

REGULATION ON FOOD HYGIENE

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SECTION ONE

Objective, Scope, Legal Basis and Definitions

Objective

ARTICLE 1 – (1) The objective of the present Regulation is to define the general rules pertaining to food hygiene to be complied with by food business operators starting with the primary production of food to its provision to the final consumer with the aim of ensuring the protection of consumers in terms of food safety.

Scope

ARTICLE 2 – (1) The present Regulation covers procedures and principles pertaining to general hygiene rules to be ensured by food business operators, as well as their responsibilities, throughout all stages of production, processing and distribution, including the primary production stage.

(2) The present Regulation shall apply also to importation and exportation controls, and food business operators subject to the Regulation on Special Hygiene Rules for Animal Foodstuffs.

(3) The present Regulation shall not apply to;

- a) Primary production for personal consumption,
- b) Food preparation, processing and storage for personal consumption,
- c) The direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;
- d) Collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen.

Legal Basis

ARTICLE 3 – (1) The present Regulation has been prepared on the basis of:-

- a) Articles 22, 24, 27, 28, 29, 30, 31, 32 and 34 of the Law dated 11/06/2010 and No.5996 on Veterinary Services, Plant Health, Food and Feed,

b) Council Regulation on Hygiene of Foodstuffs No. 852/2004/EC of the European Parliament and the Council.

Definitions

ARTICLE 4 – (1) In addition to the definitions provided in Article 3 of the Law No. 5996, the definitions given in the second paragraph of this Article shall also apply.

(2) For the purposes of the implementation of the present Regulation, the following definitions shall apply;

a) Packaging/package: The placing of one or more wrapped foodstuffs in a second container, and the latter container itself;

b) Ministry: Ministry of Food, Agriculture and Livestock,

c) Contamination: The presence or introduction of a hazard,

d) Equivalent: Different systems or measures capable of attaining the same goals,

e) Food Hygiene: The measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use,

f) Food Business: An activity relevant to any stage of food production, processing and distribution by profit or non-profit public agencies and institutions and real or legal persons,

g) Hermetically Sealed Container: A container that is designed and intended to be secure against the entry of hazards,

h) Potable Water: Water for human consumption meeting the minimum requirements laid down in the Regulation dated 17/02/2005 and No. 25730 on Waters for Human Consumption,

i) Processing: Any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes,

j) Unprocessed products: Foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed,

k) Processed Products: Foodstuffs resulting from the processing of unprocessed products which contain ingredients that are necessary for their manufacture or to give them specific characteristics,

l) Law: Law No. 5996 on Veterinary Services, Plant Health, Food and Feed,

m) Wrapping/Wrapper: The placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself,

n) Final Consumer: The final consumer that will not employ the food for any commercial business or activity,

o) Clean Seawater: Natural, artificial or purified seawater or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities,

p) Clean Water: Clean seawater and fresh water of a similar quality;

q) Establishment: Any unit of a food business;

SECTION TWO

General Obligations of Food Business Operators, General Principles, General and Specific Hygiene Requirements

General Obligations of Food Business Operators

ARTICLE 5 – (1) Food business operators is responsible for ensuring that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.

General Principles

ARTICLE 6 – (1) Food hygiene rules specified in the present Regulation for food business operators have been designated by taking into consideration the following general principles:

a) Primary responsibility for food safety rests with the food business operator.

b) It is necessary to ensure food safety throughout the food chain, starting with primary production and extending to the final consumer.

c) It is important, for food that cannot be stored safely at ambient temperatures, particularly food that must be stored under cold conditions, to maintain the cold chain.

d) General implementation of procedures based on the critical control points/HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility.

e) Guides to good practice are an important instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with principles of hazard analysis and critical control points/HACCP.

f) It is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment.

g) It is necessary to ensure that imported foods are subject to at least the same hygiene rules as food produced within the country, or to an equivalent rule.

General and specific hygiene rules

ARTICLE 7 – (1) Food business operators carrying out primary production and those associated operations listed below shall comply with Articles 8 and 9 of the present Regulation and, in cases involving animal products, the specific hygiene requirements specified in Regulation on Specific Hygiene Rules for Animal Foodstuffs.

a) Activities pertaining to the transport, storage, sorting and similar operations of primary products at the place of production, provided that this does not substantially alter their nature or lead to new hazards.

b) Activities pertaining to the transport of live animals, where this is necessary to achieve the objectives of this Regulation.

c) In the case of products of plant origin, fishery products and wild game, transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment.

(2) Food business operators involved in any one of food production, handling and distribution stages following the activities specified in paragraph one of this Article is responsible for compliance with the general hygiene requirements included in Section Three of the present Regulation, as well as the specific hygiene requirements included in the Regulation on Specific Hygiene Rules for Animal Products.

(3) Food business operators are obliged, as required by their respective fields of activity, to adopt the following specific hygiene measures:

a) Compliance with microbiological criteria for foodstuffs.

b) Implementation of the procedures necessary to meet the objectives of this Regulation.

c) Compliance with temperature control requirements for foodstuffs;

d) Maintenance and registration of the cold chain;

e) Sampling and performance or outsourcing of analyses.

(4) In the absence of designated sampling or analysis methods in the relevant legislation, food business operators shall use methods that offer equivalent results to those obtained using the reference method, if they are scientifically validated in accordance with internationally recognised rules or protocols.

(5) Food business operators may employ good practice guides to ensure compliance with the obligations envisaged under the present Regulation.

General hygiene rules for primary production and associated operations

ARTICLE 8 – (1) As far as possible, food business operators responsible for primary production shall ensure that primary products are protected against contamination to the extent possible, having regard to any processing that primary products will subsequently undergo.

(2) Food business operators shall comply with the provisions of the relevant legislation relating to the control of hazards in primary production and associated operations, including:

a) Taking measures to control contamination arising from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products and biocides and the storage, handling and wastes.

b) Taking measures relating to animal health and welfare and plant health that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents.

(3) Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin shall take adequate measures with regard to the following:

a) Keeping any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed, clean and, where necessary after cleaning, to disinfect them in an appropriate manner.

b) Keeping clean and, where necessary after cleaning, to disinfect, in an appropriate manner, equipment, containers, crates, vehicles and vessels.

c) Ensuring, as far as possible, the cleanliness of animals going to slaughter and, where necessary, animals used for production of animal food.

d) Using potable water, or clean water, whenever necessary to prevent contamination;

e) Ensuring that staff handling foodstuffs are in good health and undergo training on health risks.

f) Preventing, as far as possible, animals and pests causing contamination.

g) Storing and handling waste and hazardous substances so as to prevent contamination.

h) Preventing the introduction and spread of contagious diseases transmissible to humans through food, including by taking precautionary measures when introducing new animals and reporting suspected outbreaks of such diseases to the Ministry.

i) Taking account of the results of any relevant analyses carried out on samples taken from animals or other samples that have importance to human health.

j) Using feed additives and veterinary medicinal products in the manner specified by the relevant legislation.

(4) Food business operators producing or harvesting plant products shall take adequate measures for the following:

a) Keeping clean and, where necessary after cleaning, to disinfect, in an appropriate manner, facilities, equipment, containers, crates, vehicles and vessels.

- b) Ensuring, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, plant products.
 - c) Using potable water, or clean water, whenever necessary to prevent contamination.
 - d) Ensuring that staff handling foodstuffs are in good health and undergo training on health risks.
 - e) Preventing, as far as possible, animals and pests causing contamination.
 - f) Storing and handling wastes and hazardous substances so as to prevent contamination.
 - g) Taking account of the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health.
 - h) Using plant protection products and biocides in the manner specified by the relevant legislation.
- (5) Food business operators responsible for primary production are responsible for implementing corrective action for problems detected during official audits and checks.

Record-keeping for primary production and associated operations

ARTICLE 9 – (1) Food business operators are obliged to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business and to present these records to the Ministry and to the receivers upon request.

(2) Food business operators rearing animals or producing primary products of animal origin are obliged, in particular, to keep records on the following:

- a) The nature and origin of feed fed to the animals.
- b) Veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods.
- c) The diseases that may affect the safety of products of animal origin.
- d) The results of any analyses carried out on samples taken from animals or other samples taken for diagnostic purposes that have importance for human health.
- e) All relevant reports on checks carried out on animals or products of animal origin.

