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(FOOMA)

**General design requirements for safety
and hygiene of food processing
machinery — Part 2: General design
requirements for hygiene**

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Foreword

This Japanese Industrial Standard has been revised by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by The Japan Food Machinery Manufacturers' Association (FOOMA) with a draft being attached, based on the provision of Article 12, paragraph (1) of the Industrial Standardization Act applied *mutatis mutandis* pursuant to the provision of Article 16 of the said Act. This edition replaces the previous edition (**JIS B 9650-2** : 2011), which has been technically revised.

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JIS B 9650 series consists of the following 2 parts under the general title *General design requirements for safety and hygiene of food processing machinery* —:

Part 1 : General design requirements for safety

Part 2 : General design requirements for hygiene

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General design requirements for safety and hygiene of food processing machinery — Part 2 : General design requirements for hygiene

Introduction

This Japanese Industrial Standard corresponds to a product safety standard among the types of safety standard specified in **JIS Z 8051**, and is a type-C standard shown in Foreword of **JIS B 9700**. A methodology for risk assessment and risk reduction complies with the requirements specified in **JIS B 9700**.

In designing machinery and its auxiliary equipment used for processing and production of food (hereafter referred to as food processing machinery), risks due to food processing machinery causing harm to workers/operators, those due to food produced by machinery causing harm to health of consumers, and also those for food producers suffering economic losses due to recall, etc. of food shall be considered. **JIS B 9650** series specifies general requirements regarding safety aspects to handle harms against workers/operators, and general requirements regarding hygienic aspects to handle harms against health of consumers caused by produced food and economic damages to producers, in respective parts.

1 Scope

1.1 This Standard specifies requirements specified in **JIS B 9700** as well as the extended requirements, among general requirements for hygienic design that address the hygienic aspect of food processing machinery.

1.2 This Standard is applicable to machinery/devices of open-system or closed-system that perform a batch process or a consecutive process. It is not applicable to an integrated manufacturing system that connects and uniformly operates multiple food processing machinery having different functions in a coordinated manner.

NOTE Safety of integrated manufacturing systems is provided in **ISO 11161**.

1.3 This Standard is applicable to food processing machinery classified as industrial machinery used in business locations such as factories that mass produce commercial food or its raw materials, using a certain energy as power source and to heat and control. However, it is not applicable to food processing machinery classified as professional-use machinery used in kitchens of households, restaurants, etc.

Refer to **JIS B 9650-1** for examples of major groups of food processing machinery.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

- JIS B 9650-1 *General design requirements for safety and hygiene of food processing machinery — Part 1 : General design requirements for safety*
- JIS B 9700 *Safety of machinery — General principles for design — Risk assessment and risk reduction*
- JIS B 9705-1 *Safety of machinery — Safety-related parts of control systems — Part 1 : General principles for design*
- JIS B 9960-1 *Safety of machinery — Electrical equipment of machines — Part 1 : General requirements*
- JIS Z 9101 *Graphical symbols — Safety colours and safety signs — Part 1 : Design principles for safety signs and safety markings*
- ISO 14159 *Safety of machinery — Hygiene requirements for the design of machinery*
- ISO 21469 *Safety of machinery — Lubricants with incidental product contact — Hygiene requirements*
- ISO 3864-2 *Graphical symbols — Safety colours and safety signs — Part 2 : Design principles for product safety labels*
- ISO 3864-3 *Graphical symbols — Safety colours and safety signs — Part 3 : Design principles for graphical symbols for use in safety signs*
- IEC/IEEE 82079-1 *Preparation of information for use (instructions for use) of products — Part 1 : Principles and general requirements*

3 Terms and definitions

For the purpose of this Standard, the terms and definitions given in **JIS B 9700** and **JIS B 9650-1**, and the following apply.

3.1

hygiene

assurance that food processed, cooked and eaten/drunk according to the intended usage would not adversely affect the health of consumers, as well as structure where hygienic risks are reduced to an acceptable level

NOTE In some cases, the term “sanitary” is used to express the hygienic aspect of food processing machinery. “Sanitary” is used mainly in the U.S. as a term to express hygienic aspect of food processing machinery; however, it is not used in relevant **ISOs** including **ISO 14159**, a type-B standard.

