
Obblighi igienici e norme volontarie per le macchine alimentari

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Obblighi igienici per materiali base, progettazione, costruzione e impiego

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Obblighi igienici per l'industria alimentare

D.P.R. 26 marzo 1980, n. 327

(Regolamento di esecuzione della Legge 30 aprile 1962, n. 283, e successive modificazioni, in materia di disciplina igienica della produzione e della vendita delle sostanze alimentari e delle bevande)

Art. 28

Ai fini del rilascio delle autorizzazioni e della vigilanza da parte dell'autorità sanitaria competente, gli stabilimenti e laboratori di produzione, **devono essere provvisti di impianti, attrezzature ed utensili riconosciuti idonei sotto profilo igienico-sanitario e **costruiti** in modo da consentire la facile, rapida e completa pulizia.**

Regulation (EC) No 852/2004 on the hygiene of foodstuffs

ANNEX II

GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS

CHAPTER V - Equipment requirements

1. All articles, fittings and equipment with which food comes into contact are to:

(a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;

(b) be so **constructed**, be **of such materials** (*costruiti in materiale tale*) and be (che, se) kept in such good order, repair and condition as to minimise any risk of contamination;

(c) with the exception of non-returnable containers and packaging, be so **constructed**, be **of such materials** (*costruiti in materiale tale*) and be (che, se) kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected; and

(d) be **installed** in such a manner as to allow adequate cleaning of the equipment and the surrounding area.

N.B. la traduzione in italiano è errata (**per i Regolamenti CE vale la versione in inglese**)

Esempio di errori “concettuali” nella traduzione italiana di Regolamenti CE

Regolamento (CE) 852/2004 - Articolo 5 - Analisi dei pericoli e punti critici di controllo	Regulation (EC) 852/2004 - Article 5 - Hazard analysis and critical control points
<p>b) identificare i punti critici di controllo nella fase o nelle fasi in cui il controllo stesso si rivela essenziale per prevenire o eliminare un rischio o per ridurlo a livelli accettabili;</p> <p>c) stabilire, nei punti critici di controllo, i limiti critici che differenziano l'accettabilità e l'inaccettabilità ai fini della prevenzione, eliminazione o riduzione dei rischi identificati;</p> <p>... omissis...</p> <p>e) stabilire le azioni correttive da intraprendere nel caso in cui dalla sorveglianza risulti che un determinato punto critico non è sotto controllo;</p> <p>f) stabilire le procedure, da applicare regolarmente, per verificare l'effettivo funzionamento delle misure di cui alle lettere da a) ad e);</p> <p>g) predisporre documenti e registrazioni adeguati alla natura e alle dimensioni dell'impresa alimentare al fine di dimostrare l'effettiva applicazione delle misure di cui alle lettere da a) ad f).</p>	<p>(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;</p> <p>(c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;</p> <p>... omissis...</p> <p>(e) establishing corrective actions when monitoring indicates that a critical control point is not under control;</p> <p>(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) <u>are working effectively</u>;</p> <p>(g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).</p>

EU - GUIDANCE DOCUMENT (2005): Implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses

HACCP AND PREREQUISITE REQUIREMENTS

Food hygiene is the result of the implementation by food businesses of prerequisite requirements and procedures based on the HACCP principles.

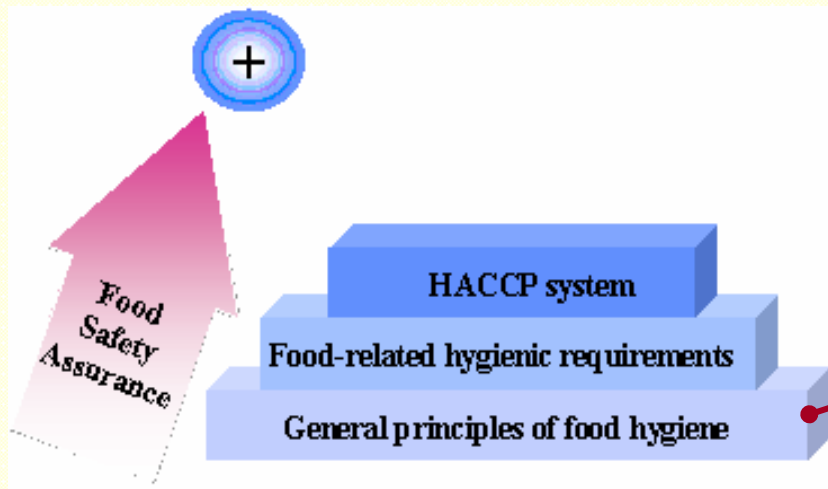
The prerequisite requirements provide the foundation for effective HACCP implementation and should be in place before a HACCP based procedure is established.

HACCP systems are not a replacement for other food hygiene requirements, but a part of a package of food hygiene measures that must ensure safe food. It must in particular be borne in mind that prior to establishing HACCP procedures “prerequisite” food hygiene requirements must be in place, including in particular:

- Infrastructural and **equipment requirements**,
Etc.

Joint FAO/WHO Food Standards Programme CODEX ALIMENTARIUS COMMISSION

- **Food hygiene:** all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain
- **Food safety** - assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.
- **Food suitability** - assurance that food is acceptable for human consumption according to its intended use.



