Effective use of food traceability in product recall

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Abstract: This chapter provides an overview of product recall process and highlights the need for traceability to achieve an effective product recall. The key tasks of a recall procedure are described and we explain how food traceability can be effectively use in product recall. We also explain how the recall process can be optimized by reducing the batch dispersion and root causes analysis through the traceability system. The link between the recall process and the different types of traceability according to the visibility and the management policy (Internal and external) and according to the level of detail of the traceability process (Unitary and batch traceability) is described.

Keywords: Traceability, product recall, root causes, recall size, batch dispersion

1. Introduction

Due to globalization of exchanges (several suppliers and customers across all continents), product complexity (several ingredients and complex manufacturing processes) and regulations (accountability of the manufacturer on its product), product recall is nowadays a challenge that is facing more and more industries (Kumar, 2014).

Product recall is "*any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor*". It should be made the difference between product recall and product withdrawal. The latter is defined *as "any measure aimed at preventing the distribution, display and offer of a product dangerous to the consumer"* (EU, 2001). According to the degree of dangerousness of the product, three classes of recall are distinguished (Kumar and Budin, 2006):

- Class 1: This is the more stringent class. It is advocated when the use or exposure to the product can cause serious and lasting health problems or death.
- Class 2: The product may cause temporary health problems but can lead in the long-term to serious problems.
- Class 3: With the lowest severity, it concerns cases where there is no health risk.

The strategy and the impact of the recall obviously vary according to the class concerned. A company may decide to issue a voluntary recall or forced to do so by authorities.

Although product recall may concern any type of product, but it is especially more frequent and critical in the field of food products (see reports (Commission, 2013b) and (Commission, 2013a)).

The causes of these recalls mainly come from raw materials (contamination, wrong dosage, foreign objects, etc.), equipment (failure, configuration mistakes, etc.) or processes (design errors,

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manufacturing, labeling, marking, handling, etc.) (Commission, 2013b, Commission, 2013a, Kumar and Budin, 2006, Kumar, Potter *et al.*, 2012, Hora *et al.*, 2011, Berman, 1999).

As the causes of a recall may arise from the materials or the process itself, traceability shall therefore bear on these two aspects namely material and process traceability. The determination of the causes of a nonconformity will depend in large part on the quality of the traceability system.

First, in the nest section, we describe the key tasks of any recall procedure. In Section 3, we explain how food traceability can be effectively use in product recall. The issue of reducing the size of the recall size through the reduction of the dispersion and root causes analysis is addressed in Section 4. The contribution of internal and external traceability to the product recall process is presented in Section 5 and finally, we make a distinction between unitary traceability and batch traceability and their uses in the recall process in Section 6.

2. Product recall

The product recall scenarios are quite varied depending on the type of product, the type and scope of the supply chain and regulation the regulations that are in force. These scenarios also vary depending on the lifetime of the product, its manufacturing process and the actors involved in its life cycle (manufacturer, distributor, and retailer) (Wynn *et al.*, 2011, Hora *et al.*, 2011, Kumar, 2014, Malickson, 1983).

Because of the unforeseen nature of such incidents and the need to react quickly in the event of product recalls, one should be prepared in advance. The actions to be implemented to cope with this type of incident should be well defined in advance. It is in this spirit that the authorities of some countries provide product recall guidelines. That is the case, for instance, for the USA *(US Food and Drugs Administration (FDA), Consumer Products Safety Commission [CPSC], National Highway Traffic Safety Administration [NHTSA])* (CPSC, 2014, FDA, 2014), the EU (PROSAFE, 2011, services, 2014) and Australia *(Australian Competition and Consumer Commission)* (Branch and Commission). Standardization bodies such as GS1 (GS1, 2012) or industrial federations have also developed product recall standards. The GS1 product recall standard for example defines and standardizes critical attributes to be collected and exchanged between partners in the supply chain and authorities during a recall. More or less similar recall procedures have been published in the literature. Analysis of these procedures allows to identify the main actions carried out during a recall. In (Wynn *et al*., 2011), the authors propose a generic workflow to coordinate the product recall process and communication with stakeholders. The main identified activities were:

- In-depth assessment of the situation in order to investigate the causes and involved products and entities
- Risk analysis to decide whether or not to make a recall and to determine the scope of the recall
- When a recall is decided, perform the call by following a pre-established guide
- Correct the causes of the recall
- Communicate and document the incident

Kumar relates the recall procedure of a large international group that includes the following steps 1) notification to the relevant authorities of the intention of the company to undertake a recall, 2) publication of the recall notice on the media (websites and / or newspapers), 3) incentive for customers to return products and 4) compensation to customers on the basis of existing laws and the causes of the recall (Kumar, 2014). Berman divide the recall activities into three groups depending on whether they are carried out before, during or after the recall (Berman, 1999). Product recall being by definition unpredictable, it should be anticipated. Among preventive actions, B. Barry cites the designation of a

product recall committee and a coordinator, the establishment of a planning of security operations, the development and maintenance of effective channels of communication, the development and maintenance of efficient products and customers databases. Safety analysis, budget estimation, information of the intermediaries and end customers, the recovery of recalled products and repair or replacement of the recalled products are the activities promoted during the recall. After the recall, the author suggests to tackle the restoration of the reputation of the firm and to evaluate the effectiveness of the recall process. Hamory and Duffy identified six actions to be taken following the detection of the problem requiring a recall, which are: verification and characterization of the problem, the determination of the scope of the problem, information for in-house staff, warning the other stakeholders, the implementation of corrective action (recall, replacement, repair, destruction) and the documentation of the recall process (Riggs Duffy and Hamory, 1987).

By analysing these different procedures, we find common actions to all of these procedures expressed differently by the authors or sometimes in an implicit way. These common actions that contribute to achieve an efficient recall are: root cause analysis, risk analysis, the recall itself, communication and documentation and post-crisis management.

2.1. Cause analysis

Analysis of the causes should take place immediately after the detection or reporting of non-compliance. Non-compliance may be detected by the manufacturer, distributor, retailer, consumer or authorities (Magno, 2012, Kumar, 2014, Riggs Duffy and Hamory, 1987). The determination of the causes may be obvious or may require further investigation. The causes can be determined by analyzing the traceability data related to manufacturing and distribution processes. Thanks to the determination of the causes, one can situate accountability for the detected non-compliance. The causes may result from the manufacturing process, transportation, storage or use (Riggs Duffy and Hamory, 1987). The information collected during this cause analysis phase will serve in all the other actions of the recall process (Kramer *et al*., 2005).

2.2. Risk analysis

Risk analysis can be performed after the reporting and confirmation of non-compliance or after the search of the causes of the non-compliance. One of the risk analysis objectives is to decide whether or not a recall is necessary. This decision may be taken by authorities and imposed on the manufacturer. The recall decision can also be taken voluntarily by producers when it is aware of the danger or as a precautionary measure. The risk analysis also helps to define the products to be recalled. If the causes of the non-compliance are not known, all manufactured lots are generally recalled.

A SWOT (Strengths, Weaknesses, Opportunities y Threats) analysis can be used to decide whether it is appropriate to make a recall in the case of a voluntary recall. FMEA (Failure Mode and Effects Analysis), HACCP (Hazard Analysis Critical Control Points) and fault-tree methods can also be used for risk assessment.

Risk analysis can be used as a preventive measure to avoid the recall or as corrective action to better manage the crisis related to the product recall by choosing the most appropriate corrective action (Berman, 1999). It assists in determining the criticality class of the recall and thus to make appropriate decisions. Among the possible strategies, the company may decide to make a full or a selective recall, to issue a warning or to modify the instruction manual and/or the labelling (Berman, 1999).

2.3. The recall itself

When a recall is decided, two cases can be distinguished. In the first case, the product is still within the supply chain in a warehouse, stored by a distributor or at a retail outlet. In the second case, the

product has reached the end customers. The first case is relatively easier to manage. If a good traceability exists, it will be easier to determine which items to recall and their locations. In the second case, the task is more delicate and require the cooperation of the retailer and the media to inform potential holders of the products of their dangerousness and induce them to return the non-compliant products. In the latter case, it is necessary to master the communication with the public. To encourage consumers to return defective products, awards, in addition to reimbursement of the defective product, can be granted to them (Berman, 1999). To manage the process, the product recall can be treated as a reverse logistics process (Hora *et al*., 2011). The recalled faulty products are either repaired or destroyed.

