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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