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Towards computer-aided hygienic design: Definition of a knowledge-based system for food processing equipment

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ABSTRACT

Hygienic design requires the definition of rules allowing the correct development of food processing systems. The knowledge collection in this field would certainly help designers and engineers in developing hygienic-compliant systems. This paper aims to provide a knowledge-based (KB) system for gathering hygienic design guidelines for the design of food processing machinery and equipment. The KB system is based on a specific ontology that has been used to collect 78 hygienic design rules from different sources. The rules repository can be considered a backbone for the subsequent development of a CAD-based tool for an automatic search and detection of non-compliant design features. Starting with a CAD model, the KB system was used to check the compliance of a fish stick production machinery. Results highlight how the adoption of the KB system in the early design phase would anticipate hygienic design issues avoiding several design reviews.

1. Introduction

A global trend in the food industry deals with minimal food processing and preservation. Good sanitary/hygienic engineering and design practice is a tool that leads manufacturers in the development of food processing systems able to avoid food contamination by microorganisms, particles, and chemicals (Lelieveld et al., 2014). Sanitary design is a term primarily used in the United States to describe the key elements recommended for food plants and food plants equipment to provide safe processing for human and animal foods (Marriott et al., 2018). Hygienic design is the term used more broadly in Europe to describe the safe construction of food handling and processing equipment (Costa et al., 2013). The two terms may be considered interchangeable, and the term “hygienic design” is commonly used in engineering design. There are many objectives that are covered by the hygienic design approach that allows to prevent batch contamination in machines and equipment used for food processing, to reduce the downtime required for an item of process equipment to be cleaned and drained, and to make specific areas and equipment inspectable and maintainable (Faille et al., 2018; Bénézech et al., 2002). European legislation (i.e., the Machinery Directive Directive 2006/42/EC) is forcing manufacturers of equipment in the European Union to design equipment and machines used in the production of food, pharmaceuticals, and cosmetics according to hygienic design criteria., A variety of directives, codes, guidelines, and recommendations specifying hygienic design requirements and constraints have been published (i.e., EHEDG European Hygienic Engineering & Design Group). All the rules specified in these documents suggest preventing physical, chemical, and microbiological contamination of foodstuffs during storage, handling, processing, and distribution (Pfaff et al., 2011; Jullien et al., 2003). Even if the publication of EHEDG guidelines aims to help designers with applicable knowledge, the systematic collection of hygienic design knowledge and its application in the machine/equipment design process (e.g., EHEDG certification process) is a complex and time-consuming process due to the following reasons: (i) the complexity of design features in components and assemblies adopted in this type of systems, (ii) the large number of components and different materials used in food processing systems, (iii) the difficulties of engineers and designers in consulting several sources (e.g.; handbooks, standards) during the food processing systems development. Thus, the development of hygienically designed equipment appears initially more expensive than similarly performing poorly designed equipment, even if more cost-effective in the long term because reducing or eliminating product recalls, lost production, and possible production site closure, due to contamination arising from poorly designed equipment (Schmidt et al., 2020). In this context, the adoption of smart design tools able to develop hygienic design-compliant systems seems beneficial in the preliminary phases of product design (Pereira Pessôa and Jauregui Becker, 2020; Datta, 2016;

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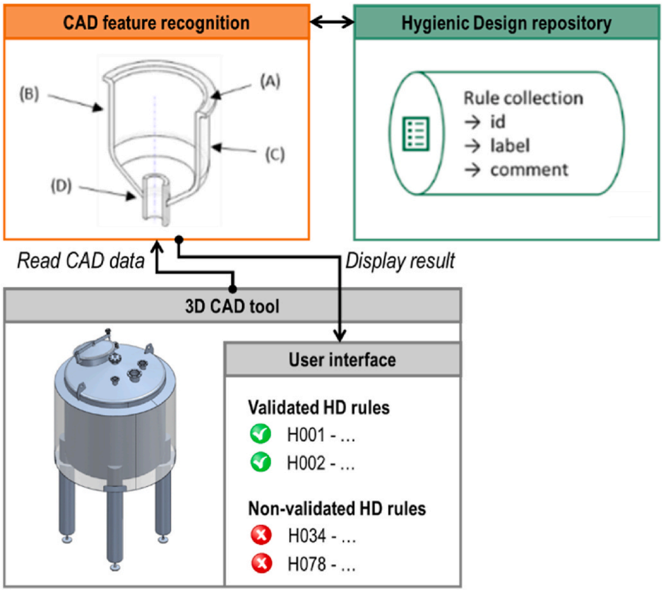


Fig. 1. Schematic representation for hygienic design method in the early design stages of food processing systems.

Amit et al., 2011). Their adoption deals with two main concerns of the engineering design process: the anticipation of manufacturing/assembly/maintenance/lifecycle issues, and the collection/sharing of knowledge. The analysis of the literature shows a few examples of how engineering knowledge can be collected and reused to anticipate manufacturing issues in the early phase of product design (Favi et al., 2022). This is the case of CAD-based tools developed in the context of design for manufacturing and assembly (Jezernik and Hren, 2003; Selvaraj et al., 2009; Campi et al., 2022), design for the environment (Morbidoni et al., 2011; Chen et al., 2017; Tao et al., 2018), and design to cost (Hoque et al., 2013; Mandolini et al., 2020). In the mentioned works, the idea underpinning the adoption of CAD tools is the possibility to read and use design features from CAD models for specific analysis. However, considering that hygienic design principles are used during the development and review of EHEDG-certified devices, the possibility to link this knowledge with geometrical product features and parameters allows for the development of a CAD-based hygienic design tool (virtual prototyping). The objective of this paper is to define a method for the application of hygienic design in the early design stages of food processing systems in accordance with hygienic design criteria and requirements. The novel aspect of the present work is the possibility of creating a structured design framework, that is able to link rules developed in the context of hygienic design with engineering design tools commonly used in the product development process (e.g.; CAD tool). The framework allows to collect tacit knowledge from several sources and to translate this knowledge into explicit and reusable knowledge that can be used during the development of food processing systems. The presented approach is characterized by a method to formalize hygienic design engineering knowledge (ontology-based method) that is used as a structured repository for collecting hygienic design rules. The ontology used to collect this knowledge is mainly based on geometrical data retrieved by the feature analysis of the 3D CAD model (feature recognition approach) as well as technical features defined in this context (materials, type of components, etc.). The overall framework is conceived to quickly address design issues in a virtual environment, and it relies on a solid grasp of the geometry of the machinery. Since some of the basic guidelines are not based on geometrical features and parameters possible limitations are observed in the frame of this work. The method can be considered the backbone for a subsequent development of a CAD-based tool for an automatic search and detection of non-compliant design features in accordance with hygienic design.