3.2

consumer

persons and animals who finally consume food

3.3

harm (in terms of hygiene)

damages/impairments that consumers suffer due to non-conforming products in terms of hygienic quality (also referred to as health harms), or economic losses that employers suffer due to non-conforming products in terms of hygienic quality

NOTE 1 Also called as “harm on hygienic aspect” to distinguish it from “harm on safety aspect”.

NOTE 2 Examples of economic losses include the collection cost of food assessed as non-conforming in terms of hygienic quality derived from food processing machinery.

3.4

hazard (in terms of hygiene)

state of food, or biological, chemical or physical factors contained in food, which could adversely affect health and hygienic quality of food

NOTE Also called as “hazard on hygienic aspect” to distinguish it from “hazard on safety aspect”.

3.5

hygienic risk

combination of the probability of harm on hygienic aspect and the severity of harm, caused by food processing machinery

NOTE 1 This term is used to distinguish the risks in terms of labour safety and the risks in terms of hygiene, when the both are considered simultaneously.

NOTE 2 Risks in terms of labour safety (safety risks) are defined in **JIS B 9650-1**.

3.6

food contact surface

surfaces and portions of food processing machinery, to which raw materials, materials, half-finished products and foods directly or secondarily contact during food processing process, and surfaces, positions and removable parts of food processing machinery that might cause cross-contamination by the contact with part or entire body of operators or tools during processing

NOTE Refer to Figure A.1.

3.7

non-food contact surface

exposed surfaces other than those specified as food contact surfaces

NOTE Refer to Figure A.1.

3.8

food splash area

surface or positions from which part of raw materials, materials, half-finished products

and foods do not return to food contact surfaces under the intended usage condition, even if they accidentally splash and adhere to such area

NOTE Refer to Figure A.1.

3.9

disinfection

treatment to reduce the number of microorganisms on a surface or in the environment using chemical agents or physical method such as heating to the level in which the safety on hygienic aspect of food (hereafter referred to as safety of food or food safety) and the quality conformity as a product on a hygienic aspect are not impaired

NOTE 1 In the narrow sense, disinfection means to kill fungal bodies themselves. In some cases in Japan, to kill pathogenic bacteria on a surface of solid objects is referred to as antisepsis.

NOTE 2 In some cases in Japan, to kill fungal bodies themselves using the heat of 100 °C or under is called pasteurization.

NOTE 3 In some cases in Japan, “disinfection” is usually used, but “antisepsis” is also used in the treatment of food.

NOTE 4 In some cases in Japan, in the surface treatment of food processing machinery, both “disinfection” and “antisepsis” are used.

3.10

sterilization

process to remove or inactivate all microorganisms including spores and endospores

NOTE 1 “Sterilization” herein means “commercial sterilization”. “Commercial sterilization” refers to “Commercial sterility” in Code of Federal Regulations Title 21 (CFR21), Part 113 of Food and Drug Administration of the United States Department of Health and Human Service, which is a measure to inactivate all microorganisms that significantly affect the public health and to prevent stored foods from rotting under normal conditions.

NOTE 2 In the United Kingdom, sterilization means disinfection.

NOTE 3 “Sterilization” is used for both the treatment of devices and treatment of food in Japan.

3.11

aseptic process

process to use equipment which has been sterilized before use to prevent the secondary contamination by microorganisms while the equipment usage

3.12

disinfectability

property that disinfection can be conducted by an intended method

3.13

durability

property that surfaces or structures can maintain the intended function for intended usage period and usage condition

3.14

corrosion resistant materials

materials that have durability against chemical/electrochemical actions and maintain required surface characteristics, when food processing machinery and devices attached to food processing machinery (hereafter referred to as food processing machinery/devices) are used under the intended condition (behaviour of food, cleaning, disinfection, sterilization etc.) for the intended period

3.15

non-toxic

property of material that does not generate or release substances hazardous to health under the intended usage condition

3.16

non-absorbent

property of material that does not absorb contacting substances under the intended usage condition

3.17

smooth

surface roughness condition that satisfies the intended hygienic requirement

3.18

self draining

prevention of liquid retention and draining of liquid toward intended direction, by way of structure, installation method, shape and surface finish

3.19

crevice

fracture such as crack, fissure and structural gap that might allow contaminant ingress

3.20

dead space

space where food, detergent, disinfectant, contaminant etc. are retained, or space where it is difficult to completely remove them by normal cleaning operation and to recognize them with visual inspection

3.21

bond

adhesive agent to join materials, parts etc.

3.22**seal**

treatment to close opening for appropriate prevention of the ingress and pass of substances from outside and inside

3.23**contaminant**

any substances such as biological factors, chemical factors and physical factors (foreign substances) which may unintentionally contaminate food

NOTE They can impair safety of food.

3.24**contamination**

ingress of contaminants into food or food manufacturing environment, or generation of contaminants inside them

3.25**soil**

totally unnecessary substances at the places, such as food residue adhered to the surface of food processing machinery

NOTE It may or may not include microorganisms.

3.26**pest, vermin**

small animals that adversely affect the quality of food [including mammals, bird species, reptile species and insects]

3.27**cleaning**

action to remove soils to the intended level

3.28**cleaning in place**

system which automatically cleans the manufacturing lines and food processing machinery without disassembling them, using appropriately-installed closed system

3.29**cleanable**

property that the density or amount of contaminants at the intended place can be re-

duced to the target level by cleaning with intended method

3.30

readily removable

property that food processing machinery/device can be separated/disassembled by an intended method using a hand or simple tool

3.31

accessible

property that the target position can be easily exposed by an intended method using a simple tool, and an operator can visually check and touch with hands

3.32

readily accessible

property that the target position can be exposed by an intended method not using a tool, and an operator can visually check and touch with hands

4 List of main hazards

4.1 General

ISO 14159 shows hazards on a hygienic aspect as three types of biological hazards, chemical hazards and physical hazards. However, it is impossible to identify specific hazards according to only these three types on a hygienic risk assessment. Main hazards such as structure in which these hazards can occur are as follows (refer to Annex B).

4.2 Hazards arising from constituent materials

4.2.1 Materials (general)

If the constituent materials of food processing machinery are inadequate for the intended usage, there is a possibility that food is contaminated with these materials during usage period due to such causes as corrosion, crack, breakage, abrasion, surface peel-off, tear, pinhole, crevice, elution of toxic substances, contamination derived from materials, absorption/sorption ¹⁾ of substances, and heat resistance property or chemical resistance property inadequate for intended usage.

Note ¹⁾ Sorption means a phenomenon in which absorption and adsorption of gas molecules and solutes occur simultaneously to fine dents or fine pores on the surface of solid substance.

4.2.2 Constituent materials of food contact surface (including metallic materials and non-metallic materials)

Breakage of constituent materials not only causes physical harms such as mixture of foreign substances but also can trap food, detergent etc. There is a possibility that rotting of trapped food, trapped detergent etc. cause biological, chemical or physical harms. Also, there is a possibility that elution of constituents that can damage human health or a material that absorbs/sorbs food ingredient causes chemical harms.

4.3 Hazards arising from design/manufacture of food contact surface

4.3.1 Surface shape

Small crevices, fissures, pinholes, inadequate surface roughness etc. can cause residue of food, detergent, microorganism etc., and rotting of residual food. There is a possibility that these events cause biological, chemical and physical harms. There is a possibility that surface shapes that splash or adhere food, detergent etc. to surroundings cause biological, chemical and physical harms similarly.

4.3.2 Cleanability

Structure difficult to clean to the intended level or to check the level of cleanliness can cause residue of food, detergent, microorganism etc., and rotting of residual food. There is a possibility that these events cause biological, chemical and physical harms.

4.3.3 Disinfectant capability and sterility

Structure difficult to disinfect and sterilize to the intended level can cause residue of microorganisms more than foreseen. There is a possibility that these events cause biological harms due to growth and contamination of microorganisms into food.

4.3.4 Ingress of microorganisms in aseptic process

For food processing machinery that specifically manufactures aseptic food, if it has structure that cannot surely prevent the ingress of microorganisms from outer environment onto food contact surface, there is a possibility that it can cause biological harms due to ingress of microorganisms.

