The Global Language of Business

Incident Reporting User Guide

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About This Guide

This guide describes actions around reporting a product incident.

Read this guide to learn about the details of how the incident reporting process is set up and how the incident reporting process works with GS1 Canada Product Recall from various perspectives.

About Incident Reporting

Incident Reporting is a service that helps report a product health or safety incident to Health Canada and to other parties, so that appropriate actions around the incident can be taken.

Under Health Canada’s Canada Consumer Product Safety Act, the industry is responsible for making sure its products are safe.

Section 14 of this Act states that you - as part of the industry - must report to Health Canada after you become aware of a health or safety incident involving your consumer product.

GS1 Canada Incident Reporting allows you to log an incident report (including both 14 (2) and 14(3) reports). A copy of these reports are automatically sent to Health Canada, and you receive a Health Canada Case and Submission number. With Incident Reporting, you can easily manage incident reports that you have created and those that you have received from other sources. By tracking the status of these incidents with Incident Reporting, you can ensure that the right steps have been taken to alleviate concerns about the product you and your trading partners provide to consumers.

Incident Reporting User Roles

All incident reporting user roles are assigned by your Company Administrator or Service Administrator. For instructions on establishing user roles for Incident Reporting, in the myGS1 home page, under "Tell me more", see the *myGS1 Administrator Guide*.

There are three user roles that are important to Incident Reporting:

- Initiator – Creates the incident report and sends it to the Incident Reporting Approver.
- Approver – Reviews a completed incident report and either rejects or approves the report. If the incident reporter is not the product supplier, an approved incident report is sent to the supplier. If the incident reporter is the product supplier, the incident report might be converted to a product recall notification.

- Receiver – The supplier reviews an approved incident report and confirms or rejects the details. If confirmed, the details of the incident report might be converted to a product recall notification.

In a smaller company, it is possible for a single user to have the Incident Reporting Initiator and Incident Reporting Approver roles assigned to a single individual.

Logging into Incident Reporting

If you have never logged into myGS1 before, or if you have received an Account Updated email, to log in to Incident Reporting for the first time, you must have received a Welcome email from GS1 Canada. This email gives you the instructions to log in for the first time.

To open subsequent sessions of Incident Reporting, you will use an email address and password.

Steps:

1. To open the login page, go to https://www.gs1ca.org/login.asp?.
2. Enter your email address and password.

   If you have forgotten your password, click Forgot Your Password and follow the instructions.

3. Click Login.

After you log into myGS1, your landing page appears.

If you have access to multiple companies or company divisions, you must select a company from the drop-down list.

After you have selected a company or company division, or if you have access to only one company, the myGS1 Home page appears.

The My Tools panel displays a link to each GS1 Canada tool to which your company is registered.

4. Select the Incident Reporting link.

   The Select Mock Incident Reporting or Live Incident Reporting page appears.

5. Select Live Incident Reporting.

   The Incident Reporting main page appears.

The main page is a console from which you can perform multiple tasks.

Incident Reporting Main Page

After you complete the login process, the Incident Reporting main page appears. In the bar across the top at the right, there is a number of command links:

- Access Mock Incident Reporting – Open the Mock Incident Reporting environment. You can practice issuing an incident report in this environment. For information about Mock Incident Reporting, see the Mock Incident Reporting User Guide.
- myGS1 – Exit Incident Reporting and return to myGS1.

Under the command bar is the Incident Reporting banner. On the right side of the banner, your name, your company name and your user role or roles appear.

Under the Incident Reporting banner is the tab bar. The Incident Reporting main page shows the following tabs:

- Received Incidents - showing a list table of received incident reports. For help with received incidents, see "Manufacturer Receives an Incident Report from Another Party" (page 13).
- Manage Incidents - showing a list table of incident reports initiated by your company. For help with managing incidents, see "Manufacturer Learns About a Health and Safety Event" (page 11).
- Search Received. For help with the Search function, see "Search Received and Search Created" (page 14).
- Search Created. For help with the Search function, see "Search Received and Search Created" (page 14).

If you have a large list of items on a table, to help find a specific item, you can change how these table lists appear. For more information, see "Finding Items in a Table" (page 14).

Overview of Creating an Incident Report

In spite of our best efforts to prevent it, a health and safety incident from a manufacturer's product can happen to anyone.

When an incident happens, the supply chain industry is responsible by law to capture information about the incident and report it to Health Canada and to the manufuacturer. The manufacturer has a number of options for what to do around taking the next steps.

The next two chapters describe these processes as follows:

- Capturing Information for an Incident Report
- Manufacturer Options for Incident Reporting

Capturing Information for an Incident Report

Read this chapter to learn about providing details of a health and safety incident. You want to initiate an Incident Report.

