OPERATIONAL GUIDE FOR THE RECALL OF IMPORTED FOODS IN THE PACIFIC
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IN THE PACIFIC
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Introduction

Background

The recall of food is a fundamental tool countries can use to effectively manage risks related to food safety incidents and emergencies. Measures to implement food recalls need to be embedded in the national legal framework for food safety, and food business operators ideally should be required to have food recall plans in place. To assist businesses to more effectively and efficiently conduct food recalls, food safety authorities need to develop guidance for business operators that keeps pace with legislative developments, train inspectors in food recall procedures, work in collaboration with businesses, and educate and inform consumers.

The need for Pacific island countries and areas to develop and improve food recall systems is even more urgent given the limited resources governments in the Pacific have to ensure the safety of food and the significant increase in reliance on imported food, which now represents a large percentage of all food being consumed in the Pacific. The globalization of the food chain has led to a greater variety of food available to Pacific islanders. However, the globalization of food not only brings benefits, it also increases the risk of unsafe food spreading across borders.

Purpose of the operational guide

In 2012, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) developed the FAO/WHO guide for developing and improving national food recall systems. The guide provides support to countries in establishing and implementing an effective national food recall system to respond to food safety events or emergencies. Drawing on demonstrated best practices, the elements for an effective national food recall system, as well as the process for establishing, reviewing and/or improving the national food recall system, are described as essential components of a national food safety system.

This guide has been developed based on the 2012 guide. The principles outlined in that document are applied in this practical operational guide that is tailored to the unique Pacific context and specifically focuses on recalls of imported foods and the use of the International Food Safety Authorities Network (INFOSAN) as a mechanism for rapid exchange of information among countries.

Target audience

The primary target audience for this guide – Operational Guide for the Recall of Imported Foods in the Pacific – is food safety authorities and all other national authorities working in the area of food safety in Pacific island countries and areas. They will also be useful for businesses importing, manufacturing and wholesaling food in the Pacific and for consumer organizations operating in the Pacific. Engaging these latter groups will facilitate the development of an effective recall system, applying the notion of “shared responsibility”. In turn, this will better protect public health, reduce risk to businesses and enhance confidence in the safety of the food supply.
Definitions

Food recall
The action to remove food from the market at any stage of the food chain, including food possessed by consumers. In this document, food recalls are discussed in relation to food safety issues including hazards, allergens, labelling concerns and nutritional inadequacy concerns for infants.

Food recall plan
The procedures and arrangements that a food business operator may have in place to retrieve food and food products from the food chain if a problem arises.

Food business operator
The person/company who undertakes, whether for profit or not, any activities related to any stage of the food chain.

Food safety authority
The relevant government agency, ministry, authority, unit or group that is tasked with the responsibility for ensuring that food safety recall systems are in place and operate according to requirements. For example, the food safety authority may regulate, enforce, implement, inspect, audit and verify food recalls conducted by food business operators.

Lot
A definitive quantity of a commodity produced essentially under the same conditions.

National food recall system
The system or framework that national governments put in place for effective food recalls. The system or framework may include the legislative framework, guidance, training, communication mechanisms, record-keeping, evaluation, etc.

Traceability
The ability to follow the movement of a food through specified stage(s) of production, processing and distribution.
1. Food safety events leading to the recall of a food product

Food safety events requiring a recall may be of several kinds: microbial contamination, chemical contamination, the presence of a foreign object, the presence of an unlabelled allergen, incorrect labelling, and/or nutritional inadequacy, especially in foods targeting infants.

1.1 Microbial, chemical and physical hazards

The event may relate to microbial contamination where the food product becomes contaminated with various pathogens such as bacteria, viruses or parasites. Recalls of this type may pose a significant health risk for consumers depending upon the pathogen implicated. Particularly vulnerable consumers may include pregnant women and their unborn babies, young children, older people and immunocompromised individuals. Chemical contamination includes contamination of a food with substances likely to pose a risk to consumer safety, such as high levels of mercury, lead, melamine, etc. Contamination of food with biotoxins (such as histamine in fish, aflatoxins in nuts and paralytic shellfish toxin in shellfish) is another cause of food recalls. The presence of foreign matter (such as glass, metal and plastic objects) with the potential to cause harm to human health is a further form of contamination warranting a food’s recall.

1.2 Allergens and labelling errors

Another form of food safety event warranting a recall is the presence in the food of an undeclared allergen. The presence of the allergen is itself not a cause for recall provided those consumers who are at-risk are properly informed. While the presence of an allergen without declaration might in itself be a labelling omission or error, the potential adverse health impact warrants that undeclared allergens be recognized as a separate category of food safety event. Finally, recalls classified as a “labelling recall” could still put the public at risk if, for example, the product is meant to be fortified and is labelled as being fortified but fortification levels of the product do not comply with the labelling. Another example of a labelling error of potential concern is labelling with an incorrect use-by date or no use-by date, when required. A further example of a food safety event related to labelling might be the failure to label in an appropriate language, for example English or French, and that failure could result in misuse of the product leading to harm.

1.3 Nutritional inadequacy

In recent decades, child mortality has decreased considerably, but still millions of children under 5 years of age die each year, mainly from preventable causes. Immediate breastfeeding – putting the baby to the mother’s breast within an hour of birth – would significantly reduce neonatal mortality. Yet, while breast milk is the best and safest source of nutrients for infants, many parents still purchase infant formula products. In addition to the potential of preparing such formula with unsafe water supplies, the nutritional inadequacy of infant formula products can also create public health problems for infants relying on that formula as their main source of nutrients. In 2004, at least 50 Chinese babies died and more than 100 were severely malnourished after being fed fake milk formula. The fake products contained only 6% of the vitamins, minerals and protein needed for a growing infant. One brand contained less than one gram of protein per 100 grams, and iron and zinc were entirely absent. In some cases the babies died after just a few days of being fed on these products. In such extreme cases, a food recall is warranted.
2. Recognizing the need for the recall of a food product

Recognition by food safety authorities that contaminated food is about to be, or has already been, imported into a country or territory can be achieved in several different ways. The authorities may be informed by international organizations, by authorities in the country of origin, by authorities in trading partner countries, by other authorities within their country (e.g. foreign affairs), by business operators, through consumer complaints or as a result of inspection and/or analysis.

2.1 Notification from International Food Safety Authorities Network (INFOSAN)

INFOSAN is an international network managed by WHO and FAO. It is an electronic network of food safety authorities in 181 Member States. It is able to exchange information rapidly regarding the international distribution of unsafe food with the potential to impact on human health. Each country should designate an INFOSAN emergency contact point for food safety emergency situations. Countries may also identify INFOSAN focal points in the ministries and agencies responsible for food safety. The INFOSAN emergency contact point can act as a national contact point for information exchange domestically among ministries and agencies involved, as well as between the country of concern and the INFOSAN Secretariat.

The network is managed by the INFOSAN Secretariat, with WHO as the primary contact address. The Secretariat maintains a list of national emergency contact points. However, because food safety is a multidisciplinary endeavour, it is seldom dealt with by a single agency in any given country. INFOSAN also includes other members called INFOSAN focal points who act as contacts for other national agencies involved in food safety across the food chain. The Secretariat has a significant role in informing a country’s INFOSAN emergency contact point if a food that may be contaminated and unsafe for human consumption has entered international trade.

Given that Pacific island countries and areas have limited human resources, it is important that the INFOSAN emergency contact point be available to receive information provided by INFOSAN at all times to ensure the information is received, interpreted and acted upon in a timely manner. In situations where the primary officer at the emergency contact point is not able to receive this information in a timely manner – for example, the officer responsible as the contact point is on leave or is off-island and has limited Internet connectivity – it is essential that another officer monitors communication between the contact point and the INFOSAN Secretariat.

The information received from INFOSAN generally will be dynamic in nature, as additional information is obtained about the extent of the food safety concerns associated with the product or products. This means that as more information becomes available there will be ongoing communication between the INFOSAN Secretariat and the INFOSAN emergency contact point.

2.2 Notification from outside the country or area

The food safety authorities in the country of export origin may have identified a product that is of concern in their own country and that may have been exported beyond its borders. As a result of tracing the distribution of the affected product, they may be able to identify that the product has been exported, that it has been exported to the Pacific or more specifically that it has been exported to a specific country or area in the Pacific. This information may be shared through INFOSAN,
through the INFOSAN in the Pacific group on the INFOSAN Community Website, and through direct
communication between food safety authorities or through the foreign affairs department. In the
past there have been delays in information reaching the relevant food safety authorities when it
has been provided through the more formal pathways of foreign affairs departments. It is therefore
essential to both maximize use of the INFOSAN and to ensure that national food recall systems are
developed with effective interagency communication that allows a rapid response to food safety
events. Another way that notification could arise from outside the country or area is through direct
communication between trading partners (exporter/importer) without the involvement of national
authorities. Again this may result in a delay in the information reaching the relevant food safety
authorities. When information about a food recall is shared directly from authorities or businesses
in the country of origin and no notification has yet been received through INFOSAN, the INFOSAN
food safety emergency contact point should pass that information immediately to the INFOSAN
Secretariat.

