

8.3.2. Method of Investigation When Outside Tolerance/Standards.

Standard

Is there a method of investigation and corrective action when results are outside tolerance/standard?

This should link to recall procedure, see clause 10.3.

This might be through the corrective action process as per clause 10.2.

Purpose

To ensure all out of specification results are investigated and actions taken do not affect the feed safety or quality of finished products.

Reason

Results that are outside tolerance standards for raw material, finished product and equipment calibrations, et al, shall be treated the same across the operators feed safety quality system. Consistency will enable the operator to address all facets of a feed safety investigation and corrective action where applicable. The ability to monitor and assess the outcome of investigation will also provide helpful insight into the ability of the operators feed safety quality system to provide consistently high standard products.

What is Acceptable?

All out of tolerance or out of specification results need to be investigated and any actions taken documented along with person authorised to make decisions. Product or materials shall not be sold where there are test results indicating requirements are not met. This might be:

- Raw material test results.
- Finished product test results.
- Equipment calibration status.
- Expiry dates exceeded.

Investigation methods shall be consistent across the operating system, and these shall be outlined in a procedure. The procedure might be related to one or more of the following where applicable:

- Follow non-conformance procedure and documentation.
- Processing raw material outside specification (Fact Sheet 6.2.7).
- Results from sampling and testing, outside tolerance standards (Fact Sheet 7.1.6).
- Issue recall & investigation, if applicable (Fact Sheet 10.3.1).
- Initiate corrective action, identify root cause (Fact Sheet 10.2.1).
- Consider rework if applicable (Fact Sheet 8.4.1).

A risk assessment will identify the urgency and requirements of a recall. The operator shall ensure the appropriate classification and actions follow.

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