4.3.5 Drainage property

Structure in which liquids are intended to be drained but not adequately drained can cause residue of liquid or rotting of residual liquid. There is a possibility that these events cause biological, chemical and physical harms.

4.3.6 Dead space

Structure not allowing further disassembling, sufficient cleaning and disinfection, and that cause difficulty in visual check of these results can cause residue of food, detergent, microorganism etc., and rotting of residual food. There is a possibility that these events cause biological, chemical and physical harms.

4.3.7 Permanent joint

Concave and convex, crevice, corrosion, pinhole etc. at permanent joints due to inadequate welding can prevent sufficient cleaning and disinfection, and can cause residue of food, detergent, microorganism etc., and rotting of residual food. There is a possibility that these events cause biological, chemical and physical harms.

4.3.8 Removable joint

Removable joints such as pipes, parts and movable parts can cause residue of food, detergent, microorganism etc., and rotting of residual food. These joints can cause parts drop, sealing material breakage and the like. There is a possibility that these

events cause biological, chemical and physical harms.

4.3.9 Fillet/internal corner/groove

Inadequate fillet/internal corner/groove can prevent sufficient cleaning and disinfection, and can cause residue of food, detergent, microorganism etc., or rotting of residual food. There is a possibility that these events cause biological, chemical and physical harms.

4.3.10 Seal (gasket, packing, O-ring, joint ring etc.)

Inadequate seals against the intended usage can cause elution of constituent from seal, absorption/sorption of food ingredient, residue of food, detergent, microorganism etc., or rotting of residual food. If elastomer is used for seals, it can cause breakage due to excessive compression, ingress of food due to insufficient compression etc. There is a possibility that these events cause biological, chemical and physical harms.

NOTE A “gasket” herein refers to a seal on static surface without moving part (static seal), and a “packing” refers to a seal on dynamic surface such as a rotating part (dynamic seals) (refer to **JIS B 0116**).

4.3.11 Belt and conveyor belt

Usage of belt inadequate for the intended usage can cause residue of food, detergent, microorganism etc., rotting of residual food, absorption of food ingredient, and unraveling of belt materials. There is a possibility that these events cause biological, chemical and physical harms. Also, there is a possibility that food retains on a conveyor belt that is difficult to clean. There is a possibility that retention of food causes biological, chemical and physical harms.

4.3.12 Fastener (bolts such as screw, tightening tools such as rivet, and fittings)

Cleaning of all crevices in fasteners is difficult, and they can cause residue of food, detergent, microorganism etc., and rotting of residual food. Fasteners can drop due to loosening. There is a possibility that these events cause biological, chemical and physical harms.

4.3.13 Inhibition of process flow

Movable parts such as spring and opening inside the process flow that transfers food continuously (flow of food in transfer process) can inhibit the transfer of food, and cause residue of food, detergent, microorganism etc., and rotting of residual food. There is a possibility that these events cause biological, chemical and physical harms.

4.3.14 Shaft and bearing

Structure not readily accessible for cleaning of shaft joint and bearing subjected to ingress of food can cause residue of food, detergent, microorganism etc., and rotting of residual food. If sealing structure of bearing part is inadequate, or sealing is inadequate, lubricant oil can leak to food contact surface. There is a possibility that these events cause biological, chemical and physical harms.

4.3.15 Structure of sensor and sensor attaching position

A sensor attaching position to measure temperature, pressure etc. can cause residue of food, detergent, microorganism etc., and rotting of residual food. Inadequate structure of sensor can cause leakage of substances from the sensor inside. There is a possibility that these events cause biological, chemical and physical harms.

4.3.16 Opening, cover, guard and door

Openings, covers, guards and doors having structure not readily accessible or not accessible for cleaning can cause residue of food, detergent, microorganism etc., and rotting of residual food. Inadequate structure of these parts can break. There is a possibility that these events cause biological, chemical and physical harms.

4.3.17 Observation window

Observation windows that are difficult to clean can cause residue of food, detergent, microorganism etc., and rotting of residual food. Also, observation windows having inadequate structure can break. There is a possibility that these events cause biological, chemical and physical harms.

