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Animal food production

Second edition

World Health Organization

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THE CODEX ALIMENTARIUS COMMISSION

The Codex Alimentarius Commission is an intergovernmental body with more than 180 members, within the framework of the Joint Food Standards Programme established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), with the purpose of protecting the health of consumers and ensuring fair practices in the food trade. The Commission also promotes coordination of all food standards work undertaken by international governmental and non-governmental organizations.

The *Codex Alimentarius* (Latin, meaning Food Law or Code) is the result of the Commission's work: a collection of internationally adopted food standards, guidelines, codes of practice and other recommendations. The texts in this publication are part of the Codex Alimentarius.

ANIMAL FOOD PRODUCTION
Second edition

The Codex guidelines and codes of practice concerning animal food production are published in this compact format to allow their wide use and understanding by governments, regulatory authorities, food industries and retailers, and consumers. This second edition includes texts adopted by the Codex Alimentarius Commission up to 2009.

Further information on these texts, or any other aspect of the Codex Alimentarius Commission, may be obtained from:

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CODE OF HYGIENIC PRACTICE FOR MEAT

CAC/RCP 58-2005

Adopted 2005. This Code supersedes the following Codex Codes of Practice: *Recommended International Code of Hygienic Practice for Fresh Meat* (CAC/RCP 11-1976); *Recommended International Code of Hygienic Practice for Game* (CAC/RCP 29-1983); *Recommended International Code for Ante-Mortem and Post-Mortem Inspection of Slaughter Animals and for Ante-Mortem and Post-Mortem Judgement of Slaughter Animals and Meat* (CAC/RCP 41-1993); *Recommended International Code of Hygienic Practice for Processed Meat and Poultry Products* (CAC/RCP 13-1976); *Recommended Code of Hygienic Practice for Poultry Processing* (CAC/RCP 14-1976); *Recommended International Code of Practice for the Production, Storage and Composition of Mechanically Separated Meat Intended for Further Processing* (CAC/RCP 32-1293).

CODE OF HYGIENIC PRACTICE FOR MEAT

CAC/RCP 58-2005

1. INTRODUCTION

Meat has traditionally been viewed as a vehicle for a significant proportion of human food-borne disease. Although the spectrum of meat-borne diseases of public health importance has changed with changing production and processing systems, continuation of the problem has been well illustrated in recent years by human surveillance studies of specific meat-borne pathogens such as *Escherichia coli* O157:H7, *Salmonella* spp., *Campylobacter* spp. and *Yersinia enterocolitica*. In addition to existing biological, chemical and physical hazards, new hazards are also appearing e.g., the agent of bovine spongiform encephalopathy (BSE). Furthermore consumers have expectations about suitability issues which are not necessarily of human health significance.

A contemporary risk-based approach to meat hygiene requires that hygiene measures should be applied at those points in the food chain where they will be of greatest value in reducing food-borne risks to consumers. This should be reflected in application of specific measures based on science and risk assessment, with a greater emphasis on prevention and control of contamination during all aspects of production of meat and its further processing. Application of HACCP principles is an essential element. The measure of success of contemporary programmes is an objective demonstration of levels of hazard control in food that are correlated with required levels of consumer protection, rather than by concentrating on detailed and prescriptive measures that give an unknown outcome.

At the national level the activities of the Competent Authority having jurisdiction at the slaughterhouse (usually Veterinary Administrations[1]) very often serve animal health as well as public health objectives. This is particularly the case in relation to ante- and post-mortem inspection where the slaughterhouse is a key point in animal health surveillance, including zoonoses. Regardless of jurisdictional arrangements, it is important that this duality of functions is recognized and relevant public health and animal health activities are integrated.

A number of national governments are implementing systems that redefine the respective roles of industry and government in delivering meat hygiene activities. Irrespective of the delivery systems the competent authority is responsible for defining the role of personnel involved in meat hygiene activities where appropriate, and verifying that all regulatory requirements are met.

[1] OIE is currently working on guidelines on application at national level addressing 'ante- and post-mortem activities in the production of meat to reduce hazards of public and animal health significance'.

The principles of food safety risk management[2,3] should be incorporated wherever appropriate in the design and implementation of meat hygiene programmes. Specifically, work conducted by JEMRA, JECFA and FAO/WHO Expert Consultations and resulting risk management recommendations should be considered. Further, newly-recognised meat-borne risks to human health may require measures additional to those usually applied in meat hygiene, e.g., the potential for zoonotic transmission of central nervous system disorders of slaughtered livestock means that additional animal health surveillance programmes may need to be undertaken.

