Product Design & Development Procedure

Purpose

The purpose of this procedure is to ensure that new product development and changes to existing products, packaging, and manufacturing processes are systematically controlled so that food safety, legality, and quality requirements are consistently achieved. It establishes a structured approach to the assessment, approval, and validation of product design activities, including the evaluation of hazards, implementation of appropriate controls, and verification that products can be manufactured to the required standards. This procedure also ensures that product shelf life is determined using appropriate methods and supported by documented evidence, such that products remain safe and of the intended quality throughout their defined life.

Scope

This procedure applies to the control of new product development and changes to existing products, packaging, and manufacturing processes, including the assessment of hazards, implementation of controls, validation of product formulation and processing capability, and determination of product shelf life. These activities form part of the Food Safety & Quality Management System at **[COMPANY NAME]**.

This procedure covers:

- new product development
- changes to existing product formulation
- changes to product packaging
- changes to manufacturing processes
- restrictions applied to the introduction of hazards
- formal approval of new products and product changes prior to factory introduction
- assessment of hazards associated with new products and changes
- trials using production equipment to validate product formulation and manufacturing processes
- initial shelf-life trials
- shelf-life determination
- recording and retention of shelf-life trial results
- documented science-based justification for assigned shelf life where trials are impractical

This procedure does not define requirements for document control, which are defined in:

- PRO-3.2 Document Control Procedure

This procedure does not define requirements for record completion and maintenance, which are defined in:

- PRO-3.3 Record Completion & Maintenance Procedure

All activities governed by this procedure shall be consistent with the intent of:

- POL-1 Food Safety, Quality, Legality & Authenticity Policy
- POL-2 Food Safety Plan (HACCP) Governance Policy
- POL-5 Product Control Policy
- POL-3 Food Safety & Quality Management System Policy
- POL-3A Documented Information & Records Management Policy

Responsibilities

Senior Management

Senior management are responsible for:

- Providing adequate organisational resources to support the effective implementation of product design, development, validation, and approval activities
- Establishing organisational arrangements that enable product development and change activities to be controlled in accordance with defined safety, legality, and quality requirements

Technical / Quality Management

Technical / Quality Management are responsible for:

- Establishing, implementing, and maintaining the product design and development control system defined within this procedure
- Defining and applying development scope restrictions to ensure that product and process developments remain within site capability and established hazard controls
- Reviewing development concepts, formulations, and process conditions to determine acceptability in relation to safety, legality, and quality requirements
- Ensuring that hazard assessment activities are completed and that appropriate control measures are defined and implemented prior to progression and approval
- Approving progression of development activities where safety, compliance, and control requirements are satisfied
- Reviewing and approving product specifications, process controls, and associated FSQMS updates prior to product introduction into routine production
- Approving final readiness of the development product based on evidence of consistent manufacture and compliance with defined requirements
- Defining shelf-life determination requirements, including assessment criteria and supporting evidence expectations, and approving assigned shelf life based on review of results or technical justification
- Ensuring that monitoring, verification, and testing activities are implemented following product approval to confirm ongoing compliance with defined product requirements

NPD Manager

The NPD Manager is responsible for:

- Coordinating product development activities and managing progression through defined development stages and decision gates
- Managing formulation development, prototype assessment, and progression decisions to ensure alignment with defined product intent and requirements
- Coordinating cross-functional inputs from technical, production, and other relevant functions during development and validation activities
- Defining and documenting trial process instructions and parameters required to support controlled execution of factory trials
- Planning and coordinating factory trials and ensuring that trial outcomes are assessed against defined criteria to determine progression
- Managing reformulation, process adjustment, and repeat trial activities where development outputs do not meet defined requirements
- Coordinating shelf-life trial activities, including defining study parameters and ensuring that required assessments are completed
- Ensuring that development changes are identified, recorded, and incorporated into progression decisions and implementation requirements

Production / Operations Management

Production / Operations Management are responsible for:

- Assessing process capability, equipment suitability, and operational conditions to support scale-up and factory trial activities
- Executing factory trials and validation activities in accordance with defined trial requirements and ensuring controlled operation during trials
- Implementing approved process specifications and work instructions into routine manufacturing operations following product approval
- Ensuring that manufacturing activities for new and modified products are carried out in accordance with defined process controls and operational requirements
- Maintaining operational conditions necessary to support product safety, quality, and compliance during routine production

HACCP Team

The HACCP Team are responsible for:

- Assessing development activities to determine whether changes to products, materials, or processes introduce new or modified hazards
- Determining whether existing hazard controls remain valid or whether further hazard assessment or control measures are required during development progression
- Confirming that appropriate hazard controls are defined and implemented prior to progression between development stages and prior to product approval

Quality Assurance Personnel

Quality Assurance personnel are responsible for:

- Evaluating product outputs from factory trials to confirm alignment with defined safety, legality, and quality requirements
- Supporting verification of development and validation outcomes to determine whether progression criteria have been met
- Supporting implementation of monitoring and verification activities associated with approved products to confirm ongoing compliance

All Employees

All employees are responsible for:

- Following the requirements of this procedure when involved in product development, product change, trial, or manufacturing activities
- Reporting any issues or deviations that may affect product safety, legality, or quality during development, validation, or production
- Cooperating with development, trial, assessment, and review activities as required within their role

Procedure Requirements

Product Development Scope and Restriction Control

Product design and development activities shall be controlled so that new products and changes to existing products, packaging, and manufacturing processes do not introduce unacceptable risks to product safety, legality, or quality, or adversely affect existing site operations.

