1. Purpose

To ensure a standardized way of working within Ausnutria regarding allergen management, to minimize the risk of allergen contamination and to meet legal requirements.

2. Scope

All ingredients, i.e:

- raw materials,
- technical aids,
- additives,
- carrier materials, and
- compound materials that make up less then 2% of the final product and do otherwise not require labelling.

All materials that may come directly into contact with raw materials, primary packaging materials, intermediate product and finished products (eg. Lubricating oil).

3. Allergen management process

3.1 Identification allergen containing materials

Raw materials

The company maintains a continuously up to date listing of all raw materials containing allergens used at its premises, which also identifies all blends and formulas to which the allergen containing materials are added. See "Overzicht grondstoffen met allergenen" (Overview of raw materials with allergens) located at T:\Samenwerken\QA Corporate\Allergenen). This overview is reviewed at least annually.

New Product development is handled through the NPD department as per C.402.1.001 New Product Development. During this process, new raw materials can be selected. These are managed as described in C.400.1.004 New ingredient management. Allergen information is gathered via the raw material specification(s) and supplier questionnaires. New raw material suppliers are selected as described in procedure C.304.1.001 Supplier selection and assessment. Allergen management is part of the supplier audits.

New raw materials should be assessed by the Management of Change team (MOC team). See C.300.1.008 Change management.
In case a new raw material contains allergens, or the composition of the end products changes (eg. Higher amount of allergen bearing ingredient), the possible risks are evaluated. Heerenveen and Leeuwarden use the VITAL calculation, see C.301.2.002 Application Vital Method.

Other materials

Materials (such as lubricating oil) that pose a risk by direct or indirect contact with raw materials (including primary packaging), intermediate products and finished products shall be food grade and of a known allergen status.

3.2 Risk analysis

Allergens and management of risks of cross-contamination with allergens is included in the HACCP risk analyses and in the prerequisite programs.
Leeuwarden: L.00.0.029 Gevarenanalyse HACCP, L.00.0.009 Basisvoorwaardenprogramma
Heerenveen: HP.00.0.006 Gevarenanalyse, HP.00.0.009 Basisvoorwaardenprogramma
Kampen: K.33.1.001 HACCP Handboek, K.30.5.005 Basisvoorwaardenprogramma
Ommen: O.00.0.006 Gevarenanalyse HACCP

These include:
• consideration of the physical state of the allergenic material (i.e. powder, liquid, particulate)

• Identification of potential points of cross-contamination through the process flow
• assessment of the risk of allergen cross-contamination at each process step
• identification of suitable Controls to reduce or eliminate the risk of cross-contamination.

CQA Outsource and Supply maintains a list of the allergen-containing materials handled on site (P:\Quality Assurance\FOR> PRO MM 01 overzicht leveranciers-artikelen……xlsx). This includes:
- Raw materials
- Finished products
- NPD ingredients
- Processing aids

The allergen management system is reviewed at least annually.

3.4 Vital calculation
The VITAL calculation tool is applied to regular end products. It is used to calculate the allergen protein concentration (ppm) in a product(group). The product groups are determined based on the allergen they contain. The calculation is performed on the final recipe with the highest percentage of allergen (worst case). For more information on the Vital method, see C.301.2.002 Vital application and calculation.

3.5 Control measures
Based on hazard analysis and assessment of associated risk, control measures have been put in place to ensure that allergen cross contamination risk is minimized, these include:

- Building requirements, including systems to restrict the movement of airborne dust containing allergenic material. See C.301.1.010 Prerequisite programmes - Building Hygiene Requirements
- Equipment requirements. See C.301.1.015 Prerequisite programmes – Equipment design (EHEDG)
- Use of identified, dedicated equipment and utensils for processing and cleaning. See C.301.1.014 Prerequisite programmes - Cleaning & Disinfection
- Allergen containing materials are identified and, where needed, physically separated from non-allergen containing materials during storage, internal transport, processing and packaging.
  Raw materials containing the allergen milk (lactose) are stored as regular raw material. For raw materials containing allergens other than milk, the storage conditions are indicated in "Overzicht grondstoffen met allergenen" (Overview of raw materials with allergens) located at T:\Samenwerken\QA Corporate\Allergenen). In the event of damage during storage, the deviations procedure must be followed.
    - Corporate: C.300.1.012 Non-conforming products
    - Leeuwarden: L.30.1.015 Afhandelen interne afwijkingen
    - Heerenveen: HP.30.1.001 Afwijkingen management
    - Kampen: K.30.1.011 Afwijkingen procedure
    - Ommen: O.30.1.002 Klachten en afwijkingen
- Production planning manages the change-over from products containing an allergen to products not containing the allergen and the neccesary cleaning / flushing between these production runs.
- Waste handling and spillage controls. See also C.301.1.017 Waste disposal
- Personnel / house rules. See C.301.1.012 Prerequisite programmes - Personal hygiene / House rules

3.6 Labeling
Allergens present in the product, either by design or by potential manufacturing cross-contamination, are declared on the label for consumer products, and on the label or the accompanying documentation for products intended for further processing.
Labeling requirements are followed as per REGULATION (EU) No 1169/2011.