2. SCOPE AND USE OF THIS CODE

The scope of this code covers hygiene provisions for raw meat, meat preparations and manufactured meat from the time of live animal production up to the point of retail sale. It further develops the *Recommended International Code of Practice – General Principles of Food Hygiene*[4] in respect of these products. Where appropriate, the Annex to that code (Hazard Analysis and Critical Control Point System and Guidelines for its Application) and the *Principles for the Establishment and Application of Microbiological Criteria for Foods*[5] are further developed and applied in the specific context of meat hygiene.

For the purposes of this code, meat is that derived from domestic ungulates, domestic solipeds, domestic birds, lagomorphs, farmed game, farmed game birds (including ratites) and wild game. This Code of Practice may also be applied to other types of animals from which meat is derived, subject to any special hygienic measures required by the competent authority. Further to general hygiene measures applying to all species of animal as described above, this code also presents specific measures that apply to different species and classes of animals, e.g. wild game killed in the field.

The hygiene measures that are applied to the products described in this code, should take into account any further measures and food handling practices that are likely to be applied by the consumer. It should be noted that some of the products described in this code may not be subjected to a heat or other biocidal process before consumption.

Meat hygiene is by nature a complex activity, and this code refers to standards, texts and other recommendations developed elsewhere in the Codex system where linkages are appropriate, e.g., *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995), *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007), *General Guidelines for Use of the Term "Halal"* (CAC/GL 24-1997) and *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004).

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[2] *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (Procedural Manual of the Codex Alimentarius Commission).

[3] CAC/GL 63-2007: *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM).*

[4] CAC/RCP 1-1969.

[5] CAC/GL 21-1997.

To provide information that will enhance consistency, linkages should also be made to the standards, guidelines and recommendations contained in the OIE Terrestrial Animal Health Code that relate to zoonoses.

Subsets of the general principles (Section 4) are provided in subsequent sections within 'double-line boxes'. Where guidelines are provided at the section level, those that are more prescriptive in nature are presented in 'single-line boxes'. This is to indicate that they are recommendations based on current knowledge and practice. They should be regarded as being flexible in nature and subject to alternative provisions so long as required outcomes in terms of the safety and suitability of meat are met.

Traditional practices may result in departures from some of the meat hygiene recommendations presented in this code when meat is produced for local trade.

3. DEFINITIONS

For the purposes of this code, the following definitions apply. (Note that more general definitions relating to food hygiene appear in the *Recommended International Code of Practice – General Principles of Food Hygiene*[6]).

Abattoir Any establishment where specified animals are slaughtered and dressed for human consumption and that is approved, registered and/or listed by the competent authority for such purposes.

Animal Animals of the following types:

- Domestic ungulates;
- Domestic solipeds;
- Domestic birds i.e. poultry;
- Lagomorphs;
- Farmed game;
- Farmed game birds, including ratites;
- Wild game, i.e. wild land mammals and birds which are hunted (including those living in enclosed territory under conditions of freedom similar to those of wild game);
- Animals as otherwise specified by the competent authority.

Ante-mortem inspection[7] Any procedure or test conducted by a competent person on live animals for the purpose of judgement of safety and suitability and disposition

Carcass The body of an animal after dressing.

Chemical residues Residues of veterinary drugs and pesticides as described in the Definitions for the Purpose of the Codex Alimentarius[8].

[6] *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

[7] These and other procedures and tests stipulated by the Competent Authority, may also be conducted, in particular for the purposes of animal health.

[8] Procedural Manual of the Codex Alimentarius Commission.

Competent authority[9] The official authority charged by the government with the control of meat hygiene, including setting and enforcing regulatory meat hygiene requirements.

Competent body A body officially recognised and overseen by the competent authority to undertake specified meat hygiene activities.

Competent person A person who has the training, knowledge, skills and ability to perform an assigned task, and who is subject to requirements specified by the competent authority.

Condemned Inspected and judged by a competent person, or otherwise determined by the competent authority, as being unsafe or unsuitable for human consumption and requiring appropriate disposal.

Contaminant Any biological or chemical agent, foreign matter, or other substance not intentionally added to food that may compromise food safety or suitability.[10]

Disease or defect Any abnormality affecting safety and/or suitability.

