CANNABIS VOLUNTARY RECALL GUIDE

Voluntary Recalls of Cannabis and Cannabis Products under the *Cannabis Act* and *Cannabis Regulations*

Government of Canada Gouvernement du Canada

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

Disclaimer: Guidance documents provide information about the requirements of the governing statutes and regulations and promote compliance with them. Alternate approaches to the principles and practices in this document may be acceptable if they meet the requirements of the Cannabis Regulations.

This document should be read in conjunction with relevant sections of the *Cannabis Act* and its Regulations. In cases of discrepancies between this document and the *Cannabis Act* and its Regulations, the latter shall prevail.

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1.0 Purpose

This guide provides information on the requirements of the *Cannabis Act* and *Cannabis Regulations* related to voluntary recalls of cannabis and cannabis products. It helps licence holders understand their role in a voluntary recall and promotes their compliance with recall requirements.

Federal licence holders	• Cultivation (nurseries, standard and micro) • Processing (standard and micro) • Sales for Medical Purposes • Research
Federal permit holders	• Import (medical or scientific purposes) • Export (medical or scientific purposes)

In addition, provincial and territorial distributors and retailers that are authorized under subsection 69(1) of the *Cannabis Act* are subject to some but not all recall requirements under the *Cannabis Regulations.*

The *Cannabis Regulations* do not apply to a holder of a licence under the *Industrial Hemp Regulations*.

Sections 46 and 235 (i.e., requiring a system of control for recalls) of the *Cannabis Regulations* do not apply to a holder of a licence for analytical testing or to a holder of a cannabis drug licence (exempted by section 3 of the *Cannabis Regulations*). For cannabis drug licences, recall requirements under the *Food and Drugs Act* and its Regulations apply.

This guide provides information on the requirements for licence holders to:

- Establish and maintain a system of control for the voluntary recall of cannabis or cannabis products, including conducting a recall simulation
- Keep sale, distribution and export records for cannabis or cannabis products
- Report voluntary recalls of cannabis or cannabis products to Health Canada
- Conduct a voluntary recall of cannabis or cannabis products

2.0 Scope

This guide applies to the recall requirements that are set out in the following sections of the *Cannabis Regulations*:

- Section 5.3: Prohibitions on selling voluntarily recalled cannabis products
- Sections 224, 225, and 226: Records on cannabis inventories
- Section 227: Records on cannabis sold, distributed or exported
- Sections 46 and 235: System of control for recalls and recall simulation
- Section 247: Recall reporting process

These requirements apply to licence holders engaged in cannabis activities that are subject to the *Cannabis Regulations*, with the exception of analytical testing and cannabis drug licence holders. Although the recall requirements do apply to licence holders for research, the nature and extent of the recall simulation will depend on the scope of the activities being conducted by the research licence holders (i.e., if they are authorized to sell or distribute).

Under section 5.3 of the *Cannabis Regulations,* provincial and territorial distributors and retailers that are authorized under subsection 69(1) of the *Cannabis Act* are prohibited from selling a cannabis product that they know is the subject of a voluntary recall related to the quality of the cannabis product or to non-compliance with Parts 5 or 6 of the *Cannabis Regulations.*

Health Canada uses a voluntary and collaborative approach to work with licence holders and other parties to ensure effective recalls.

However, this does not preclude Health Canada from taking other actions consistent with the Compliance and enforcement policy for the *Cannabis Act*. For example, in certain circumstances, a ministerial order requiring a recall or other measures could be used under section 75 or section 76 of the *Cannabis Act.*

3.0 Definitions

3.1 Definitions

The *Cannabis Act* and the *Cannabis Regulations* contain definitions of terms, some of which are included here for ease of use. The source is indicated in brackets. In addition to terms defined in the Act and Regulations, other terms are also included below for the purpose of interpreting this document.

Brand element Includes a brand name, trademark, trade name, distinguishing logo, graphic arrangement, design or slogan that is reasonably associated with a brand of

	cannabis. (*Cannabis Act)*
Cannabis	A cannabis plant and anything referred to in Schedule 1 to the Act. Does not include anything in Schedule 2 to the Act. (*Cannabis Act*)
Cannabis product	Cannabis of only one of the classes that are set out in Schedule 4 to the Act — or a cannabis accessory if that accessory contains such cannabis — after it has been packaged and labelled for sale to a consumer at the retail level, but does not include cannabis that is intended for an animal, a cannabis accessory that contains cannabis that is intended for an animal, or a drug containing cannabis. (*Cannabis Regulations)*
Client	In respect of a holder of a licence for sale for medical purposes, an individual who is registered with that holder of the licence under subsection 282(1). (*Cannabis Regulations*)
Consumer	An individual who has obtained a cannabis product to be used for non-commercial purposes. This definition includes a client.
Distribute	Include administering, giving, transferring, transporting, sending, delivering, providing or otherwise making available in any manner, whether directly or indirectly, and offering to distribute. (*Cannabis Act*)
Effectiveness check	A review of the recall process that includes a survey of those affected by a cannabis recall (e.g., supply chain customers) to verify they have received the recall notification and are aware of their responsibilities with respect to the recall. The effectiveness check may include verification of the actions taken.
Licence holder	The holder of a licence issued under the *Cannabis Act*, other than a holder of a licence that is subject to the *Industrial Hemp Regulations*.
Produce	In respect to cannabis, means to obtain it by any method or process, including by manufacturing; synthesis; altering its chemical or physical properties by any means; or cultivating, propagating or harvesting it or any living thing from which it may be extracted or otherwise obtained. (*Cannabis Act*)
Recalling licence holder	A licence holder who commenced and is responsible for conducting a recall.
Recall strategy	A planned course of action taken by a recalling licence holder to conduct a recall.
Risk type	The numerical designation assigned to a recall that corresponds to the relative degree of risk presented by the cannabis or cannabis product being recalled. There are three recall types (i.e., Type I, II or III) based on the degree of risk for health and safety.
Sell	Include offer for sale, expose for sale and have in possession for sale. (*Cannabis Act*)

Supply chain customer	Anyone who received, purchased or used cannabis or cannabis products that the recalling licence holder can identify and contact directly or indirectly, including federal licence holders, persons authorized to sell cannabis under a provincial or territorial Act, and clients.

