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# **XVIII WORKSHOP MÉTODOS RÁPIDOS Y AUTOMATIZACIÓN EN MICROBIOLOGÍA ALIMENTARIA**

**La importancia del  
control ambiental en la  
industria alimentaria y  
su repercusión en los  
esquemas GFSI**



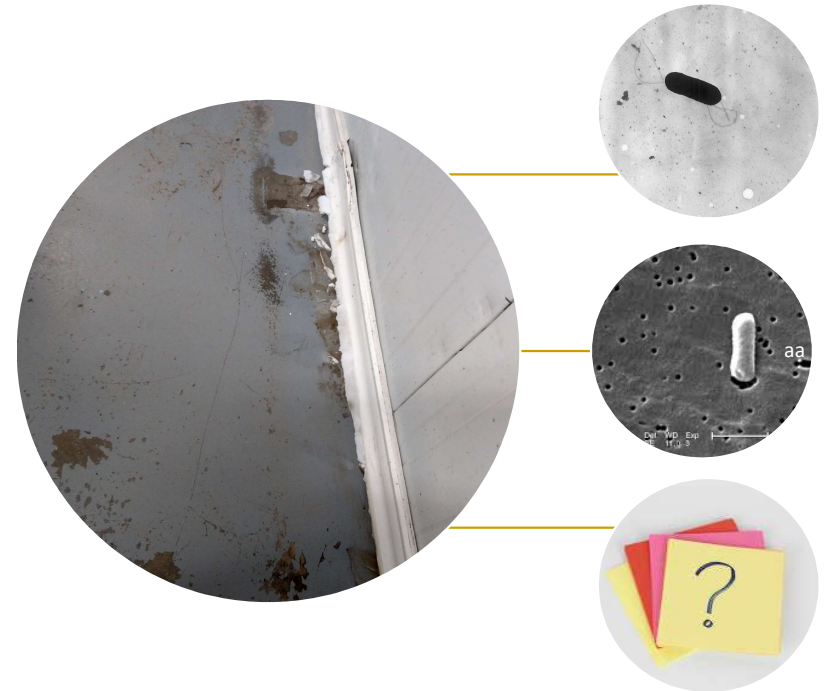


## ENVIRONMENTAL PATHOGEN

A pathogen capable of surviving and persisting within the manufacturing, processing, packing or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen.

Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella spp.* but do not include the spores of pathogenic spore forming bacteria.

Fuente: Food and Drug Administration (FDA). 21 CFR 117.3 Definitions



# ENVIRONMENTAL PATHOGEN



## Microorganismos transitorios

Fuentes de contaminación:

- Materias primas (incluyendo material de envase)
- Personal

Normalmente se eliminan a través de los planes de limpieza y desinfección

No se establecen en las instalaciones

## Microorganismos resistentes

Se establecen en las instalaciones... rincones y/o grietas → nichos – refugios ambientales

Las zonas donde se encuentran los nichos son difíciles de limpiar y desinfectar

Permanecen en las instalaciones por largos periodos de tiempo.



# ZONIFICACION



La zonificación es útil para reducir la propagación potencial de patógenos en instalaciones que fabrican productos listos para consumir  
Implica la separación de, por ejemplo, de producto cocinado de producto crudo, incluyendo personal de producción, útiles de trabajo, ....

## Evaluación documentada

Aspectos a considerar:

- Infraestructura
- Flujos del personal, materias primas, semielaborados,...
- Áreas de contacto cruzado
- Flujos del aire
- Servicios (aire comprimido)
- Áreas colindantes

## Determinación del control a realizar

Preguntas básicas referentes a:

- Características de la formulación del producto
- El producto o ingredientes están asociados a la contaminación del patógeno
- Validación de los procesos
- Exposición al entorno
- Ingredientes utilizados para elaborar los productos listos para el consumo
- El producto final es soporte de crecimiento de patógenos (*L. monocytogenes*)

## Plan de monitorización

Finalidad:

- Verificar el programa de limpieza y desinfección
- Verificar que el sistema de zonificación evita la contaminación cruzada y la presencia de nichos
- Entender las posibles circunstancias cambiantes (instalaciones, planes de I+d,...)

# ZONIFICACION



## Zona D

Vestuarios, cantinas, pasillos, talleres de Mantenimiento...



## Zona C

Incluye suelos, paredes, techos, rejillas y equipos



## Zona B

Áreas adyacentes a las de contacto directo con el producto (delantales, soportes, paneles de equipos...)



## Zona A

Áreas en contacto directo con el product (Cintas transportadoras, cajas, utensilios de trabajo, manipuladores (manos),...)

Contaminación más frecuente.

Analizando estas áreas se aumenta la probabilidad de detectar posibles fuentes de contaminación antes de que aparezca en el producto.



# ENVIRONMENTAL MONITORING - GFSI SCHEMES

## 4.11.8 ENVIRONMENTAL MONITORING

Risk-based environmental monitoring programmes shall be in place for pathogens or spoilage organisms. At a minimum, these shall include all production areas with open and ready-to-eat products.

### 4.11.8.1

The design of the environmental monitoring programme shall be based on risk, and at a minimum include:

- sampling protocol
- identification of sample locations
- frequency of tests
- target organism(s) (e.g. pathogens, spoilage organisms and/or indicator organisms)
- test methods (e.g. settle plates, rapid testing and swabs)
- recording and evaluation of results.

The programme and its associated procedures shall be documented.

### 4.11.8.2

Appropriate control limits shall be defined for the environmental monitoring programme.

The company shall document the corrective action to be taken when monitored results indicate a failure to meet a control limit, or when monitored results indicate an upward trend of positive results.

### 4.11.8.3

The company shall review the environmental monitoring programme at least annually and whenever there are:

- changes in processing conditions, process flow or equipment
- new developments in scientific information
- failures of the programme to identify a significant issue (e.g. regulatory authority tests identifying positive results which the site programme did not)
- product failures (products with positive tests)
- consistently negative results (e.g. a site with a long history of negative results should review its programme to consider whether the correct parts of the factory are being tested, whether the testing is being conducted correctly, whether the tests are for the appropriate organisms, etc.).



# ENVIRONMENTAL MONITORING - GFSI SCHEMES



## 4.11 HOUSEKEEPING AND HYGIENE



### FUNDAMENTAL

Housekeeping and cleaning systems shall be in place which ensure appropriate standards of hygiene are maintained at all times and the risk of product contamination is minimised.

### 4.11.3

Limits of acceptable and unacceptable cleaning performance shall be defined for food contact surfaces and processing equipment. These limits shall be based on the potential hazards relevant to the product or processing area (e.g. microbiological, allergen, foreign-body contamination or product-to-product contamination). Therefore, acceptable levels of cleaning may be defined by visual appearance, ATP bioluminescence techniques (see glossary), microbiological testing, allergen testing or chemical testing as appropriate.

The site shall define the corrective action to be taken when monitored results are outside of the acceptable limits.

Where cleaning procedures are part of a defined prerequisite plan to control the risk of a specific hazard, the cleaning and disinfection procedures and their frequency shall be validated and records maintained. This shall include the risk from cleaning chemical residues on food contact surfaces.





# ENVIRONMENTAL MONITORING – GFSI SCHEMES



## 2.5.7 ENVIRONMENTAL MONITORING (FOOD CHAIN CATEGORIES C, I & K)

The organization shall have in place:

- a) Risk-based environmental monitoring program;
- b) Documented procedure for the evaluation of the effectiveness of all controls on preventing contamination from the manufacturing environment and this shall include, at a minimum, the evaluation of microbiological and allergen controls present;
- c) Data of the monitoring activities including regular trend analysis.

### 11.5 Monitoring sanitation effectiveness

Cleaning and sanitation programmes shall be monitored at frequencies specified by the organization to ensure their continuing suitability and effectiveness.



## ENVIRONMENTAL MONITORING – GFSI SCHEMES



<b>5.6 Product and Process Analysis</b>	
5.6.1	<p>Testing plans, for internal and external analysis shall be justified by risk assessment, to ensure product quality, safety, legal and specific customer requirements are met. The plans shall cover topics such as:</p> <ul style="list-style-type: none"><li>- raw materials,</li><li>- semi-processed products,</li><li>- finished products,</li><li>- packaging materials,</li><li>- contact surface of processing equipment</li><li>- relevant parameters for environmental control.</li></ul> <p>All results of testing shall be recorded.</p>

## ENVIRONMENTAL MONITORING – GFSI SCHEMES



4.10.5	<p>Based on hazard analysis and assessment of associated risks, the effectiveness of the cleaning and disinfection measures, shall be verified. The verification shall be based on an appropriate sampling schedule considering :</p> <ul style="list-style-type: none"><li>- visual inspection</li><li>- rapid testing</li><li>- analytical testing methods</li></ul> <p>Resultant corrective actions shall be documented.</p>
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# GRACIAS POR VUESTRA ATENCIÓN

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