





Recall / withdraw a product

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Recall / withdraw a product

Recall / withdraw a product

Areas affected by, and subject to guidelines from STAND are:

- · Implementation of actions when an incident occurs, using the notification schema for recall, withdrawal or blocking of a product
- Alternative ways to track and trace an item in the value chain

Implementation of actions when an event occurs

If an event occurs, the supplier of the product must carry out a risk analysis as quickly as possible.

Risk Analysis

The EU directive on general product safety and food safety / traceability requires manufacturers to take precautions to avoid risk through

- · withdrawal of products from the market, or
- effective notification or recall of consumer products.

This assumes that companies are familiar with the risks the products may have and have preparedness to ensure that they act quickly, correctly and efficiently in case of adverse events.

Risk assessment may also contain items other than food safety. It is especially the risk that products with quality errors will be released to the market, which can have major financial consequences and harm the reputation of the company.

The risk analysis always takes the starting point of an intentional or real event, something unforeseen as occurring and which implies a potential risk. The degree of risk must be determined (probability x consequence).

Procedures, contingency routines etc. must be prepared to ensure that the event is handled in a fast, correct and efficient manner. This also includes communication measures internally within the company, towards the other part of the value chain, towards authorities and consumers. The risk analysis consists of three elements that both government and industry should work in a similar way:

- 1. Risk assessment
- 2. Risk management (withdrawal / recall)
- 3. Risk communication

1. Risk assessment

The elements of a risk assessment are: Product, type of risk, probability and consequences.

For products that the company distributes and sells in the value chain, the following must be considered:

- Type of risk
 - · consumer health and safety
 - corporate reputation
 - · economic aspects.
- The likelihood of an event occurring in most cases is a purely subjective assessment and can for example be graded
 - 1. = Low (rare occurrence)
 - 2. = Medium (occasional)
 - High (often occurring)
- The consequence, especially the health, is also a subjective assessment that can be graded in the same way as the probability
 - 1. = Low
 - 2. = Medium
 - 3. = High

Compilation and treatment of the above factors gives an assessment of the risk that the company must consider.

The supplier must do a worse-case risk assessment where the supplier considers risk of the product being used in a different way from the purpose.

2. Risk management (withdrawal / recall)

Based on the risk assessment, it must be decided what actions should be done for the product.

Examples of actions:

a) Withdrawal

Withdrawal means removing the products from the value chain distributors / store. The purpose is to prevent products reaching the consumer.

Withdrawal does not imply any kind of notification to the consumer. However, in some cases where the product may have been sold to the consumer, still only a withdrawal in the distribution chain / shop will be carried out. It is therefore assumed that the product does not cause any health hazard and that it is a small quantity.

b) Recall

Recall is the procedure that is implemented when the product may have reached the consumer.

There is a possible high risk that the products may be hazardous to health.

It is crucial for the company that the recall is made known to the public.

According to the Food Law, the actors have a duty to issue a warning.

The company must consider possible alternatives with stakeholders, including authorities, based on regulations, procedures, contingency routines and the like. It must be clearly described how the products are to be handled and who is responsible for this.

Examples of handling:

- · Distributor / Retailer disposes of the product on-site
- · The product is destructed at an approved waste management facility
- The product is returned to the distributor and further to the supplier
- Consumers must dispose of, or return the product

The parties must clarify who is responsible, for example, the distributor must deliver products to the supplier or the supplier must retrieve products himself at the distributor / retailer.

The supplier must also consider whether it is necessary to inform the authorities of the incident. If the consumer is informed, it is important that the supplier has the capacity to handle any customer requests.

3. Risk Communication

Open and correct information must be communicated to customers (possibly suppliers), the press and authorities.

Distributors have constructed their own systems and routines for alerting crisis situations and blocking of the products against their distribution warehouses and retailers.

This ensures a consistent and effective handling of withdrawal, recall or blocking internally within the companies.

Alarm / Notification

In case of an emergency, notification of recall or withdrawal shall be given to a point of contact agreed by the parties in advance. At the distributors, the alert can be the distributor's quality department, asset protection department or distribution warehouse (to be agreed between supplier and customer). The point of contact should always be staffed.

Use of the RECALL portal / notification schema

In case of recall / withdrawal notification, Tradesolution's RECALL portal or <u>Notification schema for recall, withdrawal or blocking</u> of a product shall be used. Notification schema will be phased out over time, at a time decided by STAND.

Here is an animation of how the ReCall portal can be used in case of a recall:

The RECALL-portal / notification schema can also be used in situations that do not present a health risk, but where you want to recall products with a quality issue.

All written notification to distributors / distribution warehouses must be confirmed by oral conversation.

Distributors have constructed their own systems and routines for alerting crisis situations and blocking of the products against their distribution warehouses and retailers. It is recommended that the suppliers take a thorough look at these.

Information to authorities and the media

It is recommended that interested parties (supplier and customer) mutually inform each other before proceeding with information.

