

ANNEX I

PRIMARY PRODUCTION

PART A:

GENERAL HYGIENE PROVISIONS FOR PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS

I. SCOPE

1. This Annex applies to primary production and the following associated operations:
 - (a) the transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature;
 - (b) the transport of live animals, where this is necessary to achieve the objectives of this Regulation; and
 - (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.

II. HYGIENE PROVISIONS

2. As far as possible, food business operators are to ensure that primary products are protected against contamination, having regard to any processing that primary products will subsequently undergo.
3. Notwithstanding the general duty laid down in paragraph 2, food business operators are to comply with appropriate Community and national legislative provisions relating to the control of hazards in primary production and associated operations, including:
 - (a) 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 disposal of waste; and
 - (b) 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.
4. Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are to take adequate measures, as appropriate:
 - (a) to keep 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) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, equipment, containers, crates, vehicles and vessels;
 - (c) as far as possible to ensure the cleanliness of animals going to slaughter and, where necessary, production animals;
 - (d) to use potable water, or clean water, whenever necessary to prevent contamination;

- (e) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;
 - (f) as far as possible to prevent animals and pests from causing contamination;
 - (g) to store and handle waste and hazardous substances so as to prevent contamination;
 - (h) to prevent 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 competent authority;
 - (i) to take account of the results of any relevant analyses carried out on samples taken from animals or other samples that have importance to human health; and
 - (j) to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation.
5. Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:
- (a) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, facilities, equipment, containers, crates, vehicles and vessels;
 - (b) to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, plant products;
 - (c) to use potable water, or clean water, whenever necessary to prevent contamination;
 - (d) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;
 - (e) as far as possible to prevent animals and pests from causing contamination;
 - (f) to store and handle wastes and hazardous substances so as to prevent contamination;
 - (g) to take account of the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health; and
 - (h) to use plant protection products and biocides correctly, as required by the relevant legislation.
6. Food business operators are to take appropriate remedial action when informed of problems identified during official controls.
- III. RECORD-KEEPING
7. Food business operators are 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. Food business operators are to make relevant information contained in these records available to the competent authority and receiving food business operators on request.
8. Food business operators rearing animals or producing primary products of animal origin are, in particular, to keep records on:
- (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 occurrence of 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; and
 - (e) any relevant reports on checks carried out on animals or products of animal origin.
9. Food business operators producing or harvesting plant products are, in particular, to keep records on:
- (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; and
 - (c) the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health.
10. The food business operators may be assisted by other persons, such as veterinarians, agronomists and farm technicians, with the keeping of records.

PART B:

RECOMMENDATIONS FOR GUIDES TO GOOD HYGIENE PRACTICE

1. National and Community guides referred to in Articles 7 to 9 of this Regulation should contain guidance on good hygiene practice for the control of hazards in primary production and associated operations.
2. Guides to good hygiene practice should include appropriate information on hazards that may arise in primary production and associated operations and actions to control hazards, including relevant measures set out in Community and national legislation or national and Community programmes. 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 competent authority;
 - (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.

ANNEX II

GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS (EXCEPT WHEN ANNEX I APPLIES)

INTRODUCTION

Chapters V to XII apply to all stages of production, processing and distribution of food and the remaining Chapters apply as follows:

- Chapter I applies to all food premises, except premises to which Chapter III applies;
- Chapter II applies to all rooms where food is prepared, treated or processed, except dining areas and premises to which Chapter III applies;
- Chapter III applies to those premises listed in the heading to the Chapter;
- Chapter IV applies to all transportation.

CHAPTER I

GENERAL REQUIREMENTS FOR FOOD PREMISES

(OTHER THAN THOSE SPECIFIED IN CHAPTER III)

1. Food premises are to be kept clean and maintained in good repair and condition.
2. The layout, design, construction, siting and size of food premises are to:
 - (a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise airborne contamination, and provide adequate working space to allow for the hygienic performance of all operations;
 - (b) be such as to protect against 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; and
 - (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 are to 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 is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food are to 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 are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.
6. Sanitary conveniences are to have adequate natural or mechanical ventilation.
7. Food premises are to have adequate natural and/or artificial lighting.
8. Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to 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, adequate changing facilities for personnel are to be provided.
10. Cleaning agents and disinfectants are not to be stored in areas where food is handled.

CHAPTER II

SPECIFIC REQUIREMENTS IN ROOMS WHERE FOODSTUFFS ARE PREPARED, TREATED OR PROCESSED (EXCLUDING DINING AREAS AND THOSE PREMISES SPECIFIED IN CHAPTER III)

1. In rooms where food is prepared, treated or processed (excluding dining areas and those premises specified in Chapter III, but including rooms contained in means of transport) the design and layout are to permit good food hygiene practices, including protection against contamination between and during operations. In particular:
 - (a) floor surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors are to allow adequate surface drainage;
 - (b) wall surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business operators can satisfy the competent authority that other materials used are appropriate;
 - (c) ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to 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 are to be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment are, where necessary, to be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows are to remain closed and fixed during production;
 - (e) doors are to be easy to clean and, where necessary, to disinfect. This will require the use of smooth and non-absorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate; and

- (f) surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate.
- 2. Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to 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 Chapter VII and be kept clean and, where necessary, disinfected.

CHAPTER III

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

- 1. Premises and vending machines are, so far as is reasonably practicable, to 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. In particular, 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. This will require the use of smooth, washable, corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate;
 - (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 and/or facilities for the hygienic storage and disposal of hazardous and/or inedible substances and waste (whether liquid or solid) are to be available;
 - (g) adequate facilities and/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 so far as is reasonably practicable.

CHAPTER IV

TRANSPORT

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/or 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 in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or are to be marked "for foodstuffs only".
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.

CHAPTER V

EQUIPMENT REQUIREMENTS

1. AH 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 and be 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 and be 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.
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.

CHAPTER VI

FOOD WASTE

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 containers, unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect.
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 managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests.
4. All waste is to be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.

CHAPTER VII

WATER SUPPLY

1.
 - (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. When such water is used, adequate facilities are to be available for its supply.
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. It is to be of the same standard as potable water, unless the competent authority is satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.
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.

CHAPTER VIII

PERSONAL HYGIENE

1. Every person 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. Any person so affected 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.

CHAPTER DC

PROVISIONS APPLICABLE TO FOODSTUFFS

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, or might reasonably be expected 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 harmful deterioration 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 (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).
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. The cold chain is not to be interrupted. However, 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. During thawing, foods are to be subjected to temperatures that would not result in 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.

CHAPTER X

PROVISIONS APPLICABLE TO THE WRAPPING AND PACKAGING OF FOODSTUFFS

1. Material used for wrapping and packaging are not to 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.

CHAPTER XI

HEAT TREATMENT

The following requirements apply only to food placed on the market in hermetically sealed containers:

1. any heat treatment process used to process an unprocessed product or to process further a processed product is;
 - (a) to raise every party of the product treated to a given temperature for a given period of time; and
 - (b) to prevent the product from becoming contaminated during the process;
2. 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;
3. the process used should conform to an internationally recognised standard (for example, pasteurisation, ultra high temperature or sterilisation).

CHAPTER XII

TRAINING

Food business operators are to ensure:

1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;
2. that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received adequate training in the application of the HACCP principles; and
3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors.