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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Contents

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 the following licence holders understand their role in a voluntary recall and promotes their compliance with recall requirements.

Federal licence holders

- Cultivator (nurseries, standard and micro)
- Processor (standard and micro)
- Sales
- Analytical Testing
- Research

Federal permit holders

- Import (medical, research, hemp)
- Export (medical, research, hemp)

While not subject to the recall requirements under the *Cannabis Regulations*, this guide provides information on the voluntary recall process to persons authorized to sell cannabis under a provincial or territorial Act.

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

Sections 46 and 235 of the *Cannabis Regulations* do not apply to the holder of a cannabis drug licence, as recall requirements under the *Food and Drugs Act* and its Regulations will apply.

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

- Establish and maintain a system of control for the recall of cannabis or cannabis products
- 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 voluntary recall requirements set out in the following sections of the *Cannabis Regulations*:

- Sections 224, 225, 226 and 227: Records on cannabis sold, distributed or exported

- Sections 46 and 235: System of control for recalls
- Section 247: Recall reporting process

Cannabis recall requirements apply to all federal licence and permit holders engaged in cannabis activities that are subject to 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. In certain circumstances, a ministerial order requiring a recall or the taking of other measures could be issued, if, for example, Health Canada believes such a recall would address an issue of public health or public safety and the recalling licence holder is not willing to voluntarily recall the cannabis or cannabis product (section 76 of the *Cannabis Act*).

3.0 Definitions

3.1 Definitions

The *Cannabis Act* (the 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.

Brand	Includes a brand name, trademark, tradename, distinguishing logo, graphic arrangement, design or slogan that is reasonably associated with a brand of cannabis.
Cannabis	A cannabis plant and anything referred to in Schedule 1 to the Act but 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 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 the cannabis product to be used for non-commercial purposes. This definition includes a client.
Distribute	Includes 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	A review that includes a survey of those affected by a recall (supply chain

check	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 action 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 a recall.
Recall strategy	A planned course of action taken by a recalling licence holder to conduct a recall.
Risk type	The numerical designation (i.e., Type I, II or III), 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 based on the degree of concern for health and safety.
Sell	Includes 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 a cannabis product, including other 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 to 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. The reasons for initiating a recall include 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 licence holder 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 clients to advise against use of the cannabis or cannabis product, if applicable
- Providing instructions to supply chain customers and clients 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 while 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, this would be the licence holder who owns the product brand and whose information is listed on the label.

Under the *Cannabis Regulations,* the recalling licence holder has specific responsibilities, including reporting obligations. Nevertheless, a recall is a collaborative process among all licence holders and other 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

Health Canada documents and monitors recalls, provides guidance to licence holders and verifies compliance 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.

6.0 Establishing and using documented procedures

Under section 46 of the *Cannabis Regulations,* licence holders, other than 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 these documents must be retained, as outlined under section 235 of the *Cannabis Regulations*.

Licence holders must have documented processes with regard to maintaining sale and distribution records and carrying out recalls, which includes recall reporting. Each step may be documented as a single procedure or as a number of procedures, depending on the structure of the quality system, and licence holders must be able to demonstrate that the procedures are being followed. 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.

Written 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

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 that all supply chain customers complete their parts of the recall procedure, roles and responsibilities should be discussed and specified with them. This will help ensure an effective recall.

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

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 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 and distributed. It is expected that information listed in the records will be sufficient to allow licence holders to trace and account for all of the cannabis and cannabis products being recalled. These records must be maintained for two years.

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

Section 224: Inventory of cannabis other than oil

Section 225: Inventory of cannabis oil

Section 226: Receipt of cannabis

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

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.

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 and determine the actions required to correct the problem. Once the need for a recall has been identified, the licence holder should review 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 product 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 for commencing the recall should be developed. The recalling licence holder should be able to quickly identify supply chain customers who may be affected.

Having documented recall procedures enables the recalling licence holder to develop a recall strategy that includes:

- 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 an affected product and how to provide this information to Health Canada. The extent and type of recall action depends on the risk associated with the problem or 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 product

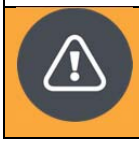
The recalling licence holder must provide a risk evaluation within 72 hours of notifying Health Canada that the recall has been initiated, as per section 247(3) of the *Cannabis Regulations*.