Production equipment

Sanitary design / Installation
Cleaning / sanitation
Preventive maintenance
Calibration

Codex Alimentarius: RECOMMENDED INTERNATIONAL CODE OF PRACTICE GENERAL PRINCIPLES OF FOOD HYGIENE

4.3 EQUIPMENT

4.3.1 GENERAL

Equipment and containers (other than once-only use containers and packaging) coming into contact with food, should be **designed and constructed** to ensure that, where necessary, they can be adequately cleaned, disinfected and maintained to avoid the contamination of food.

Equipment and containers should be **made of materials** with no toxic effect in intended use.

Where necessary, equipment should be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection, monitoring and, for example, to facilitate inspection for pests.

Per esportare negli USA

21 CFR Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (2004)

Subpart C-Equipment - 110.40 Equipment and utensils

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The **design, construction, and use** of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

All equipment should be so **installed and maintained** as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food.

They shall be made of **nontoxic materials** and **designed** to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

Etc.

Materiali a contatto - Legislazione italiana

Disciplina orizzontale

- **D.M. Sanità 21 marzo 1973**, con successive modifiche, disciplina gli imballaggi, recipienti ed utensili destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale
Aggiornato con le modifiche introdotte da 28 successivi D.M.

Disciplina verticale

- **D.M. Salute 6 aprile 2004, n. 174**. Regolamento concernente i materiali e gli oggetti che possono essere utilizzati negli impianti fissi di captazione, trattamento, adduzione e distribuzione delle acque destinate al consumo umano.

Food Contact Materials - EU Legislation

Food contact materials and articles are regulated by three types of directives:

- The **Framework Regulation (EC) No 1935/2004** sets up general requirements for all food contact materials
- **Specific Directives** cover single groups of materials and articles listed in the Framework Regulation
- **Directives** on Individual Substances or groups of substances used in the manufacture of materials and articles intended for food contact

Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food

Article 1 - Purpose and subject matter

This Regulation shall apply to materials and articles, including active and intelligent food contact materials and articles, (hereinafter referred to as materials and articles) which in their finished state:

(a) are intended to be brought into contact with food;
... omissis ...

This Regulation shall **not apply to**:

... omissis ...

(c) fixed public or private water supply equipment.

Article 3 - General requirements

1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with **good manufacturing practice** (*) so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

(a) endanger human health (*Safety*); or

(b) bring about an unacceptable change in the composition of the food (*Suitability*); or

(c) bring about a deterioration in the organoleptic characteristics thereof. (*Suitability*)

(*) vedere slide N° 18

continua: **Regulation (EC) No 1935/2004**

Article 8 - General requirements for the authorisation of substances

1. When a list of substances as referred to in points (a) and (b) of the second subparagraph of Article 5(1) is adopted, anyone seeking an authorisation for a substance not yet included in that list shall submit an application in accordance with Article 9(1).

2. No substance shall be authorised unless it has been **adequately and sufficiently demonstrated that**, when used under the conditions to be set in the specific measures, the final material or article **satisfies the requirements** of Article 3 and, where they apply, Article 4.

continua: **Regulation (EC) No 1935/2004**

Article 9 - Application for authorisation of a new substance

1. To obtain the authorisation referred to in Article 8(1), the following procedure shall apply:
 - (a) an application shall be submitted to the competent authority of a Member State accompanied by the following:
 - (i) the name and address of the applicant;
 - (ii) a **technical dossier** containing the information specified in the guidelines for the safety assessment of a substance to be published by the Authority (EFSA) (*);
 - (iii) a summary of the technical dossier;
 - (b) the competent authority referred to in (a) shall:
 - (i) acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;
 - (ii) inform the Authority without delay; and
 - (iii) make the application and any supplementary information supplied by the applicant available to the Authority;
- Etc.

(*) vedere slide 23

continua: **Regulation (EC) No 1935/2004**

Article 16 - Declaration of compliance

1. The specific measures referred to in Article 5 shall require that materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them.

Appropriate documentation shall be available to demonstrate such compliance.
That documentation shall be made available to the competent authorities on demand.

N.B. L'industria alimentare è comunque responsabile della effettiva conformità ai requisiti di legge dei materiali che ha messo a contatto con i prodotti alimentari immessi sul mercato

continua: **Regulation (EC) No 1935/2004**

Article 17 – Traceability ()*

1. The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.
2. With due regard to technological feasibility, business operators shall have in place **systems and procedures** to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by this Regulation and its implementing measures used in their manufacture are supplied. That information shall be made available to the competent authorities on demand.
3. The materials and articles which are placed on the market in the Community shall be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information.

() nella traduzione italiana “Traceability” è correttamente tradotto “Rintracciabilità”, mentre in altri casi lo stesso termine è erroneamente tradotto “Tracciabilità”.*

continua: **Regulation (EC) No 1935/2004**

ANNEX I

List of groups of materials and articles which may be covered by specific measures

1. Active and intelligent materials and articles
2. Adhesives
3. Ceramics
4. Cork
5. Rubbers
6. Glass
7. Ion-exchange resins
8. Metals and alloys
9. Paper and board
10. Plastics
11. Printing inks
12. Regenerated cellulose
13. Silicones
14. Textiles
15. Varnishes and coatings
16. Waxes
17. Wood

N.B.1 L'idoneità dei materiali deve essere riferita alle condizioni d'uso esplicitamente previste:

- **tipologia di alimenti a contatto**
- **temperatura, durata e ripetitività del contatto**
- **modalità di detergenza e sanificazione applicate**

N.B.2 Non sono compresi gli acciai inossidabili, che in Italia continuano ad essere regolamentati dal D.M. 21 marzo 1973, in maniera non aggiornata e più restrittiva rispetto ad altri Stati europei

Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food

Article 1 - Subject matter

This Regulation lays down the rules on good manufacturing practice (GMP) for the groups of materials and articles intended to come into contact with food (hereafter referred to as materials and articles) listed in Annex I to Regulation (EC) No 1935/2004 and combinations of those materials and articles or recycled materials and articles used in those materials and articles.

Article 2 - Scope

This Regulation shall apply to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances.

The detailed rules set out in the Annex shall apply to the relevant individually mentioned processes, as appropriate.

continua: **Regulation (EC) No 2023/2006**

Article 3 - Definitions

For the purpose of this Regulation, the following definitions shall apply:

- (a) 'good manufacturing practice (GMP)' means those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof;
- (b) 'quality assurance system' means the total sum of the organised and documented arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use;
- (c) 'quality control system' means the systematic application of measures established within the quality assurance system that ensure compliance of starting materials and intermediate and finished materials and articles with the specification determined in the quality assurance system;
- (d) 'non-food-contact side' means the surface of the material or article that is not directly in contact with food;
- (e) 'food-contact side' means the surface of a material or article that is directly in contact with the food.

continua: **Regulation (EC) No 2023/2006**

Article 4 - Conformity with good manufacturing practice

The business operator shall ensure that manufacturing operations are carried out in accordance with:

- (a) the general rules on GMP as provided for in Article 5, 6, and 7,
- (b) the detailed rules on GMP as set out in the Annex.

Article 5 - Quality assurance system

1. The business operator shall establish, implement and ensure adherence to an effective and documented quality assurance system. That system shall:
 - (a) take account of the adequacy of personnel, their knowledge and skills, and the organisation of the premises and equipment such as is necessary to ensure that finished materials and articles comply with the rules applicable to them;
 - (b) be applied taking into account the size of the business run by the operator, so as not to be an excessive burden on the business.
2. Starting materials shall be selected and comply with preestablished specifications that shall ensure compliance of the material or article with the rules applicable to it.
3. The different operations shall be carried out in accordance with pre-established instructions and procedures.

continua: **Regulation (EC) No 2023/2006**

Article 6 - Quality control system

1. The business operator shall establish and maintain an effective quality control system.
2. The quality control system shall include monitoring of the implementation and achievement of GMP and identify measures to correct any failure to achieve GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.

Article 7 - Documentation

1. The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to specifications, manufacturing formulae and processing which are relevant to compliance and safety of the finished material or article.
2. The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to records covering the various manufacturing operations performed which are relevant to compliance and safety of the finished material or article and with respect to the results of the quality control system.
3. The documentation shall be made available by the business operator to the competent authorities at their request.

Article 8 - Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 August 2008.

continua: **Regulation (EC) No 2023/2006**

ANNEX - Detailed rules on good manufacturing practice

Processes involving the application of printing inks to the non-food contact side of a material or article

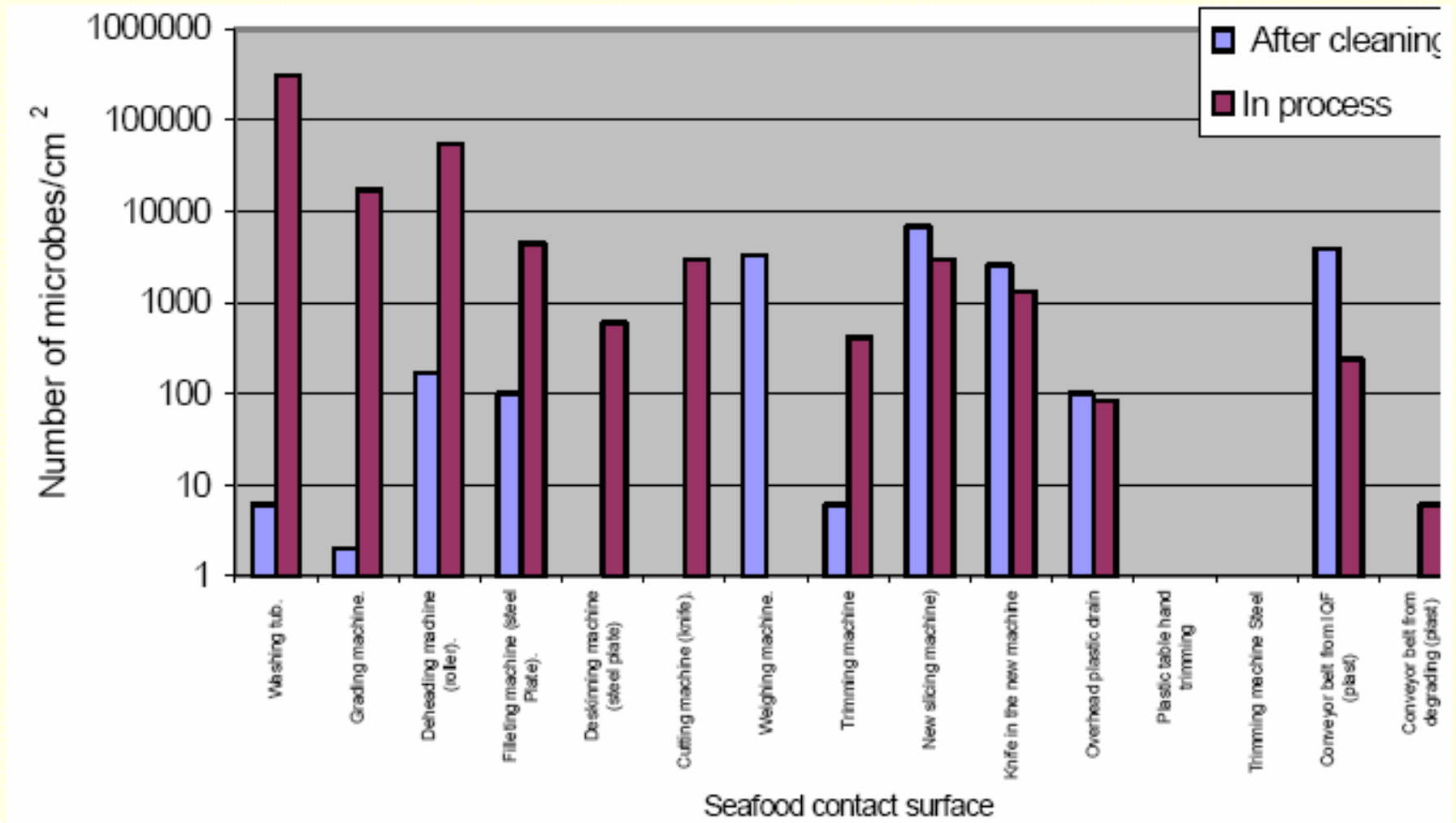
1. Printing inks applied to the non food-contact side of materials and articles shall be formulated and/or applied in such a manner that substances from the printed surface are not transferred to the food-contact side:
 - (a) through the substrate or;
 - (b) by set-off in the stack or the reel, in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.
2. Printed materials and articles shall be handled and stored in their finished and semi-finished states in such a manner that substances from the printed surface are not transferred to the food-contact side:
 - (a) through the substrate or;
 - (b) by set-off in the stack or reel, in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.
3. The printed surfaces shall not come into direct contact with food.

