Industrievereinigung für Lebensmitteltechnologie und Verpackung e.V.

MERKBLATT
No. 120 / 2022
Hygienic Design Confectionary Machines

IVLV Working Group: Confectionary Machines

Guideline for the evaluation of the hygienic design of confectionery machines

Gefördert durch:
Bundesministerium für Wirtschaft und Klimaschutz
aufgrund eines Beschlusses des Deutschen Bundestages

AiF Mitglied

This guide consists of three parts

Part 1: Introduction

Part 2: Checklists to clarify the task

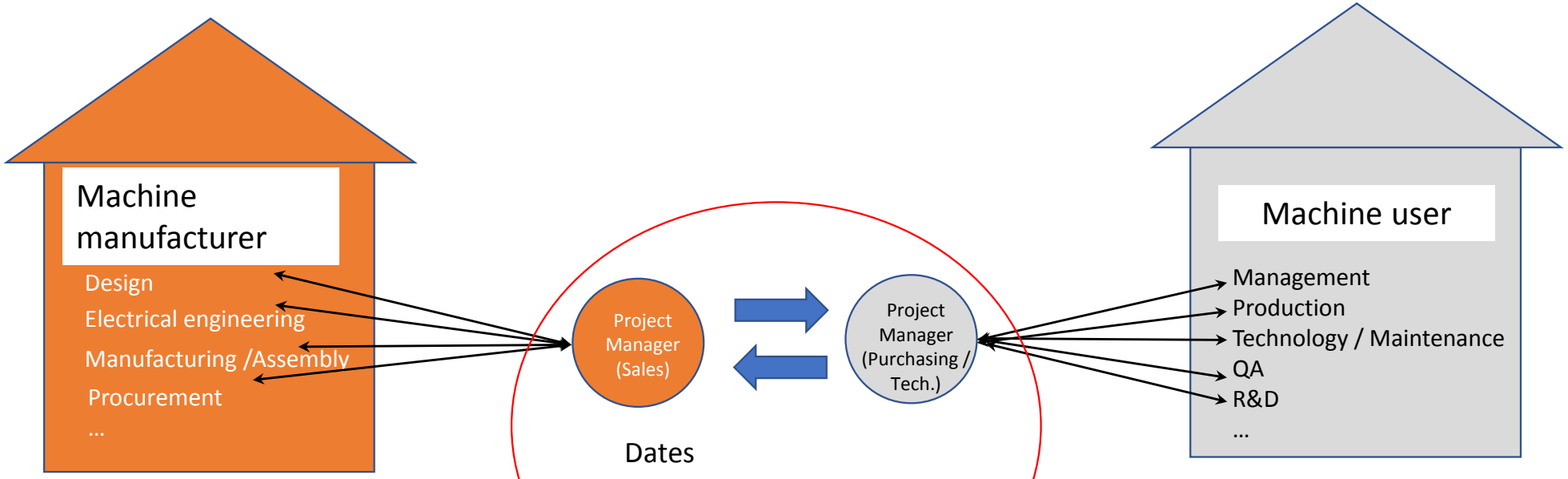
Part 3: Checklists for evaluating the hygienic constructional design

Starting question

How can serious errors with regard to hygienic design be avoided in the procurement process of confectionery machines?

Procurement process of a machine/plant

Procurement process between machine manufacturer and machine user



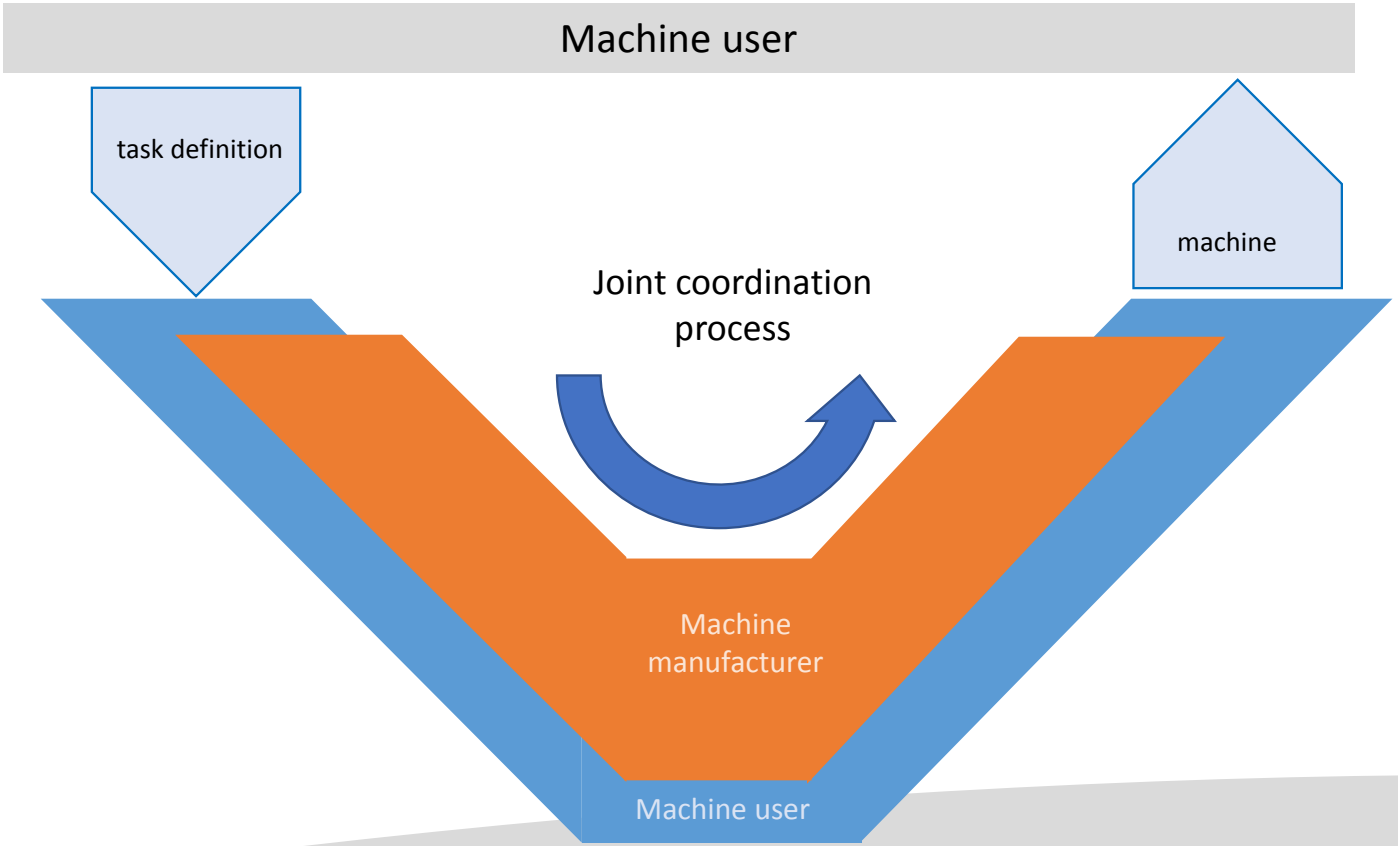
Cost pressure
Standardisation
New technologies
New legal requirements
Machine know-how
…

Hygiene

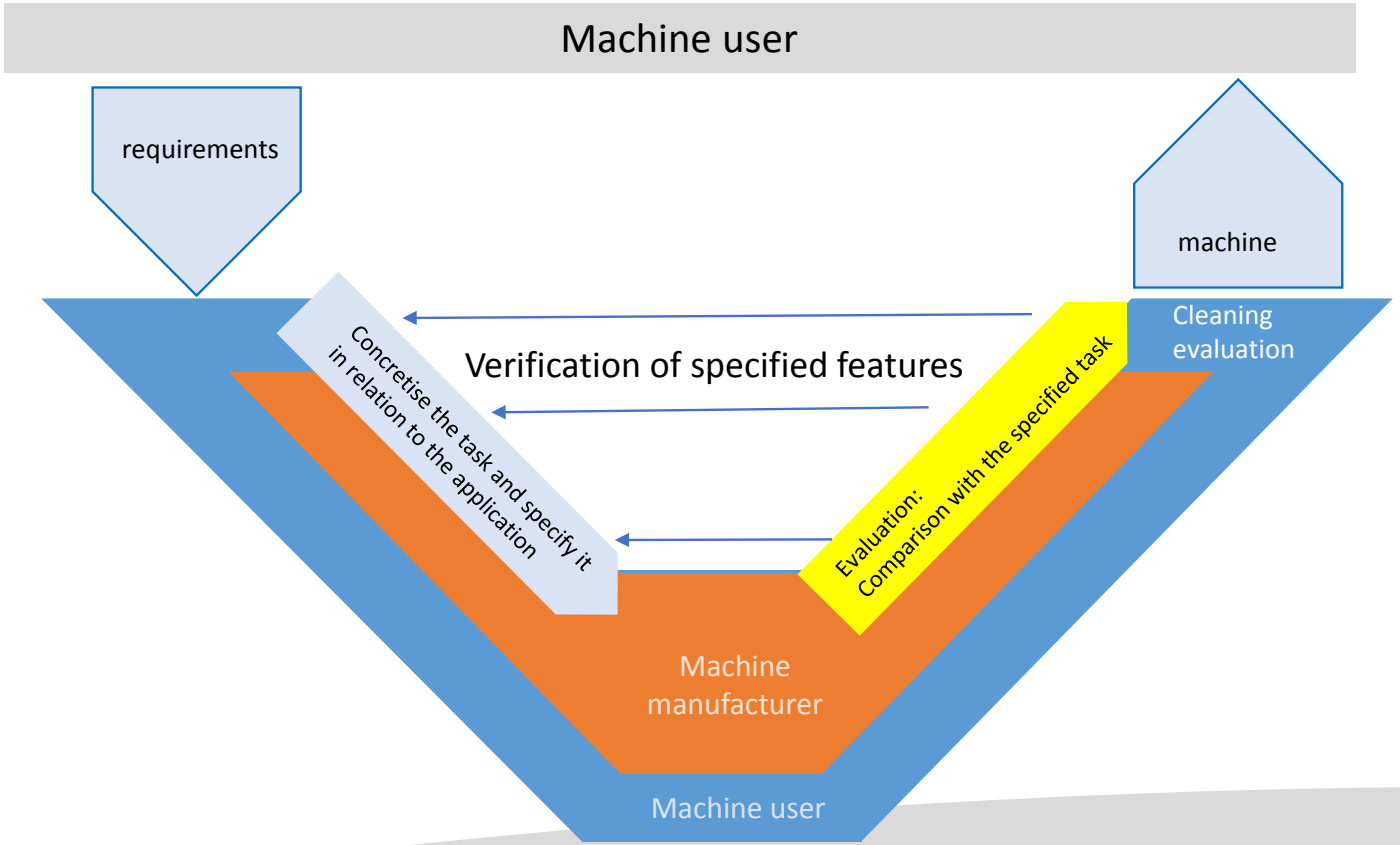
New products / capacity expansion
Improved product quality
High availability
Production costs (technology, personnel, org.)
Low maintenance costs / specifications / standardisation
Easy maintenance/cleaning
QA / audit requirements
Production know-how ...

Hygiene

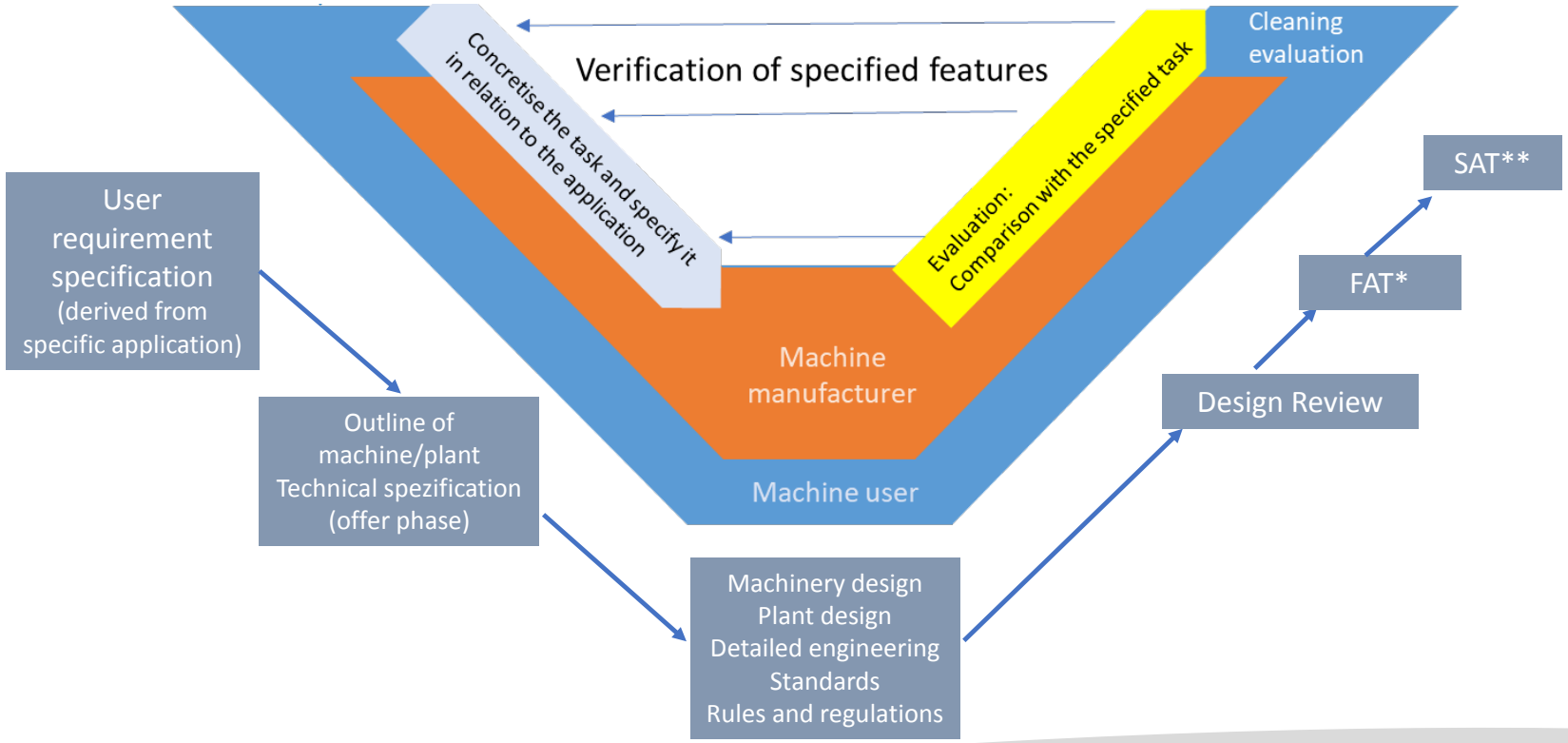
Coordinated procurement process of a machine/plant



