L.N. 385 of 2005

VETERINARY SERVICES ACT
(CAP. 437)

Hygiene of Foodstuffs Rules, 2005

BY virtue of the powers conferred by articles 8 and 9 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title, scope and applicability.

1. (1) The title to these rules is the Hygiene of Foodstuffs Rules, 2005.

(2) The scope of these rules is to implement the provisions found under European Union Council Directive 93/43/EEC regarding the hygiene of foodstuffs.

(3) These rules aim at laying down the general rules of hygiene for foodstuffs and the procedures for verification of compliance with these rules.

Definitions.

2. (1) For the purposes of these rules, the following definitions shall apply -

the "Act" means the Veterinary Services Act;

"the Commission" means the European Commission;

"the Community" means the European Community as established under the Treaty establishing the European Community;

"the competent authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

"food business" means any undertaking, whether for profit or not and whether public or private, carrying out any or all of the following: preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling or offering for sale or supply of foodstuffs,

"food hygiene", hereinafter called "hygiene" means all measures necessary to ensure the safety and wholesomeness of foodstuffs. The measures shall cover all stages after primary production (the latter including, for example, harvesting, slaughter and milking), during preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer,

"Member State" means a State which is a Member within the European Community;

"wholesome food" shall mean food which is fit for human consumption as far as hygiene is concerned.

Manufacturing and sale or supply of foodstuffs.

3. (1) The preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply of foodstuffs shall be carried out in a hygienic way.

(2) Food business operators shall identify any step in their activities which is critical to ensuring food safety and ensure that adequate safety procedures are identified, implemented, maintained and reviewed on the basis of the following principles, used to develop the system of HACCP (Hazard analysis and critical control points):

(i) analysing the potential food hazards in a food business operation,

(ii) identifying the points in those operations where food hazards may occur,

(iii) deciding which of the points identified are critical to food safety, the 'critical points',

(iv) identifying and implementing effective control and monitoring procedures at those critical points,

(v) reviewing the analysis of food hazards, the critical control points and the control,

(vi) monitoring procedures periodically and whenever the food business operations change.

(3) Food business operators shall comply with the rules of hygiene as listed in the Schedule to these rules. Derogations from certain provisions of the said Schedule may be granted according to the procedure laid down in Article 14 of the Directive.

Adoption of specific criteria.

4. Without prejudice to more specific rules of the European Union, microbiological criteria and temperature control criteria for certain classes of foodstuffs may be adopted in accordance with the procedure laid down in Article 14 of the Directive and after consulting the Scientific Committee for Food set up by Decision 74/234/EEC.

Guides to good hygiene practice.

5. (1) Member States shall encourage the development of guides to good hygiene practice which may be used voluntarily by food businesses as a guide to compliance with the provisions of rules 3 of these rules.

(2) Where the guides to good hygiene practice referred to in sub-rule (1) hereof are developed, they shall be developed as follows:

(i) by food business sectors and representatives of other interested parties, such as appropriate authorities and consumer groups,

(ii) in consultation with interests substantially affected, including the competent authorities,

(iii) where appropriate, having regard to the Recommended International Code of Practice, General Principles of Food Hygiene of the Codex Alimentarius.

(3) The guides referred to in sub-rules (1) and (2) may be developed under the aegis of a national standards institute referred to in list 2 of the Schedule to Council Directive 83/189/EEC of the 28th March 1983 laying down a procedure for the provision of information in the field of technical standards and Rules.

(4) Member States shall assess the guides to good hygiene practice referred to in sub-rules (1) and (2) hereof with a view to determining the extent to which they may be presumed to comply with rule 3 of these rules.

(5) Member States shall forward to the Commission those guides to good hygiene practice which they presume to comply with

Article 3 of the Directive. The Commission shall make these guides available to the Member States.

(6) Where one or more Member States, or the Commission, consider that, for the purposes of harmonization, there may be a need for guides to good hygiene practice to be developed on a European basis (hereafter referred to as 'European guides to good hygiene practice'), the Commission shall consult Member States in the framework of the Standing Committee on Foodstuffs in accordance with Article 14 of the Directive. The object of this consultation shall be to consider the case for such voluntary guides in the sectors or activities concerned, and, where such guides are considered necessary:

(i) to indicate the intended scope, subject matter and timetable for development of such voluntary guides, taking into account the time needed for consultation with interests substantially affected by them, and

(ii) to refer such voluntary guides for development and/or assessment under the aegis of a European standards institute.

