

<b>Code</b>	PRO-016-00
<b>Name</b>	TRACEABILITY AND WITHDRAWAL OF FINISHED PRODUCT
<b>Date of issue</b>	December 15, 2018
<b>Date of modification</b>	December 15, 2018
<b>Objective</b>	<ul style="list-style-type: none"> <li>• Establish the guidelines for traceability and product recall.</li> <li>• Have the ability to track travel through the specified stages of production, storage and distribution.</li> <li>• To be able to carry out the monitoring (traceability) of PT to the customer (one forward), and through the process, to the supplier, manufacturer of MP, Packaging that comes into contact with food, materials and other supplies (one towards behind).</li> <li>• Having the ability to recover a product that has gone on the market, at the point of sale or with the final consumer due to a Safety or Quality problem.</li> </ul>
<b>Responsible</b>	Responsible for the Safety and Quality system.

## GENERALITIES

### 1. Traceability

Set of those pre-established and self-sufficient procedures that allow to know the history, location and trajectory of a product or batch of products along the supply chain at a given time, through certain tools. Identification of products such as raw materials, packaging materials, intermediate products and finished product, by assigning a single lot for each delivery of raw material, production and finished product, this lot is assigned by the Production Manager.

Quality Control must ensure that the lot corresponding to the product is clearly identified. The records involved in the traceability of the products must include at least:

- Raw material records including supplier, transport, reception conditions, storage and unique identification of each receipt (date of receipt and batch).
- Production records and quality control results.
- Storage logs of the finished product.
- Shipping records where the customer is specified and the transport used.
- The list of documents related to traceability is documented.



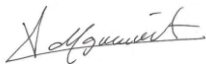





## 2. Producto recall

If a problem occurs with the finished product, whether due to a complaint, return or when internally it is detected that any ingredient, process stage or finished product presents safety problems, a product withdrawal should be considered, for which the Group of Retirement Management must request the information corresponding to the traceability of the product in suspicion of those responsible for the safekeeping of the records and give immediate notice to the Secretary of health of the state where they, depending on the problem that arises, identify the risk and decide if it gives Health secretary follow-up or give notice to the Cofepris (commission of health operations). SQF and the certifying body will be notified in writing within 24 hours of the identification of a food safety case that requires public notification. The SQFI will be notified by email, at [foodsafetycrisi@sqfi.com](mailto:foodsafetycrisi@sqfi.com).

## 3. Formation of the Retirement Management Group.

The formation of the Retirement Management Group is as follows:

NAME	AREA	FUNCTION	CELL PHONE	FIRM
Sandra Castillo Cervantes	Quality Management	Team Leader Responsible for the correct application of the system	4433902495	
Gerónimo Villanueva Noguera	Chief Executive Officer Responsible for Marketing and Sales	Member	5514747104	
Margarita Ruan Chávez	Production Management and Purchasing Manager	Member	4432278397	
Rafael Dueñas Vargas	Technology Management	Member	4434400710	
Cleotilde Sotomayor Arroyo	Production and Quality Supervisor	Member	4431042226	
Sarah Paredes	Logistics and Foreign Trade	Member	5566736564	

## 4. Withdrawal strategy

factors that can lead to a withdrawal strategy:

- a) Public complaint
- b) Exchange of information between national or international institutions or agencies.
- c) General public: consumers, distributors, buyers, etc.
- d) Verification procedures by the Authority.
- e) Result of the analyzes performed on the product, when applicable.

The Withdrawal Management Group must analyze the product information with problems affecting safety, if necessary by calling the safety and quality system team, and determine whether it is necessary to carry out a withdrawal or not. The collection of information, its analysis and the conclusions of the Retirement Management Group are recorded in the Traceability Evaluation and Product Recall format. In case the withdrawal proceeds, the Retirement Management Group must coordinate the recovery of all the affected product:

## 5. Product withdrawal notification.

Notify that the delivery or sale, as the case may be, of said lot must be suspended by telephone. If it is possible to rely on corporate communications from THE CLIENTS.

Notify by any communication system available to the State Authority and the state communicate to the Federal Commission for Protection against Health Risks COFEPRIS if required. SQF and the certifying body will be notified in writing within 24 hours of the identification of a food safety case that requires public notification. The SQFI will be notified by email, at [foodsafetycrisi@sqfi.com](mailto:foodsafetycrisi@sqfi.com)

- The basic information that a product recall notification must contain is:
  - a) Product to be recalled. If there is knowledge of the following details, these must be provided to the Authority: trade name, brand, lot number, barcode or any other that is useful for the identification thereof.
  - b) Amount of product to be withdrawn from the market, also inform the amount of product that is still in possession.
- Pick up the product at distribution centers, facilities and / or points of sale if necessary.
- The product removed must be identified and segregated until the Safety and Quality System team can meet and decide the final disposition of the product:
  - a) Reprocessing: if the product can return to conformity.



- b) Willing for a different use, as long as the product is safe for the intended use.
- c) Destroy or dispose of as garbage in accordance with the PRO-002 WASTE MANAGEMENT procedure and the MAN-007-00 MANUAL PRODUCT MANAGEMENT DOES NOT CONFORM.

Once the product is ready, the Retirement Management Group must request the corresponding corrective action. And attach a copy of the records involved in the analysis and disposition of the products.

## **6. Product removal procedures when it has been exported to the US**

When a product subject to withdrawal has been distributed to the United States of America and does not satisfy all the sanitary conditions described in this Model Ordinance, IF OR IF FOOD gives COFEPRIS notice to the sanitary operations commission area, it is at In turn, you must immediately report the situation to the Food and Drug Administration (FDA), so that this US Health Authority. can carry out the conducive measures. SQF and the certifying body will be notified in writing within 24 hours of the identification of a food safety case that requires public notification. The SQFI will be notified by email, at [foodsafetycrisi@sqfi.com](mailto:foodsafetycrisi@sqfi.com) .

## **7. Product recall evaluation**

Once the product recall is finished, the Retirement Management Group must evaluate the effectiveness of the product recall and the performance of those involved. In case of detecting deviations, the Retirement Management group must request the necessary Corrective Actions. The evaluation is recorded in the Product withdrawal evaluation format. PRO-024-00 CORRECTIVE AND PREVENTIVE MEASURES

## **8. Termination of product withdrawal actions.**

The withdrawal of the product from the market must end once the Authority has determined that the disposition of the product has been adequate or that the corrections have been implemented.

## **9. Mock product recall**

Annually, the Retirement Management Group must conduct a mock recall in order to measure the capacity of product recall, as well as the efficiency of the recall program.


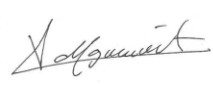



The Withdrawal Management Group determines a fictitious cause of product recall and carries out the established withdrawal as mentioned in this manual. The Retirement Management Group reports the results of the drill and feedback to the areas involved.

In case the result of the simulation is unsatisfactory (for example, the total identification of the affected product is not achieved, or it takes more than two days in the withdrawal) the Retirement Management group requests the necessary corrective actions and reschedules the simulation 3 months later.

## 10. Directory

<b>LEGAL ADVICE</b>	Miguel Uriarte García	55 3717 2703 <a href="mailto:muriarte@cimpulsa.com">muriarte@cimpulsa.com</a>
<b>REGULATORY ADVICE</b>	Directory Ministry of Health of Mexico	312 11 35 ó 317 20 47
	Directory Cofepris	50805200 ext. 1391
	Directory SQF	<a href="mailto:foodsafetycrisi@sqfi.com">foodsafetycrisi@sqfi.com</a>
	Directory FDA MyFDA Support Team Registrar Corp 144 Research Drive Hampton, Virginia 23666	Tel: +1-757-224-0177 Fax: +1-757-224-0179 Email: <a href="mailto:myfda@registrarcorp.com">myfda@registrarcorp.com</a> Web Site: <a href="https://www.myfda.com">https://www.myfda.com</a>
<b>EXPERT ADVICE</b>	SQF certification directory: SGS de México, S.A. de C.V. Reforma 560, col. Lomas de Chapultepec, Delegación Miguel Hidalgo, Ciudad de México. C.P. 11000	52 55 5387 2154
	PEST CONTROL FUMOCC Gregorio López	4431283106

Produced by:	Validated by:	Verified by:
 Quality supervisor	 Production manager	 Head of Safety System