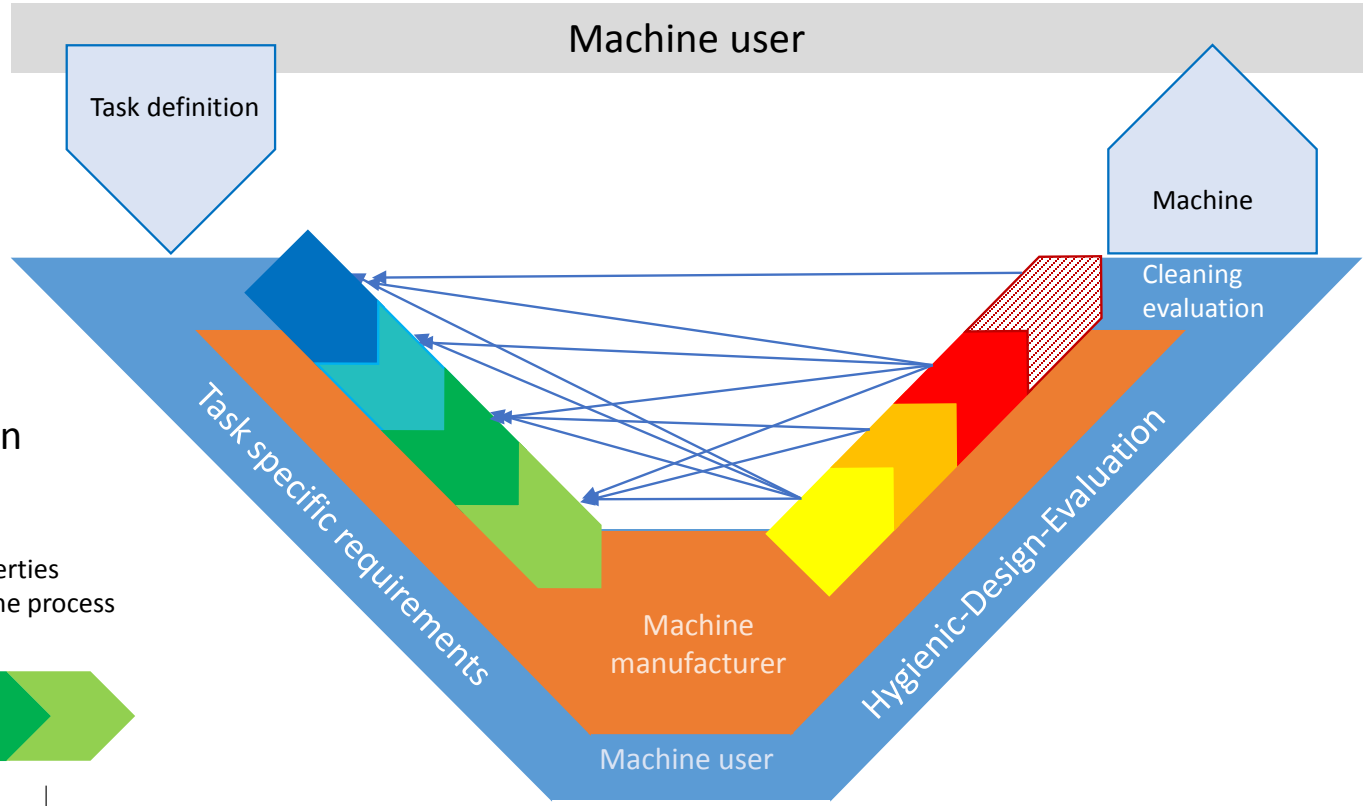
Procurement process of a machine/plant



Guide: Checklists for the different phases of the V-Model



V-Model of the Hygienic Design Evaluation



Task definition

products

What?

Product properties relevant for the process

How?

Production process

Technical concept (machine/plant)

Evaluation

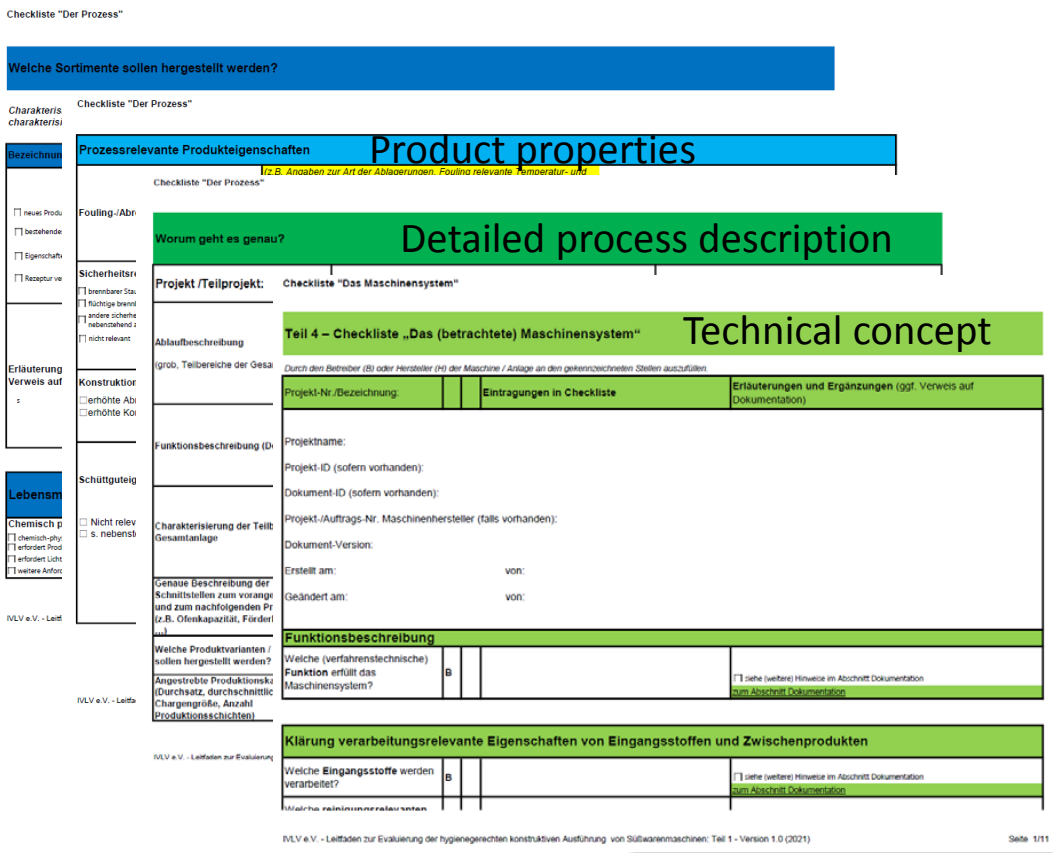
Evaluation cleaning plans*

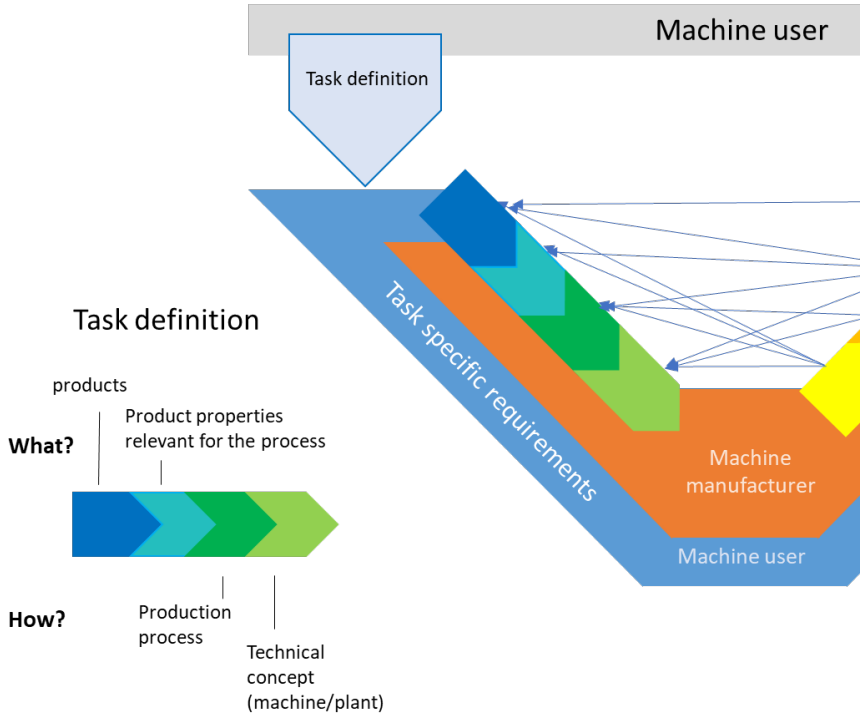
Evaluation information for use

* Not in the scope of the HD evaluation guide, as cleaning plans are drawn up under the responsibility of the machine operator.

Guide: The V-Modell Documents

Task specific requirements

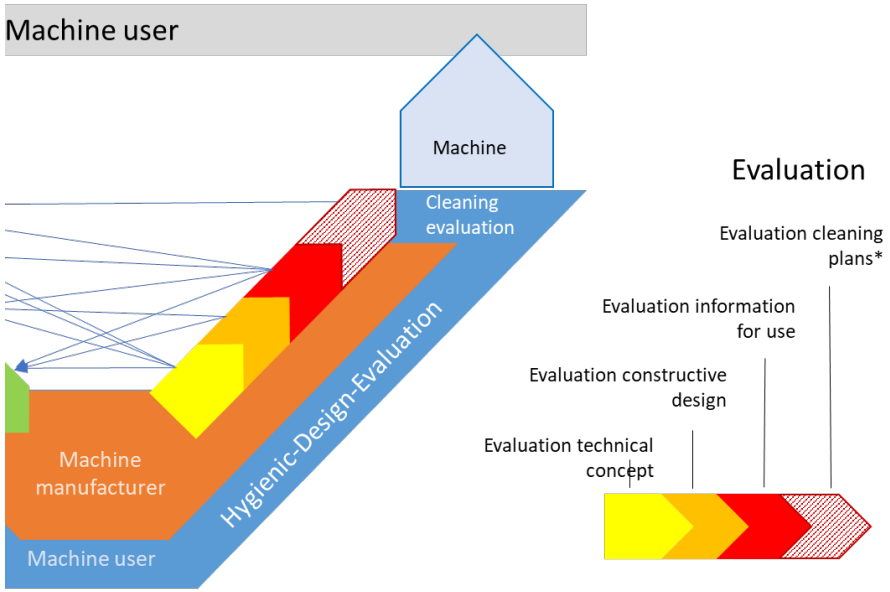




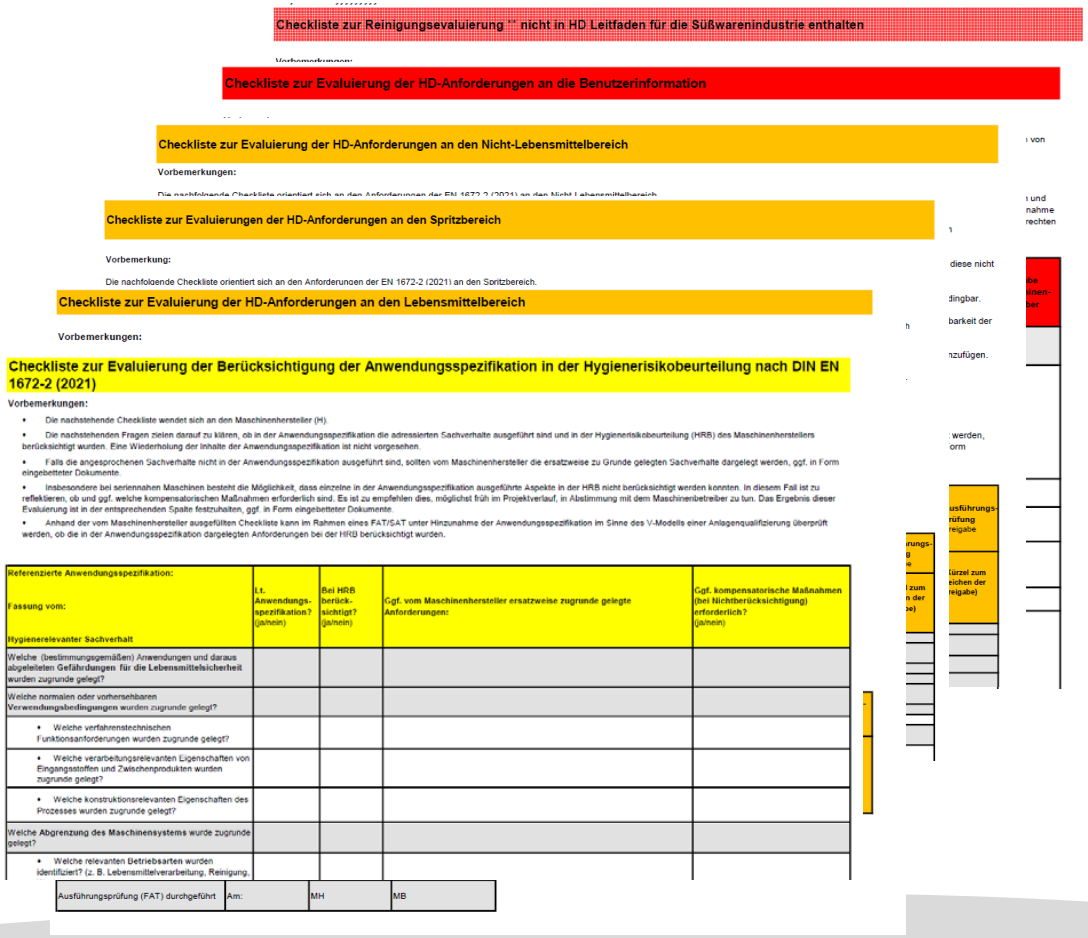
Record and provide hygiene-relevant product and process properties

Guide: The V-Modell Documents

Evaluation of Hygienic Design



* Not in the scope of the HD evaluation guide, as cleaning plans are drawn up under the responsibility of the machine operator.



Checkliste zur Reinigungsevaluierung " nicht in HD Leitfaden für die Süßwarenindustrie enthalten

Checkliste zur Evaluierung der HD-Anforderungen an die Benutzerinformation

Checkliste zur Evaluierung der HD-Anforderungen an den Nicht-Lebensmittelbereich

Vorbemerkungen:

Checkliste zur Evaluierungen der HD-Anforderungen an den Spritzbereich

Vorbemerkung:

Die nachfolgende Checkliste orientiert sich an den Anforderungen der EN 1672-2 (2021) an den Spritzbereich.

Checkliste zur Evaluierung der HD-Anforderungen an den Lebensmittelbereich

Vorbemerkungen:

Checkliste zur Evaluierung der Berücksichtigung der Anwendungsspezifikation in der Hygienerisikobeurteilung nach DIN EN 1672-2 (2021)

Vorbemerkungen:

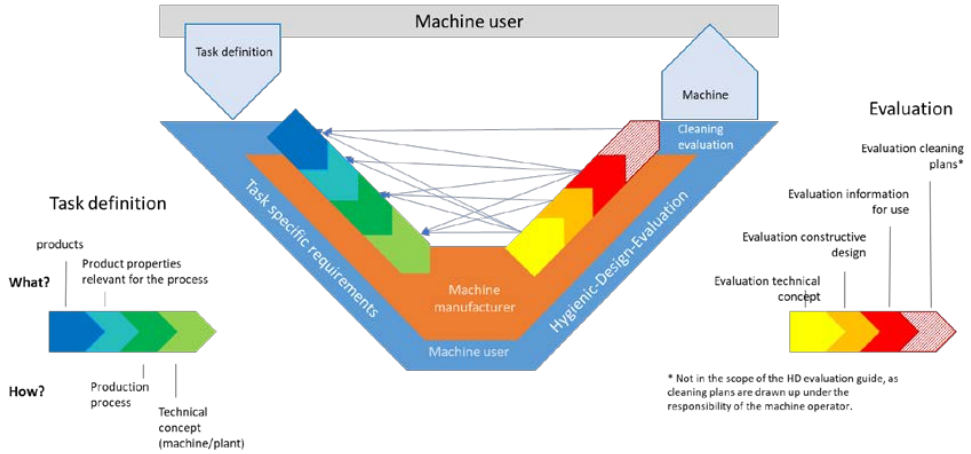
- Die nachstehende Checkliste wendet sich an den Maschinenhersteller (H).
- Die nachstehenden Fragen zielen darauf zu klären, ob in der Anwendungsspezifikation die adressierten Sachverhalte ausgeführt sind und in der Hygienerisikobeurteilung (HRB) des Maschinenherstellers berücksichtigt wurden. Eine Wiederholung der Inhalte der Anwendungsspezifikation ist nicht vorgesehen.
- Falls die angesprochenen Sachverhalte nicht in der Anwendungsspezifikation ausgeführt sind, sollten vom Maschinenhersteller die ersatzweise zu Grunde gelegten Sachverhalte dargelegt werden, ggf. in Form eingebetteter Dokumente.
- Insbesondere bei serienahen Maschinen besteht die Möglichkeit, dass einzelne in der Anwendungsspezifikation ausgeführte Aspekte in der HRB nicht berücksichtigt werden konnten. In diesem Fall ist zu reflektieren, ob und ggf. welche kompensatorischen Maßnahmen erforderlich sind. Es ist zu empfehlen dies, möglichst früh im Projektverlauf, in Abstimmung mit dem Maschinenbetreiber zu tun. Das Ergebnis dieser Evaluierung ist in der entsprechenden Spalte festzuhalten, ggf. in Form eingebetteter Dokumente.
- Anhand der vom Maschinenhersteller ausgefüllten Checkliste kann im Rahmen eines FAT/SAT unter Hinzunahme der Anwendungsspezifikation im Sinne des V-Modells einer Anlagenqualifizierung überprüft werden, ob die in der Anwendungsspezifikation dargelegten Anforderungen bei der HRB berücksichtigt wurden.

Referenzierte Anwendungsspezifikation: Fassung vom: Hygienerelevanter Sachverhalt	i.t. Anwendungs-spezifikation? (ja/nein)	Bei HRB berück-sichtigt? (ja/nein)	Ggf. vom Maschinenhersteller ersatzweise zugrunde gelegte Anforderungen:	Ggf. kompensatorische Maßnahmen (bei Nichtberücksichtigung) erforderlich? (ja/nein)
Welche (bestimmungsgemäßen) Anwendungen und daraus abgeleiteten Gefährdungen für die Lebensmittelsicherheit wurden zugrunde gelegt?				
Welche normalen oder vorhersehbaren Verwendungsbedingungen wurden zugrunde gelegt?				
• Welche verfahrenstechnischen Funktionsanforderungen wurden zugrunde gelegt?				
• Welche verarbeitungsrelevanten Eigenschaften von Eingangsstoffen und Zwischenprodukten wurden zugrunde gelegt?				
• Welche konstruktionsrelevanten Eigenschaften des Prozesses wurden zugrunde gelegt?				
Welche Abgrenzung des Maschinensystems wurde zugrunde gelegt?				
• Welche relevanten Betriebsarten wurden identifiziert? (z. B. Lebensmittelverarbeitung, Reinigung,				

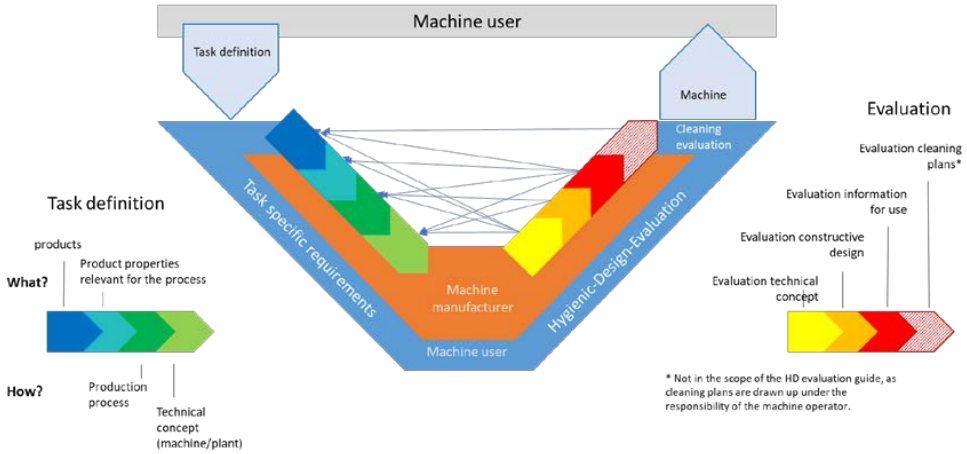
Ausführungsprüfung (FAT) durchgeführt	Am:	MH	MB

Summary: the V-Model

- The V-model originates from technical development.
- The client/machine user defines the task in writing.
- The contractor/machine manufacturer designs and builds the machine on this basis.
- During product development, the individual phases are recorded in writing.
- There is a step-by-step check or comparison between the task definition and the machine design as well as the detailed execution up to the finished machine, which is put into operation at the customer's (verification of specified features).



V-Modell - Proposal for the application to confectionery machines



Recommendation of the IVLV Working Group Confectionery Machines

The machine manufacturers have the detailed knowledge of how a machine must be constructed according to the requirements of applicable standards and legal regulations.

The machine operators manufacture a wide variety of products with the machines. This results in application-specific tasks that flow as boundary conditions into the iterative process of hygiene hazard reduction to be carried out by the machine manufacturer in accordance with EN 1672-2:2021.

The checklists provided serve to record the tasks in a structured manner and to check that they have been taken into account.

The intention is to work together.

The lists are structured in such a way that they can be filled in gradually during the course of the project.

They give the machine manufacturer the opportunity to ask the machine user about all aspects of the task that are relevant to the project and to clarify questions in the context of the application of applicable standards and legal regulations, so that no serious changes have to be made in the further course of the project or at the customer.

They are intended to give the machine user the opportunity to question the complex requirements from standards and other regulations.

Industrievereinigung für Lebensmitteltechnologie und Verpackung e. V.

Guideline for the evaluation of the hygienic design of confectionery machines
Part 2: Checklists to clarify the task

Contents

Use the jumpmarks in the table of contents to go directly to the respective checklists!
Use the key combination Ctrl + z to return to the starting point

Industrievereinigung für Lebensmitteltechnologie und Verpackung e. V.

Guideline for the evaluation of the hygienic design of confectionery machines

Part 2: Checklists to clarify the task

Introduction

This guide consists of three parts
Part 1: Introduction
Part 2: Checklists to clarify the task
Part 3: Checklists for evaluating the hygienic constructional design

Part 2 of the guide contains checklists for clarifying the application-specific tasks in the procurement process of a machine/plant against the background of hygienic production and machine design in the confectionery industry. The guide follows the planning steps in an investment project. It serves the purpose of clarifying the application-specific task for the technical design of a confectionery production or packaging machine. The guideline corresponds to Part 3 of the guideline "Checklists for evaluating the hygienic design of confectionery machines".

This part of the guide contains several checklists that will be filled in gradually as the project progresses. It is recommended to include supplementary or explanatory documents directly in the document.

This guide does not contain any technical requirements for machine systems. It has the character of a recommendation regarding the procedure. Essential questions are addressed. The guide does not claim to have covered all relevant issues. Adaptations to the respective project may be useful.

This document is designed as a working document. Copying and adapting the guide is permitted. If changes are made to the checklists, it is recommended that a note of change be made in the header of the respective checklist.

This guide was developed within the IVLV working group Confectionery Machinery. The following companies were involved in the preparation:

Alfred Ritter GmbH & Co. KG
August Storck KG
Chocoladenfabriken Lindt & Sprüngli AG
Chocolats Halba
Delica AG
Food Masters Freiberg AG
Hansella GmbH
J.G. Niederegger GmbH & Co.
Mondelez International
Netzsch Feinmahltechnik GmbH
Sollich KG
VDMA e.V. Nahrungsmittelmaschinen und Verpackungsmaschinen
Wback GmbH
Winkler und Dünnebier Süßwarenmaschinen GmbH
Ingenieur-Beratung Dr. Burkhard Eckermann

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Explanations on the use of the document

1) Use the jump marks in the table of contents to go directly to the parts of the document that interest you. At the end of each checklist you will find a link back to the table of contents.

2) It is recommended to keep the entries in the checklists as concise as possible and to refer to supplementary documents. This can be done in link form using the <insert><link> function. The referenced document can also be inserted directly as an object into the designated cell of the checklist. To do this, use the function <Insert><Object><Create from file>. Insert the object as a symbol.

3) At various points in the checklists, notes for completion are inserted in italics and highlighted in colour, partly in the form of examples. It is recommended to overwrite these notes - for reasons of clarity.

Referenced standards

DIN EN 1672-2	DIN EN 1672-2:2021-05 Nahrungsmittelmaschinen - Allgemeine Gestaltungsleitsätze - Teil 2: Anforderungen an Hygiene und Reinigbarkeit; Deutsche Fassung EN 1672-2:2020 Englischer Titel Food processing machinery - Basic concepts - Part 2: Hygiene and cleanability requirements; German version EN 1672-2:2020 Ausgabedatum 2021-05
DIN EN 415-11	DIN EN 415-11:2021-12 Sicherheit von Verpackungsmaschinen - Teil 11: Ermittlung von Effizienz und Verfügbarkeit; Deutsche Fassung EN 415-11:2021 Englischer Titel Safety of packaging machines - Part 11: Determination of efficiency and availability; German version EN 415-11:2021 Ausgabedatum 2021-12

References

IVLV AG Süßwarenmaschinen (2022)
Guideline for the evaluation of the hygienic design of confectionery machines

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Definition of terms in the project

The definitions of EN 1672-2 (2021) and the following definitions apply:

Characterisation of product and media properties	
Abrasion	Material loss due to abrasion
abrasiv	causing abrasion
corrosion	(from Latin corrodere 'to decompose', 'to eat away', 'to gnaw away') is, from a technical point of view, the reaction of a material with its environment that causes a measurable change in the material. Corrosion can lead to an impairment of the function of a component or system. Corrosion caused by living organisms is called biocorrosion.
	(Source: Wikipedia, German edition)
corrosive	causing corrosion
allergen	Allergenic product ingredients
	Note: typical triggers are pollen, animal hair, components of mites, food (such as fish, chicken egg white, nuts), drugs (such as penicillin).
microbiologically stable	No microbiological growth in the product at (normal) ambient temperature
microbiologically unstab	Microbiological growth possible in the product at (normal) ambient temperature

Characterisation Temperature ranges:	
deep-frozen	storage, processing, and/or distribution (at controlled climate conditions) below -15 °C
	Note: Temperature range based on the European Pharmacopoeia
refrigerated	storage, processing, and/or distribution (at controlled climate conditions) +2°C to +8°C
	Note: Temperature range based on the European Pharmacopoeia
cool	storage, processing, and/or distribution (at controlled climate conditions) +8°C to +15°C
	Note: Temperature range based on WHO Guidance Documents

(controlled) roomtemper	storage, processing, and/or distribution (at controlled climate conditions) +15°C to+B47 +25°C
	Note: Temperature range based on the European Pharmacopoeia
ambient temperature	Storage, processing and/or distribution in a geographically and seasonally dependent, not generally specified temperature range. Note: Temperatures may vary widely; geographical and seasonal factors may be relevant. Where relevant, at least the place of use and other items should be specified by mutual agreement.
controlled temperature	Includes temperature control in the specified range ("control"), monitoring of compliance with the control range ("monitor") and documentation of the measured data.

Characterisation of surrounding areas (production areas)	
Hygiene area	Area of the production environment of machine systems for which special hygiene requirements - defined by the machine operator - apply.
	Note 1: adapted to different hygienic requirements of the products to be manufactured, different Hygiene areas are defined
	Note 2: The hygiene area can be divided into different hygiene zones based on a hygiene risk assessment. hygiene risk levels can be distinguished. A distinction is often made between zones with a low, medium or high hygiene risk. The basis of the hygiene risk assessment is not only the consideration of contaminants but also the reflection of possible transmission paths into the food (transmission vectors).
	Part of the hygiene area, which includes the installation area of the machine system as well as the adjacent areas that are required to allow cleaning of the machine system.
immediate hygiene area	Note 1: The installation area of the machine system must not contain any fixtures (e.g. drains, gutters) whose cleaning is hindered by the machine's set-up.
	Note 2: Above open areas of the machine system, there shall be no fixtures over which a contamination (e.g. by foreign bodies, dust, condensation) of the product can occur.
Non-hygiene area	Area of the production environment of machine systems that is not classified as a hygiene area.
Black' area	Synonym for non-hygiene area
'White' area	Synonym for hygiene area
Cold area	Production area not characterised by process-related increased ambient temperatures
	Note: a further classification of the cold area according to temperature ranges is possible. For classification criteria s. Section "Characterisation temperature ranges".

Warm area	Production area characterised by process-related increased ambient temperatures
Wet area	Production area that is wet cleaned
Dry area	Production area that is cleaned dry
ATEX zone	Production area with explosive atmosphere
(ATEX-range)	Note: The ATEX zone can be classified according to applicable directives and standards and, if necessary, further subdivided according to this classification.

Characterisation machine areas	
machine system	Machines and systems with defined system limits in relation to the insertion of processed goods (packaged goods and/or packaging materials/packaging aids), operating materials, the delivery of application units, waste or rejects.
	source DIN 8743:2014
food area	machine and machine components surfaces which are exposed to food or from which food or other materials can drain, drip, diffuse or be drawn into the food Source: EN 1672-2:2020
splash area	area composed of surfaces on which part of the food can splash or flow along under intended conditions of use and does not return into the food Note 1 to entry: Part of the food in the splash area is no more food according to Article 2 of Regulation (EC) No. 178/2002
	Source: EN 1672-2:2020
non-food area	any area other than food area or splash area
	Source: EN 1672-2:2020
surfaces for direct produ	Machine surface, intended for direct contact with the food or its ingredients.
surfaces for indirect contact	Machine surfaces, intended for contact with product-contacting surfaces of food contact materials and articles, but not for direct product contact.
	Note: Example: Contact with product-contacting surfaces of packaging materials that are subsequently filled.

