

HAZARD AND RISK MANAGEMENT

Sl.No	Requirement of standard	Guidance	Reference
2	Hazard and risk management		
2	Hazard analysis and risk assessment		
2.1.1	<p>The hazard analysis and risk assessment (HARA) shall be developed, reviewed and managed by a multi-disciplinary team that includes those responsible for quality, technical, manufacturing operations and other relevant functions (e.g. engineering, product development).</p> <p>The multi-disciplinary team shall have a designated team leader who shall be suitably trained and able to demonstrate competence and experience of hazard analysis and risk assessment.</p> <p>The team shall be able to demonstrate competence in hazard analysis and risk assessment principles.</p> <p>The team shall ensure that the appropriate knowledge and expertise are available for the development and maintenance of an effective HARA, including being kept up to date with factory changes and customer requirements as they occur.</p>	<p>The hazard and risk management plan is developed, reviewed and managed by a multidisciplinary team that includes those responsible for Quality, Production, Engineering / maintenance, Operations and other relevant functions (HARA) Team. The team shall ensure that the appropriate knowledge and expertise are available for the development and maintenance of an effective HARA, including being kept up to date with factory changes and customer requirements as they occur.</p>	Annex 06 - HARA Team

Sl.No	Requirement of standard	Guidance	Reference
2.2	Prerequisite programmes		
2.2.1	<p>The team shall establish and maintain environmental and operational programmes necessary to create an environment suitable to produce safe and legal products (prerequisite programmes). As a guide these may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> • supplier approval and purchasing (section 3.6) • maintenance programmes for equipment and buildings (section 4.7) • cleaning and housekeeping (section 4.8) • product contamination control (section 4.9) • pest management (section 4.11) • product development (section 5.1) • print control (section 5.3) • dispatch and transport (section 5.9) • personnel training and competence (section 6.1) • personal hygiene requirements (section 6.2) <p>The control measures and monitoring procedures for the prerequisite programmes shall be clearly documented and shall be included within the development and reviews of the HARA.</p>	<p>The company shall establish and maintain an environmental and operational programme necessary to create an environment suitable to produce safe and legal food products (prerequisite programmes). The control measures and monitoring procedures for the prerequisite programmes shall be clearly documented and shall be included within the development and reviews of the HARA. Documented SOPs shall be established to effectively implement the PRP system.</p>	Annex 6A - PRP related SOPs

Sl.No	Requirement of standard	Guidance	Reference
2.3	Describe the product		
2.3.1	The scope of the HARA shall be clearly defined and shall include all products and manufacturing operations within the intended scope of certification.	The scope of the HARA shall be clearly defined and shall include all products and manufacturing operations within the intended scope of certification.	-
2.3.2	<p>A full description of the products or groups of products shall be developed, which includes all relevant information. As a guide, this may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> • composition (e.g. raw materials, additives, inks, varnishes, coatings and other print chemicals) • origin of raw materials, including use of recycled materials • treatments and processes undertaken • intended use of the finished products and defined restrictions on use, e.g. direct contact with food or other hygiene-sensitive products • functional properties • storage conditions and expected usable life of the finished product. 	<p>The description of the products to include composition (e.g. raw materials, ingredients, allergens, recipe)</p> <ul style="list-style-type: none"> • composition (e.g. raw materials, additives, inks, varnishes, coatings and other print chemicals) • origin of raw materials, including use of recycled materials • treatments and processes undertaken • intended use of the finished products and defined restrictions on use, e.g. direct contact with food or other hygiene-sensitive products • functional properties • storage conditions and expected usable life of the finished product. 	Annex 07 - Product Description

Sl.No	Requirement of standard	Guidance	Reference
2.3.3	<p>All relevant information needed to conduct the HARA shall be collected, maintained, documented and updated. As a guide, this may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> • historical and known hazards associated with specific processes, raw materials and finished products • relevant codes of practice or recognised guidelines • legislation relevant to the manufacturing and sale of finished products • customer requirements • a copy of any existing site HARA plans (e.g., for products already in manufacture at the site) • a map of the premises and equipment layout • intended use of the product (where known) • known likely product defects that affect safety • allergen-containing raw materials • conditions for storage, method of transport and distribution • packing materials used for the protection of the finished product. 	<p>The information needed for HARA includes:</p> <ul style="list-style-type: none"> • historical and known hazards associated with specific processes, raw materials and finished products • relevant codes of practice or recognised guidelines • legislation relevant to the manufacturing and sale of finished products • customer requirements • a copy of any existing site HARA plans (e.g., for products already in manufacture at the site) • a map of the premises and equipment layout • intended use of the product (where known) • known likely product defects that affect safety • allergen-containing raw materials • conditions for storage, method of transport and distribution • packing materials used for the protection of the finished product. 	-

