



Control of Nonconforming Product

FSKN 13

GFSI Basic Level

- The organisation shall ensure that any product, which does not conform to requirements, is clearly identified and controlled to prevent unintended use or delivery.

Presentation Outline

- Definitions
- Requirements for Nonconforming Products
- Management and Records



Definition

Nonconforming Product

- Food product produced during a loss of control that necessitates a correction.
- Includes all product back to the last valid determination that the process was under control.



Requirements for Nonconforming Products

- Actions will be taken to prevent the nonconforming product from entering the food chain unless it can be assured that:
 - The food safety hazard(s) of concern has(have) been reduced to the defined acceptable levels,
 - The food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering the food chain, or
 - The product still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the nonconformity.



Requirements for Nonconforming Products

- All lots of product affected by a nonconforming situation shall be held under control of the organization until they have been evaluated.
- If products that have left control of the organization are subsequently determined to be unsafe, the organization shall notify relevant interested parties and initiate a withdrawal.
- The controls and related responses and authorization for dealing with potentially unsafe products shall be documented.



ISO 22000:2005

Evaluation for Release

- Each lot of product affected by the nonconformity shall only be released as safe when any of the following apply:
 - Evidence other than the monitoring system demonstrates that the control measures have been effective.
 - Evidence shows that the combined effect of the control measures for that particular product complies with the performance intended.
 - The results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the food safety hazard(s) concerned.

ISO 22000:2005

Disposition of Nonconforming Products

- Following evaluation, if the lot of product is not acceptable for release it shall be handled by one of the following activities:
 - Reprocessing or further processing within or outside the organization to ensure that the food safety hazard is eliminated or reduced to acceptable levels.
 - Destruction and/or disposal as waste.

Records

- Records for corrective actions and nonconformities must include:
 - The actual production records for the product
 - A standard form listing the following:
 - Hold number, deviation, reason for hold, date and code of product held, name of responsible individual
 - Authority recommendations on final disposition of product in question
 - Accurate accounting of all units in question
 - Statement of the procedure for handling the nonconformity



QUESTIONS?



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