It is important that authorities and media are informed at the right time. What information that is required depends on the severity and extent of the event / crisis.

Additional Information

Additional information about the case may include:

- · Copy of press releases
- · Further information on risks or hazards when consumed
- · Information about when the product is expected to be available again (reported fit for consumption) in case all products are withdrawn
- Where to find additional information
- · A precise description of the handling of the product, both at the distributor and retailer

Closure of the case

It is important that the event / crisis is terminated when it is under control. The information that should be communicated is:

- · The time when the product fit for consumption is available again
- Identification (characteristics) of a product fit for consumption
- · Economic conditions (settlement, crediting)

In cases where the product is to be destroyed, this must be done at an approved disposal facility, and without danger of contamination.

Recommended traceability methods in the value chain

Traceability using pallet labelling and EDI Despatch Advice

The recommended traceability method involves labelling load carriers with GS1 labelling system combined with EDI Despatch Advice (Advance Shipping Notice(ASN)).

For products distributed through the retailer's distribution warehouses, the industry's unified guidelines for the identification and Distribution Units (DU) are based on GS1 standards.

STAND Tracking

To conduct traceability, each actor in the value chain must have a system that can store and process Distribution Units (DU) or logistic units with unique identifiers.

The importance of SSCC as the primary tracking key for deliveries

SSCC is the most important tracking key in the retail value chain. For each pallet identified and marked with SSCC, all products that are on the pallet are linked with full tracking information (GTIN, batch / lot and shelf life). This information is sent to the buyer in an EDI Despatch Advice.

A prerequisite for the tracking information to remain intact is that an SSCC is not reused.

Reusing a SSCC can result in a pallet being stopped at the Goods Reception by the recipient's IT system, anticipating that the pallet has been received earlier. The recipient must then issue a new SSCC for the pallet, mark it and link the contents of the pallet to the new SSCC.

Since the pallet now has a new SSCC, it can no longer be used as a mutual tracking key in the retail value chain. In case of an incident with a possible recall / withdrawal of products, this could be critical.

STAND has therefore decided the following:

"For trading in Norway, it is a requirement that SSCC shall not be reused until after a minimum of 6 years. This is rooted in the Norwegian Food Safety Law, requiering a minimum traceability of 5 years. This also includes products that are outside the scope of the Norwegian Food Safety Law".

Traceability at and from sender

Each packaging level (Consumer Units (CU), Stock Keeping Units (SKU), Distribution Units (DU)) has an assigned GTIN and must include a bar code on the label.

On Consumer Unit (CU), GTIN should preferably be labelled with the EAN-13 bar code symbol.

Stock Keeping Unit (SKU) on the Distribution Unit (DU) must be labelled with an approved bar code symbology and linked to the Distribution Unit's (DU) unique identification.

Each pallet must be labelled with one GS1-128 bar code pallet label. The label contains a unique identifier (SSCC) which enables a link between the Stock Keeping Unit (SKU) on the pallet and the batch / lot number stored in the sender's IT systems.

If the pallet is split or changed (for example, to one Mixed pallet or Promotional Unit, it shall be identified with a new GS1-128 label and SSCC. Mixed pallets are not labelled with product information.

The product information is attached to the pallet's SSCC by scanning each Stock Keeping Unit (SKU) when the Distribution Unit (DU) is being assembled.

Once the sender has created the connection between the Stock Keeping Unit (SKU and the Distribution Unit (DU) and secured this, the information can be used to make an EDI Despatch Advice.

The EDI Despatch Advice is then sent from the sender to the recipient of the products. The parties are identified with GLN. This provides a clear and secure identification of the parties and is central to traceability. The Despatch Advice contains all relevant product information (GTIN, batch / lot and shelf life) about the shipment, and that it ties it to each Distribution Unit (DU) using SSCC.

For shipment, the supplier scans all outgoing Distribution Units (DU) and thus has a unified link between the individual product, its associated batches and which customer receives the product. This also enables effective control of the sending of correct products to customers.

Sender sends EDI Despatch Advice to recipient at agreed time.

Traceability at receiver

When the products arrive at the recipient, each pallet will be scanned.

All Stock Keeping Units (SKU) and Distribution Unit (DU) information is received in the EDI Despatch Advice. Using the EDI Despatch Advice, the tracking information is taken care of and significantly simplifies the products receipt.

The link to the product information occurs when the recipient scans the SSCC on each Distribution Unit (DU). Here, the recipient connects information about the products (GTIN, batch and shelf life information, against the sender (GLN).

For a Standard pallet all relevant information can be scanned from the Distribution Unit (DU) labels. This ensures that correct products are received at the same time as traceability information can be linked to the individual supplier. This simplifies and ensures the sharing of proper traceability information.

Mixed pallets must be split into the warehouse, and through IT support ensure that accurate and statutory traceability information is safeguarded and connected correctly.