General	
information for use	protective measure consisting of communication links (for example, text, words, signs, signals, symbols, diagrams) used separately or in combination, to convey information to the user
	(according to DIN ISO EN 12100 (2011)
	Note 1: The requirements forthe information for use are specified in section 6.4. of the standard.

	Note 2: The instruction handbook is part of the information for use.
instruction handbook	Part of information for use provided to the machine user by the machine manufacturer, which contains instructions and notes related to the use of the machine in all its life phases.
	(according to DIN ISO EN 20607)

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Checklist „Overview“

Project-ID: ***xxxxxxx***
Project-name: ***yyyyyyy*** *is automatically transferred to the following checklists*

To be completed by the operator of the machine / system

Change documentation
Document ID (if available):
Project/order no. Machine manufacturer (if available):
Document version:
Created on: by:
Modified on: by:

What is the project about?

short description:		If applicable, order number / date of order placement:
List of sub-projects (if relevant)		If applicable, order number / date of order placement:

Who is involved?

	Name	Contact details
Project Manager Client (CL)		
Project Manager Contractor (CO)		
Manager CL sub-project ……...		
Manager CO sub-project ……...		

What dates are planned?

Specification / clarification by client (CL) by	
Specification / clarification by contractor (CO) by	
Award negotiation from ... To	
Design approval by CL	
Date FAT with CL and CO	
Delivery date	
Period of Commissioning	
SAT with CL and CO	
Production readiness	

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Enquiry and offer' checklist

Project-ID: xxxxxxx
Project-name: yyyyyyy

To be filled in by the operator of the machine / plant.
If necessary, add further tables for sub-processes that run in different machines. To do this, click on the plus sign at the bottom right at the end of the table.

Change documentation

Document ID (if available):

Project/order no. Machine manufacturer (if available):

Document version:

Created on: by:

Modified on: by:

What should be done?

Project /Subproject+A83:		
Brief description of the functional and performance requirements:		Supplementary documents (as bound objects)

Example: Hollow body plant:

Sub-plant	**Hygiene area?**	**wet / dry area?**	**Cold/warm area**	**ATEX-area?**
Mould emptying control				
Mould change				
Mould heating				
Dosing (tray)				

For complex plants: Break down the entire plant into sub-plants and assign the sub-plants to production areas.	Vibrating					
	Shell formation					
	Mould cleaning					
	Shell cooling					
	Mould heating					
	Dosing (filling)					
	Vibration					
	Filling cooling					
	Mould heating					
	Dosing (lid)					
	Vibrating					
	Scraper Lid					
	Final cooling					
	Twisting					
	Forming					
Production capacity / shift operation?						
Special requirements with regard to consumer groups? (e.g. infants, sick persons, allergy sufferers)						Supplementary documents (as bound objects)
Special processing requirements? (Halal/Kosher, etc.)						Supplementary documents (as bound objects)
Integration into existing production environment?						Supplementary documents (as bound objects)
Enquiry	from: by (name, department, contact					Supplementary documents (as bound objects)

Changes in functional and performance requirements after award of contract		

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How should it be done?		
Project / sub-project:		Supplementary documents (as bound objects)
Proposal machine concept:	Function:	
	Differentiation from upstream and downstream process steps:	
Offer:	from: by (name, department, contact details):	

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The process - what exactly is it about?
Product range - processing-relevant product properties - concept manufacturing process

Project-ID: xxxxxxx
Project-name: yyyyyyy

To be filled in by the operator of the machine / plant.
If necessary, add further tables for sub-processes that run in different machines.

Change documentation

Document ID (if available):

Project/order no. Machine manufacturer (if available):

Document version:

Created on: **by:**

Modified on: **by:**

Product range' checklist - Which ranges are to be produced?

At this point, characterise (the operator) the products to be processed. If product groups differ in terms of their properties, these must be characterised separately.

Name of the product group/assortment:		
☐ new product assortment ☐ Existing product assortment (product samples available) ☐ Properties of the formulation comparable with existing product range (insert name) ☐ Recipe available (see inserted document), clarify confidentiality!		
Explanations and additions (reference to documentation if necessary)	☐ see (further) notes in the documentation section	To the documentation section

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Food relevant properties

Chemical physical stability

- ☐ chemically-physically stable
- ☐ Requires product conditioning
- ☐ Requires light protection
- ☐ further requirements

☐ see (further) notes in the documentation section

To the documentation section

Microbiological stability

- ☐ Microbiologically stable
- ☐ Microbiologically unstable
- ☐ Subsequent product pasteurisation or sterilisation
- ☐ Requires cooling during processing
- ☐ Requires product conditioning
- ☐ Requires cooling during storage
- ☐ further requirements

☐ see (further) notes in the documentation section

To the documentation section

Allergenic product ingredients

- ☐ No allergenic ingredients
- ☐ dedicated lines - Mono production lines
- ☐ Aiming for the greatest possible removal of
- ☐ No special cleaning requirements
- ☐ Not relevant (no product contact)
- ☐ further requirements

☐ see (further) notes in the documentation section

To the documentation section

Special requirements such as Halal, Kosher etc.?

Other product properties relevant to processing

- ☐ Aroma carry-over
- ☐ increased abrasiveness
- ☐ increased corrosiveness
- ☐ Products sticky
- ☐ further requirements

☐ see (further) notes in the documentation section

To the documentation section

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Project name:

Project ID (if available):

Document ID (if any):

Project/order no. Machine manufacturer (if any):

Document version:

Created on: **by:**

Modified on: **by:**

Checklist 'Process-relevant product characteristics'

Fouling / cleaning properties	*(e.g. information on the type of deposits, fouling relevant temperature and time information on process control)* ☐ see (further) notes in the documentation section	To the documentation section
Safety-relevant factors ☐ combustible dust ☐ Volatile combustible substances ☐ Other safety-related factors (as listed opposite) ☐ Not relevant	*(e.g. information on dust holding capacity, dust explosion class / ignition energy)* ☐ see (further) notes in the documentation section	To the documentation section
Design-relevant factors ☐ increased abrasiveness ☐ increased corrosiveness	*(e.g. information on chloride content or aggressive cleaning media, pH value of the product, foreign bodies such as sand).* ☐ see (further) notes in the documentation section	To the documentation section
Bulk good properties: ☐ not relevant ☐ see requirements opposite	*(e.g.: Information on void ratio (enclosed air content), abrasion resistance, bulk density (filled/knocked), degassing, flow behaviour, glass transition temperature, hygroscopy, moisture content / content of volatile substances Particle size distribution, (e.g. solubility, time consolidation, wettability, surface energy / surface charge (electrostatic properties), abrasiveness)* ☐ see (further) notes in the documentation section	To the documentation section back to top Back to 'Contents'

Project name:	
Project ID (if available):	
Document ID (if any):	
Project/order no. Machine manufacturer (if+A72 any):	
Document version:	
Created on:	**by:**
Modified on:	**by:**

Checklist 'Concept manufacturing process - How should the product be manufactured?'

Project / sub-project:		**Supplementary documents** (as bound objects)
Process description (rough, sub-areas of the overall system)	*E.g. hollow body plant: mould empty control - mould change - mould heating - dosing (shell) - vibration - shell formation - mould cleaning - shell cooling - mould heating - dosing (filling) - vibration - filling cooling - mould heating - dosing (lid) - vibration - stripper lid - final cooling - twisting - demoulding*	
Functional description (detail)		
Characterisation of the sub-areas of the overall facility		
Exact description of the interface to the preceding and to the following process step (e.g. oven capacity, conveyor belt width ...)		
Which product variants / recipes are to be produced? (Overview)		
Target production capacity? (throughput, average/max. batch size, number of production shifts)	*Individually for each product variant, as there may be different process times*	

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Checklist 'The (Considered) Machine System'

link to section documentation

Project-ID: xxxxxxx
Project-name: yyyyyyy

To be completed by the operator of the machine / plant.
If necessary, add further tables for sub-processes that run in different machines.

Subject			**Entries in checklist**	**Explanations and additions** (reference to documentation if necessary)
Change documentation: **Document ID (if available):** **Project/order no. Machine manufacturer (if available):** **Document version:** **Created on:** **by:** **Modified on:** **by:**				
Functional description				
What (process technology) function does the machine system fulfil?	**B**			☐ see (further) comments in section documentation zum Abschnitt Dokumentation
Clarification of processing-relevant properties of input materials and intermediate products				
Which **input materials** are processed?	**B**			☐ see (further) comments in section documentation link to section documentation
Which **cleaning-relevant properties of the input materials** must be taken into account?	**B**		*(see part 3)*	☐ see (further) comments in section documentation link to section documentation

Subject			Entries in checklist	Explanations and additions (reference to documentation if necessary)
Which special **processing-relevant properties of the input materials** must be taken into account?	**B**		*(see part 3)*	☐ see (further) comments in section documentation link to section documentation
Which **quality-relevant technical boundary conditions** must be observed in the processing procedure?	**B**	**H**	**Requirements of the operator:** • pH value product and cleaning media: • Abrasiveness Product • Temperature range Process • … **Are there any restrictions on the part of the machine manufacturer?** **Agreement between operator and machine manufacturer:**	☐ see (further) comments in section documentation link to section documentation
What are the **quality requirements** regarding the manufactured (intermediate) product?	**B**	**H**	**Requirements of the operator:** **Are there any restrictions on the part of the machine manufacturer?** **Agreement between operator and machine manufacturer:**	☐ see (further) comments in section documentation link to section documentation

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Subject			Entries in checklist	Explanations and additions (reference to documentation if necessary)
Clarification of design-relevant properties of the process				
Does the machine system contain a food area according to EN 1672-2 (2021)?	**B**		☐ yes ☐ no If applicable: More detailed **description of the food area**: If applicable: More detailed **description of the splash area**:	☐ see (further) comments in section documentation link to section documentation
Cleaning - How is the machine system cleaned? **Cleaning characterisation:** ☐ dry ☐ wet ☐ wet with spry lye ☐ CIP (piping system ☐ CIP (vessel) ☐ WIP (open areas, further description required)	**B**		**Which areas are to be cleaned automatically?** (CIP/WIP) **Which cleaning agents and, if applicable, disinfectants are used?** In what concentration? At what temperatures? Are there any specifications by the machine manufacturer? **Removal of parts:** Do parts have to be removed for cleaning? What tools may be required? Are there aids for storing and, if necessary, transporting the dismantled parts? **Is there a washing area for cleaning dismantled parts?** (where? what equipment?) **How often is cleaning carried out?** ☐ after every batch ☐ after every production shift ☐ at weekends after production ☐ intermediate leaning within long production periods ☐ pre-cleaning after longer interruptions of production (e.g. prior to production start after weekends)	

Subject			Entries in checklist production start after weekends)	Explanations and additions (reference to documentation if necessary)	
			Notes: **Is disinfection/sterilisation necessary?** ☐ no ☐ sterilisation by steam (piping systems) ☐ sterilisation by steam (vessels) ☐ sterilisation by steam (machine cabinet) ☐ wet chemical disinfectio of surfaces with direct/indirect food contact or of surfaces within the splash area ☐ wet chemical disinfection of other surfaces (please **Which disinfection and sterilisation media are used?** (Generic name or trade name; pH value, concentration) Are there **any other requirements with regard to cleaning and sterilisation**?	☐ see (further) comments in section documentation link to section documentation	
What are the **maintenance intervals**?	**B**			☐ see (further) comments in section documentation link to section documentation	
Which **lubricants** are used?	**B**			☐ see (further) comments in section documentation link to section documentation	back to top of checklist back to table of contents

Clarification of installation and installation-relevant boundary conditions (incl. technical interfaces)

Boundaries of the machine system			Requirements of the operator regarding Interface(s) to upstream machine systems Interface(s) to downstream machine systems Interfaces to higher-level, upstream or downstream IT systems Interfaces to supply lines Temperature installation environment	

Subject			Entries in checklist	Explanations and additions (reference to documentation if necessary)
	B	H	**Are there any restrictions on the part of the machine manufacturer?** Comparison with Interface list **Agreement between operator and machine manufacturer:**	☐ see (further) comments in section documentation link to section documentation
What should be considered with regard to the installation environment?			**Is documentation on the installation environment available? (B)** Is it a greenfield or a brownfield project? What are the constraints on the carrying capacity of the soil? Is the environment classified as a hygiene zone? Is there any documentation on the classification? Is the environment classified as a cold or warm area? Is the environment classified as a dry or wet area? Is the environment classified as an Atex area? Where are drains installed or planned that must not be built over? What overbuilding, e.g. cables or pipelines, must be taken into account? What capacities of supply media can be provided and in What quality? are these sufficient **Has a site visit been carried out? BH** What are the installation restrictions?	

Subject			Entries in checklist	Explanations and additions (reference to documentation if necessary)
	B	**H**	Where are drains installed or planned that may not be built over? What overbuilding, e.g. cables or pipelines, must be taken into account? What requirements for **parking areas for the supply and, if applicable, temporary storage of processing goods** are to be taken into account? **BH** Which requirements regarding the **accessibility of the machine system** have to be considered? **BH** What restrictions exist with regard to the **transport and installation of the modules of the machine system within the production site** of the machine operator (e.g. restrictions due to size and permissible load-bearing capacity of goods lifts)? **B** What **modifications/adaptations must be made before the machine system can be set up**? **BH** **How will the installation environment be cleaned? B**	☐ see (further) comments in section documentation link to section documentation
What influence does the installation environment have?	**B**		What products are produced next to or above it? How are the neighbouring plants cleaned? Humidity/aerosols due to neighbouring cleaning?	☐ see (further) comments in section documentation

Subject			Entries in checklist	Explanations and additions (reference to documentation if necessary)
				see (further) comments in section documentation link to section documentation
What must be observed with regard to delivery, installation and commissioning?	**B**	**H**	Requirements of the operator: How is **transport to the installation site** carried out? (Access road, on the factory premises, crane required for installation? Hall crane available? Size and load capacity of the goods lift sufficient?) **Lifting equipment** (Which is required, who is responsible?) What **preparatory work** must be completed? What **time windows** are available? **Partitions to neighbouring plants** during assembly/commissioning What **provisions** of equipment will be made by the machine operator? What are the requirements regarding the **provision of personnel** (for delivery, assembly and commissioning)? Are there any **restrictions on the part of the machine manufacturer**? **Agreement between operator and machine manufacturer:**	☐ see (further) comments in section documentation link to section documentation

Clarification of boundary conditions for the operation of the machine/plant				
What are the requirements (qualification, number of staff) for the operating and maintenance personnel?	**B**	**H**	*(e.g. regarding Operating and training concept number of operators required qualification special requirements for hygiene training of operating and maintenance personnel)*	

Subject			Entries in checklist	Explanations and additions (reference to documentation if necessary)
			Agreement between operator and machine manufacturer:	☐ see (further) comments in section documentation link to section documentation
Which immission/emission requirements must be observed?	**B**		*(e.g. noise, exhaust air, waste water, radiation, aerosols - occupational health and safety and environmental protection)*	☐ see (further) comments in section documentation link to section documentation

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Clarification of boundary conditions of FAT, SAT and performance acceptance				
What are the requirements for upstream partial acceptances (FAT)?	**B**	**H**	(e.g. *Verification of proper installation* *function test dry or with ubstitute product (e.g. water)* *Safety checks* *FAT checklist of the customer available?* *FAT checklist of the machine manufacturer available?)* **Requirements of the machine operator:** **Are there any restrictions on the part of the machine manufacturer?** **Agreement between operator and machine manufacturer:**	☐ see (further) comments in section documentation link to section documentation
Which requirements exist with regard to the general conditions of a performance acceptance? (Performance test) - Supplement to EN 415-11 (2021)			**Agreement operator/machine manufacturer on:** **Specification of the processed goods** (input) o Ingredients	

Subject			Entries in checklist	Explanations and additions (reference to documentation if necessary)
			o Packaging materials o Packaging aids o Process media in contact with the product **Quality requirements Output** **Clarification of the interfaces** of the machine system, e.g. to o Upstream and downstream machine systems o Supply of processing goods o Energy supply o Disposal of production and, if applicable, packaging waste o Cleaning systems (in the case of external CIP) o Upstream, downstream and higher-level information processing systems	
	B	**H**	**Acceptance time** **number and tasks of operating personnel** **Clarification of the prerequisites for acceptance readiness**, e.g. o Availability of personnel o Availability of processing goods in specified quality and sufficient quantity o Operational readiness of the cleaned machine system (as well as upstream and downstream systems) Clarification of the **procedure to be followed in the event of an interruption or termination of the acceptance run** Clarification of the **documentation of the Acceptance run and the evaluation**	☐ see (further) comments in section documentation link to section documentation

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Change Documentation - Overview

The contents of the overview are automatically taken from the change documentation of the documents listed. If necessary, the line height must be adjusted in order to see all changes.