Health Canada assigns hazard types to recalls based on the information provided in the notification received from the licence holder. This hazard type establishes the timeline to commence the recall.

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

Table 1: Hazard type classification for recalls

Hazard type	Description	Example
Type I	There is a reasonable probability that the use of or exposure to the cannabis or cannabis product will cause serious adverse health consequences or death	One lot of cannabis oil for medical purposes was released for sale that was contaminated with *E. coli*.
Type II	The use of or exposure to the cannabis or cannabis product may cause temporary adverse health consequences or the probability of serious adverse health consequences is remote	Cannabis oil was bottled and mistakenly labelled with a lower concentration of THC than what was in the product • Product packaging: 5.2% THC • Actual product: 15% THC
Type III	The use of, or exposure to, the 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 for illustrative purposes only. Each recall scenario is unique and the risk should be assessed based on the definition of hazard types.

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 product, 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 initial contact with supply chain customers, based on the hazard type that will be assigned by Health Canada.

Table 2: Timelines to initiate contact 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 the 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.

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 cannabis and cannabis product and quarantine any stock. Instructions to notify supply chain customers who may be selling or distributing the affected product to other supply chain customers should be detailed in the notification.

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

- The date the recall communication is being sent
- The name of the cannabis product that is subject to the recall
- A description of the 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 cannabis or cannabis product
- Instructions to immediately cease further sale, distribution or use of any of the remaining cannabis or cannabis product
- Instructions regarding disposal of the cannabis or cannabis product, with specific steps for their destruction or return
- A request for a prompt response to confirm receipt and 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.

Supply chain customers may also develop their own communications to be included with those from the recalling licence holder if they are carrying the recall forward. If they do, the recalling licence holder's specific risk information or direction should not be changed.

8.3 Inform Health Canada of the recall

Section 247 of the *Cannabis Regulations* outlines the requirements for reporting a voluntary recall of cannabis or a cannabis product to Health Canada.

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

Recalls must be reported to Health Canada by contacting hc.compliance-cannabis-conformite.sc@canada.ca

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

Three types of reports must be sent to Health Canada during a recall:

- The initial report containing information that must be provided prior to commencing a recall (subsections 247(1) and 247(2) of the *Cannabis Regulations*)
    - Risk evaluation 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*)
- The final report (subsections 247(4) and (5) of the *Cannabis Regulations*)

The anticipated completion date of the recall must be provided in the initial report to Health Canada. A rationale should be provided if the completion is expected to take longer than two weeks.

Appendix C provides more information on these reports and a checklist of what needs to be included in them.

8.4 Notify supply chain customers and begin recall

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

8.4.1 Identifying affected supply chain customers

Recall procedures should describe how to generate a list of affected supply chain customers and include a method for locating customer 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

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, alternative distribution methods could be considered for recall notices, as outlined in table 3.

Table 3: Alternative distribution methods for recall communications

Method	Examples
Websites	• Publish on company website • Health Canada's Recall and Safety Alerts website
Social media platforms	• Twitter and/or 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 clients
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 product, such as receipt of returned affected product. Once acknowledgement that the initial notification of the recall was received, the licence holder should complete other actions related to the recall, as applicable:

- Having the cannabis or cannabis product returned for destruction
- Having the supply chain customer destroy the product
- Providing new labelling
- Correcting the 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 include:

- Submitting progress reports to Health Canada
- Evaluating the recall's effectiveness

- Checking completion of recall actions
- Product correction, if applicable
- Product disposal, if applicable

8.5.1 Submitting progress reports to Health Canada

The recalling licence holder should submit progress reports to Health Canada at agreed-upon intervals provided 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 respondents
- The number of non-respondents
- The quantity of cannabis and cannabis product returned and/or destroyed
- The estimated time frame for completion, if revised from the original

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 customer response.

Responses may involve written acknowledgement that the supply chain customers received, read and understood the recall. The recalling licence holder may also require supply chain customers to provide information about the status of affected products. The 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 has been implemented
Supply chain customer feedback	Verify the following: • All supply chain customers have been notified • The number 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.
Client and consumer feedback, if applicable	Determine the following: • The number of clients or consumers who have contacted the recalling licence holder • How clients or consumers learned about the recall, to help analyze the effectiveness of various communication channels • The number of units returned, if applicable If few clients or 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-responders

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

Health Canada expects licence holders' recall procedures to reflect follow-up with non-responders. Table 5 outlines guidelines for follow-up efforts.