(7) In developing the European guides to good hygiene practice referred to in sub-rule (6), all necessary measures shall be taken in order to:

(i) ensure that such guides are developed by representatives of food business sectors and representatives of other interests substantially affected, such as, for example, the competent authorities and consumer groups,

(ii) ensure that the contents of such guides comply with the provisions of rule 3 of these rules and, where appropriate, have regard to the Recommended International Code of Practice, General Principles of Food Hygiene of the Codex Alimentarius,

(iii) ensure that the contents of such guides are practicable for the food industry sectors to which they refer throughout the Community,

(iv) ensure that the relevant guides to good hygiene practice drawn up in accordance with sub-rules (1) and (3) are taken into account,

(v) ensure that all interests substantially affected by such guides, including Member States, are consulted and their comments taken into account.

(8) The titles and references of European guides to good hygiene practice developed in accordance with the procedure in paragraphs 6 and 7 Article 5 of the Directive are published in the C series of the Official Journal of the European Communities. Member States shall ensure that such published guides are drawn to the attention of the relevant food business sectors and the appropriate authorities in their territories.

Application of European Standards.

6. Member States shall, if they consider it appropriate, recommend food business operators to apply the European Standards of the EN 29000 series in order to implement the general rules of hygiene and the guides to good hygiene practice.

National Provisions.

7. (1) Subject to the Treaty, Member States may maintain, amend or introduce national hygiene provisions that are more specific than those laid down by the Directive, provided that such provisions:

(i) are not less stringent than those given in the Schedule,

(ii) do not constitute a restriction, hindrance or barrier to trade in foodstuffs produced in accordance with the Directive.

(2) Until detailed provisions have been laid down in accordance with Article 4 of the Directive, Member States may maintain, amend or introduce the relevant national provisions, subject to the Treaty.

(3) Should a Member State deem it necessary, in the cases provided for in paragraphs 1 and 2 of Article 7 of the Directive, to adopt new legislation or amend existing legislation, it shall communicate to the Commission and the other Member States the measures envisaged and give the reasons justifying them. The Commission shall consult the Member States within the Standing Committee on Foodstuffs set up by Decision 69/414/EEC if it considers such consultation to be useful or if a Member State so requests.

The Member State may take the envisaged measures only three months after such communication and provided that it has not received an opinion to the contrary from the Commission.

In the latter event, before the expiry of the period referred to in the second subparagraph, the Commission shall initiate the procedure provided for in Article 14 of the Directive in order to determine whether the envisaged measures may be implemented subject, if necessary, to the appropriate amendments.

Controls.

8. (1) The competent authorities shall carry out controls in accordance with Directive 89/397/EEC in order to ensure that the provisions of Article 3 of this Directive and, where appropriate, any provisions laid down pursuant to Article 4 of this Directive are being complied with by food businesses. In doing so, due consideration shall be given to the guides to good hygiene practice referred to in Article 5 of this Directive, where they exist.

(2) Inspections by competent authorities shall include a general assessment of the potential food safety hazards associated with the business. Competent authorities shall pay particular attention to critical control points identified by food businesses to assess whether the necessary monitoring and verification controls are being operated.

Member States shall provide that all food premises are inspected at a frequency which has regard to the risk associated with the premises.

(3) The competent authorities shall ensure that controls on foodstuffs imported into the Community are carried out in accordance with Directive 89/397/EEC for the purpose of ensuring that the relevant provisions of Article 3 and, where appropriate, any provisions laid down pursuant to Article 4, are being observed.

Failure to comply with rules.

9. (1) If while carrying out the controls referred to in rule 8, the competent authorities ascertain that failure to comply with the provisions of rule 3 or, where appropriate, any provisions laid down pursuant to rule 4 might result in risks to the safety or wholesomeness of foodstuffs, they shall take appropriate measures which may extend to the withdrawal and, or the destruction of the foodstuff or to the closure of all or part of the undertaking for an appropriate period of time.

In determining the risk to food safety or wholesomeness regard shall be had to the nature of the food, the manner in which it is handled and packed and any process to which the food is subjected before supply to the consumer and the conditions under which it is displayed and, or stored.

(2) Member States shall take the necessary measures to ensure that any natural or legal person affected by the control has a right of appeal against the measures taken by the competent authority following the control.

Threats to human health.

10. (1) If a hygiene problem likely to pose a serious risk to human health arises or spreads in the territory of a third country, the Commission, either on its own initiative or at the request of a Member State, shall take the following measures without delay, depending on the seriousness of the situation:

(i) suspend imports from all or part of the third country concerned and, where necessary, from the transit third country, and, or

(ii) lay down special conditions for foodstuffs from all or part of the third country concerned.

(2) The Commission may, in the case provided for in sub-rule (1), take interim protective measures regarding the foodstuffs concerned.

(3) Except in an emergency, the Commission shall consult the Member States before taking the measures referred to in sub-rules (1) and (2).

(4) The Commission shall notify the Council and the Member States without delay of any decision taken pursuant to sub-rules (1) and (2).