2.3 Notification from within the country or area

Food business operators may identify the potential problem themselves through their own in-house
testing, which may indicate there may be a potential problem with a particular food product or
batch. They may receive consumer or trade complaints, for example, a phone call or email from a
customer or wholesaler informing the business about a potential problem. They may also receive
information from a supplier of a raw material or from an importer who may notice that a product has
been damaged during transportation from the country of export origin, or who has been informed by
the company from which they have imported the product that there are potential safety concerns.

Food safety authorities may also be informed of a possible concern with a food product
from agriculture and fisheries officials, customs officers, trade inspectors, consumer council
representatives, or other government departments with a role to play in the food production and
consumption chain. It is therefore important that each of these agencies is aware of who needs to be
contacted in the food safety authority.

Notification from within the country or area may also occur as a result of monitoring and surveillance
programmes. In such cases, it is again important that there is a strong link between those agencies
conducting monitoring and surveillance and food safety authorities.
3. Product identity

When food safety authorities become aware that a defective and potentially unsafe food product may be in circulation, it is imperative that they take immediate action to properly identify the potentially defective food product as thoroughly as possible.

To properly identify the food so it can be better determined if the product has been imported into the country or area so action can be taken to protect human health, if necessary, it is important to obtain information regarding the following:

- the product identity including its trade name (as it appears on the product packaging), the type of the food (for example, instant noodles), date markings, packaging sizes and types, and any other identifying markings available including any codes such as lot or batch codes;
- images of the product(s) and product labels;
- the defect’s or contaminant’s identity and possible public health consequences of consuming affected food;
- the results of any testing undertaken;
- name and address of the manufacturer and country of origin/country of manufacturer, packer, seller, exporter, importer, as appropriate of the product; and
- any details that relate to the export of the product and to the importer, including an export certificate.

Gathering this information will enable the food safety authorities to communicate more effectively regarding a product of public health concern, and if the product is in international circulation (imported/exported) it will also make for a more effective communication with INFOSAN.
4. Determining if a food has been imported and assessing the risk

When food safety authorities receive information that a defective food product may be in circulation, it is important that they quickly put in place a process to assess the risk in order to make the best management decisions possible. If the information has arisen from outside the country or area, the next step is to confirm whether the product has been imported. This may require the authority to communicate directly with importers and to examine relevant imported food control records held by the concerned agencies/authorities, for example biosecurity, customs and health. Alternatively the food safety authority in the country of origin may be able to provide information regarding the dates and means of export to the Pacific.

4.1 Assessing the risk

As risk assessment and risk management processes are ideally separated, this means it would be ideal to have already established a risk assessment team for such food safety emergencies.

A risk assessment team could be established in a number of ways. For example, a team could:

- include an individual from within the agency responsible for food safety control, working with experts with knowledge of chemical and microbiological hazards in foods and where needed experts in the nutrition of infants or immunology;
- make use of the INFOSAN Secretariat and any risk assessment that would be undertaken as part of the work of INFOSAN; and/or
- include a separate group of experts providing advice to the agency responsible for food safety.

Both a risk assessment and a preexisting standard need to be defensible to senior officials, business operators and the public. If the risk assessment results in an imported food product being banned, it may also need to be defensible to authorities in the country of origin.

4.2 Identifying the hazard

In any risk assessment, the first step is to be clear about the hazard associated with the food safety event. This means the risk assessment team needs to identify the hazard as thoroughly as possible and then characterize it before assessing the likely exposure of the population to the hazard in order to inform risk managers of the risk associated with the contamination event.

Risk assessment can be strengthened if food safety authorities and risk assessors prepare information on known food hazards in advance and keep this information readily available. This information is not only useful in the risk assessment process but also in communicating the risk to higher officials, other agencies, and regulators, business operators and the public.

Of course, the food safety event may be associated with a novel hazard or an unusual hazard that has not been considered in the gathering of such information. Again the presence of microbiologists and chemists in the risk assessment team will help quickly gather the relevant information. In addition, the INFOSAN Secretariat can be invaluable in providing information regarding novel or unusual hazards.
Alternatively, it may be that the country or area has already established a standard for the particular hazard in a given food and that such a standard has been developed based on a prior risk assessment. This might already be the case for all standards developed in the country that are based upon those put forward by the Codex Alimentarius Commission. If a risk-based standard exists, it may not be necessary to conduct a full risk assessment given the time constraints present during emergencies.

**Box 1. Example of a rapid risk assessment on foods adulterated with melamine in 2008**

**Hazard identification**

Melamine is a chemical compound that has a number of industrial uses, including the production of laminates, glues, dinnerware, adhesives and flame retardants. It is a name used both for the chemical and for the product. There are no approved direct food uses for melamine, nor are there any recommendations in the Codex Alimentarius. Melamine is illegally added to inflate the apparent protein content of food products. Because it is high in nitrogen, the addition of melamine to a food artificially increases the apparent protein content as measured with standard tests.

The hazard associated with an imported food may be clearly identified when the country’s food safety authorities have been notified by the INFOSAN Secretariat or by the exporting country’s food safety authorities. In contrast, the hazard may not be as clearly identified if the food safety event has been brought to attention through consumer complaints or by notification from food business operators.

Where the hazard has yet to be determined, for example consumers are ill but the cause of illness has not yet been identified, there is an urgent need for cooperative action with epidemiologists, analysts and food business operators to identify the hazard as soon as possible.

**4.3 Characterizing the hazard**

To better understand or characterize the hazard associated with an imported food, it is important to identify the characteristics of the hazard that affect its ability to cause disease in the host, for example infectivity, pathogenicity, virulence or toxicity. It is important to understand the toxicological and adverse health effects that may be associated with exposure to the hazard and who is susceptible to such a hazard, including if there are people among the exposed population who might be more susceptible because of their age, immune status, concurrent illness, medical treatment, genetic background, pregnancy, nutritional status or social status. In characterizing the hazard’s health effects it is also important that risk assessors determine the short- and long-term consequences of the hazard as well as the persistence of the hazard in the food. In addition, environment and human and dose-response data may also be considered.

**Box 2. Example of a rapid risk assessment on foods adulterated with melamine in 2008**

**Hazard characterization**

Trace quantities of melamine and related compounds that are of no toxicological importance may legitimately be present in food. This may arise during processing through leaching from food-grade melamine contact material. Melamine may be detected in beverages at levels of 0.5, 0.7, 1.4 and 2.2 mg/kg in coffee, orange juice, fermented milk, and lemon juice, respectively. The United States Food and Drug Administration had previously prepared an interim risk assessment for melamine and related compounds. This risk assessment established a tolerable daily intake (TDI) of 0.063 mg/kilogram body weight/day.
4.4 Assessing exposure

Dietary exposure assessments and intake assessments are also an important part of any risk assessment. Many countries’ food safety authorities use internationally accepted “dietary modelling” techniques to conduct dietary exposure assessments. These assessments consider the potential exposure of populations to chemicals such as food additives, pesticide residues and chemical contaminants. They look at the hazard level or concentration and the food consumption data for the populations of interest.

Most Pacific island countries and areas are only just initiating these assessments, and expertise in this area is in the development phase. Again this is an area where food safety authorities of Pacific island countries and areas can make use of existing expertise and exposure assessments available through INFOSAN. Other sources of valuable information in this area include the WHO/FAO Joint Expert Committee on Food Additives (JECFA) and the Joint Meeting on Pesticide Residues (JMPR). Using these sources, combined with any data the country or area has on food consumption, will make the exposure assessment more relevant to the particular country’s situation. Other sources of information could include Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food) and other countries food intake data and import/trade data, especially for countries heavily relying on food imports such as Kiribati, Nauru and Tuvalu.

Box 3. Example of a rapid risk assessment on foods adulterated with melamine in 2008

Dietary exposure assessment

- For infant formula, at levels of contamination of 100 ppm an infant will quickly exceed the TDI, if fed exclusively on formula.
- In products containing 10% milk powder, at melamine concentrations of 10 mg/kg, unrealistic amounts of food would have to be consumed to exceed the TDI (e.g. 44 kg for a 70 kg adult).
- With 100 mg/kg of melamine, a 20 kg child would have to eat more than 1 kg of that food before exceeding the TDI.
- With 1000 mg melamine per kg of food, adults would still have to consume over 400 g of food to exceed the TDI, and a 20 kg child 130 g.

Based on levels of melamine detected in White Rabbit candy, a concentration of melamine of 180 mg/kg was set for foods similar to White Rabbit candies, i.e. soft, chewy, confectionery.

4.5 Characterizing the risk

Risk characterization brings together the information from the hazard characterization and the exposure assessments to generate a risk estimate. Risk characterization presents the results of the risk assessment and is intended to respond to the risk managers’ needs. The risk characterization may apply to the whole population or for a specific subpopulation, for example infants, pregnant or lactating women, older people or people who are immunocompromised. The risk characterization may vary from country to country, and it may have to be completed for a variety of risk management strategies.
Box 4. Example of a rapid risk assessment on foods adulterated with melamine in 2008

**Risk characterization**

- It has to be noted that there is a large uncertainty regarding toxicity, and insufficient information is available regarding specific sensitivity of infants. There is also a lack of information on the interaction of melamine and cyanuric acid.
- For infant formula, even at relatively low levels of adulteration, an infant will quickly exceed the TDI for melamine, if consuming formula only.
- Foods with low levels of dairy-based ingredients, such as candies and biscuits, are likely to be infrequently consumed and in small amounts so they are not considered to be a high-risk food for potential dietary exposure to melamine, even if the dairy ingredient has been adulterated.

Every risk assessment has some degree of uncertainty attached to its results (the characterization of risk). For example, there will be times when you have to make some assumptions because there are data gaps. Assessments or assumptions need to be identified clearly. The risk characterization should include a description of the strengths and limitations of the assessment along with their impact on the overall assessment.

### 4.6 Managing the risk

The risk assessment will allow authorities to determine the risk of harm from the defective product to the public and enable them to take appropriate actions to mitigate any harm arising from the product. It may be that limits already apply to the hazard or there may be a need to establish such limits or modify such limits.

The risk assessment may also identify whether or not the defective food product has yet been distributed to wholesalers, retailers and the general public. Depending upon the extent of distribution of the defective food product, there may be need for businesses to initiate either a trade recall or a more broadly applied recall to retailers and consumers.

Generally a trade-level recall is conducted when defective food product has not been available to the general public but has been sold to other food businesses. A more broadly applied recall involves recovering a food product from all points in the production and distribution network, including any affected product in the possession of consumers.

Box 5. Risk management decision related to foods adulterated with melamine in 2008

**Risk characterization**

When considering regulatory actions to be taken on contaminated food products, the potential human health impact, availability of foods and other factors should be taken into account, along with the uncertainty associated with the risk characterization.

- A maximum level of 1 mg/kg for melamine in infant formula is considered appropriate.
- A maximum level of 2.5 mg/kg for melamine in dairy-based foods and foods containing dairy-based ingredients is appropriate and acceptable.
- A level of melamine above 2.5 mg/kg is indicative of food adulteration.
- Food contaminated with melamine above these levels is recalled and destroyed.
5. Legislation related to food recalls

The optimal key components of a legal framework include provisions that address:

- food recall plans;
- notification of food safety authority of a possible recall;
- traceability;
- empowerment of the food safety authority to enforce recalls, when required and conducting recalls when necessary; and
- the implementation of, and cooperation with, a food recall.

Under the national legal framework, food business operators should only be allowed to market safe food. If the food safety authority determines that there is a reasonable probability that a food is adulterated, unfit, unsafe, unsuitable or mislabeled and that the consumption or use of the food may cause adverse health consequences to humans, the authority should provide any and all business operators relevant to the manufacture, wholesale or import of the food with an opportunity to cease distribution and initiate a food recall in accordance with published guidance provided by the food safety authority.

In order to ensure that any food product that may be harmful to human health is removed from the food distribution chain as quickly and as smoothly as possible, it is helpful for food businesses be as prepared as they can be to initiate a recall of a defective food product. Therefore it is desirable for food safety authorities to require that businesses engaged in the wholesale supply, manufacture or importation of food have a written food recall plan in place.

A food recall plan is a written document food business operators prepare detailing their recall systems. It enables a food business operator to recall unsafe food from the marketplace and consumers, effectively and efficiently, in order to protect public health and safety. Box 6 provides an example of legislation requiring this to occur.

Box 6. Food recall plans

1. A food business operator engaged in the wholesale supply, manufacture or importation of food shall:

   (a) have in place a plan to effectively and efficiently recall food;
   (b) set out this plan in a written document and make this document available to an authorized officer upon request;
   (c) test that the plan is functional at least every two years; and
   (d) apply all appropriate aspects of this plan when recalling food unless a variation to the plan is requested by an authorized officer of the food safety authority.

(N.B. Boxes 6–14 include portions of sample food safety legislation, and the various elements or clauses of the sample legislation are numbered consecutively throughout Boxes 6–14.)
Food businesses operators need to contact government as soon as they consider a food recall is, or may be, needed (see Box 7 for legislative clauses addressing this need). This will ensure there is coordination in the recall process as the business may not be the only business having to recall a food product. Notification to the food recall contact point will ensure that all levels of government can facilitate the recall procedure.

**Box 7. Notifying the food safety authority of a recall**

2. A food business engaged in the wholesale supply, manufacture or importation of food that considers a food recall is, or may be, required shall:
   
   (a) inform the national food safety authority as soon as possible after recognizing the concern; and
   
   (b) provide the food safety authority with all information identified as necessary in its food recall plan.

3. A food business other than those businesses prescribed in Clause 2 that considers a food recall is, or may be, required shall inform the national food safety authority as soon as possible after recognizing the concern and provide full information describing the product of concern.

When a food business operator wants to remove food from the marketplace because of quality and not because of concerns for human health, the business should not be permitted to declare a food recall as this will misinform the public and possibly reduce the importance consumers place on food recall notifications. In the situation, where the food business desires to withdraw a food for quality purposes, it should do so as a “food withdrawal”. To illustrate when a business operator may implement a food withdrawal rather than a recall, a withdrawal may be conducted when:

- food has been labelled with the incorrect best-before date;
- food has been contaminated by fermenting yeasts and the product pouch swells;
- food has flat sour thermophilic spore formers present causing the food to sour; or
- food contains foreign objects such as soft pieces of bandages.

**Box 8. Food withdrawals**

4. A food recall shall not be employed by a food business withdrawing food for a quality issue or any other issue not potentially impacting on human health.

5. A food business shall:
   
   (a) inform the relevant food safety authority prior to announcing a food withdrawal to the public; and
   
   (b) not be required to inform a food safety authority when conducting a food withdrawal at the trade level only.

In order to ensure the safety of food, it is necessary to consider all aspects of the food production and distribution chain as a continuum because each element may have a potential impact on food safety. As a given business is part of that food production and distribution chain, it is important that it be clear about its suppliers and be certain that the food being supplied to the business is safe.

It is therefore necessary that a business maintains good records of its suppliers and of the safety and
quality of the food being supplied. The business also has an ethical obligation to know to whom the product is being distributed. When the product is being sold to the general public, it would prove both difficult and intrusive to gather the information beyond what is currently being done. However, importers, wholesalers and manufacturers who distribute the food product to retailers, caterers and other food businesses should keep records of customers – names, addresses and other contact details – and a description of the product supplied to them and the date of supply. Traceability does not in itself improve food safety outcomes, but it can contribute to the protection of consumers against deceptive marketing practices and facilitation of trade on the basis of accurate product description.

An example of legislation requiring the traceability of food is provided in Box 9. The traceability tool should be able to identify at any specified stage of the food chain from production to distribution from where the food came (one step back) and to where it went (one step forward) as appropriate to the objectives of the food inspection and certification system.

Box 9. **Traceability**

6. A food business operator shall keep record of and provide, to the reasonable satisfaction of an authorized officer upon request, the following information relating to food on a food premises:
   (a) the name and business address of the business or person supplying the food to the food business;
   (b) the name and business address of the manufacturer or packer where the manufacturer or packer is the business’ supplier or where the information is otherwise available;
   (c) the name and business address of the importer where the food is imported; and
   (d) the trade name, product identity and a description of the food sufficient to indicate the true nature of the food.

7. In addition to the requirements prescribed in Clause 6, a food business involved in the manufacture, wholesale or importation of a food shall keep record of and provide, to the reasonable satisfaction of an authorized officer upon request:
   (a) complete and up-to-date records of all batches of raw materials and finished food manufactured, wholesaled or imported; and
   (b) the name and business address of any and all businesses to which the product has been distributed.

8. In relation to the records prescribed in Clauses 6 and 7, a food business operator shall:
   (a) hold the records for a minimum number of years as identified by the food safety authority;
   (b) identify personnel responsible for obtaining and maintaining the records;
   (c) identify procedures employed in obtaining and maintaining these records; and
   (d) make the records available upon request of an authorized officer.