EFSA Guidelines

- Guidance document on the submission of a dossier on a substance to be used in Food Contact Materials for evaluation by EFSA by the Panel on food additives, flavourings, processing aids and materials in contact with food (AFC):
http://www.efsa.europa.eu/EFSA/Scientific_Document/afc_note_for_guidance_fcm_en1.pdf

**"NOTE FOR GUIDANCE FOR PETITIONERS
PRESENTING AN APPLICATION FOR THE
SAFETY ASSESSMENT OF A SUBSTANCE TO
BE USED IN FOOD CONTACT MATERIALS
PRIOR TO ITS AUTHORISATION"
(Updated on 08 June 2006)**

Distribution of microbes in the processing environment after cleaning and in processing after 8 working hrs in a fish plant located in Reykjavik, Iceland during December 2002 (The United Nations University – Fisheries Training Programme)



Direttive “Macchine”

Directive 89/392/EEC
Directive 89/392/CEE (**D.P.R. 459/96**)

Directive 98/37/EC

on the approximation of the laws of the Member States relating to machinery
(attualmente in vigore, ma non risulta recepita formalmente dallo Stato italiano)

ANNEX I

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF MACHINERY AND SAFETY COMPONENTS

2. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY

2.1. **Agri-foodstuffs machinery**

Where machinery is intended to prepare and process foodstuffs (e.g. cooking, refrigeration, thawing, washing, handling, packaging, storage, transport or distribution), it must be so **designed and constructed** as to avoid any risk of infection, sickness or contagion and the following hygiene rules must be observed:

continua: **Direttive “Macchine”**

Directive 2006/42/EC on machinery, and amending Directive 95/16/EC (recast)

ANNEX I - Essential health and safety requirements relating to the design and construction of machinery

2. **SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY**

Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).

2.1. **FOODSTUFFS MACHINERY** AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS

2.1.1. **General**

Machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion.

continua: **Directive 2006/42/EC**

The following requirements must be observed:

- (a) materials in contact with, or intended to come into contact with, foodstuffs or cosmetics or pharmaceutical products must satisfy the conditions set down in the relevant Directives. The machinery must be **designed and constructed** in such a way that these materials **can be cleaned before each use**. Where this is not possible disposable parts must be used;
- (b) all surfaces in contact with foodstuffs or cosmetics or pharmaceutical products, other than surfaces of disposable parts, must:
 - be smooth and have neither ridges nor crevices which could harbour organic materials. The same applies to their joinings,
 - be **designed and constructed** in such a way as to reduce the projections, edges and recesses of assemblies to a minimum,
 - be **easily cleaned and disinfected**, where necessary after removing easily dismantled parts; the inside surfaces must have curves with a radius sufficient to allow thorough cleaning;
- (c) it must be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be **completely discharged** from the machinery (if possible, in a 'cleaning' position);

continua: **Directive 2006/42/EC**

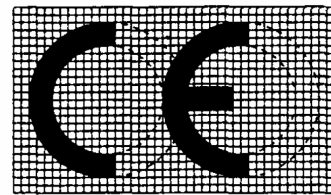
- (d) machinery must be **designed and constructed** in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in, areas that cannot be cleaned;
- (e) machinery must be **designed and constructed** in such a way that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery must be **designed and constructed** in such a way that continuing compliance with this requirement can be checked.