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Project-name: yyyyyyy

Change documentation 'overview'

='"Overview"'!A5:C5

Change documentation 'Enquiry and Offer'

='"Enquiry and offer" '!A4:C4

Change documentation 'The Process'

Change documentation

Document ID (if available):

Project/order no. Machine manufacturer (if available):

Document version:

Created on: by:

Modified on: by:

Change documentation 'The Machine System'

Change documentation:

Document ID (if available):

Project/order no. Machine manufacturer (if available):

Document version:

Created on: by:

Modified on: by:

Documentation

Embed documents here
For this use key combination <insert><text><Object>
The checklists include links to this section 'documentation'
You may set links to the documents in this section by the way of the key combination <ctrl>+<k>

Attachments to checklist 'overview'

Name of document	embedded document
Test-Dokument	Testdokument.docx

Attachments to checklist 'enquiry and offer'

Name of document	embedded document

Attachments to checklist 'the process'

Dokumentname	eingebundenes Dokument

Attachments to checklist 'The Machine System'

Dokumentname	eingebundenes Dokument

Industrievereinigung für
Lebensmitteltechnologie und Verpackung e. V.

Guideline for the evaluation of the hygienic design of confectionery machines

Part 3: Checklists for evaluating the hygienic design of confectionery machines

Table of contents

Use the jump marks in the table of contents to go directly to the respective checklists!

Industrievereinigung für
Lebensmitteltechnologie und Verpackung e. V.

Guideline for the evaluation of the hygienic design of confectionery machines

Part 3: Checklists for evaluating the hygienic design of confectionery machines

Foreword

This guide consists of three parts
Part 1: Introduction
Part 2: Checklists to clarify the task
Part 3: Checklists for evaluating the hygienic constructional design

Part 3 of the guide addresses essential aspects of a systematic evaluation of the hygienic design of confectionery machines. The guide contains several checklists for this purpose.

The checklist "Consideration of the task" serves to check whether the hygiene-relevant boundary conditions from the application-specific task[1] were considered in the hygiene risk assessment of the machine manufacturer and - if no boundary conditions were formulated in the task for the hygiene-relevant facts addressed in the checklist - which boundary conditions were used as a basis as a substitute. The hygiene-relevant issues were formulated in accordance with the iterative process of hygiene risk reduction set out in EN 1672-2 (2021).

The checklists for evaluating the hygienic design (of the food area, the splash area and the non-food area) as well as the user information refer - as far as possible - to the relevant passages of DIN EN 1672-2 (2021) with regard to the respective requirement. Consultation of the standard is therefore indispensable for the application of the checklist.

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This guideline was developed within the IVLV working group Confectionery Machinery. The following companies were involved in the preparation:

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August Storck KG
Chocoladenfabriken Lindt & Sprüngli AG
Chocolats Halba
Delica AG
Food Masters Freiberg AG
Hansella GmbH
J.G. Niederegger GmbH&Co.
Mondelez International
Netzsch Feinmahltechnik GmbH
Sollich KG
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Explanations on the use of the document

1) Use the jump marks in the table of contents to go directly to the parts of the document that interest you. At the end of each checklist you will find a link back to the table of contents.

2) It is recommended to keep the entries in the checklists as concise as possible andrefer to supplementary documents This can be done in link form using the <insert><link> function. The referenced document can also be inserted directly as an object into the designated cell of the checklist. To do this, use the function <Insert><Object><Create from File>. Insert the object as a symbol.

3) At various points in the checklists, notes for completion are inserted in italics and highlighted in colour, partly in the form of examples. It is recommended to overwrite these notes - for reasons of clarity.

4) The checklists are formatted so that they can be printed out.

Scope of application

This practical guide addresses essential aspects of a systematic evaluation of the hygienic design of machines and systems for the production and packaging of confectionery that fall within the scope of DIN EN 1672-2 (2021).

Introduction

DIN EN 1672-2 (2021) establishes a close connection between the hygiene risk assessment (HRA) and the constructive design of a machine. The hygiene risk assessment in the sense of EN 1672-2 (2021) is an iterative process that systematically reflects the relevant aspects, whereby the characteristics of the relevant aspects can vary from one application to the next. As a result, the hygiene risk assessment should ensure that the identified hygiene risks are eliminated and reduced as far as reasonable and that the remaining residual risks can then be controlled. Avoidance has priority over compensatory measures to control residual risks. The result of the hygiene risk assessment is reflected - on the one hand - in the design of the machine system in connection with the associated user information ('information for use') on machine operation, cleaning and disinfection as well as maintenance (design and user information cannot therefore be evaluated independently of each other) and - on the other hand - in the documentation of the identified residual risks and measures (recommendations) for their control.

The first step in evaluating the hygienic design of a machine system is to check whether the boundary conditions specified in the application-specific task have been taken into account in the hygiene risk assessment. EN 1672-2 provides some information on this, which has been compiled in the checklist "Consideration of the task". This step precedes the actual evaluation of the design of the machine system under consideration.

The checklists for the hygienic design of the machine system under consideration are based on the requirements and design recommendations of DIN EN 1672-2 (2021) for individual aspects of a design, the fulfilment of which for the addressed aspect - and only for this aspect - means that a hygienic design can be assumed, irrespective of the application. Deviations are possible - provided that nothing to the contrary is specified in DIN EN 1672-2 (2021) and provided that the deviation does not conflict with public law in the country of the place of installation - if this deviation has been reflected in the hygiene risk assessment of the machine manufacturer. DIN EN 1672-2 (2021) thus allows the machine builder leeway in the design to meet the different hygiene requirements in the most diverse application scenarios for food processing machines, but only in the context of an application-related hygiene risk assessment.

The checklists for evaluating the hygienic design are a tool for checking the design proposed by the machine manufacturer against the background of the application-specific task (design check) and the hygienic design in the context of a FAT or SAT (execution check). It enables systematic verification of compliance with the requirements and design recommendations of DIN EN 1672-2 (2021). It makes deviations from the requirements and implementation recommendations transparent and, in the case of deviations, establishes the reference to the hygiene risk assessment.

Since the design cannot be evaluated independently of the corresponding 'information for use', this publication contains a further checklist that addresses aspects for which information can be expected in the 'information for use' according to DIN EN 1672-2 (2021).

Referenced standards

DIN EN 1672-2	DIN EN 1672-2:2021-05 Nahrungsmittelmaschinen - Allgemeine Gestaltungsleitsätze - Teil 2: Anforderungen an Hygiene und Reinigbarkeit; Deutsche Fassung EN 1672-2:2020 Englischer Titel Food processing machinery - Basic concepts - Part 2: Hygiene and cleanability requirements; German version EN 1672-2:2020 Ausgabedatum

DIN EN 415-11	DIN EN 415-11:2021-12 Sicherheit von Verpackungsmaschinen - Teil 11: Ermittlung von Effizienz und Verfügbarkeit; Deutsche Fassung EN 415-11:2021 Englischer Titel Safety of packaging machines - Part 11: Determination of efficiency and availability; German version EN 415-11:2021 Ausgabedatum 2021-12
DIN 10528	DIN 10528:2017-08 Lebensmittelhygiene - Anleitung für die Auswahl von Werkstoffen für den Kontakt mit Lebensmitteln - Allgemeine Grundsätze

Literature

IVLV AG Süßwarenmaschinen (2022)
Leitfaden zur Evaluierung der hygienegerechten konstruktiven Ausführung von Süßwarenmaschinen

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Definition of terms in the project

The definitions of EN 1672-2 (2021) and the following definitions apply:

Characterisation of product and media properties	
Abrasion	Material loss due to abrasion
abrasiv	causing abrasion
corrosion	(from Latin corrodere 'to decompose', 'to eat away', 'to gnaw away') is, from a technical point of view, the reaction of a material with its environment that causes a measurable change in the material. Corrosion can lead to an impairment of the function of a component or system. Corrosion caused by living organisms is called biocorrosion.
	(Source: Wikipedia, German edition)
corrosive	causing corrosion
allergen	Allergenic product ingredients
	Note: typical triggers are pollen, animal hair, components of mites, food (such as fish, chicken egg white, nuts), drugs (such as penicillin).
microbiologically stable	No microbiological growth in the product at (normal) ambient temperature
microbiologically unstable	Microbiological growth possible in the product at (normal) ambient temperature

Characterisation temperature ranges:	
deep-frozen	storage, processing, and/or distribution (at controlled climate conditions) below -15 °C
	Note: Temperature range based on the European Pharmacopoeia
refrigerated	storage, processing, and/or distribution (at controlled climate conditions) +2°C to +8°C
	Note: Temperature range based on the European Pharmacopoeia
cool	storage, processing, and/or distribution (at controlled climate conditions) +8°C to +15°C
	Note: Temperature range based on WHO Guidance Documents

(controlled) roomtemperature	storage, processing, and/or distribution (at controlled climate conditions) +15°C to+B47 +25°C
	Note: Temperature range based on the European Pharmacopoeia
ambient temperature	Storage, processing and/or distribution in a geographically and seasonally dependent, not generally specified temperature range. Note: Temperatures may vary widely; geographical and seasonal factors may be relevant. Where relevant, at least the place of use and other items should be specified by mutual agreement.
controlled temperature	Includes temperature control in the specified range ("control"), monitoring of compliance with the control range ("monitor") and documentation of the measured data.

Characterisation of surrounding areas (production areas)

Hygiene area	Area of the production environment of machine systems for which special hygiene requirements - defined by the machine operator - apply.
	Note 1: adapted to different hygienic requirements of the products to be manufactured, different Hygiene areas are defined
	Note 2: The hygiene area can be divided into different hygiene zones based on a hygiene risk assessment. hygiene risk levels can be distinguished. A distinction is often made between zones with a low, medium or high hygiene risk. The basis of the hygiene risk assessment is not only the consideration of contaminants but also the reflection of possible transmission paths into the food (transmission vectors).
immediate hygiene area	Part of the hygiene area, which includes the installation area of the machine system as well as the adjacent areas that are required to allow cleaning of the machine system.
	Note 1: The installation area of the machine system must not contain any fixtures (e.g. drains, gutters) whose cleaning is hindered by the machine's set-up.
	Note 2: Above open areas of the machine system, there shall be no fixtures over which a contamination (e.g. by foreign bodies, dust, condensation) of the product can occur.
Non-hygiene area	Area of the production environment of machine systems that is not classified as a hygiene area.
Black' area	Synonym for non-hygiene area
White area	Synonym for hygiene area
Cold area	Production area not characterised by process-related increased ambient temperatures
	Note: a further classification of the cold area according to temperature ranges is possible. For classification criteria s. Section "Characterisation temperature ranges".

Warm area	Production area characterised by process-related increased ambient temperatures
Wet area	Production area that is wet cleaned
Dry area	Production area that is cleaned dry
ATEX-Zone (ATEX-area)	Production area with explosive atmosphere
	Note: The ATEX zone can be classified according to applicable directives and standards and, if necessary, further subdivided according to this classification.

Characterisation machine areas	
machine system	Machines and systems with defined system limits in relation to the insertion of processed goods (packaged goods and/or packaging materials/packaging aids), operating materials, the delivery of application units, waste or rejects.
	source DIN 8743:2014
food area	machine and machine components surfaces which are exposed to food or from which food or other materials can drain, drip, diffuse or be drawn into the food Source: EN 1672-2:2021
splash area	area composed of surfaces on which part of the food can splash or flow along under intended conditions of use and does not return into the food Note 1 to entry: Part of the food in the splash area is no more food according to Article 2 of Regulation (EC) No. 178/2002
	Source: EN 1672-2:2021
non-food area	any area other than food area or splash area
	Source: EN 1672-2:2021
surfces for direct product contact	Machine surface, intended for direct contact with the food or its ingredients.
surfaces for indirect contact	Machine surfaces, intended for contact with product-contacting surfaces of food contact materials and articles, but not for direct product contact.
	Note: Example: Contact with product-contacting surfaces of packaging materials that are subsequently filled.

General	
information for use	protective measure consisting of communication links (for example, text, words, signs, signals, symbols, diagrams) used separately or in combination, to convey information to the user (according to DIN ISO EN 12100 (2011) Note 1: The requirements forthe information for use are specified in section 6.4. of the standard.

	Note 2: The instruction handbook is part of the information for use.
instruction handbook	Part of information for use provided to the machine user by the machine manufacturer, which contains instructions and notes related to the use of the machine in all its life phases. (according to DIN ISO EN 20607)
cleanable	designed and constructed so that soils can be removed (source: EN 1672-2:2020)
easily cleanable	designed and constructed to be cleanable by a simple cleaning method, where necessary after removing easily dismountable parts Note 1 to entry: Simple cleaning methods could be, e.g. vacuum cleaning, cleaning in place (CIP) or cleaning after dismantling parts without the need of tools (e.g. spanner) for dismantling. (source: EN 1672-2:2020)
easily accessable	designed and constructed to permit removal, visual inspection and replacement, where necessary after removing easily dismountable parts Note 1 to entry: Easily dismountable means without the need of tools (e.g. spanner).(source: EN 1672-2:2020)

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Acronyms used

HRA	Hygiene Risk Assessment
M	Machine manufacturer
O	Machine operator
FAT	Factory Acceptance Test (at machine manufacturer site)
SAT	Site Acceptance Test (at machine operator site)

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Referenced application-specific task: version dated Hygiene-relevant facts	According to User Requirement Specification? (yes/no)	Considered in HRA? (yes/no)	If applicable, requirements used as a substitute by the machine manufacturer:	If applicable, compensatory measures (in case of non-consideration) required? (yes/no)

Project-ID: *xxxxxxxxx*
Projectname: *yyyyyyyyy*

Projekt-ID und Projektname werden automatisch in die folgenden Checklisten übernommen

Checklist for evaluating the consideration of the application-specific task as boundary conditions the hygiene risk assessment according to EN 1672-2: 2020

Vorbemerkungen:

- The checklist below is addressed to the machine manufacturer (H).
- The following questions are aimed at clarifying whether the addressed issues are specified in the application-specific task and have been taken into account as boundary conditions in the hygiene risk assessment (HRA) of the machine manufacturer. A repetition of the contents of the application-specific task is not intended.
- If the issues addressed are not specified in the terms of reference, the machine manufacturer should present the issues on which they are based as a substitute, if necessary in the form of embedded documents.
- Particularly in the case of near-series machines, it is possible that individual aspects specified in the task could not be taken into account in the HRA. In this case, it is necessary to reflect whether and, if so, which compensatory measures are required. It is recommended to do this as early as possible in the course of the project, in consultation with the machine operator. The result of this evaluation should be recorded in the corresponding column, if necessary in the form of embedded documents.