In case a food business fails to respond to a food safety event by initiating a food recall cooperatively, the food safety authority needs to be empowered to compel a food business operator to undertake a recall and to ensure they do so in accordance with national legislation; the food safety authority should also be able to supervise food business operators while undertaking the activities associated with a food recall. Boxes 10 and 11 provide an example of legislation that may be used for this purpose.
Box 10. Mandatory food recalls

9. If a manufacturer, wholesale business or importing business refuses to fails to voluntarily cease distribution or recall a food within the time and in the manner prescribed by the food safety authority, the minister responsible for the food safety authority may, by order, require any and all business operators to:

(a) immediately cease distribution of the food;
(b) conduct a food recall in compliance with guidance from the food safety authority;
(c) cooperate, assist and not interfere with actions implemented by the food safety authority to:
   i. conduct a recall where required;
   ii. publish information relating to the recall;
   iii. communicate with food business operators and their employees;
   iv. communicate with members of the public;
   v. investigate the origin and destination of the incriminated food;
   vi. ensure the removal of the food from distribution and sale;
   vii. detain, seize, quarantine, destroy and dispose of the food;
   viii. access business premises to conduct inspections and audits; and
   ix. obtain, remove and hold documentation of relevance to the food recall; and
(d) cooperate, assist and not interfere with any other requests and actions required by the food safety authority to withdraw the affected food effectively and efficiently.

Box 11. Mandatory food recalls and associated offences

10. It shall be an offence if:

(a) a food business operator fails to comply in a timely manner with the minister’s order made under Clause 9; or
(b) a food business operator or any of their employees fails to comply with the requirements of Clause 9.

The legal framework should empower the food safety authority to conduct a recall when and where required, to enforce the provisions associated with food recall and traceability, and to exercise legal action against food business operators who are in violation of these provisions. In such instances, the food safety authority should be given legal authority immediately to detain and seize unsafe food regardless of its location and in accordance with the national legal system. The food safety authority should have authority to investigate the origin and destination of the suspect food, as well as to communicate with any food business operators or the general public about unsafe food, as appropriate, to ensure protection of public health and to initiate necessary legal procedures. To undertake this function, the food safety authority should be granted the power to inspect food business operators and routinely to conduct inspections/audits to verify documentation associated with the recall plan and traceability system.
Retail businesses, catering businesses, hospitals, and any other suppliers and customers of the business that is associated with a recall need to cooperate with and not interfere with the implementation of the food recall either by the food business or the food safety authority. Legislation should also make it an offence for a business or its employees to not cooperate with or interfere with a recall. Box 12 provides an example of such legislation.

**Box 12. Interfering with food recalls**

11. If a food retail business, catering business, hospital or any other supplier – or customer of the business – that is conducting a recall in compliance with guidance published by the food safety authority fails to assist and interferes with the implementation of the food recall, the minister responsible for the food safety authority may, by order, require any and all food business operators to:
   (a) immediately cease distribution of the food;
   (b) cooperate, assist and not interfere with actions taken to:
      i. conduct a recall;
      ii. publish information relating to the recall;
      iii. ensure the removal of the food from distribution and sale; and
      iv. detain, seize, quarantine, destroy and dispose of the food; and
   (c) cooperate, assist and not interfere with any other requests and actions required by the food safety authority to withdraw the affected food effectively and efficiently.

12. It shall be an offence if a food business fails to comply completely and in a timely manner with the minister’s order made under Clause 11.

Recalled food products may be recovered by retailers and wholesalers via their trade customers or via direct returns from the public. The recovered product may be returned to a central site or, in the case of a widely distributed food product, to major recovery sites. Accurate records should be kept of the amount of food product recovered (identification of product and quantity). Also, food that is subject to recall must be handled in accordance with legislative requirements. This legislation needs to require that businesses hold and separate food subject to a recall and food for disposal in general from other food held on the premises. Box 13 provides an example of such legislation. The decision on how to destroy the product or otherwise handle it needs to be discussed with and monitored by authorities.
Box 13. Holding of food for disposal

13. A food business shall ensure that food subject to a food recall shall hold the food and separate it from other food on the premises and label it “recalled food”, until it is:
   (a) destroyed or otherwise used or disposed of so that it cannot be used for human consumption;
   (b) returned to its supplier;
   (c) processed in a way that ensures its safety and suitability; or
   (d) relabelled.

14. It shall be an offence if a food business:
   (a) fails to comply with its obligations under Clause 13; or
   (b) offers for sale, for human or animal consumption, the food being recalled.

Food recall legislation should also specifically require that a person or business conducting a food recall be liable for the cost of the recall, including the cost of disposal and destruction of the affected food and any cost incurred by or on behalf of food safety authorities in connection with the recall (see Box 14).

Box 14. Cost of a recall to be borne by business

15. A food business operator shall be liable for the cost of a food recall regardless of whether the recall is conducted by the business or the food safety authority.

16. The costs referred to in Clause 15 shall include but not be limited to:
   (a) the cost of holding, disposing and destruction of the affected food;
   (b) the cost of communicating with businesses and the public where required;
   (c) any cost incurred by or on behalf of the food safety authority; and
   (d) any cost incurred by or on behalf of local and provincial authorities conducting activities in support of the recall and the food safety authority.

17. The payment of funds associated with the cost liabilities identified in Clause 16c and 16d shall be paid directly to the accounts of the food safety authority for subsequent distribution by the relevant national authorities to those agencies incurring the cost associated with the recall.

18. A food business operator conducting a food recall shall be required to provide a full cash refund to consumers and trading partners returning recalled food.
6. Communication and information sharing within the food safety authority

Food safety officials in a country’s or area’s food safety authority should identify a single contact point, such as a food recall coordinator, and the recall coordinator should nominate an alternative person to monitor the contact point when the coordinator cannot be reached. The coordinator is the person who has responsibility for requesting a risk assessment and supporting the risk assessment process. The coordinator will also be the focal person to liaise all concerned ministries involved and the food business operators about the food recall. The coordinator will collaborate with the contact person at the business in order to gather all necessary information on the food product to be recalled, including why the food is being recalled and action to be undertaken. The coordinator will also assist in the classification of the type of recall, and the development of communications with the public and businesses, and also liaise with senior officers and local health authorities about the food recall. It is imperative that the food recall coordinator ensures communication with senior officials is effective so that they too understand the hazard and risk associated with the defective food product and are able to support the coordinator and defend the coordinator’s actions when required.

The recall coordinator also needs to clarify the need for communication with international organizations and what that means. Under international obligations, it will be a necessity to ensure effective communication with international organizations if the food is in international trade. The recall coordinator may or may not be the INFOSAN emergency contact and is unlikely to be the International Health Regulations (IHR) contact point. To ensure effective communication with IHR and INFOSAN, these two contact points should either be part of the coordination team or clear communication pathways should be established and be effective between them and the recall coordinator.

If the food recall coordinator identifies a need for other members of ministries or departments of health to be engaged in the recall process, he or she should request through a senior officer that a recall coordination team be established within the food safety authority. The coordination team may be necessary for a number of reasons, including the need to obtain additional information for the risk assessment. There may initially be a large quantity of information to collect and analyse. There will be recall information to collect and analyse. It may also be a different unit that has essential information on dietary habits of the population, or a different unit that conducts laboratory analyses, or has a better understanding of essential nutrients in the case of defective infant formula. If a recall coordination team cannot be physically established it is still essential that effective communication with other relevant national health authorities be effective.

An expanded coordination team may also be required if the food business operator fails to conduct the food product recall as guided by food safety authorities’ guidance or in accordance with legislation. In this situation, the recall may have to be initiated as a mandatory recall, which will increase the pressure on food safety authorities to take efficient and effective action.

Where the business is conducting the recall in cooperation with the food safety authority, the food recall coordination team still needs to monitor and analyse the distribution list produced by the recalling food business operator and determine if any follow-up actions are required by the business.
All these steps that need to be taken by the food safety authorities are summarized in Box 15.

**Box 15. Actions for food safety authorities in a food recall scenario**

1. receive information of a possible need for a food recall;
2. establish communication path with relevant businesses;
3. identify all products to be recalled;
4. conduct a rapid risk assessment;
5. notify INFOSAN if the food is in international trade;
6. assemble the food safety authority’s (in some cases the health ministry’s) recall coordination team;
7. reconfirm the identity of all products to be recalled;
8. establish a unique food recall identity number;
9. provide guidance to the recalling business on trade notification;
10. ensure that all products have been detained and segregated;
11. prepare a press release (if required) in support of the business conducting the recall;
12. monitor and analyse the recall;
13. verify the effectiveness of the recall by contacting the recalling business and some of those in the distribution list;
14. monitor the recalled product(s) destruction and disposal or other control;
15. receive and analyse reports of the recall from the business conducting the recall; and
16. review the actions of the recall coordination team in the recall process.
7. Engaging partners in the national government

The recall coordination team may require a multiagency approach depending on the circumstances. Procedures that outline the notification process may be established to facilitate multiagency preparedness. It is particularly useful for agencies involved in border control to be involved and be informed as customs and agricultural quarantine officers might be best placed to prevent further import of the affected product(s). It is essential, therefore, that they know exactly the products on which to focus their attention. Therefore, the food safety authority’s recall coordinator could either expand the recall coordination team or ensure there is an appropriate contact point in these agencies with whom he or she can share the relevant information and the roles and responsibilities of each are clearly defined.