2.1.2. **Instructions**

The instructions for foodstuffs machinery and machinery for use with cosmetics or pharmaceutical products must indicate **recommended products and methods for cleaning, disinfecting and rinsing**, not only for easily accessible areas but also for areas to which access is impossible or inadvisable.

*Gli Stati membri dovranno recepire il testo della direttiva entro il 29 giugno 2008 e le disposizioni in essa contenute diventeranno obbligatorie dal **29 dicembre 2009**.*

continua: **Direttive “Macchine”**



Fin dall'entrata in vigore della prima Direttiva “Macchine” (89/392/EEC), la marcatura “**CE**” riportata dal costruttore sulla macchina è una dichiarazione di conformità a tutti gli obblighi pertinenti (*autocertificazione*)

Molta attenzione è stata sempre posta agli aspetti di sicurezza del lavoro

Forse non tutti i soggetti interessati sono stati finora consapevoli degli obblighi igienici aggiuntivi per le macchine destinate all'industria alimentare

Regulation (EC) No 852/2004 on the hygiene of foodstuffs

ANNEX II

GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS

CHAPTER V

Equipment requirements

2. Where necessary, equipment is to be **fitted with any appropriate control device** to guarantee fulfilment of this Regulation's objectives.

Codex Alimentarius: RECOMMENDED INTERNATIONAL CODE OF PRACTICE GENERAL PRINCIPLES OF FOOD HYGIENE

4.3 EQUIPMENT

4.3.2 FOOD CONTROL AND MONITORING EQUIPMENT

In addition to the general requirements in paragraph 4.3.1, equipment used to cook, heat treat, cool, store or freeze food should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and maintain them effectively. Such equipment should also be designed to allow temperatures to be **monitored and controlled**.

Where necessary, such equipment should have effective means of **controlling and monitoring** humidity, air-flow and any other characteristic likely to have a detrimental effect on the safety or suitability of food. These requirements are intended to ensure that: harmful or undesirable micro-organisms or their toxins are eliminated or reduced to safe levels or their survival and growth are effectively controlled; where appropriate, critical limits established in HACCP-based plans can be monitored; and temperatures and other conditions necessary to food safety and suitability can be rapidly achieved and maintained.

Per esportare negli USA

21 CFR Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (2004)

Subpart C-Equipment - 110.40 Equipment and utensils

- (e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.
- (f) **Instruments and controls** used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Aseptic processing and packaging systems

(1) Product sterilizer

- a) Temperature-indicating device.
- b) Temperature-recording device.
- c) Temperature recorder-controller.
- d) Product-to-product regenerators.
- e) Differential pressure recorder-controller.
- f) Metering pump.
- g) Product holding tube.
- h) Flow-diversion systems.
- i) Equipment downstream from the holding tube.
- j) Operation

continua: **Per esportare negli USA**

The US Department of Agriculture (USDA)/Food Safety & Inspection Service (FSIS) **pre-approves** equipment for use in meat, poultry, and egg product facilities (FSIS, 2004).

Similarly, the USDA/Agricultural Marketing Service (AMS)/Dairy Division has an **approval process** for equipment used in manufactured dairy facilities under their inspection.

*La FDA prevede una valutazione di conformità per i nuovi impianti, in particolare quelli utilizzati per LACF (Low Acid Canned Food), sulla base della documentazione di **validazione** fornita dal richiedente.*

USA Sanitary Standards

Standards for sanitary fabrication, construction, and design of food equipment have been developed by a variety of standards organizations.

While there are subtle differences between these standards, the primary intent of each organization is the application of sound sanitary principles in food equipment manufacture.

The primary food equipment organizations are:

- **3-A Sanitary Standards, Inc.**,
- the National Sanitation Foundation (NSF), and
- Underwriters Laboratories.

3A Sanitary Standards

Starting from '70 years, 3A Standards have been developed for a variety of equipment used in the dairy industry, as well as some equipment used in egg processing.

The founding organizations of 3A represent equipment manufacturers, dairy processors, and regulatory officials.

3A Standards are used as a reference under the *Grade A Pasteurized Milk Ordinance (PMO)*, the official regulatory document for the *National Conference on Interstate Milk Shipments (NCIMS)*.

3-A Sanitary Standards may also be required under many state and local regulations.

N.B. in pratica, la conformità 3 A SS è generalmente richiesta dal mercato per tutte le macchine alimentari

continua: **3-A Sanitary Standards**

Doc.No.	Title (Effective)
01-08	Storage Tanks (11/2001)
02-10	Centrifugal and Positive Rotary Pumps (1/2006)
04-04	Homogenizers and Reciprocating Pumps (11/1996)
05-15	Stainless Steel Automotive Transportation Tanks (11/2002)
10-04	Filters Using Single Service Filter Media (11/2000)
11-08	Plate-Type Heat Exchangers (1/2007)
12-07	Tubular Heat Exchangers (11/2003)
13-10	Farm Milk Cooling and Holding Tanks (11/2003)
16-05	Product Evaporators and Vacuum Pans (8/1997)
17-10	Formers, Fillers, and Sealers of Containers for Fluid Products (11/2002)
18-03	Multiple-Use Rubber and Rubber-Like Materials (8/1999)
19-05	Batch and Continuous Freezers Ice Cream, Ices, and Other Similarly Frozen Foods (11/1999)
20-24	Multiple-Use Plastic Materials (11/2006)
21-01	Centrifugal Separators and Clarifiers (11/2006)
22-08	Silo-Type Storage Tanks (11/2004)
23-05	Equipment for Packaging Viscous Products (10/2006)
24-02	Non-Coil Type Batch Pasteurizers (11/1989)
25-03	Non-Coil Type Batch Processors (11/2002)