2.4. Communication and documentation

The management of the incident related to the recall includes internal communication (legal department, management, employees …) and external communication with other stakeholders in the supply chain (suppliers, subcontractors ...) with authorities, media, customers and the general public. The constraints and means vary depending on the interlocutor. It is appropriate to be prepared in advance and not to improvise. Because a communication error could have significant financial and legal consequences. The messages delivered should be consistent and comply with the legal obligations. External communication is often about the causes of the recall and corrective actions taken or to be taken (Hora *et al*., 2011). The concerned products, the nature of the problem and the primary contact person must be correctly indicated (Berman, 1999). The company responsible for the recall must inform its employees and partners (intermediaries, distributors) about the nature of the risk and the procedure put in place to make the recall (Berman, 1999). The media can help in the management of the crisis by informing the public concerned about the crisis and the procedure to be followed to reduce risk. They can also complicate the management of the crisis by creating panic among consumers, blurring the message or by affecting the company's brand image (Malickson, 1983). Clear communication policy must be set to take advantage of the media and minimize the effects of negative publicity.

2.5. Post-crisis management

All actions undertaken as part of the recall process must be recorded. This documentation of the incident could be used for continuous improvement to prevent such an incident from happening again or for managing litigation cases. The documentation also helps to remember the causes and actions put in place to be better prepared in the future. It also enables to transmit to competent authorities information on the management of the crisis and to learn much from this experience.

Despite the challenges that can entail a recall, the scientific literature in this area is not very abundant (Magno, 2012). Existing studies are often on the impacts (financial, on the brand image ...) that can have a recall and management organisation for this type of crisis. To successfully complete the various actions recommended by the different approaches, companies must have reliable and detailed knowledge of the failure causing the recall and the severity and extent of the incident. This knowledge is best acquired through a comprehensive and reliable traceability system. The fast and reliable determination of root causes of the incident and the identification of the other potentially affected products allows for a targeted recall and limiting the direct and indirect impacts of the recall. The analysis of root causes requires a lot of time and resources according to the stage of the life cycle from which the defect comes (design, manufacturing, storage, distribution, use). When the fault is likely to endanger users and if the root cause is not easily identifiable, the recall is made first and the search for the root cause is subsequently carried out (see fig. 1).

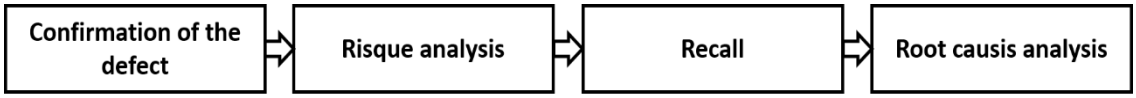

Figure 1. The sequence of recall tasks when the analysis of root causes is performed after the recall itself

The recall done this way most often concerns the entire production lot. For of a batch production and in the case of contamination, recalling the entire batch is justified. But in the case of other types of production and when the fault does not concern the whole production lot, recalling the whole lot is unjustified and entails additional costs that are avoidable. In the latter case, one should look for the root causes first and only recall the products identified as potentially faulty (see fig. 2).

Figure 2. Recall procedure with the analysis of root causes before performing the recall

B. Berman (Berman, 1999) provides some example of direct and indirect costs of a product recall. Investigation costs, transportation and storage costs, reimbursement and fines costs are examples of expenses faced by company performing a recall. Knowing the life cycle of the product from the origin of raw materials and its path is essential to identify the products to be recalled and set an effective procedure for the recall. That is why traceability plays a key role in product recall process (Kumar, Wynn *et al*., 2011, Kumar and Budin, 2006). Given that the causes of a recall can come from materials or from the process itself, traceability must cover both the materials and processes. The EU requires for certain products (food and drugs) the possibility to trace all the items from suppliers to final consumers (Kumar, 2014, Wynn et al., 2011, Dabbene et al., 2014). Through good traceability, we can determine, locate and date with certainty the events that occurred during the product life cycle. It will therefore be possible to search for the root causes and to identify the products likely to present the same failure. The ability to trace the product to be recalled is a common need for all recall procedures previously mentioned (Wynn *et al*., 2011). The determination of the causes of non-compliance where these are not obvious will depend, in large part, on the quality of the existing traceability system. In the following section, we will examine the relationship that exists between the product recall procedure and the traceability system.

3. Traceability and product recall

If traceability is imposed in some cases by the regulation, it is primarily to allow the identification of all potentially defective items in the event of product recalls (Storøy *et al*., 2013, Thakur, 2010). According to the ISO 22005 standard, traceability systems contribute to the search for the cause of nonconformity and enable, if necessary, withdraw and / or recall products (ISO, 2007).

Within the framework of product recall, two types of traceability are necessary: tracking or forward traceability and tracing or backward traceability (Wynn *et al*., 2011, Storøy *et al*., 2013).

The tracking or forward traceability makes it possible to determine the finished products containing a particular ingredient or having undergone a particular process. Tracing or Backward traceability, in turn, is useful in identifying suppliers and processes that have contributed to production of a particular product.

Traceability data may be minimum and contain only the date of manufacture, expiry date and batch number, for example. It can likewise be richer including process data serialized at item level. The finer

the traceability data is, the most targeted the recall is (Moe, 1998, Berman, 1999). Targeted recall borderline the recall to only defective items. It thus allows to reduce the direct and indirect impacts of the recall.Kumar and Budin give examples of recalls in which a massive recall was conducted beyond the non-compliant products because that traceability was lacking (Kumar and Budin, 2006).

The recall also requires internal and external traceability. External traceability serves among others for determining the location of items to be recalled and to coordinate recall actions. The internal traceability contributes to the achievement of root causes analysis to determine the causes of non-compliance and to perform a targeted recall.

4. Minimizing of the size of the recall through the traceability system by the reduction of the dispersion and root causes analysis

Usual strategy which consists of recalling entire lots without knowing the status (compliant or not) of recalled products is expensive and does not foster continuous improvement (Diallo *et al.*, 2014). This strategy induces sometimes unjustified and avoidable costs. These are direct costs related to the recall activities and indirect cost especially the impact on the brand image. These massive recalls are generally carried out without knowing the status of all the recalled products. There are several examples where companies do very large recall because they cannot identify really defective items (Hora *et al.*, 2011). In this section, we discuss the different two possibilities to reduce the number of recalled products: reduction of the dispersion and determination of root causes to optimize the size of the recalled lots.

Some work has addressed the issue of reducing the number of recalled products. In (Kumar, 2014), the FMEA method and fault tree were used to determine the causes of non-compliance and to assess the reliability of the recall supply chain. In (Kumar and Budin, 2006), the HACCP method is used to prevent a recall or to better manage the crisis caused by the recall. In order to estimate the cost borne by each actor of the supply chain during a recall, the authors of (Piramuthu *et al.*, 2013) drew on a probabilistic model of the place of contamination. They determine the level of the supply chain at which the recall should be done. The considered supply chain consists of three levels: producer, distributor and retailer. Conze and Kruger define the recall strategy to adopt based on a probabilistic risk analysis (Conze and Kruger, 2013). The work published by Chen and Schweickert propose to determine the conditional probability of a product recall knowing that the products just before or after are recalled (Chen and Schweickert, 2004). They calculate the probability of recalling products adjacent to a recalled product.

Among the approaches determining root causes to optimize the size of the recalled lots, we can distinguish those using deterministic reliability engineering tools such as FMECA, HACCP, cause effect diagram and fault tree from those taking a probabilistic approach. In the industrial context with complicated and difficult to model processes and involving uncertainty, the use of deterministic methods with categorical decisions is not always justifiable. It is therefore necessary to define a probabilistic causal analysis model taking into account these uncertainties (Kumar, 2014). The other solution proposed to reduce the recall size is to reduce the dispersion.