3.2 Icons

This icon is used in this guide to highlight information of interest.

Important: Key or cautionary information.

4.0 What is a recall?

A recall, in respect of cannabis or a cannabis product that has been sold, distributed or exported, includes any action taken by a licence holder to correct or remove the cannabis or cannabis product from sale and distribution, and to notify all affected supply chain customers and the public of a problem or potential problem with the cannabis or cannabis product. Reasons for initiating a voluntary recall can include, but are not limited to, a licence holder becoming aware that the cannabis or cannabis product presents or may present a health or safety risk or that it may not meet the requirements of the Act and its Regulations.

During a recall, typical actions to be taken by a recalling licence holder with regard to the affected cannabis or cannabis product include:

- Informing Health Canada
- Ceasing the production, distribution and sale of the cannabis or cannabis product
- Removing the cannabis or cannabis product from the supply chain
- Correcting or destroying the cannabis or cannabis product, if applicable
- Contacting affected supply chain customers to notify them to stop further distribution and sale of the cannabis or cannabis product
- Contacting affected consumers to advise against use of the cannabis or cannabis product, if applicable
- Providing instructions to supply chain customers and consumers on what to do with the cannabis or cannabis products remaining in possession
- Assessing the effectiveness of the recall
- Taking corrective measures to prevent the problem underlying the recall from recurring

In addition, Health Canada posts a recall notice on its Recalls and Safety Alerts website.

A recall is intended to minimize the risk associated with a problem or potential problem with the cannabis or cannabis product by removing it from the supply chain and providing important health and safety information to the public.

5.0 Roles and responsibilities

While the requirements related to voluntary recalls apply to all licence holders in the supply chain, the most readily identifiable licence holder is encouraged to take responsibility for initiating a recall. Typically, the most readily identifiable licence holder—known as the recalling licence holder once the recall is initiated—is the licence holder who owns the product brand or whose information is listed on the label.

Under the *Cannabis Regulations,* licence holders have specific responsibilities related to recalls, including conducting recall simulations, reporting, and notification obligations. Nevertheless, a recall is a collaborative process among all parties in the supply chain.

The recalling licence holder should communicate the decision to commence a recall to all supply chain customers.

The effectiveness of the collaboration between the recalling licence holder and its supply chain customers depends, in part, on the extent to which each supply chain customer:

- Understands its own roles and responsibilities
- Defines and documents its expectations with other parties in the supply chain
- Communicates and shares recall information
- Maintains effective documentation with respect to distribution, inventory and sale

Health Canada documents and monitors recalls, provides guidance to licence holders and verifies compliance (e.g., request for information or inspection) with the recall requirements of the *Cannabis Regulations*. Health Canada is committed to making data and information available to Canadians, including posting recall notices on the Recall and Safety Alert website.

Under section 5.3 of the *Cannabis Regulations,* provincial and territorial distributors and retailers that are authorized under subsection 69(1) of the *Cannabis Act* are prohibited from selling a cannabis product that they know is the subject of a voluntary recall in Canada if the recall was initiated for one of the following reasons:

- There is concern about the quality of the cannabis product.
- Good production practice requirements (Part 5 of the *Cannabis Regulations)* have not been met.
- Cannabis product requirements (Part 6 of the *Cannabis Regulations)* have

not been met.

Provincially and territorially authorized distributors and retailers should be aware of recalls commenced by licence holders. Section 8.4.2 of this guide lists possible methods of communication for licence holders to communicate recall notices to supply chain customers.

6.0 Establishing and using documented procedures

Under section 46(1) of the *Cannabis Regulations,* licence holders, other than a licence holder for analytical testing or a cannabis drug licence holder, must establish and maintain a system of control that permits the rapid and complete recall of every lot or batch of cannabis that has been sold or distributed. This means that well-documented processes must be in place and that documents must be retained, as outlined under section 235 of the *Cannabis Regulations*.

Licence holders must establish documented processes with regard to maintaining sale and distribution records and carrying out recalls, including recall reporting (section 247). Each step of the recall process may be documented as a single procedure or as a number of procedures, depending on the structure of the quality system.

Licence holders must be able to demonstrate that they follow their established procedures during a recall. In addition, licence holders who use multiple procedures must be able to show that all parts of the distribution record and recall processes are reflected in the overall system of control.

The written recall procedures should:

- Define key activities
- Assign responsibilities
- Provide a detailed description of steps taken from the beginning to the end of the process
- Address the information required by the *Cannabis Regulations*, including keeping records (sections 226 and 227) and recall reporting (section 247)

When a recall is commenced or a recall notification is received, the licence holders involved should:

- Follow their written procedures
- Ensure that each employee responsible for any step in the procedure:
    - Has access to the procedure
    - Understands their responsibilities

- Is appropriately trained and qualified
- Receives support from management to ensure they follow the procedure

- Keep records as required, as outlined in section 7.0 of this guide

Activities described in recall procedures should have a time frame, where appropriate. Time frames should be based on the level of risk: the higher the risk, the faster the action needs to take place. In particular, timing needs to be specified for:

- Notifying Health Canada
- Notifying affected supply chain customers
- Following up with anyone who does not respond to the recall notification

To ensure an effective recall, everyone involved in the process, including supply chain customers, must understand their roles and responsibilities and how to complete their parts of the recall including the management of records.

A checklist of recall steps and a sample recall process flow chart can be found in Appendices A and B, respectively.

6.1 Recall Simulation

Licence holders, other than a licence holder for analytical testing or a cannabis drug licence holder, must conduct a recall simulation (or mock recall) at least every 12 months in order to ensure a recall plan is effective (subsection 46(2) of the *Cannabis Regulations*). Licence holders must conduct the simulation based on their established recall procedures.

Existing licence holders as of October 17, 2019, must complete a recall simulation within 12 months of October 17, 2019. Any licence holders who receive their licence after October 17, 2019, must complete a recall simulation within 12 months of the date the licence was received.

After the recall simulation has been completed, licence holders must document the details of how the recall was conducted and the results, and retain this document for at least two years after the day on which the recall simulation was completed. Licence holders are not required to notify Health Canada of the recall simulation or provide the recall simulation document at the time of the simulation. However, Health Canada may request it at any time or verify compliance during an inspection.

For example, a licence holder might decide to conduct a recall simulation within its own supply chain for a lot of cannabis or a cannabis product that the licence holder knows has reached the consumer market. The simulation could include identifying the problem as well as all of the supply chain customers who are affected, to ensure the licence holder's contacts are up to date.

To document the details of the recall simulation, including how it was conducted and the results, the licence holder could include:

- A description of the scenario
- The date and time of the simulation
- The effectiveness of the simulation, such as
    - Whether employees followed the recall procedure
    - Whether all affected supply chain customers were identified quickly
    - Whether the amount of recalled product could be reconciled with the amount produced, distributed and in inventory
    - Any problems encountered during the simulation and when and how they will be corrected (e.g., updates to training and procedures)

Section 8.5.2 of this guide provides information on evaluating a recall's effectiveness that could also be used to evaluate a recall simulation.

As was noted in Section 2.0 of this document, although the recall requirements do apply to licence holders for research, the nature and extent of the simulation will depend on the scope of the activities being conducted by the research licence holders (i.e., if they are authorized to sell or distribute).

7.0 Keeping sale, distribution and export records

The process that licence holders follow to create and keep sale, distribution and export records varies depending on sales as well as accounting and shipping procedures. Keeping records may involve a number of procedures and personnel. Records that identify the current location of affected cannabis and cannabis products during a recall should be readily available.

To conduct a timely and effective recall, licence holders must create and maintain records for all cannabis sold, distributed and in inventory. It is expected that information listed in the records will be sufficient to allow licence holders to trace and account for all of the affected cannabis and cannabis products being recalled. In addition, processing licence holders must keep records of ingredients that are obtained or produced to make a cannabis extract, cannabis topical, or edible cannabis. These records must be retained for two years.

Sections 224 to 227 of the *Cannabis Regulations* provide more information about the requirement related to inventory and distribution records.

Section 224: Inventory

Section 225: Inventory cannabis extract, cannabis topical or edible cannabis

Section 226: Cannabis obtained from another person

Section 226.1: Things to be used as ingredients

Section 227: Sale, distribution and export of cannabis

Licence holders should ensure that their records are stored in a way that protects the integrity of the records and allows them to be easily retrieved.

The time needed to access records should be identified as part of the recall process. To permit rapid and complete recalls, licence holders should be able to retrieve the relevant records within one business day.

If the record keeping system is changed, licence holders must ensure access to records generated prior to the change is maintained.

8.0 Recall process

The recall process has six steps, divided into two main parts: initiating a recall (sections 8.1 to 8.3 of this guide) and commencing a recall (sections 8.4 to 8.6 of this guide).

Initiating a recall

1. Identify the need to initiate a recall
2. Develop a recall strategy and determine scope of the recall
3. Inform Health Canada of the recall

Commencing a recall

4. Notify supply chain customers and begin the recall
5. Follow up with Health Canada and supply chain customers
6. Review and close the recall

Details on each step are outlined below, in order, but some may occur simultaneously.

The recalling licence holder is involved in all six steps. Other licence holders and supply chain customers participating in the recall are involved in steps 4, 5 and 6.

To manage or participate in a recall, licence holders are expected to follow their established recall procedures, as outlined in section 6 of this guide.

8.1 Identify the need to initiate a recall

A licence holder should consider initiating a recall if they become aware that cannabis or a cannabis product:

- Presents a risk to health or safety
- Does not or may not meet the requirements of the Act or Regulations

There are many ways a licence holder might become aware of a problem or potential problem with cannabis or a cannabis product. These include a complaint and subsequent investigation, inspections, internal quality control testing, pesticide testing, or internal audits. Product issues may be related to non-compliance and/or substandard quality, such as:

- Improper packaging and labelling
- Lack of adherence to good production practices
- Issues arising from improper storage, shipping or handling

Quality systems should include ways to identify product issues.

It is the responsibility of the licence holder to perform a risk evaluation (section 8.2.1 of this guide) and determine the actions required to correct the problem. Once the need to initiate a recall has been identified, the recalling licence holder should review its current inventory to identify and quarantine any affected cannabis and cannabis product still under its control. Quarantine measures can include physical and/or electronic methods to prevent affected cannabis or cannabis products from being sold or distributed.

8.2 Develop a recall strategy and determine scope of the recall

Once the licence holder has determined that a recall is necessary, the scope of the recall (i.e., determining which cannabis and cannabis products need to be recalled) should be defined and a strategy to commence the recall should be developed. The recalling licence holder should follow its established recall procedures to develop the recall strategy and quickly identify supply chain customers who may be affected.

The recall strategy should include:

- A risk evaluation
- The scope of the recall within the supply chain
- Timelines

- A communications plan
- The content of the recall notifications that will be sent to supply chain customers and, if applicable, to consumers
- The initiation date, the date(s) progress reports will be submitted to Health Canada and the anticipated closure date of the recall

8.2.1 Risk evaluation

The licence holder's recall procedures should provide clear instructions on how to evaluate the risk associated with the affected cannabis or cannabis product and how this information will be provided to Health Canada. The extent and type of recall action depends on the risk associated with the affected cannabis or cannabis product or the potential problems that underlie the recall.

When evaluating the risk, the recalling licence holder should take into account:

- The nature and degree of the problem or potential problem
- The nature of the population at risk
- The size of the population at risk
- The extent of supply chain customer awareness of the problem
- Whether adverse health consequences have occurred from using the affected cannabis or cannabis product

The recalling licence holder must provide Health Canada with a risk evaluation within 72 hours of notifying Health Canada that the recall has been initiated, as per section 247(3) of the *Cannabis Regulations*.

Health Canada assigns risk types to recalls based on the information provided in the notification received from the licence holder. The risk type is used to establish the timeline to commence the recall.

Table 1 describes the three risk type classifications for recalls and provides illustrative examples.

Table 1 Risk type classification for recalls		
Risk type	**Description**	**Example**
Type I	There is a reasonable probability that the use of or exposure to the affected cannabis or cannabis product will cause serious adverse health consequences or death	One lot of edible cannabis contaminated with *E. coli*.
Type II	The use of or exposure to the affected	Cannabis extract was bottled and

	cannabis or cannabis product may cause temporary adverse health consequences or the probability of serious adverse health consequences is remote	mistakenly labelled with a lower concentration of total THC than what was in the product • Product packaging: 5.2 µg/g THC • Actual product: 15 µg/g THC
Type III	The use of, or exposure to, the affected cannabis or cannabis product is not likely to cause any adverse health consequences	One run of a product label was printed without the mandatory health warning messages.

These examples are illustrations, as each recall scenario is unique. Health Canada assesses the risk based on the risk type descriptions above.

8.2.2 Scope of recall within the supply chain

The recall strategy should define the scope of the recall, which is the extent to which the affected cannabis or cannabis product has been distributed in the supply chain and the number of supply chain customers who are involved. The recalling licence holder should base the scope of the recall on the amount of affected cannabis or cannabis products, where and how it was or is being used, and the risk it poses to the public.

8.2.3 Timelines

The recall strategy must define timelines for key activities. Table 2 outlines suggested maximum timelines for making the first contact with supply chain customers, based on the risk type assigned by Health Canada.

Table 2 Contact timelines for recalls	
Recall type	**Timeline for action**
Type I	Initial contact should be made as soon as possible, and at most within **one business day** of commencing the recall
Type II	Initial contact should be made as soon as possible, and at most within **four business days** of commencing the recall
Type III	Initial contact should be made as soon as possible, and at most within **seven business days** of commencing the recall

The recalling licence holder must develop a detailed plan that shows estimated timelines for each action, based on:

- The complexity of recall actions
- The number of supply chain customers and geographic distribution
- The risk associated with the affected cannabis or cannabis product

8.2.4 Recall communications plan and content

The recall strategy must include a communications plan that defines the method and content for all communications associated with the recall. Recall notifications to supply chain customers should be brief and to the point and should not contain irrelevant information, promotional material or any element that may detract from the message and the risk.

To prevent further sale and distribution of the affected cannabis or cannabis product, it is important to instruct supply chain customers to immediately stop the sale and distribution of the affected cannabis and cannabis product and quarantine any stock. The recall notification should include detailed instructions to notify other supply chain customers who may be selling or distributing the affected cannabis or cannabis product.

In general, recall notifications to supply chain customers should include the following, in English and French:

- The date the recall notification is being sent
- The name of the affected cannabis or cannabis product that is subject to the recall
- A description of the affected cannabis or cannabis product being recalled, including catalogue number, lot number(s), serial number(s) or other descriptive information to enable the immediate and accurate identification of the cannabis
- The reason for recall and any risk associated with the use of the affected cannabis or cannabis product
- Instructions to immediately cease further sale, distribution or use of any of the remaining affected cannabis or cannabis product
- Instructions regarding disposal of the affected cannabis or cannabis product, with specific steps for destruction or return
- A request for a prompt response to confirm receipt of the notification as well as understanding of the actions required

The recalling licence holder is responsible for sending out recall notifications to its supply chain customers. To encourage a quick response, recall notifications might include:

- Pre-addressed post cards
- A toll-free number for telephone replies
- A form to complete and return by fax or email

- A link in an email that the recipient can click to acknowledge receipt of the recall notification

The recalling licence holder should clearly mark recall notifications with **Cannabis Recall** in a bold and easily identifiable manner.

If supply chain customers are carrying the recall forward, they may also develop their own communications to be included with those from the recalling licence holder. If they do, the recalling licence holder's original notification, with the risk information and directions, should not be changed.

8.3 Inform Health Canada of the recall

Section 247 of the *Cannabis Regulations* outlines the requirements to report a voluntary recall of cannabis or a cannabis product to Health Canada. The recalling licence holder must report the recall to Health Canada by e-mail at hc.compliance-cannabis-conformite.sc@canada.ca

Health Canada must be informed prior to commencing the recall (i.e., before notifying supply chain customers). The report to Health Canada must specify whether the affected cannabis or cannabis product was sold or distributed in Canada or exported from Canada.

Based on the information received, Health Canada will publish a recall notice on the Recalls and Safety Alerts website that identifies the issue, the risk type and any actions that consumers should take.