continua: **3-A Sanitary Standards**

Doc.No.	Title (Effective)
26-04	Sifters for Dry Products (11/2001)
27-05	Equipment for Packaging Dry Products (11/2002)
28-03	Flow Meters (11/1995)
29-02	Air Eliminators (11/2000)
30-01	Farm Milk Storage Tanks (9/1984)
31-04	Scraped Surface Heat Exchangers (1/2006)
32-02	Uninsulated Tanks (8/1994)
33-01	Polished Metal Tubing (11/1994)
34-02	Portable Bins for Dry Products (09/1992)
35-02	Blending Equipment (12/2005)
36-01	Inline Rotor-Stator Mixers (11/2003)
38-00	Cottage Cheese Vats (8/1997)
39-01	Pneumatic Conveyors for Dry Products (11/2003)
40-03	Bag Collectors (7/2006)
41-02	Mechanical Conveyors for Dry Products (11/2005)
42-01	In-Line Strainers (11/1997)
44-03	Diaphragm Pumps (11/2001)
45-02	Crossflow Membrane Modules (11/2003)

continua: **3-A Sanitary Standards**

- 46-03 Refractometers and Energy-Absorbing Optical Sensors (11/2002)
- 49-01 Air Driven Sonic Horns for Dry Products (11/2001)
- 50-01 Level Sensing Devices for Dry Products (11/2001)
- 51-01 Plug-Type Valves (11/1998)
- 52-02 Plastic Plug-Type Valves (11/1998)
- 53-03 Compression-Type Valves (12/2006)
- 54-02 Diaphragm-Type Valves (11/1997)
- 55-01 Boot Seal-Type Valves (11/1996)
- 56-00 Inlet and Outlet Leak-Protector Plug-Type Valves (5/1993)
- 57-01 Tank Outlet Valves (11/1996)
- 58-00 Vacuum Breakers and Check Valves (6/1992)
- 59-00 Automatic Positive Displacement Samplers (11/1993)
- 60-00 Rupture Discs (9/1983)
- 61-01 Steam Injection Heaters (9/2006)
- 62-01 Hose Assemblies (11/1996)
- 63-03 Sanitary Fittings (11/2002)
- 64-00 Pressure Reducing and Back Pressure Regulating Valves (11/1993)
- 65-00 Sight and/or Light Windows and Sight Indicators in Contact With Product (11/1994)

continua: **3-A Sanitary Standards**

Doc.No.	Title (Effective)
68-00	Ball-Type Valves (11/1996)
70-01	Italian-Type Pasta Filata Style Cheese Cookers (11/2002)
71-01	Italian-Type Pasta Filata Style Cheese Moulders (11/2002)
72-01	Italian-Type Pasta Filata Style Moulded Cheese Chillers (11/2002)
73-01	Shear Mixers, Mixers, and Agitators (10/2005)
74-03	Sensors and Sensor Fittings and Connections Used on Equipment (1/2006)
75-00	Belt-Type Feeders (11/1998)
78-01	Spray Cleaning Devices Intended to Remain in Place (11/2003)
81-00	Auger-Type Feeders (11/1998)
82-00	Pulsation Dampening Devices (11/2002)
83-00	Enclosed Cheese Vats and Tables (11/2003)
84-01	Personnel Access Ports for Wet Applications (3/2007)
85-00	Double-Seat Mixproof Valves (11/2004)
88-00	Machine Leveling Feet and Supports (12/2006)
E-600	Egg Breaking & Separating Machines (1/1998)
E-1500	Shell Egg Washer (1/1998)

3-A Accepted Practices

Doc.No.	Title (Effective)
603-07	Sanitary Construction, Installation, Testing, and Operation of High-Temperature Short-Time and Higher-Heat Shorter-Time Pasteurizer Systems (11/2005)
604-05	Supplying Air Under Pressure for Contact with Product or Product Contact Surfaces (11/2004)
605-04	Permanently Installed Product and Solution Pipelines and Cleaning Systems (8/1994)
606-05	Design, Fabrication, and Installation of Milking and Milk Handling Equipment (11/2002)
607-05	Spray Drying Systems (11/2004)
608-02	Instantizing Systems (11/2001)
609-03	Method of Producing Steam of Culinary Quality (11/2004)
610-01	Sanitary Construction, Installation, and Cleaning of Crossflow Membrane Processing Systems (11/2003)
611-00	Farm Milk Cooling and Storage Systems (11/1994)

European Harmonised Standards

"Harmonised standards" are European standards, adopted by CEN, CENELEC or ETSI, following a mandate issued by the European Commission after consultation of Member States. They are developed through an open and transparent process, built on consensus between all interested parties.

Compliance with harmonised standards, of which the reference numbers have been published in the Official Journal and which have been transposed into national standards, **provides presumption of conformity to the corresponding essential requirements of the EC directives**.

Compliance with harmonised standards remains voluntary, and manufacturers are free to choose any other technical solution that provides compliance with the essential requirements. In a number of cases compliance with harmonised standards also increases the options for conformity assessment procedures.

A supporto delle Direttive "Macchine", in sede europea sono state emanate norme volontarie relative alle macchine per l'industria alimentare in generale e per singole tipologie di tali macchine.