- Technical Management shall define and apply scope restrictions for product development with reference to site capabilities and established hazard controls.
    - Scope restrictions shall include consideration of allergen risks, microbiological risks, physical contamination risks, product composition, and product claims.
    - Scope restrictions shall prevent progression of any development that cannot be controlled within the site's existing or approved operational conditions.
- Proposed new products and changes to existing products, packaging, or manufacturing processes shall be assessed to confirm compatibility with site facilities, equipment, and processing capability. Developments that require conditions, controls, or capabilities that are not available or cannot be implemented in a controlled manner shall not proceed.
- The impact of proposed developments on existing products, production activities, and site conditions shall be assessed prior to progression. Assessment shall ensure that cross-contamination risks, operational conflicts, and adverse effects on established controls are identified and prevented.

- Product development activities shall be conducted under the coordination of the NPD Manager. The NPD Manager shall manage progression through defined development stages and coordinate technical, production, and commercial inputs.
- Development activities shall only proceed where proposals comply with the defined scope restrictions established by Technical Management, and where any identified safety or hazard considerations have been assessed in accordance with the requirements of this procedure.
- Changes arising from product development activities that affect controlled documents shall be identified and implemented in accordance with the Document Control Procedure.

Development Stage Control and Approval

A structured, stage-based development control process shall be applied to ensure that all product and process developments progress through defined decision points, with each stage confirming that safety, legality, quality, and operational requirements are achieved prior to advancement. Progression between stages shall be controlled through defined evaluation criteria, with development activities coordinated by the NPD Manager and subject to technical approval where safety or compliance considerations apply.

- **Gate 1 — Concept and Feasibility Assessment**
  Early-stage concepts shall be evaluated to determine whether proposed developments are suitable for progression based on defined technical, safety, and operational criteria.
    - Concepts shall be reviewed by the NPD Manager to confirm alignment with intended product characteristics, site capability, and customer requirements prior to development activity commencing.
    - Technical Management shall assess proposed concepts to determine whether known hazards, regulatory constraints, or site limitations prevent safe or compliant development, and concepts that cannot be controlled within existing site capabilities shall not progress.
    - Where new raw materials are proposed, approval status shall be confirmed and, where required, supplier approval and raw material specification shall be completed in accordance with the Supplier & Raw Material Approval and Performance Monitoring Procedure and the Specifications Management Procedure prior to progression.
    - Where the concept introduces potential changes to product safety or hazard profile, the HACCP team shall determine whether further hazard assessment is

required before development proceeds, and where risks cannot be adequately controlled, progression shall not occur.

- **Gate 2 — Product Development (Bench / Kitchen Trial)**
  Product formulations and prototypes shall be developed and assessed at small scale to demonstrate that the intended product can achieve defined quality, safety, and sensory characteristics.
    - Formulations shall be developed by the NPD Manager and assessed against defined product intent to confirm that key characteristics can be achieved prior to scale-up.
    - Preliminary safety and quality attributes shall be evaluated by Technical Management or a member of the HACCP Team to confirm that the product can be produced without introducing uncontrolled hazards.
    - Development outputs that do not meet defined product intent or safety requirements shall be reformulated under the coordination of the NPD Manager prior to progression.
    - Changes to formulation or ingredient profile shall be reviewed by Technical Management or a member of the HACCP Team to determine whether they affect hazard controls, and the HACCP team shall determine whether existing controls remain valid, further assessment is required, or development shall not proceed until identified risks are addressed.
    - Where formulation introduces new or modified raw materials, material approval and specification shall be completed prior to progression in accordance with the Supplier & Raw Material Approval and Performance Monitoring Procedure and the Specifications Management Procedure.

- **Gate 3 — Pre-Production and Scale-Up Assessment**
  Development outputs shall be assessed for compatibility with site processes and readiness for factory trial to ensure that scale-up can be performed under controlled conditions.
    - Process requirements, equipment capability, and production conditions shall be assessed by Production or Operations Management to confirm that the product can be manufactured using existing site processes or defined modifications.