Any Member State may refer the Commission's decision to the Council within 30 days of the notification referred to in sub-rule (1). The Council, acting by a qualified majority, may confirm, amend or revoke the decision adopted by the Commission. If the Council has not taken a decision within 30 days, the decision of the Commission is deemed to be revoked.

(5) Where a Member State officially informs the Commission of the need to take safeguard measures and the Commission has not had recourse to the provisions of sub-rules (1) and (2), that Member State may take interim protective measures with regard to imports of the foodstuffs in question.

When a Member State takes interim protective measures, it shall inform the other Member States and the Commission.

Within ten working days, the Commission shall put the matter before the Standing Committee on Foodstuffs in accordance with the procedure laid down in rule 14 with a view to the extension, amendment or abrogation of the national interim protective measures.

New information available.

11. (1) Where as a result of new information or of a reassessment of existing information, Malta has good reason to suspect that application of the detailed provisions laid down pursuant to rule 4 constitutes a health risk, the competent authority may temporarily suspend or restrict application of the provisions in question in Malta. It shall inform the other Member States and the Commission thereof without delay and give reasons for its decision.

(2) The Commission shall examine the reasons given by the Member State referred to in sub-rule (1) as soon as possible in the Standing Committee on Foodstuffs and shall deliver its opinion and take any necessary measures in accordance with the procedure laid down in rule 14.

Competent Authority.

12. Member States shall designate the competent authorities responsible for the control of hygiene and shall notify the Commission about them.

International Standards.

13. Amendments to references to international standards, such as those of the Codex Alimentarius, contained in this rule, may be adopted in accordance with the procedure laid down in rule 14.

Standing Committee of Foodstuffs.

14. (1) The Commission shall be assisted by the Standing Committee on Foodstuffs (hereinafter referred to as "the Committee").

(2) The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission.

(3) The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

(4) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

(5) If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

(6) If, three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

SCHEDULE

Preface

1. Chapters V to X of this Schedule apply throughout all stages after primary production during preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer.

The remaining chapters of the Schedule apply as follows:

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

2. The terms 'where appropriate' and 'where necessary' used in this Schedule mean for the purposes of ensuring the safety and wholesomeness of foodstuffs.

I. General requirements for food premises (other than those specified in Chapter III) 1. Food premises must be kept clean and maintained in good repair and condition.

2. The layout, design, construction and size of food premises shall:

(a) permit adequate cleaning and/or disinfection;

(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 cross contamination between and during operations by foodstuffs, equipment, materials, water, air supply or personnel and external sources of contamination such as pests;

(d) provide, where necessary, suitable temperature conditions for the hygienic processing and storage of products.

3. An adequate number of washbasins must be available, suitably located and designated for cleaning hands. An adequate number of flush lavatories must be available and connected to an effective drainage system. Lavatories must not lead directly into rooms in which food is handled.

4. Washbasins for cleaning hands must be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. When necessary, the provisions for washing food must be separate from the hand-washing facility.

5. There must be suitable and sufficient means of natural or mechanical ventilation. Mechanical air flow from a contaminated area to a clean area must be avoided. Ventilation systems must be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.

6. All sanitary conveniences within food premises shall be provided with adequate natural or mechanical ventilation.

7. Food premises must have adequate natural and/or artificial lighting.

8. Drainage facilities must be adequate for the purpose intended; they must be designed and constructed to avoid the risk of contamination of foodstuffs.

9. Adequate changing facilities for personnel must be provided where necessary.

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):

(a) floor surfaces must be maintained in a sound condition and they must be easy to clean and, where necessary, 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 must allow adequate surface drainage;

(b) wall surfaces must be maintained in a sound condition and they must be easy to clean and, where necessary, 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 and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable moulds and the shedding of particles;

(d) windows and other openings must be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment must where necessary be fitted with insect proof screens which can

be easily removed for cleaning. Where open windows would result in contamination of foodstuffs, windows must remain closed and fixed during production;

(e) doors must be easy to clean and, where necessary, 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;

(f) surfaces (including surfaces of equipment) in contact with food must be maintained in a sound condition and be easy to clean and, where necessary, disinfect. This will require the use of smooth, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate.

2. Where necessary, adequate facilities must be provided for the cleaning and disinfecting of work tools and equipment. These facilities must be constructed of materials resistant to corrosion and must be easy to clean and have an adequate supply of hot and cold water.

3. When appropriate, adequate provision must be made for any necessary washing of the food. Every sink or other such facility provided for the washing of food must have an adequate supply of hot and/or cold potable water as required and be kept clean.

III Requirements for movable and/or temporary premises (such as Marquees, market stalls, mobile sales vehicles) premises used primarily as a private dwelling house, premises used occasionally for catering purposes, and vending machines 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 contaminating foodstuffs and harbouring pests, so far as is reasonably practicable.

