



Decree 9 March 2005 n.32

REPUBLIC OF SAN MARINE

Hygiene standards for food products

We Captains Regent

the Most Serene Republic of San Marino

Having seen Law 29 October 1992 n.85

Having seen the resolution of the State Congress dated 28 February 2005 n.45;

Making use of our faculties,

We decree, promulgate and order to publish:

Art.1

This Decree establishes, without prejudice to the provisions of Law no. 85 of 29 October 1992 and those provided for by the relevant implementing Decrees, the general hygiene rules for food products and the methods of verification regarding compliance with these rules.

Article 2

(Definitions)

For the purposes of this Decree:

- food hygiene: all measures necessary to guarantee the safety and integrity of food products.
These measures concern all phases following primary production, in particular: preparation, transformation, manufacturing, packaging, storage and transport of food products; • food company: any company that carries out one or more of the following activities: the

preparation, transformation, manufacture, packaging, storage, transport of food products, including street selling; • wholesome foods: foods suitable for human consumption from a hygienic point of view. • SSOP- (*Sanitation Standard Operating Procedures*) :
Standard Operating Procedures
Hygiene
- HACCP- (*Hazard Analysis and Critical Control Point*): Risk Analysis and Critical Points Check).

Art.3

(General provisions)

Food business owners must ensure that the preparation, processing, manufacturing, packaging, storage and transportation of food products are carried out in a hygienic manner. For this purpose, the technical-structural and hygienic-functional requirements are reported in the Annex, which are essential for obtaining and subsequently maintaining the health authorization referred to in article 10 of Law 92/85.

Compliance with what is reported in the aforementioned Annex also represents the essential prerequisite in order to be able to fulfill the obligations referred to in the following articles 4 and 5.

CHAPTER I

Article 4

(SSOP)

Each company must develop, apply and maintain a written program containing hygiene procedures according to the following requirements:

A. Development of the hygiene plan

1. The program must describe all hygiene procedures that a company must conduct on a daily basis, before (pre-operational) and during work (operational), sufficient to prevent direct contamination or adulteration of food products;
2. the plan must be signed by the owner of the company or by the person in charge who is responsible for the application and verification of what is indicated in the plan itself; 3. the procedures that must be activated before the start of the operation must be identified working day and must be directed at least to cleaning the surfaces in contact with food, equipment and utensils;
4. the frequency with which each cleaning procedure is activated and must be indicated the person(s) responsible for applying and maintaining the indicated cleaning plan must also be indicated;
5. the effectiveness of the plan must be confirmed through appropriate microbiological tests.

B. Application of the hygiene plan

1. Every company must apply the pre-operational hygiene plan procedures before starting some jobs;
2. each company must apply all other procedures according to the indicated frequency; 3. each company must monitor the effective application of the cleaning plan and any other procedure indicated by the plan on a daily basis.

C. Maintenance of the hygiene plan

1. Each company must regularly evaluate the effectiveness of the plan and all procedures aimed at preventing food contamination and must review them to keep them effective in the event of changes to equipment, tools, operating procedures, personnel, etc.

D. Corrective actions

1. Each company must take appropriate corrective actions regarding the hygiene plan when either following company self-monitoring or following checks carried out by the relevant health authority, it is found that the application and/or maintenance of the plan itself has not been capable of preventing food contamination;
2. the corrective actions must include procedures to ensure appropriate provisions relating to products that may have been contaminated, to restore adequate hygienic and sanitary conditions and to prevent the recurrence of the causes that led to the contamination, also providing for the possibility of reviewing and modifying the plan .

E. Registration

Each company must keep sufficient records to document the application and monitoring of the plan and any corrective actions taken; the records must be signed by the person in charge.

F. Validation

1. The hygiene plan must be validated by the Veterinary Service of the Environmental Hygiene Service when it is first compiled; it will then be the task of the same Office to verify its effective application. For this purpose, all the records required by the plan must be made available to the relevant authorities at the time of inspection checks in the company.
2. The public and private structures referred to in the art. are subject to the obligations of this article. 3 of Law 25 May 2004 n.69, as well as schools of all levels, if they administer meals.

CHAPTER II

Art.5

(HACCP)

The companies referred to in article 2 with the exclusion of commercial retail sales activities, as defined by Law 25 July 2000 n. 65, " *Regulation of trade and rules for the development of the commercial distribution network*" must also identify every phase in their activity that could prove critical for food safety and guarantee that the appropriate safety procedures are identified, applied, maintained and updated, making use of of the 7 principles on which the HACCP system is based.

Therefore, a self-control manual must be drawn up which must contain:

1. The analysis of the *potential risks* identified for each specific food production and the preventive measures implemented by the company to control these risks;

2. the identification of a point, of an operating procedure, during the production phases of a specific food, in which a control can be applied that can prevent, eliminate or reduce the identified potential risk to acceptable levels: *Critical Control Point* (CCP);
3. the designation of the *Critical Limits* identified for each *Critical Control Point* ; 4. the identification and application of control and surveillance procedures, including the frequency, of such *Critical Control Points*;
5. the list of *Corrective Actions* that must be developed following any possible deviation from a *Critical Limit* at a given *Critical Control Point*. In particular, the description of the *Corrective Actions* must guarantee that:

to. the cause of the deviation is identified and eliminated, b. the *Critical Point* is under control after *the Corrective Action* has been applied, c. preventive measures are established to avoid the recurrence of the deviation, d. no food produced during the non-compliance phase can enter the market;

1. a data recording system that documents the monitoring action of the *Critical Control Points* and all the verification actions of the procedures described in the manual with the relevant frequency; 2. a verification procedure regarding the functioning of the manual and a periodic review, at least annually, and/or on the occasion of changes in some work process or changes relating to the type of work activity, risk analysis, critical points and control and surveillance procedures.

The manual must also contain indications regarding the execution of appropriate chemical and/or microbiological tests, to confirm their effectiveness.

The correct drafting of the manual must also guarantee the traceability of food products, if health reasons require it.

The manual must be dated and signed by the company manager; signature implies acceptance and the commitment to apply what is indicated in the manual.

Article 6

(Supervision)

The Veterinary Service of the Environmental Hygiene Service must check the correct preparation of the manuals referred to in article 5.

This verification must be done by evaluating the potential risks concerning food safety, in relation to the specific activity carried out by the food company, paying particular attention to the

Critical Control Points highlighted in the manual, in order to ensure that monitoring and verification operations are carried out correctly by the company manager.

Compliance with the procedures established by the manual will then be subject to continuous checks by the Veterinary Service, which must check actual compliance with what is indicated in the manual.

For this purpose, the manager of the food company must keep available to the competent health authority all the information concerning the nature, frequency and results of the controls deriving from the application of the manual.

Art.7

(Implementation times)

Food companies operating in the area at the time this Decree comes into force must comply with the obligations established within one year.

New activities must comply with legal obligations within 3 months of obtaining the health authorization.

Article 8

(Revocation)

The lack or failure to meet the requirements or essential conditions set out in the Annex to this Decree, entail either the refusal to issue or the revocation of the Health Authorization.

Failure to draw up the hygiene plan referred to in article 4 and/or failure to draw up the self-control manual referred to in article 5 also entails the revocation of the health authorization and an administrative fine ranging from €1459 to €5165.

Article 9

(Sanctions)

Failure to comply with what is indicated in the hygiene plan or in the self-control manual, incorrect , and/or the keeping of the required records, entails an administrative fine from €150 to €5165 depending on the severity of the deficiency found; in the event of a repeat offense, the accessory sanction of suspension of business activity may be added as established by the Law 92/85, article 12, paragraph 8.

Except in the case in which it does not constitute a more serious crime, any other infringement found during the verification will be sanctioned in accordance with the dictates of Law 92/85

Given by Our Residence, on 9 March 2005/1704 dFR

THE CAPTAINS REGENTS

Giuseppe Arzilli - Roberto Raschi

THE SECRETARY OF STATE

FOR INTERNAL AFFAIRS

Rosa Zafferani

ATTACHED

*Int
ro
du
ces
Hon
or*

1. Chapters V to

The remaining chapters of the Annex apply as follows:

- Chapter I to all rooms except those covered by Chapter III, Chapter II to all rooms in which food is prepared, treated or processed, except those covered by Chapter III and excluding rooms used as canteens, Chapter III to premises listed in the chapter title, Chapter IV to all types of transport.
 -
1. The terms "where appropriate" and "where necessary" used in this Annex aim to ensure the safety and integrity of food products.

THE

General requirements for premises (other than those specified in Chapter III)

1. Premises must be kept clean, maintained and kept in good condition.
2. The layout, design, construction and dimensions of food premises must:
 - a. allow adequate cleaning and/or disinfection; b. be such as to prevent the accumulation of dirt and contact with toxic materials, the penetration of particles into food products and, to the extent feasible, the formation of condensation or undesirable mold on surfaces;
 - c. allow correct hygiene practice while also preventing cross-contamination, during operations, between food products, equipment, materials, water, air exchange or personnel interventions and excluding external agents of contamination such as insects and other harmful animals;
 - d. provide, where necessary, adequate temperature conditions for processing e hygienic storage of products.

