Health Canada
Health Products and Food Branch

PRODUCT RECALL PROCEDURES

TABLE OF CONTENTS

Health Protection Branch
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* Health Products and Food Branch Inspectorate is currently reviewing this document. A Policy on Recall and a Guidance Document for Industry will be available in 2002.

Canada

PRODUCT RECALL PROCEDURES

1. Recall - Background and Objectives

Recall is an effective method of removing or correcting violative products that may represent a health hazard to the consumer or user. It is an action taken by a manufacturer, distributor, or importer to carry out their responsibility to protect the public health and well-being.

During recalls, the primary role of the Health Protection Branch is to closely monitor the effectiveness of the firm's recall actions and to provide scientific, technical and operational advice. If a recalling firm's performance is deemed to be inadequate, the Branch is prepared to take appropriate action to remove the product from sale or use. A firm's recall does not preclude enforcement actions being taken by the Branch, as deemed appropriate, either during or following the completion of the recall.

2. Definitions

(a) "Product" means any domestic or imported food, drug, cosmetic, device, radiation emitting device, and any advertisement thereof,as defined under the Food and Drugs Act and the Radiation Emitting Devices Act.

(b) 1. "Recall" with respect to a product, other than a medical device, means a firm's removal from further sale or use, or correction, of a marketed product that violates legislation administered by the Health Protection Branch.

2. "Recall" with respect to a medical device that has been marketed means any action taken in respect of the device by the manufacturer or importer thereof after becoming aware that the device

(i) is or may be hazardous to health,

(ii) fails or may fail to conform with any claims made by the manufacturer or importer relating to the effectiveness, benefits, performance characteristics or safety of the device, or

(iii) does not comply with the Food and Drugs Act or Medical Devices Regulations to recall or correct the device or to notify the owner or user of the device of the defectiveness thereof.

3. The definition of "Recall" does not include a "product withdrawal" or a "stock recovery".

(c) "Correction" means repair, modification, adjustment, relabelling, or inspection (including patient monitoring) of a product without its physical removal to some other location.

(d) "Recalling firm" means the firm that initiates a recall. It is usually the firm that has primary responsibility for the manufacture/import and marketing of the product to be recalled.

(e) "Consignee" means anyone who received, purchased, or used the product being recalled.

(f) "Product withdrawal" means a firm's removal from further sale or use, or correction of a marketed product that does not violate legislation administered by the Health Protection Branch. It is not considered to be a recall.

(g) "Stock recovery" means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm. It is not considered to be a recall.

(h) "Recall strategy" means a planned specific course of action to be taken in conducting a specific recall, which addresses itself to matters such as the depth of recall, need for public warnings, and extent or effectiveness checks for the recall.

(i) "Recall classification" means the numerical designation, i.e. Class I, Class II or Class III, assigned by the Health Protection Branch to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

(1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

(2) Class II is a situation in which the use of, or exposure to, a violative product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.

(3) Class III is a situation in which the use of, or exposure to, a violative product is not likely to cause any adverse health consequences.

3. Recall Notification

It is imperative that before or upon initiating a recall, the recalling firm notifies the Health Protection Branch. The basic information required includes the following:

1. The name of the recalled product and, where applicable, the identifying model designation, serial number, code, lot number and any other means of identification.

2. The total quantity of the recalled product originally in his possession.

3. The total quantity of the recalled product that had been distributed up to the time of the recall.

4. Area of the distribution of the recalled product by province and, if exported, by country.

5. The quantity of the recalled product still in his possession.

6. The reason for initiating the recall.

This information is usually provided verbally but it should be confirmed in writing. For drugs and medical devices, please refer to the specific recall notification requirements in the Food and Drug Regulations and the Medical Devices Regulations respectively.

4. Health Hazard Evaluation and Recall Classification

Before initiating a recall, the firm will normally gather, correlate and evaluate all known information on the nature and extent of the reputed health risk. An evaluation of the health hazard presented by a product being recalled or considered for recall will also be conducted by Health Protection Branch scientists and will take into account, but need not be limited to, the following factors:

(1) Whether any disease or injuries have already occurred from the use of the product.

(2) Assessment of hazard to various segments of the population, e.g., children, surgical patients, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

(3) Assessment of the degree of seriousness of the health hazard to which the population at risk would be exposed.

(4) Assessment of the likelihood of occurrence of the hazard.

(5) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination. The recalling firm is given every opportunity to contribute to the information on which the health hazard evaluation is made by the Health Protection Branch who, on the basis of this determination, assigns the recall a classification, i.e., Class I, Class II or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

5. Recall Strategy

(a) General

A recall strategy that takes into account the following factors will be developed by the recalling firm to suit the individual circumstances of the particular recall:

i) Results of health hazard evaluation.

ii) Ease in identifying the product.

iii) Degree to which the product's deficiency is obvious to the consumer or user.

iv) Degree to which the product remains unused in the marketplace.

v) Continued availability of essential products.

The Health Protection Branch will provide scientific, technical and operational advice to the recalling firm in the development of the recall strategy as well as evaluate its effectiveness and recommend changes, as deemed appropriate. Additional investigation, analysis and compliance actions may also be carried out by the Branch.

(b) Elements of a recall strategy

A recall strategy will address the following elements regarding the conduct of the recall:

(1) Depth of recall - Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:

i) Consumer or user level, which may vary with product, including any intermediate wholesale or retail level; or

ii) Retail level, including any intermediate wholesale level; or

iii) Wholesale level.

(2) Recall Communications - From the recalling firm to its affected accounts. See Item 6, page 6.

(3) Public Warning - The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. It is reserved for urgent situations (Class I and occasionally Class II Recalls) where other means for preventing use of the recalled product appear inadequate. The Assistant Deputy Minister decides whether a public recall announcement is mandatory and whether the Health Protection Branch will issue the warning.

The recall strategy will specify the type of public warning, for example:

i) General public warning through the general news media, either national or local as appropriate, or

ii) Public warning through specialized news media, e.g., professional, trade or ethnic press, or to specific segments of the population such as physicians, hospitals, etc.

(4) Effectiveness checks - The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination thereof. The recalling firm is responsible for conducting effectiveness checks. The firm's recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted by the recalling firm as follows:

i) Level A - 100 percent of the total number of consignees to be contacted;

ii) Level B - Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees;

iii) Level C - 10 percent or less of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis; or

iv) Level D - No effectiveness checks.

The Health Protection Branch, sometimes assisted by other health agencies, may carry out its own effectiveness checks as part of monitoring the recalling firm's performance. This is a separate exercise which must not be considered as part of, or supplement to, the recalling firm's responsibilities for adequate effectiveness checks.

6. Recall Communications

(a) General

A recalling firm is responsible for promptly notifying each of its affected accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:

(1) That the product in question is subject to a recall;

(2) That further distribution or use of any remaining product should cease immediately;

(3) Where applicable and required as part of the recall strategy, that the direct account should in turn notify its accounts that received the product about the recall;

(4) Instructions regarding what to do with the product.

(b) Implementation

As determined by the recall strategy, a recall communication can be accomplished by telephone, telex, telegrams, or special delivery letters conspicuously marked, preferably in bold red type, on the letter and envelope: "DRUG (or FOOD, BIOLOGIC, etc.) RECALL". The letter and the envelope should also be marked: "URGENT" for Class I and Class II recalls. Telephone calls or other personal contacts should ordinarily be confirmed by one of the other above methods and/or documented in an appropriate manner.

(c) Contents

(1) A recall communication should be written in accordance with the following guidelines:

(i) Be brief and to the point;

(ii) Identify clearly the product, size, lot number(s), code(s), or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;

(iii) Explain concisely the reason for the recall and the hazard involved;

(iv) Provide specific instructions on what should be done with respect to the recalled products; and

(v) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by allowing the recipient to place a collect call to the recalling firm.

(2) The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, follow-up communications should be sent to those who fail to respond to the initial recall communication.

(d) Responsibility of recipient

Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with paragraphs (b) and (c) of this section.

7. Termination of a Product Recall

A recall will be terminated when the Health Protection Branch and the recalling firms are in agreement that the product subject to the recall has been removed and proper disposition or correction has been made.

8. General Industry Guidance

A recall can be disruptive of a firm's operation and business, but there are several steps a firm can take in advance to minimize this disruptive effect. While the following is provided as guidance, it should be noted that some of it is a requirement under current legislation administered by the Health Protection Branch.

