: The e-mail subject line **must** use the key word <u>incident</u>. Please note that the system uses the key word as criteria for accepting e-mails. If the key word is not included in the subject line, the system will automatically **return** the e-mail to the sender.

2. **Only incident reports**: The e-mail should reference only incident reports i.e., no bundling of incidents with submissions or other document types into a single e-mail.

3. **Version Control**: Do not forward a hard copy or CD/DVD version of the document. An automatic acknowledgement will be forwarded to the applicant upon receipt.

4. **Other Documents**: Please note that only the specified document types will be accepted. Any accompanying documents (i.e., cover letters, rationales, etc.) will be returned to the sender. This information should be forwarded directly to the individual that requested the information.

5. **Virus Check**: The applicant must scan the files for viruses and provide the PMRA with details of the software used (name, version, date of virus signature update file and company) in the body of the e-mail.

6. **Attachments**: The maximum size of an attachment that can be emailed to the PMRA is 5 megabytes.

Appendix A   Systems and Symptoms

System	Symptom	
Gastrointestinal System	Abdominal distension	Abnormal feces colour
	Abnormal tongue colour	Anorexia
	Bloating	Bloody diarrhea
	Bloody stool	Bloody vomit
	Burning mouth	Burning throat
	Constipation	Diarrhea
	Difficulty swallowing	Drooling Excessively
	Dry mouth	Dry throat
	Gagging	Inappropriate defecation
	Irritated throat	Loss of appetite
	Melena	Nausea
	Oral hemorrhage	Rectal hemorrhage
	Regurgitation	Retching
	Salivating excessively	Sore throat
	Stomach cramps	Stomach pain
	Stomach ache	Tongue swelling
	Vomit	Weight loss
Respiratory System	Abnormal lung sounds	Asthma
	Bronchitis	Bronchospasm
	Burning lungs	Burning nose
	Burning sinuses	Burning throat
	Chest congestion	Choking
	Coughing	Cyanosis
	Difficulty Breathing	Dyspnea
	Epistaxis	Heavy breathing
	Irritated nose	Irritated throat
	Itchy throat	Laboured breathing
	Mouth breathing	Nasal congestion
	Nose bleed	Panting
	Pulmonary edema	Rapid breathing
	Respiratory congestion	Respiratory distress
	Respiratory failure	Respiratory irritation
	Respiratory pain	Runny nose
	Scratchy throat	Shortness of breath
	Sneezing	Sore throat
	Stuffy nose	Tachypnea
	Wheezing	

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System	Symptom	
Nervous and Muscular Systems	Abasia	Abnormal gait
	Abnormal posture	Aching
	Aggressive behaviour	Agitation
	Anxiety	Ataxia
	Bizarre behaviour	Collapse
	Coma	Confusion
	Convulsions	Depression
	Difficulty concentrating	Difficulty getting up
	Difficulty talking	Difficulty walking
	Disorientation	Dizziness
	Extensor rigidity	Fainting
	Fasciculations	Head shaking
	Headache	Holding tail to side
	Lameness	Loss of coordination
	Memory loss	Muscle cramps
	Muscle pain	Muscle spasm
	Muscle trembling	Muscle tremors
	Muscle twitching	Muscle weakness
	Numbness	Paralysis
	Paresis	Recumbent
	Rigidity	Seizure
	Shakiness	Shaking
	Skittish	Slight paralysis
	Slurred speech	Staggering
	Stiffness	Sweating profusely
	Tail twitching	Trembling
	Unconsciousness	
Cardiovascular System	Abnormally fast heart rate	Abnormally high blood pressure
	Abnormally low blood pressure	Abnormally slow heart rate
	Arrhythmia	Bradycardia
	Chest pain	Chest tightness
	Fainting	Heart murmur
	Hypertension	Hypotension
	Irregular heart rate	Palpitations
	Shock	Tachycardia
Renal System	Anuria	Blood in urine
	Dialysis required	Frequent urination
	Kidney pain	Lack of control of urination
	Low urine output	Painful urination
	Polyuria	Renal failure
	Urinary incontinence	
Skin	Bleeding	Blister
	Bruises	Burning skin
	Burns (2nd or 3rd degree)	Burns (superficial)
	Cracked skin	Cyanosis
	Dermatitis	Erythema
	Flushed	Hair loss
	Hives	Hyperesthesia