Sl.No	Requirement of standard	Guidance	Reference
2.4	Construct and verify the process flow diagram		
2.4.1	<p>A flow diagram shall be prepared to cover each product, group of products or manufacturing process. This shall set out the sequence and interaction of the steps in the operation. As a guide, this may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> • 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 • 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 dispatch • customer returns or materials to be returned to the supplier. 	<p>Flow diagram is prepared by HARA team for the products or process categories. Flow diagrams are prepared in detail include the following approval of artwork and specification;</p> <ul style="list-style-type: none"> • receipt and preparation of raw materials such as additives, inks and adhesives • each step of the manufacturing process or work in progress retention stage • 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 dispatch • customer returns or materials to be returned to the supplier. 	Annex - 08
2.4.2	<p>Confirmation shall be completed by the HARA team to ensure the accuracy of the flow diagram(s) at least annually and whenever there are changes, by following the actual process flow diagram in relevant areas on site. Records of verified flow diagrams shall be maintained.</p>	<p>After preparation of the flow diagrams, the HARA team shall verify the accuracy of the flow diagram by checking it with on- site process steps and record for the same is maintained. This will be done annually or any change in the process by way of addition equipment, process change, new product.</p>	-

Sl.No	Requirement of standard	Guidance	Reference
2.5	List all potential hazards associated with each manufacturing step, conduct a hazard analysis and consider any measures to control identified hazards		
2.5.1	<p>The HARA team shall identify and record all the potential hazards that are reasonably expected to occur at each manufacturing process step, and consideration of the following types of hazards:</p> <ul style="list-style-type: none"> • microbiological • physical • chemical • The HARA shall take into account, the potential for: • migration of substances • issues arising from the use of recycled materials • limitations of use of the product • foreseeable unintended use by the customer or consumer • defects critical to consumer safety • hazards that may have an impact on the functional integrity and performance of the final product in use • malicious intervention • raw material fraud (e.g., substitution, adulteration or misrepresentation) • allergen contamination risks. 	<p>The HARA team shall identify and record all the potential hazards. This shall include hazards present in raw materials, those introduced during the process or surviving the process steps, and consideration of the following types of hazard:</p> <ul style="list-style-type: none"> • microbiological • physical contamination • chemical and radiological contamination • migration of substances • issues arising from the use of recycled materials • limitations of use of the product • foreseeable unintended use by the customer or consumer • defects critical to consumer safety • hazards that may have an impact on the functional integrity and performance of the final product in use • malicious intervention • raw material fraud (e.g., substitution, adulteration or misrepresentation) • allergen contamination risks. 	Annex - 09

Sl.No	Requirement of standard	Guidance	Reference
2.5.2	<p>The HARA team shall conduct a hazard analysis to identify the significant hazards (i.e., those hazards that are reasonably likely to occur at an unacceptable level), which need to be prevented, eliminated or reduced to acceptable levels. Consideration shall be given to at least the following:</p> <ul style="list-style-type: none"> • likelihood of occurrence, considering prerequisite programs in the absence of additional control • severity of the outcome. 	<p>The HARA team shall conduct a hazard analysis to identify the significant hazards. Consideration shall be given to the following:</p> <ul style="list-style-type: none"> • likely occurrence of hazard • severity of the effects on consumer safety • vulnerability of those exposed • presence or production of toxins, chemicals or foreign bodies 	
2.5.3	<p>The HARA team shall consider the control measures necessary to prevent or eliminate each product safety hazard or reduce it to an acceptable level. Consideration may be given to using more than one control measure, including relevant prerequisites. Where elimination of the hazard is not practical, justification for acceptable levels of the hazard in the finished product shall be determined and documented.</p>	<p>The HARA team shall consider the control measures using one or more control measure including pre requisite programmes.</p>	-
2.5.4	<p>Where the control of a specific product safety hazard is achieved through prerequisite programmes (see requirement 2.2), or control measure other than a critical control measure (see requirement 2.6), this shall be stated. The adequacy of the programme to control the specific hazard shall be validated.</p>	<p>Where the control of a specific product safety hazard is achieved through prerequisite programmes, or control measure other than CCP, the adequacy of the programme to control the specific hazard shall be validated.</p>	-

Sl.No	Requirement of standard	Guidance	Reference
2.6	Determine the critical control measure		
2.6.1	<p>For each hazard that requires control, control measures shall be reviewed to identify those that are critical. This requires a logical approach and may be facilitated by use of a decision tree.</p> <p>Critical control measures shall be those controls which are required in order to prevent or eliminate a product safety hazard or reduce it to an acceptable level.</p> <p>If a hazard is identified at a step where control is necessary for safety, but the control does not exist, the product or manufacturing operation shall be modified at that step, or at an earlier step, to provide a control measure.</p>	<p>This requires a logical approach and may be facilitated by use of a decision tree.</p> <p>CCPs shall be those control points which are required in order to prevent or eliminate a product safety hazard or reduce it to an acceptable level.</p>	Annex - 10
2.7	Establish validated critical limits for each critical control measure		
2.7.1	<p>For each critical control measure, the appropriate critical limits shall be defined in order to identify clearly whether the manufacturing process is in or out of control. Critical limits shall be:</p> <ul style="list-style-type: none"> • measurable wherever possible • supported by clear guidance or examples where measures are subjective (e.g. photographs). 	<p>For each CCP, the appropriate critical limits shall be defined. Critical limits shall be:</p> <ul style="list-style-type: none"> • measurable wherever possible (e.g. time, temperature, pH) • supported by clear guidance or examples where measures are subjective (e.g. photographs) 	Annex - 11
2.7.2	<p>The HARA team shall validate each critical control measure including critical limits. Documented evidence shall show that the control measures selected, and critical limits identified are capable of consistently controlling the hazard to the specified acceptable level.</p>	Validation of CCP and Critical Limits for CCPs	Annex - 12