The recalling licence holder sends Health Canada three types of reports during a recall:

- **An initial report** must be sent containing information that must be provided prior to commencing a recall (subsections 247(1) and 247(2) of the *Cannabis Regulations*)
    - **A risk evaluation** must be sent within 72 hours of providing the initial report (subsection 247(3) of the *Cannabis Regulations)*
- **Progress reports** (subparagraphs 247(1)(j)(ii) and (2)(j)(ii) of the *Cannabis Regulations*)
- **A final report** must be sent (subsections 247(4) and (5) of the *Cannabis Regulations*)

In addition to other information about the affected cannabis and cannabis product, the anticipated completion date of the recall must be provided in the initial report to Health Canada. A rationale should be provided if completion is expected to take longer than two weeks.

Appendix C provides a checklist of the information that must be included in the reports.

8.4 Commence the recall and notify supply chain customers

Commencing the recall begins when the recalling licence holder notifies its affected supply chain customers of the recall. It involves the recalling licence holder and includes any supply chain customers who have further sold, distributed or exported the affected cannabis or cannabis product.

8.4.1 Identifying affected supply chain customers

The recalling holder's recall procedures should describe how to generate a list of affected supply chain customers and include a method to locate consumer contact information.

Sale, distribution and export records will help determine how many supply chain customers will need to be contacted.

8.4.2 Method of notification

The recall procedures should describe how the recall will be communicated to affected supply chain customers. Both primary and secondary methods of communication should be identified.

Every effort should be made to ensure the most appropriate person in the supply chain is contacted and a record of that contact should be kept.

Some of the ways that recall communications can be accomplished include:

- Telephone calls
- Email
- Fax
- Special delivery letters that have tracking and receipt confirmation (i.e., registered mail, courier)

If telephone calls are used, it is recommended that a written follow-up be done to ensure all details are shared and to establish a clear record of the communication.

Depending on the scope of the recall, additional distribution methods could be considered for recall notices, as outlined in table 3.

Table 3 Additional distribution methods for recall communications	
Method	**Examples**
Websites	• Publish on company website • Health Canada's Recall and Safety Alerts website
Social media platforms	• Twitter • Facebook • Blogger networks
Media/marketing outlets	• Media release (e.g., Canada Newswire) • Video news release • National news conference

	• Paid notices in newspapers, magazines, radio, television or online • Paid notices in product catalogues, newsletters and other marketing materials
Direct notice	• Mail outs to addresses or telephone calls to numbers identified through distribution records • Emails and text messages to consumers
Posters	• Retailers

8.4.3 Tracking responses to recall notifications

Recall procedures should describe how the recalling licence holder will record and track responses to recall notifications. Records showing that appropriate efforts have been made to contact all supply chain customers should be maintained. These records could include:

- Dates of attempted contact
- Name and title of person contacted
- Means of contact (e.g., phone, email, mail)
- A record of the discussion once contact was successful
- Whether recall instructions were understood and carried out
- Completed response forms
- Related correspondence

Documentation and confirmation of contact could include a fax-back form, email response or telephone log. The details of all contact made with a supply chain customer should be documented and appropriate follow-up with supply chain customers who do not respond should be completed.

8.4.4 Completing and tracking recall actions

The recalling licence holder must also complete and track other required actions related to the affected cannabis or cannabis product, such as receipt of returned affected product. Once acknowledgement that the initial notification of the recall is received, the recalling licence holder should complete other actions related to the recall, as applicable, including:

- Having the affected cannabis or cannabis product returned for destruction
- Having the supply chain customer destroy the affected cannabis or cannabis product

- Providing new labelling
- Correcting the affected cannabis or cannabis product

The recalling licence holder should track each action that is completed. Because some recalls involve multiple actions, the licence holder may choose to use spreadsheets or databases to track completion of recall actions.

8.4.5 Controlling the affected cannabis or cannabis product

Recall procedures must identify how the affected cannabis or cannabis product is to be handled until it is corrected or destroyed. Any returned cannabis or cannabis product must be controlled to prevent it from being sold, distributed, exported or used in error.

8.5 Follow up with Health Canada and supply chain customers

The recalling licence holder is required to complete a number of steps to follow up with Health Canada and supply chain customers. These can include:

- Submitting progress reports to Health Canada
- Evaluating the recall's effectiveness
- Checking that recall actions have been completed
- Product correction, if applicable
- Product disposal (destruction or return), if applicable

8.5.1 Submitting progress reports to Health Canada

The recalling licence holder should submit progress reports to Health Canada at the agreed-upon intervals in the initial report. They should contain the following:

- The number of supply chain customers notified of the recall and date and method of notification
- The quantity of affected cannabis and cannabis product in possession of each supply chain customer
- The number of respondent supply chain customers
- The number of non-respondent supply chain customers
- The number of subsequent attempts to contact non-respondent supply chain customers
- The quantity of affected cannabis and cannabis product returned and/or destroyed
- The estimated time frame for completion of the recall if revised from the original date

8.5.2 Evaluating the recall's effectiveness

The recall strategy should specify how the effectiveness of the recall will be evaluated. This is known as an effectiveness check. In most cases, effectiveness can be monitored from the initial notification through to the supply chain customers' responses.

Responses may involve written acknowledgement that the supply chain customers received, read and understood the recall. The recalling licence holder may also request supply chain customers to provide information about the status of the affected cannabis or cannabis product. The recalling licence holder should evaluate the effectiveness of each recall action.

Table 4 sets out some best practices to use when determining recall effectiveness.

Table 4 Recall effectiveness best practices

What to review	Action
Overall process	Confirm with certainty that the recall procedure and process have been implemented
Supply chain customer feedback	Verify the following: • All supply chain customers have been notified • The number of supply chain customers that have responded back • The number of units destroyed or returned by supply chain customers, if applicable If few supply chain customers respond to confirm receipt of the information, more effort may be required to reach them to confirm that action has been taken.
Consumer feedback, if applicable	Determine the following: • The number of consumers who have contacted the recalling licence holder • How consumers learned about the recall, to help analyze the effectiveness of various communication channels • The number of units returned, if applicable If few consumers have responded, more work may be required to understand the reason and additional effort may be necessary to ensure the recall has been properly communicated.

