



## Product Recall in Multiple Recall Jurisdictions Implementation Guideline

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## Document Summary

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7	7 February 2012	John Ryu	Resolved and incorporated Full Product Recall Work Group comments Posted for 30 day community review
8	16 March 2012	John Ryu	Resolved and incorporated community review comments Posted for eBallot
1.0.0	3 April 2012	John Ryu	Updated document as approved.

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# 1. Introduction

## 1.1. Purpose of this Document

 **Note:** Product Recall and Recall are terms used interchangeably in this document.

This document provides guidance on how to execute the Product Recall Process in conformance with GS1 standards when it impacts products traded in more than one recall jurisdiction. The document covers the recall process from initiation through to close-out.

The document outlines how the issuing trading partner will meet the requirements of recall recipient and regulatory authorities in each affected recall jurisdiction.

## 1.2. Definition Recall Jurisdiction

The geographical area of the country, province, state, city within each specific regulation applies to the management of the execution of product recall. Recall jurisdictions are not mutually exclusive and within a specific geographical area multiple jurisdictions may exist. Recall issuer and receiver have to be aware of all relevant regulations in the jurisdictions they trade product.

- A state or provincial law may impose additional requirements or mirror a national law

## 1.3. Who Can Use this Document?

This document is intended for use by commercial trading partners who may need to jointly take action to manage a product recall. It focuses on the needs of those persons who are responsible for issuing or receiving product recalls within their organization. These individuals may also be responsible for communicating progress with regulatory authorities.

The document will be useful for individuals with responsibility for:

- Quality assurance/product safety
- Production/operations
- Trade Relations
- Corporate Affairs

## 1.4. What is the Scope of this Document?

This Implementation Guide can be used by organizations trading any product and in any recall jurisdiction. The document does not provide guidance on how to manage product recalls directly with end-users (i.e. consumers).

## 1.5. Where can I get Additional Help?

Users are encouraged to contact their local GS1 Member Organization who can provide guidance on the use of GS1 keys and local data messaging practices. A complete list of GS1 Member Organizations is available on the GS1 global website ([www.gs1.org](http://www.gs1.org)).

## 1.6. GS1 Product Recall Standard

The GS1 Product Recall standard defines the process and data needed for managing product recall communications between trading partners anywhere in the world. They define the process and information necessary to effectively communicate product safety issues within the supply chain and to stop continued sale or forward logistics. The standard enables trading partners of all scales to comply with the regulatory needs of individual recall jurisdictions and trading partners.

Product recalls increase in complexity when they impact products, trading partners and regulatory authorities in multiple recall jurisdictions. For this reason, it is critically important that all impacted parties share a common understanding of the foundational recall business processes, the data needed to support those processes and the data messages that are applicable.



**Note:** Trading parties and Tracing (Traceability) Partners are used interchangeably in this document.

## 2. Foundational Product Recall Principles

The GS1 Product Recall standard outlines the key business principles that ensure it is consistently and effectively deployed across all industries and geographies. Users should be familiar with these and they are provided in the Appendix.

Three of these principles impact the issuance and management of product recalls impacting more than one recall jurisdiction described below.

### 2.1. Principle 1: Product Recall Governance.

Product Recalls are governed by the applicable local regulations, policies and guidelines within a recall jurisdiction. A recall jurisdiction is typically the country in which the Product Recall Notification (PRN) is being issued.

In some cases, different regulations across states, provinces, territories or municipalities could mean that more than one recall jurisdiction may exist within a country. Additionally, the same laws and regulations could exist across more than one country due to bi-lateral or regional agreements.

Differences in regulatory requirements for PRN across jurisdictions may impact:

- Data requirements
- Regulator authorisation
- Which recipients should be notified
- Which organisation or regulator must initiate the product recall(s)
- Management of returned products
- Reporting status of Product Recall to regulators
- Other aspects

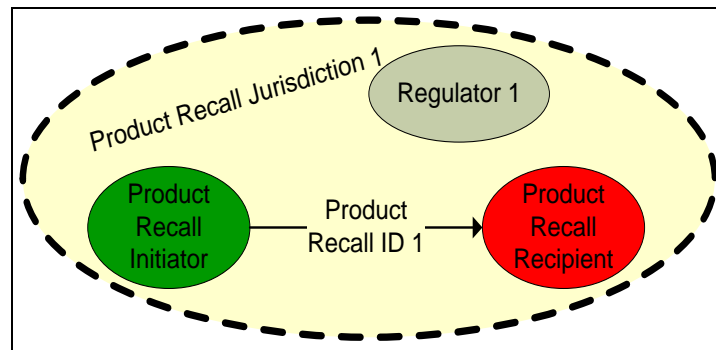
A PRN is therefore created, issued and managed within the context of each recall jurisdiction.

### 2.2. Principle 2: Product Recall Identification.

PRN are globally uniquely identified based on the following guidelines:

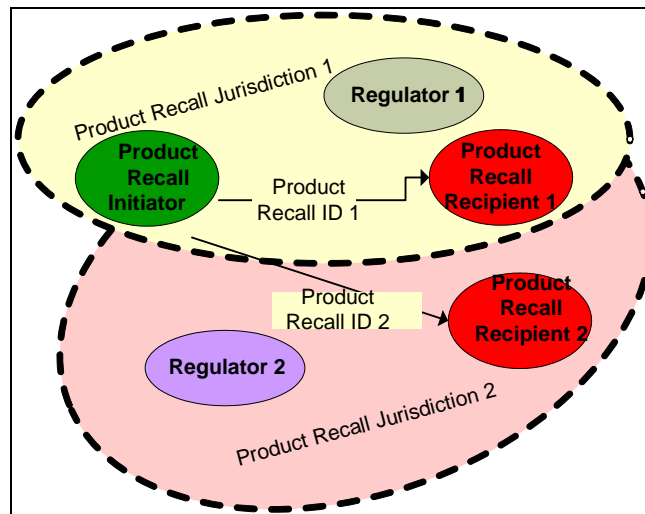
1. Where a product recall is executed only within a single recall jurisdiction, only a single PRN, identified with a globally unique PRN identifier is required (refer to Figure 1)
2. Where a product recall is executed across multiple recall jurisdictions, **with common recall jurisdictional requirements**, only a single PRN, identified with a globally unique PRN identifier is required (refer to Figure 2)
3. Where a product recall is executed across multiple recall jurisdictions, **with differing recall jurisdictional requirements**, a separate PRN is issued, each identified with a globally unique PRN identifier is required for each jurisdiction (refer to Figure 3)

**Figure 1** Single PRN in one recall jurisdiction for one product recall recipient



- A PRN issued by one Product Recall Initiator to one Product Recall Recipient.
- The PRN is governed by a regulator in one recall jurisdiction.
- All traceability partners involved with the product recall are subject to and governed by the rules and regulations in that recall jurisdiction.

**Figure 2** Single PRN in two recall jurisdictions (Common Requirements) for multiple product recall recipients

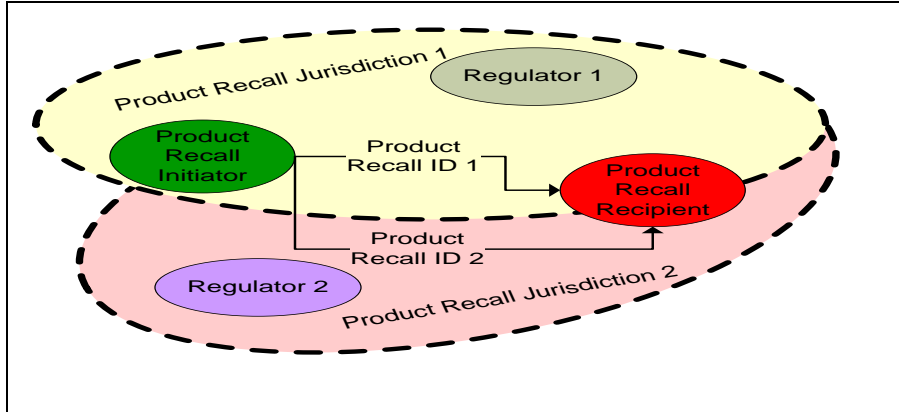


- A PRN issued by one Product Recall Initiator to multiple Product Recall Recipients.
- The PRN is governed by regulators in two recall jurisdictions BUT with common requirements



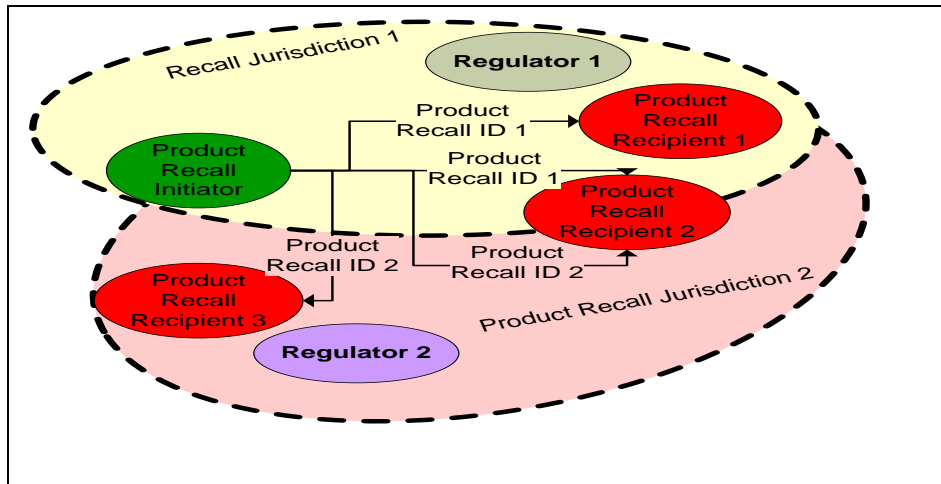
- All traceability partners involved with the product recall are subject to and governed by common rules and regulations in the two recall jurisdictions.