It is also possible that inspectors of the Department of Trade might be well placed to monitor retail outlets to monitor the recall effectiveness of a business operator’s recall. Alternatively this might be the responsibility of rural and town council environmental health officers. To prevent unnecessary duplication of work and inconsistent messaging it is important that roles and responsibilities are identified and agreed before a recall takes place. A list of contacts should be prepared in advance and be kept up to date.

Box 16. Example of contact details at the national and international levels

<table>
<thead>
<tr>
<th>INFOSAN Secretariat</th>
<th>Ministry/Department of Health Food Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Food Safety and Zoonoses</td>
<td></td>
</tr>
<tr>
<td>World Health Organization (WHO)</td>
<td></td>
</tr>
<tr>
<td>Avenue Appia 20, 1211 Geneva 27</td>
<td></td>
</tr>
<tr>
<td>SWITZERLAND E-mail: <a href="mailto:infosan@who.int">infosan@who.int</a></td>
<td></td>
</tr>
<tr>
<td>INFOSAN Emergency Contact Point</td>
<td>National IHR Focal Point</td>
</tr>
<tr>
<td>Phone: xxxxxxxxx</td>
<td>Phone: xxxxxxxxx</td>
</tr>
<tr>
<td>Email: xxxxxxxxx</td>
<td>Email: xxxxxxxxx</td>
</tr>
<tr>
<td>Internet: xxxxxxxxx</td>
<td>Internet: xxxxxxxxx</td>
</tr>
<tr>
<td>Customs</td>
<td>Agriculture Quarantine/Biosecurity</td>
</tr>
<tr>
<td>Contact: xxxxxxxxx</td>
<td>Contact: xxxxxxxxx</td>
</tr>
<tr>
<td>Phone: xxxxxxxxx</td>
<td>Phone: xxxxxxxxx</td>
</tr>
<tr>
<td>Email: xxxxxxxxx</td>
<td>Email: xxxxxxxxx</td>
</tr>
<tr>
<td>Internet: xxxxxxxxx</td>
<td>Internet: xxxxxxxxx</td>
</tr>
<tr>
<td>Ministry/Department of Trade</td>
<td>Foreign Affairs</td>
</tr>
<tr>
<td>Contact: xxxxxxxxx</td>
<td>Contact: xxxxxxxxx</td>
</tr>
<tr>
<td>Phone: xxxxxxxxx</td>
<td>Phone: xxxxxxxxx</td>
</tr>
<tr>
<td>Email: xxxxxxxxx</td>
<td>Email: xxxxxxxxx</td>
</tr>
<tr>
<td>Internet: xxxxxxxxx</td>
<td>Internet: xxxxxxxxx</td>
</tr>
</tbody>
</table>
8. Engagement with provincial and local governments

Provincial and/or local governments may be the appropriate levels to check that food businesses have removed recalled foods from sale. It is also likely that it will be provincial and local authorities who oversee the destruction of the defective food product and who provide certification of what and how much product has been destroyed. It is therefore essential that the food recall coordinator be familiar with communication pathways to these levels of government and these pathways should be identified before a recall is implemented and be used when a recall is in operation. In each level and geographical location of government there needs to be defined food recall contact points with whom the national food recall coordinator can communicate and that food recall contact point should be empowered to coordinate action in the local government area or province. Prior to a food recall being implemented there should also be documented agreement on the roles and responsibilities of the three levels of government – national, provincial and local, and staff at all three levels should be familiar with this documented agreement. As with national government contacts, a list of contacts at provincial and local levels should be prepared in advance and be kept up to date.

9. Communicating with international partners

As discussed earlier in this operational guide, INFOSAN may be the source of information about a potentially imported food product being unsafe for human consumption and an important resource in the rapid risk assessment. Once a recall involving a food in international trade is being conducted in a country or area in the Pacific, it is important that INFOSAN be informed of the recall. The information useful to INFOSAN could include:

- food safety hazards;
- product identity including food category;
- quantity of product that has been recalled;
- purpose of the recall, if INFOSAN itself was not the source of the original information about the need to recall;
- level of the recall;
- human health impact in the country or area, if any has been identified including number of people ill, numbers of hospitalized, and number of people who have died after consuming the food product; and
- the results of any product analysis related to the hazard(s).
Given that INFOSAN makes use of INFOSAN emergency contact points, the recall coordinator in the food safety authority (if not the INFOSAN emergency contact point) needs to ensure this information is available to the relevant contact point in a timely and accurate manner. The information should also be provided to the relevant National IHR Focal Point.

Box 17 provides an example of an INFOSAN emergency alert where authorities in a particular country (Country A) detected thyrotoxicosis in nine adults and one infant and subsequently linked the illness to a particular batch of a given food. The food safety authority of Country A identified the hazard and undertook a rapid risk assessment. The importer was involved in a discussion and consequently initiated a consumer recall procedure. Food safety authorities initiated action to alert medical practitioners and the INFOSAN emergency contact point posted an alert to INFOSAN. This simple example of an INFOSAN emergency alert illustrates how the INFOSAN emergency contact point in Countries B to D would receive the information from the INFOSAN emergency contact point network and gives some indications of who the INFOSAN emergency contact point of Country B should inform and how.

Box 17. Sample INFOSAN EMERGENCY ALERT 28 December 20XX


Country A has informed WHO that illness (thyrotoxicosis) in nine adults and one infant was linked to a soy milk product, XXXX soy milk. Distribution records indicate that the affected product has been exported to Country A, Country B, Country C and Country D. This brand of soy milk is enriched with a seaweed product. The product has been found to contain very high levels of iodine (31 000 µg/L). At these levels, tolerable daily intake is likely to be exceeded with as little as 30 mL consumed per day by an adult. A healthy daily iodine intake is about 80–150 µg with a recommended safe upper limit of 1100 µg per day for adults, and from 200 µg for 1–3 year olds to 900 µg for 14 year-olds. Daily consumption of a cup of XXXX soy milk could lead to a daily iodine intake of more than 7500 µg at the levels tested. In Country A, the affected product has been in the marketplace for approximately 3–6 months and has a long shelf life.

The product details are as follows:

1. FOOD TYPE: soy milk
2. BRAND NAME: , XXXX Soy Milk
3. DATE MARKING: All dates up to and including Best Before 03.11.11
4. APN/EAN/TUN NUMBER: 93123360XXXXX
5. PACKAGE DESCRIPTION: Tetra Pak
6. PACKAGE SIZE: 1 litre
7. COUNTRY OF ORIGIN: Country E
8. BUSINESS IDENTITY (Here specify company name and address)

Action taken by Country A: The Country A importer of the product has initiated a consumer-level recall for the XXXX soy milk. Medical practitioners are being advised of this incident via professional organizations and information tailored to medical practitioners will be available from the food safety authority (in this case Department of Health) website.

Please contact the INFOSAN Emergency Duty Officer on +41 79 832 3835 or emergencyinfosan@who.int if you have any questions.
The INFOSAN emergency contact point should first inform the IHR focal point of the existence of human illness related to the product in Country A. Next the INFOSAN emergency contact should inform his or her superior officers in the food safety authority/health department and initiate action to bring together the recall coordination team. The recall coordinator should communicate with the customs and biosecurity agencies to both assess if the product has indeed entered the country and to prevent any further product with those identifying numbers entering the country. The recall coordinator should identify which importers may import the product. The National IHR Focal Point should be part of the recall coordination team so that both the human health and the food product sides are kept informed of progress. The National IHR Focal Point should notify national health authorities and seek to inform provincial and local health authorities and prepare information for sharing with medical practitioners. The food recall coordinator should also notify provincial and local food authorities in a manner coordinated with the actions of the National IHR Focal Point. The recall coordinator should ensure the actions taken are recorded and ensure the INFOSAN emergency contact point is fully aware and able to communicate with the INFOSAN Secretariat to keep it informed of progress on any recall being implemented and any monitoring being undertaken.