System	Symptom	
	Inflammation of the skin	Irritated skin
	Itchy skin	Jaundice
	Lesion	Pain
	Pale mucous membrane colour	Pallor
	Peeling skin	Photosensitivity
	Rash	Red skin
	Skin sensitivity	Tingling skin
Eye	Blindness (temporary)	Bloodshot eye
	Blurred vision	Burn on the eye
	Burning eye	Cloudy vision
	Conjunctival injection	Conjunctivitis
	Contraction of the pupil	Corneal abrasion
	Decreased pupillary light reflex	Decreased vision
	Difficulty focussing	Double vision
	Dry eye	Foreign body sensation in eye
	Glazed eye	Irritated eye
	Itchy eye	Miosis
	Nystagmus	Pain
	Permanent change in vision	Photophobia
	Pinpoint pupils	Protrusion of the third eyelid
	Pupil dilation	Red eye
	Squinting	Swollen eye
	Tearing	Unreactive pupil
	Watery eye	
Ear	Earache	Hearing loss
	Ringing in ear	Tinnitus
General	Adipsia	Bad taste in mouth
	Chemical taste in mouth	Chills
	Clingy	Death
	Dehydration	Diaphoresis
	Discomfort	Drowsiness
	Edema	Fatigue
	Fever	Grass ingestion
	Hair loss	Head bobbing
	Hemorrhage	Hesitancy to move
	Hiding	Hissing
	Hoarseness	Hyperactivity
	Hyperthermia	Hypothermia
	Insomnia	Irritable
	Joint pain	Laryngitis
	Lethargy	Licking
	Lightheadedness	Listless
	Loss of balance	Loss of voice
	Malaise	Metallic taste in the mouth
	Multiple chemical sensitivity	Neoplasia
	Pacing	Pain
	Pale mucous membrane colour	Pica
	Polydipsia	Restlessness
	Rubbing face	Sleepines

System	Symptom	
	Subdued	Sweating profusely
	Swelling	Tucking tail
	Vocalizing	Weakness
Liver	Bilirubinuria Enlargement of the liver Hepatomegaly Hyperbilirubinemia Hepatic failure	Elevated liver enzymes
Reproductive System	Birth defect Low sperm count Mental retardation at birth Premature birth Stillborn infant	Infertility Low weight at birth Miscarriage Spontaneous abortion
Blood	Anemia Hyperglycemia Hypoglycemia Leukocytosis Thrombocytopenia	Bleeding Hypoalbuminemia Hypokalemia Leukopenia

Appendix B   Alphabetical Symptom

Symptom	System
Abasia	Nervous and Muscular Systems
Abdominal distension	Gastrointestinal System
Abnormal feces colour	Gastrointestinal System
Abnormal gait	Nervous and Muscular Systems
Abnormal lung sounds	Respiratory System
Abnormal posture	Nervous and Muscular Systems
Abnormal tongue colour	Gastrointestinal System
Abnormally fast heart rate	Cardiovascular System
Abnormally high blood pressure	Cardiovascular System
Abnormally low blood pressure	Cardiovascular System
Abnormally slow heart rate	Cardiovascular System
Aching	Nervous and Muscular Systems
Adipsia	General
Aggressive behaviour	Nervous and Muscular Systems
Agitation	Nervous and Muscular Systems
Anemia	Blood
Anorexia	Gastrointestinal System
Anuria	Renal System
Anxiety	Nervous and Muscular Systems
Arrhythmia	Cardiovascular System
Asthma	Respiratory System
Ataxia	Nervous and Muscular Systems
Bad taste in mouth	General
Bilirubinuria	Liver
Birth defect	Reproductive System
Bizarre behaviour	Nervous and Muscular Systems
Bleeding	Skin
Bleeding	Blood
Blindness (temporary)	Eye
Blister	Skin
Bloating	Gastrointestinal System
Blood in urine	Renal System
Bloodshot eye	Eye
Bloody diarrhea	Gastrointestinal System
Bloody stool	Gastrointestinal System
Bloody vomit	Gastrointestinal System
Blurred vision	Eye
Bradycardia	Cardiovascular System
Bronchitis	Respiratory System