2. Material and methods

The application of hygienic design in the early design stages of food processing systems requires design data available from a CAD model. CAD models are developed in the embodiment design phase of the product development process (Pahl et al., 2007) using 3D solid modelling software (generally called CAD tools). CAD tools are widespread in engineering departments aiding the creation, modification, analysis, or optimization of a design. CAD is one part of the whole digital product development activity within the product lifecycle management processes. Far more than geometrical features are stored in a CAD model, including the type of components, materials, assembly, and manufacturing information. The framework of the hygienic design method is presented in Fig. 1. Within the framework, the knowledge-based (KB) system is linked with the CAD tool through a CAD feature recognition system which is querying the CAD model (reading CAD data) to identify features and related parameters. Those features and parameters that are not compliant with the hygienic design rules stored in the KB system (DfH database) are displayed within the CAD model through a dedicated user interface (DfH user interface) that facilitates the identification of features to modify for hygienic design compliances of the CAD model. A KB system is used for the classification of hygienic design rules. The KB system is grounded on three main pillars: (i) knowledge acquisition, (ii) knowledge processing, and (iii) knowledge representation.

2.1. Knowledge acquisition phase

Knowledge acquisition concerns the literature analysis and industry best practices investigation for the collection of hygienic design rules. The knowledge acquisition phase is characterized by two main steps: (i) unstructured collection of design rules for different sources, and (ii) characterization of design features and numerical parameters characterizing a specific design rule. The knowledge acquisition phase starts with the analysis of the literature (e.g.; guidelines, handbook, research papers, standards, technical reports, master, and Ph.D. thesis) related to the hygienic design topic. In many of the analysed sources (e.g., EN 1672-2:2021), hygienic design rules are available as a list of examples with wrong and correct design options, even if this does not apply to most of EHEDG guidelines. In other sources, hygienic design rules are not explicitly stated, and engineering skills and competencies are required to extract design rules. Besides, practical knowledge about hygienic design coming from industries operating in the field of food processing systems, such as machines and equipment, was processed and retrieved with dedicated meetings and interviews. The technical documents investigated for this work were classified, depending on their type, into three classes: (a) handbooks, (b) book chapters and technical manuals, and (c) guideline documents. In particular, the following handbooks belonging to group (a) represented the main sources for collecting the most of the hygienic design rules addressed in this work: (i) Lelieveld et al. (2014) (Lelieveld et al., 2014), (ii) Lelieveld et al. (2016) (Lelieveld et al., 2016), (iii) Holah and Lelieveld (2011), and (iv) Motarjemi and Lelieveld (2013). The book chapters and technical manuals belonging to group (b) were useful in acquiring additional examples for case studies and applications of some hygienic design rules, in particular the following were examined: (i) Moerman and Lorenzen (2017), (ii) Moerman (2017), (iii) Moerman and Kastelein (2014), and (iv) Holah and Campden (2000). Finally, a series of guidelines (EHEDG Doc, 2004a; EHEDG Doc, 2018; EHEDG Doc, 1993; EHEDG Doc, 2007; EHEDG Doc, 2004b; EHEDG Doc, 1997; EHEDG Doc, 2020a; EHEDG Doc, 2020b; EHEDG Doc, 2005; EHEDG Doc, 2006) produced by EHEDG to support the food industry in applying the best practices of the hygienic design were also consulted. The acquisition phase allowed a collection of 78 hygienic design rules as the first scan of all the

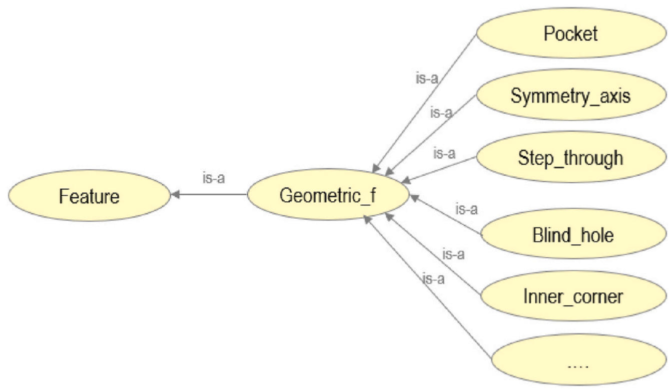


Fig. 2. Example of ontology web language representation for the "geometric_f".

mentioned documents (see Annex 1).

2.2. Knowledge processing phase

Knowledge processing concerns the structure of the hygienic design rules as well as the framework definition for the hygienic design rules repository. This phase requires the use of ontology engineering for the problem conceptualization, reflecting assumptions and requirements made in the problem-solving using the knowledge base. The developed ontology-based system allows translating a checklist (hygienic design rules list) coming from the previous step into a structured set of rules that are characterized by specific CAD features, mathematical equations, and thresholds for their verification. The selected ontology for this research work is based on two domains, each one aiming at labelling and organizing a specific attribute of the product/CAD model within a cluster of available options. The first domain is related to CAD features, and it catalogues them according to several logics, depending on the role played by the feature under investigation within the hygienic design rule to implement. In detail, a CAD feature can be considered, among the others (Favi et al., 2022), as: (i) geometric feature (geometric_f)), (ii) assembly feature (assembly_f), (iii) component feature (component_f), and (iv) functional feature (functional_f). The classification of the geometric features is preliminary to the application of hygienic design rules dealing with the shape of the CAD features as resulting from their manufacturing, e.g., hole, fillet, chamfer, edge. Fig. 2 describes the ontology domain related to the geometric features, under the form of an OWL (Ontology Web Language) graph. The assembly features instead are distinguished according to the relationship created between two (or more) features with the aim of connecting two or more parts. The proposed ontology involves two levels for this clustering: (i) type of connection (e.g., permanent or non-permanent joint), and (ii) specific feature of the connection (e.g., screw thread, pins -among the features belonging to the not-permanent joints type- or welding -among the features belonging to the permanent joint type). Fig. 3 describes the ontology domain related to the assembly features in the OWL form. The classification based on component features distinguishes the CAD features according to their belonging to standard components (e.g., bearing, pump, shaft, O-ring), usually recognizable by the part name or by a distinctive code (Staub-French et al., 2003). Fig. 4 describes the ontology domain related to the assembly features in the OWL form. Finally, the classification of the functional features is addressed based on the function of the analysed features in the part or in the assembly (e.g., fastener hole, reinforcement rib). In this work, the functional role used to cluster the CAD features is related to the state of the surface to which they belong, therefore in this specific case they are referred to as surface features. As shown in Fig. 5 (ontology domain related to the assembly features in OWL form), three possible options are given: (i) food contact surfaces, i.e.: surface in contact with food during the process, (ii) splash areas, i.e.: surfaces potentially meet food, and (iii) non-food contact surfaces, i.e.: surfaces never in contact with food during the process. Table 1 highlights the four different models of feature recognition used at the basis of the proposed ontology, considering a bolted joint (screw and support). In the first example (Table 1–a), the outer edges and faces of the screw are identified as geometrical feature, while, in the second example (Table 1–b), the screw that interact with the plate are an assembly feature. The screw itself (Table 1–c) is classified as a component feature (either according to the name/code of the part) and, finally, through a manual user selection indicating food contact surfaces the head of the screw is classified as functional feature (Table 1–d).