Dressing The progressive separation of the body of an animal into a carcass and other edible and inedible parts.

Equivalence The capability of different meat hygiene systems to meet the same food safety and/or suitability objectives.

Establishment A building or area used for performing meat hygiene activities that is approved, registered and/or listed by the competent authority for such purposes.

Establishment operator The person in control of an establishment who is responsible for ensuring that the regulatory meat hygiene requirements are met.

Food safety objective (FSO) The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).

Fresh meat Meat that apart from refrigeration has not been treated for the purpose of preservation other than through protective packaging and which retains its natural characteristics.

Game depot A building in which killed wild game is temporarily held prior to transfer to an establishment, and which is approved, registered and/or listed by the competent authority for this purpose. (Note that for the purposes of this code, a game depot is a particular type of establishment).

Good Hygienic Practice (GHP) All practices regarding the conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.[11]

Hazard A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.[12]

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[9] The Competent Authority provides official assurances in international trade of meat. Requirements for certification for public health and fair trade purposes have been developed by the Codex Committee on Food and Import and Export Inspection and Certification Systems (ref. CAC/GL 26-1997). Requirements for certification for animal health (including zoonoses) purposes are contained in the OIE Terrestrial Animal Health Code (ref. Section 1.2 Obligations and ethics in international trade). Both should be read in parallel where veterinary certification is required.

[10] *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

[11] WHO Teachers Handbook, 1999.

[12] Definitions for the Purpose of the Codex Alimentarius (Procedural Manual of the Codex Alimentarius Commission).

Hunter A person involved in the killing and/or bleeding, partial evisceration and partial field dressing of killed wild game.

Inedible Inspected and judged by a competent person, or otherwise determined by the competent authority to be unsuitable for human consumption.

Manufactured meat Products resulting from the processing of raw meat or from the further processing of such processed products, so that when cut, the cut surface shows that the product no longer has the characteristics of fresh meat.

Meat All parts of an animal that are intended for, or have been judged as safe and suitable for, human consumption.

Meat hygiene All conditions and measures necessary to ensure the safety and suitability of meat at all stages of the food chain.

Meat preparation Raw meat which has had foodstuffs, seasonings or additives added to it.

Mechanically separated meat (MSM) Product obtained by removing meat from flesh-bearing bones after boning or from poultry carcasses, using mechanical means that result in the loss or modification of the muscle fibre structure.

Minced meat Boneless meat which has been reduced into fragments.

Official inspector A competent person who is appointed, accredited or otherwise recognised by the competent authority to perform official meat hygiene activities on behalf of, or under the supervision of the competent authority.

Organoleptic inspection Using the senses of sight, touch, taste and smell for identification of diseases and defects.

Performance criterion The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a performance objective (PO) or a food safety objective (FSO).

Performance objective The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to a food safety objective (FSO) or appropriate level of protection (ALOP), as applicable.

Post-mortem inspection[13] Any procedure or test conducted by a competent person on all relevant parts of slaughtered/killed animals for the purpose of judgement of safety and suitability and disposition.

Primary production All those steps in the food chain constituting animal production and transport of animals to the abattoir, or hunting and transporting wild game to a game depot.

Process control All conditions and measures applied during the production process that are necessary to achieve safety and suitability of meat.[14]

[13] These and other procedures and tests stipulated by the Competent Authority, may also be conducted, in particular for the purposes of animal health.

[14] The "process" includes ante- and post-mortem inspection.

Process criterion The physical process control parameters (e.g. time, temperature) at a specified step that can be applied to achieve a performance objective or performance criterion.[15]

Quality assurance (QA) All the planned and systematic activities implemented within the quality system and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality.[16]

Quality assurance (QA) system The organisational structure, procedures, processes and resources needed to implement quality assurance.

Raw meat Fresh meat, minced meat or mechanically separated meat.[17]

Ready-to-Eat (RTE) products Products that are intended to be consumed without any further biocidal steps.

Risk-based Containing any performance objective, performance criterion or process criterion developed according to risk analysis principles.[18]

Safe for human consumption Safe for human consumption according to the following criteria:

- has been produced by applying all food safety requirements appropriate to its intended end-use;
- meets risk-based performance and process criteria for specified hazards; and
- does not contain hazards at levels that are harmful to human health.