Referenced application-specific task: version dated Hygiene-relevant facts	According to User requirement Specification? (yes/no)	Considered in HRA? (yes/no)	If applicable, requirements used as a substitute by the machine manufacturer:	If applicable, compensatory measures (in case of non-consideration) required? (yes/no)
Which (intended) uses and derived hazards for food safety were taken as a basis?				
What normal or foreseeable conditions of use were used as a basis?				
• Which procedural functional requirements were taken as a basis?				
• Which processing-relevant properties of input materials and intermediate products were used as a basis?				
• Which design-relevant properties of the process were used as a basis?				

Referenced application-specific task: **version dated** **Hygiene-relevant facts**	**According to User Requirement Specification?** (yes/no)	**Considered in HRA? (yes/no)**	**If applicable, requirements used as a substitute by the machine manufacturer:**	**If applicable, compensatory measures (in case of non-consideration) required? (yes/no)**
Which delimitation of the machine system was used as a basis?				
• Which **relevant operating modes** were identified? (e.g. food processing, cleaning, maintenance)				
• What **qualification requirements** (for operating, cleaning and maintenance personnel) were used as a basis? Do these differ for the modes of operation identified as relevant? If so, in what way?				
• Which **space limits** were used as a basis in relation to (a) the range of movement of the machine and of all its parts (e.g. access to maintenance openings); b) space requirements for persons interacting with the machine during operation, cleaning and maintenance. NOTE Space requirements can include necessary space for e.g. cleaning, removing parts. (c) Space requirement for processing goods in the immediate vicinity of the machine, which may be could lead to conflicts with a) and b)? (d) Space requirements for extensions of the machine system to be provided by the operator, which could possibly lead to conflicts with a) and b)? (e) Space requirements due to restrictions of the installation environment (e.g. existing fixtures such as columns, drains that cannot be built over, passageways etc.)?				
• What **time limits** were used as a basis in relation to (a) Life of the machine and/or some of its components?				

Referenced application-specific task: **version dated** **Hygiene-relevant facts**	**According to User Requirement Specification?** (yes/no)	**Considered in HRA? (yes/no)**	**If applicable, requirements used as a substitute by the machine manufacturer:**	**If applicable, compensatory measures (in case of non-consideration) required? (yes/no)**
(b) Recommended maintenance intervals (c) Recommended cleaning and, if applicable, disinfection/sterilisation intervals?				
• Which **requirements for cleaning** (e.g. dry or wet cleaning), the **required degree of cleaning** and **supply media relevant for cleaning and sterilisation** (e.g. CIP or SIP media) were taken as a basis ?				
Which hygiene- and cleaning-relevant boundary conditions with regard to food safety factors were taken as a basis with regard to …?				
• Variance in the initial quality of the processed goods or ingredients				
• Consumer groups (e.g. infants, sick persons, allergy sufferers)?				
• Status of the food (e.g. due to microbiological sensitivity and physical instability of the food and its source materials)?				
• Special processing requirements (e.g. Kosher or Halal)?				
What are the boundary conditions regarding the **installation environment** were taken as a basis with regard to …?				
• **Constructional conditions (e.g. hygiene zones, ...)**				
• **Climatic conditions (e.g. temperature, humidity, direct sunlight, ...)**				
• **Possible contamination by the environment** (e.g. as a result of dust exposure, by neighbouring processing operations, by cleaning the environment, by draughts...).				
Which hygiene- and cleaning-relevant boundary conditions with regard to the **electrical installation** were taken as a basis?				

Referenced application-specific task: **version dated** **Hygiene-relevant facts**	**According to User Requirement Specification?** (yes/no)	**Considered in HRA? (yes/no)**	**If applicable, requirements used as a substitute by the machine manufacturer:**	**If applicable, compensatory measures (in case of non-consideration) required? (yes/no)**
Which **residual risks** and measures derived from them to control them have been documented with regard to the significant hazards listed in EN 1672-2:2020, Chapter 4? (Reference to corresponding document, if applicable)				
If the application-specific task is changed after the above-mentioned reference date: What effects does this have on the constructive design?				

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Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release

Project-ID: xxxxxxxxx
Projectname: yyyyyyyyy

Checklist for the evaluation of HD requirements for the food area according to EN 1672-2:2020

Introduction:

The following checklist is based on the requirements of EN 1672-2:2020 for the food area.

For all devices/machine elements mounted in a machine for construction materials, surfaces, connections, etc. requirements for the food area will apply unless these devices/machine elements have not been attributed to the splash area or the non-food area. (Mounted devices/machine elements attributable to the splash area or the non-food area are to be evaluated according to the requirements for these areas).

As far as possible, the checklist refers to the relevant passages of EN 1672-2:2020 with regard to the respective requirement. For the application of the checklist, consultation of the standard is therefore indispensable.

The verification of documents (such as material certificates or test protocols) may be required to verify the fulfilment of the respective requirement. In this case, the non-availability of the corresponding documents leads to the non-fulfilment of the requirement.

It is recommended to attach the required documents to the 'information for use' or to include notes in the 'information for use' on how to request for these documents for the purpose of requirement evaluation.

Requirements that are not relevant for the machine system under consideration are to be marked accordingly in column 2.

Deviations from the relevant requirements are to be indicated in column 2 and briefly outlined in column 3. If several deviations are found, it is recommended to number them consecutively.

In case of identified deviations from the relevant requirements, references to compensatory measures to control residual hygiene risks should be inserted in column 4, preferably in the form of references to the user information. Notes and explanations on this can be entered in column 5. If more space is required, it is recommended to do this in the form of embedded documents.

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
	(yes/no/not relevant)	(in keywords)	(preferably reference to corresponding place in the 'information for use')	Notes, explanations, further documents, design adjustments agreed between machine manufacturer **M** and machine operator **O**, if applicable.	(signature to indicate release)	Notes, explanations, further documents	(signature to indicate release)

Design-check carried out	date	sign **M**	sign **O**

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
check of design changes and design-freeze carried out:	date	sign **M**	sign **O**				
Execution-check (FAT) carried out	date	sign **M**	sign **O**				
change audit and release execution	date	sign **M**	sign **O**				

Delimitation of the food area of the machine system							
• Does the machine manufacturer have documentation of the delimnation?							
• Is there consensus between **M** and **O** regarding the delimination documented by **M**?							
Do the materials of construction used meet the requirements of EN 1672-2: 2020 chapters 5.2.1 and 5.2.2, in particular with regard to							
• Suitability for the intended use under normal or foreseeable conditions of use?							
• the fulfilment of the general requirements for material surfaces according to section 5.2.1?							
• the fulfilment of the requirements specific to the food area according to section 5.2.2?							
· Information in instruction handbook about unsuitable operating conditions, cleaning procedures and cleaning and disinfecting agents? (section 5.2.1)							
• Existing declarations of compliance for materials covered by specific measures according to Regulation (EC) No 1935/2004 Art. 5?							
• Existing declarations of conformity for materials covered by national specific measures applicable to the place of installation of the machine system according to Regulation (EC) No 1935/2004 Art. 6?							
• If applicable, further material certificates or declarations of conformity relevant to the installation site of the machine system. (If applicable:Explain in notes column)							
Remark:							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
DIN 10528 (2017) "Food hygiene - Guidance for the selection of materials intended to come into contact with foodstuffs - General principles" provides an overview of requirements for materials for use in the food area for the installation site Germany.							
Evaluation of the constructive design of the food area							
Does the finish of the surfaces comply with the requirements ofEN 1672-2:2020 chapter 5.3.2.1 in particular with regard to							
• **Absence of crevices**?							
• **Surface roughness**? Are there any special (additional) requirements for the surface topography?							
• **Drainability**?							
• **Design of corners formed from two surfaces** (dihedral angle)**?**							
• **Design of corners formed by three or more surfaces** (dihedral angles)?							
• Execution of **flush surface connections**?							
• Execution of **overlapping surface connections**?							
Does the **design of the joints** comply with the requirements of EN 1672-2:2020 chapter 5.3.2.2 in particular with regard to							
• **Evaluation of avoidability?**							
· **permanent joints (**EN 1672-2:2020 section 5.3.2.2.2)?							
• **dismountable joints**? o is **sealing** required? (always required if not subject to routine dismantling) o **joints subjected to routine dismantling**: Is information on dismantling, cleaning and, if necessary, disinfection frequencies and procedures provided in the operating instructions? o Does the **design of the sealing points** meet the requirements of EN 1672-2:2020 section 5.3.2.2.3?							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
o Does the **sealant** meet the requirements for materials and surfaces? o **Disassembling of sealing constructions:** Does the instruction handbook contain detailed guidance (instructions) for disassembly, cleaning and assembly? o Does the instruction handbook give **data or methods for the verification of the material characteristics** related to the requirements for the replacement of the seals?							
Does the **design of the fasteners** comply with the requirements of EN 1672-2:2020 section 5.3.2.3 in particular with regard to							
• **evaluating the inevitability of their use**?							
• the fulfilment of the relevant requirements of sections 5.2.2 and 5.3.2.1.1 of EN 1672- 2:2020 for **materials and surfaces**?							
• of the information provided in section 5.3.2.3.1. on **design features** of the fasteners?							
• **fasteners embedded in a counter-sunk spot-face**? (section 5.3.2.3.2)							
• the design of **pin or bolt connections** (e.g. for connection to drive spindles)? (section 5.3.2.3.3)							
• accessability for **visual inspection**?							
• **cleaning instructions** in the instruction handbook?							
Does the **design of the (product and media) drainages** comply with the requirements of EN 1672-2: 2020 section 5.3.2.4, in particular with regard to							
• preferably **self-draining containers?**							
• **self-draining pipes**?							
• **self-draining of pumps** (including required installation instruction in the instruction handbook)?							
Dead spaces - Bearings - Shaft passages							
• Have **dead spaces** been avoided in accordance with the requirements of EN 1672-2:202 section 5.3.2.5?							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
• Does **design of the bearings** comply with the requirements of EN 1672-2:2020section 5.3.2.6?							
• Does the **design of the shaft passages with dynamic sealing** (e.g. shaft sealing) comply with the requirements of EN 1672-2: 2020 section 5.3.2.7?							
Do **lubricants and other hazardous substances** comply with the requirements of EN 1672-2: 2020 section 5.3.2.8 in particular with regard to							
• **evaluating the inevitability of their use**?							
• the correspondence of the **requirements for lubricants** of EN ISO 21469:2006?							
• the equivalence of the **requirements** of EN ISO 21469:2006 **for other hazardous substances** used (where applicable)?							
Does the design of the lubrication zones comply with the requirements of EN 1672-2:2020 section 5.3.2.9 in particular with regard to							
• **Placement of the lubrication zones** outside the food area?							
• **Design of the lubricant outlets?**							
• **Marking of the inlet points?**							
• **Avoidance of overlubrication?**							
• If applicable, **explanation of the technical unavoidability** of placing lubrication points within the food area?							
Does the **design of the measuring instruments and sampling devices** comply with the requirements of EN 1672-2:2020 section 5.3.2.10 in particular with regard to							
• Evaluation of the **need for placement in the food area**?							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
• fulfilment of the relevant requirements of sections 5.2.2 and 5.3.2 of EN 1672-2: 2020?							
Does the design of the **panels, covers, doors, guards and their fastening systems** comply with the requirements of EN 1672-2:2020 section 5.3.2.11 in particular with regard to							
• Evaluation of the **need for placement in the food area**?							
• fulfilment of the relevant requirements of sections 5.2.2 and 5.3.2 of EN 1672-2: 2020 for the food area?							
• the general, not food-area-specific requirements from EN 1672-2: 2020 section 5.3.2.11							
Does the **design of the control cabinet and junction box** comply with EN 1672-2:2020 section 5.3.2.12 in particular with regard to							
• evaluating the need for placement in the food area?							
the fulfilment of the relevant requirements of sections 5.2.2 and 5.3.2 of EN 1672-2 for the parts involved in the food area?							
• the sealing of the control cabinet against the food area?							
• the general, not food areaspecific r-equirements for the design of control devices?							
• the general, not food-area-specific requirements for the design of cable glands?							
the general, not food-area-specific requirements for the design of turn-locks for control cabinets?							
• the general, not food-area-specific requirements for the design of bow and rotary handles?							
Does the **insulation** comply with the requirements of EN 1672-2:2020 section 5.3.2.13, especially with regard to							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
• evaluation of the **need for placement in the food area**?							
· the fulfilment of the relevant requirements of sections 5.2.2 and 5.3.2 of EN 1672-2:2020 for the parts involved in the food area?							
• the general, not food-area-specific requirements for insulation design?							
Does the **design of the installed valves** correspond							
• relevant requirements of sections 5.2.2 and 5.3.2 of EN 1672-2:2020 for area allocated to the food area?							
• With regard to installation, do the requirements of section 5.3.2.4 (drainage) apply? (Including corresponding installation instructions in the instruction handbook)							
• The requirement of cleanability of all product-exposed surfaces (by appropriate switching of the valve during cleaning)? (Including documentation of the required circuits in the instruction handbook).							
Design of built-in parts (e.g. sensors, spray heads)							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
• Does the design of **built-in parts (e.g. sensors, spray heads)** with regard to the surfaces attributable to the food area comply with the relevant requirements of sections 5.2.2 and 5.3.2 of EN 1672-2:2020?							
Does the **design of motors** in the food area comply with the requirements of section 5.3.6.2 of EN 1672-2:2020, in particular with regard to							
• evaluation of the **need for placement in the food area**?							
• fulfilment of the relevant requirements of sections 5.2.2 and 5.3.2 of EN 1672-2: 2020?							
• the requirements for **guiding the air flow** from cooling fans?							
· the requirement to **avoid fan openings** in the food and splash areas? (Section 5.3.6.5)							
Does the design of supply systems (such as cables, pipes and connections) in the food area comply with the requirements from sections 5.3.6.3 and 5.3.6.4 of EN 1672-2:202, in particular with regard to							
• evaluation of the **need for placement in the food area**?							
• fulfilment of the relevant requirements of sections 5.2.2 and 5.3.2 of EN 1672-2: 2020?							
• the use of preferably open type trays and supports or sealed hollow profiles?							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
• avoiding bundling of flexible cables and pipes							
ventilation openings and orientation of airflow from ventilation?							
· Does the orientation of the air flow from ventilation comply with the requirements of section 5.3.6.5 of EN 1672-2:2020?							
• Is the requirement to avoid ventilation openings in the food and splash areas fulfilled? (Section 5.3.6.5)							
Does the **design of hinges** in the food area comply with the requirements of section 5.3.6.6 of EN 1672-2:2020, in particular with regard to							
• evaluation of the **need for placement in the food area**?							
• fulfilment of the relevant requirements of sections 5.2.2 and 5.3.2 of EN 1672-2: 2020?							
the requirements for easy cleaning and easy accessibility? (If parts need to be removed, they must be easily detachable, i.e. without tools).							
• the design for easy disassembly and sealing of moving parts?							
• minimum distance between hinges?							
Do the markings (according to EN ISO 12100:2010, 6.4.4 a) and b)) as well as pictograms and warnings for the safe use of the machine (according to EN ISO 12100:2010, 6.4.4 c)) comply with the requirements of section 6.1 of EN 1672-2:2020, in particular with regard to							
• evaluation of the **need for placement in the food area**?							
• fulfilment of the relevant requirements of sections 5.2.2 and 5.3.2 of EN 1672-2: 2020?							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
the acceptability of the design for application in the food area?							
Distance and accessibility for cleaning							
· Do the distance and accessibility for cleaning comply with the general requirements of EN 1672-2:2020 section 5.3.5.1, especially with regard to the required information on installation in the instruction handbook? Is this information compatible with the space limitations shown in the requirements specification?							
· Do the distance and accessibility for cleaning comply with the requirements of EN 1672-2:2020 section 5.3.5, in particular also in relation to the ergonomic design principles for machines according to EN 1005-2:2003 + A1:2008, EN 1005-3:2002+A1:2008 and EN 1005-4:2005+A1:2008?							