8.5.3 *Following up with non-respondent supply chain customers*

If supply chain customers do not respond to the first notification, the recalling licence holder must follow up with them. Non-responders are supply chain customers from whom the recalling licence holder does not receive confirmation of receipt of the recall.

Health Canada expects recalling licence holders to follow up with non-responders. Table 5 outlines guidelines for follow-up efforts.

Table 5 Follow-up efforts based on recall risk type

Recall risk type	Follow-up efforts
Type I	There should be no non-responders. If there are non-responders, justification should be provided and records should be maintained.
Type II	Three follow-up efforts have been made, using different contact methods as appropriate. Records should be maintained.
Type III	Two follow-up efforts have been made, using different contact methods as appropriate. Records should be maintained.

8.5.4 *Checking completion of recall actions*

The recalling licence holder should review tracking mechanisms for its corrective actions, which could include contacting supply chain customers or retrieving and/or destroying affected cannabis or cannabis products, to ensure all of the affected cannabis and cannabis products have been addressed. Recalling licence holders are responsible for ensuring that all recall actions are complete.

Health Canada recognizes that recall actions depend on the consent and cooperation of supply chain customers. If the supply chain customer does not permit or conduct the actions required by the recall despite repeated attempts to communicate their importance, the recalling licence holder should include this information in its recall records and notify Health Canada.

The recalling licence holder should review all information collected during this step to determine if additional action must be taken to address the problem or potential problem that underlies the recall. This may include revising or adding to its recall strategy.

8.5.5 *Product correction*

If the affected cannabis or cannabis product will be corrected, the corrections should be done as outlined in the recall strategy and standard operating procedures. The recalling licence holder should keep appropriate records that clearly show how the affected cannabis or cannabis product has been corrected, such as putting a corrected label on a product if the initial label was incorrect or contained missing information.

8.5.6 Product disposal

When affected cannabis or a cannabis product has been returned and will not be corrected, the recalling licence holder should dispose of it as outlined in its recall strategy and standard operating procedures. The recalling licence holder should keep appropriate records to show that disposal of the affected cannabis or cannabis product has been completed.

8.6 Review and close the recall

The steps required to review and close recalls are:

- Completing a final review of all recall actions
- Submitting a final report to Health Canada
- Closing the recall
- Completing and maintaining final documentation

8.6.1 Completing a final review

The recall procedure requires a final review to determine if the recall is ready to be closed. A recall may only be closed once it has been completed, meaning that all notifications and follow-up actions have been completed and the problem or potential problem has been addressed. A qualified person or group must do a final review to ensure the recall file contains the necessary documentation related to all recall actions that were taken.

The recalling licence holder must review the following information, as applicable, before determining that a recall is complete and ready to be closed:

- The number of units affected
- The number of units returned, if applicable
- The number of units destroyed, if applicable
- The number of units corrected, if applicable
- The number of units that could not be located, if applicable
- The final completion date for the recall
- Assurance that all supply chain customers received the recall information
- A detailed plan to prevent the problem from recurring, including any steps that will be taken to improve quality control, if applicable

The final review can provide valuable information about the recalling licence holder's recall strategy and procedures, and this may be used to refine the strategy for future recalls.

8.6.2 Submitting a final report to Health Canada

The recalling licence holder must submit a final report to Health Canada within 30 days after the recall has been completed, as per section 247(4) of the *Cannabis Regulations*.

8.6.3 Closing the recall

The recalling licence holder must document the completion of the recall. The person who determines that the recall is complete and can be closed should be familiar with all aspects of the recall process.

Once Health Canada receives the final recall report, Health Canada sends a response to the recalling licence holder to confirm that the recall is closed.

8.6.4 Completing and maintaining final documentation

The recalling licence holder must keep copies of the initial report, risk assessment, progress reports and final report for at least two years as per subsection 247(6) of the *Cannabis Regulations*. Health Canada may request this information at any time or during an inspection.

9.0 Contact us

Voluntary recalls for cannabis or cannabis products should be reported to Health Canada by contacting hc.compliance-cannabis-conformite.sc@canada.ca.

If you have specific questions about cannabis or cannabis product voluntary recalls, email Health Canada at cannabis@canada.ca.

If you have general questions about the *Cannabis Act* and its Regulations, email cannabis@canada.ca.

Alternatively, you can reach the Controlled Substances and Cannabis Branch at 1-866-377-7705.

10.0 Feedback—Help us improve

Health Canada is committed to providing all stakeholders with timely, accurate and reliable information. This includes providing applicants and licence holders with the information they need to comply with the *Cannabis Act* and its Regulations.

We would appreciate receiving your feedback on whether this guide was useful, and we welcome your suggestions for improvement. Email your feedback to us at cannabis@canada.ca and indicate in the subject line Feedback on the Cannabis Voluntary Recall Guide.

Appendix A: Checklist for recalls

This checklist summarizes the steps recalling licence holders should follow during a recall. It can be used in conjunction with the recall procedures outlined in section 8 of this guide.

Step 1: Identify the need for a recall

- ☐ The licence holder has identified an issue with the cannabis or cannabis product. The licence holder should assess the need for a recall by reviewing issues such as:
    - Does the cannabis or cannabis product pose a risk to health and safety?
    - Does it meet the requirements of the *Cannabis Act* and *Cannabis Regulations*?
    - Does it have quality deficiencies?
    - Is action required to mitigate the risk?
- ☐ If the product has been sold, distributed or exported and the recalling licence holder determines that it should be recalled, proceed to step 2.