The second domain of the proposed ontology is used to classify the materials of the product represented through the CAD model. According to Ashby (2010), two clusters are needed for a complete definition of the material: (i) material class (e.g.; metallic or polymeric), (ii) material family (e.g.; stainless steel, aluminium alloy). Whenever is required, an additional level to further specify the type of material (e.g.; AISI 304, AISI 316 within the stainless steel material family) can be added to include also specific guidelines available from the scientific literature or

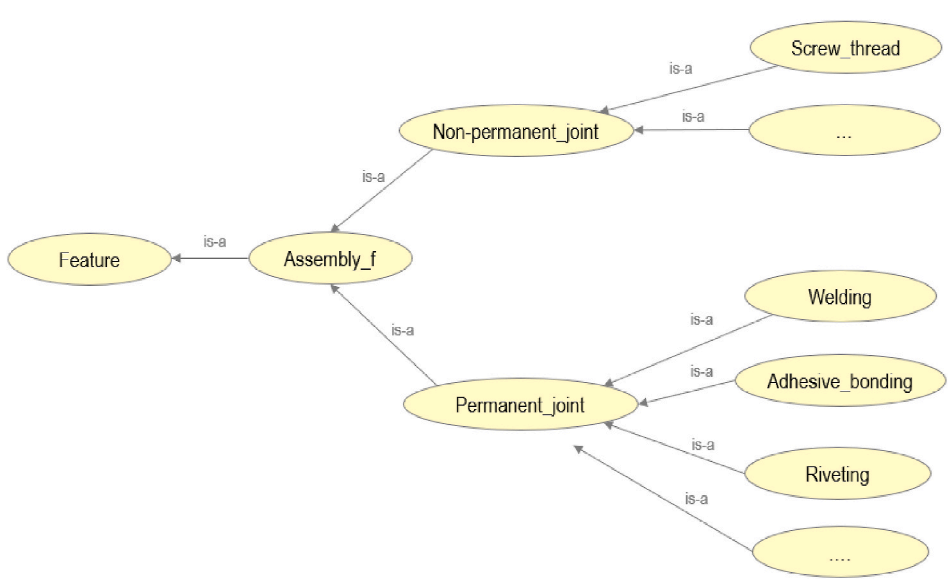


Fig. 3. Example of ontology web language representation for the "assembly_f".

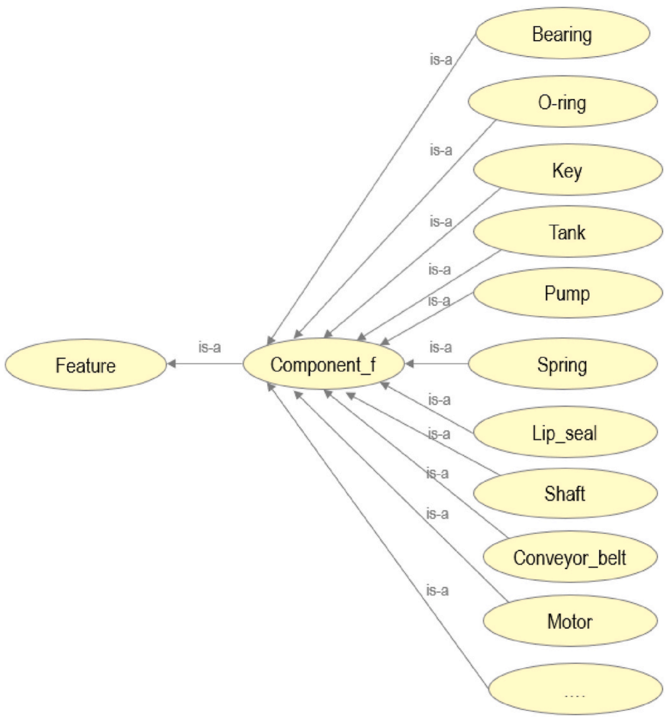


Fig. 4. Example of ontology web language representation for the "component_f".

industrial good practices. Fig. 6 displays the ontology representation for the materials.

In addition to these clusters, other data are mandatory to completely define the presented ontology: (i) the numerical parameter (value) associated with the feature to be recognized, (ii) the syntax used to describe the rule, and (iii) the type of rule. The numerical parameter is usually a dimension or a quantifiable entity whose actual value shall be acquired during the feature recognition phase, and which is crucial for the verification of the rule. With reference to syntax, a rule can be expressed by means of language or in a mathematical form. While the former allows exposing the rule by means of a sentence, the latter consists typically of an equation representing a numerical threshold, consisting of a single value or an allowed range of values, for the numerical parameter. The type of rule is an attribute used to rank and to differentiate the hygienic design rules according to their importance. Three levels of importance, as displayed in Fig. 7, are considered for the hygienic design rules: (i) information, (ii) warning, and (iii) critical. This rating system for the hygienic design is defined following available models from engineering literature and setting appropriate criteria (Guangquan et al., 2021). In this case, the criterium used to define this 3-point scale is the probability of generating a hygienic risk on the product. Indeed, the rules belonging to the information level are best practices in hygienic design with a low probability to generate hygienic hazards on the product, that can happen in specific situations. The warnings are correlated to situations which very likely could generate a hygienic hazard in standard working conditions. Finally, the critical rules are the ones whose violation leads to a surely hygienic hazard on the product. Fig. 8 displays by means of a flow chart the working algorithm which the knowledge-based system exploits to verify every rule collected within its inner database. Two examples are reported hereafter to better clarify how the described ontology is used to translate the hygienic design checklist collected during the knowledge acquisition phase to structured actions to perform on a specific parameter belonging to a specific feature recognized in the CAD model. In the first example, a rule acquired from (EHEDG Doc, 2004b) is considered, stating that "to avoid crevices, by metal-to-metal contact, the welded seams must not be intermittent but continuous". Fig. 9 presents the graphical representation of this rule (what to do and what to avoid), and Table 2 displays the methodological steps of the knowledge-based system.

In the second example, the correct O-ring static seal mounting according to hygienic design requirements is considered in Fig. 10, as described in (EHEDG Doc, 2020a). The rule suggests putting the static seal as close as possible to the food contact area, to avoid the formation of crevices by metal-to-metal contact. Table 3 provides the needed details and the locations where the knowledge-system can find them.

2.3. *Knowledge representation phase*

Knowledge representation concerns the way hygienic design knowledge is shared and presented to the user. The rules derived from the acquisition phase and structured according to the selected ontology are then ordered within a database and labelled with a code, consisting of "Hxxx", where "H" is for "hygienic" and "xxx" are three digits used as a serial number to unambiguously identify every rule within the database which collect them all. Then, the syntax definition of hygienic design rules and all the necessary information to include within the repository, such as pictures about the correct/wrong design, are generated. The syntax definition is performed by keeping the consistency among different rules and providing the same level of details and information for the user. The syntax included necessary/mandatory information and optional information. Necessary/mandatory information

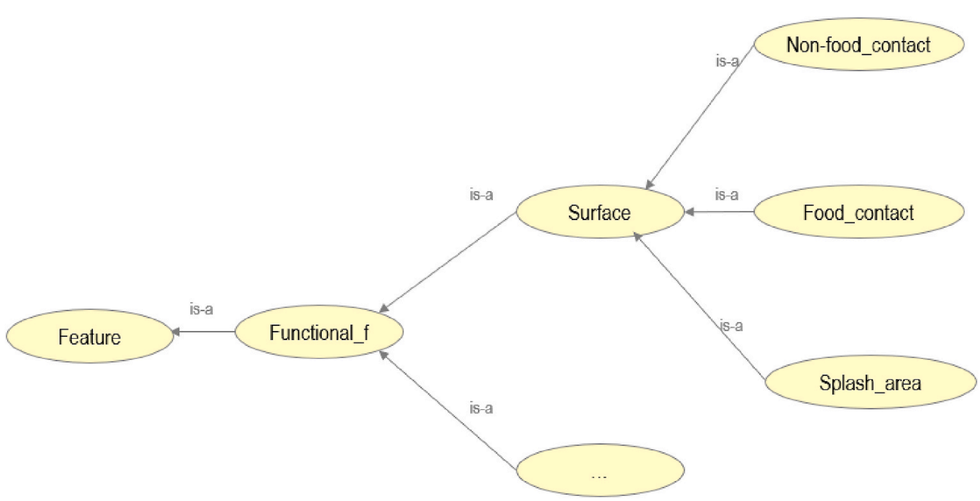
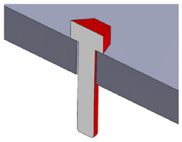
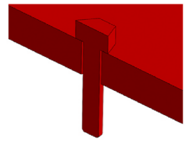
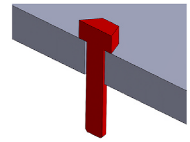
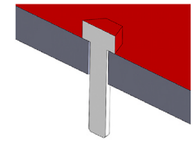


Fig. 5. Example of ontology web language representation for the "functional_f".

Table 1
Examples of recognition of several CAD features on a screw employed within a bolted connection according to the classification of levels within the developed ontology.

Ontology levels	geometrical_f	assembly_f	component_f	functional_f
Example	A 	B 	C 	D 
Description	Geometric feaure: • surfaces that generate sharp edges. • Sharp edges	Assembly feature: • type of connection: non-permanent joint, • specific feature of the connection: screw thread	Component feature: • standard component: screw	Functional feature: • food contact surfaces: yes

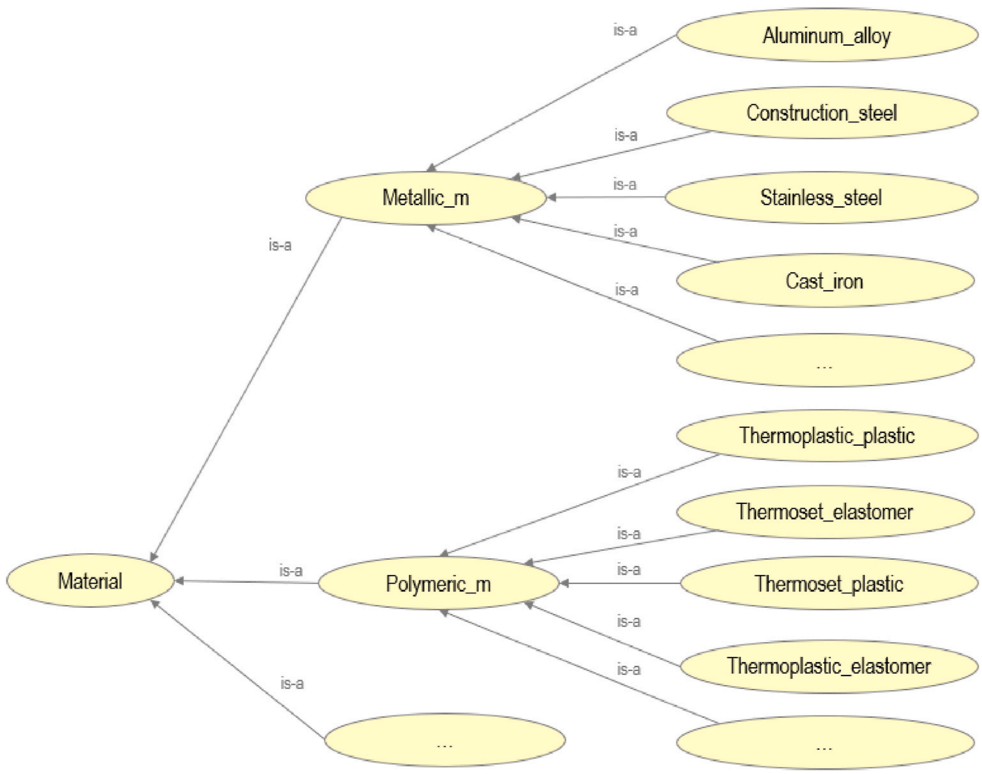


Fig. 6. Example of ontology web language representation for the "material".

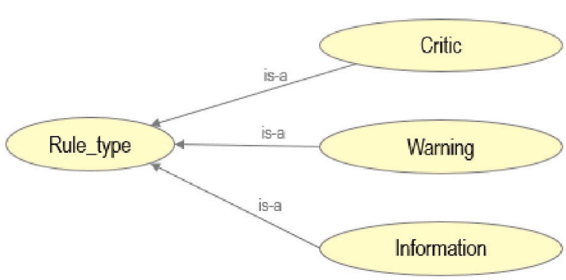


Fig. 7. Example of ontology web language representation for the "rule type".

is providing the minimum set of knowledge to perform a design improvement. Necessary/mandatory information consists of the design action to do (verb), and the subject which requires modification (name). Optional information gives additional data that allow clarifying the context of the required design action. This consists for example in the features of the subject (e.g., shape, dimensions, orientation, position) which affect the verification of the rule, the location where the rule has to be satisfied (e.g., on food contact surfaces), boundary conditions related to the need to verify the rule. Even the type of the rule has to be reported (i.e.: information, warning, or critical) in order to make the designer aware of the potential consequences which neglecting the application of the rule can lead to. For instance, the first example reported in section 2.2 would result in the following printed output for the designer:

- *Rule ID:* H016
- *Verb:* Avoid
- *Subject:* intermittent weld seams
- *Optional information:* on food contact surfaces

Some additional details to better explain the reasons which justify the application of the rule can also be provided, together with a tip about how to solve the problem and re-design the feature under investigation

