1 OBJECTIVE

To ensure a multidisciplinary Hazard Analysis and Risk Assessment team is in place to develop and manage the hazard and risk analysis system and ensure this is fully implemented and evaluated for its effectiveness.

To implement and maintain a formal Hazard Analysis and Risk Assessment system to ensure that all hazards to product safety, quality and legality are identified and appropriate controls established.

2 METHOD

2.1 Hazard Analysis and Risk Assessment team

A multi-disciplinary team possessing the necessary knowledge and experience in hazard and risk analysis is appointed to develop, review and manage the Hazard Analysis and Risk Assessment system. This team is led by an appointed Team Leader. Refer to the **Hazard Analysis and Risk Assessment Team Appointment Letters**.

The Hazard Analysis and Risk Assessment team is responsible for the collection and evaluation of the technical data required for the Hazard Analysis and Risk Assessment Study (HARA). All relevant information needed to conduct the hazard analysis is collected, maintained, updated and documented. Refer to the **HARA Study**

The hazard & risk team structure is documented in the **Organogram**. Refer **Organogram**

The hazard & risk team being a multifunctional team are all directly involved in process changes and are kept up to date with factory changes and customer requirements as they occur through informal discussions and/or email. Refer to **Process Control Procedure.**

Membership of the hazard & risk management team will be reviewed annually or following a change to a team member's job description or a change in personnel affecting the hazard & risk management team.
The team members will sign appointment letters following the review detailing their individual responsibilities.

2.2 Good Manufacturing Practises (GMPs)

GMPs are established, implemented and maintained to assist in controlling the likelihood of;

- introducing product safety hazards to the product through the manufacturing, storage and distribution environment;
- microbiological, chemical, foreign objects and allergen contamination of products, including cross contamination between products
- defects critical to consumer safety
- hazards that may have an impact on the functional integrity and performance of the final product in use

These GMPs include but are not limited to the following elements:-

a) Site Standards
b) Process Control
c) Housekeeping and Cleaning
d) Pest Control
e) Personal Hygiene
f) Transport, Storage and distribution
g) Training and Competence
h) Senior Management Commitment & Continual Improvements
i) Internal audits
j) Traceability
k) Corrective and Preventative Actions
l) Specifications

2.3 Design HARA

When a new product that does not form part of an existing HARA study is being developed, a new HARA study is started as part of the Product Design and Development Procedure.

This study ensures that the hazards related to the product and processes have been identified and their elimination or reduction to acceptable levels validated to produce a safe product.

If an extension of existing product range is developed, the current HARA study is reviewed and changes are implemented accordingly.

If changes are made on current products, the current HARA study is reviewed and changes are implemented accordingly.

2.4 Hazard and Risk Methodology

A brief description of each step follows:

2.4.1 Terms of Reference / Scope of Study

The scope of the hazards and risk analysis is clearly defined and cover all products and processes included within the intended scope of certification.

This includes:-

- Product and/or Process
- Hazards to be considered
- Starting point (Commencement of Control)
- End Point (End of control)

When conducting the hazard analysis risk assessment, the hazard & risk team takes into account:

- Historical and known hazards associated with specific processes, raw materials and finished products
- Legislation relevant to the manufacturing and sale of finished product

- Customer requirements
- Map of the premises and equipment layout
- Intended use of the product (where known)
- Allergen containing raw material
- Copy of existing site HARA plan
- Conditions for storage, method of transport and distribution
- Packing materials used for the protection of the finished product
- Known likely product defects that affect product quality and safety.
- Codex Alimentarius
- Foodstuffs, cosmetics and disinfectant Act, 1972
- SANS 241 Drinking Water
- SANS 10049 Food Safety Management - Requirements for GMP's
- SANS 10330:2001 Requirements for a Hazard Analysis and critical control point system
- Relevant FDA and EU regulations

Changes in regulations and legislation are monitored through email subscriptions and notifications and reviewed at management review meetings. (Ref 1.2F1)

2.4.2 Product **Description**

A full description of the product is developed, which includes all relevant information on product safety, quality and legality, to assist in identifying possible hazards as appropriate, including the following:

- Composition, e.g., raw materials, inks, varnishes, additives, coatings and other print chemicals
- Origin of raw material including use of recycled materials.
- Treatments and processes undertaken
- Intended use of the finished product and defined restrictions on use, for instance, direct food contact or other hygiene-sensitive products.
- Functional Properties
- Storage conditions and expected usable life of the finished product.