To do this, you can be a retailer, a distributor, an importer or a manufacturer. You might have received product from a supplier or you might be the manufacturer of that product. As well, you are a subscriber to GS1 Canada Incident Reporting.

You might have learned about a health and safety event outside of Incident Reporting, for example:

- Directly from a consumer or from someone representing a consumer
- From another party in the supply chain
- From an industry expert or a scientific report
- From a standards report or a government report

By capturing information about this incident, you will be notifying Health Canada and allowing investigation and notification actions to begin.

Creating the Incident Report

From the point of view of Health Canada, this process helps you complete a 14(2) report.

To open the Create Incident page, from the Manage Incidents tab, click Create New Incident Report.

For Incident Report Initiators, creating and submitting an incident report is presented in a wizard format that verifies your data input so that you don't leave out any important information.

The names of each wizard stage appear in the left column. As you work through the process, click Next to save and continue. A check mark appears next to each stage name indicating that a stage is complete.

The following is an overview of the wizard stages.

Stage 1: Create Report
To open this page, select Manage Incidents and click Create New Incident Report.

Specify the details that will identify this incident report and make it distinct from any other incident report.

The form on this page appears first. No other stages are visible until this form has been completed and saved.

In **Purpose of Report**, select "14(2) - Information regarding incident".

If you are the manufacturer and you have determined that this is not an incident, see "Notification - Evaluated as Not an Incident" (page 11).

Special note: If you are a manufacturer and you are creating this incident, the fields for **Who are you?** and **Product Received from** should both show "Manufacturer".

At the bottom of the form, click Next.

Stage 2: Edit Report Details
Describe the incident, identify the product and the manufacturer, and specify distribution details.

The page shows the Report Details page with a navigation column on the left. The top of the navigation column shows "Edit".

While you are completing the Edit details, you can click any of the links in the navigation column to review what you have done and revise, if necessary. You can complete the four sub stages in any order. This description follows the order in the navigation column.

This step has four sub stages:

- Incident - Provide details of the incident and persons affected by the incident.
- Product - Specify the product identifier (GTIN or other identifier type), product name and description details.
- Manufacturer - Here you identify the manufacturer. If you are a manufacturer and you are reporting on a product that you supply to others, this sub stage does not appear.
- Supplier and Distribution - If the supplier is a GS1 Canada subscriber, the company name appears in the **Select Supplier** list. Select that name and all company details appear in the fields. If the supplier is not a GS1 Canada subscriber, in **Select Supplier** choose "Non-subscribed" and fill in the form with business name, address and so on.

Stage 3: Review Incident Report
Review a snapshot of all incident report details, including the status of the incident report and number of attachments.

Stage 4: Take Action
To send the report to an Incident Report Approver within your organization, in the Submit Incident Report for Approval panel, read and approve the Claim of Confidentiality and Privacy Notice and click Submit for Approval. A success message appears.

If your user profile includes the roles of both Incident Reporting Initiator and Incident Reporting Approver, you can approve the incident now. Skip ahead to "Rejecting or Approving an Incident Report" (below) and start at step 4.

If your role is Incident Reporting Initiator only, the report is placed in the Approver's queue with the status "Submitted for Approval". The Approver's process is described below.

For a description of actions on this page, see "Details of Actions" (page 15).

Continue with Rejecting or Approving an Incident Report.

Rejecting or Approving an Incident Report

This section describes how to review and either approve or reject an Incident Report.

To approve or reject an incident report, you must log in to Incident Reporting as an Incident Reporting Approver. You can reject or approve an incident report with status "Submitted for Approval".

The Manage Incidents page shows a list of incident reports, each one showing a summary description of report type, status and other details.

Steps:

1. Find an incident report with status "Submitted for Approval".
2. Click the plus sign next to the Incident Report Title.

   A series of buttons appears.

3. Click Approve or Reject.

   The Report Details page appears.

4. Review all report details for accuracy.
5. To reject the incident report, do the following:
   a. In the Action list, click Reject.

      The Reject Incident Report page appears.

   b. Describe the reason for rejecting this incident report.
   c. Click Reject.

      A success message appears.

   The incident report has been sent back to the Incident Reporting Initiator with the status "Draft".

6. To approve the incident report, do the following:
   a. In the Action list, click Approve.

      The Approve Incident Report page appears.

   b. Click Approve.

      A success message appears showing a case number and a submission number.

The incident report has been forwarded to the named supplier with the status "Pending Confirmation."

Other Actions that you can Perform

You can perform other actions on an incident report while it is in the status "Submitted for Approval":

- Download PDF – Download a PDF document version of report details for the selected incident report.
- Notes – Create or add to a note thread that can be used by other Recall users to help communicate issues around this notification.

Manufacturer Options for Incident Reporting

As a product manufacturer, you will learn about a health and safety incident surrounding your product from one of multiple sources:

- Manufacturer Learns About a Health and Safety Event
- Manufacturer Receives an Incident Report from Another Party

Manufacturer Learns About a Health and Safety Event

In this section, as a manufacturer, you learn about an event from new information, for example, where there is incorrect or insufficient information on the product label. You might also learn about an event from a party who is not a GS1 Canada subscriber. This party does not have access to the Incident Reporting service and they have described the details of the event to you.

You are the first party to create the notification and you have a number of options.

- You can resolve this issue within two days
- It will take more than two days to resolve this issue

You Can Resolve this Issue Within Two Days

Before you create an Incident Report, you can determine whether or not this is an incident by reviewing the four criteria set out in section 14 of the Canada Consumer Product Safety Act.

If you can quickly decide that this event is not an incident, you can still log the event details and notify the appropriate parties.

Notification - Evaluated as Not an Incident

Follow the instructions as described in "Creating the Incident Report" (page 8). In Stage 1, when you are creating the report, in **Purpose of Report**, select "Notification - Evaluated as Not an Incident".

After you approve the Incident Report, The Confirm Incident page appears. Here you must describe why this is not an incident.

After confirming, the incident is reported to Health Canada and you receive a Case Number and a Submission Number. Unless you are contacted by another party about this incident, no further action is required.

14(3) - Proposed Measure

If you can quickly determine what actions to take around an un-reported incident, you can create an Incident Report that outlines your actions. Note that this process is rarely used.

Follow the instructions as described in "Creating the Incident Report" (page 8). In Stage 1, when you are creating the report, in **Purpose of Report**, select "14(3) - Proposed Measure".

As a manufacturer who is reporting on a product that you supply to others, in **Select Supplier** choose "Myself" and your company details and contact information appear in the fields.

It Will Take More Than Two Days to Resolve This Issue

If you are the manufacturer and if you are the first to take action after you have learned about an incident, do the following:

1. Create the 14(2) Health Canada report, as described in "Creating the Incident Report" (page 8).

   As the manufacturer, note the following:

   In the Supplier and Distribution sub stage, in Select Supplier, choose "Non-Subscribed". A set of fields appears for you to identify yourself as the supplier. In Business Name enter your business name. In the Supplier Contact Information panel, enter the contact first name, last name and email address. After you click Next, the Review page shows all your company information, including address, city, country and so on.

2. Approve the report in your usual way.

   The report is sent to Health Canada. A message at the top of the page shows the Health Canada Case Number and Submission Number.

   In Manage Incidents, the report appears with the status "Pending Confirmation".

   Because you created the report, it remains in your Manage Incidents tab. You can treat this report as though it is a received incident.

3. After you have completed your evaluation, you can confirm this report as an incident and describe corrective measures to be taken.

Manufacturer Receives an Incident Report from Another Party

You have received an incident report from another party and you have completed your evaluation of the incident. Read this section to learn how to take action on this incident. For the product supplier, this process is the most common application of Incident Reporting.

To receive an incident, you must log in to Incident Reporting with Incident Reporting Receiver permissions.

The Incident Reporting Receiver receives incident reports from trading partners and reviews that information, including attachments, to recommend what corrective measures are to be taken. The Incident Reporting Receiver cannot create, approve, or send an Incident Recall.

Confirming or Rejecting an Incident Report

To open the Received Incident Reports page, from the Welcome page, click the Received Incidents tab.

The Received Incident Reports page shows a list of incidents submitted by various incident initiators. In the list, the Status value for incident reports that require your confirmation appear in red-coloured text. The Status value is "Pending Confirmation".

Steps:

1. In the Received Incident Reports page, click an Incident Report Title.

   The Report Details page appears.

2. View the details of the incident report.
3. The left column of this page shows actions that you can take:
   - To view this document in PDF format, click Download PDF.
   - To add or view a comment around this issue, click Notes. For help with notes, see "Details of Actions" (page 15).
4. To confirm or reject the incident, in the Action area click Confirm.

   The Confirm Incident page appears.

5. To reject this incident report and send it back to the Incident Reporting Initiator, do the following:
   a. In Confirm the Incident, select Not an Incident.

      The Not an Incident panel appears.

   b. Describe the reason for rejecting this incident report.
   c. Click Confirm.

   A success message appears.

   The incident report appears in the Received Incident Reports page with status "Not an Incident".

6. To confirm this report as an incident, do the following:
   a. In Confirm the Incident, select Incident.
   b. Complete details in the Corrective Measures Information panel.
   c. Click Confirm.

   A success message appears, showing an Incident Report ID, Case Number and Submission Number.

   The incident report appears in the Received Incident Reports page with status "Confirmed".

Next Steps for the Supplier

If you have confirmed an incident report, the following appear on the report:

- Case Number - generated by the system when the incident is initiated
- Incident Report ID - generated by the system when the incident is confirmed
- Submission number - generated by Health Canada

If you decide that your next step is to create a product recall notification based on this incident, log into Recall and follow steps to create a notification. For reference, the *Recall User Guide* is posted on the Recall Technical Documents page.

Search Received and Search Created

In the Incident Reporting main page, there are tabs for Search Received and Search Created.

Use these two versions of the search tool to quickly find Incident Reporting notifications that you have either received from a trading partner or created and sent to trading partners.

To open the search page, select either Search Received or Search Created.

Enter values into various boxes on the search form and click Search. Notifications that appear match the specified search criteria.

Finding Items in a Table

Read this topic to learn about how to change how a table appears to help you find a specific item or series of items.

If the list contains a large number of items, to help find a specific item you can change the way this list appears:

- In Manage Incidents, to view the most recent incident report at the top of the list, select the Show Latest Incident Report check box.

- To find an item using a pattern of characters, in Search type some characters and then click Search.

  Only those items that match the pattern appear in the list.

Details of Actions

This chapter describes details of various actions you can perform in Incident Reporting. Descriptions of actions are presented in alphabetical order.

Case Override

Use Case Override to revise the case number of an incident report. Use this only for an incident report with status "Pending Confirmation".

1. In Manage Incidents, click the plus sign (+) next to an incident report and click Case Override.

   The Case Number Override page appears.

2. In Case Number, revise the value.
3. Click Save Progress.

The case number is changed.

Copy

Use Copy to quickly create an incident report that has several common details. For example, you can report on similar incidents with multiple products.

To create a copy of an incident report:

1. In Manage Incidents, click the plus sign (+) next to an incident report and click Copy.

   The Report Details page appears with a success message about the copy process.

2. Step through the Edit process and make appropriate changes to the incident report.

The copy incident report appears in the list on the Manage Incidents page.

Close

Change the status of an incident report to "Closed".

Delete

In Manage Incidents you can delete a notification with status "Draft".

Caution: You cannot undo this action.

Steps:

1. Click Delete.

   A confirming message appears.

2. Click Delete.

The Manage Incidents page appears with the notification removed.

Edit

You can revise details of an incident report with status "Draft".

Notes

When you add a note, you are creating a note thread that can be used by other Incident Reporting users or by targeted contacts to help communicate issues around this incident report.

To quickly open the Notes page from either Received Incidents or Manage Incidents, click the plus sign (+) next to an incident report and click Notes. If there are existing note threads, they appear in a list.

To add a note, click Add New Topic.

Steps:

1. Fill in values in the appropriate fields.

   Optionally you can add an attachment.

2. Click Save.

   A success message appears at the top of the page.

3. The page title shows Note Thread and contains three panels.

   Incident Details – Identification of the incident report.

   Note Title – The note appears in a list. You can update or delete an individual note in a note thread.

   Reply – Answer a question or send another type of communication to the originator of the note. Also, you can add an attachment here. When you click Add Reply, the reply appears in the Note Title panel.

4. To return to the Notes page, click Back to Notes.

To view an existing note, click View next to the Note Title. For instructions, see step 3, above.

Submit for Approval

Use this if you are initiating an incident report.

Steps:

1. In the navigation column of a draft notification, click Submit for Approval.

   The Submit Incident Report for Approval page appears.

2. Read the Claim of Confidential Business Information and select the check box to indicate that you have read it.
3. Read the Health Canada authorization and select the check box to indicate that you provide this authorization and that you have the authority to do so.
4. If all stages of this process are complete, click Submit for Approval.

   A confirming message appears at the top of the page.

In Manage Incidents, the incident report status appears as "Submitted for Approval".

Update

As an Incident Reporting Initiator, you can update (or extend) a recall with the status "Confirmed". When you update, you create an extension to the existing incident report. The updated incident report tracks the link between the updated and original incident report.

To open an incident report for update, on Manage Incidents click the plus sign (+) next to an incident report and click Update. The Report Details page appears.

The incident report status changes to "Draft". If you go back to Manage Incidents before you complete the updated details, to complete the update you will open this notification with the Edit button.

Mandatory attributes show a red asterisk (*) next to the attribute label.

Steps:

1. In Reason for Update describe changes to the original incident report.
2. Follow steps for creating an incident report.

   For a description of the steps, see "Overview of Creating an Incident Report" (page 7).

3. After you finish updating the notification, submit it for approval.

View

View details of an incident report.

Withdraw

You can take back an incident report that has been submitted for approval.

1. In Manage Incidents, click the plus sign (+) next to an incident report and click Withdraw.

   The Withdraw Incident Report from Approval page appears.

2. Click Withdraw.

   A success message appears at the top of the page.

In Manage Incidents, the incident report appears with status "Draft".

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