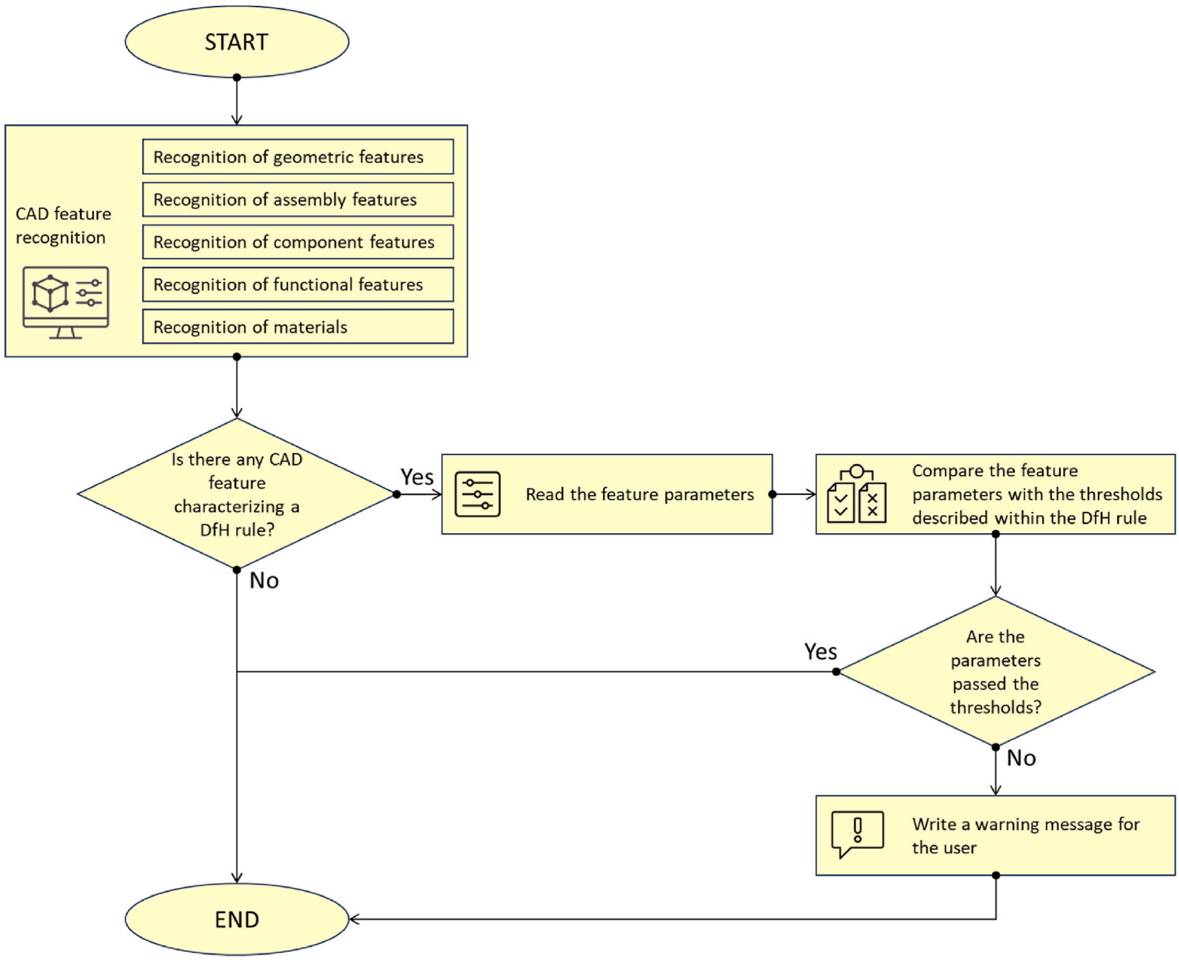


Fig. 8. Flow chart of visualization for the algorithm which the knowledge-based system applies for verifying each rule.

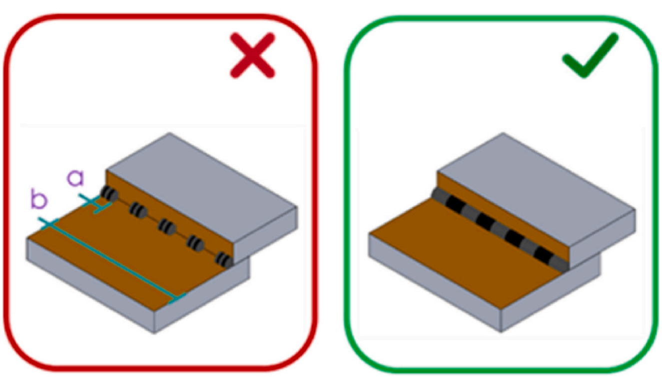


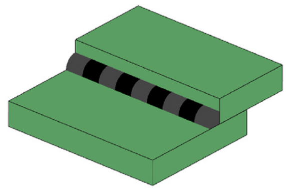
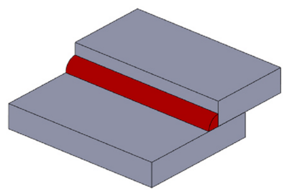
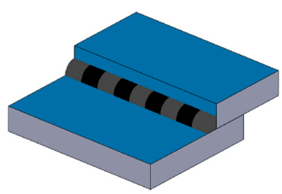
Fig. 9. Welded joints: non-hygienic (on the left) vs. hygienic (on the right) solutions.

which does not satisfy the rule. Two additional information are provided: (i) the suggested installation procedure need to avoid possible contamination, and (ii) the cleaning procedure to be followed to address the correspondent issue. The description of the installation procedure, if the issue involves some assembly features, provides information, in broad outlines, about the sequence of actions to be performed in order to assembly groups of components together in order to avoid the possible generation of hidden areas or dead spaces, where microorganisms can survive and grow. On the other hand, when the issue identified by the hygienic design rule could be solved with a proper and periodic cleaning procedure or a periodic cleaning procedure is mandatory for a given design, this has to be briefly illustrated to the user. Finally, a picture illustrating the problem, with a comparison between a non-hygienic solution and a hygienic one, can help the designer in properly understand how to address the issue.

3. Case study

In this section, part of the equipment that composes a complex food processing system (fish stick production) is analysed to test the proposed approach and to clarify the potential benefits introduced by the anticipation of hygienic design issues. The CAD model representation and details for this equipment are reported in Fig. 11. The features of the 3D CAD model were manually investigated in compliance with the hygienic design repository previously described. Among the 78 hygienic design rules defined with the described ontology (see Annex 1), the analysis of the CAD model highlights how seven features do not respect the rules stored in the databases. Not-compliant features refer to the H001 (Avoid the use of sharp edges in food contact surfaces), H022 (Avoid the over-dimensioning of the O-ring housing), H023 (Select the proper material for the O-ring), H039 (Avoid the use of horizontal pipes or with a slope less than 3°), H063 (Avoid residual teeth and undercuts), H067 (Avoid the use of screws and threaded elements to connect a shaft and relative hub), and H078 (Avoid flange and pipe fitting with different diameters). For the sake of brevity, only three of these rules are described in detail. The first one is the H067 – Avoid the use of screws and threaded elements to connect a shaft and relative hub. This rule describes how sharp edges of threaded components are difficult to clean and to sanitize. The

Table 2
Example of application of the knowledge-based system on the issue displayed in Fig. 9

Geometrical features	Two overlapped plates (highlighted in light green)	
Assembly features	Level 1: permanent joint Level 2: welding (highlighted in red)	
Component features	Not required	–
Functional features	Food contact surfaces (highlighted in light blue)	
Materials	Level 1: metallic Level 2: not required	–
Numerical parameters	"a": length of the weld seam "b": length (in the same direction of the weld seam) of the sheet to weld	See Fig. 9
Mathematical equation	a/b < 1	–
Type of rule	Critical	–

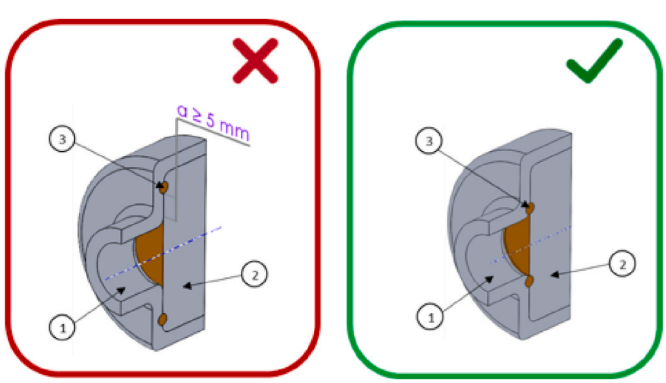
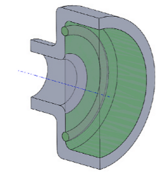
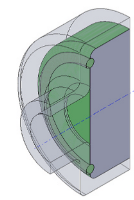
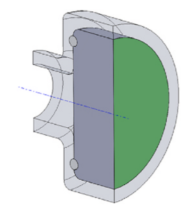
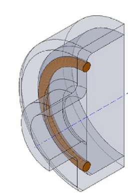
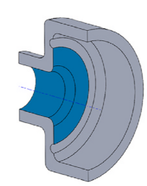
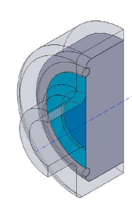