1. Prepare and maintain a detailed written recall system or plan that will permit a rapid

and effective product recall. This would include the identification of all internal and external personnel involved in the recall action and their functions and responsibilities; the channels and means of communication; the control of returned stock, etc.

2. Use sufficient coding of products to permit positive lot identification and to facilitate effective recall of those lots.

3. Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention.

9. Recall Responsibilities - Health Protection Branch

Recalls will be given high priority at all levels of the Branch. Prompt and complete fulfillment by Branch personnel of their specific recall responsibilities is required. This may require adjusted work hours, stand-by, overtime and sacrifice of scheduled work. The major responsibilities of key personnel are as follows:

REGIONAL RECALL COORDINATORS - FIELD OPERATIONS DIRECTORATE

1. Provides an early alert on the possibility of Class I and Class II recall situations to the National Recall Coordinator.

2. Upon a recall initiated in that region, promptly advises a National Recall Coordinator by telephone and submits an initial INFORMATION ON RECALL report to the Operations and Compliance Division by telecopier within 24 hours.

3. Submits adequate data for the purpose of obtaining health hazard evaluations and recall classifications via the Operations and Compliance Division.

4. Participates in the development of the recall strategy.

5. Implements the recall strategy in that region. This includes the co-ordination and allocation of resources, regional work units, Branch dealings with the recalling firm and other agencies, including requirements under working agreements with provincial health departments.

6. Monitors the effectiveness of the firm's recall actions. Provides scientific and

operational advice to the recalling firm, usually via district office.

7. Provides status reports to the Operations and Compliance Division until a recall is considered as being terminated.

NATIONAL RECALL COORDINATOR - FIELD OPERATIONS DIRECTORATE

1. Seeks and reviews information on all product recalls. This includes contact with foreign agencies, either directly or through the Department of External Affairs.

2. Provides an early alert on the possibility of Class I recall situations to the appropriate Bureau Recall Coordinator and Directors-General.

3. Obtains health hazard evaluations from the other Directorates and participates in the classification of each recall by that Directorate.

4. Co-ordinates the development of the recall strategy. This includes a decision on whether to recommend to the Director-General of the Field Operations Directorate that a public announcement be mandatory.

5. Co-ordinates the implementation of the recall strategy. This includes co-ordination of resources and the communication of recall information between regions and with the headquarters contacts of other federal departments.

6. Maintains liaison with the recall coordinators of the other Directorates and obtains scientific advice as necessary.

7. Exchanges scientific and operational advice with the regional coordinators as necessary.

8. In conjunction with the regional coordinators, evaluates the effectiveness of the recall actions.

9. Provides necessary information to Media Officers and assists in the preparation of departmental news releases.

BUREAU RECALL COORDINATOR - FOOD, DRUG, AND ENVIRONMENTAL

1. Upon request, provides written health hazard evaluations or re-evaluations to National Recall Coordinator (Field Operations Directorate) and classification of each recall.

2. Participates in the development of the recall strategy. This includes a decision on whether to recommend to the Director-General that a public announcement be mandatory.

3. Maintains liaison with the National Recall Coordinator and provides scientific advice as necessary.

4. Provides scientific information to Media Officers and assists in the preparation of news releases.

MEDIA OFFICER

1. Prepares and issues Branch public recall announcements in the form of news releases.

DIRECTORS-GENERAL: FOOD, DRUG, AND ENVIRONMENTAL HEALTH DIRECTORATES

1. On the basis of the health hazard evaluation, decides whether to recommend to the Assistant Deputy Minister that a public announcement be mandatory and the technical content of the announcement.

2. Approves the content of news releases if prepared by the recalling firm.

3. Maintains knowledge of all Class I Recalls and others as appropriate.

DIRECTOR-GENERAL: FIELD OPERATIONS DIRECTORATE

1. On the basis of the operational considerations within the total recall strategy makes recommendations to the Assistant Deputy Minister whether a public announcement is required.

2. Informs the recalling firm that a public announcement is mandatory, as decided by the Assistant Deputy Minister.

3. Maintains knowledge of all Class I Recalls and others as appropriate.

4. Provides operational direction within the Field Operations Directorate as he deems necessary for Class I Recalls.

ASSISTANT DEPUTY MINISTER

1. Decides whether a public recall announcement be mandatory. Approves HPB news releases.

2. Maintains knowledge of all Class I Recalls.