Similarly it is important that the food safety authority provides information to the relevant authority in the food product’s country of origin of the recall being conducted and the health impact, if any. This may be shared through direct contacts where they exist, through foreign affairs and through the INFOSAN and IHR networks.
10. Guiding businesses in preparation of a food recall plan

Recalling a food product is a planned action. It is, therefore, essential that it be a legal requirement for food businesses involved in importing, manufacturing and wholesaling food to have a written food recall plan in place and to follow this plan in the event of a recall. To ensure business operators are aware of and able to understand and follow any legislation related to their food recall obligations and are properly prepared for implementing a recall in association with food safety authorities, it is important that food safety authorities provide clear guidance and support to businesses. Ideally, this guidance should be provided when businesses that import, manufacture and wholesale food in the Pacific are developing their own food recall plans. It is also useful to engage all businesses and consumer representative organizations when developing the national food recall system as retailers and consumer representatives also need to understand their roles in a cooperative food recall system with shared responsibilities.

A good food recall plan will generally have a number of basic elements:

1. a food recall step-by-step guide and checklist (see Section M of this guide for the 10 critical steps to be taken when conducting a food recall);
2. a food recall management team identified and trained;
3. a system for recording complaints and acting on them;
4. a system for tracing food through suppliers and trade customer lists and receiving and distribution records;
5. communication templates including those for trade notification, media releases and on-site notifications;
6. a system for keeping record of food products that have been recalled (see section Q of this guide);
7. a system for evaluating the effectiveness of a recall; and
8. a plan to review the recall plan and test its appropriateness and effectiveness.

The recall management team allows the business to act quickly and effectively. As a minimum, it should be made up of:

- a contact person with decision-making capacity;
- quality assurance and technical advisory personnel;
- media communications personnel;
- records management personnel; and
- marketing and distribution personnel.

It may also be appropriate for a business to have of legal counsel as part of its recall management team or at least have an identified legal counsel who the team can consult with, if necessary.
The food recall plan should identify the team members by name and provide their phone for work hours and after work hours as well as specifying their roles and responsibilities. In addition, the plan should provide an alternative person for every member in case the member is not contactable when a recall needs to be considered.

The food recall plan should also include a record of training for the recall management team indicating when the training occurred, what the training was comprised of and who provided the training.

The system of recording complaints and acting on them should be documented. The recall plan should include an example of a Complaints Record that a business should hold where the following information is obtained:

- Complainant details: name, address, telephone number(s) of the complainant and whether they still have some food and have they made complaint elsewhere.
- The product problem: chemical taste, allergic reaction, illness, object in the food:
- Illness/injury details:
  - when was the product consumed (date and time);
  - if the product been consumed before;
  - number of people consuming the product;
  - number of people ill and names and ages of the people ill;
  - amount of product consumed;
  - time the people became ill;
  - symptoms of illness in order of occurrence/description of injury;
  - physician consulted/physician name, contact number, date of contact; and
  - current status of illness/injury.
- Product details.
- Retail details: name and address of store where purchased and date of purchase.

The food recall plan should also include documentation identifying how the complaint was acted on. If the business is an importing business it should examine whether the problem occurred at the import storage facility, during transportation or at the manufacturer. If a wholesaler, there should be a determination of whether the problem occurred at the wholesale premises or at the importer, where imported, or at the manufacturer. Similarly, a manufacturing business needs to look back along its supply chain and in its own facility. The food recall plan should contain documentation on action taken. Records should include a Complaint Investigation and Referral Record with information such as:

- the name of the person at the business who investigated the complaint;
- date and time of the investigation and the findings; and
- to whom the complaint was referred and when, if the problem is not arising from the business itself, for example the importer or the manufacturer.
The recall plan should also have a Record of Initial Action Taken. Even if the product has been imported and the problem has arisen overseas there is still a need to make a decision on whether a recall, withdrawal or other action is required. The Record of Initial Action Taken should identify:

- the complaint;
- the investigation finding;
- the decision to recall, not recall, withdraw the food or other appropriate action;
- the contact with the food safety authorities – identity of whom contacted and when – if appropriate; and
- the people signing off on the initial action decision.

To ensure a food recall is effective it is essential that the business have a system for tracing a food both forwards and backwards. Therefore, a food recall plan should contain an Approved Suppliers List, Receiving Records, Trade Customer List and Distribution Records. The Approved Suppliers List needs to specify the:

- suppliers trade name;
- suppliers contact details;
- first date supplied by the supplier; and
- date when supply stopped, if stopped; and the reason for stopping supplies from that supplier.

The Receiving Records need to include as a minimum the:

- date and time the product was received;
- a description of the product received;
- the lot code;
- the use-by or best-before dates of the product;
- the temperature of food that is meant to be refrigerated or frozen;
- supplier identity; and
- the decision to accept or reject the product and the identity of person making the decision.

The Trade Customer List should as a minimum specify:

- trade name and address of businesses receiving food products from the given business;
- the type of business – manufacturer, distributor, retailer, catering services, restaurant; and
- the name and contact details at the receiving business.

The Distribution Records need to include as a minimum the:

- date and time the product was shipped out of the business’ facility;
- the name and a description of the product distributed;
- the lot code;
- the use-by or best-before dates of the product;
● the temperature of food that is meant to be refrigerated or frozen;
● the identity of the businesses that will be receiving the product; and
● the amount of product and lot codes shipped to each business.

If the business imports and distributes the prepackaged product as is, or wholesales as is, these records would suffice. However, for a manufacturer there is also a need to have a record that links the supply lot codes to the lot codes of a manufactured product.

The food recall plan should also include a template record that summarizes the findings of the verification process outlined in Section P of this guide. It should also include a template checklist as outlined in Section P.

The food recall plan should also include a plan to review the recall plan not only after implementing a recall procedure, but also more regularly to ensure the recall plan is up-to-date for the products being imported, manufactured or sold in the retail market. Reviews can also assist a business to obtain up-to-date records regarding to whom it is selling its products. Reviews can also be conducted in association with staff training and refreshers and can perhaps even involve getting staff to simulate a food recall to ensure those who need to take actions are aware of their roles and responsibilities. This testing of the recall should also be recorded in documentation with a description of the test scenario, the date of the test, who participated in the test and how the application of the recall plan worked or did not work, and what modifications to the plan are identified as a result of the test.
11. Guiding businesses in recalling an unsafe food product

Effective national food recall systems rely on food business operators to take action to recall foods under the guidance and oversight of the food safety authority.

In conducting a food recall, a food business has a number of critical steps to undertake:

1. Assemble the recall management team identified in the food recall plan and inform all members of the decision to conduct and recall and the reason for that decision. Ensure it is clear who will make announcements on behalf of the team.
2. Notify food safety authorities immediately with information prescribed in Boxes 15–17.
3. Initiate and maintain records as prescribed in the food recall plan.
4. Identify all products to be recalled by:
   - looking back along the processing line (if manufacturing food) to see if other products (for example different flavourings, brines, etc.) may also be potentially contaminated; and
   - looking at other products imported from the same manufacturer and asking the manufacturer to look back along their processing line to determine if other products may also be affected.
5. Detain and segregate products that are in the control of the business at all of its premises.
6. Prepare a trade notification in collaboration with food safety authorities.
7. Prepare a media release, if required because food has been distributed to the public. Have this release approved by the food safety authorities.
8. Prepare a list of business where the product has been distributed and provide this list to the food safety authorities.
9. Contact the businesses and identify the fate of the product using the trade notification. Identify the product that has been held and segregated and the product that has not.
10. Verify the effectiveness of the recall by ensuring the product has been held, segregated and returned.
11. Control the recalled product to ensure they do not re-enter the market.
12. Take action on the recalled products under the supervision of those acting on behalf of the food safety authorities.
13. Review the food recall process.

All communication between the food recall coordinator, the food safety authority and the business conducting the recall should be clear and complete. To assist in this matter it is important that a guidance note be prepared in advance identifying the information required by food safety authorities. The guidance note should specify that businesses that are initiating a food recall should provide product information, complete sets of packaging labels and individual product labels of the affected product(s), business information, the reason for the recall and other relevant information relating to the recall, and information on complaints received (if any), prior to initiating a recall. The guidance to business needs to describe the product information and business information required from the business responsible for the product being recalled. Such guidance is provided in Boxes 18–19.
Box 18. **Product information required for a food recall**

- trade name;
- product name (include brand name and generic name);
- description of the product – for example dried, fermented, paste, liquid, powder, diced, whole, flavouring;
- the type of packaging – for example, box, tray with plastic wrap, can, pPak, plastic, glass;
- package sizes;
- lot or batch numbers;
- best before or expiration dates;
- quantity; and
- country of origin.

Box 19. **Business information required for a food recall**

- the name and address of the business initiating the recall;
- the role of the business, for example importer, wholesaler, manufacturer;
- identification of person with whom the authority will be communicating with when using the contact information – for example, the contact point;
- contact information including phone/fax number/email address; and
- the name and address and contact information for either the importer or the manufacturer in the country of origin, if imported.