Fig. 10. O-ring static seal mounting: non-hygienic (on the left) vs. hygienic solution (on the right).

feature recognition system identified as "assembly_f" the "screw_tread", the "shaft", and the "hub" while as "functional_f" the "food_contact" state of the surface. In the case of this rule, no geometrical features and

Table 3
Example of application of the knowledge-based system on the issue displayed in Fig. 10

Geometrical features	(1) surface of the first element in contact with the second element (highlighted in light green);	
	(2) surface of the second element in contact with the first element (highlighted in light green);	
	(3) surface of the second element not in contact with the first element	
Assembly features	Not required	–
Component features	Static seal (O-ring) (highlighted in brown)	
Functional features	Food contact surfaces (highlighted in light blue)	 

(continued on next page)

Table 3 (*continued*)

Materials	Level 1: metallic Level 2: not required	–
Numerical parameters	"a": minimum distance between the O-ring and the contact point between element 1 and element 2 closest to the food contact surface	See Fig. 10
Mathematical equation	a ≥5 mm	–
Type of rule	Warning	–

equations needs to be checked and simply changing the method of assembly (e.g., using an adhesive joint or a shaft with a key and sealing solutions) makes the design compliant with the hygienic design rules, avoiding design reviews, and anticipating issues during product use. Fig. 12 highlights in orange the not-compliant features recognized from the 3D CAD model and the description of the hygienic design rule including possible suggestions. The second one is the H039 – Avoid the use of horizontal pipes or with a slope less than 3°. This rule is necessary to avoid fluid retention/stagnation in piping that is used to move the food from one part to another of the system. The feature recognition system identified as "component_f" the "pipe", as "geometric_f" the "axis" of the pipe, and the "base plane" (which is the floor surface oriented as perpendicular to the gravity vector), while as "functional_f" the "food_contact" state of the surface. In this case, the equation used to verify this rule is that the angle between the axis of the pipe and the floor surface (α) is lower than 3° ($\alpha < 3°$). The original design shows that α is zero degrees and thus the design does not respect the specific hygienic design rule. A possible solution could be to modify the pipe geometry and avoid horizontal pipes in reference to the floor surface. Fig. 13 highlights in orange the not-compliant features recognized from the 3D CAD model and the description of the hygienic design rule including possible suggestions. The third one is the H078 – Avoid flange and pipe fitting with different diameters. This rule describes how a flange characterized by two pipes with different diameters can cause a microbiological risk area. The feature recognition system identified as

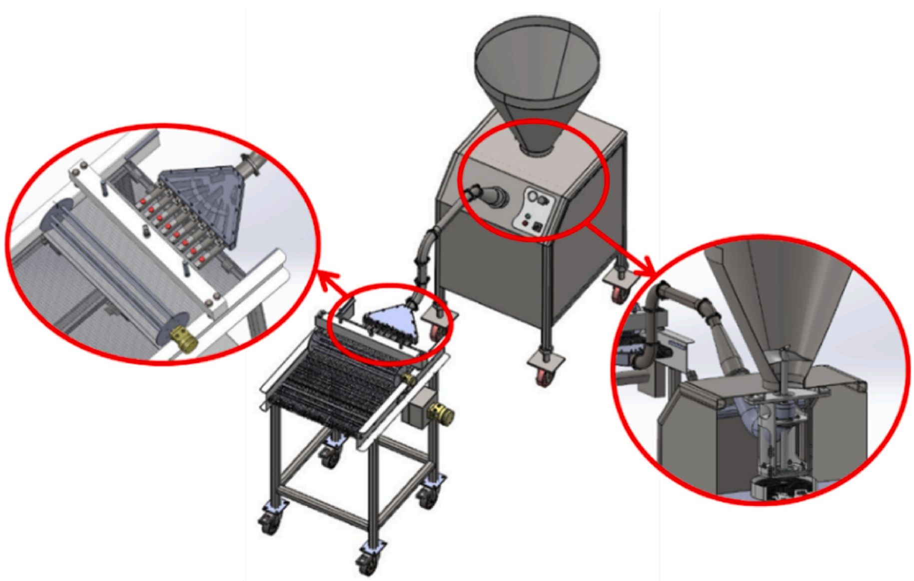


Fig. 11. 3D CAD model of the fish stick processing system.

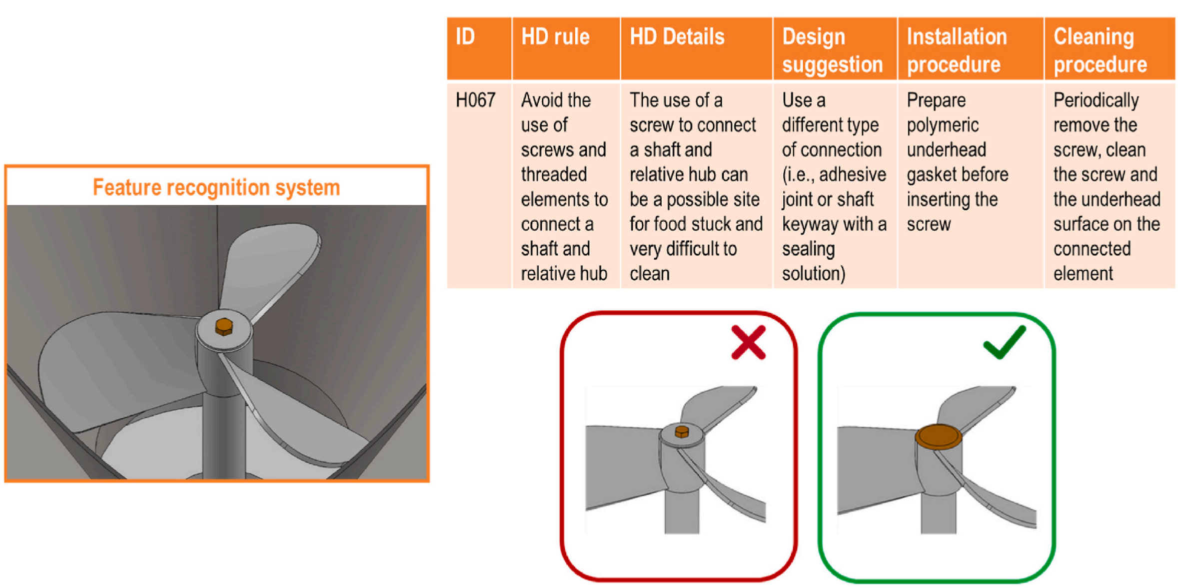
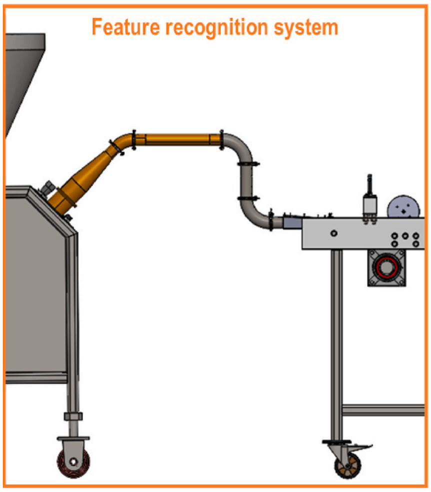


Fig. 12. Non-compliant features for H067 and description of the hygienic design rule.



ID	HD rule	HD Details	Design suggestion	Installation procedure	Cleaning procedure
H039	Avoid the use of horizontal pipes or with a slope less than 3 degree	The use of horizontal pipes may cause fluid retention/stagnation	Make pipes non horizontal or use a valve for fluid evacuation	--	Cleaning In Place (CIP), or equipment by means of fast collar clamps following by Cleaning Out of Place (COP)

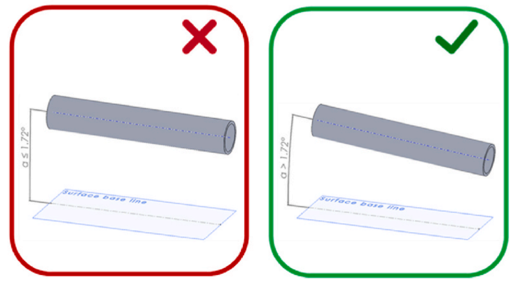
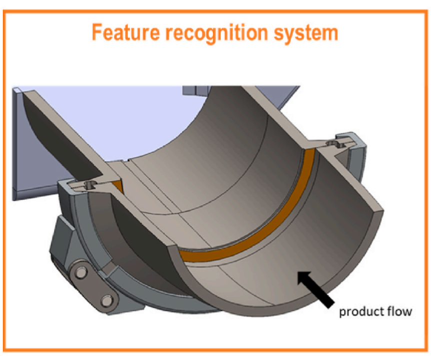


Fig. 13. Non-compliant features for H039 and description of the hygienic design rule.



ID	HD rule	HD Details	Design suggestion	Installation procedure	Cleaning procedure
H078	Avoid flange and pipe fitting with different diameters	The pipe fitting with different pipe diameters can create a possible site for food stuck and very difficult to clean	Use the same diameter for the pipes connected by a flange or make the flange accessible	Assembly the two flanged elements together with bolts and providing for the presence of a gasket between them	Cleaning In Place (CIP) (direction of flow identical to that of the product) , or disassembly of the two elements following by Cleaning Out of Place (COP)

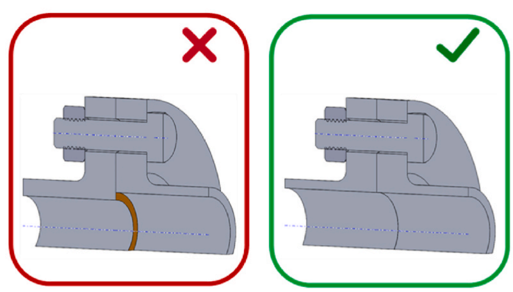


Fig. 14. Non-compliant features for H039 and description of the hygienic design rule.

"component_f" the "pipe" (both pipe_1 and pipe_2), as "geometric_f" the "axis" of the pipe, and the "inner_diameter" (both pipe_1 and pipe_2), while as "functional_f" the "food_contact" state of the surface. In this case, the equation used to verify this rule is $D1 = D2$, where D1 is the inner_diameter of the pipe_1 and D2 is the inner_diameter of the pipe_2. The original design shows that $D1 \neq D2$ thus creates a niche (crevice) where food can be stuck for a long time making difficult the cleaning and the sanification process. To avoid this hygienic issue the same diameter shall be used for both pipes. Fig. 14 highlights in orange the not-compliant features recognized from the 3D CAD model and the description of the hygienic design rule including possible suggestions. Again, the adoption of fast collar clamps makes the piping system easy to disassemble for cleaning operations. Even if with this solution the equipment is compliant with hygienic requirements, it requires additional operations during product use which could be avoided by using the same diameters for the two pipes.

4. Results and discussion

Table 4 provides a summary of the number of the identified rules, distinguished according to the rule type and the ontology parameter, among the adopted ones. In particular, a set of 78 rules was identified (see Annex 1). Among the full list of rules, 39 were classified as critical, 24 as warning and 15 as info. Considering the feature recognition domain defined within the ontology, it is worth highlighting that most of the design rules require a feature recognition based on component feature (component_f), followed by geometric feature (geometric_f)), and finally assembly feature (assembly_f), respectively 51, 39, and 24 rules. In addition, considering functional feature (functional_f), 75 of 78 rules refer to surface features, in particular 58 to food contact surfaces (i.e.: surfaces in contact with food during the process), 14 to splash areas (i.e.: surfaces potentially meet food), while only 3 to non-food contact surfaces (i.e.: surfaces not in contact with food during the process). On

Table 4
Number of rules found distinguished according to the rule type and the ontology parameter.

	N° OF RULES	Tot.	Ontology parameter				
			geometric_f	assembly_f	component_f	functional_f	Material
Rule type	Critical	39	20	14	22	36	18
	Warning	24	13	6	19	24	12
	Information	15	6	4	10	15	9
	TOTAL	78	39	24	51	75	39

the other hand, considering the material domain, 39 rules are driven by the type of material used in the design of equipment used in food processing. Following a manual feature recognition system from a CAD model and the use of the proposed database, the testing phase shows the system is capable to identify several design issues in complex food processing equipment. This advantage leads engineers and designers to a quick design review in a virtual environment, avoiding time-consuming and costly activities dedicated to the manufacturing of physical prototypes. The proposed tool can also be coupled with a computational fluid dynamics simulation tool to provide a complete computer-aided engineering suite for the development of food processing systems.

5. Conclusions

With the adoption of the proposed CAD-based hygienic design method, a set of 78 rules were established for the correct development of food processing systems and equipment. Based on the classified rules (explicit knowledge) the main result obtained by the adoption of this method is the possibility to couple these rules with geometrical features retrieved by the analysis of the 3D CAD model. The feature recognition method was used as a means to carry this knowledge and make it available during the design phase. The identification of non-compliant features is beneficial for a real-time modification of the component during its development. This result is significant compared to the state-of-the-art tools that are applied downstream of the 3D modelling and design. The proposed ontology was able to collect the knowledge referring to the hygienic design topic and it can be used for future development of new rules. The rules collection cannot be considered completed with this work since it is a continuous activity that evolves over time. The same approach can also be used to formalize internal knowledge or tacit knowledge retrieved by food processing companies that are using the food processing systems daily. In this way a large quantity of information can be formalized through the adoption of the defined ontology and used to share it with new engineers and to create a structured repository for store and enlarge company knowledge that is manufacturing machines and equipment for food processing. Moreover, the use of this type of hygienic design rules, integrated with other target design methodologies (e.g., Design for Assembly, Design for Manufacturing) will aid designers and engineers in the correct development of food systems early in the design phase reducing the use of recursive design reviews and iterations. The application of the presented method will lead to a cost reduction not only before the system delivery but also considering the life cycle, reducing the maintenance operations necessary for cleaning and sanitization of the machine/equipment.

