RISK ASSESSMENT PACK

Microbiological Contamination

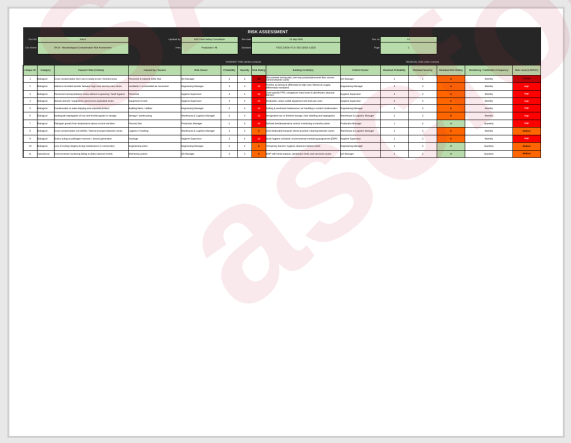
Where micro-organisms get into product on your site, what raises or lowers the likelihood, and which controls actually reduce the residual risk. Written to be defended, not just filed.

What you get

- **The risk assessment workbook (Excel)**
  Fully editable, with drop-down lists, automatic inherent and residual risk scoring, colour coded risk bands, a populated worked example you can adapt, and a built in action tracker.
- **The governing procedure (Word)**
  The SOP the risk assessment sits under, written to the same standard, ready to adopt with your company name and approver.
- **A step by step completion guide (Word)**
  Purpose and clauses, what to gather first, the scoring method worked through with a real example, the register column by column, verification and review, and the mistakes auditors find most often.
- **A read me first sheet (Word)**
  What is in the pack, who it is for, what you must edit before use, and how to get help.

Standards this pack supports

ISO 22000:2018 cl. 8.2.4 h) and 8.5.2, ISO 22002-1:2025 cl. 12.1 and 12.2, ISO 22002-100:2025 cl. 12, FSSC 22000 V7 cl. 2.5.11 and 2.5.12



The actual risk register in this pack, shown at reduced size.

Once off payment. No subscription.
Editable Word and Excel. Instant download.

R690 | USD 34

Inside the step by step guide

Every pack includes a written guide that walks a quality manager through the scoring method, the register column by column, residual risk, verification and review, and the mistakes auditors find most often on this subject. This is one page of it.

LOGO	*[COMPANY NAME]* **Food Safety Management System**	**Doc No: RA14**	Page 1 of 5
Subject: Microbiological Contamination - How to Complete This Risk Assessment			
Compiled by: ASC Food Safety	**Approved by: [YOUR APPROVER]**	**Date: 01 Sep 2026**	**Rev no: 01**

HOW TO COMPLETE THIS RISK ASSESSMENT

1. PURPOSE

This guide explains how to complete the RA14 Microbiological Contamination Risk Assessment supplied with it. That assessment decides how much control your site needs over the routes by which micro-organisms reach product: traffic between raw and ready-to-eat areas, air movement between zones, people, shared equipment and tools, condensation, storage segregation, drains and the loss of segregation during maintenance or building work.

The pack contains four files: the risk assessment workbook, the governing procedure, this guide, and a Read Me First file. Together they give you the assessment, the method behind it and the procedure that the controls in the register refer to.

Completed and kept up to date, the risk assessment provides evidence against: ISO 22002-1:2025 clause 12.1 and clause 12.2, which require areas with a potential for microbiological cross contamination, airborne or from traffic patterns, to be identified and a segregation or zoning plan to be implemented covering separation of raw from finished or ready-to-eat product, structural segregation, access controls with a change into the required workwear, traffic patterns and equipment segregation including dedicated tools, and air pressure differentials; ISO 22002-100:2025 clause 12; ISO 22000:2018 clause 8.2.4 h), measures for the prevention of cross contamination; and FSSC 22000 Version 7.0 clause 2.5.11, hazard control and measures for preventing cross-contamination.

This is a prerequisite programme risk assessment. It is not a hazard analysis. It decides how much control the prerequisite programme needs and shows that the decision was made on evidence. Its output is an input to your hazard analysis under ISO 22000:2018 clause 8.5.2 and to management review under clause 9.3.