2. In particular and where necessary:

(a) appropriate facilities must 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 must be in a sound condition and be easy to clean and, where necessary, disinfect. This will require the use of smooth, washable, non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate;

(c) adequate provision must be made for the cleaning and, where necessary, disinfecting of work utensils and equipment;

(d) adequate provision must be made for the cleaning of foodstuffs;

(e) an adequate supply of hot and/or cold potable water must 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) must be available;

(g) adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions must be available;

(h) foodstuffs must be so placed as to avoid, so far as is reasonably practicable, the risk of contamination.

IV Transport 1. Conveyances and/or containers used for transporting foodstuffs must be kept clean and maintained in good repair and condition in order to protect foodstuffs from contamination and must, where necessary, be designed and constructed to permit adequate cleaning and/or disinfection.

2. Receptacles in vehicles and/or containers must not be used for transporting anything other than foodstuffs where this may result in contamination of foodstuffs. Bulk foodstuffs in liquid, granular or powder form must be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers must 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 must be marked 'for foodstuffs only'.

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 must be effective separation of products, where necessary, to protect against the risk of contamination.

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

5. Foodstuffs in conveyances and/or containers must be so placed and protected as to minimize the risk of contamination.

6. Where necessary, conveyances and/or containers used for transporting foodstuffs, must be capable of maintaining foodstuffs at appropriate temperatures and, where necessary, designed to allow those temperatures to be monitored.

V Equipment requirements

All articles, fittings and equipment with which food comes into contact shall be kept clean and:

(a) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimize any risk of contamination of the food;

(b) 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 thoroughly cleaned and, where necessary, disinfected, sufficient for the purposes intended;

(c) be installed in such a manner as to allow adequate cleaning of the surrounding area.

VI Food waste

1. Food waste and other refuse must not be allowed to accumulate in food rooms except so far as is unavoidable for the proper functioning of the business.

2. Food waste and other refuse must be deposited in closable containers unless food business operators can satisfy the competent authority that other types of containers used are appropriate.

These containers must be of an appropriate construction, kept in sound condition and where necessary be easy to clean and disinfect.

3. Adequate provision must be made for the removal and storage of food waste and other refuse. Refuse stores must be designed and managed in such a way as to enable them to be kept clean and to protect against access by pests and against contamination of food, drinking water, equipment or premises.

VII Water supply

1. There must be an adequate supply of potable water as specified in Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption (1). This potable water must be used whenever necessary to ensure foodstuffs are not contaminated.

2. When appropriate, ice must be made from water which meets the specifications referred to in Directive 80/778/EEC. This ice must be used whenever necessary to ensure foodstuffs are not contaminated. It must be made, handled and stored under conditions which protect it from all contamination.

3. Steam used directly in contact with food must not contain any substance which presents a hazard to health or is likely to contaminate the product.

4. Water unfit for drinking used for the generation of steam, refrigeration, fire control and other similar purposes not relating to food, must be conducted in separate systems, readily identifiable and having no connection with, nor any possibility of reflux into, the potable water systems.

VIII Personal hygiene

1. Every person working in a food handling area shall maintain a high degree of personal cleanliness and shall wear suitable, clean and, where appropriate, protective clothing.

2. No person, known or suspected to be suffering from, or to be a carrier of, a disease likely to be transmitted through food or while afflicted, for example with infected wounds, skin infections, sores or with diarrhoea, shall be permitted to work in any food handling area in any capacity in which there is any likelihood of directly or indirectly contaminating food with pathogenic micro-organisms.

IX Provisions applicable to foodstuffs

1. No raw materials or ingredients shall be accepted by a food business if they are known to be, or might reasonably be expected to be, so contaminated with parasites, pathogenic micro-organisms or toxic, decomposed or foreign substances that, after normal sorting and/or preparatory or processing procedures hygienically applied by food businesses, they would still be unfit for human consumption.

2. Raw materials and ingredients stored in the establishment shall be kept in appropriate conditions designed to prevent harmful deterioration and to protect them from contamination.

3. All food which is handled, stored, packaged, displayed and transported shall 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. In particular, food must be so placed and/or protected as to minimize any risk of contamination. Adequate procedures must be in place to ensure pests are controlled.

4. Raw materials, ingredients, intermediate products and finished products likely to support the growth of pathogenic micro-organisms or the formation of toxins must be kept at temperatures which would not result in a risk to health. Consistent with food safety, limited periods outside temperature control are permitted

where necessary to accommodate the practicalities of handling during preparation, transport, storage, display and service of food.

5. When foodstuffs are to be held or served at chilled temperatures they must be cooled as quickly as possible following the final heat processing stage, or final preparation stage if no heat process is applied, to a temperature which would not result in a risk to health.

6. Hazardous and/or inedible substances, including animal feedstuffs, shall be adequately labelled and stored in separate and secure containers.

X Training Food business operators shall ensure that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity.