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Manual of Good Practices for Food or Feed Recalls

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ABSTRACT

Product recall is a fundamental food safety risk management tool. The key to successful implementation of a recall is recognizing the importance of shared responsibility between government/competent authority and industry. Within the recall process, the main objective for the competent authority is to protect public health by ensuring the rapid removal of unsafe foods or feeds from the market. To address the impact of a globalized food supply on the facilitation of recalls, competent authorities around the world have adopted regulations addressing product tracing through the food supply chain, clarifying responsibilities within the recall process, mandatory recall authority for food safety agencies, and disposal of contaminated products. During the recall process, the key areas in which the competent authority plays a vital role include: Communication; Coordination, Initiation and Completion of the Recall Process; Evaluation of Effectiveness of the Recall Process; Data collection, and Providing Guidance and Training to Industry and other Stakeholders.

1. Introduction

According to the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), a recall is *"The action to remove food from the market at any stage of the food chain, including that possessed by consumers,"* (FAO, 2012) In the context of risk analysis, a food or feed recall is one of the most important tools in a food safety control authority's risk management options. In essence, a recall is also the recognition that a failure has occurred somewhere in the safety assurance system, and is a last resort to remedy such failure and protect human or animal health.

A food or feed product might be recalled for various reasons. Among the most serious are those related to contamination with a biological hazard (pathogenic microorganisms, parasites, biotoxins); a chemical hazard (pesticides, antibiotics, toxic compounds, heavy metals, animal drugs, lubricants, etc.); a physical hazard (particles of glass, plastic, metal, rocks, etc.); undeclared allergens (peanuts, milk, eggs, etc.); and the presence of filth. In general, all of these factors are potentially harmful to consumers or animals and could occur either accidentally or intentionally.

A second set of situations that may trigger a recall is non-compliance with regulations. Among

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this group, the most common ones are mislabeling, use of non-permitted additives, fraud (underweight, product identity, etc.), and preventive plan failures in production or processing. Although some instances of non-compliance may result in a health hazard to humans or animals, a recall on this basis would usually be a precautionary or an enforcement measure.

2. Need for an Efficient and Effective National Recall System

In fulfilling their mandate to ensure food safety – including feed safety insofar as "food animals" enter the human food chain and may bring with them hazards acquired through feeds – food safety control authorities cannot rely entirely on industry and commerce to conduct a thorough removal of a faulty food or feed product from the marketplace and consumers' homes. Therefore, although recalls are primarily the responsibility of producers, processors and importers, the competent authority must supervise and monitor food recalls in coordination with them. To that effect, a national food and feed recall plan should exist in parallel to the individual recall plans that each food producer, processor and importer must have as part of their preventive food safety assurance system.

The need for a national food and feed recall plan has become more pressing as the world has moved from regional integration schemes to a globalized marketplace. Globalization has had a major impact on food systems. For example, the scale of production in many sectors of the food and feed industry has ballooned to the point where a single product may reach hundreds of thousands of consumers in many countries or areas of a country.

Distribution chains, in turn, have reached proportions never seen before. This is how the "world supermarket" has sprung up in many countries, where products from all over the world can be found regardless of the season. The more extensive the distribution chain, the more difficult a food or feed recall becomes, especially if the product is marketed internationally. This was the case in 2012 when frozen strawberries from China, used by a catering company that supplied school lunches across Germany, caused 11,000 cases of norovirus gastroenteritis.

With such scales of production and distribution, the threat of massive foodborne illness outbreaks has also multiplied. This was demonstrated by international incidents in Europe, such as the *E. coli* O104:H4 in German sprouts that sickened 3,000 and caused 31 deaths across Europe in 2011, and nation-wide events like the 2008 salmonellosis outbreak in 47 USA states and the District of Columbia – supposedly from Mexican jalapeño chili peppers – that caused 1329 cases and at least one death (Foodsafetynews.com, 2014).

In addition, many countries are undergoing extensive demographic changes as their elderly population increases, with corresponding increases in the population's overall susceptibility to infectious diseases such as listeriosis. Moreover, the introduction of ethnic foods not previously known in a country may also bring foodborne hazards hitherto little known to the local food safety control authorities.

All of the above highlights the need for a robust national food and feed recall plan and a recall system to implement it, which many developing countries are lacking. The lack of a national recall plan represents a serious void in a country's food safety control system, since the recall plan should be a basic component of a wider national emergency response system. There must be an official guideline on the procedures to be followed when a food or feed is found or suspected to harbor a human health or animal health hazard and must be recalled. Otherwise, at the time of a foodborne illness outbreak, there will likely be not only confusion as to what steps to take and who should take them, but there could also be a mishandling of the situation (e.g. unjustified recalls, erroneous communications, panic, etc.) leading to incomplete or lengthy recalls and adverse effects for entire sectors of industry or the consumers.

This manual has been developed to facilitate the creation of such a national recall plan and system, complementing the work done earlier on this subject by other organizations. (FAO, 2012).

3. Objectives of a Food or Feed Recall

The general objective of a food or feed recall is to protect the health of consumers and animals. From the official perspective, a food or feed recall has several specific objectives:

i. Withdraw from the market, as rapidly and completely as possible, foods or feeds that present a hazard to human or animal health.
ii. Inform the public and the media about the identity of the recalled product, the reasons for the recall, and the procedure that must be

followed to return the product to the manufacturer or retailer.

iii. Ensure that the recalled food products or feeds are disposed of appropriately.

There are other objectives from the standpoint of industry, of which the most important would be to safeguard the company's image, regain the public trust in its products, and minimize the losses.

4. Types of Food and Feed Recalls

According to the U.S. Food and Drug Administration (FDA) there are three types of recalls depending on the risk posed by the hazard and its potential severity:

> *"Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.*
>
> *Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.*
>
> *Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences."*

Examples of Class I recalls would be those due to such contaminants as pathogenic bacteria in ready-to-eat foods, toxins or class I allergens. A Class II recall, in turn, may occur in response to the finding of undeclared ingredients, filth, packaging defects or reports of tampering, whereas a Class III recall may be caused by findings of inaccurate weight or mislabeling. The classification of a recall will have a bearing on the urgency, scope and extent of publicity given to it by the competent authority. (Enforcement Policy, 2012)

5. Scope of a Food or Feed Recall

The scope of a recall depends on the type of product, its production or processing schedule, the availability of an effective, detailed traceability system of the product, and the extent of the producer's or manufacturer's supply and distribution network:

i. *The type of product* – perishable or shelf stable – will have a bearing on the period of time during which the food or feed would be expected to be kept before being consumed. Extra time may be added as a precaution to account for possible consumer storage of the product (e.g. a perishable in frozen state). In addition, a product that may be used also as an ingredient in other foods or feeds (e.g. chocolate, peanut butter) could make it necessary to expand the recall to other products.

ii. *The production or processing schedule* may influence the scope of the recall. For example, if production is scheduled by batch or by day, it might be possible to limit the recall to the defective or non-compliant batch, lot (crop collection area of a farm or farm itself), or processing day.

iii. *The detail in the traceability system* used by the producer or processor will be determinant regarding the possibility of isolating a particular batch, lot or consignment of a food or feed for recall. Otherwise, the lack of such detail or of a traceability system altogether would make it necessary to expand the recall to all the products under the particular name and brand, with potentially serious economic losses to the producer or manufacturer.

iv. *The extent of the supply and distribution network* is a factor in determining the scope of a recall because it defines the territory where the food or feed is most likely to be consumed.

6. Origin of Food or Feed Recalls

A food or feed recall may be undertaken by the competent authority for various reasons:

i. Response to an alert issued by a foreign country or an international organization such as the World Health Organization (WHO) through its International Food Safety Authorities Network (INFOSAN).

ii. Complaints from customers.

iii. Alerts from companies using a particular ingredient or intermediate product found to be contaminated or harboring other types of hazards.

iv. Reports by the national health surveillance system (hospitals, clinics).

v. Findings by regular official monitoring of contaminants in foods and feeds.
vi. Failures in food safety assurance systems in production or processing reported to the food safety control authority by a producer, processor or importer, or found during an inspection.

7. National Food or Feed Recall Plan

It is necessary to distinguish between a national food and feed recall plan from the individual recall plans that every producing, processing or importing establishment must have as part of its Hazard Analysis and Critical Control Plan. Both are complementary and therefore should fit into each other seamlessly. There are excellent descriptions of a company's recall plan (IFAS, 2010; Proyecto Innova Chile) and therefore this Manual is limited to the "national" plan.

To structure an effective and efficient food and feed recall plan it is necessary to ensure that various preconditions are met. (Fig. 1) These preconditions are the background against which the recall plan can be developed and include:

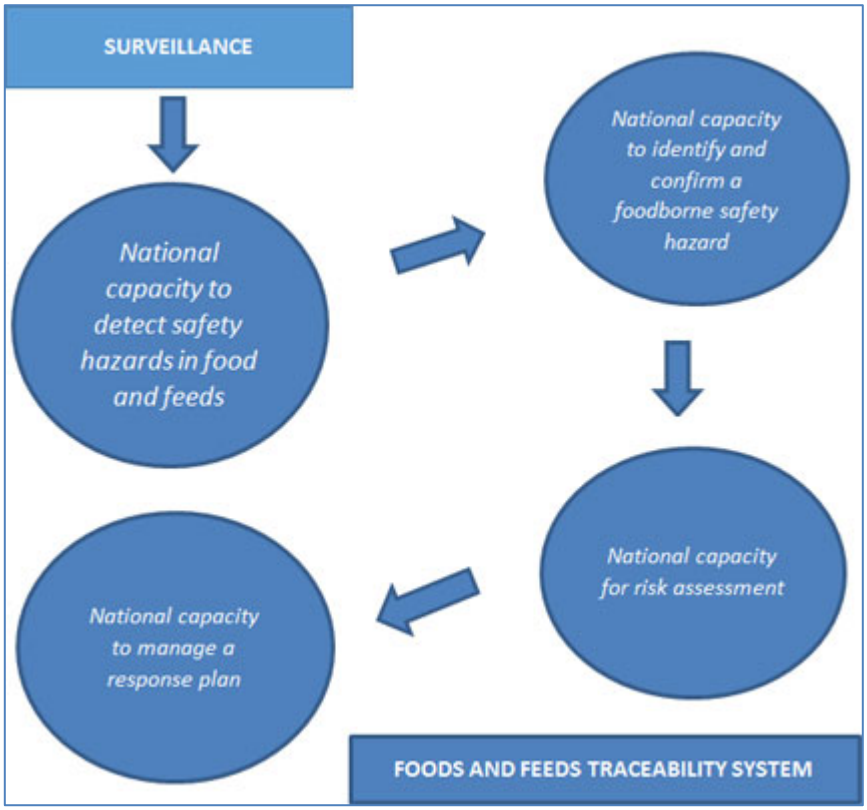

Fig. 1 - Preconditions for an effective and efficient food and feed recall system

7.1 Traceability system for food products and feeds

A traceability system should be mandatory for all foods and feeds marketed in a country so that every producer, processor or importer would be able to track its products forward down the distribution chain at any time (CAC, 2006). In the case of firms exporting to the United States, the traceability system must also operate backwards (FSMA, 2011). That is, a producer, processor or importer must be able to retrace to their origin the ingredients and other inputs used in the product.

According to the Codex Alimentarius' Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System – CAC GL 60-2006, the legislation should make the food operator responsible for identifying and storing the information it can control, that is to say, what it can verify and guarantee as part of its normal operations. This means that every operator should collect the information relevant to the safety and traceability of its food and feed products, storage and transport conditions, and processing and

distribution under its control. Therefore, for traceability to function properly in the food and feed sector, it is absolutely necessary to involve all the agents that participate in the production, transformation and distribution of the food or feed product.

Some countries have tried to establish a single traceability system across its food industry. This might be possible for specific categories of products but not so for all products and establishments. Each company might want to make its product traceability system (i.e., the information contained therein) more or less detailed to suit its needs.

A traceability system is also of importance to industry. In its absence it would be necessary to recall all products of the same type carrying the particular brand name, for it would not be possible to discriminate on the basis of production batch, lot or day. This could be economically disastrous for a producer, processor or importer.

7.2 National capacity to detect safety hazards in food and feeds

This capacity is given by an epidemiological surveillance system able to detect potential or ongoing foodborne illness outbreaks. Such a system relies on information provided by hospitals, direct medical reports, public and private laboratory reports – all of which would require mandatory reporting – a public complaint system that allows consumers to alert the competent authority and the company about faulty foods or feeds, inspection reports, and regular sampling of foods and feeds in the market conducted by the competent authority and other official agencies (e.g., Ministries of Agriculture).

In addition, the competent authority should routinely monitor and process information received from foreign food safety authorities and international organizations about hazards detected in foods and feeds that the country might be importing.

7.3 National capacity to identify and confirm a foodborne safety hazard

This capacity is given by adequately equipped laboratories and staff trained in appropriate sample taking, handling, and processing techniques. A guide for assessing the technical status of a food safety laboratory has been published by the Codex Alimentarius (CAC, 1997).

7.4 National capacity to assess the risk posed by a hazard and its severity

Risk assessment capability is often lacking in the food safety control system of many developing countries. There are international guidelines on the development of food safety risk analysis (CAC, 2012), and more specifically, of risk assessment for foods and feeds (CAC, 2007). It involves specialized training in statistical techniques and epidemiology (CAC, 1999), and its importance derives from the fact that the assessment of the risk posed by a hazard in a food or feed and its severity will determine, to a large extent, the class and urgency assigned to a recall.

When there is no local risk assessment capability, food safety control authorities may tend to overreact and base recall decisions on the precautionary principle: "when in doubt, recall." This is unfair to industry and the public. An arbitrary recall decision – not based on science, by definition – is only a way out for the "competent" authority. A careful, detailed, but swift evaluation of the risk posed by the hazard and its severity is part of the food safety control authority's responsibility to the public and to producers, processors, and importers, whose image and even economic survival may be at stake.

In the absence of local risk assessment capabilities, however, the food safety control agency may seek assistance from the corresponding food safety control authorities in neighboring countries, and/or request assistance from international organizations such as the Pan American Health Organization (PAHO) or the Food and Agriculture Organization of the United Nations (FAO). However, these procedures take time that may be critical in controlling a potential or ongoing foodborne illness outbreak.

7.5 National capacity to manage a response plan of action to contain or eliminate the hazard

Having a national emergency response plan can be of great help in the event of a food or feed recall. In fact, a recall plan could be part of such a wider national emergency response plan. In either case, however, it is essential that the competent authority conduct recall simulation exercises periodically, to ascertain that the recall plan and system are effective and efficient. The best recall plan is worthless if there is no capacity to manage it appropriately.

8. Critical Elements of a National Food and Feed Recall System

A national food and feed recall system relies on several key elements to ensure transparency and effectiveness. Some of these elements must be provided through legislation whereas others would usually be created via regulations. The elements of a recall system that must be clearly stipulated in the legislation are the following:

8.1 Authority

The power to demand from industry or directly undertake a food or feed recall by the designated national food safety control authority (i.e. the competent authority) must be in place. This authority should be granted clearly in the national food legislation.

Although a refusal by a company to conduct a recall is unusual in view of the possible consequences, it does happen occasionally For example, in 2014, the Food Safety and Inspection Service (FSIS), issued a public health alert, when a company refused to expand a recall of egg products considered by the FSIS to be unfit for human consumption (Food Safety News, 2014).

If the competent authority has the power to demand a recall and a company refuses, the competent authority must be empowered to conduct the recall by itself, charge the company the costs thereby incurred, and take other punitive actions according to regulations.

8.2 Leadership

The legislation should clearly assign the authority to order or conduct a recall to a single agency, which could act individually or be the leader of a larger, coordinated group of government agencies. Failure to designate a single authority as the pivot of food and feed recalls would likely result in confusion, delays, equivocal messages to the media and the public, and even antagonism between government agencies. The exception would be when several government agencies are in charge of various food groups, as mentioned earlier. In this case, the authority must be granted to all those agencies, each within its jurisdiction.

The designation of the competent authority, however, might follow the lines of jurisdiction prescribed in the legislation for food groups in those cases when the country has more than one food safety control agency. Such is the case of the United States with regard to meats, poultry, shelled eggs and catfish, which are under the U.S. Department of Agriculture's FSIS oversight, whereas all other foods are the purview of the FDA's Department of Health and Human Services.

8.3 Responsibility

The food regulatory system should clearly stipulate that food and feed business operators are primarily responsible for the removal of their unsafe products from the market, in cooperation with and monitored by the competent authority.

It is the producers, processors and importers who have a good handling of their distribution chain and can more readily get in touch with its clients. They can also quantify the defective product that may still be in their own warehouse. This highlights the importance of having a well-structured recall plan as part of every establishment's food safety control system. Furthermore, a recall implies logistics that may be quite costly, and it is the producer, processor or importer who should carry the economic burden of the recall. An excellent guide for preparing recall plans by industry has been published (Archer et al., 2014).

8.4 Other Elements of a National Food and Feed Recall System

Other elements of a national food and feed recall plan do not need to be legislated, but must be in place for the plan to be effective and efficient. These elements are:

8.4.1 Communication

The food safety regulatory system needs to have a communication plan and open channels within itself and with industry, the media, and the public. The communication plan should describe how information is to be disseminated, who will be informed, and who is in charge of doing it.

Risk communication is determinant in the preparation for and response to an event such as a food or feed recall (Sandman, 2003). This communication – the interaction between government, the food safety control authorities, scientific institutions, industry, media and consumers – allows all those that have been or could be exposed to the hazard in any way to participate in its reduction or prevention.

Historically, the world has suffered from large and serious errors in the risk communication process. The lessons learned from such mishaps is that communication programs implemented by governments must be based on transparency and

respond to public concerns, so that the public health protection objective can be achieved with as little disturbance as possible to community life. Risk communication should not be simply a mechanism for disseminating information, but it should also promote knowledge, understanding and exchange of information, and should help increase public confidence on the decisions made during a sanitary emergency.

A communication plan that considers interaction and exchange of information and opinions at all levels and from all stakeholders must be available before, during and after a recall. The plan must include sample messages about the nature of a hazard and its risk, and ensure that scientific and technical sources designated to deliver them do it in a simple, clear way and taking into consideration the views and concerns of non-experts. This approach, however, might be difficult or impossible in crisis situations, but even then mechanisms must be sought to achieve the community's cooperation and understanding.

Communications prior and during a recall event must be frequent, up-to-date, and coordinated through a single office or agency to avoid confusion. There should be a trained, designated spokesperson to provide information to all stakeholders. Contradictory messages must be avoided and messages must be delivered clearly and be transparent. Messages will be different for and tailored to each specific audience.

Each food or feed operator, in turn, should have its own communication policy and messages as part of their recall plan. However, to ensure there are no contradictions, the latter should be cleared with the coordinating agency before being issued. The media can promote or reinforce public behavior when facing a hazard and an inadequate communications approach to the hazard and its risk could trigger doubts among consumers and even undue alarm and panic.

Cell phones, internet and the social networks thereby developed have become a challenge for authorities with regard to communication with the public. A well-designed communications plan must be an inherent element in a recall plan and must take advantage of modern technologies. Today, globalization of information, the speed with which it can be disseminated and the capacity of individuals to deliver and spread messages are competing with more traditional media like radio and television that are less efficient in reaching the population. These are factors that must not be ignored in developing or modernizing communication plans, since they can contribute to a more efficient dissemination of information in times of crisis, to respond to public misinterpretations, and to help create a good rapport with consumers. A guide on good practices for using social media in risk communication is available (Tinker, 2014).

8.4.2 Response Plan

The existence of a national, general plan to respond to sanitary incidents (which include food and feed hazards) is necessary. The recall plan, in fact, should be part of such a wider response plan. Guides for preparing rapid response plans for sanitary emergencies have been published (FDA, 2013; FAO/WHO, 2012). Similar to the food and feed recall plan, the proper functioning of the rapid response plan must be tested periodically by means of mock exercises.

8.4.3 Disposal guidelines

There must be a plan for disposal of recalled products and for monitoring their destruction or reprocessing (if the latter is feasible). The volume of product involved in a recall might be very large, and the type of product and classification of the recall may determine its likely destination. Therefore, provisions for its disposal must be made in advance to prevent last-minute decisions that may create environmental or logistic problems. It is not uncommon that perishable products might have been consumed – or their shelf-life may have expired – by the time a recall is initiated. As a result, a recall of durable products (e.g. frozen, canned) may involve larger volumes that one for perishables and may be harder to handle because those products can be kept by consumers for a long time.

8.4.4 Continuous improvement

An evaluation procedure for completed recalls to detect weaknesses and strengths (lessons learned) and allow for further improvement of the recall plan must be in place. To that end, it is necessary to collect detailed information about the entire recall events and from all sources, and to communicate effectively at all levels, so that the information gathered can be used as a reference in similar, future events.

9. Conclusion

The key to the implementation of a successful recall of a defective feed or food product within a national safety assurance system is the existence of a national recall plan that includes all the elements discussed in this manual.

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