**Figure 3** Single PRN in multiple recall jurisdictions (Different Requirements) for one product recall recipient



- A PRN issued by one Product Recall Initiator to one Product Recall Recipient operating in two recall jurisdictions.
- The PRN is governed by regulators in two recall jurisdictions with different requirements
- All traceability partners involved with the product recall are subject to and governed by the rules and regulations in their relevant recall jurisdiction.

**Figure 4** Single PRN in two recall jurisdictions (Different Requirements) for multiple product recall recipients





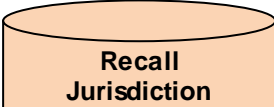

- A PRN issued by one Product Recall Initiator to multiple Product Recall Recipients.
- This Figure illustrates when a PRN is governed by regulators in two recall jurisdictions.
- All traceability partners involved with the product recall are subject to and governed by the rules and regulations in that recall jurisdiction.

### 2.3. Principle 3: Product Recall Data

Product recall issuers must provide all of the information needed by individual traceability partners within a product recall jurisdiction. This requires assembling and exchanging for four types of recall

data within a PRN. All of this data is needed in order to execute the recall effectively at the receiving traceability partner location.

**Table 1** Product Recall Data Category

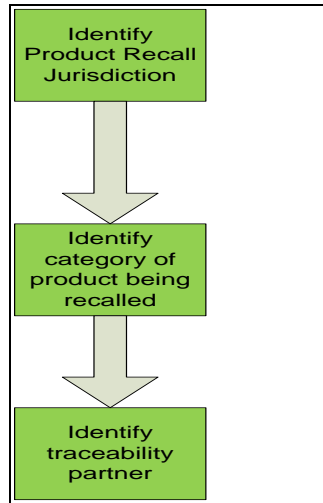
<b>Product Recall Notification Data Types</b>			
			
Definition	Definition	Definition	Definition
Data elements that are common to all Product Recall Notifications	Product Recall data that specifically identifies the category or classification of the traceable item being recalled	The data required by the regulatory requirements of the relevant Product Recall jurisdiction	The data required to support specific traceability partner relationships
Examples	Examples	Examples	Examples
<ul style="list-style-type: none"> <li>• Globally unique Product Recall identifier</li> <li>• Product Recall name</li> <li>• Global Product Classification</li> </ul>	<ul style="list-style-type: none"> <li>• Ingredients</li> <li>• Hazard definitions</li> <li>• Formulation and strength</li> </ul>	<ul style="list-style-type: none"> <li>• Language requirements</li> <li>• Severity classifications</li> <li>• Notification coverage</li> </ul>	<ul style="list-style-type: none"> <li>• Arrangements for returns, shipping &amp; handling</li> <li>• Provision of product specifications unique to the traceability relationship</li> </ul>

- **Global:** This type of PRN data includes basic information that is exchanged as part of every recall, regardless of the product, country, traceability partner or jurisdiction. When a product recall affects multiple jurisdictions and more than one PRN is required, the Global Recall data is common across all PRNs. The standardization of Global Recall Data enables a level of interoperability across user recall solutions across jurisdictions.
- **Category:** Data relates to standard information that is relevant to the commodity being traded. Product Recall data will vary across Food, Health, General Merchandise and other product categories. Although Category data is standardized within product categories, Jurisdictional requirements could impact product categorization across jurisdictions. For example, a Nutritional Snack Bar classified as a food product in one jurisdiction could be considered to be a Therapeutic good in another jurisdiction and therefore impacting category information for the same product across jurisdictions.
- **Recall Jurisdiction:** Information that is required by a regulatory authority within a specific product category in a recall jurisdiction.
- **Traceability Partner:** Information that is specific to the requirements of an individual trading partner

PRN traceability partners should consider the following when creating a PRN:

1. Identify the product recall jurisdiction governing the PRN
2. Identify the category of product being recalled in context of the product recall jurisdiction
3. Identify traceability partner specific

**Figure 5** Traceability partner consideration process flow

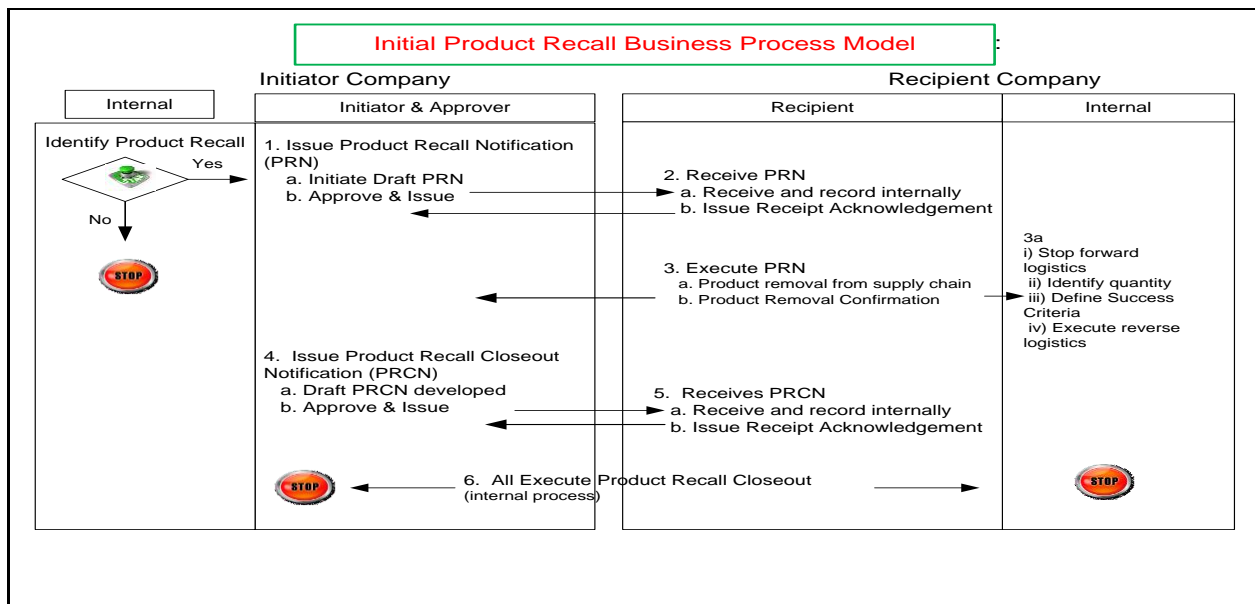


### 3. Implementation Procedures

#### 3.1. High Level Business Process Overview

Product recall issuers and recipients follow a standard process for recall notification and resolution. This process has 6 major steps or phases. This 6 step process is repeated for each recall recipient, in each affected recall jurisdiction.

**Figure 6** 6 Step Product Recall Process



**Note:** When issuing a Product Recall Notification, specific GTINs are listed as being subject to the recall. The GTINs listed should be from the affected level of the hierarchy.

This means that if the issue is with the case, the case GTIN should be listed. If the issue is with the each, the each GTIN should be listed. This insures that the appropriate actions are taken and unaffected products are not removed from the supply chain. For example:

- If the recall is issued because the case label incorrectly lists the contents of the case as 25 cans instead of 24 cans, an issue with the case packaging, for a case of 24 cans of tomato soup, the recall is issued for the case GTIN not the each GTIN. This recall should only get a return or removal of the 24 can case with that GTIN, not the manufacturer's other cases with 12 cans or 48 cans.
- If the recall were issued for the each level, then every case of the soup is suspect to being recalled. This would recall the 24 can case, 12 can case, and the 48 can case. This type of recall is overreaching and removes product from the supply chain unnecessarily.

## 3.2. Detailed Business Process Steps

### 3.2.1. Step 1: Issue Product Recall Notification

#### **Purpose**

To notify individual trading partners of the need to recall product within each (impacted) recall jurisdiction.

#### **Outcome**

Each affected trading partner receives an authorized PRN that is tailored to their needs within the specified recall jurisdiction. A product recall recipient operating in multiple recall jurisdictions will receive individual PRN(s) for each recall jurisdiction.

#### **Pre-Requisites**

The need to issue a PRN must be approved internally within the issuing organization by an authorized individual. This is usually an officer of the company. Recall issuers understand the unique information needs of individual trading partners (i.e. product recall recipients).