Symptom	System
Bronchospasm	Respiratory System
Bruises	Skin
Burn on the eye	Eye
Burning eye	Eye
Burning lungs	Respiratory System
Burning mouth	Gastrointestinal System
Burning nose	Respiratory System
Burning sinuses	Respiratory System
Burning skin	Skin
Burning throat	Gastrointestinal System
Burning throat	Respiratory System
Burns (2nd or 3rd degree)	Skin
Burns (superficial)	Skin
Chemical taste in mouth	General
Chest congestion	Respiratory System
Chest pain	Cardiovascular System
Chest tightness	Cardiovascular System
Chills	General
Choking	Respiratory System
Clingy	General
Cloudy vision	Eye
Collapse	Nervous and Muscular Systems
Coma	Nervous and Muscular Systems
Confusion	Nervous and Muscular Systems
Conjunctival injection	Eye
Conjunctivitis	Eye
Constipation	Gastrointestinal System
Contraction of the pupil	Eye
Convulsions	Nervous and Muscular Systems
Corneal abrasion	Eye
Coughing	Respiratory System
Cracked skin	Skin
Cyanosis	Respiratory System
Cyanosis	Skin
Death	General
Decreased pupillary light reflex	Eye
Decreased vision	Eye
Dehydration	General
Depression	Nervous and Muscular Systems
Dermatitis	Skin
Dialysis required	Renal System

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Symptom	System
Diaphoresis	General
Diarrhea	Gastrointestinal System
Difficulty Breathing	Respiratory System
Difficulty concentrating	Nervous and Muscular Systems
Difficulty focussing	Eye
Difficulty getting up	Nervous and Muscular Systems
Difficulty swallowing	Gastrointestinal System
Difficulty talking	Nervous and Muscular Systems
Difficulty walking	Nervous and Muscular Systems
Discomfort	General
Disorientation	Nervous and Muscular Systems
Dizziness	Nervous and Muscular Systems
Double vision	Eye
Drooling Excessively	Gastrointestinal System
Drowsiness	General
Dry eye	Eye
Dry mouth	Gastrointestinal System
Dry throat	Gastrointestinal System
Dyspnea	Respiratory System
Earache	Ear
Edema	General
Elevated liver enzymes (e.g. LDH, GOT, GPT, alkaline phosphatase, ALT, AST)	Liver
Enlargement of the liver	Liver
Epistaxis	Respiratory System
Erythema	Skin
Extensor rigidity	Nervous and Muscular Systems
Fainting	Nervous and Muscular Systems
Fainting	Cardiovascular System
Fasciculations	Nervous and Muscular Systems
Fatigue	General
Fever	General
Flushed	Skin
Foreign body sensation in eye	Eye
Frequent urination	Renal System
Gagging	Gastrointestinal System
Glazed eye	Eye
Grass ingestion	General
Hair loss	Skin
Hair loss	General
Head bobbing	General

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Symptom	System
Head shaking	Nervous and Muscular Systems
Headache	Nervous and Muscular Systems
Hearing loss	Ear
Heart murmur	Cardiovascular System
Heavy breathing	Respiratory System
Hemorrhage	General
Hepatic failure	Liver
Hepatomegaly	Liver
Hesitancy to move	General
Hiding	General
Hissing	General
Hives	Skin
Hoarseness	General
Holding tail to side	Nervous and Muscular Systems
Hyperactivity	General
Hyperbilirubinemia	Liver
Hyperesthesia	Skin
Hyperglycemia	Blood
Hypertension	Cardiovascular System
Hyperthermia	General
Hypoalbuminemia	Blood
Hypoglycemia	Blood
Hypokalemia	Blood
Hypotension	Cardiovascular System
Hypothermia	General
Inappropriate defecation	Gastrointestinal System
Infertility	Reproductive System
Inflammation of the skin	Skin
Insomnia	General
Irregular heart rate	Cardiovascular System
Irritable	General
Irritated eye	Eye
Irritated nose	Respiratory System
Irritated skin	Skin
Irritated throat	Gastrointestinal System
Irritated throat	Respiratory System
Itchy eye	Eye
Itchy skin	Skin
Itchy throat	Respiratory System
Jaundice	Skin
Joint pain	General