The guidance also needs to prescribe information that will facilitate the recall and facilitate an assessment of the extent of the distribution of the food to be recalled. The business will be responsible for providing the information in Box 20 as a minimum. Food businesses providing such information may regard parts of it as commercially sensitive and to ensure that they feel protected they should identify what information should not be disclosed. Only through consultation can the authorities be aware of this need and able to control what information is disclosed. The authorities should not, however, be restricted in successfully supporting or implementing the food recall.

Box 20. **Recall information required**

- Explain how the product is contaminated or otherwise defective or in violation of standards, and if contaminated, the type and level of contamination, if known.
- Identify the potential consequences to human health.
- If the recall is due to the presence of a foreign object, describe the foreign object, for example the size, composition, hardness and sharpness.
- If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s) and formulation(s).
- Total quantity imported and date(s) of import.
- Amount distributed (if distributed or sold) and the relevant dates of distribution and distribution channel.
- The identification and address of businesses to whom the product has been distributed or sold.
- Quantity being held by the recalling business and where it is being quarantined.
12. Communicating with trade customers

Trade customers need to be notified to stop distribution of the food product. The food business operator conducting the recall is responsible for advising all trade customers that the food is being recalled. This includes any businesses to which they have distributed the affected product. Where the affected product has been distributed to customers, such as wholesalers and/or retailers, a recall notification should be prepared and provided to all such trade customers.

Box 21 provides an example of a recall notification. Such notifications should be flagged in large bold print with the words such as “URGENT FOOD RECALL”. The notification should identify the company taking the recall action. The notification should then include a heading such as “PRODUCT IDENTIFICATION” followed by an accurate and complete description of the product and any codes used to identify the product, for example lot/unit numbers, expiration date. It would be useful if the label of the product to be recalled accompanied the recall notification letter. The letter should also include a heading such as “REASONS FOR THE RECALL” and this section should identify the problem and any potential health hazard(s) associated with it. The notification should also specifically identify “ACTIONS REQUIRED” by the trade customers.

Box 21. Example of a trade notification form

<table>
<thead>
<tr>
<th>URGENT FOOD RECALL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company name ……………………………………………………………………………………………………………………………</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PRODUCT IDENTIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food name …………………………………………………………………………………………………………………………………</td>
</tr>
<tr>
<td>Food details …………………………………………………………………………………………………………………………………</td>
</tr>
<tr>
<td>Batch / lot / unit Identification ……………………………………………………………………………………………</td>
</tr>
<tr>
<td>“use-by” or “best-before” date …………………………………………………………………………………………………</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>REASONS FOR THE RECALL</th>
</tr>
</thead>
<tbody>
<tr>
<td>…………………………………………………………………………………………………………………………………………………</td>
</tr>
<tr>
<td>…………………………………………………………………………………………………………………………………………………</td>
</tr>
<tr>
<td>…………………………………………………………………………………………………………………………………………………</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>ACTIONS REQUIRED</th>
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<tbody>
<tr>
<td>…………………………………………………………………………………………………………………………………………………</td>
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<td>…………………………………………………………………………………………………………………………………………………</td>
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</table>

<table>
<thead>
<tr>
<th>LEVEL OF RECALL:</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Trade only</td>
</tr>
<tr>
<td>☐ Trade and general public</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Contact details</th>
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<tbody>
<tr>
<td>…………………………………………………………………………………………………………………………………………………</td>
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</table>

<table>
<thead>
<tr>
<th>Contact details for the food safety authority recall coordinator</th>
</tr>
</thead>
</table>
The notification should be clear as to what level of distribution the recall is being conducted and clearly advise the trade customers if they need to also notify their trade customers in case they have further distributed the product. The notification should also identify that fact in media releases. Shop notifications to customers asked to return the product should provide an explanation of how to do so. It is therefore important that the recall notification provides food retailers with instructions about the collection and/or disposal of recalled food. Food retailers are responsible for removing all recalled food products from sale and (if the food is not for immediate destruction or disposal) ensuring it is held, separated and identified. They are also responsible for accepting returns of the recalled product from consumers and issuing refunds. They must also comply with the directions of the recalling business. The notification letter ideally could include a copy of any press release.

Retailers and other businesses must ensure that recalled food is not sold or available for sale to consumers. The notification to retailers should provide clear instructions to remove the product from sale, to quarantine the product and to avoid further distribution of the product. To ensure the trade customers have received and understand the notification, the business conducting the recall should confirm with its customers that the notification has been received, for example, by requesting email confirmation of having received the notification and understanding the actions required.

In the case of products sold at retail stores, it is not appropriate for employees or representatives of the business initiating the recall to remove the product from retail shelves without informing store management of the recall. Only if store managers are informed will they understand that this product should not be sold.

Where affected product may have been distributed to retailers in a village or purchased by village retailers who may then resell the product in a village retail outlet, local authorities need to support the recall by informing both village retailers and responsible people in the village.
13. Communicating with consumers

Where the food product may pose a significant health hazard and the product to be recalled is already in the hands of consumers, the consumers need to be informed as quickly as possible. This may mean informing the public initially through radio, television and social media.

A radio or television announcement should include a warning to consumers by the food business operator not to eat the food (which should be clearly identified), with a specific best-before date or use-by date (where applicable). It may also note that the company’s other products are not affected by the recall, if this is correct. The announcement should inform consumers about where the product has been available. It should advise them not to consume the product and to return it to where they bought it for a cash refund.

As with other communications to consumers, it should also advise them that anyone concerned about his or her health should seek medical advice. Using multiple communications methods such as those previously identified is the best approach and it would be appropriate to also prepare a press release as a priority. A media or press release may be prepared by the business, or the relevant food safety authorities if it is concerned with what the food business has prepared or published or if the food business has not acted in a timely manner in accordance with guidance. If the business prepares the press release it should consult with food safety authorities before it is issued, and if a business is still uncertain how to prepare a media or press release the food safety authority can assist them by providing the business with a draft. Box 22 provides an example of an appropriate press release. A media release via television or radio should say the same things.

Box 22. Example of a press release

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Trade Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>(sizes of affected product identified)</td>
<td>(use-by or best-before dates identified)</td>
</tr>
<tr>
<td>(product picture inserted)</td>
<td></td>
</tr>
</tbody>
</table>

The recalled product(s) has/have been available for sale in [product outlets and/or areas identified].

Problem: The recall of this product (these products) is due to (identify the problem, for example microbial contamination with Salmonella, chemical contamination with lead, metal fragments, the presence of an undeclared allergen – peanuts, insufficient nutrients present).

Food Safety Hazard: If the reason is Salmonella then “Food products contaminated with (Salmonella) may cause illness if consumed”; if the reason is lead then “Food products contaminated with (lead) may cause illness if consumed”; if the reason is glass then “Food products containing (glass) may cause injury if consumed”; if the reason is allergens then “Any consumers who have a (insert undeclared allergen) allergy or intolerance may have a reaction if the product is consumed”; if insufficient nutrients in infant formula then “Infants consuming this product may be receiving insufficient nutrients for normal growth”.

What to do: If the reason is microbial, physical or chemical contamination then “Consumers should not consume this product and if they have and are concerned they should seek medical advice”; if the reason is undeclared allergen then “Consumers who have a (insert undeclared allergen) allergy or intolerance should not consume this product”; if insufficient nutrients in infant formula then “infants should not consume this product”. Customers should return the product(s) to the place of purchase for a full cash refund. We apologize for any inconvenience.

Contact details: For further information contact (insert company contact details, including telephone number and web address, if available).
Another means of communicating with consumers is to place a prominent in-store notification (Box 23) at retail points for the affected product. The best location for this type of notification is at the point of entry to the store, cash registers and the shelves where the product had previously been on sale. This should be used in addition to other means of communication with consumers.

**Box 23. Example of an in-store notification**

**WARNING**

A picture of the affected food

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Company Name:  

Food name/description:  

Pack size:  

Batch/lot/unit identification:  

Details of what is wrong with the product:  

Actions the consumer should take:  

Company address and contact details:  

---
14. Identifying if the recall is effective

It is the recalling business’s responsibility to assure that the recall is effective. It is recommended that businesses use a checklist to conduct an effectiveness check (see Box 24). The effectiveness check should verify that a business recall notification letter was received by the wholesale or retail or other business that received food product. The checklist should not only highlight the need to check that the notification letter was received, but also that the customer read and understood the letter and followed the recall instructions. The effectiveness check should also verify whether or not the recall reached the appropriate level in the distribution chain.