#### **Business Process Step Details**

Step 1 is managed by the issuer of the recall and requires two sub-steps:

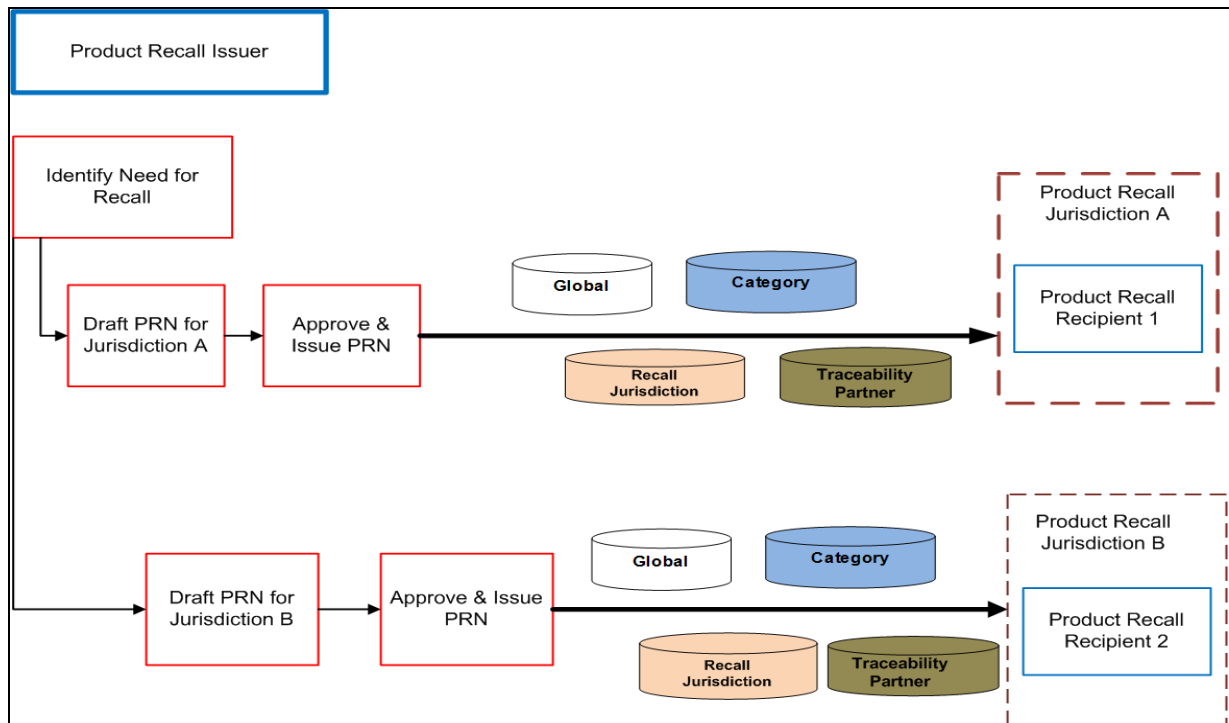
##### Step 1a Draft Product Recall Notification developed:

Product Recall Initiator completes a draft PRN providing global, commodity, recall jurisdiction-specific and recipient-specific information.

The draft PRN is submitted to an authorized internal Product Recall Approver.

##### Step 1b Draft Product Recall Notification approved & issued:

The Product Recall Approver reviews the draft PRN and determines whether to approve for distribution. Once approved, the Product Recall Approver determines the specific date & time the PRN is issued.

**Figure 7** Product Recall step 1 in multiple recall jurisdictions


### 3.2.2. Step 2: Receive Product Recall Notification

#### Purpose

To enable each product recall recipient to understand that a PRN has been issued within the specified recall jurisdiction.

#### Outcome

Each affected product recall recipient records the issuance of the product recall within their business systems (business systems may be electronic or manual processes). This marks the beginning of the product recall process for the recipient.

#### Pre-Requisites

Trading partners will have defined individual requirements (if any) for acknowledging PRN and updates to them. Product recall recipients are familiar with the recall regulations in each recall jurisdiction where they operate.

#### Business Process Step Details

Step 2 is managed by each recipient of the product recall and may require two sub-steps:

##### 2a The Product Recall Recipient receives the Approved PRN

The product recall recipient records the PRN in their internal business systems.

##### 2b PRN acknowledged:

Where necessitated by traceability partner agreement, the Product Recall Recipient sends a receipt to the Product Recall initiating traceability partner acknowledging that the PRN was successfully received.

Where a traceability partner is operating in more than one recall jurisdiction, a separate acknowledgement is needed for each unique PRN received.

### 3.2.3. Step 3: Execute Product Recall Notification

#### Purpose

To execute the product recall in accordance with:

The product information and instructions provided in the PRN as well as any subsequent updates (to the notification or to supporting documents).

Regulations within each recall jurisdiction

#### Outcome

Continued distribution or sale of affected product is stopped in each affected recall jurisdiction. The recall recipient removes product from inventory as specified by the recall issuer and by local regulations.

#### Pre-Requisites

Trading partners have defined individual requirements (if any) for acknowledging product removal confirmations and updates to them.

#### Business Process Step Details

Step 3 is managed by each recipient of the product recall and may require two sub-steps:

##### 3a Product removed from supply chain:

The product recall recipient issues internal communications to begin the process of executing the product recall. This is to stop forward logistics movement or stop sale, product disposition or possibly triggering reverse logistics

This process comprises four sub processes:

- i. Defines success criteria by initiator and / or recipient
- ii. Identification of product quantity in the control of the recipient traceability partner supply chain
- iii. Stops forward logistics
- iv. Execution of reverse logistics or disposal

##### 3b Product Removal Confirmation:

Where necessitated by traceability partner agreement, the Product Recall Recipient confirms the progress of the Product Recall by issuing a Product Removal Confirmation. This process step can be repeated. The Product Removal Confirmation is sent to the Product Recall Initiator traceability partner who will use this information as input in the Product Recall Closeout process step.

### 3.2.4. Step 4: Issue Product Recall Closeout

#### Purpose

To enable product recall issuers to communicate that the product recall is concluded (i.e. it is being closed). This is needed by each product recall recipient, within each recall jurisdiction.

#### Outcome

Each product recall recipient understands that the product recall is closed out and records this information to their internal business systems. The product recall issuer and recipient may use this step to communicate final disposition of recalled products. Once closed, a PRN cannot be re-opened.

#### Pre-Requisites

Both the recall issuer and recipient agree that the product recall has been executed to the best of its ability and has met regulatory requirements.

The need for issuing a product recall closeout is determined by the trading partner relationship or regulatory requirements within each product recall jurisdiction.

#### **Business Process Step Details**

##### 4a Draft Product Recall Closeout Notification developed:

The Product Recall Initiator prepares a draft Product Recall Closeout Notification formally indicating that the product recall event is now closed out. This draft is sent to the Product Recall Approver for review & approval.

##### 4b Draft Product Recall Closeout Notification approved & issued:

The Product Recall Approver reviews the draft Product Recall Closeout Notification and determines whether to approve or reject. Once approved, the Product Recall Approver determines the specific date & time the Product Recall Closeout Notification is issued to the Product Recall Recipient.

### **3.2.5. Step 5: Receive Product Recall Closeout**

#### **Purpose**

To enable product recall recipient to begin the process of product recall closeout within their internal business systems.

#### **Outcome**

The product recall recipient can record the closeout notification and begin closing the PRN within internal business systems.

#### **Pre-Requisites**

Both the recall issuer and recipient agree that the product recall has been executed to the best of their abilities and has met regulatory requirements. The need for issuing a product recall closeout is determined by the trading partner relationship or regulatory requirements within each product recall jurisdiction.

#### **Business Process Step Details**

##### 5a Product Recall Closeout Notification received:

The Product Recall Recipient receives the approved Product Recall Closeout Notification and records it internally.

##### 5b Acknowledgement of Product Recall Closeout Notification:

Where necessitated by trading partner agreement, the Product Recall Recipient confirms the receipt of the Product Recall Closeout Notification by returning a Product Recall Closeout Acknowledgement.

### **3.2.6. Step 6: Execute Closeout**

#### **Purpose**

To enable the Product Recall issuer and recipient to complete the closeout process within their business systems and complete any necessary reporting required by regulatory authorities.

#### **Outcome**

The PRN is closed in both the issuer and recipient internal business systems

#### **Pre-Requisites**

None

#### **Business Process Step Details**

The PRN is closed. No additional action is required.

## 4. Business Examples

- ✓ **Note:** The following examples 4.1 and 4.2 are a part of the supply chain process where products may be identified and need to be recalled. These examples provide different situation for the various industry sectors.