- Where process changes are required, trial process instructions and parameters shall be defined and documented by the NPD Manager to enable controlled execution of factory trials.
- Technical Management or a member of the HACCP Team shall review proposed process conditions and product characteristics to determine whether changes affect hazard controls, and the HACCP team shall determine whether existing controls remain valid or whether further assessment is required prior to progression.
- Development shall not proceed to factory trial where process capability, control measures, or hazard controls cannot be confirmed as adequate.

- **Gate 4 — Factory Trial and Validation**
  Factory trials shall be conducted where necessary to confirm that the product can be consistently manufactured at site scale while meeting defined safety and quality requirements.
  - Where factory trials are undertaken, they shall be planned and coordinated by the NPD Manager and executed by Production or Operations personnel. Where factory trials are not required, justification shall be documented to demonstrate how product safety, legality, quality, and process capability have been validated.
  - Product outputs from factory trials shall be evaluated by the NPD Manager and Quality Assurance personnel to assess performance against defined safety, legality, and quality requirements and to determine whether progression criteria have been met.
  - Where trial outputs do not meet defined criteria, the NPD Manager shall coordinate reformulation or process adjustment, and further trials shall be conducted prior to progression.
  - Trial results shall be reviewed to determine whether process capability is demonstrated, and where consistent manufacture cannot be achieved, development shall not proceed.
  - Where trial outcomes indicate changes to hazard controls, the HACCP team shall determine whether additional assessment or control measures are required prior to progression.

- **Gate 5 — Product Approval and Pre-Launch Control**
  Final product approval shall confirm that all technical, safety, and operational requirements have been met prior to introduction into routine production.
    - Technical Management shall review development evidence to confirm that the product can be consistently manufactured to meet defined safety, legality, and quality requirements. Final approval for new products and changes to product formulation, packaging, or methods of processing shall be granted by the HACCP team leader or an authorised HACCP team member prior to introduction into the factory environment.
    - Product specifications shall be finalised and approved in accordance with the Specifications Management Procedure prior to introduction into routine production.
    - Site procedures and controls for storage and dispatch shall be reviewed and updated as necessary to ensure that product-specific handling, storage conditions, and transport requirements are correctly defined and implemented, consistent with the requirements of the Storage Facilities Procedure and the Dispatch & Transport Procedure.
    - Shelf-life determination shall be completed in accordance with this procedure, using documented protocols and supporting evidence, and where formal testing or analysis is required, these activities shall be conducted in accordance with the Product Inspection, On-site Testing & Laboratory Analysis Procedure.
    - Allergen information associated with the product and its constituent raw materials shall be reviewed, and documented allergen listings and associated controls shall be updated and implemented in accordance with the Management of Allergens Procedure prior to introduction into routine production.
    - Packaging and labelling requirements shall be defined and approved in accordance with the Product Packaging Control Procedure and the Labelling & Pack Control Procedure prior to product launch, and where new or amended raw materials or primary packaging are introduced, raw material risk assessment, supplier approval status, specifications, and intake acceptance controls shall be reviewed, updated, and implemented in accordance with the Supplier & Raw Material Approval and Performance Monitoring Procedure and the Specifications Management Procedure. Controls shall be implemented to ensure that only the correct and current version of printed packaging is accepted and used, and that obsolete or superseded packaging is identified, segregated, and prevented from use in accordance with the Supplier & Raw Material Approval and Performance Monitoring Procedure.

- Final process specifications and work instructions shall be established, implemented, and controlled in accordance with the Control of Operations Procedure prior to routine manufacture following successful completion of factory trials and product approval.
- Product shall not be introduced into routine production until release criteria have been defined, all affected FSQMS controls have been updated and implemented, and product release is controlled in accordance with the Product Release Procedure.

- **Gate 6 — Post-Approval Integration and Control**
  Approved products and processes shall be incorporated into routine site operations with controls maintained to ensure ongoing compliance with defined requirements.
  - Production or Operations Management shall ensure that routine manufacture is carried out in accordance with approved process specifications and work instructions.
  - Technical Management shall ensure that monitoring, verification, and testing activities are implemented to confirm ongoing compliance with product safety and quality requirements.
  - Where deviations from defined specifications or process controls are identified, appropriate action shall be taken to restore control and prevent recurrence prior to continued manufacture.

Development Change Identification and Control

Changes arising from product development activities shall be identified, assessed, and controlled to ensure that impacts on product safety, legality, quality, and site operations are appropriately managed.

- The NPD Manager shall ensure that changes to products, raw materials, packaging, processes, equipment, and site conditions identified during development are recorded and maintained within development documentation.
- Changes identified during development shall be reviewed to determine their potential impact on:
  - product safety, legality, and quality
  - HACCP plans and hazard controls

  - site procedures and operational controls
  - raw material, packaging, and finished product specifications

- Where changes have implications for controlled documents or site controls, requirements for update shall be identified during development and incorporated into progression decisions within the gated process.
- Implementation of changes to controlled documents and site procedures shall be completed prior to introduction into routine production in accordance with the Document Control Procedure and relevant referenced procedures.
- Development shall not progress to product approval where required changes to controls, procedures, or documentation have not been defined.

