OrganiTrust® Hazard and Risk Assessment and Critical Control Points Template

Template for a systematic approach to HRA and CCP formation, addressing physical, chemical and biological hazards.

- The licensee must complete this document as part of the certification application pack.
- The licensee must assess the risk of the product and any associated articles.
- The licensee must identify all potential hazards pertaining to processing safety, quality or sustainability during the full product life cycle.
- The licensing application must be accompanied by a Product Description Report (annex II).

III.I. Product intended use summary

Provide a detailed breakdown of the intended use of the product, with information on the demographics of previous purchasers or market group, including any vulnerable or at-risk groups.

III.II. Process flow diagram

Provide a flow diagram of the full production process, including:

a. sourcing of materials, ingredients and components;
b. all production steps;
c. inspection;
d. quality control;
e. packaging labelling/decoration;
f. packing;
g. storage;
h. distribution;
i. end-of-life recovery.

III.III. List of raw materials and incoming materials

Provide a detailed outline of the product composition, with ingredient, component or material concentrations or proportional abundance, including:

a. ingredients and raw materials;
b. processing aids and any substances used during manufacturing;
c. any known final residual NIAS;
d. all non-core ingredient substances, such as inks and outer label adhesives.

Process	Material	Description (including trade name)	Hazard	Supplier	Product/ Catalogue number

III.IV. Plant layout flow diagram with employee/product flow

III.V. Physical, chemical and biological hazard identification

III.V.I. Identify all core use parameters, considering potential product safety, sustainability, conformity or quality issues which could occur at each stage, such as (but not limited to):

a. core functionality requirements;
b. maximum or minimum use temperatures and other use conditions and restrictions;
c. machine use and tolerances;
d. physical or chemical product contamination;
e. microbiological contamination;
f. end-of-life disposal hazard and sustainability.

III.V.II. Establish specifications for each core use parameter.

III.V.III. Describe the potential risk attached to each hazard identified and assess the likelihood of identified risks without controls using the risk matrix.

		Evaluation and action policy	Non-acceptable risk level	Critical control point: critical risk control system required (CCP)	Control point: non-critical risk control system required (CP)
	Effect	No human or environmental health impact	Minor human or environmental health impact	Moderate/ reversible human or environmental health impact	
Likelihood of hazard occuring	Not possible or expected to occur during product or facility life or no known affect on exposed individuals				
	Unlikely, but may possibly happen during product or facility life or unlikely, but could affect vulnerable exposed indviduals				
	Could occur several times during product or facility life or could affect vulnerable exposed individuals				
	Could occur at any point/on a regular basis during product or facility life or could affect exposed individuals				

III.V.IV. Product packaging must also be assessed for fitness for purpose and be suitable to protect the product from damage and maintain its integrity, protecting the consumer from injury, preventing contamination and ensuring sustainability.

III.VI. Critical control points

III.VI.I. Identify any CCPs, defined as those control points that are compulsory to prevent or avoid a serious product safety, sustainability, quality or integrity hazard and provide specifications or critical limits to identify whether correct controls are being maintained in the production process. Provide evidence of reasonable industrial or scientific rationale, where relevant legislation or codes of practice are absent.

III.VI.II. A fully documented control plan system must be established, ensuring product safety, sustainability and conformity to each critical use parameter.

a. Monitoring systems must be outlined ensuring compliance with critical limits, with records maintained and documented procedures for the monitoring of each CCP included in internal audits for standard compliance.
b. Procedures for validation, verification and annual review must be outlined to confirm that the system is working effectively, including auditing of the system.