(3) Food business operators producing or harvesting plant products are, in particular, to keep records on the following:

- a) Any use of plant protection products and biocides.
- b) Any occurrence of pests or diseases that may affect the safety of products of plant origin.

c) The results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health.

(4) Food business operators may recruit the assistance of persons with relevant Professional training for record-keeping.

SECTION THREE

General Hygiene Requirements for Food Businesses apart from Primary Production and Associated operations

General requirements for food businesses apart from those listed in Article 12

ARTICLE 10 – (1) Food premises are ensured to be kept clean and maintained in good repair and condition.

(2) The layout, design, construction, siting and size of food premises shall:

a) Provide adequate working space to permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination and to allow for the hygienic performance of all operations.

b) Prevent the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces.

c) Permit good food hygiene practices, including protection against contamination and, in particular, pest control.

d) Where necessary, provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.

(3) An adequate number of flush lavatories shall be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which food is handled.

(4) An adequate number of washbasins are to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands shall be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food shall be separate from the hand-washing facility.

(5) There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems shall be so constructed as to enable filters and parts requiring cleaning or replacement to be readily accessible.

(6) Personnel lavatories and shower and locker rooms shall have adequate natural or mechanical ventilation.

(7) Food premises shall have adequate natural and/or artificial lighting.

(8) Drainage facilities shall be adequate for the purpose intended. They shall be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they shall be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled.

(9) Where necessary, changing units and facilities of adequate number and capacity, permitting hygienic distribution of uniforms, as well as an adequate number of showers for personnel shall be provided.

(10) Cleaning agents and disinfectants shall not be stored in areas where food is handled.

Specific requirements for rooms where food is prepared, treated or processed apart from dining areas and food businesses listed in Article 12

ARTICLE 11 – (1) Rooms where food is prepared, treated or processed, including rooms where transport vehicles are stored, shall be designed and planned to permit good food hygiene practices, including protection against contamination between and during operations:

a) Floor surfaces shall be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. Floor surfaces are required to be constructed of impervious, non-absorbent, washable and non-toxic materials. Where appropriate, floors shall allow adequate surface drainage.

b) Wall surfaces shall be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. Wall surfaces are required to be constructed of impervious, non-absorbent, washable and non-toxic materials and to have a smooth surface up to a height appropriate for the operations.

c) Ceilings or, where there are no ceilings, the interior surface of the roof and overhead fixtures shall be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mould and the shedding of particles.

d) Windows and other openings shall be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment are, where necessary, to be fitted with pest-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows shall remain closed and fixed during production.

e) Doors shall be easy to clean and, where necessary, to disinfect and constructed of smooth and non-absorbent materials.

f) Surfaces in areas where foods are handled and in particular those in contact with food, including equipment surfaces, shall be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. Surfaces should be constructed of smooth, washable corrosion-resistant and non-toxic materials.

(2) Adequate facilities shall be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities shall be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water.

(3) Adequate provision is to be made, where necessary, for washing food. Every sink or other such facility provided for the washing of food is to have an adequate supply of hot and/or cold potable water consistent with the requirements of Article 16 of this Regulation and be kept clean and, where necessary, disinfected.

Requirements for movable and/or temporary premises such as marquees, market stalls, mobile sales vehicles, premises used primarily as a private dwelling house, but where foods are regularly prepared for placing on the market, and vending machines

ARTICLE 12 – (1) Premises and vending machines shall be so sited, designed, constructed and kept clean and maintained in good repair and condition as to avoid the risk of contamination, in particular by animals and pests.