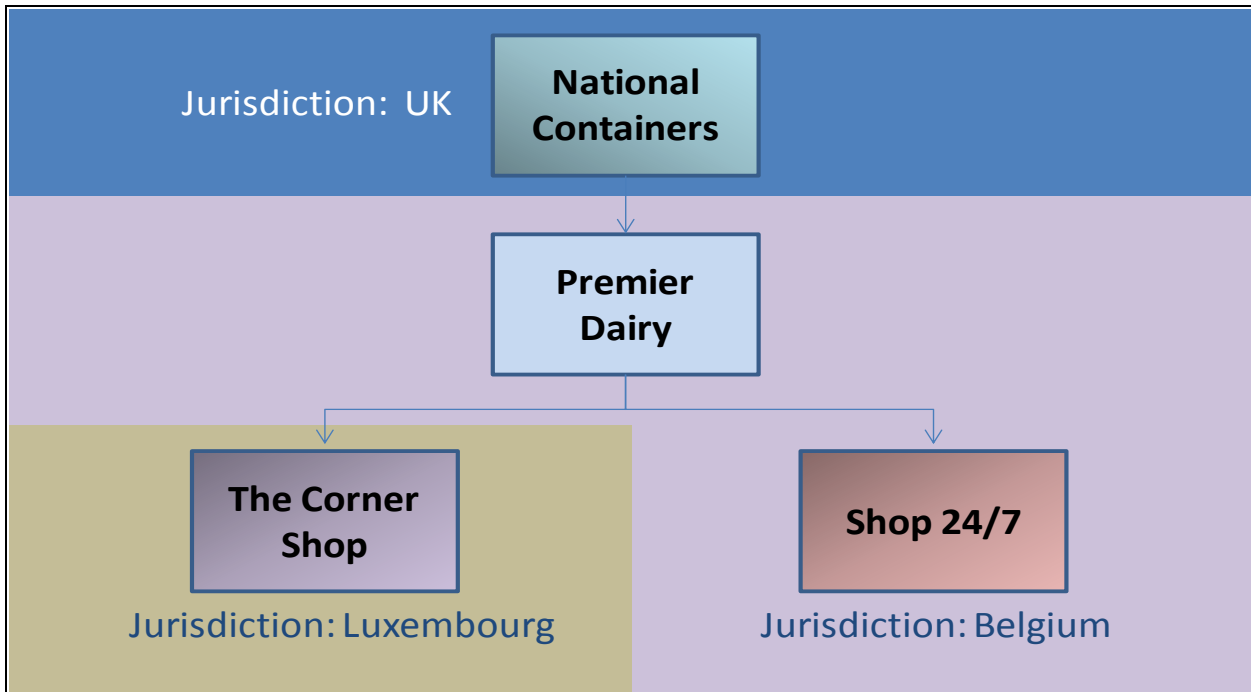
### 4.1. Business Example 1

The following fictitious business example illustrates the considerations for multi-jurisdictional Product Recall Notifications (PRNs). In this case study, a UK based packaging supplier issues a PRN to a Food Manufacturing company based in Belgium. The packaging recall impacts two products being produced by the recall recipient. This in turn triggers two Associated PRN issued by the Manufacturing Company targeting two retailers, operating in separate recall jurisdictions.

#### 4.1.1. Who are the traceability parties?

- **National Containers** is a small packaging supplier based in the UK. National Containers serves the food manufacturing industry through its line of highly reliable plastic cans and boxes. These products are used by the food industry to package consumer products that must be protected from air and moisture.
- **Premier Dairy** is a mid-sized processor of dairy products and prides itself on a popular line of flavoured butter products which are marketed under the Gourmet Butter brand. Premier Dairy distributes its Gourmet Butter brand exclusively through direct buying agreements with grocery retailers in Belgium and Luxembourg. Premier Dairy operates a single manufacturing and distribution facility in Brussels which serves retailer customers in both countries.
- **Shop 24/7** is a mid-sized grocery retailer operating shops in urban locations throughout Belgium. Shop 24/7 carries a wide assortment of convenience foods, including the Gourmet Butter brand. All inbound product is received at Shop 24/7's distribution centre in Brussels. From this point, Shop 24/7 manages its own distribution to its company-owned shops.
  - Shop 24/7 strictly follows the GS1 6-step process for product recall notifications and recommends the same of all their vendors.
- **The Corner Shop** is a small specialty food shop operating from a single retail location in the city of Luxembourg providing Premier Dairy's Gourmet Butter brand.
  - This retailer follows the GS1 6-step process for managing recalls and recommends all vendors to adopt the same practice.



**Figure 8** Traceability Partners represented in respective recall jurisdictions


#### 4.1.2. What happened?

**March 1:** National Container manufactures a single production lot of plastic cans for exclusive use by Premier Dairy in the packaging of their Gourmet Butter products. The entire production lot is shipped later that same day from National Container to Premier Dairy’s manufacturing plant in Belgium.

- National Container GTIN: 50012345678900 500 cases
- Production Lot: A10-0301

**March 5:** Premier Dairy manufactures a single production lot of their Pecan-flavoured Gourmet Butter. Later that day, they also manufacture a single small production lot of their Apple-flavoured Gourmet Butter. In both production runs, National Container plastic cans from Lot A10-0301 are used.

- Premier Dairy Pecan-flavoured Gourmet Butter GTIN: 54012345678906 Lot: 15-9-11
- Premier Dairy Apple-flavoured Gourmet Butter GTIN: 54012345678968 Lot: 15-9-12

**March 6:** Premier Dairy ships pecan-flavoured Gourmet Butter to Shop 24/7’s distribution centre. The shipment comprises:

- 200 cases Pecan-flavoured Gourmet Butter GTIN: 54012345678906 Lot: 15-9-11

Later that day, Shop 24/7 begins re-distributing the product to its network of retail shops.

**March 7:** Premier Dairy ships apple-flavoured Gourmet Butter to The Corner Shop in Luxembourg.

The shipment comprises:

- 5 cases Apple-flavoured Gourmet Butter GTIN: 54012345678968 Lot: 15-9-12

Staff at the Corner Shop immediately begins replenishing the product on store shelves.

### 4.1.3. How did the impacted traceability partner respond?

**March 8:** The Quality Control Department at National Container reviews production samples from production lot A10-0301 and detects a manufacturing defect that permits the can to leak. At worst, product in the can will spoil and become rancid. This is a serious production failure. Inventory and customer records show that the faulty product has already been shipped to Premier Dairy.

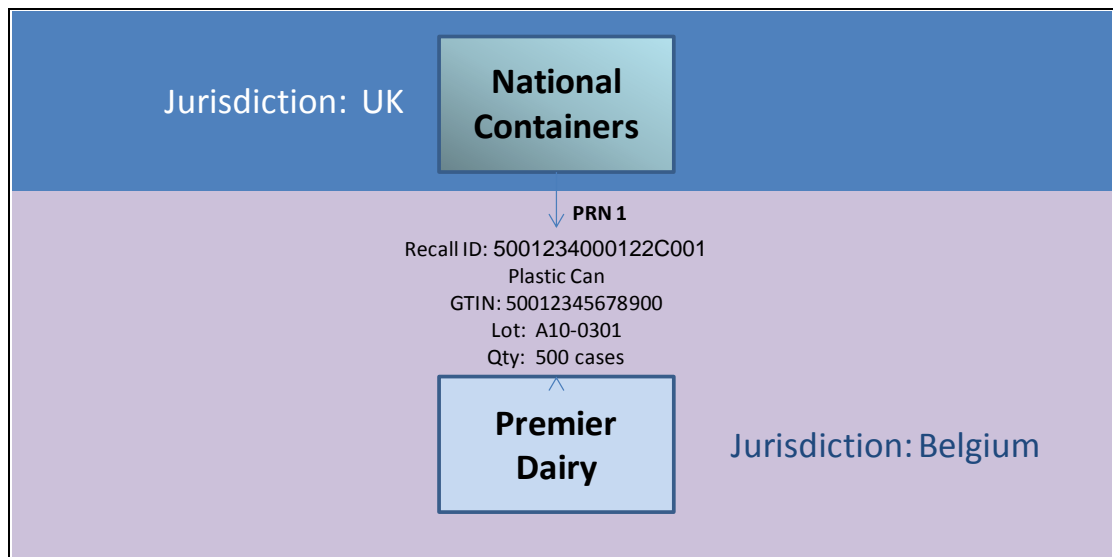
National Container decides that a product recall of their plastic cans has to be issued. Fortunately, the production fault is limited to a single customer and production lot. The applicable recall jurisdiction is Belgium and the recall will be governed by the regulations specified in the Belgian Food Act.

**March 9:** National Container notifies their contact at Premier Dairy with the news that their plastic can is being recalled with the issuance of an electronic PRN from National Container to Premier Dairy uniquely identifying the recall and all relevant details. National container is uniquely identifying this recall using the GS1 document identification standard (GDTI). Additionally, National Container communicated via email a set of success criteria for the recall to Premier Dairy.

#### **PRN1 (See Figure 9 PRN details)**

- The globally unique recall identifier is 5001234000122C001.
- National Container GS1 Global Company Prefix: 5001234
- Document: 000122 (internal document type used for product recall)
- Check digit: C
- Product recall serial number: 001

**Figure 9** Details of PRN



A copy of the PRN is provided to the Belgian regulatory authority as required by national regulation.

Once received by Premier Dairy, they respond with an electronic message acknowledging receipt of National Container's PRN.