Symptom	System
Kidney pain	Renal System
Laboured breathing	Respiratory System
Lack of control of urination	Renal System
Lameness	Nervous and Muscular Systems
Laryngitis	General
Lesion	Skin
Lethargy	General
Leukocytosis	Blood
Leukopenia	Blood
Licking	General
Lightheadedness	General
Listless	General
Loss of appetite	Gastrointestinal System
Loss of balance	General
Loss of coordination	Nervous and Muscular Systems
Loss of voice	General
Low sperm count	Reproductive System
Low urine output	Renal System
Low weight at birth	Reproductive System
Malaise	General
Melena	Gastrointestinal System
Memory loss	Nervous and Muscular Systems
Mental retardation at birth	Reproductive System
Metallic taste in the mouth	General
Miosis	Eye
Miscarriage	Reproductive System
Mouth breathing	Respiratory System
Multiple chemical sensitivity	General
Muscle cramps	Nervous and Muscular Systems
Muscle pain	Nervous and Muscular Systems
Muscle spasm	Nervous and Muscular Systems
Muscle trembling	Nervous and Muscular Systems
Muscle tremors	Nervous and Muscular Systems
Muscle twitching	Nervous and Muscular Systems
Muscle weakness	Nervous and Muscular Systems
Nasal congestion	Respiratory System
Nausea	Gastrointestinal System
Neoplasia	General
Nose bleed	Respiratory System
Numbness	Nervous and Muscular Systems
Nystagmus	Eye

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Symptom	System
Oral hemorrhage	Gastrointestinal System
Pacing	General
Pain	Skin
Pain	Eye
Pain	General
Painful urination	Renal System
Pale mucous membrane colour	Skin
Pale mucous membrane colour	General
Pallor	Skin
Palpitations	Cardiovascular System
Panting	Respiratory System
Paralysis	Nervous and Muscular Systems
Paresis	Nervous and Muscular Systems
Peeling skin	Skin
Permanent change in vision	Eye
Photophobia	Eye
Photosensitivity	Skin
Pica	General
Pinpoint pupils	Eye
Polydipsia	General
Polyuria	Renal System
Premature birth	Reproductive System
Protrusion of the third eyelid	Eye
Pulmonary edema	Respiratory System
Pupil dilation	Eye
Rapid breathing	Respiratory System
Rash	Skin
Rectal hemorrhage	Gastrointestinal System
Recumbent	Nervous and Muscular Systems
Red eye	Eye
Red skin	Skin
Regurgitation	Gastrointestinal System
Renal failure	Renal System
Respiratory congestion	Respiratory System
Respiratory distress	Respiratory System
Respiratory failure	Respiratory System
Respiratory irritation	Respiratory System
Respiratory pain	Respiratory System
Restlessness	General
Retching	Gastrointestinal System
Rigidity	Nervous and Muscular Systems

Symptom	System
Ringing in ear	Ear
Rubbing face	General
Runny nose	Respiratory System
Salivating excessively	Gastrointestinal System
Scratchy throat	Respiratory System
Seizure	Nervous and Muscular Systems
Shakiness	Nervous and Muscular Systems
Shaking	Nervous and Muscular Systems
Shock	Cardiovascular System
Shortness of breath	Respiratory System
Skin sensitivity	Skin
Skittish	Nervous and Muscular Systems
Sleepiness	General
Slight paralysis	Nervous and Muscular Systems
Slurred speech	Nervous and Muscular Systems
Sneezing	Respiratory System
Sore throat	Gastrointestinal System
Sore throat	Respiratory System
Spontaneous abortion	Reproductive System
Squinting	Eye
Staggering	Nervous and Muscular Systems
Stiffness	Nervous and Muscular Systems
Stillborn infant	Reproductive System
Stomach cramps	Gastrointestinal System
Stomach pain	Gastrointestinal System
Stomachache	Gastrointestinal System
Stuffy nose	Respiratory System
Subdued	General
Sweating profusely	Nervous and Muscular Systems
Sweating profusely	General
Swelling	General
Swollen eye	Eye
Tachycardia	Cardiovascular System
Tachypnea	Respiratory System
Tail twitching	Nervous and Muscular Systems
Tearing	Eye
Thrombocytopenia	Blood
Tingling skin	Skin
Tinnitus	Ear
Tongue swelling	Gastrointestinal System
Trembling	Nervous and Muscular Systems

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Symptom	System
Tucking tail	General
Unconsciousness	Nervous and Muscular Systems
Unreactive pupil	Eye
Urinary incontinence	Renal System
Vocalizing	General
Vomiting	Gastrointestinal System
Watery eye	Eye
Weakness	General
Weight loss	Gastrointestinal System
Wheezing	Respiratory System