4.3.18 Actuator (such as button and lever) and operation panel

Actuators ²⁾ and operation panels touched by operators during food processing, which are difficult to clean, can cause residue of food and detergent, and rotting of residual food. Also, actuators having inadequate structure can break. There is a possibility that these events cause biological, chemical and physical harms.

Note ²⁾ Actuators herein refer to manual controllers such as push buttons and levers (refer to **JIS B 9660-1**).

4.3.19 CIP

Structure having dead spaces, poorly cleaned parts, inadequate seals etc. to which intended CIP cannot apply can cause residue of food and detergent, and rotting of residual food. Also, sealing materials of inadequate sealing can break. There is a possibility that these events cause biological, chemical and physical harms.

4.3.20 Hinge

Hinges having crevices that are difficult to clean can cause residue of food and detergent, and rotting of residual food. Also, hinges having inadequate structure can break or split. There is a possibility that these events cause biological, chemical and physical harms.

4.3.21 Replacement parts (filter etc.)

Parts such as filters, for which regular replacement is necessary, can cause residue of food and detergent, and rotting of residual food due to degraded functions, breakage, inadequate installation etc. Also, materials inadequate for use can cause elution of constituent substances. There is a possibility that these events cause biological, chemical and physical harms.

4.3.22 Gas and liquid handling devices used in food processing

Inadequate structure of gas and liquid handling devices used with food processing

machinery for agitation and refrigeration of food, addition to food, etc. can cause failures due to breakage and inadequate installation. Also, materials inadequate for use can cause elution of constituent substances. There is a possibility that these events cause biological, chemical and physical harms.

4.4 Hazards arising from design/manufacture of food splash area

Refer to hazards and hazardous events specified in 4.3.

4.5 Hazards arising from design/manufacture of non-food contact surface

4.5.1 General structure

Structure having dents and crevices, and structure difficult to clean and to check the cleanliness can cause absorption/sorption, residue, retention or accumulation of dusts, water, contaminants, detergent, etc., and generation, ingress etc. of pests. There is a possibility that these events cause biological, chemical and physical harms.

4.5.2 Fastener (screw etc.)

Cleaning of all crevices in fasteners is difficult, and they can cause residue and retention of water, detergent etc. Also, fasteners can drop. There is a possibility that these events cause biological, chemical and physical harms.

4.5.3 Fold of containers etc. (rim)

Folded rims of containers etc. of elements of food processing machinery can cause residue of water ingress due to splash etc., detergent etc., and ingress of pests. There is a possibility that these events cause biological, chemical and physical harms.

4.5.4 Rib, reinforcing

Ribs/reinforcing of food processing machinery that is difficult to clean can cause residue of water, detergent etc., ingress of pests, and corrosion between different metals. There is a possibility that these events cause biological, chemical and physical harms.

4.5.5 Lighting, glass parts etc.

Lighting, instruments and other glass parts provided on food processing machinery can cause scattering of fractions due to breakage. There is a possibility that these events cause physical harms.

4.5.6 Motor, motor drive part and enclosure of motor

Motors, motor drives and motor enclosures can cause accumulation and rotting of dusts in crevices etc., and ingress of pests. Paints can peel-off and lubricant oil etc. can leak. There is a possibility that these events cause biological, chemical and physical harms.

4.5.7 Step and stage on production line

Dusts can drop on food contact surfaces from operators going up and down on steps/stages or these floors. There is a possibility that these events cause biological and physical harms.

4.5.8 Caster

Casters having structure that have difficulty in cleaning can cause accumulation and rotting of dusts. There is a possibility that these events cause biological and physical harms.

4.5.9 Label such as warning display

Labels such as warning display made from inadequate materials for the intended usage condition can peel off or break due to the effects of heat, ultraviolet rays, detergent etc. There is a possibility that these events cause physical harms.

4.5.10 Drain part

Drain parts that have difficulty in discharging/draining as intended can cause residue and rotting of waste liquid, or contamination of work areas. There is a possibility that these events cause biological and chemical harms.

4.5.11 Thermal insulating material such as heat insulating material

Bare thermal insulating materials or covers of thermal insulating materials having crevices can cause residue of water ingress, detergent etc. in the thermal insulating materials or in the crevices of covers, and ingress of pests. There is a possibility that these events cause biological, chemical and physical harms.

4.5.12 Fillet/internal corner/groove

Inadequate fillet/internal corners/grooves can cause residue of water, detergent, microorganism etc., and rotting of dusts derived from residual food. There is a possibility that these events cause biological, chemical and physical harms.

4.5.13 Power transmission part (such as belt and chain) of power unit

Power transmission parts such as belts and chains of power units that have difficulty in cleaning can cause accumulation of dusts, abrasion powders etc. and scattering of lubricant oil. There is a possibility that these events cause biological, chemical and physical harms.

4.5.14 Lubricant part (such as shaft and bearing)

Lubricant parts that have difficulty in lubricant oil feeding, operations such as detaching/attaching parts related to feeding oil, cleaning adhered oils etc., and that do not allow check of remaining lubricant oil can cause generation of abrasion powders due to shortage of lubricant oil, or leakage of lubricant oil due to excessive oil. There is a possibility that these events cause chemical and physical harms.

4.5.15 Enclosed space

Sealed spaces inside that have difficulty in cleaning and check of cleanliness can cause residue of water ingress, detergent etc. and ingress of pests. There is a possibility that these events cause biological, chemical and physical harms.

4.5.16 Opening, cover and door

Opening, cover and door that have difficulty in cleaning and check of cleanliness can cause residue of water ingress, detergent etc. and ingress of pests. If the structure is

fragile, they can cause abrasion, crack, deformation etc. There is a possibility that these events cause biological, chemical and physical harms.

4.6 Installation of machinery

Installation areas of food processing machinery/devices that are difficult to clean, and structure of installation areas of food processing machinery/devices that is difficult to access can cause residue, rotting etc. of soils. There is a possibility that these events cause biological, chemical and physical harms.

4.7 Fluids in machinery

Fluid such as lubricant oil, cooling medium, heating medium, and oil of hydraulic/pressure gauge can leak. There is a possibility that these events cause chemical harms.

4.8 Instrumentation devices and control systems

Failure of instrumentation devices, control systems etc. concerning quality control of food processing machinery on a hygienic aspect can cause poor disinfection, oversight of foreign substances etc. There is a possibility that these events cause biological and chemical harms.

4.9 Unintended supply suspension of electricity and utility

Unintended supply suspension of electricity and utility (compressed air, vapour etc.) can cause inadequacy of intended cleaning and disinfection, retention of food etc. There is a possibility that these events cause biological, chemical and physical harms.

4.10 Pneumatic/hydraulic system

Failure of valves of pneumatic and hydraulic systems can cause mixture of foreign substances into food, contamination of work area etc. There is a possibility that these events cause chemical and physical harms.

5 Risk assessment on hygiene aspect

5.1 General

Methodology for risk assessment and risk reduction of food processing machinery shall be in accordance with **JIS B 9700**.

Risk estimation and evaluation in risk assessment of food processing machinery shall be conducted with reference to the process shown in Figure 1. The residual risks for both of hygienic and safety aspects should be acceptable (adequately reduced), and the resulting levels of both risks should be balanced as far as possible. If protective measures for risk reduction are determined only for targeting the hygienic risks without considering safety risks, and then safety risk reduction activities are added later, introduction of protective measures for reducing safety risks such as cut and wound may be inhibited. Such an inadequate risk assessment is also true to the cases where hygiene risk reduction activities are added after the determination of protective measures for safety risk reduction.

Since hygienic risks and safety risks are different in nature, when attempts are

made to balance the level of residual risks of both risks in accordance with the repetitive process, the overall residual risks tend to become higher compared to the case where the residual risks of either one are reduced. Therefore, the goal of risk reduction shall be the reduction of residual risks to the level as low as reasonably practicable ³⁾.

Note ³⁾ This idea is called ALARP “As Low As Reasonably Practicable” principle, and used mainly in the functional safety field. Refer to **JIS C 0508-5**.

In the case where the level of residual risks of hygienic risks or safety risks cannot be made acceptable (cannot be adequately reduced) even when all the protective measures reasonably executable are introduced, the change in the limitation on machinery shall be considered.