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ADAPTED FMEA – BASED HYGIENIC RISK ASSESSMENT OF WELDING PROCEDURES FOR STAINLESS STEEL FOOD PROCESSING PIPELINES

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Abstract: This paper proposes an engineering–based Hygienic Failure Mode and Effects Analysis (HFMEA) model for assessing the contamination risk associated with welding procedures applied in stainless steel pipelines used in food processing installations. The study correlates structural discontinuities identified by non–destructive testing methods (penetrant testing and radiographic inspection) with microbiological contamination levels determined through sanitation testing (NTG and coliform bacteria). Four welding procedures frequently encountered in maintenance interventions were evaluated: oxyacetylene welding, manual metal arc welding (MMA), MAG welding, and TIG welding. Based on severity, occurrence, and detectability parameters, a Hygienic Risk Priority Number (H–RPN) was calculated for each process. The results demonstrate significant differences in hygienic risk levels, enabling the development of a structured engineering decision framework for selecting welding technologies in hygienic applications. The proposed model provides a transferable methodology for risk–oriented evaluation of welded joints in food processing systems

Keywords: hygienic welding, FMEA, food safety engineering, stainless steel pipelines, risk assessment

INTRODUCTION

In modern food processing installations, stainless steel pipelines are essential components responsible for the transport of liquid and semi-liquid food products under controlled hygienic conditions. Unlike conventional industrial piping systems, these installations operate under strict sanitary constraints, where surface integrity and cleanability directly influence microbiological safety and regulatory compliance. Hygienic design principles emphasize smooth, non-porous, and easily cleanable surfaces to prevent product contamination and biofilm development [8,4].

Austenitic stainless steels such as AISI 304 (1.4301) are widely used in food-processing equipment due to their corrosion resistance, passive oxide stability, and compatibility with cleaning-in-place (CIP) systems [8]. However, the hygienic performance of a pipeline is not determined solely by base material properties. Fabrication processes - particularly welding - can locally modify surface morphology and introduce structural discontinuities that compromise cleanability and increase microbial retention risk [1,3].

Surface defects such as porosity, lack of penetration at the weld root, undercuts, excessive reinforcement, and oxidation residues may create micro-crevices that retain organic matter and moisture. These irregularities facilitate microbial adhesion and biofilm formation, phenomena extensively documented in food microbiology research [5,6]. Once established, biofilms significantly reduce the effectiveness of sanitation procedures and may act as persistent contamination sources in food-processing lines.

European regulatory frameworks, including Regulation (EC) No. 1935/2004 on materials intended to come into contact with food and Regulation (EC) No. 2023/2006 on good manufacturing practice, impose strict requirements regarding the safety and suitability of food-contact surfaces. In parallel, the European Hygienic Engineering and Design Group (EHEDG) provides engineering guidelines specifying that welded joints in hygienic equipment must be continuous, smooth, and free from cracks, inclusions, and cavities [4]. Despite these recommendations, maintenance interventions in industrial environments often involve multiple welding technologies applied under time constraints and non-ideal conditions, leading to variable quality levels.

Conventional weld quality evaluation is typically performed according to structural standards such as EN ISO 5817, focusing on mechanical integrity and geometric tolerances. While these criteria ensure structural safety, they do not directly quantify hygienic risk. A welded joint may meet structural acceptance levels yet still present microscopic or geometric features capable of harboring microorganisms. Therefore, there is a need for an integrated evaluation method that combines structural defect characterization with microbiological performance indicators.

Failure Mode and Effects Analysis (FMEA) is a systematic risk assessment methodology originally developed in aerospace engineering and later incorporated into quality and reliability management systems [9,14]. By evaluating Severity, Occurrence, and Detection parameters, FMEA enables prioritization of failure modes through a Risk Priority Number (RPN). Although widely applied in manufacturing processes and safety-critical systems [9], its adaptation to hygienic risk assessment in food-processing equipment - particularly for welded joints - remains insufficiently explored.

The present study addresses this gap by developing an adapted Hygienic-FMEA (HFMEA) framework for the evaluation of welding procedures applied to stainless steel food pipelines. Using experimental data obtained from microbiological sanitation testing and non-destructive examination methods, correlations are established between weld discontinuities and contamination levels. The proposed model generates a Hygienic Risk Priority Number (H-RPN) that enables classification and ranking of welding procedures according to their hygienic risk.

By integrating structural inspection results with microbiological indicators in a structured risk-based methodology, this research contributes a transferable engineering tool for decision-making in fabrication and maintenance activities within food-processing installations.