(2) Where necessary;

a) Appropriate facilities are to be available to maintain adequate personal hygiene including facilities for the hygienic washing and drying of hands, hygienic sanitary arrangements and changing facilities.

b) Surfaces in contact with food are to be in a sound condition and be easy to clean and, where necessary, to disinfect. These surfaces shall be constructed of smooth, washable, corrosion-resistant and non-toxic materials.

c) Adequate provision is to be made for the cleaning and, where necessary, disinfecting of working utensils and equipment.

d) Where foodstuffs are cleaned as part of the food business' operations, adequate provision is to be made for this to be undertaken hygienically.

e) An adequate supply of hot and/or cold potable water is to be available.

f) Adequate arrangements or facilities for the hygienic storage and disposal of hazardous and/or inedible substances and liquid or solid waste are to be available.

g) Adequate facilities or arrangements for maintaining and monitoring suitable food temperature conditions are to be available.

h) Foodstuffs are to be so placed as to avoid the risk of contamination to the extent possible.

Transport

ARTICLE 13 – (1) Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and disinfection.

(2) Receptacles in vehicles and/or containers are not to be used for transporting anything other than foodstuffs where this may result in contamination.

(3) Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products.

(4) Bulk foodstuffs in liquid, granulate or powder form are to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers are to be marked "For Foodstuffs Only" in a clearly visible and indelible fashion, in Turkish or in both Turkish and any other foreign language, to show that they are used for the transport of foodstuffs.

(5) Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination.

(6) Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimise the risk of contamination.

(7) Where necessary, conveyances and/or containers used for transporting foodstuffs are to be capable of maintaining foodstuffs at appropriate temperatures and allow those temperatures to be monitored.

Equipment requirements

ARTICLE 14 – (1) All materials, tools and equipment shall:-

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 and be kept in such good order, repair and condition as to minimise any risk of contamination.

c) With the exception of non-recycled containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected.

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

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

(3) Where chemical additives have to be used to prevent corrosion of equipment and containers, they are to be used in accordance with good practice.

Food waste

ARTICLE 15 – (1) Food waste, non-edible by-products and other refuse are to be removed from rooms where food is present as quickly as possible, so as to avoid their accumulation.

(2) Food waste, non-edible by-products and other refuse are to be deposited in closable container or an appropriate alternative system in line with the objective of this Regulation.

These containers are to be of an appropriate construction, kept in sound condition, be suitable for cleaning and, where necessary, disinfection.

(3) Adequate provision is to be made for the storage and disposal of food waste, non-edible by-products and other refuse. Refuse stores are to be designed and used in such a way as to enable them to be kept clean and, where necessary, protected from animals and pests.

(4) All waste is to be eliminated in a hygienic and environmentally friendly way and to be prevented from constituting a direct or indirect source of contamination.

Water supply

ARTICLE 16 – (1) Water to be used at food businesses shall be supplied in such a manner as to satisfy the following conditions:

a) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated.

b) Clean water may be used with whole fishery products. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods. Clean water may also be used for external washing of these products. When clean water is used, facilities and procedures for the supply of clean water are to be available for its supply in order to prevent the emergence of a source of contamination for the foodstuff.

(2) Where non-potable water is used, for example for fire control, steam production, refrigeration and other similar purposes, it is to circulate in a separate duly identified system. Non-potable water is not to connect with, or allow reflux into, potable water systems.

(3) Recycled water used in processing or as an ingredient is not to present a risk of contamination. The quality of such water must be at the same level as that of potable water unless the Ministry establishes that the water will not affect the compliance of the final state of the foodstuff with health requirements.

(4) Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water. It is to be made, handled and stored under conditions that protect it from contamination.

(5) Steam used directly in contact with food is not to contain any substance that presents a hazard to health or is likely to contaminate the food.

(6) Where heat treatment is applied to foodstuffs in hermetically sealed containers it is to be ensured that water used to cool the containers after heat treatment is not a source of contamination for the foodstuff.

Personnel Hygiene

ARTICLE 17 – (1) All personnel working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.

(2) No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to

be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination.

(3) Any person so affected by the symptoms specified in the second article of this Article and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the food business operator.

Provisions applicable to foodstuffs

ARTICLE 18 – (1) A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be contaminated with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.

(2) Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent deterioration, putrefaction and protect them from contamination.

(3) At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.

(4) Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored.

(5) Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins are not to be kept at temperatures that might result in a risk to health and in such a manner as to interrupt the cold chain. Limited periods outside temperature control are permitted, to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that it does not result in a risk to health. Food businesses manufacturing, handling and wrapping processed foodstuffs are to have suitable rooms, large enough for the separate storage of raw materials from processed material and sufficient separate refrigerated storage.