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Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccordin g to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release

Project-ID: xxxxxxxxx
Projectname: yyyyyyyyy

Checklist for evaluating the HD requirements for the splash area

Introduction:

The following checklist is based on the requirements of EN 1672-2:2020 for the splash area.

The design requirements for the food area apply, unless weakened requirements are explicitly stated in section 5.2.3 and section 5.3.3.

For all devices/machine elements mounted in a machine for construction materials, surfaces, connections, etc. requirements for thesplash area will apply unless these devices/machine elements have not been attributed to the food area or the non-food area. (Mounted devices/machine elements attributable to the food area or the non-food area are to be evaluated according to the requirements for these areas).

As far as possible, the checklist refers to the relevant passages of EN 1672-2:2020 with regard to the respective requirement. For the application of the checklist, consultation of the standard is therefore indispensable.

The verification of documents (such as material certificates or test protocols) may be required to verify the fulfilment of the respective requirement. In this case, the non-availability of the corresponding documents leads to the non-fulfilment of the requirement.

It is recommended to attach the required documents to the 'information for use' or to include notes in the 'information for use' on how to request for these documents for the purpose of requirement evaluation.

Requirements that are not relevant for the machine system under consideration are to be marked accordingly in column 2.

Deviations from the relevant requirements are to be indicated in column 2 and briefly outlined in column 3. If several deviations are found, it is recommended to number them consecutively.

In case of identified deviations from the relevant requirements, references to compensatory measures to control residual hygiene risks should be inserted in column 4, preferably in the form of references to the user information. Notes and explanations on this can be entered in column 5. If more space is required, it is recommended to do this in the form of embedded documents.

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccordin g to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
	(yes/no/not relevant)	(in keywords)	(preferably reference to corresponding place in the 'information for use')	Notes, explanations, further documents, design adjustments agreed between machine manufacturer **M** and machine operator **O**, if applicable.	(signature to indicate release)	Notes, explanations, further documents	(signature to indicate release)
Design-check carried out	date	sign **M**	sign **O**				
check of design changes and design-freeze carried out:	date	sign **M**	sign **O**				
Execution-check (FAT) carried out	date	sign **M**	sign **O**				

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
change audit and release execution	date	sign **M**	sign **O**				
Delimitation of the splash area of the machine system							
• Does the machine manufacturer have documentation of the delimnation?							
• Is there consensus between **M** and **O** regarding the delimination documented by **M**?							
Do the materials used meet the requirements of EN 1672-2:2020 section 5.2.1 and section 5.2.3, in particular with							
• Suitability for the intended use under normal or foreseeable conditions of use?							
• the fulfilment of the general requirements for material surfaces according to section 5.2.1?							
• the fulfilment of the requirements specific to the splash area according to section 5.2.3?							
· Information in the instruction handbook about unsuitable operating conditions, cleaning procedures and cleaning agents and disinfectants?							
Note: DIN 10528 (2017) "Food hygiene - Guidance for the selection of materials intended to come into contact with foodstuffs - General principles" provides an overview of requirements for materials for use in the food area for the installation site Germany.							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
Preliminary remark: Unless otherwise specified in this standard, the splash area shall be designed and constructed to meet the same requirements as the food area. As the food does not return to the food area, the technical design criteria may be less stringent than in the food. Note: It is recommended to start from the requirements for the food area and to document and, if necessary, justify deviations from them.							
Does the **finish of the surfaces** comply with the requirements of EN 1672-2:2020? o The corresponding requirements for the food area according to chapter 5.3.2.1 apply.□ o With regard to surface roughness, the requirements can be weakened.□ o With regard to the design of corners (dihedral angles), designs in accordance with Section 5.3.3.3 are permissible. Are the requirements fulfilled with regard to							
• **Absence of crevices?**							
• **Surface roughness**? Have the requirements been weakened compared to the requirements for the food area, if applicable?							
• **Drainability**							
• **Design of corners formed from two surfaces** (dihedral angle)**?**							
• **Design of corners formed by three or more surfaces** (dihedral angles)?							
• Execution of **flush surface connections**?							
• Execution of **overlapping surface connections**?							
Does the design of the connections comply with the requirements of EN 1672-2:2020? • The corresponding requirements for the food area apply • Connection by welding or gluing, connection by profile: As a mitigation, the designs set out in sections 5.3.3.3 and 5.3.3.4 are also permissible. • Fasteners: By way of derogation, the designs set out in section 5.3.3.5 are also permissible **Are the requirements from chapter 5.3.2.2 fulfilled, especially with regard to**							
• **Evaluation of avoidability?**							
• **Permanent joints** (EN 1672-2:2021 section 5.3.2.2.2)**?**							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
• **dismountable joints** (EN 1672-2:2020 section 5.3.2.2.3? o **Is sealing required**? o **joints subjected to routine dismantling**: Is information on dismantling, cleaning and, if necessary, disinfection frequencies and procedures provided in the operating instructions? o Does the **design of the sealing points** meet the requirements of EN 1672-2:2020 section 5.3.2.2.3? o Does the **sealant** meet the requirements for materials and surfaces? o **Disassembling of sealing constructions:** Does the instruction handbook contain detailed guidance (instructions) for disassembly, cleaning and assembly? o Does the instruction handbook give **data or methods for the verification of the material characteristics** related to the requirements for the replacement of the seals?							
Does the design of the fasteners comply with the requirements of EN 1672-2:2020? • The corresponding requirements for the food area apply • Fasteners: By way of derogation, the designs set out in section 5.3.3.5 are also permissible Are the requirements from chapter 5.3.2.3 fulfilled, especially with regard to							
• **evaluating the inevitability of their use**?							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
• the fulfilment of the relevant requirements of sections 5.2.2 and 5.3.2.1.1 of EN 1672- 2:2020 for **materials and surfaces**?							
• of the information provided in section 5.3.2.3.1. on **design features** of the fasteners?							
• **fasteners embedded in a counter-sunk spot-face**? (section 5.3.2.3.2)							
• the design of **pin or bolt connections** (e.g. for connection to drive spindles)?							
• accessability for **visual inspection**?							
• **cleaning instructions** in the instruction handbook?							
Does the **design of the (product and media) drainages** comply with the requirements of EN 1672-2: 2020? o If applicable: The relevant requirements for the food area apply. o Surfaces are to be designed in such a way that product is guided away from the food area Are the requirements from chapter 5.3.2.4 fulfilled, especially with regard to							
• preferably **self-draining containers?**							
• **self-draining pipes**?							
• **self-draining of pumps** (including required installation instruction in the instruction handbook)?							
Dead spaces - Bearings - Shaft passages • The corresponding requirements for the food area apply							
• Have **dead spaces** been avoided in accordance with the requirements of EN 1672-2:202 section 5.3.2.5?							
• Does **design of the bearings** comply with the requirements of EN 1672-2:2020section 5.3.2.6?							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
• Does the **design of the shaft passages with dynamic sealing** (e.g. shaft sealing) comply with the requirements of EN 1672-2: 2020 section 5.3.2.7?							
Do lubricants and other hazardous substances comply with the requirements of EN 1672-2: 2020? • The requirements for the food area apply Are the requirements from chapter 5.3.2.8 fulfilled, especially with regard to							
• **evaluating the inevitability of their use**?							
• the correspondence of the **requirements for lubricants** of EN ISO 21469:2006?							
• the equivalence of the **requirements** of EN ISO 21469:2006 **for other hazardous substances** used (where applicable)?							
Does the design of the lubrication zones comply with the requirements of EN 1672-2:2020? • The corresponding requirements for the food area apply Are the requirements from chapter 5.3.2.9 fulfilled, especially with regard to							
• **Placement of the lubrication zones** outside the food area?							
• **Design of the lubricant outlets?**							
• **Marking of the inlet points?**							
• **Avoidance of overlubrication?**							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
• If applicable, **explanation of the technical unavoidability** of placing lubrication points within the food area?							
Does the design of the measuring instruments and sampling devices comply with the requirements of EN 1672-2:2020 sectionl 5.3.2.10 in relation to the areas associated with the splash area, in particular in relation to							
• compliance with the relevant requirements of sections 5.2.3 and 5.3.3 of EN 1672-2:2020?							
Does the **design of the panels, covers, doors, guards and their fastening systems** comply with the requirements of EN 1672-2:2020 • The requirements for the food area apply • With regard to construction materials and construction, the requirements for the splash area apply. Are the requirements in section 5.3.2.11 are met, in particular with regard to							
• the fulfilment of the relevant requirements of clauses 5.2.3 and 5.3.3 of EN 1672-2:2020 for the parts involved in the splash area ?							
• the general, non-food specific requirements from EN 1672-2:2020 section 5.3.2.11?							
Does the **design of the control cabinet and junction box** comply with EN 1672-2:2020 • The requirements for the food area apply • With regard to construction materials and construction, the requirements for the splash area apply. Are the requirements in section 5.3.2.12 are met, in particular with regard to							
• the fulfilment of the relevant requirements of clauses 5.2.3 and 5.3.3 of EN 1672-2:2020 for the parts involved in the splash area ?							
• the sealing of the control cabinet against the food area?							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
• the general, not food-area-specific requirements for the design of control devices?							
• the general, not food-area-specific requirements for the design of cable glands?							
the general, not food-area-specific requirements for the design of turn-locks for control cabinets?							
• the general, not food-area-specific requirements for the design of bow and rotary handles?							
Does the **insulation** comply with the requirements of EN 1672-2:2020 • The requirements for the food area apply • With regard to construction materials and construction, the requirements for the splash area apply. Are the requirements in section 5.3.2.13 are met, in particular with regard to							
• the fulfilment of the relevant requirements of clauses 5.2.3 and 5.3.3 of EN 1672-2:2020 for the parts involved in the splash area ?							
• the general, not food-area-specific requirements for **insulation design**?							
Does the design of the installed valves comply with the requirements of EN 1672-2:2020? • The requirements for the food area apply • With regard to construction materials and construction, the requirements for the splash area apply. Are the requirements met, in particular with regard to							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
• With regard to the areas to be assigned to the splash area, the relevant requirements of sections 5.2.3 and 5.3.3 of EN 1672-2:2020?							
Design of built-in parts (e.g. sensors, spray heads)							
• Does the design of built-in parts (e.g. sensors, spray heads) with regard to the surfaces attributable to the splash area comply with the relevant requirements of sections 5.2.3 and 5.3.3 of EN 1672-2:2020?							
Does the **design of motors** in the splash area comply with the requirements of section 5.3.6.2 of EN 1672-2:2020, in particular with regard to							
• the fulfilment of the relevant requirements of clauses 5.2.3 and 5.3.3 of EN 1672-2:2020 for the parts involved in the splash area ?							
• the requirements for **guiding the air flow** from cooling fans?							
Does the design of supply systems (such as cables, pipes and connections) in the splash area comply with the requirements from sections 5.3.6.3 and 5.3.6.4 of EN 1672-2:2020, in particular with regard to							
• the fulfilment of the relevant requirements of clauses 5.2.3 and 5.3.3 of EN 1672-2:2020 for the parts involved in the spray area ?							
• the use of preferably open type trays and supports or sealed hollow profiles?							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
• avoiding bundling of flexible cables and pipes							
ventilation openings and orientation of airflow from ventilation?							
· Does the orientation of the air flow from ventilation comply with the requirements of section 5.3.6.5 of EN 1672-2:2020?							
• Is the requirement to avoid ventilation openings in the food and splash areas fulfilled? (Section 5.3.6.5)							
Does the **design of hinges** in the splash area comply with the requirements of section 5.3.6.6 of EN 1672-2:2020, in particular with regard to							
• evaluation of the **need for placement in the splash area**?							
• the fulfilment of the relevant requirements of clauses 5.2.3 and 5.3.3 of EN 1672-2:2020 for the parts involved in the spray area ?							
• the requirements for cleanability and easy accessibility?							
• minimum distance between hinges?							
Do the markings (according to EN ISO 12100:2010, 6.4.4 a) and b)) as well as pictograms and warnings for the safe use of the machine (according to EN ISO 12100:2010, 6.4.4 c)) comply with the requirements of section 6.1 of EN 1672-2:2020, in particular with regard to							
• the fulfilment of the relevant requirements of clauses 5.2.3 and 5.3.3 of EN 1672-2:2020 for the parts involved in the spray area ?							
· the acceptability of the design?							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
Distance and accessibility for cleaning							
· Do the **distance and accessibility for cleaning** comply with the general requirements of EN 1672-2:2020 section 5.3.5.1, especially with regard to the required information on installation in the instruction handbook? Is this information compatible with the space limitations shown in the requirements specification?							
· Do the distance and accessibility for cleaning comply with the requirements of EN 1672-2:2020 section 5.3.5, in particular also in relation to the **ergonomic design principles for machines** according to EN 1005-2:2003 + A1:2008, EN 1005-3:2002+A1:2008 and EN 1005-4:2005+A1:2008?							

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Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release

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Checklist for the evaluation of HD requirements for the non-food area

Introduction:

The following checklist is based on the requirements of EN 1672-2:2020 for the non-food area.