**N.B. Le norme sono volontarie, ma permettono di adempiere in maniera corretta e completa ai corrispondenti obblighi di legge.
Chi non le adotta si assume l'onere di una validazione documentata della propria macchina per dimostrarne la conformità.**

Norme armonizzate europee nell'ambito delle “Direttiva Macchine”

Macchine per l'industria alimentare in generale:

- CEN EN 1672-2:1997 Concetti di base — Parte 2: Requisiti igienici

Macchine specifiche per l'industria alimentare (Requisiti di sicurezza e di igiene):

- CEN EN 1678:1998 Tagliaverdure
- CEN EN 1974:1998 Affettatrici
- CEN EN 453:2000 Impastatrici
- CEN EN 454:2000 Impastatrici planetarie
- CEN EN 1673:2000 Forni a carrello rotativo
- CEN EN 1674:2000 Sfogliatrici per panificazione e pasticceria
- CEN EN 12505:2000 Centrifughe per lavorazione oli e grassi commestibili
- CEN EN 12041:2000 Formatrici
- CEN EN 12043:2000 Celle di lievitazione
- CEN EN 12853:2001 Frullatori e fruste portatili
- CEN EN 13289:2001 Essiccatori e raffreddatori per pasta
- CEN EN 13378:2001 Presse per pasta
- CEN EN 13379:2001 Stenditrici, sfilatrici, convogliatori e magazzini di canne, per pasta
- CEN EN 13390:2002 Macchine per torte e crostate
- CEN EN 12267:2003 Seghe circolari
- CEN EN 12268:2003 Seghe a nastro
- CEN EN 12355:2003 Scuoiatrici, scotennatrici e asportatrici di membrane
- CEN EN 12854:2003 Miscelatori a barre

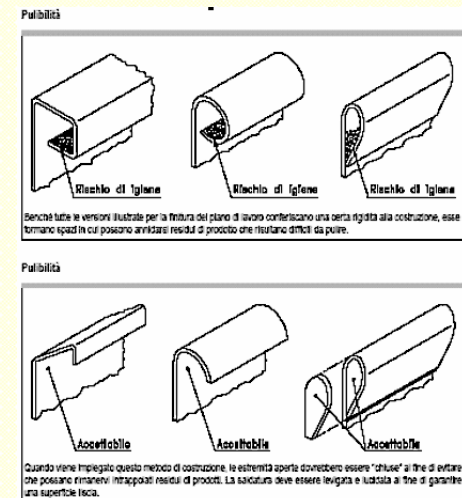
- CEN EN 13208:2003 Pelaverdure
- UNI EN 13379:2002 Stenditrici, sfilatrici e troncatrici, convogliatori di canne, accumulatori per canne
- UNI EN 1674:2002 Sfogliatrici per panificazione e pasticceria
- UNI EN 1673:2002 Forni a carrello rotativo
- UNI EN 12043:2002 Celle di lievitazione intermedia
- UNI EN 12041:2002 Formatrici
- EN 12852:2002 Macchine per la lavorazione di alimenti e frullatori
- EN 12853:2003 Frullatori e sbattitori portatili
- EN 13390:2003 Macchine per torte e crostate
- EN 13732:2003 Refrigeranti del latte sfuso alla stalla - Requisiti di costruzione, prestazione, idoneità all'utilizzo, sicurezza e igiene
- EN 12855:2003 Rotating bowl cutters
- EN 12268:2004 Seghe a nastro
- EN 12267:2004 Seghe circolari
- EN 13208:2004 Pelaverdure
- EN 12854:2004 Frullatori ad immersione
- EN 12355:2004 Macchine scuoiatrici, scotennatrici e asportatrici di membrane
- EN 12331:2005 Macchine tritacarne
- EN 13870:2005 Chop cutting machines
- EN 12463:2005 Macchine riempitrici e macchine ausiliarie
- EN 13621:2005 Asciugatrici per l'insalata
- EN 13871:2005 Cubes cutting machinery
- EN 13886:2005 Cooking kettles equipped with powered stirrer and/or mixer

Norma UNI EN 1672-2:1998 - “Macchine per l’industria alimentare – Concetti di base – Requisiti di sicurezza e igiene”

Si riferisce specificatamente alle macchine per i prodotti da forno e per la lavorazione delle carni, alle affettatrici, ad attrezzature per grandi cucine, alle centrifughe per oli e grassi, alle linee di pastificazione e ai raffreddatori in massa per latte. Tuttavia, è estendibile a molte altre tipologie di macchine per l’industria alimentare.

In base a questa norma, la scelta dei materiali e la progettazione (con riferimento a superfici, giunzioni, angoli e spigoli interni, spazi morti, cuscinetti e supporti lubrificati, strumentazione, pannelli, coperchi e portelli, strumenti di controllo) devono essere finalizzate alla eliminazione o alla sostanziale riduzione dei pericoli igienici derivanti da cause microbiologiche (patogeni, germi alterativi e tossine), da cause chimiche (detergenti, disinfettanti e lubrificanti) e da corpi estranei (derivanti dalla materia prima, dalla macchina o da altre fonti).

