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Place of the Audit	MTK. Tekstilciler Sitesi 5747 / 10 sokak no:18 Bornova İzmir
Audit Date	30-31.10.2025/17.11.2025
Evaluation Standard	BS EN 17141 –Biocontamination control ISO 14159 – Hygiene Requirements for Machinery EN 1672-2 – Hygiene Requirements of Food Processing Machinery EU 1935/2004 – Food Contact Materials EU 10/2011 – Plastic Materials FDA CFR 21 – Food Contact Substances EU 2023/2006 – Good Manufacturing Practice
Product evaluation date	11-14.11.2025
Test material	Vegetable Fogging / Humidification Unit
Model	OZOFOG, HUMI-FOG, FOG-PLUS, DRY-FOG
Report Date	21.11.2025
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Scope Of the Report	Hygienic Product Evaluation
Appointed Technical Expert	Aylin DENLİ ÇOBAN Dr. Eng. (Mechanical Engineer) 
Technical Regulatory Responsible	BURCU ATABAŞ Mechanical Engineer 
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1. General Hygienic Design Overview

The SÜSOY Vegetable Fogging / Humidification Unit System has been evaluated in accordance with the essential hygienic design principles defined in **ISO 14159 (Safety of machinery – Hygienic requirements for the design of machinery)** and **EN 1672-2 (Food processing machinery – Hygiene requirements)**.

The device operates by generating fine water mist (fog) that increases surface humidity on fresh vegetables. Since the equipment does **not directly handle, process or mechanically contact food**, it falls under the classification of **indirect food-contact equipment**. This modifies the hygienic design requirements but does not eliminate them.

The evaluation confirms that structural materials, water pathway components, internal surfaces, and mist-generation zones comply with hygienic design expectations for **non-food-contact but food-adjacent equipment**.

2. Hygienic Level Classification (Level 3 – Justification)

Based on EN 1672-2 hygiene levels, the SÜSOY Vegetable Fogging / Humidification Unit System is classified as:

HYGIENE LEVEL 3

(Compliant with the International Standard and cleanable without disassembly)

Justification for Level 3 designation:

2.1. Indirect Product Contact:

The device does not have direct food-contact surfaces. Only treated water mist (fog) reaches the produce surface. The internal water path (tubing, filter, nozzles) therefore represents **indirect food contact**, requiring materials compliant with hygienic standards.

2.2. Cleanability Without Disassembly:

Surfaces, water lines, and fogging chamber can be cleaned in place.



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UV and ozone systems support microbial reduction.

No complex internal geometries that require dismantling for hygiene.

23. Absence of High-Level Sterility Requirements:

Since the product is fresh vegetables (not sterile, aseptic, or RTE high-risk products), the equipment does **not** need Level 4 or Level 5 hygienic classification.

24. Risk Profile:

- Biological risk exists only through water quality.
- Chemical and physical hazards are minimal due to design.
- Microbial risks are addressed through integrated UV–Ozone treatment.

This classification aligns with the intent of EN 1672-2 for equipment used in open food environments without critical contamination risk.

3. Indirect Food Contact Evaluation

Although the equipment does not directly touch the product, the **mist emitted from the system settles on fresh vegetables**, which categorizes the water path components as: **“Indirect Food Contact Components”**

This requires the following conditions:

- Materials must be food-grade or compliant with EU Framework Regulation 1935/2004 or equivalent.
- Components must resist corrosion, leaching, and microbial growth.
- O-rings, seals, tubing, reservoir surfaces, and mist nozzles must withstand repeated cleaning and disinfecting cycles.

Assessment Result:

All examined components are suitable for indirect food contact and comply with hygienic design requirements.




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Although the equipment does not mechanically touch food, mist droplets generated inside the system ultimately deposit on edible surfaces. Therefore the system must comply with the hygienic design rules applicable to:

- water circuits supplying food environments
- surfaces exposed to airborne contact
- components affecting microbiological quality of droplets

Assessment Summary:

Assessment Area	Requirement	Result
Direct food contact	None	N/A
Indirect droplet contact	Must be hygienically designed, corrosion-resistant	Compliant
Water pathway materials	Food-compatible, non-toxic, no chemical migration	Compliant
Microbial control	UV + ozone disinfection, low-risk water quality	Compliant
Chemical transfer	No lubricants or fluids contacting mist	Compliant
Foreign bodies	Closed mist outlet prevents contamination	Compliant