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CRediT authorship contribution statement

Francesco Musiari: Writing – original draft, Writing – review & editing, Investigation, Validation. **Fabrizio Moroni:** Formal analysis, Investigation, Resources, Writing – review & editing. **Alessandro Pirondi:** Funding acquisition, Conceptualization, Supervision, Writing – review & editing. **Claudio Favi:** Methodology, Validation, Data curation, Writing – original draft.

Declaration of competing interest

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Data availability

No data was used for the research described in the article.

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Annex 1

Table A1
Database of hygienic design rules collected during the knowledge acquisition step

ID	HD Rule	Type of rule (C = critical, W = warning, I = information)
H001	Avoid the use of sharp edges in food contact surfaces	C
H002	Avoid tight radius of curvature (R) (R < 6 mm) on surfaces in contact with the product.	W
H003	Avoid acute angles (α < 90°) on surfaces in contact with the product.	C

(*continued on next page*)

Table A1 (*continued*)

ID	HD Rule	Type of rule (C = critical, W = warning, I = information)
H004	Avoid butt welding to connect two surfaces forming a corner	C
H005	Avoid welding made close to the bend (L = 0 ± 3 mm) on the part made by bending.	W
H006	Avoid unsuitable arithmetic roughness values (Ra >0.8 μm) in product contact surfaces.	W
H007	Choose materials suitable for coming in contact with the product.	I
H008	Avoid gaps between two surfaces to be joined in the area in contact with the product (L = 0).	C
H009	Avoid non-permanent connections in the area in contact with the product unless periodic disassembly is planned on site.	I
H010	Avoid direct metal-to-metal joints.	C
H011	Avoid nailed connections in the area in contact with the product.	C
H012	Avoid glued connections in the area in contact with the product.	C
H013	Avoid direct product/spring contact.	C
H014	Avoid direct product/thread contact.	C
H015	Avoid cavities, protruding edges or gaps (a) between two parts in contact with the product (a >0).	C
H016	Avoid intermittent weld seams on food contact surfaces.	C
H017	Avoid improperly finished weld seams.	W
H018	If possible, avoid angle welding connection between two overlapping sheets.	I
H019	Avoid welding pipes with different diameters (D1 ≠ D2).	C
H020	Avoid radial misalignment in axisymmetric elements to be welded.	C
H021	Avoid radial misalignment in axisymmetric elements to be connected.	C
H022	Avoid the over-dimensioning of the O-ring housing	W
H023	Select the proper material for the O-ring	I
H024	Prevent the distance (L) between the clamping element and the end of the innermost tube from being too high (L ≥ 2 mm).	C
H025	Avoid positioning the O-ring between two product contact elements at an excessive distance (a) from the product area (a ≥5 mm)	W
H026	If possible, avoid direct contact of the product with screw or nut heads.	W
H027	If possible, avoid conventional anti-unscrewing devices in areas in contact with the product.	W
H028	Avoid countersunk screws in areas in contact with the product.	C
H029	Avoid screws with inserts in areas in contact with the product.	C
H030	Avoid the presence of undrainable areas (H ≥ D/2).	C
H031	Avoid insufficiently drainable vessel bottoms (α < 3°).	W
H032	Avoid the presence of undrainable areas (H > 0).	C
H033	Avoid shaded areas in the vessel near the nozzles (L/D > 2).	C
H034	Avoid nozzles perpendicular to the side surface of the vessel (α < 5°).	C
H035	Prevent the probe housing in the nozzle from being an area of microbial proliferation.	I
H036	Prevent the sealing element on the probe from being too far from the product contact zone (a >0 ± 3 mm)	W
H037	Prevent the lid from forming an area that is difficult to clean.	W
H038	Avoid lids with flat or concave outer surfaces.	W
H039	Avoid the use of horizontal pipes or with a slope less than 3°	C
H040	Avoid elbows or deflections on horizontal pipes that impair their drainage.	C
H041	Avoid connections between two pipes of different diameters that make drainage impossible/difficult.	C
H042	Pay attention to the length (L) of the eccentric connection between two pipes.	I
H043	Avoid T-sections having length (L) greater than diameter (D) (L/D > 1).	C
H044	Avoid designing the T-section by neglecting the characteristics and velocity of the fluid that will flow through it.	I
H045	Choose the T-section configuration according to the rheology of the fluid being moved.	I
H046	Avoid swept-tees having length (L) greater than diameter (D) (L/D > 1).	C
H047	Avoid swept-tees on horizontal pipes.	W
H048	Avoid using centrifugal pumps that tend to stagnate fluid or are not self-draining.	W
H049	Avoid centrifugal pumps that limit venting at start-up.	I
H050	Avoid lobe pumps with a horizontal suction/delivery axis.	W
H051	Avoid mechanical drive systems inside the product area.	W
H052	Avoid mechanical drive systems inside the product area without appropriate guards.	C
H053	Avoid motors with fins in the area of potential contact with the product.	C
H054	Avoid dynamic shaft-recipient connection in the product area if possible.	W
H055	Avoid dead spaces, threads, slits and sharp edges in food agitators.	I
H056	Avoid too high values of the axial length (L) of the seal on the side in contact with the product (L/D > 0.1).	C
H057	Avoid too small values of the radial gap (h) between seal and shaft (h/D < 0.16).	C
H058	Avoid traditional dynamic seals on aseptic systems.	I
H059	If possible, avoid bearings within the area in contact with the product.	W
H060	Avoid bearings with single dynamic seal on vertical shafts.	W
H061	If possible, avoid tabs/keys in areas in direct contact with the product.	W
H062	Avoid tabs/tabs with very tight edge radius of curvature (R) (R < 3 mm).	C
H063	Avoid residual teeth and undercuts	C
H064	Avoid direct metal-to-metal contact between elements in the shaft-hub-cap connection	W
H065	Avoid traditional threaded connections to connect two shafts in aseptic applications.	I
H066	Avoid hollow rollers on belt/roller conveyor systems.	W
H067	Avoid the use of screws and threaded elements to connect a shaft and relative hub	C
H068	Avoid mounting the bearing near the product contact area without appropriate protection.	W
H069	Avoid metal/plastic joints between two conveyor belts.	I
H070	Avoid positioning the motor near the conveyor/roller belt without means of protection.	I
H071	Avoid the use of buttons with non-hygienic design.	I
H072	Avoid placement of plants at a too low height (h) above the ground (h < 300 mm).	C
H073	Avoid placing two adjacent implants at a too small distance (s) (s < 1000 mm).	C
H074	Avoid the design of casters (of D > 100 mm) with a too small distance (s) from the frame (s < 10 mm).	C
H075	Avoid the design of casters (of D ≤ 100 mm) with a too small distance (s) from the frame (s < 6 mm).	C

(*continued on next page*)

Table A1 (*continued*)

ID	HD Rule	Type of rule (C = critical, W = warning, I = information)
H076	Avoid direct metal-to-metal joints in threaded connections in product contact areas.	C
H077	Avoid drawing surfaces that might constitute shaded areas or difficult to sanitize (ΔR > 0) with classical CIP methods.	W
H078	Avoid flange and pipe fitting with different diameters	C

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