

6.2.6. Processing Raw Material Outside of Specification.

Standard

Are raw materials found to be outside specification clearly identified and appropriately dealt with by authorised personnel?

Confirm who is authorised to deal with this issue.

Purpose

To ensure that authorised personnel are responsible for approving or rejecting raw material that falls outside its specification.

Reason

Outside of specification refers to a result that falls outside the predetermined acceptance criteria and/or standard. Setting an acceptance criteria for all incoming raw materials is a key component of an operators quality assurance system, ensuring the safety, efficacy and reliability of finished product.

What is Acceptable?

A procedure for the management of raw materials outside specification may be used. Alternatively, reference can be made in the operators Inwards good procedure (Fact Sheet 6.2.1 & 6.2.2) or a Non-conformance or Corrective Action Procedure (Fact Sheet 8.3.2). Sampling and testing shall be conducted as per Fact Sheet 7.1.1 & 7.1.2.

Authorised Personnel

Authorised personnel trained for accepting or rejecting raw material shall have practical experience of the potential cause and risks associated with material outside of specification. Some of these may require re-testing, issuing a non-conformance and/or root cause analysis. The trained personnel determine the correct course of action to minimise risks further down the production line.

The training and refresher training of these personnel shall follow the principles set out in Fact Sheet 3.2.

Raw Material Specification

The operator shall have a register of approved raw material and their specifications. These may be also referred to as purchasing standards. The specification should contain, but not limited to:

1. Product identification, including grade or type.
2. Nutritional composition (i.e. protein, energy, moisture).
3. Physical and chemical properties.
4. Microbiological limits.
5. Contaminant Limits, if applicable (i.e. Heavy metals).
6. Advice, Signal Headings (i.e. GMO status, RAM).
7. Packaging & storage requirements.
8. Testing & sampling requirements with specified results.

Under testing and sampling, the testing protocol required for quality control shall be listed. The type of sampling method and reference to any internal or external method of analysis may also be listed.

Determine outside of specification cause

Potential causes may include:

1. Analytical error: associated with the method, instrument or technique during testing.

2. Sampling error: Has there been contamination in the sampling process? Is the sample size sufficient? Are representative samples collected?
3. Environmental factors: Has the sample been suitably sealed and stored? Has weather affected its integrity?
4. Raw material variation: Supplier has failed to provide a consistent quality raw material. Manufacturing process may have introduced contaminants or impurities affecting final product quality.

Course of Action

With reference to the testing procedure of each raw material, the quality personnel shall review test results from on-site or off-site testing against material specification. Any out of specification result needs to be reviewed for feed safety risks. If goods are accepted, then the quality personnel are to authorise the delivery docket. Should the goods be rejected they are to be isolated from use, labelled appropriately, and remain in the quarantine area until returning to the supplier.

The investigation for out of specification results may include:

1. Repeat sampling and testing: According to set criteria/methods or instruction provided by external laboratory.
2. Issuing non-conformance: Where the variation is found to be a manufacturing issue, the quality personnel responsible for conducting an investigation may issue a non-conformance to supplier.
3. Root cause analysis: In-depth investigation to identify underlying reason for result (an example of root cause methodology is the 5 why method).

Fact Sheet 8.3.2 provides details on the method of investigation, when outside tolerance/standards.

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