Sl.No	Requirement of standard	Guidance	Reference
2.7.3	Where equipment settings are critical to the safety or legality of the product, changes to the equipment settings shall only be completed by trained and authorised personnel. Where applicable, controls shall be password-protected or otherwise restricted.	Where equipment settings are critical to the safety or legality of the product, changes to the equipment settings shall only be completed by trained and authorised personnel. Where applicable, controls shall be password-protected.	-
2.8	Establish a monitoring system for each critical control measure		
2.8.1	<p>A monitoring procedure shall be established for each critical control measure to ensure compliance with critical limits. The monitoring system shall be able to detect loss of control of the measures and, wherever possible, provide information in time for corrective action to be taken. As a guide, consideration may be given to the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> • on-line measurement • off-line measurement at predetermined intervals • continuous measurement. 	<p>Monitoring of CCPs shall be;</p> <ul style="list-style-type: none"> • online measurement • offline measurement • continuous measurement (e.g. thermographs, pH meters). 	Annex - 11
2.8.2	Records associated with the monitoring of each critical control measure shall include the date, time and result of measurement, and shall be signed by, or be electronically traceable to the person responsible for the monitoring.	CCP monitoring records to be established.	Annex - 11

Sl.No	Requirement of standard	Guidance	Reference
2.9	Establish a corrective action plan		
2.9.1	<p>The HARA team shall specify and document the corrective action to be taken when monitored results indicate a failure to meet a control limit, or results indicate a trend towards loss of control. This shall include the action to be taken by nominated personnel regarding:</p> <ul style="list-style-type: none"> • any products that have been manufactured during the period when the activity was out of control • how control was regained • how potential recurrence is minimised. 	Initiate corrective actions where ever there are failure to meet the critical limit.	Annex - 11
2.10	Validate the hazard analysis and risk assessment plan and establish verification procedures		
2.10.1	HARA plans shall be validated prior to any changes which may affect product safety, to ensure that the plan will effectively control the identified hazards before implementation. For existing HARA plans, this may be achieved using the established processes detailed in requirements 2.10.2 and 2.10.3.	Initial validation of CCPs before implementation	Annex - 12
2.10.2	<p>Verification procedures shall be established to confirm that the HARA plan, including controls managed by prerequisite programmes, continues to be effective. Examples of verification activities include:</p> <ul style="list-style-type: none"> • internal audits • review of records where acceptable limits have been exceeded • review of complaints or feedback • review of incidents of product withdrawal or recall. 	<p>Procedures of verification shall be established. This may include activities such as:</p> <ul style="list-style-type: none"> • internal audits • review of records where acceptable limits have been exceeded • review of complaints by enforcement authorities or customers • review of incidents of product withdrawal or recall. 	-

Sl.No	Requirement of standard	Guidance	Reference
	<ul style="list-style-type: none"> Results of verification shall be recorded and communicated to the HARA team. 	Results of verification shall be recorded and communicated to the HARA team.	
2.10.3	<p>The HARA team shall review the plan, prerequisites and flow diagrams at least annually and prior to any change that impacts the potential hazards and/or the control measures which may affect product safety. As a guide, these may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> change in raw materials or supplier of raw materials change in product composition change in manufacturing conditions, process flow, manufacturing environment, or equipment change in packing material, storage or distribution conditions change in customer use trends in root cause and/or testing/analysis results emergence of a new risk results from verification activities as defined in clause 2.10.2 internal and external audits review following incidents of product withdrawal or recall new legislation or developments associated with raw materials, manufacturing, or product. <p>Appropriate changes resulting from the review shall be incorporated into the HARA and/or prerequisite programmes.</p> <p>Changes shall be fully documented, and the validation shall be recorded.</p> <p>Where appropriate, the changes shall also be reflected in the company's policy (clause 1.1.1) and objectives (clause 1.1.4).</p>	The HARA team shall review the plan, prerequisites and flow diagrams at least annually and prior to any change that impacts the potential hazards and/or the control measures which may affect product safety.	-

Sl.No	Requirement of standard	Guidance	Reference
2.11	Hazard analysis and risk assessment documentation and record-keeping		
2.11.1	Documentation and record-keeping shall be sufficient to enable the site to verify that the HARA and product safety controls, including controls managed by prerequisite programmes, are in place and maintained.	Documentation and record-keeping shall be in place	Annex - 11