MATERIALS AND EXPERIMENTAL PROCEDURE

▦ Materials

The experimental study was performed on stainless steel pipes made of grade 1.4301 (AISI 304), a material widely used in food processing installations due to its corrosion resistance and cleanability properties, as reported in hygienic engineering literature [8,5].

AISI 304 is commonly recommended for food-contact applications because of its passive chromium oxide layer and resistance to moderately aggressive cleaning agents [1].

Pipe characteristics:
- External diameter: 40 mm;
- Wall thickness: 1 mm;
- Length of test specimens: 100 mm.

Pipe ends were machined to ensure perpendicularity relative to the longitudinal axis in order to avoid geometric bias unrelated to welding technology.

▦ Welding procedures

Four welding technologies frequently encountered in maintenance interventions in food-processing installations were experimentally evaluated: oxyacetylene flame welding, Manual Metal Arc welding (MMA), Gas Metal Arc Welding (MAG), and Gas Tungsten Arc Welding (TIG/WIG).

All welds were executed in butt-joint configuration on stainless steel pipes (AISI 304 / 1.4301), under conditions representative of typical industrial repair operations. For each welding procedure, ten specimens were produced by certified welders.

a. Oxyacetylene Flame Welding

Oxyacetylene welding was performed using conventional gas equipment based on an oxygen-acetylene mixture. Stainless steel filler wire was used as additional material. Borax was applied to promote oxidation protection during welding;

This procedure reflects traditional maintenance practices still encountered in certain industrial environments, despite limited control of heat input and oxidation compared to modern arc welding processes.

b. Manual Metal Arc Welding (MMA)

Manual Metal Arc welding was performed using an inverter-type welding machine. Stainless steel covered electrodes ESAB OK 61.30 were used, classified according to SFA/AWS A5.4 – E308L-17.

The main parameters were:
- Electrode diameter: 1.6 mm;
- Arc voltage: 48 V;
- Welding current: 60 A.

The MMA process was selected due to its widespread use in field maintenance operations and its operational flexibility.

c. Gas Metal Arc Welding (MAG)

MAG welding was carried out using an ORIGO MAG C201 welding unit with a maximum output of 200 A. Stainless steel filler wire with a diameter of 0.6 mm was employed.

The operating parameters were:
- Arc voltage: 24 V;
- Welding current: 50 A;
- Shielding gas mixture: 82% Argon / 18% CO_2

d. Gas Tungsten Arc Welding (TIG / WIG)

TIG welding was performed using a MAGICWAVE 3000 power source. A non-consumable tungsten electrode was employed, operating with direct current electrode negative (DCEN) polarity. Stainless steel filler wire with a diameter of 0.6 mm was used as additional material.

The main parameters were:
- Arc voltage: 11 V;
- Welding current: 26 A.

TIG welding was included due to its recognized capacity to produce high-quality, low-oxidation welds suitable for hygienic applications [5,10].

All welded specimens were allowed to cool under ambient conditions. No post-weld mechanical polishing or surface finishing operations were applied, in order to preserve the surface morphology generated strictly by each welding technology.

The resulting welded joints were subsequently subjected to microbiological sanitation testing and non-destructive examination, forming the experimental basis for the Hygienic-FMEA risk assessment model.

DEVELOPMENT OF THE HYGIENIC-FMEA MODEL

Rationale for adapting FMEA to hygienic welding assessment

Failure Mode and Effects Analysis (FMEA) is a structured reliability engineering methodology used to identify potential failure modes, evaluate their effects, and prioritize corrective actions through a Risk Priority Number (RPN) [7,9,14]. Traditionally applied in aerospace, automotive, and manufacturing systems, FMEA evaluates risk based on three parameters: Severity (S), Occurrence (O), and Detection (D).

In welded food-processing pipelines, the primary „failure mode" is not structural collapse but hygienic failure - defined as the capacity of a weld discontinuity to promote microbial retention and contamination. Existing welding standards such as EN ISO 5817 focus on geometric and structural acceptability but do not directly quantify hygienic implications [11].

Therefore, an adapted framework - Hygienic-FMEA (HFMEA) - was developed in this study to integrate:

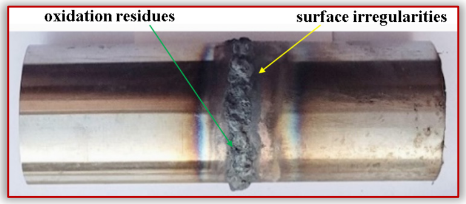
- Structural discontinuities identified by NDT;
- Microbiological contamination levels determined experimentally;
- Detectability of defects during inspection.

The objective is to generate a Hygienic Risk Priority Number (H-RPN) enabling classification of welding technologies according to hygienic risk level.

Definition of Hygienic Failure Modes (HFM)

Based on penetrant testing and radiographic inspection, the following discontinuities were identified across the analyzed welding procedures:

- Surface oxidation and slag inclusions;
- Porosity;
- Lack of penetration at weld root;
- Excess penetration;
- Geometric irregularities and uneven bead profiles.



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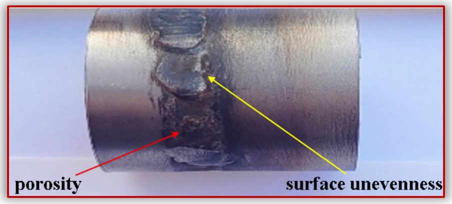

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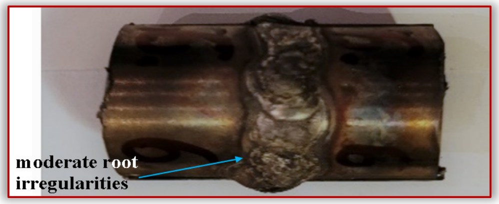

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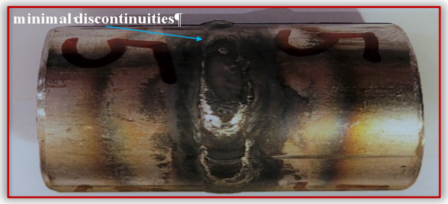

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Figure 1 – Representative weld discontinuities associated with different welding technologies used in hygienic applications [12]
a) Oxyacetylene welding; b) MMA welding; c) – MAG welding d) TIG welding

According to hygienic engineering literature, surface irregularities and crevice-type defects significantly increase microbial adhesion and biofilm formation probability [2,6]. These discontinuities were therefore defined as hygienic failure modes within the HFMEA framework. Each welding technology was characterized by its dominant defect typology.

HFMEA risk parameters

Severity (S)

Severity represents the hygienic impact of a specific discontinuity if contamination occurs. The scoring scale (1-5) was defined considering (table 1):

- crevice formation potential;
- cleanability under CIP conditions;
- biofilm retention probability [2,4,8].

Table 1 – Severity level

Severity level	Hygienic impact description
1	Smooth, continuous surface, minimal retention
2	Minor surface irregularity
3	Moderate geometric irregularity
4	Porosity or localized retention cavities
5	Crevice–type or oxidation–rich defect with high retention potential

Occurrence (O)

Occurrence was quantified using microbiological contamination data (NTG and coliform counts). Contamination ranges were converted into a 1-5 scale in table 2.

Table 2 – Microbiological contamination data ranges

NTG Level (CFU)	Occurrence score
1	Smooth, continuous surface, minimal retention
2	Minor surface irregularity
3	Moderate geometric irregularity
4	Porosity or localized retention cavities
5	Crevice–type or oxidation–rich defect with high retention potential

— Detection (D)

Detection evaluates the probability that a discontinuity is identified before commissioning. It was based on NDT findings as per table 3.

Table 3 – Detection level

Detection Level	Description
1	Easily detectable surface defect (PT)
2	Clearly visible irregularity
3	Detectable by radiography
4	Difficult–to–detect internal defect
5	Microstructural or concealed defect

Detection scoring reflects inspection capability rather than contamination level.