2.4.3 Site Schematic, Process Flow Diagrams, process steps and control measures

Site Schematic & Flow Diagram:

The Site Schemati**c** is a floor plan detailing the segregated areas (production lines, storage areas, personnel facilities etc).

Water Flow is indicated on the Flow Diagram.

The Flow Diagram indicates all possible areas of cross contamination by raw materials, work in progress, finished goods, and waste streams and personnel routes.

Process Flow Diagram:

A process flow diagram is prepared for each product, product group or process. This include each process step from the receipt of raw materials to despatch to the customer

The process flow diagrams include the following:

- Receipt and approval of artwork and specification
- Receipt and preparation of raw materials such as additives, inks and adhesives
- Each step of the manufacturing process or work in progress retention stage
- The sequence and interaction of each manufacturing process step
- Introduction of utilities and other contact materials (e.g. air, water and packing materials)
- Outsourced processes
- In-line testing or measuring equipment
- The use of rework and recycled materials
- Waste
- Finished product storage and distribution.
- Any subcontracted operations
- Customer returns or materials to be returned to the supplier.

2.4.4 On-site Verification of Flow Diagram and Plant Schematic

The **Site Schematic**, **Flow Diagram** and **Process Flow Diagram** are verified on site for accuracy and completeness and approved by the Hazard and risk team. This is done annually and whenever there are changes, by following the actual process flow diagram in relevant areas in site. Records of verification is maintained.

2.4.5 Hazard Analysis

The hazard & risk team shall identify and record all potential hazards that are reasonably expected to occur with incoming material and at each manufacturing step-in relation to the product and process. The hazards considered include:

- Microbiological
- Physical
- Chemical contamination (e.g. taint, odour, allergen, component transfer from inks varnishes and glues)
- Potential issues arising from the use of recycled materials
- Legality
- Defects critical to consumer safety
- Hazards that may have an impact on the functional integrity and performance of the final product in use
- Potential for unintended migration of substances from the packaging material into food or other hygiene sensitive products.
- Potential for malicious intervention.
- Foreseeable unintended use by the customer or consumer.
- Potential for raw material fraud (e.g. substitution, adulteration or misrepresentation)

- In addition to ensure awareness of the potential for any aspect of the process to go out of control, and to have mitigating measures in place the following hazards are considered:
- Product quality defect
- Defects that may have an impact on the functional integrity and performance of the final product in use.
- Defects which result in the production of products which are outside customer-specified quality parameters.
- Limitations of the use of the product.
- Allergen contamination risks.

2.5 Incoming Raw material, Packaging Material

A Hazard Analysis for Raw Materials / Packaging Material and Processing aids is conducted and recorded on a **Sensitive Raw Material (SRM) Analysis** with the aid of a SRM Decision Tree

2.6 Process / Product

A Hazard Analysis for each type of process / product is conducted on the **Hazard Analysis**, which includes:

- Evaluation of Processing Hazards
- Identification of appropriate control measures necessary to prevent, eliminate or reduce each hazard to acceptable levels.
- Where control is through a GMP, the GMP is reviewed to ensure it adequately controls the risk identified and where necessary, improvements are implemented

When identifying the hazards, consideration is given to the following:

- The effectiveness of pre-requisite programmes
- The steps preceding and following the specified operation
- The process equipment, utilities/ services and surroundings

The acceptable level of the hazard in the product is determined through information obtained from one or more of the sources below:

- Specifications or other information communicated by the organisation constituting the subsequent step in the supply chain. For products intended for further processing.

- The maximum levels found acceptable by the Hazard & Risk Team, considering acceptable levels agreed with customer and/or established by legislation and recognised International Standards and, in the absence thereof, through scientific literature and professional experience.

All justification for the results of the determination is recorded.