(6) Where foodstuffs are to be held or served at chilled temperatures they are to be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature which does not result in a risk to health.

(7) The thawing of foodstuffs is to be undertaken in such a way as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins in the foods and not to pose a risk to health. Where run-off liquid from the thawing process may present a risk to health it is to be adequately drained. Following thawing, food is to be handled in such a manner as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins.

(8) Hazardous and/or inedible substances, including animal feed, are to be adequately labelled and stored in separate and secure containers.

Provisions on wrapping and packaging of foodstuffs

ARTICLE 19 – (1) Material used for wrapping and packaging may not be a source of contamination.

(2) Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.

(3) Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured.

(4) Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect.

Heat treatment

ARTICLE 20 – (1) The following requirements apply only to food placed on the market in hermetically sealed containers:

a) Any heat treatment process used to process an unprocessed product or to process further a processed product is to raise every part of the product treated to a given temperature for a given period of time and to prevent the product from becoming contaminated during the process.

b) To ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant parameters, particularly temperature, pressure, sealing and microbiology, including by the use of automatic devices;

c) The process used should conform to an internationally recognised standard such as pasteurisation, UHT or sterilisation.

Training

ARTICLE 21 – (1) Food business operators are to ensure:

a) That food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity.

b) That those responsible for the development and maintenance of the procedure referred to in first paragraph of Article 22 of this Regulation or for the operation of relevant guides have received adequate training in the application of the HACCP principles.

SECTION FOUR

Hazard Analysis and Critical Control Points/HACCP, Official Controls, Approval and Registration

Hazard Analysis and Critical Control Points/HACCP

ARTICLE 22 – (1) Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the Hazard Analysis and Critical Control Points/HACCP principles.

(2) The Hazard Analysis and Critical Control Points/HACCP consist of the following seven principles:

- a) Identifying any hazards that must be prevented, eliminated or reduced to acceptable levels,
- 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,
- c) Establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards,
- d) Establishing and implementing effective monitoring procedures at critical control points,
- e) Establishing corrective actions when monitoring indicates that a critical control point is not under control,
- f) Establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a), (b), (c), (d) and (e) are working effectively; and
- 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), (b), (c), (d), (e) and (f).

(3) When any modification is made by the food business operator in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

(4) Paragraph 1 of this Article shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and associated operations.

(5) Food business operators shall;

- a) Provide the evidence of their compliance with paragraph 1 of this Article in the manner that the Ministry requires, taking account of the nature and size of the food business.
- b) Ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times.
- c) Retain any other documents and records for an appropriate period.

Official Controls, Approval and Registration

ARTICLE 23 – (1) Food business operators shall cooperate with the Ministry in the implementation of the legislation published on the basis of the Law.

(2) Food business operators are obliged to ensure that the registration and approval procedures for its facility which is active in any one of food production, processing and distribution stages in line with the Regulation on Registration and Approval of Food Businesses.

SECTION FIVE

Guides to Good Practice and Recommendations for Guides

Guides to good practice

ARTICLE 24 – (1) The Ministry shall encourage the development of guides to good practice, subject to the conditions given below, for hygiene and for the application of Hazard Analysis and Critical Control Points/HACCP principles. The use of these guidelines prepared for business operators shall be on a voluntary basis.

(2) Guides to good practice shall be prepared by taking into consideration the following:

a) Guides to good practice shall be prepared by the food sector by taking into consideration the existing guides to good practice of the Codex Alimentarius Commission, as well as the provisions of the relevant legislation, and through the participation or opinions of relevant parties that may be affected by the guide including the Ministry and consumers' organizations.

b) The preparation of guides to good practice for food business operators involved in primary production and the activities specified in the first paragraph of Article 7 of this Regulation shall take into consideration the provisions given in Article 25 of the present Regulation.

(3) Guides to good practice may also be prepared under the auspices of the Turkish Standards Institute designated as the National Standardization Body in the Regulation on the Notification of Technical Legislation and Standards between Turkey and the European Union published on the Official Gazette dated 3/4/2002 and No. 24715.