FOOD CONTACT MATERIAL ASSESSMENT (Indirect Contact)

Component	Material	Food-Contact Status	Evaluation
Nozzle Body	Stainless Steel 304	Indirect Food Contact	Compliant
Water Hose	Food-Grade Polyurethane	Indirect Food Contact	Compliant
Water Tank	HDPE Food-Grade	Indirect Food Contact	Compliant
Ozone Chamber	Stainless Steel	Not in food zone	Compliant
Fog Outlet	Food-contact safe polymer	Indirect	Compliant

4. EN 1672-2 & ISO 14159 – General Hygienic Design Evaluation

A combined evaluation under both standards concludes:

4.1 Design Characteristics



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- Smooth internal surfaces
- No dead spaces in water lines or fog chamber
- Hygienic welded or sealed joints
- Self-draining water reservoir
- Minimal fasteners in hygienic zones
- Cleanability ensured by design

4.2 Materials

- Corrosion-resistant components
- Food-compatible water path materials
- Non-toxic elastomers and plastics
- No lubricants in any product-exposed areas

4.3 Risk Reduction Principles (ISO 14159)

- Biological risk minimized via UV and ozone
- Chemical and physical risks inherently low
- Residual risk level classified as **acceptable**

Overall Compliance Statement:

The device meets the hygienic design intent of EN 1672-2 and ISO 14159 for indirect food-contact equipment used in open produce environments.

Hygienic design and construction

Regarding the design, fabrication and installation of equipment the following basic criteria must be taken into consideration:

TABLE 1 — ISO 14159: Hygienic Requirements for Machinery

Clause	Full Requirement	Device Evaluation	Compliance
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4 Hazards	<p>Hazards associated with the transport, preparation or processing of food may arise from: • Biological causes such as pathogens, spoilage microorganisms, toxins (bacterial ingress/retention, spores, viruses, yeasts/moulds); • Chemical causes, including residues from cleaning, disinfection agents, lubricants; • Physical causes such as foreign materials from raw materials, equipment, or machine construction.</p>	<p>Device has no direct food-contact surfaces. Fog contacts vegetables indirectly. Main hygiene risks: water quality, nozzle design, drainage, condensate, cleanability. Components forming the splash zone: nozzle, water chamber, membrane, filters, UV/ozone unit. ✓</p>
5.1.1 General	<p>Hygiene measures must be selected through a hygiene risk assessment applicable to product-contact and non-product-contact areas.</p>	<p>Fogging areas and internal chamber are designed for cleaning access. Risk assessment performed. ✓</p>
5.1.2 Basic Strategy	<p>Must identify: • intended process; • hazards (Clause 4); • risk assessment for each hazard; • design measures to eliminate/reduce risks; • identification of new hazards caused by mitigations; • verification methods; • residual risks and additional instructions.</p>	<p>Process: hydration of vegetables. Hazards: microbial growth, water quality, condensate, nozzle blockage. Measures: UV, ozone, RO filtration, hygienic drainage, cleanable nozzles. ✓</p>
Hygiene Level Classification	<p>Machine may be classified as Level 1–5 after risk assessment: Level 1: partial compliance; Level 2: compliant but requires disassembly for cleaning; Level 3: fully compliant & cleanable without disassembly; Level 4/5: aseptic/sterilizable systems.</p>	<p>Device meets Level 3: fully compliant, cleanable without disassembly, not aseptic system. ✓</p>



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5.1.3 Elements of Risk Assessment	Consider: purpose, product type, further processing, intended consumer, cleaning/disinfection frequency, machine usage (continuous, intermittent, misuse).	Purpose: vegetable hydration. No further lethal step. Cleaning daily. UV+ozone mitigate microbial risk. ✓
5.2.1.1 General (Materials)	Materials shall be suitable for use, durable, cleanable, disinfectable, resistant to breakage, cracking, flaking, erosion, corrosion, and must prevent ingress of undesirable materials.	Stainless steel, silicone, polymer components; corrosion-resistant, durable, cleanable. ✓
5.2.1.2 Product Contact Surfaces	Materials must be corrosion-resistant, non-toxic, non-contaminating, non-absorbent (unless unavoidable), and resistant to processing temperatures (pasteurization, sterilization where required).	No direct food-contact surfaces; fog contact zone smooth and inert. ✓
5.2.1.3 Metals	Product-contact metals must be stainless steel or equivalent; welded, polished as required.	Internal chamber & fittings are stainless steel or coated metal. No corrosion risk. ✓
5.2.1.4 Non-metals	Polymers/elastomers must withstand cleaning chemical exposure, temperature, maintain surface integrity, and not delaminate.	Silicone hoses, polymers in nozzle/filter area are stable with water, fog, UV/ozone. ✓
5.2.1.5 Non-product Contact Surfaces	Must be corrosion-resistant, non-absorbent, non-contaminating; removable parts must eliminate hygiene risks.	All external surfaces non-absorbent & corrosion-resistant. ✓
5.2.2.1 Surface Texture	Must be free from pits, crevices, cracks; surface quality per ISO 4287 where applicable.	Nozzle and chamber surfaces smooth, free of pits/crevices. ✓



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5.2.2.2 Cleaning & Inspection	Surfaces must be cleanable; removable parts must be removable & accessible for inspection; in-situ cleaning permitted but design must allow inspection.	Nozzle, filter, tank cap removable. Internal surfaces accessible.	✓
5.2.2.3 Disinfection/Pasteurization/Sterilization	Machine must meet required disinfection/pasteurization/sterilization conditions if applicable.	Not a sterilization system; hygiene ensured by UV+ozone.	N/A
5.2.2.4 Microbial Ingress	Must prevent microbial entrance to product-contact surfaces in aseptic systems.	Not aseptic system; water path protected; UV/ozone kill microbes.	✓
5.2.2.5 Drainability	Surfaces must be self-draining or drainable, except for normal wetted surfaces.	Red and yellow drain lines fully drain system; no stagnant water.	✓
5.2.2.6 Dead Spaces	Dead spaces must be avoided.	Fog chamber & hoses designed without dead pockets.	✓
5.2.2.7 Joints	Welds must be continuous; removable joints flush & leak-tight; avoid pits/cracks; silver solder acceptable only if hygienically finished.	Welds smooth; removable joints hygienic; no cracks or cavities.	✓
5.2.2.8 Coatings	Must not delaminate, blister, flake, degrade.	No coating failure observed.	✓
5.2.2.9 Radii & Corners	Corners must be radiused for cleanability; grooves wider than deep.	Fog chamber corners radiused; no narrow grooves.	✓



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5.2.2.10 Seals & O-rings	Must minimize product contact, be cleanable, consider compression/thermal expansion.	Seals are elastic, cleanable, properly compressed.	✓
5.2.2.11 Fasteners	Avoid screws, bolts; if necessary must be cleanable; no exposed threads.	No exposed threads in splash area.	✓
5.2.2.12 Process Interruptions	Avoid springs/holes unless required; such features must be cleanable.	No unnecessary penetrations; fan/drain openings cleanable.	✓
5.2.2.13 Shafts/Bearings	Shafts passing food areas must be protected; avoid product-contact bearings.	No shafts in fog path.	N/A
5.2.2.14 Sensors	Must be installed to avoid cracks/dead spaces; must drain.	Sensors mounted flush, no crevices.	✓
5.2.2.15 Other Connections	Pipes & interfaces must be hygienically sealed and prevent soil ingress.	All pipes sealed; no soil/pest entry.	✓
5.2.2.16 Covers/Openings	Covers/panels must avoid residue accumulation, be cleanable, sloped outward.	Sloped surfaces, easy access, no residue retention.	✓
5.2.3 Non-product Contact Areas	Prevent moisture/soil retention, pest ingress; allow cleaning/inspection.	Body is enclosed, resistant, easy to clean.	✓



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6 Verification of Hygiene Measures	Compliance must be verified via documentation, inspection, or testing.	Drawings reviewed, drainage and nozzle cleanability tested.	✓
7.1 Manual	Manual must include installation, hygiene, contamination control instructions.	Manufacturer manual sufficient.	✓
7.2 Cleaning/Maintenance	Manual must define cleaning steps, chemicals, disassembly.	Cleaning procedure provided.	✓
8 Additional Information	Additional safety info required when risks cannot be controlled by design.	Only requirement: periodic UV/ozone check, water quality.	✓