Premier Dairy analyzes the impact of the defective cans and determines that a substantial portion of the packaging material has already been used in the manufacture of two Gourmet Butter flavours. Premier Dairy acts quickly to suspend the use of the remaining faulty cans within its operations. All of the unused cases of National Container cans are accounted for and disposed of as specified in the PRN.

Customer and shipping records confirm that Gourmet Butter products using the defective cans have been shipped to retail customers in Belgium and Luxembourg. The management team at Premier Dairy conclude that the faulty product poses a health risk to consumers and must issue its own recall of these products.

Shipment of Premier Dairy's Pecan-flavoured Gourmet Butter is limited to their Shop 24/7 customer in Belgium. Belgian product recall regulations will apply.

Similarly, shipment of Apple-flavoured Gourmet Butter is limited to The Corner Shop in Luxembourg and regulations in Luxembourg will govern the second recall. It is determined that the recall regulations in Belgium and Luxembourg have differing requirements and for this reason, Premier Dairy must issue two **distinct** PRNs.

**March 10:** Premier Dairy notifies their Quality Assurance contacts at Shop 24/7 and The Corner Shop of the recalls of specific products in their Gourmet Butter line with the issuance of two distinct electronic PRN. Additionally, Premier Dairy communicated via email a set of success criteria for the recall to Shop 24/7 and Corner Shop

**PRN2 (See Figure 10 PRN in multiple recall jurisdictions)** is issued from Premier Dairy to Shop 24/7 and contains the relevant details required by Belgian regulations as well as information required by Shop 24/7. Premier Dairy is uniquely identifying this recall using the GS1 document identification standard (GDTI).

- The unique recall identifier is: 5401234007992C0158.
- Premier Dairy GS1 Global Company Prefix: 5401234
- Document: 007992 (internal document type used for product recall)
- Check digit: C
- Product recall serial number: 0158

Additionally, the Premier Dairy PRN references the original (associated) PRN issued by their packaging supplier, National Container. A copy of the PRN is provided to the Belgian regulatory authority as required by regulation.

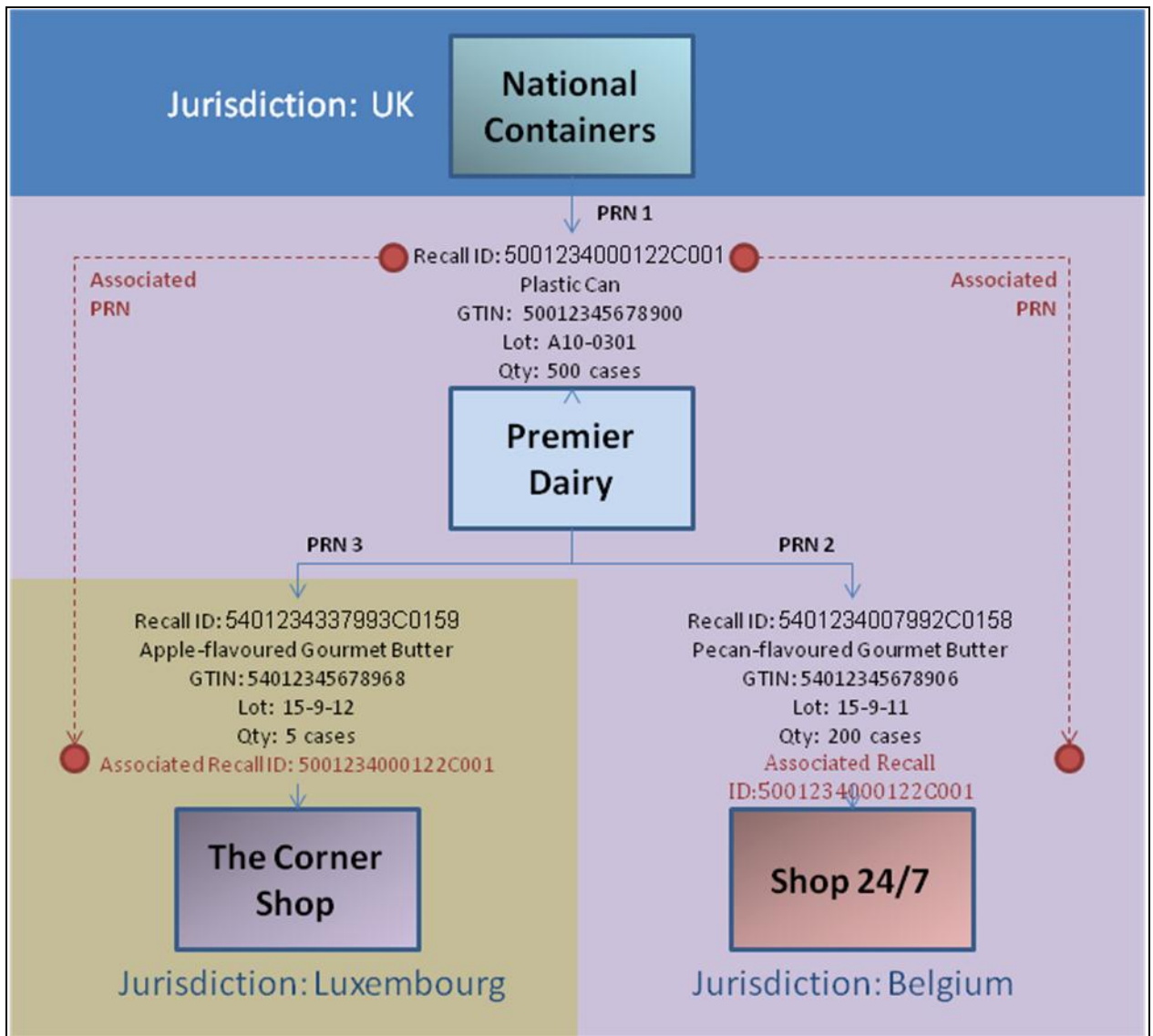
Once received, Shop 24/7 responds with an electronic message acknowledging receipt of the PRN and issues an internal notification to each store location to immediately stop any further sale of Pecan-flavoured Gourmet Butter from Premier Dairy production batch 15-9-11.

**PRN3 (See Figure 10 PRN in multiple recall jurisdictions)** is issued from Premier Dairy to The Corner Shop and contains the relevant information specified by national regulations in Luxembourg. Premier Dairy is uniquely identifying this recall using the GS1 document identification standard (GDTI).

- The unique recall identifier is 5401234337993C0159.
- Premier Dairy GS1 Global Company Prefix: 5401234
- Document: 337993 (internal document type used for product recall)
- Check digit: C
- Product recall serial number: 0159

The PRN references the original (associated) PRN issued by their packaging supplier, National Container. Regulatory authorities in Luxembourg are provided a copy of the PRN as required by national regulation.

Once received, The Corner Shop responds with an electronic message acknowledging receipt of the PRN and immediately acts to stop the sale of Apple-flavoured Gourmet Butter from Premier Dairy production lot 15-9-12.

**Figure 10** PRN in multiple recall jurisdictions


**March 28:** The Corner Shop has complied with national regulations and has notified consumers of the potential product hazard. They are confident that all unsold quantities of the specified Apple-flavoured Gourmet Butter product have been identified and together with customer returns, have been disposed of by store staff.

The Corner Shop does not expect to handle any additional recalled product and issues a GS1 product removal confirmation confirming the removal of products as per Premier Dairy's recall 5401234337993C0159

**April 2:** Shop 24/7 has met Belgian regulations by notifying consumers of the potential product hazard. Shop 24/7 is confident that all unsold quantities of the specified Pecan-flavoured Gourmet Butter product have been identified and together with customer returns, have been shipped back to Shop 24/7's distribution centre for disposal.

Shop 24/7 does not expect to handle any additional recalled product and issues a GS1 product removal confirmation confirming the removal of products as per Premier Dairy's recall 5401234007992C0158.

**April 3:** Premier Dairy is satisfied that its recall of Gourmet Butter products has been successfully executed at Shop 24/7, The Corner Shop and within their own operations. Premier Dairy issues individual electronic GS1 product recall closeout notification to both Shop 24/7 and The Corner Shop indicating that they consider the individual recalls completed/closed and no further action is anticipated.

As per regulation in Luxembourg, a copy of the product recall closeout notification is also sent to the national regulatory authority. A similar communication is not required by Belgian regulation.

**April 4:** Shop 24/7 acknowledges the Premier Dairy product recall closeout notification by issuing the appropriate electronic GS1 message. This indicates that the recall has been closed out in Shop 24/7's internal systems. The Corner Shop issues a similar acknowledgement.

Both of Premier Dairy's PRN are now completed.

**April 5:** Premier Dairy is satisfied that it has successfully executed the original PRN issued by National Container and issues a GS1 product removal confirmation confirming the removal of products as required in National Container's recall 5001234000122C001.

**April 6:** National Container has made corrections to their manufacturing process and is confident of no further problems with its plastic cans. National Container is also satisfied that Premier Dairy has effectively managed recall 5001234000122C001 and no further risk to Premier Dairy exists. A GS1 product recall closeout notification is issued to Premier Dairy.

Premier Dairy acknowledges the product recall closeout notification indicating that the product recall has been closed out in Premier Dairy's internal systems.