3.7 Validation and verification
Where a claim is made regarding the suitability of a food for allergy or food sensitivity sufferers, the the production process is fully validated to meet the stated claim and the effectiveness of the process is routinely verified.
All (allergen-related) cleaning methods are validated to ensure that they are effective and the effectiveness routinely verified. Control measures are also verified.
See C.300.1.003 Validation and C.302.1.003 Verification.

3.8 Rework
Where rework is used, or reworking operations are carried out, rework containing allergens is not used in products that do not already contain the same allergens.
Rework that contains allergens, must be identified and held in a manner that prevents allergen cross-contact.

3.9 Training
Employees involved in handling food receive specific training in allergen awareness and associated manufacturing practices.

3.10 Lactose-free products
The VITAL method cannot be used to calculate cross-contamination with lactose, as it calculates the risk of cross-contamination based on the amount of allergen protein in raw materials. Lactose is not a protein but a sugar. Therefore the lactose-free status is guaranteed as described below.

Raw materials
Relevant raw materials for lactose-free production, are tested for lactose content.

Flushing
To prevent cross-contamination with lactose, extensive flushing is performed prior to lactose-free production. The correct flushing method is determined by using the flushing matrix and registered in the production planning. After performing the flush, the lactose content of the flushing powder is tested for end products (Heerenveen & Leeuwarden).
If the lactose content of the flushing powder exceeds the established limit, (part of) the flush is carried out again until the standard (lactose content of flushing powder max. 0.05%) is met. As soon as the lactose test complies with the standard, the switch to lactose-free production can be made.
For base powder produced in Kampen, the flush powder is not tested for lactose. Instead the big bags of lactose-free base powder are all tested for lactose before release (Kampen).

- Heerenveen: HP.40.2.002 Lactose bepaling (CCP)
- Leeuwarden: L.40.2.001 Lactose bepaling
- Kampen: K.81.5.001 T3/T4 Batch scheidingsprotocol

Production deviations
In case of deviations during a lactose-free production, the batch is investigated to establish the extent of contamination with lactose. The production contaminated with lactose is blocked. Deviation procedures:

- Corporate: C.300.1.012 Non-conforming products
- Leeuwarden: L.30.1.015 Afhandelen interne afwijkingen
- Heerenveen: HP.30.1.001 Afwijkingen management
- Kampen: K.30.1.011 Afwijkingenprocedure

Product release:
Lactose-free end products are tested for lactose content before being released.

- Heerenveen & Leeuwarden: HL.40.1.002 Eindproductverificatie / end product verification
- Kampen: QC testplan

4. References

Document code	Document name
C.300.1.003	Validation
C.300.1.008	Change management
C.300.1.012	Non-conforming products
C.301.1.010	Prerequisite programmes – Building Hygiene Requirements
C.301.1.012	Prerequisite programmes – Personal hygiene / House rules
C.301.1.014	Prerequisite programmes – Cleaning & Disinfection
C.301.1.015	Prerequisite programmes – Equipment design (EHEDG)
C.301.1.017	Prerequisite programmes – Waste disposal
C.301.2.002	Application Vital method
C.302.1.003	Verification
C.304.1.001	Supplier selection and assessment
C.400.1.004	New ingredient management
C.402.1.001	New Product development
HL.40.1.001	Analyse en monitoring grondstoffen
HP.00.0.006	Gevarenanalyse
HP.00.0.009	Basisvoorwaardenprogramma
HP.30.1.001	Afwijkingen management
HP.40.2.002	Lactose bepaling (CCP)
L.00.0.009	Basisvoorwaardenprogramma
L.00.0.029	Gevarenanalyse HACCP
L.30.1.015	Àfhandelen interne afwijkingen
L.40.2.001	Lactose bepaling
K.30.1.011	Afwijkingen procedure
K.30.5.005	Basisvoorwaardenprogramma
K.33.1.001	HACCP Handboek
K.81.5.001	T3/T4 Batch scheidingsprotocol
O.00.0.006	Gevarenanalyse HACCP
O.30.1.002	Klachten en afwijkingen