Step 2: Develop a recall strategy and determine scope of the recall

- ☐ Define the recall scope from sale, distribution and export records
    - How many products are affected?
    - How many supply chain customers are affected?
    - What risk type has been assigned?
    - What action(s) are required?
- ☐ Develop a recall notification
    - Develop a notification that provides a description of the affected cannabis or cannabis product, the reason for recall, the risk associated with use, instructions on the actions to take with regard to remaining product, and a request for acknowledgement
    - Include a clear stop sale request, as applicable in the notification to supply chain customers

Step 3: Inform Health Canada of the recall

- ☐ Contact Health Canada by e-mail at hc.compliance-cannabis-conformite.sc@canada.ca and provide:
    - The name of the recalling licence holder, the licence number, and a description of the affected cannabis or cannabis product that is being recalled, including the brand name

- The number of each affected lot or batch of affected cannabis or cannabis products
- If known, the number of any lot or batch that was used to make the cannabis or cannabis product
- If applicable, information on who produced, imported, packaged or labelled the affected cannabis or cannabis product
- If the recall is related to a cannabis extract, cannabis topical or edible cannabis that is a cannabis product or that is contained in a cannabis accessory that is a cannabis product, the list of ingredients that appears on the label of the cannabis product
- If the recall is related to a cannabis accessory that is a cannabis product, the name and address of each person that produced or imported the affected cannabis accessory or any part of it
- The reasons for initiating a recall
- The quantity of affected cannabis or cannabis product that was produced or imported by the licence holder
- The quantity of affected cannabis or cannabis product that was sold or distributed by the licence holder
- The quantity affected cannabis or cannabis product that remains in possession of the recalling licence holder
- The number of supply chain customers to whom the affected cannabis or cannabis product was sold or distributed
- The period of time during which the affected cannabis or cannabis product was sold or distributed
- The recall strategy, including the intended date to commence the recall, how and when Health Canada will be notified of the progress of the recall and the proposed date for completion of the recall
- A description of any other action that is being taken or is intended to be taken with respect to the recall
- An evaluation of the risk associated with the problem or possible problem
- Contact information for a representative of the recalling licence holder
- The communications plan

Step 4: Notify supply chain customers and perform other recall actions

☐ Identify and communicate with supply chain customers

- ☐ Monitor responses and acknowledgements
- ☐ Perform other actions as required, such as quarantine or collection or destruction of the affected cannabis or cannabis product

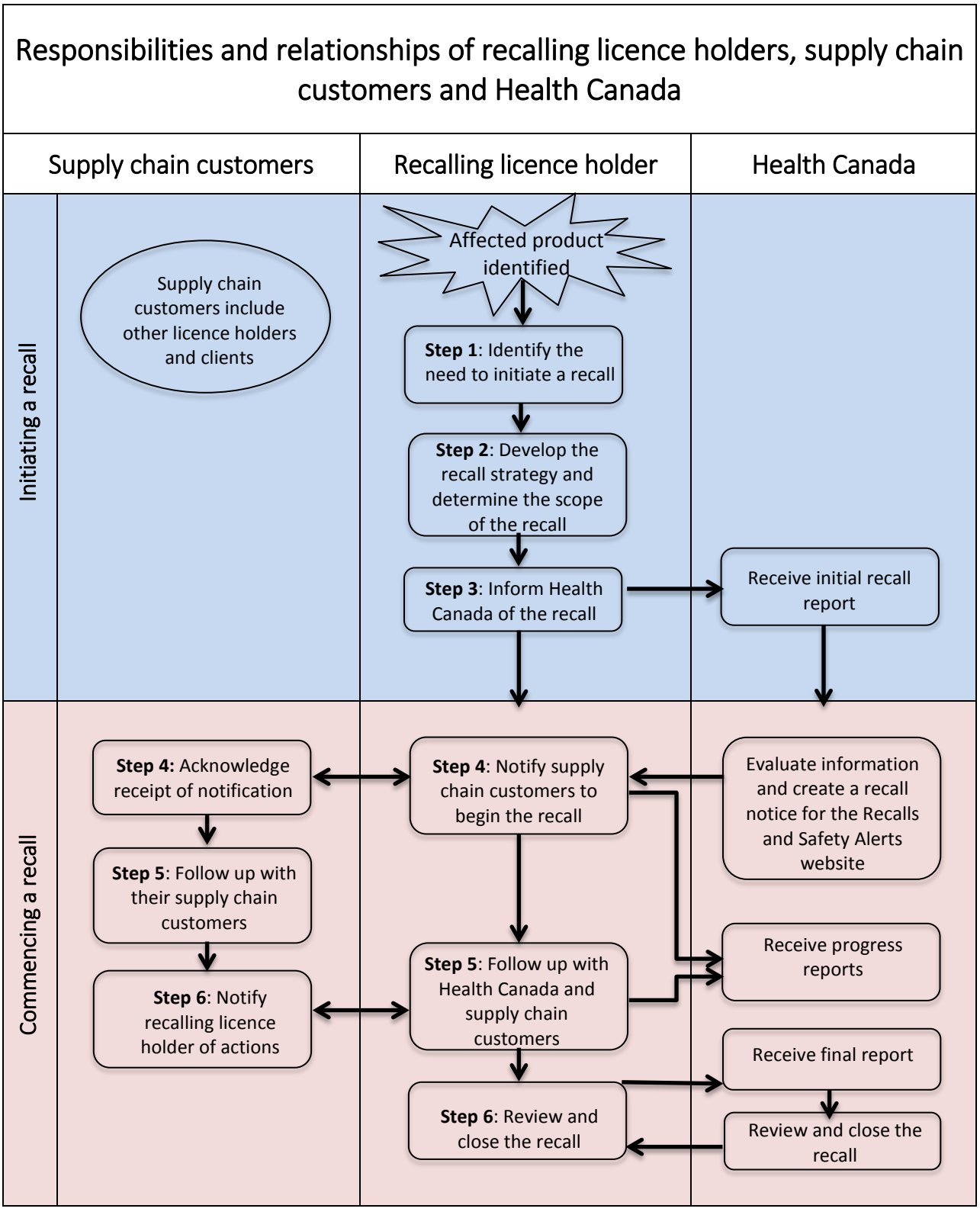
Step 5: Follow up with Health Canada and supply chain customers