2.7 Hazard Risk Analysis

A hazard risk analysis is conducted to determine, for each hazard, whether the elimination or reduction to acceptable levels is essential to the production of a safe product.

The following is taken in to consideration for each hazard:

- The source of the hazards (whether it is present or introduced)
- The probability / likelihood of occurrence
- The nature of the hazard
- The severity of the outcome by the hazard

Each hazard is evaluated according to the possible severity and the likelihood of their occurrence.

2.7.3 Qualitative Risk Rating Approach

The Risk Rating (L / M / H/ E) is recorded on Hazard Analysis section in the HARA study to identify the significant hazards (i.e. those hazards that are reasonably likely to occur at an unacceptable level) which needed to be prevented, eliminated or reduced to acceptable levels.

The **Likelihood scale** of occurrence considering prerequisite programs in the absence of additional control:

Rare	May occur only in exceptional circumstances.
Unlikely	Could occur at some time.
Possible	Might occur at some time/the event should occur at some time.
Likely	Will probably occurs in most circumstances.
Almost Certain	To occur in most circumstances

The **Severity/Magnitude** of the outcome (adverse health effects):

Low	Insignificant impact, little disruption to normal operations and/or not potential harm.
Minor	Some manageable operation disruption and/or no potential harm.
Moderate	Significant modification to normal operation but manageable, increased monitoring and/or potential to be harmful.

Major	Systems significantly compromised and abnormal operation, high level of monitoring required and/or potential to be harmful.
Extreme	Catastrophic impact, complete failure of systems and/or harmful.

The two scales are used in conjunction with the Risk Assessment Matrix below, to determine the hazard's Risk Rating.

Risk Assessment Matrix

	Low (L)	Minor (Mi)	Moderate (Mo)	Major (Ma)	Extreme (E)
Almost Certain (AC)	High	High	Extreme	Extreme	Extreme
Likely (L)	Medium	High	High	Extreme	Extreme
Possible (P)	Low	Medium	High	Extreme	Extreme
Unlikely (U)	Low	Low	Medium	High	Extreme
Rare (R')	Low	Low	Medium	High	High

2.7.4 Risk Rating Explanation

Extreme risk (E): Hazard is significant and must be reduced.
High risk (H): Hazard is significant and must be reduced.
Medium Risk (M): Hazard is Insignificant. Engineer out / administrative control.
Low risk (L): Hazard is Insignificant. Low potential harm. The hazard must be managed.

Each hazard is assessed in terms of likelihood (L) and severity (S) to determine the relevant significance (Si).
The significance is determined as follows:
Likelihood vs Severity = Significance (Risk Rating)

Significant Risk:

Yes (Y): High / Extreme Risk Rating
No (N): Low / Medium Risk Rating

2.8 Selection and assessment of control measures

The Risk Rating is recorded on the Hazard Analysis section in the HARA study. In the event that the hazard is categorised as 'Low' or 'Medium', the Critical Control Measure (referred to as CCP) Decision Tree will not be followed because it is deemed not to be a significant hazard and could consequentially be controlled through the Pre-requisite Programmes.

If the significance rating is **High or Extreme**, the hazard is further analysed in terms of the CCP Decision Tree.

Based on the hazard assessment an appropriate combination of control measures are selected which can prevent, eliminating or reducing these hazards to defined acceptable levels. All the control measures are reviewed with respect to their effectiveness against the identified hazards.

Consideration may be given to using more than one control measure, including relevant prerequisites.

The selection and categorisation of the control measure is carried out using a logical approach that includes assessment about the following:

- its effect on identified hazards relative to the strictness applied.
- the feasibility for monitoring (e.g. ability to be monitored in a timely manner to enable immediate corrections);
- its position within the system relative to other control measures.
- the likelihood of failure in the functioning of a control measure or significant processing variability.
- the severity of the consequence in the case of failure in its functioning.
- whether the control measure is specifically established and applied to eliminate or significantly reduce the level of hazards
- any possible synergistic effects (i.e. interaction that occurs between two or more measures resulting in their combined effect being higher than the sum of their individual effects)

Control measures are implemented in accordance with the HARA Study and CCP Control chart.