TABLE 2 — EN 1672-2: Hygiene Requirements for Food Processing Machinery

Clause	Full Requirement	Device Evaluation	Compliance
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MACHINE –
EN 1672-2 Food
processing
machinery –
Basic concepts –
Part 2: Hygiene
requirements

4 List of significant hazards The significant hazards are listed below:-
Biological causes, e.g., pathogens, spoilage microorganisms, toxins or pests;- Chemical causes, e.g., cleaning and disinfection agents and lubricants;- Foreign bodies and materials originating from raw materials, the machine or other sources. Each of these hazards may pose contamination risks or consumer health risks. Microbiological hazards can cause spoilage, food poisoning or other related illnesses. Chemical hazards may contaminate food or leave residues harmful to health (e.g., burns). Foreign bodies may contaminate food or cause physical harm (e.g., obstructing breathing or irritation). When designing a machine, the impact of each hazard and the measures to eliminate or reduce them must be considered.

Since the humidification device sprays mist onto open product, the biological risk is limited to water quality. The UV + ozone system ensures control of biological hazards. **Chemical Hazards** Evaluation: Suitable Explanation: No lubricants are used in the device. ✓
There is no risk of cleaning chemicals transferring to the product. **Physical / Foreign Object Hazards** Evaluation: Suitable Explanation: There is no risk of machine parts falling into the product; the mist outlet is a closed system.

EN 1672-2

5 Hygiene requirements
5.1 Hygiene risk assessment – 5.1.1 General Hazards may be eliminated or reduced through proper design, construction, installation, operation, cleaning and maintenance. Hygiene rules depend on the function of the area, the food processed and the nature of hazards. The objective is to eliminate or reduce risks to acceptable levels. Hygiene risk assessments are conducted per ISO 14159.

The machine complies with ISO 14159 and provides high accessibility for cleaning and maintenance. ✓




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EN 1672-2	<p>5.1.2 Determination of machine use limits Risk assessment shall consider:- Machine lifecycle stages;- Intended use per ISO 12100-1 (correct use, foreseeable misuse, failure consequences);- Whether the machine is single-purpose or multi-purpose;- User characteristics (age, gender, handedness, physical limitations);- User expected training level and competence.</p>	<p>The device is single-purpose (surface humidification of vegetables). The user profile is supermarket staff; minimal technical expertise is required. ✓</p>
EN 1672-2	<p>5.1.3 Estimation of hygiene risk- Estimate severity of possible harm;- Estimate probability of occurrence.</p>	<p>• Severity: Low – product is not directly processed. • Probability: Low – water treatment, UV and ozone significantly reduce risk. ✓</p>
EN 1672-2	<p>5.1.4 Evaluation of hygiene risk After estimation, it must be determined whether risks must be further reduced or whether they are acceptable. If needed, additional safety measures must be implemented and re-evaluated.</p>	<p>Risk level has been reduced to an acceptable level; no additional controls are required. ✓</p>
EN 1672-2	<p>5.1.5 Reduction of hygiene risks Requirements:- Removal or reduction of hazards by: a) designing or substituting less hazardous materials; b) ensuring hygienic conditions;- Clear operating instructions;- Defined hygienic work practices;- User information covering hazards across the machine lifecycle;- Appropriate PPE guidelines.</p>	<p>• Biological risk is reduced through UV + ozone. • Operating instructions are clear. • Training requirement is minimal. ✓</p>




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EN 1672-2	5.2 Construction materials – 5.2.1 General rules Materials must be suitable for intended use; surfaces must be durable, cleanable, disinfectable and resistant to cracking, chipping and abrasion.	All materials are durable, cleanable and resistant to breakage.	✓
EN 1672-2	5.2.2 Food area Materials must be:- corrosion-resistant;- non-toxic;- non-absorbent;- must not transfer odor, color, or taint food.(Although no direct food contact exists, mist contacts surfaces.)	Although there is no direct food-contact surface, mist contacts internal components; therefore water line and nozzle materials are food-compatible and corrosion-resistant.	✓
EN 1672-2	5.3 Design – 5.3.1 Food area – 5.3.1.1 Surfaces Surfaces must be smooth, continuous, sealed and cleanable.No cracks, dead spaces or areas where product can accumulate.	Surfaces are smooth, sealed and cleanable. No gaps exist where particles could accumulate.	✓
EN 1672-2	5.3.1.2 Connections – continuous connections Connections must be sealed and hygienic, free from gaps, voids and dead spaces.	Body connections are welded; no gaps or voids exist.	✓
EN 1672-2	5.3.1.2.2 Removable connections	Nozzle, filter and hose connections are hygienic and sealed.	✓
EN 1672-2	5.3.1.3 Fasteners	Bolted parts are not present in the food area; only on the exterior and enclosed.	✓
EN 1672-2	5.3.1.4 Drainage	Water tank drainage is self-draining. No unnecessary liquid retention exists.	✓
EN 1672-2	5.3.1.5 Internal angles and corners	No sharp corners exist in fog chamber; accessible radii support cleanability.	✓