The National Container product recall is now completed.

## 4.2. Business Example 2

The following fictitious business example illustrates the considerations for multi-jurisdictional Product Recall Notifications (PRN). In this case study, a UK based catheter supplier issues a PRN to a medical distribution company based in Canada. The catheter recall impacts two products being distributed by the recall recipient. This in turn triggers two Associated PRNs issued by the Distributor Company targeting two points of service / operators, operating in separate recall jurisdictions.

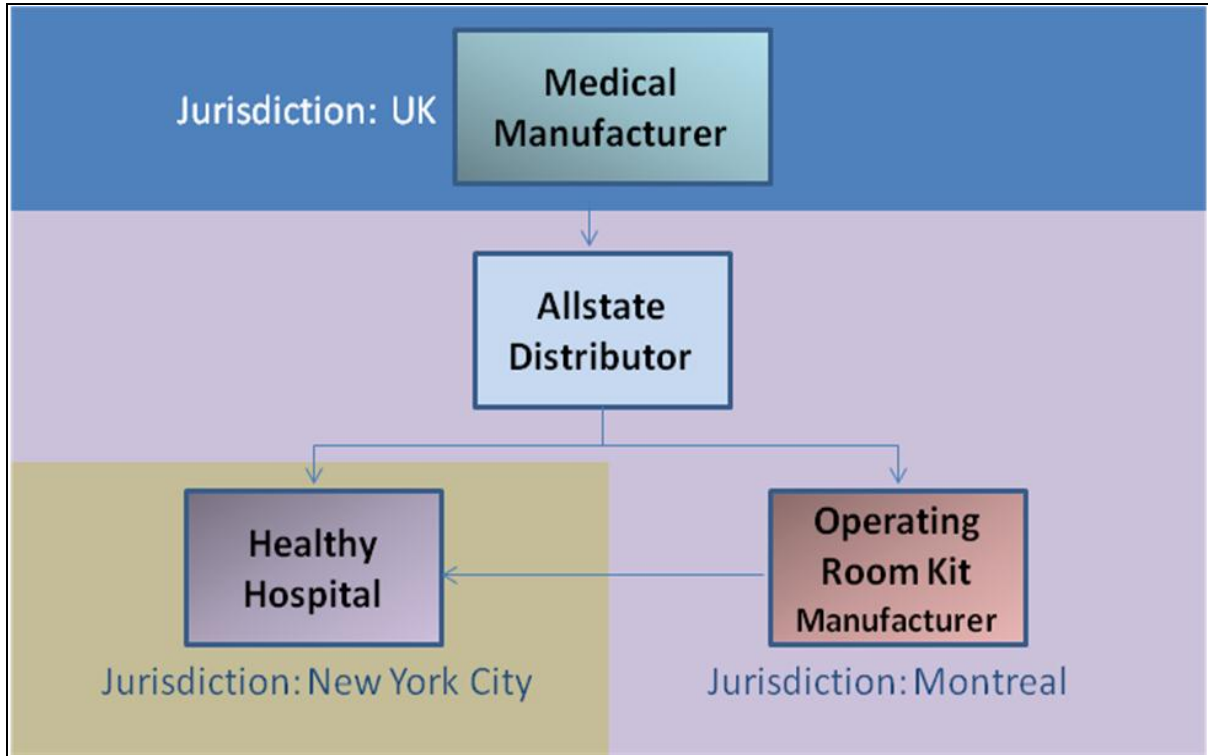
### 4.2.1. Who are the traceability parties?

- **Medical Manufacturer** is a small healthcare manufacturer based in UK. Medical Manufacturer serves the healthcare industry by the production of high quality Renal Dialysis (RD) catheters. These products are used by the healthcare industry to aid kidneys in flushing out harmful blood stream fluids.
- **Allstate Distributor** is a mid-sized distributor of healthcare products and distributes the popular line of renal dialysis catheters which are marketed under the Best RD Catheter brand. Allstate Distributor also distributes the Supreme RD Catheter brand exclusively through direct buying agreements with Operating Room Kit Manufacturer (ORKM) Montreal, Canada. Allstate Distributor operates a single manufacturing and distribution facility in Toronto which serves hospitals in Canada and the US.
- **Operating Room Kit Manufacturer (ORKM)** is a small assembler of sterile kits located in Montreal, Canada. It produces OR packs for Healthy Hospital in New York. The catheters are acquired from Allstate Distribution, the sole distributor for Medical Manufacturer in Canada and the US.
- **Healthy Hospital** is a mid-sized hospital operating in urban location in New York City. Healthy Hospital carries a wide assortment of pharmaceutical, medical devices and food. From this point, Healthy Hospital manages its own distribution to its company owned Dialysis

Centres in New York City. Healthy Hospital receives Best RD Catheters from Allstate Distributor and Supreme RD Catheters from ORKM.

- Healthy Hospital strictly follows the GS1 6-step process for product recall notifications and recommends the same of all their vendors.

**Figure 11** Traceability Partners represented in Recall Jurisdictions



#### 4.2.2. What happened?

**July 1:** Medical Manufacturer manufactures a single production lot of catheters for exclusive distribution to Allstate Distributor for the sale of their Best and Supreme RD catheters products. The entire production lot is shipped later that same day from Medical Manufacturer to Allstate Distributor distribution facility in Toronto.

- Medical Manufacturer GTIN: 60012345678907      500 cases
- Production Lot: A10-0101

**July 5:** Allstate Distributor packages an order of Best RD Catheter to Healthy Hospital in New York. Later that day, they also package a small production lot of the Supreme RD Catheters to ORKM. In both production runs, Medical Manufacturer catheters from Lot A10-0101 are used.

- Allstate Distributor Best RD Catheters GTIN: 64012345678903      Lot: 15-9-11
- Allstate Distributor Supreme RD Catheters GTIN: 64012345678965      Lot: 15-9-12

**July 6:** Allstate Distributor ships Best RD Catheters to Healthy Hospital. The shipment comprises:

- 20 cases      Best RD Catheters GTIN: 64012345678903      Lot: 15-9-11

Later that day, Healthy Hospital begins re-distributing the product to its network of dialysis centres in New York.

**July 7:** Allstate Distributor ships Supreme RD Catheters to the Operating Room Kit Manufacturer in Montreal.

The shipment comprises:

- 50 cases Supreme RD Catheters GTIN: 64012345678965 Lot: 15-9-12

Staff at the ORKM immediately begins replenishing the product on kit production line.

ORKM ships Supreme RD Catheters to Healthy Hospital

- 10 cases Supreme RD Catheters GTIN: 64012345678965 Lot: 15-9-12

### 4.2.3. How did the impacted traceability partner respond?

**July 8:** The Quality Control Department at Medical Manufacturer reviews production samples from production lot A10-0101 and detects a manufacturing defect that permits the catheter to tear. At worst, the catheter will fail, endangering the life of the patient. This is a serious production failure. Inventory and customer records show that the faulty product has already been shipped to Allstate Distributor.

Medical Manufacturer decides that a product recall of their catheters has to be issued. Fortunately, the production fault is limited to a single customer and production lot. The applicable recall jurisdiction is Canadian and the recall will be governed by the regulations specified in the Canadian Food and Drugs Act.

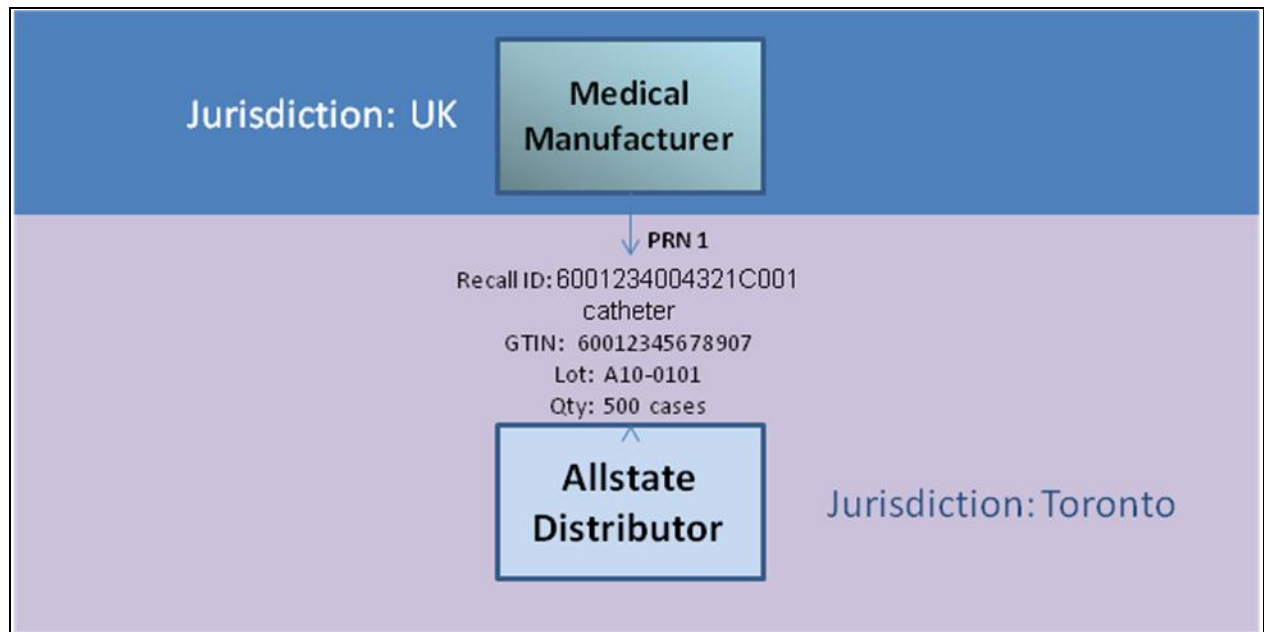
**July 9:** Medical Manufacturer notifies their contact at Allstate Distributor with the news that their catheter is being recalled with the issuance of an electronic PRN from Medical Manufacturer to Allstate Distributor uniquely identifying the recall and all relevant details. Medical Manufacturer is uniquely identifying this recall using the GS1 document identification standard (GDTI). Additionally, Medical Manufacturer communicated via phone a set of success criteria for the recall to Allstate Distributor