CCP are control points that are required to prevent, eliminate or reduce a product safety or integrity hazard to acceptable levels.
Where elimination of hazard is not practical, justification for acceptable levels of the

2.9 Establishing the CCP Control chart

A **CCP Control chart** is developed for each identified CCP and contains the following information:

- Hazard to be controlled at the CCP
- Control measure / preventive measure
- Critical limits
- Monitoring procedures
- Corrections and corrective actions to be taken if critical limits are exceeded
- Responsibilities and authorities
- Records of monitoring

2.10 Identification of Critical Limits

To monitor the CCP, critical limits are defined to identify clearly if the process is in or out of control. Critical limits are measurable where possible and the rationale for their establishment clearly documented. Relevant legislation and codes of practice are considered when establishing the limits.

Critical limits based on subjective data (such as visual inspection of product, process, handling etc) are supported by clear guidance, instructions or specifications and training.

2.11 Establish Monitoring System

A monitoring system is established for each CCP to demonstrate that the CCP follow the critical limits. The system includes all scheduled measurements or observations relative to critical limits.
The monitoring procedure can detect loss of control of measures and where possible provide information in time for corrective action to be taken and consists of relevant procedures, instructions and records that cover the following:

- Measurements and observations that provide results within an adequate time frame
- Monitoring devices used (e.g. online measurement, offline measurement or continuous measurement)
- Applicable calibration methods
- Monitoring frequency
- Responsibility and authority related to monitoring and evaluation of monitoring results
- Record requirements and methods (include the date, time and results of measurement, signed to responsible person)

The monitoring methods and frequency can determine when the critical limits have been exceeded in time for the product to be isolated before it is used.

2.12 Actions when monitoring results exceed critical limits

Planned corrective actions to be taken when critical limits are exceeded or where results indicate a trend towards loss of control are specified in the relevant Control Charts. The actions ensure that the non-conformity is identified, the parameters at the CCP are brought back under control and the recurrence is prevented. Responsibilities for monitoring the CCP and conducting Corrective Actions are also assigned.

Document procedures are established and maintained for the appropriate handling of potentially out-of-specification products to ensure that these products are not released until their safety is established. Document procedures are established and maintained for the appropriate handling of potentially out-of-specification products to ensure that these products are not released until their safety is established. Refer to Control of Non-Conforming Product Procedure which includes any products that have been manufactured during the period when the activity was out of control, how control was regained and how potential recurrence is minimized.

2.13 Updating of preliminary information and documents specifying the GMP's and the CCP Control Charts

After the CCP have been identified, the relevant documentation (Procedures / HARA studies / Work instruction) is updated accordingly.

2.13.1 Validation of Control Measure Combinations

Validation Statement

Verification procedures for the HARA plan have been established to confirm that controls, including those managed by prerequisite programmes, remain effective.

Activities such as internal audits, review of records where limits are exceeded, assessment of complaints and feedback, and review of product withdrawals or recalls are used to provide assurance of system performance.

Results of these verification activities are recorded and communicated to the HARA team as part of the continual review process.

Prior to implementation of control measures included in the CCP control plan, and after any change therein, we validate that: -

- The selected control measures can achieve the intended control of the hazards for which they are designed, including critical limits and
- The control measures are effective and capable of, in combination, ensuring control of the identified hazards to obtain product that meet the defined acceptable levels.

The results are recorded in validation studies which includes documented evidence that show that the control measures selected, and critical limits identified are capable of consistently controlling the hazard to the specified acceptable level.

If the result of the validation shows that one or both above elements cannot be confirmed, the control measure and / or combinations thereof are modified and re-assessed.

Where equipment settings are critical to the safety of legality of the product, changes to the equipment settings are completed by trained and authorizes personnel.

2.14 Hazard Analysis and Risk Assessment system review

A review of the HARA studies is carried out at least once per year and following any significant incidents or when any process changes.

The Following Changes result in a review of the relevant HARA Study:

- Change in raw material or supplier of raw materials
- Changes in product formulations/composition
- Change in manufacturing conditions, process flow, manufacturing environment or equipment
- Change to plant layout and environment

- Change in packing material, storage or distribution conditions
- Anticipated change in customer or consumer use
- Trend in root cause and/or testing / analysis results
- Emergence of a new risk
- Results from verification activities
- Internal and external audits
- Review following incidents of product withdrawal or recall
- New legislation or developments associated with raw materials, manufacturing or product
- Change in cleaning programs
- Failures in the system example Corrective actions and the need for product recall
- Change in packaging, storage or distribution system
- Receipt of info from the marketplace and indicating a health risk associated with the product
- After commissioning of new machinery and within a two-month timeframe to allow time for simulation and updating of records to be completed upon completion of records and procedures.

The review includes a verification that the Hazard Analysis and Risk Assessment system is effective and may include a review of:

- Complaints
- Product failures
- Recalls
- Product withdrawals
- Results of internal audits of prerequisite programmes
- Results from external third-party auditors
- New developments in industry associated with material, process or product.
- Process changes
- Product composition changes

2.15 Record Keeping and Documentation

Records and Documents are controlled as part of the Product Safety and Quality Management System. Refer to records control procedure and document and data control procedure respectively.

2.16 CCP Implementation

2.16.3 On-Line Visibility

A CCP Chart is displayed at the point of control which defines

2.16.4 Training

The personnel defined as responsible for monitoring / verification on the CCP Chart is specifically trained to ensure that they have the necessary skills / knowledge to conduct their duties to the required standard. Refer to the Skills matrix.

2.16.5 Records

Records of CCP Monitoring as defined on the CCP Control Chart are maintained.

2.16.6 Audits

Audits of the CCP Maintenance and Implementation are conducted in accordance with the Internal audit procedure

2.17 Performance measures and reporting

The following performance measures are reported at the annual Management Review.

- Number of CCP related findings
- Number of NCAs
- Number of Customer Complaints

RECORDS

Form No	Title	Input Responsibility	Retention Location	Retention Period	Authority for Disposal
2.1F1	Hazard & Risk Management Team Leader Appointment Letter	Risk Team	Reception	3 Years	Director
2.1F2	Management Appointment Letter	Risk Team	Reception	3 Years	Director
2.1F3	Deputy Management Appointment Letter	Risk Team	Reception	3 Years	Director
2.1F4	Hazard & Risk Management Team Member Appointment Letter	Risk Team	Reception	3 Years	Director
2.1F5	Hazard & Risk Management Team Member Appointment Letter	Risk Team	Reception	3 Years	Director
2.1F6	Hazard & Risk Management Team Member Appointment Letter	Risk Team	Reception	3 Years	Director
1.3.1	Organogram				
1.4F1	Management Review Minutes and Agenda	Risk Team	Reception	3 Years	Director
1.4F3	Risk Meeting Minutes	Risk Team	Reception	3 Years	Director
5.3	Process Control Procedure	Operations Manager	Reception	3 Years	Director
N/A	Risk Team Training Records	Risk Team	Reception	3 Years	Director
N/A	HARA Studies	Risk Team	Reception	3 Years	Director
1.2F1	Legislative Requirements	Risk Team	Reception	3 Years	Director

Date	Rev no.	Distribution List	Changes made
06 September 2016	6	SC, REC	Updated product description, Process flow diagram and System review.
20 June 2018	7	SC, REC	Reviewed procedure. Updated for review of HARA Team Members
04 September 2019	8	SC, REC	Updated procedure to include Significant Risk detail

10 July 2020	9	SC, REC	Replace hazard and risk management with Hazard analysis and risk assessment. BRC Issue 6 terminology change. Include under hazards (2.4.5) and updated 2.0 BRC HARA Assessment: • Product quality defect • Defects that may have an impact on the functional integrity and performance of the final product in use. • Defects which result in the production of products which are outside customer-specified quality parameters.
28 April 2022	10	SC, REC	Updated word from HACCP to HARA Included commissioning of new machinery into requirement to perform HARA review. Changed wording from PRP to GMP.
29 May 2025	11	SC, REC	Updated procedure to align with Issue 7 Included commissioning of new machinery into requirement to perform HARA review. Changed wording from PRP to GMP.
29 May 2025	12	SC, REC	Updated to align with Issue 7