Table 5: Follow-up efforts based on recall hazard type

Recall hazard 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 licence holder undertaking a recall should review tracking mechanisms for its corrective actions (whether contacting supply chain customers or retrieving and/or destroying affected cannabis or cannabis products) to ensure it has dealt with all affected cannabis and cannabis product. 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 cannabis or cannabis product will be corrected, the corrections should be done as outlined in the recall strategy and operating procedures. The recalling licence holder should keep appropriate records that clearly show how the affected cannabis or cannabis product have 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 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 operating procedures. The 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.

The 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 also provide valuable information about the recall strategy and procedures. The recalling licence holder may use its experiences during a recall 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 chosen to determine that the recall is complete and can be closed should be familiar with all aspects of the recall process.

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

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 section 247(6) of the *Cannabis Regulations*. Health Canada may request this information at any time.

9.0 Contact us

If you have specific questions about cannabis voluntary recalls, email Health Canada at hc.compliance-cannabis-conformite.sc@canada.ca.

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

Alternatively, you can reach the Cannabis Legalization and Regulation Branch by phone 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 hc.compliance-cannabis-conformite.sc@canada.ca and indicate in the subject line "**Feedback on the Cannabis Voluntary Recall Guide**."

Appendix A: Checklist of steps for recalls

This checklist summarizes the steps recalling licence holder should follow during a recall. It can be used in conjunction with the recall procedures and 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 affected products?
    - How many affected supply chain customers?
    - What hazard type has been assigned?
    - Determine required action(s)
- ☐ Develop a recall communications plan
    - Develop communications that provide a description of the recalled product, reason for recall, risk associated with use, instructions on what actions to take with remaining product, and a request for acknowledgement
    - Ensure a stop sale request is clearly present in the communication to supply chain customers

Step 3: Inform Health Canada of the recall

- ☐ Contact Health Canada and provide:
    - The name of licence holder and a description of the cannabis or cannabis product being recalled, including the brand name
    - The number of each affected lot or batch
    - If known, the number of any lot or batch that was used to make the 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 accessory that is a cannabis product, name and address of each person that produced or imported the cannabis accessory or any part of it
- The reasons for initiating a recall
- The quantity that was produced or imported by the licence holder
- The quantity that was sold or distributed by the licence holder
- The quantity that remains in possession of the licence holder
- The number of supply chain customers to whom it was sold or distributed
- The period of time during which the 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 recall progress 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
- ☐ Submit progress reports to Health Canada as per agreed-upon timelines

