

'Best Practice' Example: Root Cause Analysis

Scenario: A N Other & Co. produces a variety of baked products for sale in several convenience store franchises across the nation.

An operator should have weighed out a quantity of chopped coconut on their Coconut Sponge Cake production line, but mistakenly used chopped almonds in the mixture instead. As almond is an allergen and was not listed in the cakes ingredients, this resulted in a batch of the unsafe cake product being placed on the market.

A possible health risk to consumers with an allergy or intolerance to almond and other nuts was identified and A N Other & Co. issued a product recall. The business also contacted relevant allergy support organisations (who tell their members about the recall) and issued a point-of-sale notice to its customers. These notices explained why the batch of Coconut Sponge Cake was being recalled and what to do if the product had been bought.

A N Other & Co. conducted a root cause analysis (RCA) to establish the initial cause(s) of the food incident and identify actions they could take to ensure the issue did not reoccur in the future.

The following summarises the RCA undertaken:

Q

WHY did the operator make the error?

A

Operator was unfamiliar with the complete production procedure.



Q

WHY was the operator unfamiliar with the procedure?

A

Operator was trained, but no supervision or sign off had occurred to determine whether the training received was satisfactory.



Q

WHY was the training provided not satisfactory?

A

Operator's understanding of the process or the implications of diverting from the established procedure was not confirmed / signed off.



Q

WHY did this lead to the incorrect use of almonds instead of coconut in the product?

A

Operator was unable to distinguish between the coconut and almonds, as both ingredients were chopped, looked identical and were not labelled.



Q

WHY were the different ingredients not labelled?

A

Labels were removed during last clean and not replaced.



Q

WHY were the ingredient labels removed and not replaced?

A

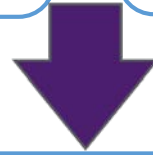
Cleaning staff didn't consider potential for error and damaged / missing labels not checked as this isn't included in anyone's duties.



Root causes

Operator's understanding of correct procedures had not been determined and the effectiveness of the training provided to new staff was not assessed.

Procedure to ensure accurate, identifiable labelling of different ingredients had not been established and the incorrect use of ingredient was missed during the manufacturing process.



Corrective actions

- Redesign training - use worksheet questions, emphasise correct procedures and include allergy awareness.
 - Assessment of trainees' understanding to be undertaken by qualified personnel (e.g. line or production manager) and countersigned document retained in records.
 - Include examples of correctly completed, annotated worksheet in work instructions (copies of which to made available in production areas).
 - Leaflets with allergy information to be made available to all staff and visitors.
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- Re-design storage area to ensure ingredients housed in dedicated locations.
 - If practical, replace ingredient labels with ones that cannot be removed.
 - Update procedure: crosscheck information at the beginning of ingredient mixing (mixing sheet, materials, packaging labelling matches the physical stock) and introduce sign off/supervision step.
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- Include label check in post-cleaning line checks.
 - Ensure cleaning staff are trained and fully understand the need to return labelled equipment in a fully operational state.
 - Ensure an individual (e.g. production manager) is authorised and responsible for post-cleaning line sign off.