2. BEFORE YOU START

Do not start in the workbook. Collect the following first, because every score you enter has to be defensible from it:

- the site layout drawing with the zones marked, and the current zoning or segregation plan, including where the boundary between low-care, high-care and high-risk actually runs
- the personnel, material, waste and packaging flow drawings, and the points where those flows cross
- the air handling schematic, the pressure differential set points and the last twelve months of differential records
- twelve months of environmental monitoring results and their trend, by zone and by site, and any repeat positives
- product and surface microbiological results, including any out of specification result and what was done about it
- the colour coding scheme for tools and cleaning equipment, and evidence that it is followed
- the gowning and hand hygiene rules for each zone and the last hygiene audit results
- the drain layout and drain cleaning records, and the record of any building or maintenance work that breached a barrier in the last year

The assessment is led by the QA Manager or Food Safety Team Leader with the Production Manager, who owns the flows and the changeovers, the Hygiene Manager, who owns the cleaning and the segregation of cleaning equipment, and the Engineering Manager, who owns the barriers, the doors and the air handling.

Inside the accompanying procedure

The pack also carries the governing procedure the risk assessment sits under, written to the same house standard and ready to adopt with your company name and approver. This is its first page.

LOGO	*[COMPANY NAME]* **Food Safety Management System**	**Doc No: RA14**	Page 1 of 5
Subject: Microbiological Contamination Procedure			
Compiled by: ASC Food Safety	**Approved by: [YOUR APPROVER]**	**Date: 01 Sep 2026**	**Rev no: 01**

MICROBIOLOGICAL CONTAMINATION PROCEDURE

1. PURPOSE

The purpose of this procedure is to define the measures [COMPANY NAME] applies to detect, prevent, control or minimise microbiological, allergen, physical and chemical contamination and cross-contamination of product, packaging and food contact materials, to a level shown to be acceptable by the hazard analysis.

2. SCOPE

This procedure applies to all raw material intake, storage, processing, packing, warehousing and dispatch areas, to all personnel, visitors and contractors, and to all equipment, tools, utilities and services that come into contact with product or the product environment.

3. REFERENCES

FSSC 22000 Scheme Version 7.0 (May 2026)

ISO 22002-1:2025, clause 12 (measures for prevention of contamination): 12.2 microbiological, 12.3 allergen, 12.4 physical and 12.5 chemical contamination

ISO 22002-100:2025, clause 12 (measures for prevention of contamination)

ISO 22000:2018, clause 8.5 (hazard control) and clause 8.2 (prerequisite programmes)

the RA14 Microbiological Contamination Risk Assessment supplied in this pack; your physical contamination risk assessment; your chemical contamination risk assessment

Your allergen management procedure, with your allergen process flow risk assessment and your allergen risk assessment

Your glass breakage management procedure; your new glass installation control; your metal, wood and glass management procedure; your glass and hard plastics register; your foreign body detection and removal procedure

Your cleaning and disinfection procedure; your environmental monitoring procedure; your microbiological testing procedure; your chemical spillage procedure; your approved chemical list; your cleaning chemical issue record; your lubricant register and lubrication schedule; work instructions your metal detector and x-ray challenge test work instruction, your allergen changeover and line clearance work instruction, your label and packaging line clearance work instruction, your sieve, magnet and filter integrity check work instruction, your glass and brittle plastic breakage response work instruction and your spill response work instruction

Cross scheme mapping. This procedure also serves BRCGS Food Issue 9 cl. 4.3 layout, product flow and segregation, with section 8 production risk zones for high risk and high care sites, IFS Food v8 cl. 4.8 plant layout and process flow and SQF Edition 9 cl. 11.7 separation of functions. Any GFSI scheme that requires cross contamination between raw and ready to eat areas to be controlled and evidenced.

4. RESPONSIBILITIES

Role	Responsibility
QA Manager / Food Safety Team Leader	Owns this procedure and the zoning plan. Approves changes to segregation, verifies effectiveness through environmental monitoring and swabbing, and reports performance to management review.
Production Manager	Applies the zoning, sequencing and changeover rules on