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EN 1672-2	5.3.1.6 Dead spaces	No dead spaces exist in fog chamber or water line.	✓
EN 1672-2	5.3.1.7 Bearings and shaft entry points	Evaluation: N/A Explanation: No bearings, shaft seals or moving shafts exist in the food area.	✓
5.3.1.10 Controls	Control devices must prevent cross-contamination.	Control panel isolated.	✓
5.3.2 Splash Area	Same principles as food area, but slightly more flexible.	Splash zone hygienic, easy to clean.	✓
5.3.3 Non-Food Area	Must prevent moisture/soil/pest accumulation.	Fully enclosed, cleanable.	✓
5.3.4 Services	Pipes, connections must not introduce hazards.	Water/electric sealed.	✓
7.1–7.3 Instructions	Manual must define use, installation, sanitation, maintenance.	Manual provided.	✓

5. BS EN 17141 –Biocontamination Control (Relevance & Assessment)

The principles of biocontamination control used in BS EN 17141 are relevant for evaluating the following:

5.1. Microbial Risk Sources

- Water reservoir
- Nozzle outlet
- Internal tubing
- Ambient air intake

5.2. Control Measures in the Device



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- **Active microbial reduction:** UV + ozone disinfection of water
- **Passive control:** Smooth materials preventing microbial growth
- **Operational control:** Routine water change, filter maintenance

5.3. Alignment With BS EN 17141 Principles

- The device achieves microbial reduction through engineered controls
- Design prevents stagnation and biofilm formation
- No aerosolization of contaminated water due to integrated treatment
- Maintenance procedures reduce long-term contamination risk

Conclusion:

Even though BS EN 17141 is not directly applicable, the misting system meets key biocontamination control principles relevant to open food environments.

Evaluation

The tests were carried out according to the BS EN 17141 standard. The evaluation of the tests was carried out with the BS EN 17141 "Evaluation of the effect of microorganisms on materials" methods. Evaluations are based on a visual assessment of the feedlot. This test is used to evaluate the behavior of materials related to the effect of a particular mold and bacteria.

The evaluation of the microbial growth on the test specimens was done according to Table 1 and in comparison to the control samples

Table 1: Evaluation of the microbial growth



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Growth intensity	Evaluation
0	no growth on microscopic examination identified
1	no growth visible to the naked eye but clearly visible under the microscope
2	Growth visible to the naked eye, up to 25% of the sample surface covered
3	Growth visible to the naked eye, up to 50% of the sample surface covered
4	significant growth, over 50% of the sample surface covered
5	strong growth, entire sample surface covered

The interpretation of the results according to methods A and C was done according to resp. based on Table 2

Table 2: Interpretation of the results

Growth intensity	Evaluation of the test material
0	Material is not used as a nutrient for microorganisms, it is "inert" or "fungistatic"/ "bacteriostatic".
1	Material contains nutrients and is only slightly soiled, so that only slight growth is possible
2 bis 5	Material is not resistant to microorganism infestation and provides nutrients for the development of microorganisms



[Signature]
Approved: Technical Manager

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Test Result

Test Material	Growth intensity of the microbial growth according to Table 1	
	Method A	Method C
Vegetable Fogg/Humidity Systems Unit	0	0
	0	0
	0	0
	0	0
	0	0

None of the specimens pursuant to method A showed bacterial growth in comparison to the negative control samples.

None of the specimens pursuant to method C showed bacterial growth in comparison to the negative control samples.

“The BS EN 17141 standard is not a design-compliance standard for this device; it is used solely as a reference method for microbiological/biocontamination testing.”



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