1. A sufficient number of washbasins must be available, adequately located and suitable for washing hands. Toilets must be available in sufficient numbers. connected to a good exhaust system. Toilets must not open directly onto food handling rooms.
2. Washbasins must have cold and hot running water, hand washing equipment and a hygienic drying system. Where necessary, food washing facilities must be separated from sinks.
3. Correct mechanical or natural ventilation must be ensured, avoiding the mechanical flow of air from a contaminated area to a clean area. Ventilation systems must be such as to allow easy access to filters and other parts that need to be cleaned or replaced.

4. All sanitary facilities in the premises where food is processed must have of a good ventilation system, natural or mechanical.
5. There must be adequate natural and/or artificial lighting in the rooms.
6. Exhaust systems must be fit for purpose, as well as designed and constructed in such a way as to avoid the risk of contamination of food products.

7. Where necessary, adequate changing facilities must be provided for the staff.



Specific requirements within premises where food products are prepared, processed or processed (excluding canteen premises and those specified in Chapter III)

1. In rooms where food products are prepared, processed or transformed (excluding rooms used as canteens):
 - to. floors must be kept in good condition, be easy to clean and where necessary to disinfect. This requires the use of resistant, non-absorbent, washable and non-toxic material, unless food operators demonstrate to the competent authority that other types of materials can be used appropriately. Where appropriate, the surface of the floors must ensure sufficient flow;
 - b. the walls of the walls must be kept in good condition and be easy to clean and where necessary to disinfect. This requires the use of material durable, non-absorbent, washable and non-toxic and a smooth surface up to a height suitable for operations, unless food operators demonstrate to the competent authority that other types of materials can be used appropriately;

- c. Ceilings and overhead fixtures must be designed, constructed and finished to avoid the accumulation of dirt and reduce condensation, the formation of undesirable mold and the shedding of particles;
- d. windows and other openings must be constructed to prevent the accumulation of dirt and those that can be opened towards the outside must, if necessary, be equipped with anti-insect nets that can be easily removed for cleaning. If opening windows causes food contamination, they must remain closed and locked during production;
- And. doors must have surfaces that are easily cleanable and if necessary disinfectable and for this purpose smooth and non-absorbent surfaces are required, unless food operators demonstrate to the competent authority that other types of materials used are suitable for the purpose;
- f. worktops (including plant surfaces) in contact with foods must be kept in good condition and be easy to maintain clean and disinfect if necessary. For this purpose, smooth, washable and non-toxic materials are required, unless food operators demonstrate to the competent authority that other types of materials used are suitable for the purpose.

2. If necessary, appropriate provisions must be made for cleaning and disinfection of work tools and systems, which must be made of corrosion-resistant material, easy to clean and have an adequate supply of hot and cold water.

3. Where appropriate, adequate provisions must be made for the necessary food washing operations. Every sink or similar system provided for washing food must have an adequate supply of hot and/or cold drinking water in order to be kept clean.



Requirements for mobile and/or temporary premises (such as pavilions, sales kiosks, truck-mounted sales stands), premises used primarily as a private residence, premises used occasionally for procurement purposes and vending machines

- 1. Premises and vending machines must be located, designed and constructed and kept clean and regularly maintained in such a way as to avoid, as far as reasonably possible; risks of food contamination and harboring of harmful agents.
- 2. In particular and where necessary:
 - to. appropriate equipment must be available to maintain adequate personal hygiene (including hygienic facilities for washing and drying hands, sanitary facilities and changing rooms);
 - b. surfaces in contact with food must be in good condition and easily washable and disinfectable if necessary. For this purpose, smooth materials are required,

washable and non-toxic, unless food operators demonstrate to the competent authority that other materials used are suitable for the purpose; c. appropriate provisions must be made for cleaning and, if necessary, disinfection of work tools and systems; d. adequate provisions must be made for cleaning food; And. an adequate supply of hot and/or cold drinking water must be available; f. appropriate storage equipment and facilities must be available e

the hygienic disposal of dangerous and/or inedible substances, as well as residues (liquid or solid); g. appropriate facilities and/or equipment must be available to maintain and

check adequate food temperature conditions; h. food products must be placed in such a way as to avoid, as far as reasonably possible, the risks of contamination.