(4) The Ministry shall take into consideration the following issues in the evaluation of guides to good practice:

a) Whether the guides to good practice have been prepared in line with the second paragraph of this Article,

b) Whether the contents of the guides to good practice are usable by the relevant sector,

c) Whether the guides to good practice provide guidance to the relevant sector with relation to the foodstuffs in its scope in order to allow for the implementation of the obligations specified in Articles 6, 7 and 22 of the present Regulation.

Recommendation for guides to good practice on primary production and associated operations

ARTICLE 25 – (1) Guides to good practice shall contain guidance on good hygiene practice for the control of hazards in primary production and associated operations referred to in the first paragraph of Article 7 of the present Regulation.

(2) Guides to good hygiene practice should include appropriate information on hazards that may arise in primary production and associated operations specified in the first paragraph of Article 7 of the present Regulation and actions to control hazards, including relevant measures

set out in the Law and national legislation and control activities undertaken by the Ministry. Examples of such hazards and measures may include:

- a) The control of contamination such as mycotoxins, heavy metals and radioactive material.
- b) The use of water, organic waste and fertilisers.
- c) The correct and appropriate use of plant protection products and biocides and their traceability.
- d) The correct and appropriate use of veterinary medicinal products and feed additives and their traceability.
- e) The preparation, storage, use and traceability of feed.
- f) The proper disposal of dead animals, waste and litter.
- g) Protective measures to prevent the introduction of contagious diseases transmissible to humans through food, and any obligation to notify the Ministry.
- h) Procedures, practices and methods to ensure that food is produced, handled, packed, stored and transported under appropriate hygienic conditions, including effective cleaning and pest-control.
- i) Measures relating to the cleanliness of slaughter and production animals.
- j) Measures relating to record-keeping.

SECTION SIX

Imports and Exports

Imports

ARTICLE 26 – (1) Hygiene requirements applicable to imported foodstuffs are to be in line with the requirements specified in Articles 6, 7, 22 and 23 of the present Regulation.

Exports

ARTICLE 27 – (1) Hygiene requirements applicable to exported or re-exported foodstuffs are to be in line with the requirements specified in Articles 6, 7, 22 and 23 of the present Regulation

SECTION SEVEN

Miscellaneous and Final Provisions

Repealed Regulation

ARTICLE 28 – (1) The Regulation on the Work Permits, Food Registration and Production License Operations for Businesses Producing Foodstuffs and Substances and Materials in Contact with Food and the Employment of Engagement Directors published on the Official

Gazette dated 27/8/2004 and No. 25566 has been repealed as of the date of publication of the present Regulation.

Transition provisions

PROVISIONAL ARTICLE 1 – (1) Food business operators already active in the sector by reason of having obtained a work permit document, a food registration document, a registration document or a document equivalent to the aforementioned before the publication date of this Regulation are under the obligation to ensure the compliance of their establishment with the establishment requirements specified in the present Regulation by 31/12/2012. However, if a food business operator will not be able to comply with the establishment requirements specified in the present Regulation by 31/12/2012 and submits a plan for the modernization of their establishment, this deadline may be extended until 31/12/2013.

(2) For establishments already in active operation, those provisions, which are not in contradiction with the present Regulation, of the Regulation on the Work Permits, Food Registration and Production License Operations for Businesses Producing Foodstuffs and Substances and Materials in Contact with Food and the Employment of Engagement Directors published on the Official Gazette dated 27/8/2004 and No. 25566; the Regulation on Procedures and Principles for Production, Functioning and Inspection of Red Meat and Meat Products published on the Official Gazette dated 5/1/2005 and No. 25691; and the Regulation on the Procedures and Principles for Functioning and Inspection of Poultry Meat and Meat Production Establishments published on the Official Gazette dated 8/1/2005 and No. 25694 shall continue to apply from the publication date of the present Regulation to the acquisition of relevant approvals.

Effectiveness

ARTICLE 29 – (1) This Regulation shall be put into effect as of its date of publication.

Execution

ARTICLE 30 – (1) The provisions of this Regulation shall be executed by the Ministry of Food, Agriculture and Livestock.