Operational Hygiene Index

OHI Pre-Assessment Questionnaire

Do you need a full Operational Hygiene Index determination?

This short self-assessment gives you a directional score between 0% and 100%, indicating how likely it is that a full OHI determination would surface actionable findings for your plant. It takes about 10 minutes and covers seven areas: product portfolio, governance, employee qualification, microbiological monitoring, production process, process engineering, and track record & visibility.

This questionnaire is a screening tool, not the OHI itself. It does not replace the ~600-question, risk-weighted methodology used in an actual OHI determination; it is designed to help you decide whether that investment is worth making now.

1. Product Portfolio (Section weight: 15%)

Water-based, low- or preservative-free formulations carry inherently higher microbiological vulnerability than solvent-based systems.

Q1. Which best describes your current product portfolio?

Answer option	Points
Predominantly solvent-based (>70% of volume)	0
Mixed solvent-based and water-based	5
Predominantly water-based (>70% of volume)	10

Q2. For your water-based products (current or planned within the next 2-3 years), how would you characterize preservative/biocide usage?

Answer option	Points
Not applicable – no water-based products, now or planned	0
Heavy reliance on preservatives across most products	3
Light or selective use of preservatives in some products	7
Preservative-free, or actively moving toward preservative-free formulations	10

2. Governance & Responsibility (Section weight: 15%)

Clear ownership and a living hygiene plan are prerequisites for consistent hygiene performance.

Q3. Is there a clearly designated person or role responsible for operational hygiene in your plant?

Answer option	Points
Yes, clearly designated and known throughout the plant	0
Informally, or shared across several roles without clear ownership	5
No designated responsibility	10

Q4. Does your plant have a documented operational hygiene plan (Betriebshygieneplan)?

Answer option	Points
Yes, documented and actively used	0

Answer option	Points
Partially documented, or exists but rarely referenced	5
No documented plan	10

Q5. Beyond the cleaning activities defined in the operational hygiene plan, are additional reactive special cleanings regularly necessary — or does the defined plan generally suffice?

Answer option	Points
The defined plan generally suffices; additional cleaning is a rare exception	0
Occasionally, additional reactive special cleaning is necessary	5
Regularly / frequently, additional reactive special cleanings are necessary	10

3. Employee Qualification (Section weight: 10%)

Operational hygiene performance depends on both qualified personnel for defined hygiene measures and regular sensitization of operators at the plant.

Q6. Is there trained, qualified personnel to carry out the measures defined in the operational hygiene plan?

Answer option	Points
Yes, dedicated qualified personnel	0
Only partially or informally qualified	5
No qualified personnel	10

Q7. Are operators at the various production facilities regularly sensitized on operational hygiene topics?

Answer option	Points
Yes, on a regular, defined basis	0
Occasionally, without a fixed schedule	5
No, not sensitized	10

4. Microbiological Monitoring (Section weight: 20%)

The scope and precision of sampling determines whether contamination is caught early or discovered as a customer complaint.

Q8. Do you conduct regular microbiological sampling (raw materials, in-process, and/or finished goods)?

Answer option	Points
Yes, on a defined regular basis	0
Occasionally, or only for select products	6
Rarely or never	10

Q9. Is the number and frequency of samples based on a defined, risk-based sampling plan?

Answer option	Points
Yes, a risk-based plan defines sample points, frequency, and count	0

Answer option	Points
A plan exists but is not clearly risk-based	5
Ad hoc, no defined plan	10

Q10. Are the nutrient media used matched to the risk profile of each sampling point (e.g., distinguishing bacteria from yeast/mold, tailored to the substrate)?

Answer option	Points
Yes, media selection is tailored per sampling point	0
A standard media set is used for most/all points	6
Not sure / not actively considered	10

5. Production Process (Section weight: 10%)

How intermediate materials are produced and held affects microbiological risk exposure.

Q11. Is production based on semi-finished slurries, or classic dry powder raw materials?

Answer option	Points
Classic powder raw materials, no slurry intermediates	0
Mixed: some slurry intermediates, some powder	5
Predominantly slurry-based production	8

Q12. Once a production batch has been released by QC, how long is it typically stored before final filling?

Answer option	Points
Filled within 24 hours of release	0
A few days (up to about 1 week)	4
One to two weeks	7
Longer than two weeks	10

6. Process Engineering & Equipment (Section weight: 20%)

Hygienic design at the point of procurement and planning is far cheaper than remediation after installation.

Q13. When planning new production or filling areas, do operational hygiene parameters play a role (e.g., CIP-capability of piping)?

Answer option	Points
Yes, hygienic design is a formal planning criterion	0
Considered informally, not systematically	5
Not considered	10

Q14. Is component procurement (e.g., tanks, pumps, filters) carried out according to hygienic design criteria (cleanability, dead-leg avoidance, surface finish, materials)?

Answer option	Points
Yes, hygienic design is a formal procurement criterion	0
Considered informally, not formally specified	5
Not considered	10

7. Track Record & Visibility (Section weight: 10%)

Past incidents and current visibility into hygiene status are strong leading indicators.

Q15. Have you had microbiological contamination incidents or related customer complaints in the last two years?

Answer option	Points
No incidents	0
One or two isolated incidents	6
Recurring incidents or complaints	10

Q16. If asked today, "what is our operational hygiene status?", could you answer with data — or would it mostly be a gut feeling?

Answer option	Points
Yes, we could answer with concrete data and metrics	0
Partially – some data exists, but no consolidated view	6
Mostly gut feeling, no consolidated data	10

Q17. Are you facing external pressure (customer audits, certification, regulatory requirements) to demonstrate hygiene control?

Answer option	Points
No specific external pressure at present	2
Some pressure, not yet formalized	6
Active, near-term requirement (e.g., upcoming audit or certification)	10

Scoring Methodology

Each answer carries a point value from 0 (mature, low risk) to 10 (gap, high risk). Within each of the seven sections, average the points scored across that section's questions to get a Section Score (0–10). Multiply each Section Score by its weight below, and sum across all seven sections to get the overall OHI Need Score, expressed as a percentage (0–100%).

Section	Weight
1. Product Portfolio	15%
2. Governance & Responsibility	15%
3. Employee Qualification	10%
4. Microbiological Monitoring	20%
5. Production Process	10%

Section	Weight
6. Process Engineering & Equipment	20%
7. Track Record & Visibility	10%

Formula: OHI Need Score (%) = Σ over all 7 sections of [Section Weight × (Section Score ÷ 10) × 100]

Worked example: if a plant scores an average of 6 out of 10 on Microbiological Monitoring (weight 20%), that section alone contributes 20% × (6/10) × 100 = 12 percentage points to the overall score.

Interpretation

Score	What it suggests
0 – 30%	Low priority. Hygiene fundamentals appear broadly in place. A focused review of specific weak points may still be worthwhile.
31 – 60%	Moderate priority. Meaningful gaps likely exist. A full or partial OHI determination would help clarify and prioritize them, especially if regulatory change on preservative use is approaching in your market.
61 – 100%	High priority. Significant structural, process, or monitoring gaps are likely present. A full OHI determination is strongly recommended, particularly if tighter regulation of preservative use is on the horizon for your market.

This questionnaire is a directional screening tool based on self-reported answers. It is not a substitute for the on-site, risk-weighted OHI determination, which examines roughly 600 data points across seven Hygiene Relevant Areas and produces a validated, reproducible score.