#### **PRN1 (See Figure 12 PRN details)**

- The globally unique recall identifier is 6001234004321C001.
- Medical Manufacturer GS1 Global Company Prefix: 6001234
- Document: 004321(internal document type used for product recall)
- Check digit: C
- Product recall serial number: 001



Figure 12 Details of PRN



A copy of the PRN is provided to the Canadian regulatory authority as required by national regulation.

Once received by Allstate Distributor, they respond with an electronic message acknowledging receipt of Medical Manufacturer's PRN.

Allstate Distributor analyzes the impact of the defective catheters and determines that a substantial portion of the catheters has already been shipped to customers. Allstate Distributor acts quickly to suspend the use of the remaining faulty catheters within its inventory. All of the unused catheters of Medical Manufacturer are accounted for and disposed of as specified in the PRN.

Customer and shipping records confirm that shipments involving the defective catheters have been shipped to customers in Montreal and New York City. The management team at Allstate Distributors conclude that the faulty product poses a health risk to consumers and must issue its own recall of these products.

Shipment of Allstate Distributor's Best RD Catheters is limited to their Healthy Hospital customer in New York City. United States product recall regulations will apply.

Similarly, shipment of Supreme RD Catheters is limited to the Operating Room Kit Manufacturer in Montreal and Canadian regulations will govern the second recall. It is determined that the recall regulations in United States and Canada have differing requirements and for this reason, Allstate Distributors must issue two **distinct** PRNs.

**July 10:** Allstate Distributors notifies their Quality Assurance contacts at Healthy Hospital and the ORKM of the recalls of specific products in their catheters line with the issuance of two distinct electronic PRNs. Additionally, Allstate Distributors communicated via email a set of success criteria for the recall to Healthy Hospital and ORKM.

**PRN2 (See Figure 13 PRN in Multiple Jurisdictions)** is issued from Allstate Distributor to Healthy Hospital and contains the relevant details required by United States regulations as well as information required by Healthy Hospital. Allstate Distributor is uniquely identifying this recall using the GS1 document identification standard (GDTI).

- The globally unique recall identifier is 6401234007992C0158.
- Allstate Distributor GS1 Global Company Prefix: 6401234



- Document: 007992 (internal document type used for product recall)
- Check digit: C
- Product recall serial number: 0158

Additionally, the Allstate Distributor PRN references the original (associated) PRN issued by their supplier, Medical Manufacturer. A copy of the PRN is provided to the United States regulatory authority as required by regulation.

Once received, Healthy Hospital responds with an electronic message acknowledging receipt of the PRN and issues an internal notification to each dialysis centers to immediately stop any further use of Best RD Catheters from Allstate Distributors production batch 15-9-11.

**PRN3 (See Figure 13 PRN in Multiple Jurisdictions)** is issued from Allstate Distributor to the ORKM and contains the relevant information specified by national regulations in Canada. Allstate Distributor is uniquely identifying this recall using the GS1 document identification standard (GDTI).

- The globally unique recall identifier is 6401234017992C0163
- Allstate Distributor GS1 Global Company Prefix: 6401234
- Document: 017992 (internal document type used for product recall)
- Check digit: C
- Product recall serial number: 0163

The PRN references the original (associated) PRN issued by the catheter producer, Medical Manufacturer. Regulatory authorities in Canada are provided a copy of the PRN as required by national regulation.

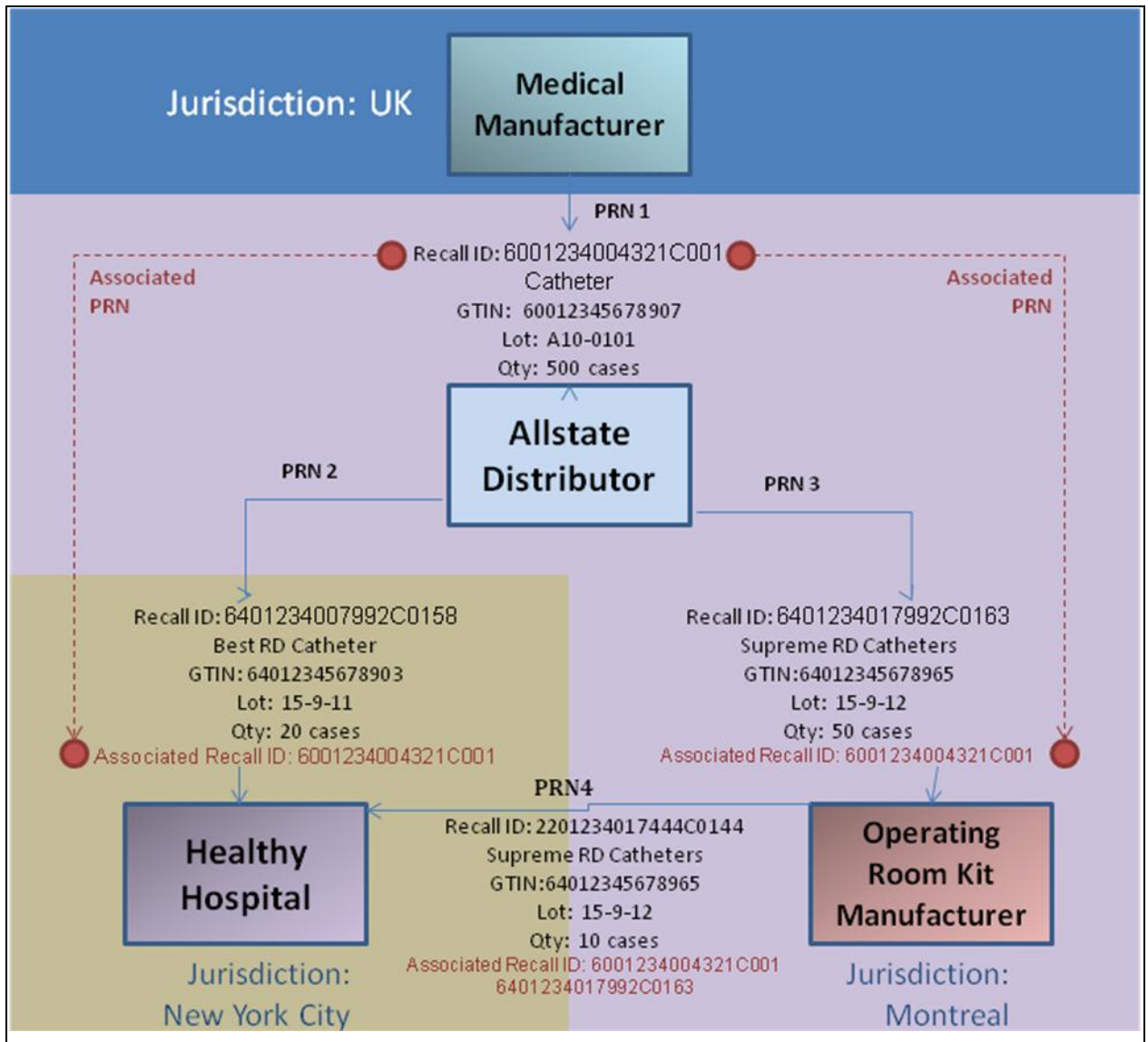
Once received, the ORKM responds with an electronic message acknowledging receipt of the PRN and immediately acts to stop the sale of Supreme RD Catheters from Allstate Distributor production lot 15-9-12.

**PRN4 (See Figure 13 PRN in Multiple Jurisdictions)** is issued from ORKM to Healthy Hospital. It contains the relevant information specified by national regulations in US. ORKM is uniquely identifying this recall using the GS1 document identification standard (GDTI). Additionally, ORKM communicates via email a set of success criteria for the recall to Healthy Hospital.

- The globally unique recall identifier is 2201234017444C0144
- ORKM GS1 Global Company Prefix: 2201234
- Document: 017444 (internal document type used for product recall)
- Check digit: C
- Product recall serial number: 0144

The PRN references the original (associated) PRN issued by the catheter producer, Medical Manufacturer and the PRN issued by the Allstate Distributor. Regulatory authorities in US are provided a copy of the PRN as required by national regulation.

