



DEPARTMENT OF HEALTH
Republic of South Africa

**POLICY GUIDELINES:
NATIONAL FOOD SAFETY ALERTS AND
OFFICIAL FOOD PRODUCT RECALLS
IN
SOUTH AFRICA**

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1. BACKGROUND

Recently South Africa has experienced incidents where certain food products had to be recalled on a national scale. One was an incident that occurred in February 2002 in the Gauteng Province, where two children died from botulism after consuming contents of a tin of canned pilchards in tomato. This incident resulted in a nationwide food safety alert and a call to withdraw all tins of pilchards in tomato, which had the same batch number as the implicated tin. Further investigation revealed that this was not a general foodborne outbreak but an isolated case, where children from a needy family consumed the contents of a badly rusted and damaged tin of pilchards in tomato, which was received by the family as donation. The incident itself revealed several shortcomings, in the food control system, which could have resulted in a more severe situation should this have been a nationwide foodborne disease outbreak. As a result several recommendations were made to the Department of Health, one of which being the need to streamline coordination between the departments and components involved in food control as well as disease prevention and control so as to be better prepared for foodborne disease outbreaks of a national (and even international) magnitude. Hence, the decision was taken to develop Policy Guidelines on National Food Safety Alerts and Official Product Recalls.

2. DEFINITIONS

Consignment of foodstuffs refers to a specific batch/lot of foodstuffs as specified on the relevant export documentation of the exporter and which can be identified by the certifying officer for inspection/sampling purposes, depending on the nature of the certification as determined by the importing country.

Food control means a mandatory, regulatory activity of enforcement by the competent health authority to provide consumer protection and ensure that all food during production, handling, storage, processing and distribution is safe, wholesome and fit for human consumption; conform to safety requirements and are honestly and accurately labelled as prescribed by law.

Food safety refers to the assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Hazard means a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Risk refers to a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazards(s) in food.

3. INTRODUCTION AND AIM

A national food safety alert refers to steps taken by the national health authority aimed at informing consumers of a potential or real health risk deriving from a specific foodstuff, which could still be available at food outlets or in the homes of consumers. It is further intended to raise awareness with the relevant health authorities responsible for the control of the foodstuff concerned. Such a food safety alert may, in some instances, be followed by a food product recall, which is conducted to protect public health and safety. Thus, the main objective of any recall is to effectively and efficiently remove from the market any food product that is unsafe for human consumption.

There is no legislation in South Africa that directly forces any food business to initiate and conduct an industry/trade food recall. In addition, it is not mandatory for any food business to have a recall plan in place. All recalls by the food industry are initiated voluntarily in the interest of public safety. However, section 2(1) of the Foodstuffs Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) prevents any person from selling food that is unfit for human consumption. In addition, the Codex Code of Ethics for International Trade in Food (see Annex A) states that all consumers are entitled to safe, sound and wholesome food and to be protected from unfair trade practices. Thus, by implication, this code of ethics also prohibits any person to put into international trade any food that is unfit for human consumption.

Although the regulations relating to inspections and investigations (R 1128 of May 1991), as promulgated under the Health Act, 1977 (Act 63 of 1977), make provision for Environmental Health Practitioners (EHPs) to detain, sample and if necessary seize any foodstuff, in their areas of jurisdiction, which is deemed harmful or injurious to human health, there is currently no national policy in place that refers to an official food product recall. As a result, it has become difficult for food control authorities to execute, monitor and record any official food product recalls that may need to be conducted in South Africa.

It has also been difficult to monitor and record any voluntary food product recalls instituted by industry.

The aim of these policy guidelines is thus to provide guidance on the roles and responsibilities of industry, but particularly, food control authorities, regarding national food safety alerts and official food product recalls, and how these should be conducted to ensure public safety. These policy guidelines also provide a framework on which the Directorate: Food Control of the Department of Health can keep a record and develop a database of official, as well as voluntary food product recalls being conducted in the country in the interest of public health. Only records of Class I and Class II food product recalls will be kept by the Directorate: Food Control.

4. CONCEPTUAL CLARIFICATION

4.1 FOOD SAFETY ALERTS

Industry may voluntarily issue a food safety alert, requesting consumers/customers to return the implicated food product to retailers and/or to the business concerned, or to dispose of it as it is not fit for human consumption. In this case, the consumers/customers are usually refunded for the products they return. For the purposes of these guidelines, this will be referred to as a voluntary food safety alert.

In other instances, for example where industry fails to issue a food safety alert, the national health authority may issue an official food safety alert, whereby provincial and municipal health authorities, and, in some cases the public, are informed of a risk associated with a particular foodstuff. Provincial and municipal authorities are usually informed in writing by the Department of Health, Directorate: Food Control, while a media release, by the Communications Unit of the Department of Health, is used to inform the public. In most cases an official food safety alert is followed by an official food product recall.

4.2 FOOD PRODUCT RECALLS

A food product recall can be conducted voluntarily by industry and is therefore referred to as a voluntary recall. All food businesses (i.e manufacturers, distributors, wholesalers, retailers, etc) share the responsibility of ensuring that the public in South Africa is protected from products that present a risk to health or gross deception, or are otherwise defective. Thus they have a moral obligation to recall any food products that have been released into the market that they know may pose a health risk to the consumers.

Universally, it is recognised that there are essentially three types of food product recalls:

Class I recall, involving a health hazard situation where there is a reasonable probability that eating the food will cause health problems or death.

Class II recall, involving a potential health hazard situation where there is a remote probability of adverse health consequences from eating the food.

Class III recall, involving a situation where eating the food will not cause adverse health consequences. Class III recalls fall outside the scope of these policy guidelines and will not be considered henceforth. Thus, henceforth, food product recalls referred to in this document refer to Class I and Class II food product recalls only.

Food product recalls can also be classified as either a trade/industry recall or a consumer recall.

A trade/industry recall involves recovery of the product from distribution centres and wholesalers, as well as from production premises, hospitals, restaurants, and other major catering establishments, as well as outlets that sell food manufactured for immediate consumption.

A consumer recall involves recovery of the product from all points in the production and distribution network, including consumers. This is a more extensive recall.

In those situations where industry fails to voluntarily conduct a food product recall, and food control authorities conduct the recall, this will be regarded as an official food products recall.

4.3 FOOD CONTROL AUTHORITIES

4.3.1 Roles and responsibilities

In South Africa food control is shared between several authorities and various components, within the health sector, at national, provincial and local level. A brief outline of the roles and responsibilities of the different authorities is as follows:

4.3.1(a) The National Department of Health:

The Directorate: Food Control administers food legislation on behalf of the Minister of Health. It is thus responsible for:

- Coordinating activities, such as food product recalls, within the country
- Setting national norms and standards
- Supporting provinces and local authorities
- Assuming the role of the National Codex Contact Point

4.3.1(b) Provincial Department of Health:

Sections responsible for, amongst others, food control at provincial level are referred to as Environmental Health Services. They are responsible for:

- Coordinating activities within the province
- Providing support to the local authorities
- Rendering specialised services (e.g import control, which is done on behalf of the national Department of Health)
- Setting protocols and strategies for health within the province

4.3.1(c) Districts/Local authorities (Municipalities):

At district/local level Environmental Health Services are also responsible for, amongst others, food control in their areas of jurisdiction. They are involved in the following activities:

- Health promotion
- Involving community participation in health-related issues
- Hygiene control (within the environment)

- Investigating complaints
- Law enforcement
- Identifying/controlling health hazards
- Monitoring for compliance to legislation

4.3.1(d) National Department of Agriculture:

At the National Department of Agriculture the Directorate: Food Safety and Quality Assurance is responsible for:

- Regulating and promoting the safety of animals and animal products
- Regulating and promoting the quality of agricultural products
- Ensuring the safety, quality and efficiency of production enhancement agents
- Promoting the safety of food of plant and animal origin

4.3.1(e) The South African Bureau of Standards (SABS):

The Division: Food and related industries of the SABS is responsible for the control of canned meat/fish products and frozen marine products. It is recognised by the European Union and other countries as the certification authority for exports related to fish and seafood products.

4.3.2 Legislation

The relevant South African legislation and the authorities that are involved in the administration and enforcement thereof include the following:

4.3.2(a) The Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972):

This Act governs the manufacture, sale and importation of foodstuffs, cosmetics and disinfectants from a safety/public health point of view and is administered by the Directorate: Food Control of the Department of Health and enforced by local authorities in their areas of jurisdiction. Import control is performed on behalf of the National

Department by Provincial Departments of Health. The Act regulates the foodstuffs as such, as well as labelling and advertising of foodstuffs. It does not regulate hygiene provisions that relate to the handling and transport of food.

4.3.2(b) The Health Act, 1977 (Act 63 of 1977):

There are several sets of regulations promulgated under this Act that have direct relevance to food safety and are enforced by local authorities in their areas of jurisdiction. These include:

- Regulations Governing General Hygiene Requirements for Food Premises and the Transport of Food (G.N. No. R. 918 of 30 July 1999), which regulate hygiene provisions that relate to, amongst others, the handling and transport of food.
- Regulations Relating to Milking Sheds and the Transport of Milk (G.N. No. R. 1256 of 27 June 1986).
- Regulations Relating to Inspections and Investigations (G.N. No. R. 1128 of 24 May 1991), which make reference to, amongst others, detention and seizures of food.
- Regulations Regarding Food and Water Vessels (G.N. No. R. 1575 of 10 September 1971), which aim to prevent the transmission of certain metals from containers to foodstuffs.
- General Regulations Promulgated in terms of the Public Health Act, 1919 (G.N. No. R. 180 of 10 February 1967), which make reference to the transport of meat and meat products.

4.3.2(c) The International Health Regulations Act, 1974 (Act 28 of 1974):

This Act provides for the approval, by the Department of Health, of the source of food for consumption at ports, airports, on vessels and on aircraft, as well as for the inspection of such premises and the sampling of food by local authorities. The provincial health departments currently approve premises on behalf of the national Department of Health.

4.3.2(d) The Agricultural Products Standards Act, 1990 (Act 119 of 1990):

This Act controls and promotes specific product quality standards for the local market and for export purposes. It is administered and enforced by the Directorate: Food Safety and Quality Assurance in the Department of Agriculture. Assignees such as the Perishable Products Export Control Board (PPECB) are appointed and authorized as assignees to do physical inspections under the Act.

4.3.2(e) The Meat Safety Act (Act 40 of 2000):

This Act is administered by the Directorate: Food Safety and Quality Assurance in the Department of Agriculture and enforced by the Departments of Agriculture of the nine provinces. It addresses, amongst others, meat safety and hygiene standards in abattoirs and regulates the importation and exportation of unprocessed meat.

4.3.2(f) The Liquor Products Act (Act 60 of 1989)

This Act is also administered by the Directorate: Food Safety and Quality Assurance of the Department of Agriculture. It addresses requirements for all liquor products except beer, sorghum and medicine.

4.3.2(g) The Standards Act, 1993 (Act 29 of 1993):

This Act is administered by the SABS and has compulsory specifications that address canned meat and fish products, as well as frozen seafoods.

5. MECHANISMS OF NATIONAL FOOD SAFETY ALERTS AND OFFICIAL FOOD PRODUCT RECALLS

These policy guidelines make provision for mechanisms by which national food safety alerts and official food product recalls can be initiated in the interest of public safety.

5.1 NATIONAL FOOD SAFETY ALERTS

A national food safety alert could be instituted by the Department of Health, Directorate: Food Control in the form of one or more of the following actions:

- Issuing an official notice to the provincial and municipal health authorities informing them of the foodstuff(s) posing a risk to human health and what steps to take to ensure the safety of consumers.
- Issuing a media release, through the Department of Health's Communication Unit, intended to inform the public of the situation in question and stating what measures should be taken by consumers to protect their health.

5.2 VOLUNTARY AND OFFICIAL FOOD PRODUCT RECALLS

There are three mechanisms by which a food product recall can be initiated:

- A recall can be undertaken voluntarily at any time by a food business (e.g a manufacturer, distributor, wholesalers, etc), and it is then referred to as a voluntary recall.
- A food control authority, in the interest of public health, can request any food business to initiate and undertake a food product recall.
- The national health authority can institute an official food product recall as described in these guidelines.

Regulations relating to Inspections and Investigations (R. 1128 of 24 May 1991), promulgated under the Health Act, 1977, make provision for local authorities to detain, sample and, if necessary, seize, in their areas of jurisdiction, foodstuffs that have been examined and deemed to be unsafe for human consumption. In addition, sections 4(1)(a) and 4(1)(b) in these regulations state that "If, after an examination of any food contemplated in regulation 2(1)(e), he (the inspector) is satisfied that such food is unsound, or unwholesome or contaminated.....by written order signed by him seize the food concerned...." These regulations thus, by implication, allow for Environmental Health Practitioners to (after receiving a written request from the National Department of Health, Directorate: Food Control, through the Provincial Health Departments) seize and detain or dispose of foodstuffs, during an official food product recall, without having to first sample

for laboratory analysis. The EHPs must, however present a written order (see annex B) to the person in charge of the food business involved. As far as is possible, industry should be encouraged to conduct its own food product recalls.

5.3 PROCEDURES DURING AN OFFICIAL FOOD PRODUCT RECALL

Key steps in instituting a national food safety alert or official food product recall include:

- Identifying a need for the food product recall
- Determining the level of a food product recall.
- Convening a Food Product Recall Committee
- Notifications
- Post recall reporting/documentation

5.3.1 Identifying a need

A national food safety alert and an official food product recall both have ramifications for industry, control authorities and consumers. Hence it is critical that all the necessary information is obtained and thoroughly analysed before a decision is made to initiate either action. It is also during this process that a food product recall should be classified either as a class I or class II recall, as indicated in these guidelines. The decision to initiate a national food safety alert or an official food product recall should be made after consultation between the relevant food business (industry), the food control authority issuing the instruction and the Department of Health (if it is not the authority issuing the instruction) and it should be in the interest of public health.

Food businesses can voluntarily initiate food safety alerts and food product recalls at any time as part of their responsibility towards ensuring consumer safety. However, as indicated earlier in these policy guidelines all Class I and Class II food product recalls should be reported to the Directorate: Food Control for record-keeping purposes.

5.3.2 Convening a committee and issuing of instructions

A Food Product Recall Committee is formed only when a need for a national food safety alert and/or an official food product recall has been identified. It should not be a standing committee. Such a Committee should be convened and chaired by the food control authority that is directly responsible for the affected food product. For example, if canned fish is being recalled, then the SABS will be the authority responsible for convening and chairing the Committee. In addition, it is up to that control authority to decide which other food control authorities should be represented on that Committee and what their roles will be during the incident. It is recommended that the affected food business be represented on the Committee. Those chosen to serve on the Committee can be informed in any manner, depending on the urgency of the matter. Requests for participation in the Committee as well as a list of all the participants should be documented. Any decline to serve on the Committee should also be documented.

The following are the suggested key role players on any Food Product Recall Committee:

- The Department of Health Directorate: Food Control
- Environmental Health Services of the Provincial Health Department in whose province the problem was first identified
- Environmental Health Services at the Local Authority in whose area of jurisdiction the problem was first identified
- The affected food business(es)

Following are role players that should be represented on the Food Product Recall Committee as necessary:

- The South African Bureau of Standards, in situations where the product being recalled falls under its control
- The Directorate: Disease Prevention and Control of the Department of Health and its provincial counterparts, in situations where the food product has been implicated in outbreaks of foodborne illness
- Department of Trade and Industry, where consumer bodies may become involved

- Relevant laboratory services, in situations where laboratory tests were conducted
- Relevant Directorates of the Department of Agriculture, depending on the product concerned

Meetings of the Food Product Recall Committee should be minuted and each role player should have access (in writing) to the following information:

- The events leading to the decision to initiate an official food product recall and how the recall is classified (e.g Class I or II)
- The name of the product being recalled as well as its full description (i.e package size and type, lot/batch identification, use-by dates, etc)
- Whether or not the product was manufactured in South Africa and if it has been exported elsewhere
- The type of assistance (if any) that is required of the role player
- Where and how the product will be disposed of
- Contact details and roles of all the other role players

5.3.3 Determining the level of an official food product recall

In order to know who else to notify of the recall and how to go about it depends on knowing whether the recall is a trade recall or a consumer recall (see section 3.2).

- If the recall is a voluntary recall, the level of the recall should be determined by the affected food business. The food business may request assistance from the relevant food control authority, such as the Department of Health, with regard to removal of the food product from retail shelves. This should only be in situations where:
 - there is a need to ensure that the product has also been removed from the informal sector
 - the magnitude of the recall is too large for the food business to complete on its own
 - the product poses such a high risk to human health that it must be removed from retail shelves as a matter of urgency, which the food business may not be able to accomplish through its own recall program

- In cases of an official food product recall, the level of the recall should be determined by either the entire recall committee or the control authority that is responsible for the product that is being recalled. This should be done (where possible) in collaboration with the food business affected.
- It is important that in determining the level of the recall, the resources that will be required to conduct the recall be taken into consideration. In the case of a trade recall, where industry voluntarily initiates and conducts a food product recall, the food business conducting the recall is responsible for providing all the necessary resources. In the case of an official food product recall the Municipalities, through their provinces, will be requested to assist (by removing the product from retail outlets).

5.3.4 Notifications

5.3.4(a) A voluntary recall:

Notification mechanisms will depend on the level of the recall. During a trade/industry recall, notification should be to the distribution network/distribution chain and trade customers. The notification should detail methods for stopping distribution and sale of the product, for storing the recovered product safely and for isolating and disposing of the product. Food businesses should maintain current contact lists of suppliers, distributors, wholesalers, retailers and customers. During a trade/industry recall it may not be necessary to notify the public. However, there may be cases where consumers/customers may be advised to return the food to the place of purchase, such as retail premises. The food business conducting the trade/industry recall should inform the businesses receiving returned goods on how they should dispose of that product. If the affected food business chooses to dispose of the affected product, this should be done in collaboration with the relevant food control authority and the necessary documentation, referring to the disposal of the product, should be acquired by the food business from the control authority as proof that the product was disposed of in the proper manner (see Annex B).

5.3.4(b) Official recall:

During an official food product recall public notification may be necessary if the product in question is offered for sale to the consumer. It is, however, also important to ensure that notifications do not cause unnecessary panic. It is thus important that the recall committee take a unanimous decision on how the notification is to be conducted and which Department or component will be responsible for drafting the content thereof and ensure its release. This is a situation where involvement by the Communications Unit of the Department of Health is vital.

The main factor affecting the notification mechanism is the classification of the recall (i.e class I or II) and how hazardous is the product that is being recalled. Thus, the mechanisms of notification will depend on the urgency of the situation. These may include the use of one or more of the following:

- Official media releases
- Paid advertisements
- The internet
- In-store announcements

According to the Codex Alimentarius Commission it is also necessary to notify the exporting country of the recall, if the implicated product was imported into South Africa, and the importing country, if the implicated product was exported from South Africa. The Commission has made available guidelines which assist countries with regard to ways in which the exporting or importing countries should be notified. The Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food (see Annex C1) would be relevant in situations where South Africa imports a food product from a particular country and finds that that product poses a health risk and initiates a recall, which may result in subsequent consignments of foodstuffs from the importing country being rejected. The Guidelines for the Exchange of Information in Food Control Emergency Situations (see Annex C2) would be relevant in situations where South Africa exports a certain product to a particular country and thereafter discovers that the exported

product is unfit for human consumption and must be recalled from the importing country. Notifications in this regard should be conducted as indicated in these Codex guidelines.

5.3.5 Post-recall reporting/documentation

Post-recall reporting is important in any recall, including an official food product recall, that was conducted in the interest of public health. This information will be used to develop a database of Class I and II recalls that were initiated from within South Africa at any given time. Information in this database will include quarterly reports of Class I and II food product recalls, the types of food products that were recalled and the reasons the food products were recalled, the levels of the recalls and, where possible, the amount of food product recalled.