The design requirements for the splash area apply, unless weakened requirements are explicitly stated in section 5.2.4 and section 5.3.4. (Please note that for the splash area, reference is made to the requirements for the food area as far as no weakened requirements are explicitly stated in section 5.2.3 and section 5.3.3)

For all devices/machine elements mounted in a machine for construction materials, surfaces, connections, etc. requirements for the non-food area will apply unless these devices/machine elements have not been attributed to the food area or the splash area. (Mounted devices/machine elements attributable to the food area or the splash area are to be evaluated according to the requirements for these areas).

As far as possible, the checklist refers to the relevant passages of EN 1672-2:2020 with regard to the respective requirement. For the application of the checklist, consultation of the standard is therefore indispensable.

The verification of documents (such as material certificates or test protocols) may be required to verify the fulfilment of the respective requirement. In this case, the non-availability of the corresponding documents leads to the non-fulfilment of the requirement.

It is recommended to attach the required documents to the 'information for use' or to include notes in the 'information for use' on how to request for these documents for the purpose of requirement evaluation.

Requirements that are not relevant for the machine system under consideration are to be marked accordingly in column 2.

Deviations from the relevant requirements are to be indicated in column 2 and briefly outlined in column 3. If several deviations are found, it is recommended to number them consecutively.

In case of identified deviations from the relevant requirements, references to compensatory measures to control residual hygiene risks should be inserted in column 4, preferably in the form of references to the user information. Notes and explanations on this can be entered in column 5. If more space is required, it is recommended to do this in the form of embedded documents.

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
	(yes/no/not relevant)	(in keywords)	(preferably reference to corresponding place in the 'information for use')	Notes, explanations, further documents, design adjustments agreed between machine manufacturer **M** and machine operator **O**, if applicable.	(signature to indicate release)	Notes, explanations, further documents	(signature to indicate release)
Design-check carried out	date	sign **M**	sign **O**				
check of design changes and design-freeze carried out:	date	sign **M**	sign **O**				
Execution-check (FAT) carried out	date	sign **M**	sign **O**				

Requirement	**Requirement fullfilled?**	**Deviation from requirement, if applicable**	**If necessary, compensatory measuresaccording to HRA**	**Design-Check**	**Design-Check** Release	**Execution-Check**	**Execution-Check** Release
change audit and release execution	date	sign **M**	sign **O**				
Delimitation of the non-food area of the machine system							
• Does the machine manufacturer have documentation of the delimnation?							
• Is there consensus between **M** and **O** regarding the delimination documented by **M**?							
• Which internal surfaces of closed parts and those parts not exposed under normal conditions of use are not subject to the cleanability requirement?							
Do the materials used meet the requirements of EN 1672-2:2020 section 5.2.1 and section 5.2.4, in particular with							
• Suitability for the intended use under normal or foreseeable conditions of use?							
• the fulfilment of the general requirements for material surfaces according to section 5.2.1?							
• the fulfilment of the requirements specific to the non-food area according to section 5.2.4?							
· Information in the instruction handbook about unsuitable operating conditions, cleaning procedures and cleaning agents and disinfectants?							
Does the design comply with the requirements of EN 1672-2:2020 section 5.3.4 for the non-food sector? Remarks: • The technical design criteria for non-food areas may be less stringent than in the spray area. • For dry cleaning, the technical design criteria for non-food areas may be less stringent than for wet cleaning.							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
Note: It is recommended to start from the requirements for the splash area and to document and, if necessary, justify deviations from them. Are the requirements fulfilled with regard toSind die Anforderungen erfüllt in Bezug auf							
• **Absence of crevices**?							
• **Design of corners formed from two surfaces** (dihedral angle)**?**							
• **Design of corners formed by three or more surfaces** (dihedral angles)?							
• Execution of **flush surface connections**?							
• Execution of **overlapping surface connections**?							
· design of **permanent joints**							
· design of **dismountable joints**							
· design of **fasteners**							
· design of the **(product and media) drainages** o For **wet cleaning**: The requirements from chapter 5.3.2.4 of EN 1672-2:2020 apply with regard to discharge							
· **Dead spaces - Bearings - Shaft passages**							
Do lubricants and other hazardous substances comply with the requirements of EN 1672-2: 2020? • The requirements for the splash area apply Are the requirements from chapter 5.3.3.6 fulfilled, especially with regard to							
• the correspondence of the **requirements for lubricants** of EN ISO 21469:2006?							
• the equivalence of the **requirements** of EN ISO 21469:2006 **for other hazardous substances** used (where applicable)?							

Requirement	**Requirement fullfilled?**	**Deviation from requirement, if applicable**	**If necessary, compensatory measuresaccording to HRA**	**Design-Check**	**Design-Check** Release	**Execution-Check**	**Execution-Check** Release
Does the design of the lubrication zones comply with the requirements of EN 1672-2:2020? • The corresponding requirements for the food area apply Are the requirements from chapter 5.3.2.9 fulfilled, especially with regard to							
• **Placement of the lubrication zones** outside the food area?							
• **Design of the lubricant outlets?**							
• **Marking of the inlet points?**							
• **Avoidance of overlubrication?**							
Does the **design of the measuring instruments and sampling devices** comply with the requirements of EN 1672-2:2020 sectionl 5.3.2.10 in relation to the areas associated with the non-food area, in particular in relation to							
• compliance with the relevant requirements of sections 5.2.4 and 5.3.4 of EN 1672-2:2020?							
Does the **design of the panels, covers, doors, guards and their fastening systems** comply with the requirements of EN 1672-2:2020 • The requirements for the food area apply • With regard to construction materials and construction, the requirements for the non-food area apply. Are the requirements in section 5.3.2.11 are met, in particular with regard to							
• the fulfilment of the relevant requirements of clauses 5.2.4 and 5.3.4 of EN 1672-2:2020 for the parts involved in the non-food area area ?							
• the general, non-food specific requirements from EN 1672-2:2020 section 5.3.2.11?							
Does the **design of the control cabinet and junction box** comply with EN 1672-2:2020 • The requirements for the food area apply • With regard to construction materials and construction, the requirements for the non-food area apply.							

Requirement	**Requirement fullfilled?**	**Deviation from requirement, if applicable**	**If necessary, compensatory measuresaccording to HRA**	**Design-Check**	**Design-Check** Release	**Execution-Check**	**Execution-Check** Release
Are the requirements in section 5.3.2.12 are met, in particular with regard to							
• the fulfilment of the relevant requirements of clauses 5.2.4 and 5.3.4 of EN 1672-2:2020 for the parts involved in the non-food area ?							
• the sealing of the control cabinet against the food area?							
• the general, not food-area-specific requirements for the design of control devices?							
• the general, not food-area-specific requirements for the design of cable glands?							
the general, not food-area-specific requirements for the design of turn-locks for control cabinets?							
• the general, not food-area-specific requirements for the design of bow and rotary handles?							
Does the **insulation** comply with the requirements of EN 1672-2:2020 • The requirements for the food area apply • With regard to construction materials and construction, the requirements for the non-food area apply. Are the requirements in section 5.3.2.13 are met, in particular with regard to							
• the fulfilment of the relevant requirements of clauses 5.2.4 and 5.3.4 of EN 1672-2:2020 for the parts involved in the non-food area ?							
• the general, not food-area-specific requirements for **insulation design**?							
Entspricht die **Ausführung der eingebauten Ventile den Anforderungen aus der DIN EN1672-2:2021-05?** • Es gelten die entsprechenden Anforderungen für den Lebensmittelbereich							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
Sind die Anforderungen erfüllt, insbesondere in Bezug auf							
• the fulfilment of the relevant requirements of clauses 5.2.4 and 5.3.4 of EN 1672-2:2020 for the parts involved in the non-food area ?							
Design of built-in parts (e.g. sensors, spray heads)							
• Does the design of built-in parts (e.g. sensors, spray heads) with regard to the surfaces attributable to the splashnon-food area comply with the relevant requirements of sections 5.2.4 and 5.3.4 of EN 1672-2:2020?							
Does the **design of motors** in the non-food area comply with the requirements of section 5.3.6.2 of EN 1672-2:2020, in particular with regard to							
• the fulfilment of the relevant requirements of clauses 5.2.4 and 5.3.4 of EN 1672-2:2020 for the parts involved in the non-food area ?							
• the requirements for **guiding the air flow** from cooling fans?							
Does the design of supply systems (such as cables, pipes and connections) in the non-food area comply with the requirements from sections 5.3.6.3 and 5.3.6.4 of EN 1672-2:2020, in particular with regard to							
• the fulfilment of the relevant requirements of clauses 5.2.4 and 5.3.4 of EN 1672-2:2020 for the parts involved in the non-food area ?							
• the use of preferably open type trays and supports or sealed hollow profiles?							
• avoiding bundling of flexible cables and pipes							
ventilation openings and orientation of airflow from ventilation?							

Requirement	**Requirement fullfilled?**	**Deviation from requirement, if applicable**	**If necessary, compensatory measuresaccording to HRA**	**Design-Check**	**Design-Check** Release	**Execution-Check**	**Execution-Check** Release
· Does the orientation of the air flow from ventilation comply with the requirements of section 5.3.6.5 of EN 1672-2:2020?							
• Is the requirement to avoid ventilation openings in the food and splash areas fulfilled? (Section 5.3.6.5)							
Does the **design of hinges** in the non-food area comply with the requirements of section 5.3.6.6 of EN 1672-2:2020, in particular with regard to							
• the fulfilment of the relevant requirements of clauses 5.2.4 and 5.3.4 of EN 1672-2:2020 for the parts involved in thenon-food?							
• the requirements for cleanability and easy accessibility?							
· minimum distance between hinges?							
Do the **markings** (according to EN ISO 12100:2010, 6.4.4 a) and b)) as well as pictograms and warnings for the safe use of the machine (according to EN ISO 12100:2010, 6.4.4 c)) comply with the requirements of section 6.1 of EN 1672-2:2020, in particular with regard to							
• the fulfilment of the relevant requirements of clauses 5.2.4 and 5.3.4 of EN 1672-2:2020 for the parts involved in the non-food area ?							
· the acceptability of the design?							
Do **distance and accessibility for cleaning** comply with the requirements of EN1672-2:2020 section 5.3.5, in particular							

Requirement	Requirement fullfilled?	Deviation from requirement, if applicable	If necessary, compensatory measuresaccording to HRA	Design-Check	Design-Check Release	Execution-Check	Execution-Check Release
· relating to **ergonomic design principles** for machines with manual handling or for mobile machinery EN 1005-2:2003+A1:2008, EN 1005-3:2002+A1:2008 and EN 1005-4:2005+A1:2008?							
• with regard to the **accessibility of the underside of the machine for cleaning** in accordance with sections 5.3.5.2.2 and 5.3.5.2.3?							
• with regard to the **cleanability of machine bases, feet, castors, wall and ceiling mountings** fulfilled according to section 5.3.5.2.4?							
• Do the distance and accessibility for cleaning comply with the general requirements from EN 1672-2:2020 section 5.3.5.1 in particular also with regard to the **required information on installation in the user information**. Is this information compatible with the space restrictions shown in the requirement specification?							

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Requirement	included in 'Information for use'?	Where in 'Information for use'?	Documented elsewhere? Where?	Notes / Explanations Machine manufacturer	Notes machine user	Clearance by machine user

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Projectname: yyyyyyyyy

Checklist for evaluating HD requirements for 'Information for use'

Preliminary remarks:

Information for use' and constructive design are to be evaluated in context. The 'Instruction handbook' as part of the 'Information for use' describe measures to control hygiene risks, e.g. in the form of cleaning and maintenance instructions, and describe residual hygiene risks.

Compensatory measures to control residual hygiene risks indicated during the evaluation of the constructive design should be described in the 'Information for use'.

The following checklist addresses aspects for which information can be expected in the user information according to EN 1672-2:2020. This also includes the description of technical and organisational measures, the effectiveness of which is assumed in the design of the hygienic construction as a result of the hygiene risk assessment. Insofar as the technical measure can be assigned to the machine system under consideration, the evaluation of the constructive design by means of the preceding checklists refers only to the evaluation of the hygienic constructive design, but not to the evaluation of its function.

Requirement	included in 'Information for use'? (yes/no/not relevant)	Where in 'Information for use'?	Documented elsewhere? Where?	Notes / Explanations Machine manufacturer	Notes machine user	Clearance by machine user
Does the user information comply with the requirements of chapter 6 of EN 1672-2:2020, in particular with regard to						
• **Information relating tothe intended use?** (section 6.2.2) including information on unsuitable operating conditions, cleaning procedures and cleaning agents and disinfectants (section 5.2.1)						
• **Information relating to residual hygiene risks** (section 6.2.3)**?**						
• **Information relating to hygienic Installation** (section 6.2.4)?						
• **Information relating to operator instructions** (section 6.2.5)?						
• **Information relating to disposable parts** (section 6.2.6)?						
• **Information relating to cleaning, disinfection, rinsing and inspection for cleanlinesss** (section 6.2.7), in particular with regard to o **Detergents and disinfectants** (sections 6.2.7.2 and 6.2.7.3)						

Requirement	included in 'Information for use'?	Where in 'Information for use'?	Documented elsewhere? Where?	Notes / Explanations Machine manufacturer	Notes machine user	Clearance by machine user
o **Information to utensils and supplies for cleaning** (section 6.2.7.4) o **Information related to rinsing** (section 6.2.7.4.2) o **Information relating to dismantling** (section 6.2.7.4.3) o **Information relating to cleanliness conditions and inspection for cleanliness** (section 6.2.7.4.4)						
· **Information relating to (hygienic) maintenan+A32ce** (section 6.2.8)						
User information on the removal of parts						
• Which parts are intended to be removed for cleaning? Are - in the case of the requirement for easy cleanability - the requirements for tool-free disassembly and assembly met? Are appropriate instructions for disassembly and assembly available?						
• Which parts are intended to be dismantled for the purpose of evaluating the cleaning success? In the case of the requirement for easy accessibility, are the requirements for tool-free disassembly and assembly met? Are appropriate instructions for disassembly and assembly available?						
• **Which parts are intended to be removed for maintenance?** Are appropriate instructions for disassembly and assembly available?						
(If relevant:) Have designed barriers to prevent contamination of the food area been implemented in the machine system and described in the 'Information for use' with respect to						

Requirement	included in 'Information for use'?	Where in 'Information for use'?	Documented elsewhere? Where?	Notes / Explanations Machine manufacturer	Notes machine user	Clearance by machine user
• Contamination by machine operators?						
• Contamination from the machine environment (e.g. dust, aerosols, foreign bodies etc.)?						
• Contamination by microorganisms?						
(if relevant) **Identification and removal of foreign bodies**						
• Have technical measures been implemented in the machine system and described in the 'information for use'?						
(if relevant) **Documentation automated cleaning**						
• Which **open areas** of the machine system are intended for automated cleaning? Is there an evaluation regarding possible cleaning shadows?						
• Which **closed areas** are intended for automated cleaning of the product ? Is there an evaluation regarding possible cleaning shadows?						
Documentation IP class requirements for the electrical installation						
• Are corresponding requirements and their fulfilment described in the 'Information for use'?						

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