

# 4.1.1 & 4.1.2. Written Formulation Master File

## Standard

4.1.1 Is there a written formulation master file, with a record of the dates of use and version numbers?  
*Either in hard copy or electronic form*

4.1.2 Is this master file maintained by an authorised person?  
*Confirm who is on the authorised person list and their experience or qualifications.*

## Purpose

To ensure a formulation master file is maintained and all changes are monitored for approval from authorised personnel.

## Reason

Formulations are central to the quality and safety of stockfeed, they are also highly confidential and should only be handled by authorised staff. By ensuring a master file is maintained, the safe and correct manufacture of stockfeed can be assured.

## What is Acceptable?

### Authorised Person

Formulations may be created by an internal staff member qualified to formulate a diet, they may also be outsourced by a third party qualified nutritionist. If the operator has an internal staff member qualified to formulate diets, this shall be specified in their job description and responsibilities (Fact Sheet 3.1.1 & 3.1.2). The personnel is authorised to create, make changes or substitutions and monitor validity of diet. They are also responsible for ensuring the Master Formulation procedure is carried out accordingly.

### Formulation Master File

Steps required to maintain a formulation master file can be found in example procedure below. The operator shall ensure a formulation master log is also maintained and contains the following, but not limited to:

Table 1. Example Master Formulation Log. Amendment Code: (RMS) Raw Material Substitution, (CusC) Customer Requesting Changes, (RMUn) Raw Material Unavailability, (RMSe) Raw Material Seasonal Variation, (Oth) Other

Code / ID	Formulation Name	Species	Amendment Code	Date Created	Valid to	Version

Example Procedure below.

# MASTER FORMULATION

## 1. PURPOSE

This procedure describes how [Insert Company Name] will control and manage all master product formulations and Bill of Materials (BOM). This procedure will provide traceability and track any formulation modification.

The procedure is intended to adhere to the Code of Good Manufacturing Practice to allow the production of high quality, safe and nutritious animal feed.

## 2. SCOPE

This procedure covers all manufacturing operations at [Insert Company Name].

Master formulations and BOM are highly confidential information and shall only be handled by authorised staff. No copies of formulations and/or BOM shall be made or distributed.

The [insert relevant positions] are directly responsible for this procedure.

## 3. TERMS & DEFINITIONS

**Formulation** – The master recipe detailing the ingredients and nutrients for a finished animal feed product. Formulations are generally calculated using a Least Cost Formulation software program and are under the control of a qualified nutritionist.

**Bill of Materials (BOM)** – Bill of Materials. The request for manufacture (which might be in the form of batch record, manufacturing instruction, or production request) provided to Production with list of materials to be used to meet formulation requirements. The BOM may be modified to account for ingredient transfer limitations within the mill, batching system error and required rounding of ingredients for practical reasons.

## 4. PROCESS

### Ingredient/Raw Material Selection

Ingredients shall be selected from Ingredient & Raw Material Register, by an experienced, qualified/authorised person. Consideration shall be given to the quality, availability and RAM status. Ensure the following elements are correct and consistent:

- Unit of measurement.
- Medication/RAM status.

### Quality Control

A quality control step shall be implemented to verify if the ingredient/raw material meets [Insert Company Name] specification. This step will allow for formula accuracy and any changes or variation to be amended in the next process steps. If any modifications are required, these shall only be managed by a qualified/authorised person and change control process.

### Formulation

A written master formulation shall be prepared by an experienced, qualified/authorised person (Managing Director and/or Nutritionist) and maintained within the Master Formulation Log.

The Master Formulation Log shall contain:

- Formulation Name.
- Formulation Code (and BOM Code if different).
- Date of Issue.
- Reason for modification or amendment (if applicable).

For each formulation the following information shall be maintained:

- The name and unique identity code of the product.
- An indication of the animal type for which the product is intended.
- Date of issue.
- The precise quantity and correct identifier for each raw material to be included.
- Micro-ingredient and hand tip information.
- Manufacturing processes such as mixing sequence, mixing times, production line, etc.

**Issue BOM**

Formulations shall be issued to Production as BOM. Each BOM can be entered either manually or via computerised batching system.

All issued BOM must be signed by the issuing person and an authorised production staff member to verify that the BOM entry into batch system was correct. The signed BOM shall be maintained in the Production Control Room in the Master BOM File.

No amendments are to be made to BOM once issued to Production, except at the directions of an authorised person (Managing Director and/or Nutritionist).

Any authorised amendment shall be documented in the daily Production Log and Manufacturing Process Instructions.

**OUTCOME**

[Insert Company Name] is committed to building a sustainable quality and safety management system and will provide the required level of resources and staff to achieve this goal.

## 5. DOCUMENTATION & RECORDS

The following records shall be maintained to assure this program was conducted according to the Quality Policy.

- Master Formulation Log
- Raw Material & Ingredient Register
- Batching Report
- Daily Production Report

## 6. DOCUMENT HISTORY

<i>Version</i>	<i>Date</i>	<i>Description of changes</i>	<i>Author</i>
1	dd/mm/yy	Created original document.	name

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