Sanitation standard operating procedures (SSOPs) A documented system for assuring that personnel, facilities, equipment and utensils are clean and where necessary, sanitised to specified levels prior to and during operations.

Suitable for human consumption Suitable for human consumption according to the following criteria:

- has been produced under hygienic conditions as outlined in this code;
- is appropriate to its intended use;[19] and
- meets outcome-based parameters for specified diseases or defects as established by the competent authority.

Validation Obtaining evidence that the food hygiene control measure or measures selected to control a hazard in a food is capable of effectively and consistently controlling the hazard to the appropriate level.[20]

Verification Activities performed by the competent authority and/or competent body to determine compliance with regulatory requirements.

Verification (Operator) The continual review of process control systems by the operator, including corrective and preventative actions to ensure that regulatory and/or specified requirements are met.

Veterinary Inspector An official inspector who is professionally qualified as a veterinarian and carries out official meat hygiene activities[21] as specified by the competent authority.

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[15] This is an interim definition for the purpose of this Code.

[16] ISO 8402.

[17] This does not preclude interventions for the purpose of pathogen reduction.

[18] This is an interim definition for the purpose of this Code.

[19] See for example the *General Guidelines for Use of the Term "Halal"* (CAC/GL 24-1997).

[20] This is an interim definition for the purpose of this Code.

[21] These may include animal health objectives.

4. GENERAL PRINCIPLES OF MEAT HYGIENE

i. Meat must be safe and suitable for human consumption and all interested parties including government, industry and consumers have a role in achieving this outcome.[22]

ii. The competent authority should have the legal power to set and enforce regulatory meat hygiene requirements, and have final responsibility for verifying that regulatory meat hygiene requirements are met. It should be the responsibility of the establishment operator to produce meat that is safe and suitable in accordance with regulatory meat hygiene requirements. There should be a legal obligation on relevant parties to provide any information and assistance as may be required by the competent authority.

iii. Meat hygiene programmes should have as their primary goal the protection of public health and should be based on a scientific evaluation of meat-borne risks to human health and take into account all relevant food safety hazards, as identified by research, monitoring and other relevant activities.

iv. The principles of food safety risk analysis should be incorporated wherever possible and appropriate in the design and implementation of meat hygiene programmes.[23]

v. Wherever possible and practical, competent authorities should formulate food safety objectives (FSOs) according to a risk-based approach so as to objectively express the level of hazard control that is required to meet public health goals.

vi. Meat hygiene requirements should control hazards to the greatest extent practicable throughout the entire food chain. Information available from primary production should be taken into account so as to tailor meat hygiene requirements to the spectrum and prevalence of hazards in the animal population from which the meat is sourced.

vii. The establishment operator should apply HACCP principles. To the greatest extent practicable, the HACCP principles should also be applied in the design and implementation of hygiene measures throughout the entire food chain.

viii. The competent authority should define the role of those personnel involved in meat hygiene activities where appropriate, including the specific role of the veterinary inspector.

ix. The range of activities involved in meat hygiene should be carried out by personnel with the appropriate training, knowledge, skills and ability as and where defined by the competent authority.

[22] Specific meat hygiene requirements should address biological, chemical and physical hazards; and pathophysiological and other characteristics associated with suitability for human consumption.

[23] *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (Procedural Manual of the Codex Alimentarius Commission); CAC/GL 63-2007: *Principles and Guidelines for the Conduct of Microbiological Risk Management*; Report of a Joint FAO/WHO Consultation on Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards, Guidelines and Related Texts; Kiel, Germany, 18-22 March 2002.

x. The competent authority should verify that the establishment operator has adequate systems in place to trace and withdraw meat from the food chain. Communication with consumers and other interested parties should be considered and undertaken where appropriate.
xi. As appropriate to the circumstances, the results of monitoring and surveillance of animal and human populations should be considered with subsequent review and/or modification of meat hygiene requirements whenever necessary.
xii. Competent authorities should recognise the equivalence of alternative hygiene measures where appropriate, and promulgate meat hygiene measures that achieve required outcomes in terms of safety and suitability and facilitate fair practices in the trading of meat.

5. PRIMARY PRODUCTION

Primary production is a significant source of hazards associated with meat. A number of hazards are present in animal populations intended for slaughter and their control during primary production, often presents considerable challenges, e.g., *E. coli* O157: H7, *Salmonella* spp. *Campylobacter* spp. and various chemical and physical hazards. A risk-based approach to meat hygiene includes consideration of risk management options that may have a significant impact on risk reduction when applied at the level of primary production[24]

Provision of relevant information on animals intended for slaughter facilitates application of risk-based meat hygiene programmes, and allows inspection procedures to be tailor-made to the spectrum and prevalence of diseases and defects in the particular animal population. This may be particularly important in situations where the presence of certain zoonotic agents is not detectable by routine organoleptic or laboratory tests, and special measures may need to be taken, e.g. possible exposure to cysts of *Cysticercus bovis*.

Voluntary or officially recognised QA systems implemented at primary production should be appropriately taken into account during verification of regulatory requirements.

The principles and guidelines presented in this section are supplemental to the objectives and guidelines in Section III of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

[24] *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (Procedural Manual of the Codex Alimentarius Commission).

5.1 Principles of meat hygiene applying to primary production

i. Primary production should be managed in a way that reduces the likelihood of introduction of hazards and appropriately contributes to meat being safe and suitable for human consumption.

ii. Whenever possible and practicable, systems should be established by the primary production sector and the competent authority, to collect, collate and make available, information on hazards and conditions that may be present in animal populations and that may affect the safety and suitability of meat.

iii. Primary production should include official or officially-recognised programmes for the control and monitoring of zoonotic agents in animal populations and the environment as appropriate to the circumstances, and notifiable zoonotic diseases should be reported as required.

iv. Good hygienic practice (GHP) at the level of primary production should involve for example the health and hygiene of animals, records of treatments, feed and feed ingredients and relevant environmental factors, and should include application of HACCP principles to the greatest extent practicable.

v. Animal identification practices should allow trace-back to the place of origin to the extent practicable, to allow regulatory investigation where necessary.

5.2 Hygiene of slaughter animals

Both primary producers and the competent authority should work together to implement risk-based meat hygiene programmes at the level of primary production that document the general health status of slaughter animals, and implement practices that maintain or improve that status, e.g., zoonoses control programmes. QA programmes at the level of primary production should be encouraged and may include application of HACCP principles as appropriate to the circumstances. Such programmes should be taken into account by the competent authority in the overall design and implementation of risk-based meat hygiene programmes.

So as to facilitate the application of risk-based meat hygiene programmes:

- Primary producers should record relevant information to the extent possible on the health status of animals as it relates to the production of meat that is safe and suitable for human consumption. This information should be made available to the abattoir as appropriate to the circumstances.
- Systems should be in place for return from the abattoir to the primary producer, of information on the safety and suitability of slaughter animals and meat, in order to improve the hygiene on the farm and, where producer-led QA-programmes are applied, to be incorporated into these programmes to improve their effectiveness.

- The competent authority should systematically analyse monitoring and surveillance information from primary production so that meat hygiene requirements may be modified if necessary.

The competent authority should administer an official programme for control of specified zoonotic agents, chemical hazards and contaminants. This should be co-ordinated to the greatest extent possible with other competent authorities that may have responsibilities in public and animal health.

Official or officially-recognised programmes for specified zoonotic agents should include measures to:

- control and eradicate their presence in animal populations, or subsets of populations, e.g., particular poultry flocks;
- prevent the introduction of new zoonotic agents;
- provide monitoring and surveillance systems that establish baseline data and guide a risk-based approach to control of such hazards in meat; and
- control movement of animals between primary production units, and to abattoirs, where populations are under quarantine restrictions.

Official or officially-recognised programmes for chemical hazards and contaminants should include measures to:

- control the registration and use of veterinary drugs and pesticides so that residues do not occur in meat at levels that make the product unsafe[25] for human consumption, and
- provide monitoring and surveillance systems that establish baseline data and guide a risk-based approach to control of such hazards in meat.

Animal identification systems, to the extent practicable, should be in place at primary production level so that the origin of meat can be traced back from the abattoir or establishment to the place of production of the animals.

Animals should not be loaded for transport to the abattoir when:

- the degree of contamination of the external surfaces of the animal is likely to compromise hygienic slaughter and dressing, and suitable interventions such as washing or shearing are not available,
- information is available to suggest that animals may compromise the production of meat that is safe and suitable for human consumption, e.g., presence of

[25] *Design and Implementation of national Regulatory Food Safety Assurance Programmes associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009).

specific disease conditions or recent administration of veterinary drugs. In some situations, transport may proceed if the animals have been specifically identified (e.g. as "suspects") and are to be slaughtered under special supervision; or
- conditions causing animal stress may exist or arise that are likely to result in an adverse impact on the safety and suitability of meat.

5.3 Hygiene of killed wild game

Only limited knowledge can be gained on the health status of populations of wild game hunted for meat; however, the competent authority should consider all sources when gathering such information. In this respect, hunters should be encouraged to provide relevant information, e.g., geographical origin of wild game, and any clinical symptoms of disease observed in wild animal populations.

Wild game should be harvested in a manner so that:
- killing methods are consistent with the production of meat that is safe and suitable for human consumption; and
- their geographical origin is not subject to relevant official prohibitions on harvest, e.g., in the case of concurrent chemical pest control programmes or animal health quarantine.

Hunters are particularly important in providing information on killed animals. They should be aware of their responsibilities in terms of supplying to the establishment, all relevant information that may impact on the safety and suitability of killed wild game meat, e.g., symptoms of disease immediately before killing, grossly-apparent diseases and defects detected during partial field dressing and/or evisceration. The competent authority should require that hunters or other people involved in harvesting of wild game undergo basic training in meat hygiene appropriate to field procurement, e.g., recognition of diseases and defects, application of GHP in partial field dressing and transport to a game depot.

As wild game are killed in the field, appropriate hygienic practices immediately following death are essential to minimise contamination of edible parts. GHP should be applied to the extent practicable during bleeding, partial dressing, e.g., removal of the head, and/or partial evisceration (where allowed by the competent authority).[26]

Bleeding and partial dressing of killed wild game in the field should include:
- bleeding and partial evisceration as soon as possible after killing (unless exempted by the competent authority for a particular species of wild game);
- partial skinning and/or partial dressing in a manner that minimises the level of contamination of edible parts to the lowest level practicable;
- removal only of those parts of the animal that are not necessary for post-mortem inspection and judgement; and

[26] Partial evisceration usually only involves removal of the gastrointestinal tract, and this aids cooling.

- retention of the lungs, liver, heart and kidneys as a minimum if partial evisceration is carried out, either by natural attachment to the carcass or identified and packaged as an attachment to the carcass, unless a hunter, who is a competent person, has carried out an inspection and has not detected or suspected abnormalities.[27]

Game depots should not be simultaneously used for a purpose other than receiving and holding killed wild game, unless the competent authority specifies other uses and conditions.

Delivery of killed wild game to a game depot or an establishment should be within time limits established by the competent authority considering harvesting, environmental conditions and desired food safety outcomes. The body and other animal parts should not be frozen before dressing and post-mortem inspection in an establishment, unless unavoidable due to ambient temperatures.

5.4 Hygiene of feed and feed ingredients

Feeding of animals during primary production should be subject to good animal feeding practice[28]. Records should be maintained at the manufacturing level, on the origin of feed and feed ingredients to facilitate verification.

There is a need for collaboration between all parties involved in production, manufacturing and use of feed and feed ingredients, so as to establish any linkage between identified hazards and the level of risk to consumers that may result from transmission through the food chain[29].

Animals should not be given feed and feed ingredients that:

- are recognised as likely to introduce zoonotic agents (including transmissible spongiform encephalopathies – TSEs) to the slaughter population; or
- contain chemical substances, (e.g., veterinary drugs, pesticides) or contaminants that could result in residues in meat at levels that make the product unsafe for human consumption.

The competent authority should implement appropriate legislation and controls governing the feeding of animal protein to animals where there is a likelihood of transmission of zoonotic agents, and this may include a ban on such feeding when justified by risk management. Any processed feed and feed ingredients should be

[27] In the case of small killed wild game, the competent authority may allow full evisceration.
[28] Codex *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004).
[29] OIE International Animal Health Code (chapters on zoonotic diseases); OIE Guidelines on antimicrobial resistance.

subject to appropriate microbiological and other criteria according to a specified sampling plan and testing protocol, and maximum limits for mycotoxins.

5.5 Hygiene of the primary production environment

Primary production of animals should not be undertaken in areas where the presence of hazards in the environment could lead to an unacceptable level of such hazards in meat.