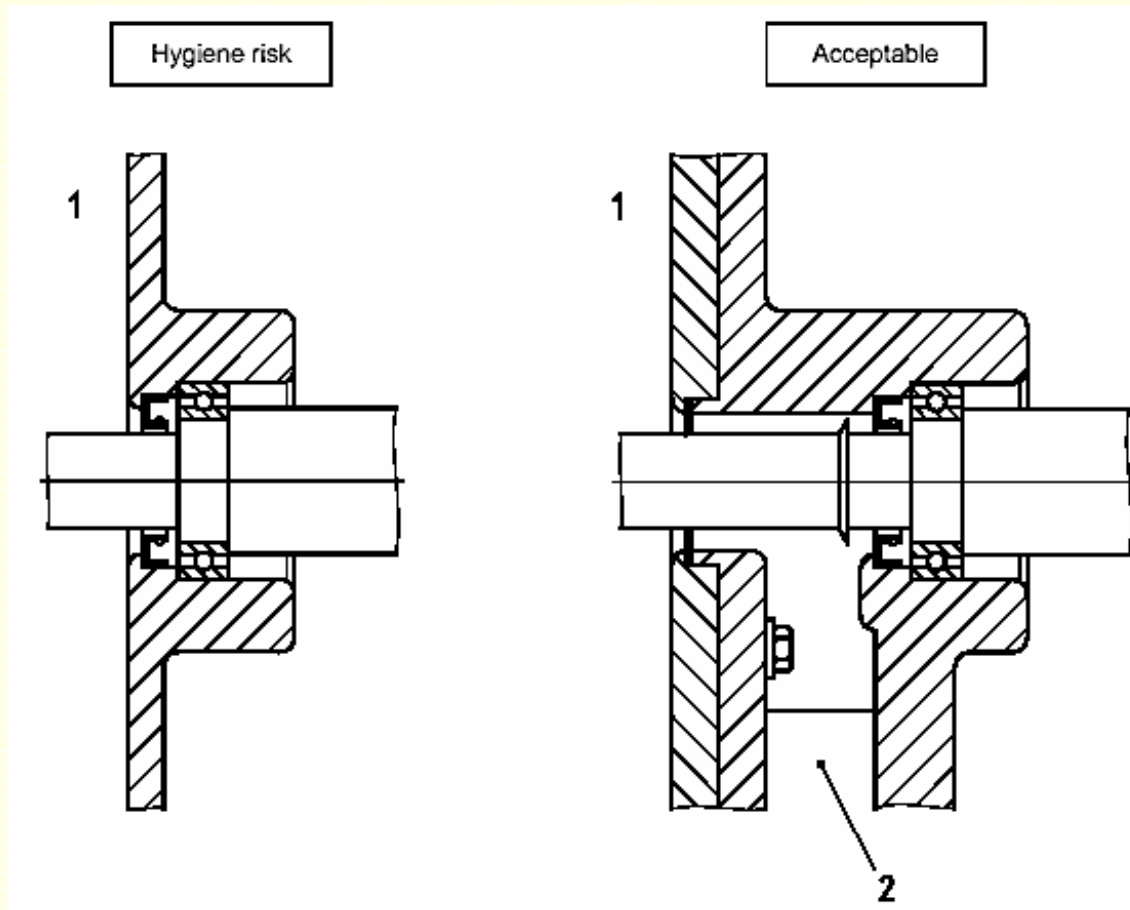
Come nel caso dello statunitense “3 A Sanitary Standard”, sono esemplificati i dettagli costruttivi non accettabili e accettabili dal punto di vista igienico.



International Standard ISO 14159:2002 - Safety of machinery - Hygiene requirements for the design of machinery

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segue: ISO 14159



Shaft entry design

Key:

1 Product side

2 Break to atmosphere

EHEDG Guidelines

(European Hygienic Engineering & Design Group)

Parallelamente alla stesura delle direttive macchine e delle norme europee specifiche, a partire dal 1992 l'EHEDG ha via via definito i criteri di progettazione e costruzione delle apparecchiature impiegate nell'industria alimentare.

Le Linee guida EHEDG hanno carattere più generale e meno vincolante rispetto alle norme armonizzate EN.

EHEDG, inoltre, ha redatto metodi di prova standardizzati per accertare sperimentalmente in maniera oggettiva l'effettiva pulibilità e sanificabilità.

La validazione delle modalità di pulizia e sanificazione è particolarmente importante, considerato che il costruttore deve descriverle nelle "istruzioni per l'uso" prescritte dalle direttive macchine, assumendosi quindi la responsabilità della loro efficacia.

Nel caso di impianti per pastorizzazione e sterilizzazione a flusso continuo, sono specificate le caratteristiche costruttive e di strumentazione che permettono di tenere effettivamente sotto controllo i parametri di processo critici ai fini dell'effetto sterilizzante applicato.

TIFQ - Istituto per la Qualità Igienica delle Tecnologie Alimentari

Nel 2005 è stato costituito

TIFQ - Istituto per la Qualità Igienica delle Tecnologie Alimentari,
atto al **rilascio dell'attestazione di conformità igienica**.

Promosso da ASSOFOODTEC ¹

(Associazione Italiana Costruttori Macchine, Impianti, Attrezzature per la Produzione la Lavorazione e la Conservazione Alimentare) in collaborazione con ASA (Azienda Servizi Anima ²),

- ¹ - UCMA (Costruttori Macchine per l'Industria Alimentare)
- Costruttori Impianti Frigoriferi
- Costruttori Affettatrici, Tritacarne e Affini
- Costruttori Macchine Caffè Espresso Attrezzature Bar
- COMACA (Costruttori Macchine per Lavorazione Carni)

- ² - Federazione delle Associazioni Nazionali dell'Industria Meccanica varia ed Affine