IV

Transport

1. The vehicles and/or containers used for the transport of food products must be kept clean and subjected to regular maintenance in order to protect the food from sources of contamination and must, if necessary, be designed and constructed in such a way as to allow adequate cleaning and disinfection.
2. Vehicle loading spaces and/or containers must not be used for transport material other than food as the latter may become contaminated. Liquid, granular or powdered bulk foods must be transported in loading compartments and/or containers/tanks reserved for the transport of food products. A clearly visible and indelible mention must be placed on the containers in one or more community languages relating to their use for the transport of food products or the mention "exclusively for food products".
3. If the vehicles and/or containers are used for the transport of other goods in addition to food or different types of food at the same time, steps must be taken to effectively separate the various products where necessary to prevent the risk of contamination.
4. If the vehicles and/or containers are used for the transport of goods other than food products or different types of food products, they must be cleaned carefully between one load and another to avoid the risk of contamination.

5. Food products in vehicles and/or containers must be placed and protected in such a way as to minimize the risk of contamination.
6. Where necessary, vehicles and/or containers used to transport food must be capable of maintaining food at adequate temperature conditions and, where appropriate, be designed so that the temperature can be controlled.

V

Equipment requirements

All material, equipment and equipment that comes into contact with food must be kept clean and:

- a. to be designed and constructed of such material as to minimize, if maintained in good condition and subjected to regular maintenance, the risks of food contamination;
- b. with the exception of containers and disposable packaging, they must be designed and constructed of such material that, if kept in good condition and subjected to regular maintenance, they always remain absolutely clean and, if necessary, sufficiently disinfected according to the intended purposes;
- c. be installed in such a way as to allow adequate cleaning of the surrounding area.

YOU

Food residues

1. Food residues and other waste must not be piled up in food processing areas unless this is unavoidable for the proper functioning of the food business.
2. Food residues and other waste must be deposited in lockable containers unless food operators demonstrate to the competent authority that other types of containers used are suitable for the purpose. These containers must be constructed appropriately, maintained in good hygienic conditions and where necessary be easily cleaned and disinfected.
3. Appropriate provisions must be made for the removal and storage of food residues and other waste. Waste storage warehouses must be designed and constructed so that they can be easily kept clean and prevent the access of insects and other harmful animals and the contamination of food products, drinking water, systems or premises.

VII

Water supply

1. The drinking water supply must be adequate, the water must be compliant with the dictates of the decree of 27 April 1993 n.67, " *Quality characteristics of water intended for human consumption*".
2. Where appropriate, ice must be produced with water compliant with the aforementioned Decree and must be used, whenever necessary, in such a way as to ensure that food products are not contaminated. It must be manufactured, handled and stored in such a way as to avoid any possible contamination.
3. Steam directly in contact with food products must not contain any substance that presents a health risk or could contaminate the product.
4. Non-potable water used for steam generation, refrigeration, fire-fighting systems and other similar non-food purposes must pass through separate pipes, easily identifiable and without any connection or possibility of backflow with the water system drinking.

VIII

Personal hygiene

1. Every person working in food processing premises must maintain a high standard of personal cleanliness and will wear suitable, clean and, where appropriate, protective clothing.
2. No person known or suspected to be suffering from or carrying a food-borne disease or having, for example, infected wounds, skin infections, sores or diarrhea shall be permitted to work in any food processing area. foods, in any capacity if there is a direct or indirect probability of food contamination with pathogenic microorganisms.

IX

Provisions applicable to food products

1. A food business must not accept raw materials or ingredients if they are contaminated, or can logically be presumed to be contaminated, by parasites, pathogenic or toxic microorganisms, decomposed or foreign substances which, even after normal sorting and/or preliminary or treatment procedures carried out in a hygienic manner are not suitable for human consumption.
2. Raw materials and ingredients stored in the establishment must be properly stored so as to avoid harmful deterioration and contamination.

3. All handled foods stored, packaged, placed and transported must be protected from any form of contamination likely to render them unfit for human consumption, injurious to health or contaminated in such a way that they cannot reasonably be consumed under such conditions. In particular, food must be placed and/or protected in such a way as to minimize any risk of contamination. Appropriate procedures must be in place to ensure the control of harmful agents.
4. Raw materials, ingredients, intermediate and finished products, on which pathogenic microorganisms can proliferate or toxins form, must be stored at temperatures that do not cause risks to public health. Compatibly with food safety, it is permitted to derogate from temperature control for limited periods, if this is necessary for reasons of practicality during the preparation, transport, storage, placement and service of food.
5. If food is to be stored or served at a low temperature, it is necessary to cool it as quickly as possible, after the last heat treatment or preparation stage has been completed.
6. Hazardous and/or inedible substances including animal feed must be properly labeled and stored in separate, tightly closed containers.

X

Training

Food operators must ensure that workers are supervised and have received training and/or training in food hygiene, in relation to the type of business.