Box 24. Recall effectiveness check (2 pages)

<table>
<thead>
<tr>
<th>COMPANY NAME &amp; LETTERHEAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall Effectiveness Check</td>
</tr>
</tbody>
</table>

Date: ______________________

To (Consignee name and address):
____________________________________________________________________________

Recall product name____________________________________________________________

Product code_________________________  Date code_________________________________

The following checklist has been sent to you as part of a recall effectiveness check required by <food safety authority> (e.g. Food Unit of the Department of Health). Please complete this checklist, sign and date it, and post or fax to Company A

<Recalling company address, fax number>_________________________________________

1) Did your company receive notification from <recalling company> that the above-listed product was being recalled?  □ YES □ NO
   If YES, when? ______________________

2) Did your firm receive shipments of the recalled product? (If NO, please sign this letter and return.)  □ YES □ NO

3) Do you have any of the recalled product?  □ YES □ NO

4) If the answer to question 3 is YES, do you plan to return the recalled product as requested, to Company A?
   □ YES  Please list the quantities and expected return delivery date: ____________________

   □ NO  Please explain your intentions: ____________________________________________
Box 24. Recall effectiveness check (letter, on-site visit)

5) Have you received illness or injury reports related to the recalled product?
   □ NO □ YES
   If yes, please provide details: ___________________________________________________

6) Did you sell the recalled product to other distributors, retailers or consignees?
   □ YES □ NO

7) If the answer to question 6 is YES, did you send a recall notice to the consignee?
   □ YES □ NO

8) If the answer to question 7 is YES, did the consignee have any product on hand?
   □ YES □ NO □ Did not enquire

Thank you for your cooperation. Please sign and date your signature below.

Signature Title ________________________________________________________________

Date Company __________________________________________________________________

Sincerely,

Signature and title Date __________________________________________________________________

<recalling company name>

The recalling business should also ensure that it keeps a record of its interactions with its trade customers in order to determine whether the recall is being undertaken successfully. An example of such a recording process is illustrated in Box 25.
Box 25. **Record of recall effectiveness**

<table>
<thead>
<tr>
<th>No.</th>
<th>Customer Identification</th>
<th>Method Used to Confirm Customer Notified</th>
<th>Quantity (% of Product Supplied) of Product Returned</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2</td>
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<tr>
<td>10</td>
<td></td>
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</tr>
</tbody>
</table>

Recall Effectiveness .......................................................... (Satisfactory/Not Satisfactory) ...........................................

Number of attached checklists supporting the statement of recall effectiveness ...........................................

Action to be taken where the effectiveness is unsatisfactory ..........................................................................

If the effectiveness checks indicate that the recall notification was not received, read and/or instructions followed, then the recalling business should take necessary steps to make the recall effective. These steps may involve sending out a follow-up notification that better identifies the product, better explains the problem and/or provides better instructions to customers.

In addition to effectiveness checks conducted by the recalling business, national food safety authorities may collaborate with provincial and local authorities to audit the recall by also contacting businesses that are meant to have received the notification.

This will assist authorities in ensuring that the recalling business and its consignees are carrying out their recall responsibilities. If audit checks determine the recall to be *ineffective*, the recalling business will be required to take appropriate corrective actions, including reissuing recall notifications.

As part of audit checks national authorities may also assess the promptness of the announcement of recall through the media; the setting up of a customer enquiry service; cooperation among importers, distributors and retailers regarding quarantining and locations for return of the food concerned; the promptness in removing the food concerned from shelves; inspections confirming that businesses have removed product from shelves; the adequacy of records of the recalled food; and the effectiveness of the efforts of the business to ensure it has a preventative process in place to avoid future problems.
15. Reporting on the food recall process

A recalling food business will be required to provide recall status reports after initiating a recall. The frequency of these status reports will be identified by the food recall coordinator of the national food safety authority at the time and will depend upon the risk associated with the defective food product and the national situation.

Reporting requirements could include an interim report to be submitted within days or weeks depending on the hazard and its potential public health consequences. This interim report is intended to assess whether or not the business conducting the recall can account for all the product recalled and has assessed if all parts of the distribution chain have received notification, understood what is required and are acting on the recall in compliance with legal requirements. This report will usually include the following information:

- dates that businesses to which product has been distributed were notified;
- the method of notification and the contact person at each business;
- the number of businesses responding;
- the quantity of product returned or quarantined from each business; and
- the quantity of product destroyed under the supervision of local authorities, or otherwise handled.

The authority should also require a final report to assess whether the recall has been carried out successfully. This includes evaluating the corrective action taken to decrease the chance of the food safety issue recurring and recording the final stock accountability numbers. This type of reporting requirement should be communicated clearly in guidance provided by the authority to businesses.

16. Termination of the recall

The recalling business must evaluate the recall to identify if the recall is ready for closure. This will be the case when all possible customer responses have been received and it is reasonable to believe that the recalled product has been recovered and destroyed or otherwise handled in agreement with legal requirements.

A final status report and documentation of the disposal of the recalled products should be provided to the food recall coordinator in the food safety authority prior to terminating the recall, and the recall may be terminated when the recalling business receives documented concurrence that the food safety authority agrees to the recall being terminated.
17. Lessons that can be learnt and how to improve

Common errors that can be recognized when conducting a recall include:

- businesses treat a potential food safety problem as a problem more associated with a processing error or a quality issue;
- failure to identify all affected products accurately and clearly;
- communication is unclear about the hazard;
- communication about the concern is lacking;
- failing to obtain (if a food safety authority) or maintain (if a business conducting a recall) comprehensive distribution records; and
- lack of awareness of a food safety concern as a result of food products being imported into the Pacific without the knowledge of authorities in the countries of origin.

Even when a food importer, wholesaler or manufacturer is aware of a potential food safety concern there may be a tendency to consider the problem as something other than a food safety matter, perhaps a production error, quality concern or other issue of less concern than a food safety problem. Consequently, food safety authorities are not informed in a timely manner as the business tries to conduct a food withdrawal rather than a recall. This can result in hazardous products not being removed from distribution and sale in a timely manner and consumers being placed at risk. To minimize this risk, food business operators, once aware of any potential concern, should notify food safety authorities immediately and seek guidance from them as to whether the issue is a matter best to be addressed as a food safety concern or otherwise.

A food importer, wholesaler or manufacturer may recognize there is a food safety concern associated with a particular product but may not fully realize the extent of products that are associated with the hazard. Testing the food recall plan on a regular basis will provide businesses greater experience in looking at all similar products that may also be impacted but vary in product size, flavouring, brine, branding, etc.
Where communication with trade customers and the public has been ineffective or unclear and the urgency that is needed to address the hazard has not been adequately recognized or people do not understand the hazard, the effect can be devastating as product may not have been removed from distribution in a timely manner and consumers may use the recalled product. It is therefore important to re-examine the importance of using the communication guidance provided by the food safety authorities (for example, guidance on trade notification and communication with the general public). It is also important to check the wording with food safety authorities before submitting notifications to trade customers or media releases to the public. It is important to be clear and concise and to advise of actions that need to be taken in a timely manner. Food safety authorities might also consider collaborating with consumer representatives to better explain the potential hazards to consumers and what recall notices are used for and what they mean.

Distribution of a food product may change with time, distribution lists may not be properly maintained and records may not be properly kept for lot codes. As a consequence, authorities may be given incomplete information, businesses may not identify the correct businesses to which the affected product has been provided and as a result consumers may be placed at risk. It is imperative that records be maintained and updated and that the product is traceable. Businesses need to improve their ability to keep such records and should work with food safety authorities to demonstrate their willingness to prepare and provide an accurate distribution list to authorities in a timely manner. Practicing test food recalls will help improve these aspects also.

Importers may not be aware of a potential food safety concerns, and authorities in the country of origin may not be aware the product has been exported to the Pacific as it is not infrequent that products meant for domestic consumption in countries such as the United States of America, the Philippines and other countries neighbouring the Pacific are consolidated and imported into Pacific island countries and areas without the knowledge of authorities in the countries of origin. Examples of this practice that have led to problems in the past include:

- the import of meat products meant for domestic consumption as a chilled product in the United States of America being imported to the Pacific as a frozen product;
- the import of White Rabbit candy manufactured in the Philippines as a product for domestic consumption in the country of origin; and
- the import of products with mandatory labelling elements rendered in an overseas domestic market’s language, which consumers in the Pacific may not understand.

In such cases it is important that food safety authorities monitor what food is being imported and notify food safety authorities in the country of origin that food meant for domestic use has been exported. In addition, importers should ensure both that the products imported comply with legislative requirements and that their records of their suppliers clearly identify that the food did not come with clearance for export from food safety authorities in the country of origin.

A business may decide to remove the product from the retail level without informing trade customers of the need for a recall. Instead they may simply send representatives to replace the affected product with new unaffected products. For some trade customers, key personnel may not even be aware the switch of products has been made or even if they are aware they may simply believe it is being made for a reason other than safety. This would result in retailers or caterers possibly having other stock that was missed in the replacement process being sold to consumers. To avoid this it is important that businesses refrain from this practice and inform trade customers through a trade notification as guided by food safety authorities.
References