- ☐ Perform an effectiveness check
- ☐ Follow up with non-respondent supply chain customers
- ☐ Ensure completion of required actions (e.g., return affected cannabis or cannabis product)
- ☐ Take additional action if required
- ☐ Submit progress reports to Health Canada as per agreed-upon timelines that include:
    - The number of respondent supply chain customers
    - The number of non-respondent supply chain customers
    - The quantity of affected cannabis or cannabis product returned or destroyed
    - The estimated time frame for completion if revised from original

Step 6: Review and close the recall

- ☐ Review recall records and documentation and ensure they are properly retained
- ☐ Dispose of affected cannabis or cannabis product as per procedures
- ☐ Submit final report to Health Canada within 30 days of recall completion or agreed-upon time frame with Health Canada that outlines the following
    - The results of the recall, including:
        - The number of units affected
        - The number of units returned, if applicable
        - The number of units destroyed, if applicable
        - The number of units that could not be located, if applicable
        - The date of completion for the recall
        - Assurance that all supply chain customers have received the recall information
    - The measures taken to prevent the problem from recurring and steps taken to resolve the problem

Appendix B: Voluntary recall process flow chart



Appendix C: Reports to Health Canada

Initial report to Health Canada

Subsections 247(1) and (2) of the *Cannabis Regulations* outline the following information that must be submitted in the initial report to Health Canada prior to commencing a recall.

- ☐ The full name and address of the recalling licence holder, as indicated on the licence
- ☐ A description of the affected cannabis or cannabis product, including:
    - Brand name
    - Identifier (catalogue number, product code, bar code, if applicable)
- ☐ The number of each lot or batch of the affected cannabis or cannabis product
- ☐ The full name and address of the licence holder(s) who imported, produced, packaged, or labelled the cannabis or cannabis product, if applicable
    - If the affected cannabis or cannabis product was obtained from another licence holder, the source should be identified.
- ☐ The reasons for commencing the recall
    - A description of the problem or potential problem with the affected cannabis or cannabis product. This should be as simple as possible, as this information will be used to create a recall notice for the Recalls and Safety Alerts website.
- ☐ The quantity of affected cannabis or cannabis product that the recalling licence holder produced or imported into Canada
- ☐ When the recall is for cannabis or cannabis product that has been sold or distributed in Canada, indicate:
    - The quantity produced or imported by the licence holder
    - The quantity sold or distributed in Canada by the licence holder
    - The quantity that remains in possession of the licence holder, if applicable
    - The number of supply chain customers to whom the licence holder sold or distributed the affected cannabis or cannabis product, and number of consumers, if applicable
    - The period during which the recalling licence holder sold or distributed the affected cannabis or cannabis product in Canada, including the first date of sale or distribution and the last date of sale
- ☐ When the recall is for cannabis or cannabis product that has been exported from Canada:
    - The quantity that was produced or imported into Canada by the recalling

licence holder, if applicable

- The quantity that was sold or distributed by the recalling licence holder in foreign countries
- The quantity that remains in the possession of the recalling licence holder, if applicable
- The number of persons to whom the recalling licence holder sold or distributed the cannabis or cannabis product in foreign countries
- The period during which the recalling licence holder sold or distributed the cannabis or cannabis product in foreign countries

☐ The recall strategy, indicating the timelines and manner that the recall will be carried out:

- The expected date of commencement of the recall
- The intended start date to contact supply chain customers
- The recall communications plan, including
  - Content of the recall notification
  - Primary and secondary methods of contacting supply chain customers
- How and when progress reports will be provided to Health Canada
- Proposed date for completion of the recall
- Copies of all intended communications about the recall in both official languages
  - Letters, notices, telephone script(s), emails to supply chain customers
  - Acknowledgement forms
  - Public notices or press releases

☐ Description of any other measures the recalling licence holder is taking or intends to take related to the recall, including a description of how the licence holder plans to prevent the problem or potential problem from recurring. This should include:

- A root cause analysis, if one has been completed
- If the recalling licence holder does not yet have a detailed plan, the report should indicate what the licence holder plans to do to understand and resolve the problem

☐ Contact information for a representative of the recalling licence holder

☐ An evaluation of the risk associated with the problem or possible problem, submitted within 72 hours of submitting the initial report

Progress reports to Health Canada

After providing the initial report to Health Canada, the recalling licence holder should provide progress reports at agreed-upon intervals, containing the following information:

- ☐ The number of supply chain customers notified of the recall
- ☐ The number of respondent supply chain customers
- ☐ The number of non-respondent supply chain customers
- ☐ The number of products returned
- ☐ The estimated time frame for completion, if revised

Final report to Health Canada

After completion of the recall, the recalling licence holder must provide a final report that contains the following information, as applicable:

- ☐ Results of the recall, including:
  - The quantity of affected cannabis or cannabis product recovered
  - The quantity of affected cannabis or cannabis product used and not recovered
  - The quantity of affected cannabis or cannabis product destroyed, if applicable
  - The number of non-respondent supply chain customers
- ☐ Measures taken to prevent a recurrence of the problem
- ☐ Completion date

The final report must be provided to Health Canada within 30 days after the completion of the recall, or within an agreed-upon extended timeline, as per subsections 247(4) and (5) of the *Cannabis Regulations*.