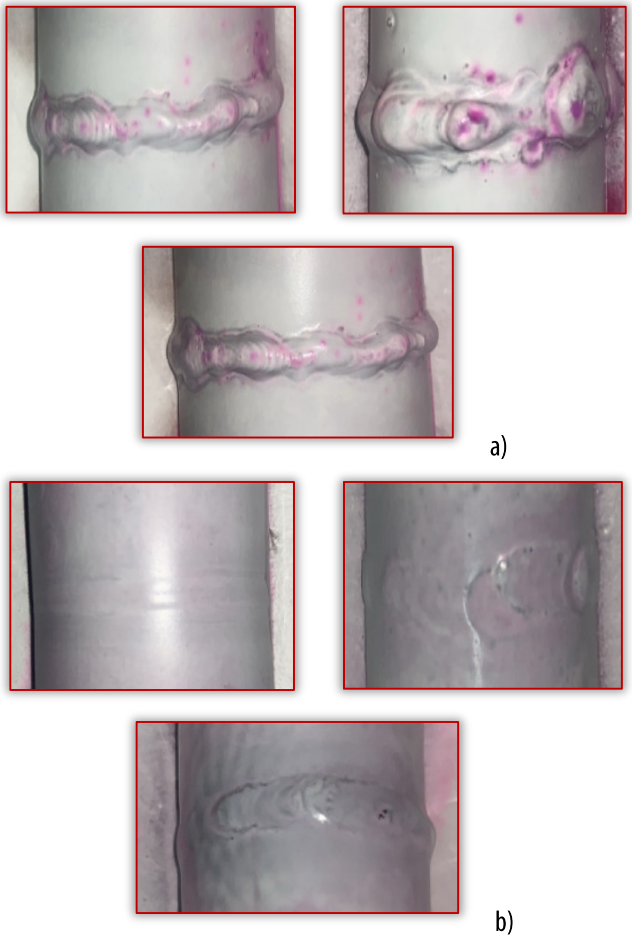
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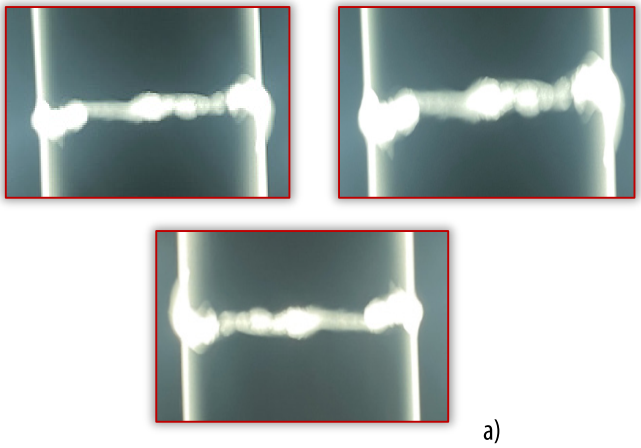
Figure 2. Surface–breaking discontinuities identified by penetrant testing in MAG and TIG welded specimens [12]; a) MAG welding, b) TIG welding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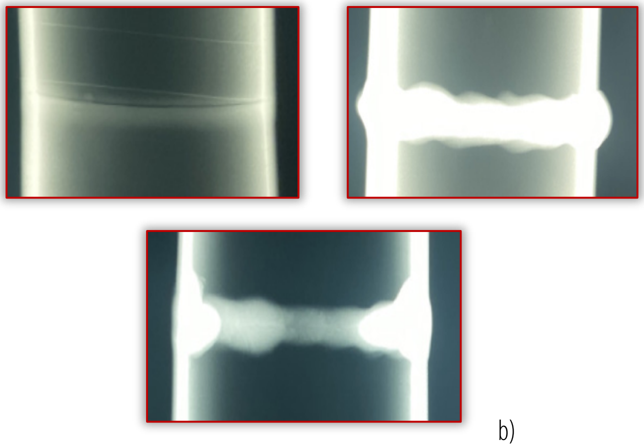
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Figure 3. Internal discontinuities detected by radiographic examination in MAG and TIG welds [12]; a) MAG welding, b) TIG welding

▦ Calculation of Hygienic Risk Priority Number (H-RPN)

The Hygienic Risk Priority Number was calculated as:

$$H - RPN = S \times O \times D$$

where:

- S represents Severity
- O represents Occurrence
- D represents Detection

This approach follows classical FMEA methodology [7,9,14], adapted for hygienic performance assessment.

▦ Application of HFMEA to welding procedures

Based on experimental findings, representative scoring was assigned, according to the data in table 4.

Table 4 – Hygienic Risk Level ranking

Welding process	S	O	D	H–RPN	Hygienic Risk level
Oxyacetylene	5	5	3	75	Critical
MMA	4	4	3	48	High
MAG	3	2	3	18	Moderate
TIG	2	1	2	4	Low

The ranking clearly differentiates the welding technologies according to hygienic risk, correlating structural discontinuity typology with microbiological contamination levels.

The HFMEA results indicate that welding technologies generating oxidation residues, irregular penetration, and surface porosity exhibit significantly higher hygienic risk scores. Conversely, TIG welding demonstrates minimal discontinuities and correspondingly low contamination levels, resulting in the lowest H-RPN value.

Importantly, the model demonstrates that structural compliance alone is insufficient for hygienic validation. Integration of microbiological data is essential for accurate risk prioritization.

The proposed HFMEA framework is transferable and may be applied to other welding interventions in hygienic installations, supporting risk-informed engineering decision-making.

RESULTS AND ENGINEERING DECISION FRAMEWORK

Microbiological Contamination Results

Sanitation testing revealed significant differences in contamination levels among the analyzed welding procedures.

Oxyacetylene welding presented the highest microbiological contamination, with NTG values exceeding 10.000 CFU in several samples and elevated coliform counts. Manual Metal Arc (MMA) welding showed intermediate contamination levels, generally within the 1.000 - 10.000 CFU range.

MAG welding maintained contamination values below 100 CFU, while TIG welding consistently produced results below 10 CFU, indicating minimal microbial retention.

These findings confirm that welding technology significantly influences the hygienic performance of stainless steel joints, consistent with literature linking surface morphology and microbial adhesion [2,6].

Correlation Between Structural Discontinuities and Contamination

Non-destructive examinations identified distinct defect patterns for each welding process:

- Oxyacetylene welding: pronounced oxidation, slag residues, and irregular internal profiles;
- MMA welding: uneven bead geometry and localized porosity;
- MAG welding: moderate root irregularities and internal discontinuities detectable radiographically;
- TIG welding: uniform bead geometry with minimal surface or internal discontinuities.

A qualitative correlation was observed between discontinuity typology and microbiological contamination level. Crevice-type defects and oxidized surfaces corresponded to significantly higher NTG and coliform values. Conversely, smooth, continuous weld profiles exhibited minimal contamination. This relationship supports the validity of integrating defect characterization into a structured hygienic risk model.

Hygienic Risk Ranking

Based on calculated H-RPN values (Section 3.5), welding technologies were classified into four hygienic risk categories according table 5.

Table 5 – Hygienic Risk Classification

H–RPN range	Hygienic Risk classification
> 60	Critical – Not acceptable for food–contact applications
30 – 60	High – Requires corrective measures or restricted use
10 – 30	Moderate – Acceptable under controlled conditions
< 10	Low – Recommended for hygienic applications

Applying this classification:

- Oxyacetylene welding → Critical risk;
- MMA welding → High risk;
- MAG welding → Moderate risk;
- TIG welding → Low risk.

The ranking provides a structured engineering basis for technology selection in food-processing installations.

Engineering decision framework for maintenance interventions

The proposed HFMEA model enables development of a decision-oriented framework for welding process selection.

Step 1 - Identify Application Context

- Direct food-contact surface;
- CIP exposure frequency;
- Hygienic classification of installation (high-care vs. low-risk zone).

Step 2 - Evaluate Welding Procedure Using HFMEA

- Determine dominant discontinuities;
- Assign S, O, D scores;
- Calculate H-RPN.

Step 3 - Apply Risk Acceptance Criteria

- If H-RPN > 60 → Procedure prohibited;
- If 30 < H-RPN ≤ 60 → Corrective action required (e.g., polishing, re-welding);
- If 10 < H-RPN ≤ 30 → Acceptable with monitoring;
- If H-RPN ≤ 10 → Recommended for hygienic pipelines.

This structured approach transforms experimental findings into a transferable engineering tool applicable beyond the specific experimental case.

Model transferability

Although developed using AISI 304 stainless steel pipes, the HFMEA framework is adaptable to:

- other austenitic stainless steel grades;
- orbital welding configurations;
- different pipe diameters;
- additional NDT techniques.

The methodology does not depend on specific numeric contamination values but on the systematic integration of structural defect characterization and microbiological assessment.

Thus, the model provides a generalized hygienic risk evaluation instrument aligned with engineering reliability principles [7,9,14].

DISCUSSION

Integration of structural and microbiological criteria

The results confirm that structural weld conformity alone is insufficient to guarantee hygienic performance in food-processing pipelines. While standards such as EN ISO 5817 classify weld quality based on geometric and internal discontinuities, they do not directly address microbial retention potential.

Previous studies in hygienic engineering demonstrate that surface roughness, crevices, and incomplete penetration zones significantly increase the probability of biofilm formation [2,6]. The present findings are consistent with this body of research: welding procedures that generated oxidation residues, porosity, or irregular penetration exhibited substantially higher NTG and coliform counts.

The HFMEA framework proposed in this study bridges this gap by integrating:

- Defect typology (structural evaluation),
- Microbiological contamination levels (sanitation testing),
- Inspection detectability (NDT capability).

This integrated approach aligns with reliability engineering principles, where failure modes are evaluated not solely by their existence but by their impact and probability of occurrence [7,9,14].

▦ Hygienic implications of welding technology selection

The experimental results demonstrate a clear hygienic hierarchy among the evaluated welding procedures. Oxyacetylene and MMA welding produced the highest Hygienic Risk Priority Numbers due to the combination of severe surface discontinuities and elevated contamination levels.

The presence of oxidation films and uneven internal geometries likely reduced cleanability and promoted microbial adhesion, consistent with hygienic design guidelines [3-5,10].

MAG welding showed improved performance compared to MMA, although internal discontinuities detectable by radiography contributed to a moderate hygienic risk classification.

TIG welding produced the lowest H-RPN values, reflecting uniform bead morphology, minimal discontinuities, and very low contamination counts. This supports recommendations from hygienic engineering practice that TIG welding - particularly when properly controlled - is preferable for food-contact stainless steel joints [3-5,10].

Importantly, the HFMEA model does not simply confirm that TIG welding performs better; it quantifies the hygienic risk difference through structured scoring. This quantification enables objective decision-making rather than reliance on qualitative judgment.

▦ Engineering value of the HFMEA approach

The adapted HFMEA model introduces several engineering advantages:

- Quantification of hygienic risk: Risk is expressed numerically (H-RPN), facilitating comparison between alternative technologies.
- Traceability of decision-making: Each score (S, O, D) is justified by experimental data or inspection findings.
- Transferability: The methodology can be extended to other welding processes, pipe geometries, or stainless steel grades.
- Alignment with preventive maintenance strategies: The model supports risk-informed selection of welding technologies during maintenance interventions.

By adapting FMEA - originally developed for reliability analysis - to hygienic evaluation, the study extends its applicability into food safety engineering [13].

▦ Limitations of the study

Several limitations must be acknowledged:

- The experimental investigation was limited to AISI 304 stainless steel pipes with a specific geometry;
- Surface roughness (Ra) measurements were not performed, which could provide additional quantitative correlation with microbial retention;
- The scoring system, although structured, contains semi-qualitative elements in Severity and Detection assessment;
- Long-term biofilm development under operational conditions was not investigated.

These limitations do not invalidate the model but indicate directions for further refinement and validation. Future studies could incorporate surface profilometry, electro-polishing effects, or extended microbiological monitoring to enhance predictive accuracy.

▦ Practical implications for food industry maintenance

Maintenance operations in food-processing plants are often performed under time constraints and economic pressure. In such contexts, welding procedure selection may prioritize convenience rather than hygienic performance [13].

The HFMEA framework provides a structured tool enabling engineers to justify technological choices based on quantified hygienic risk rather than solely on mechanical adequacy or cost considerations.

By incorporating contamination data into engineering evaluation, the approach strengthens preventive food safety management and aligns maintenance practices with hygienic design principles.

CONCLUSIONS

This study developed and validated an adapted Hygienic Failure Mode and Effects Analysis (HFMEA) model for risk-based evaluation of welding procedures applied to stainless steel pipelines used in food-processing installations.

The integration of microbiological sanitation data with structural defect characterization enabled the quantification of hygienic risk through a Hygienic Risk Priority Number (H-RPN). The results demonstrated that welding technologies generate significantly different hygienic risk levels, even when structural integrity requirements are satisfied.

Oxyacetylene and MMA welding exhibited high to critical hygienic risk values due to pronounced surface irregularities, oxidation residues, and elevated contamination levels. MAG welding presented moderate risk, primarily associated with internal discontinuities. TIG welding achieved the lowest H-RPN scores, reflecting superior surface morphology and minimal microbial retention potential.

The findings confirm that compliance with structural welding standards alone is insufficient to ensure hygienic suitability in food-contact applications. A risk-oriented evaluation framework that incorporates contamination indicators provides a more comprehensive engineering assessment.

The proposed HFMEA model offers:

- A structured methodology for correlating weld discontinuities with microbiological contamination;
- A quantitative ranking tool for welding technology selection;
- A transferable decision-support framework applicable to maintenance and fabrication activities in hygienic installations.

Although the model was developed using AISI 304 stainless steel pipe specimens, its methodological structure allows adaptation to other materials, geometries, and welding configurations.

By introducing a risk-based perspective into hygienic welding evaluation, this study contributes an engineering tool that strengthens preventive food safety strategies and supports informed technological decision-making in food-processing systems.

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