

2.2.1, 2.2.2 & 2.2.3 Equipment Design, Construction, Installation, and Maintenance

Standard

2.2.1 Is appropriately designed and constructed equipment installed to meet the requirements of manufacturing stock feed?

Emphasis on use of equipment designed for feed milling.

2.2.2 Is equipment in use designed and maintained to prevent contamination during the manufacturing process?

Equipment should be in sound condition with minimal leaks of product. Confirmed through mill walk through looking for equipment leaks.

2.2.3 Is equipment designed and installed to allow for routine cleaning, maintenance and inspection? *Relates to major pieces of plant and equipment such as hammer mill/roller mill, mixer, pellet press/cooler/crumble rolls, liquid additions, packing line. Confirm cleaning and maintenance practices through viewing records.*

Purpose

To ensure the design, construction and maintenance of equipment and plant are capable of delivering safe and consistent quality stockfeed.

Reason

The overall design and installation of plant and equipment are the initial stages that can dictate the success of equipment in use during production. Operators are to control this step in qualification to improve performance and longevity of equipment. An efficiently designed mill facilitates ease of production, flow, and reduced risk of contamination.

Equipment used for processing and mixing of feed should be capable of delivering a homogenous mixture that conforms to the specifications of the stockfeed. Routine cleaning, maintenance and inspection is a proactive approach to ensuring equipment is fit for purpose.

What is Acceptable?

Equipment design and construction, including installation, should be designed to meet product specifications. This is achieved through equipment qualifications. Qualifications should be documented to demonstrate equipment meets requirements for quality and feed safety.

Design Qualification

Considerations for designing production equipment include but are not limited to:

- Materials used for product contact surfaces allow for sanitisation (e.g. stainless steel).
- Materials used for all other equipment prevents contamination through reduction in deterioration.
- Access points for cleaning and maintenance have been considered.
- Connection points are designed to prevent product getting caught.
- Process flow allows one direction of materials to reduce cross-contamination risks.
- Opening points are coverable and lockable when not in use.

Installation Qualification

Considerations for installing production equipment include but are not limited to:

- The equipment was installed as per the design, any deviations have been documented and approved.
- All connections are fully sealed to prevent leaking.
- Access points are installed to ensure cleaning and maintenance can be completed regularly.

- The correct materials have been used.

Operational Qualification

Considerations for operating tests of production equipment include but not limited to:

- The equipment operates as expected and final product is as required.
- Operations enable full traceability and control through the production process.
- Validation studies:
 - Homogenous mixing test results with CV calculation.
 - Moisture test results if relevant (e.g. pelleting).
 - Particle sizing results if relevant (e.g. sieving or cutting/grinding).
 - Contaminant lab test results as per risk assessment and/or processes used (e.g. salmonella if heat and moisture added).
 - Computer software performs controls as required.
 - Cleaning procedures perform at required level to prevent cross contamination (e.g. RAM).
 - Flushing volumes are adequate to prevent cross contamination.

Performance Qualification

Considerations for performance qualifications includes but is not limited to:

- The HACCP system been updated to include new equipment and processes.
- Ongoing validation studies have been scheduled:
 - Annual homogenous mixing.
 - Sampling and testing programs.
 - Sequencing programs.
- Cleaning programs are written and implemented.
- Maintenance programs are written and implemented.

Records

Records of the qualification of equipment should be filed. Ongoing records of monitoring of validations studies, internal audits including inspections of equipment, cleaning, sequencing, flushing, and maintenance activities must be implemented.

Retrospective validation can be used on equipment already in place.

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