To reduce the size of the recalled lots, other authors have proposed to reduce the batch dispersion by reducing the size and the mixing of batches using linear programming (Dupuy *et al.*, 2005) or genetic algorithms and neural networks (Tamayo *et al.*, 2009). Dupuy *et al*. define the notions of downward dispersion, upward dispersion and batch dispersion. The downward dispersion of a raw material batch is "*the number of finished product batches which contain parts of this raw material batch*", the upward dispersion of a finished product batch is "*the number of different raw material batches used to produce*

this batch" and the batch dispersion is "*the sum of all raw material downward dispersion and all finished products upward dispersion*" (Dupuy *et al.*, 2005). The principle of the batch dispersion methodology is to identify and recall all the finished products containing the non-compliant raw material batch. Thus, if the downward dispersion is large, the amount of recalled products will be too. In addition, if a non-compliant product is detected, all raw material batches used to produce it must be analyzed to investigate the causes of the nonconformity. Also in this case, low upward dispersion will make analysis of the raw material batches much quicker and easier to accomplish. In brief, a low batch dispersion will allow to minimize recall size. However, before considering this solution of the reduction of the dispersion to minimize the quantity of recalled items, one should first assess how much leeway is possible in changing recipes and the costs that it involve. Indeed, in many industries, raw material batches from different suppliers for which some characteristic parameters are different are often mixed together (Memon *et al*., 2014). Furthermore, the definition of a batch depends on the type of production (continuous production or batch production) and the intended use. The input raw material is not always sufficient to characterize a batch. The series of manufacturing operations should also be considered. The definition of Dupuy *et al.* applies primarily to batch production systems.

For continuous or job production, the concept of a lot may be different from that of the batch production. In case of continuous or job production, a lot based recall may not be optimal because the articles of the same production lot may have different compositions or be produced in different conditions. Thereby, certain products of the recalled production batch may not have the non-compliance for which the recall is made.

Minimizing the size of the recall by reducing the batch dispersion as explained previously is applicable if the non-compliance is related to materials contained the final product. Production faults, operating errors and design mistakes are other potential causes of recall to consider.

5. The need of internal traceability in addition to external traceability

To successfully complete actions that contribute to achieve an effective recall, we need a reliable and thorough knowledge about the fault which caused the recall and about the severity and the extent of the problem. This knowledge is needed to quickly determine the root cause of the incident and the other potentially affected products. An effective collaboration between the different actors of the supply chain is another critical success factor. A good traceability system is necessary to achieve an effective recall. In terms of visibility and management policy, there are two levels of traceability: internal and external traceability (AISBL, 2013). Internal traceability concerns private data such as product design data and production parameters, origin of raw materials and quality records. External traceability is related to public data that the different partners in a supply chain exchange between them to ensure end-to-end traceability. The types of data, the means for data collection and storage for the two levels of traceability are different. Both level of traceability are useful for the recall process. To find the roots causes of noncompliant one mostly need the internal traceability data (Diallo *et al.*, 2014). The external traceability is necessary to determine the locations items to recall, the supplier of a given raw material and to manage the return the non-compliant products.

6. Use of batch traceability and unitary traceability in recall procedure

Depending on the level of detail of the traceability process, a distinction could be drawn between batch traceability and unitary traceability. For batch traceability, the TRU (Traceable Resource Unit) is a batch

of products. Product items belonging to the same batch are considered to be homogenous and share a common batch number. Under batch traceability procedure, for each tracked parameter, only one value is retained for all the items in the batch. The unitary traceability enable a serialized unique identification at the item level. Each item is uniquely identified using a serial number. Each item has a value for each of the tracked parameters. This requires a more complex tracking system and generates a very large amount of data. The unitary traceability is useful to achieve a targeted recall by the fact it offers extensive knowledge of the production processes and the supply chain. However, for some type of batch production system including food industry, it is not necessary to implement a unitary traceability. The batch traceability is enough for these systems because incidents derive from materials and production recipes most of the time.

7. Conclusion and perspectives

The product recall is a curative action that involves withdrawing from the market all products likely to present a defect that could affect the health or safety of consumers. To achieve an efficient recall, a reliable and adapted traceability system must be established. The actions to be implemented in case of recall should also be anticipated in order to avoid any type of impromptu action. In the case of complex industrial systems with many stakeholders, the search for root causes of a defect may be difficult and time consuming. When the variability of the process is high, with complicated and difficult to model processes and involving uncertainty, the use of deterministic methods such as FMEA, HACCP and fault tree with categorical decisions for causal analysis is not possible. Hence the need to develop more sophisticated analysis tools. Probabilistic approaches such as Bayesian network offer interesting perspectives to address these challenges through the exploitation of traceability data to complement the expert knowledge.

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