Post-recall reporting also helps in assessing the effectiveness of the recall. The effectiveness of a recall is assessed on the basis of the amount of product received in proportion to the amount of product that originally left the food business. It is thus important to ensure that during the recall, where possible, a recording system is maintained for logging food that has been returned.

Post-recall reporting also includes investigating the reason for the recall so that action can be taken to prevent a recurrence of the problem.

A post-recall report can also be used by industry, following a voluntary recall, as a means to notify the Directorate: Food Control of the recall.

6. PROCEDURAL ARRANGEMENTS AND RESPONSIBILITIES

During a national food safety alert and official food product recall the various food control authorities and health authorities at the various levels of government will at one point or another have certain tasks to fulfil. Below are procedural arrangements and responsibilities

of the authorities that would play a key role in relation to national food safety alerts and official food product recalls:

6.1 DEPARTMENT OF HEALTH

6.1.1 Directorate: Food Control

- Issue an instruction in respect of a national food safety alert or an official food product recall and notify provincial health departments of the situation and request that the instruction (usually a letter by which the Directorate was notified) be forwarded to the local authorities.
- Request action from local authorities, be it with regard to the removal of the product or conducting community awareness campaigns.
- Provide copies of the Policy Guidelines on National Food Safety Alerts and Official Food Product Recalls in South Africa to all provinces and members of the Food Product Recall Committee.
- Liase with all the role players (members of the Food Product Recall Committee) to ensure the effective and efficient implementation of the recall.
- Where necessary, liase with affected importing or exporting countries
- Maintain detailed records of the events taking place during the alert/recall and keep all stakeholders updated regarding the recall.
- Prepare summaries of national food safety alerts/official food product recalls that take place in the country for record purposes (only Class I and II recalls will be initiated and recorded by the Department of Health).
- Update the database on Class I and II food product recalls conducted in South Africa on a quarterly basis.

6.1.2 Directorate: Communicable Disease Control and Laboratory Services (see also Annex D1)

- Receive notification from the provincial communicable disease control coordinator
- Refer the notification of the outbreak to the Directorate: Food Control and other relevant units at the National Department of Health

- Notify other provinces of the outbreak and request reports on the number of patients infected and deaths and maintain records thereof
- Draft a media release, in consultation with relevant role players, and refer it to the Cluster: Communication for publication
- Determine treatment strategies for patients and refer to the provinces so that they can forward the information to the various health service providers

6.1.3 Cluster: Communication

- Receive a media release drafted either by the Directorate: Food Control or Directorate: Communicable Disease Control
- Provide inputs and comments on the contents of the media release
- Refer the media release to the Department of Health Director General, when necessary, for approval to release the notification to the media
- Refer the notification to the media and request publication thereof in newspapers and/or announce it on television and radio

6.1.4 Provincial Health Departments (Environmental Health sections)

- Receive notification either from a Local Authority or from the National Department of Health
- If notification is received from the National Department of Health, to carry out whatever instructions issued by the relevant unit within the Department
- If notification is received from the Local Authority:
 - Along with the relevant EHP at Local Authority, conduct investigations to determine the source and magnitude of the problem
 - Notify the Directorate: Food Control and the Directorate Communicable Disease Control (if consumption of the product has resulted in an outbreak of foodborne disease), as well as all other Local Authorities within the province of the situation
 - Carry out whatever instructions referred to the provinces by the relevant unit within the National Department of Health

6.2 SOUTH AFRICAN BUREAU OF STANDARDS

See Annex E.

7. CONCLUSION

There is no guarantee that any food business or country will never be faced with a food safety emergency, which may require a national food safety alert or food product recall. Thus a national policy guideline such as this will be of vital importance in the event that such an emergency arises in South Africa. It is hoped that the use of this policy guideline will ensure that all Class I and II food product recalls initiated and conducted in South Africa henceforth will be conducted effectively and successfully.

ANNEXES