Once received, the Healthy Hospital responds with an electronic message acknowledging receipt of the PRN and immediately acts to stop the sale of Supreme RD Catheters from ORKM production lot 15-9-12.

**Figure 13** PRN in multiple recall jurisdictions


**July 28:** Healthy Hospital has met United States regulations by notifying consumers of the potential product hazard. Healthy Hospital is confident that all unsold quantities of the specified Best RD Catheter product and Supreme RD Catheters have been identified.

Healthy Hospital does not expect to handle any additional recalled product and issues a GS1 product removal confirmation confirming the removal of products as per Allstate Distributor recall 6401234007992C0158 and ORKM recall 2201234017444C0144.

As per regulation in United States, a copy of the product recall closeout notification is also sent to the national regulatory authority. A similar communication is not required by Canadian regulation.

**August 2:** The ORKM has complied with national regulations and has notified consumers (Healthy Hospital) of the potential product hazard. They are confident that all unsold quantities of the specified Supreme RD catheters product have been identified and together with customer returns, have been disposed of by hospital staff.

The ORKM does not expect to handle any additional recalled product and issues a GS1 product removal confirmation confirming the removal of products as per Allstate Distributor recall 6401234017992C0163.

**August 3:** Allstate Distributor is satisfied that its recall of catheters has been successfully executed at Healthy Hospital, the ORKM and within their own operations. Allstate Distributor issues individual electronic GS1 product recall closeout notification message to both Healthy Hospital and the ORKM indicating that they consider the individual recall completed/closed and no further action is anticipated.

As per recall jurisdiction regulation, a copy of the product recall closeout notification is also sent to the national regulatory authority. A similar communication is not required by Canadian regulation.

**August 4:** Healthy Hospital acknowledges the Allstate Distributor product recall closeout notification by issuing the appropriate electronic GS1 message. This indicates that the recall has been closed out in Healthy Hospital internal systems. The ORKM issues a similar acknowledgement.

Both of Allstate Distributor's PRN are now completed.

**August 5:** Allstate Distributor is satisfied that it has successfully executed the original PRN issued by Medical Manufacturer and issues a GS1 product removal confirmation confirming the removal of products as required in Medical Manufacturer's recall 6001234004321C001.

**August 6:** Medical Manufacturer has made corrections to their manufacturing process and is confident of no further problems with its catheters. Medical Manufacturer is also satisfied that Allstate Distributor has effectively managed recall 6001234004321C001 and no further risk to Allstate Distributor exists. A GS1 product recall closeout notification is issued to Allstate Distributor.

Allstate Distributor returns a product recall closeout acknowledgement indicating that the product recall has been closed out in Allstate Distributor's internal systems.

The Medical Manufacturer product recall is now completed.

## 5. Peer-to-Peer (One to One) vs Portal Based Notifications (One to Many)

### 5.1. One to One vs One to Many

There are two models for the management of PRNs:

1. One to One [1:1]; and
2. One to Many [1:N]

#### **One to One:**

In a one to one model, each PRN is created and issued directly from the Product Recall Initiator to each Product Recall Recipient. Product Recall Initiators need to have the appropriate recall systems in place to record Global, Category, Recall Jurisdictional and Traceability Partner specific data requirements. These systems need to be able to generate PRNs and issue the PRN to affected recipients. Similarly, recipients need to have recall systems able to receive and process PRNs.

#### **One to Many:**

In a one to many model, Recall Initiators create the PRN and issue to multiple Recall Recipients.

- Global, and Category data is gathered once only by the Recall Initiators as these would be common across recipients.
- Recall Jurisdictional data is entered for each distinct recall jurisdiction.

- Traceability Partner specific data requirements, if applicable, are then added for each targeted Recall Recipient as appropriate.

## 5.2. Product Recall Portals

The emergence of Product recall portals has added a new dimension that must be considered by PRN Initiators.

A Product recall portal is a web-based service that allows PRN Initiators to create, approve and issue PRN to their traceability partners and regulators. A Product recall portals may be used for both, one to one and one to many notifications, within 1 or multiple recall jurisdictions.

With a Product recall portal, Initiators and Recipients share a common workflow process within the portal environment to manage the PRN process and report on product recall progress without the need for changing their internal recall systems.

When executing a PRN within one or across recall jurisdictions, PRN Initiators need to be aware if Product recall portals are used by their traceability partners in order to effectively execute the PRN.

Some of the considerations that must be taken into account include:

1. Registration requirements to the Product recall portal
2. Account configuration and set-up required before the use of a portal
3. GDTI Generation (Product recall portals typically generate the GDTI for a PRN created within the portal environment)
4. End to End notification process within the portal and other portal functionality

Recall Initiators might need to issue notifications to traceability partners for whom the use of a portal might be a requirement.

Recall management plans need to take into consideration traceability partner specific notification requirements, including the use of portals. Recall plans must be updated on a regular basis to capture potential changes to traceability partner notification requirements.

## 6. Appendix

### 6.1. Key Business Principles

The following business principles are central to understanding the product recall process. They are reprinted here from the GS1 product recall standard.

#### Product Recall Governance

1. A Product Recall is governed by local regulations, policy and guidelines.
2. Depending on the product and jurisdictions, regulatory bodies provide the regulations, policies and guidelines governing the Product Recall. Regulatory bodies may monitor the effectiveness or issue an order to conduct a Product Recall but typically do not execute the business process. Regulations within a Product Recall jurisdiction and Product Recall classification will determine which traceability partners are involved.

#### Identifying a Product Recall Notification

3. All Product Recall Notifications must be referenced using a globally unique identifier.
4. For the Product Recall Standard itself, the use of the GS1 key as primary identifier for recipients is recommended, the use of the GS1 Key is not mandatory for Product Recall document recipients.
5. Any change to information contained in a Product Recall Notification requires an updated Product Recall Notification to be issued with a new globally unique identifier. An updated Product Recall Notification prevails over the previous notification.
6. The party that initiates a Product Recall Notification is responsible for assigning the globally unique identifiers for each initial and any updated Product Recall Notifications.
7. An audit trail must be maintained for each Product Recall Notification and must fulfill all jurisdictional requirements. This step is termed as a “good business practice”. The issuer of the Product Recall Notification must provide reference information that enables the receiver to maintain an audit trail of all relevant changes.
8. A Product Recall Notification can reference other documents providing additional detail. Examples include design specifications, media releases, product images, etc.
9. A Product Recall Notification can reference Product Recall Notifications issued by other parties. These are known as Associated Product Recall Notifications. Referencing other Product Recalls is necessary when other Product Recalls have impacted traceable items either upstream or downstream in the supply chain. Product Recall issuers must remain aware of changes to Associated Product Recall Notifications and assess their impact.
10. The problem with a product may be initially identified by any traceability partner, 3<sup>rd</sup> party and/or regulatory authority. Awareness of an issue with a product can be identified by any source.

#### Issuing a Product Recall Notification

11. A Product Recall Notification is initiated by the party who possesses appropriate knowledge of the product, is responsible for its distribution within the supply chain and is accountable for conducting the Product Recall.
12. The Product Recall process is managed between traceability partners who have a direct commercial traceability relationship. The traceability partner issuing the Product Recall is the Product Recall Initiator. Traceability partners receiving the Product Recall Notification are the Product Recall Recipients.

- 13. The Product Recall Initiator must have the mandatory information to issue the Product Recall Notification.
- 14. The Product Recall Notification must identify the type or category of product impacted. A global classification or categorization must be applied.
- 15. A Product Recall Notification must apply to one or more:
  - Product
  - Product + Batch / Lot Number
  - Product + Serial Number
  - Product + Dates (for example expiry or best before dates)
  - Logistic Unit
  - Shipment
- 16. The globally unique Product Recall Notification identifier can apply to multiple Product Recall jurisdictions provided the jurisdictional criteria are the same. Where the jurisdictional criteria are different, separate Product Recall Notification identifiers are issued.

**Issuing Product Recall Notification Updates**

- 17. An initial Product Recall Notification is issued to initiate the Product Recall. Product Recall Notification updates can be sent to communicate changes to the initial Product Recall Notification.
- 18. When a Product Recall Notification is updated, the updated notification must be assigned a new globally unique identifier.
- 19. An updated Product Recall Notification prevails over the previous notification.

## 6.2. Glossary of Terms References

 **Note:** Reference the following documents to gain further details on implementations.

Term	Reference
GTIN	GS1 General Specification
GLN	GS1 General Specification
GDTI	GS1 General Specification
Recall Jurisdiction	Product Recall BRAD / Product Recall BMS

## 6.3. Additional Reading

- Product Recall Standard
- ISO Standards
- Product Safety Standards
- Product recall guidance report prepared for the US Grocery Industry by Deloitte ("Recall Execution Effectiveness. Collaborative Approaches to Improving Consumer Safety") for assistance in obtaining a copy, please contact GS1 US ([www.gs1us.org](http://www.gs1us.org)).