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

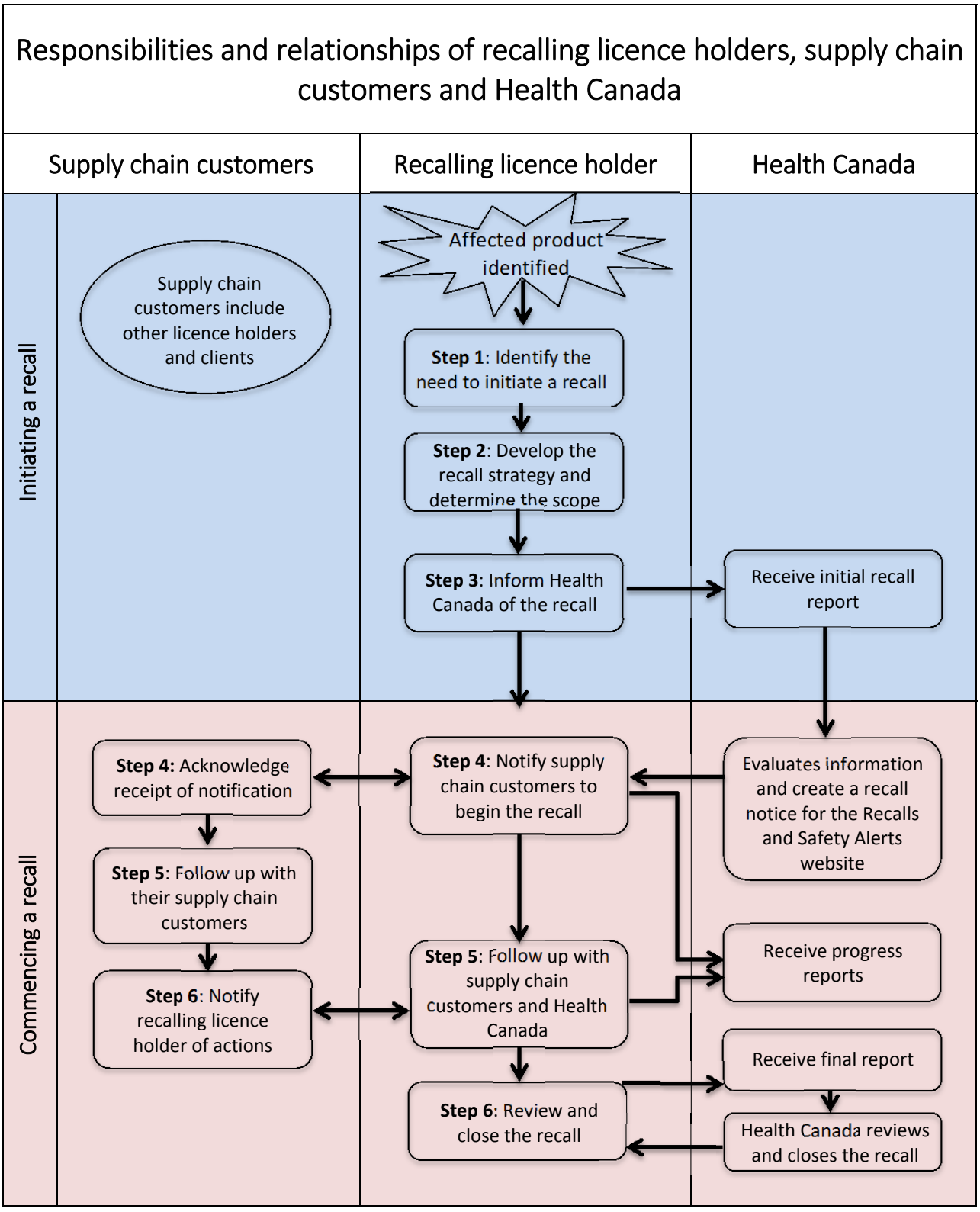
- ☐ Perform an effectiveness check
- ☐ Follow up with non-responders
- ☐ Ensure completion of required actions (e.g., return affected product)
- ☐ Take additional action if required
- ☐ Submit progress reports to Health Canada that include:
    - The number of responders

- The number of non-responders
- The quantity of 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 that they are properly retained
- ☐ Dispose of affected cannabis or cannabis products as per procedures
- ☐ Submit final report to Health Canada within 30 days of recall completion or agreed-upon timeframe 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: Cannabis 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 information that must be submitted in the initial report to Health Canada, prior to commencing a recall. The following information is provided as a guide for recalling licence holders;

- ☐ The full name and address of the recalling licence holder, as indicated on the licence
- ☐ A description of the 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 who imported, produced or packaged the cannabis or cannabis product, if applicable
    - If the affected 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 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 that the recalling licence holder produced or imported into Canada
- ☐ When the recall is for cannabis product that has been sold or distributed in Canada, indicate:
    - The quantity produced or imported by the licence holder
    - The quantity that the licence holder sold or distributed in Canada
    - The quantity of affected product 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 cannabis product, and number of clients, if applicable
    - The period during which the recalling licence holder sold or distributed the affected cannabis product in Canada, including the first date of sale or distribution and the last date of sale
- ☐ When the recall is for cannabis that has been exported from Canada:
    - The quantity that was produced or imported into Canada by the 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 licence holder, if applicable
- The number of persons to whom the licence holder sold or distributed the cannabis in foreign countries
- The period during which the licence holder sold or distributed the cannabis in foreign countries

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

- The intended start date to contact supply chain customers
- The recall communications plan, including
  - Content of the recall notification
  - Primary and secondary methods of contact 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 happening again. This should include:

- A root cause analysis, if one has been completed
- If the 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.

Progress reports should contain:

- ☐ The number of supply chain customers notified of the recall
- ☐ The number of respondents
- ☐ The number of non-respondents
- ☐ 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 product recovered
  - The quantity of product used and not recovered
  - The quantity of product destroyed, if applicable
  - The number of non-responders
- ☐ Measures taken to prevent a recurrence of the problem
- ☐ Completion date

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