Shelf-Life Determination and Supporting Evidence

- Shelf-life determination shall be completed as part of Gate 5 — Product Approval and Pre-Launch Control before introduction into routine production. This subsection defines the requirements for conducting shelf-life trials and for determining whether the product remains safe, legal, and of the required quality throughout the assigned shelf-life period.
- Shelf-life trials shall be coordinated by the NPD Manager and approved by Technical Management before commencement, with the trial design defining the product samples to be assessed, the storage conditions to be applied, the intervals at which assessment will be carried out, and the criteria against which results will be evaluated.
- Shelf-life trials shall be designed to reflect the conditions expected during manufacture, storage, transport and distribution, use, and handling so that the assigned shelf life is based on the way the product will actually be produced, stored, moved, and used.
- Product samples shall be assessed over a defined period following production to determine the point at which unacceptable deterioration or loss of conformity occurs, with the duration and frequency of assessment sufficient to establish the maximum period for which the product remains acceptable.
- Shelf-life assessment shall include review of relevant microbiological criteria, chemical criteria, and organoleptic criteria or sensory analysis, with Technical Management determining the applicable assessment criteria for the product and confirming whether results remain acceptable at each assessment point.
- Where product characteristics, intended use, or known risks make additional analytical, physical, or quality assessment necessary to support shelf-life determination, Technical

Management shall define those additional assessment requirements and ensure they are applied as part of the shelf-life trial.

- Shelf life shall only be assigned where the combined results of the shelf-life trial demonstrate that the product remains safe, legal, and of the required quality for the full assigned period under the intended conditions of manufacture, storage, transport and distribution, use, and handling.
- Where shelf-life trials prior to production are impractical, Technical Management shall produce a documented science-based justification for the assigned shelf life, using relevant scientific data, product characteristics, comparable product information, or other valid technical evidence as the basis for assignment.
- Shelf life shall not be approved where assessment results are incomplete, where deterioration is observed before the proposed shelf-life limit, or where the available evidence does not demonstrate that the product remains safe, legal, and of the required quality for the assigned period.
- Records generated through product development activities, including shelf-life determination, shall be completed and maintained in accordance with the Record Completion & Maintenance Procedure.

Training Requirements

Personnel involved in approving, assessing, reviewing, implementing, validating, and monitoring product design, development, and product change activities shall be trained to ensure effective application of this procedure.

Training requirements shall include, as applicable:

- Understanding of responsibilities for controlling new product development and product changes
- Application of hazard assessment and control measures within product development activities
- Implementation of approval controls prior to factory introduction
- Execution of validation trials and interpretation of outcomes
- Application of shelf-life determination methods and review of supporting evidence

Training shall be provided:

- On appointment to a role involving product design, development, or product change activities
- When significant changes are made to this procedure or associated control measures

- Where deficiencies or weaknesses are identified through review or verification activities

Training delivery and record control shall be managed in accordance with PRO-7.1 Training & Competence Procedure.

Records and References

Records

Records generated through the implementation of this procedure may include:

- Product development and change approval records
- Hazard assessment records for new products and product changes
- Production trial and validation records
- Shelf-life trial protocols
- Shelf-life trial results
- Shelf-life justification records

References

- PRO-3.2 Document Control Procedure
- PRO-3.3 Record Completion & Maintenance Procedure
- PRO-3.5 Supplier & Raw Material Approval and Performance Monitoring Procedure
- PRO-3.6 Specifications Management Procedure
- PRO-4.15 Storage Facilities Procedure
- PRO-4.16 Dispatch & Transport Procedure
- PRO-5.3 Management of Allergens Procedure
- PRO-5.5 Product Packaging Control Procedure
- PRO-5.6 Product Inspection, On-site Testing & Laboratory Analysis Procedure
- PRO-5.7 Product Release Procedure
- PRO-6.1 Control of Operations Procedure
- PRO-6.2 Labelling & Pack Control Procedure
- PRO-7.1 Training & Competence Procedure
- POL-1 Food Safety, Quality, Legality & Authenticity Policy
- POL-2 Food Safety Plan (HACCP) Governance Policy
- POL-3 Food Safety & Quality Management System Policy
- POL-3A Documented Information & Records Management Policy
- POL-5 Product Control Policy

Review and Approval

This procedure shall be reviewed at least every five years or sooner in the event of significant product safety or quality failures arising from product development activities, failure of validation or shelf-life determination processes to demonstrate product compliance, or

changes to regulatory or customer requirements affecting product design and development controls.

Approval and version control shall be managed in accordance with PRO-3.2 Document Control Procedure.