The competent authority should design and administer monitoring and surveillance programmes appropriate to the circumstances that address :

- hazards arising from animals and plants that may compromise the production of meat that is safe and suitable for human consumption;
- environmental contaminants that may result in levels in meat that make the product unsafe for human consumption; and
- ensuring that potential carriers such as water, are not significant vehicles for transmission of hazards.

Facilities and procedures should be in place to ensure that:

- housing and feeding platforms where used, and other areas where zoonotic agents and other hazards may accumulate, can be effectively cleaned, and are maintained in a sanitary condition (refer to Section 10);
- systems for active processing and/or disposal of dead animals and waste should not constitute a possible source of food-borne hazards to human and animal health; and
- chemical hazards required for technological reasons are stored in a manner so that they do not contaminate the environment or feed and feed ingredients and thereby pose a risk to human health.

5.6 Transport

5.6.1 Transport of slaughter animals

Transport of slaughter animals should be carried out in a manner that does not have an adverse impact on the safety and suitability of meat.[30]

Slaughter animals require transport facilities to the abattoir that ensure that:

- soiling and cross-contamination with faecal material is minimised;
- new hazards are not introduced during transport;
- animal identification as to the place of origin is maintained; and

[30] OIE International Animal Health Code (chapter on transport); Report of the OIE Working Group on Animal Welfare, October 2002.

- consideration is given to avoiding undue stress that may adversely impact on the safety of meat (such as stress-induced shedding of pathogens).

Transport vehicles should be designed and maintained so that:

- animals can be loaded, unloaded and transported easily and with minimal risk of injury;
- animals of different species, and animals of the same species likely to cause injury to one another, are physically separated during transport;
- use of floor gratings, crates or similar devices limits soiling and cross-contamination with faecal material;
- where the vehicle has more than one deck, animals are protected from cross-contamination as appropriate ;
- ventilation is adequate; and
- cleaning and sanitising is readily achieved (refer to Section 10).

Transport vehicles, and crates where used should be cleaned and if necessary sanitised as soon as practicable after animals have been unloaded at the establishment.

5.6.2 **Transport of killed wild game**

Following killing and partial dressing in the field, the body and other parts should be transported to an establishment, including a game depot, without delay and in a manner that minimises contamination of edible parts. The use of these vehicles for this purpose should be consistent with good hygienic practice and any specific regulatory requirements.

Unless deemed unnecessary due to low environmental ambient temperatures, the temperature of the body should be actively reduced as quickly as possible after partial field dressing and transport.

6. PRESENTATION OF ANIMALS FOR SLAUGHTER

Only healthy, clean and appropriately identified animals should be presented for slaughter.

All animals should be screened upon arrival at the abattoir. Where abnormalities in behaviour or appearance suggest that an individual animal or a consignment of animals should be segregated, this should occur and the competent person undertaking ante-mortem inspection should be notified.

Ante-mortem inspection is an important pre-slaughter activity, and all relevant information on animals presented for slaughter should be utilised in meat hygiene systems.

6.1 Principles of meat hygiene applying to animals presented for slaughter

i. Animals presented for slaughter should be sufficiently clean so that they do not compromise hygienic slaughter and dressing.
ii. The conditions of holding of animals presented for slaughter should minimise cross-contamination with food-borne pathogens and facilitate efficient slaughter and dressing.
iii. Slaughter animals should be subjected to ante-mortem inspection, with the competent authority determining the procedures and tests to be used, how inspection is to be implemented, and the necessary training, knowledge, skills and ability of personnel involved.
iv. Ante-mortem inspection should be science- and risk-based as appropriate to the circumstances, and should take into account all relevant information from the level of primary production.
v. Relevant information from primary production where available and results of ante-mortem inspection should be utilised in process control.
vi. Relevant information from ante-mortem inspection should be analysed and returned to the primary producer as appropriate.

6.2 Conditions of lairage

Holding of animals presented for slaughter has an important effect on many aspects of slaughter, dressing and the production of meat that is safe and suitable for human consumption. The cleanliness of animals has a major influence on the level of microbiological cross-contamination of the carcass and other edible parts during slaughter and dressing. A range of measures appropriate to the animal species may be applied to ensure that only animals that are sufficiently clean are slaughtered and to assist in reducing microbiological cross- contamination.

Quality assurance (QA) systems implemented by the establishment operator should enhance achievement of appropriate conditions of lairage on an on-going basis.

The establishment operator should ensure conditions of lairage that include:

- facilities are operated in a way that soiling and cross-contamination of animals with food-borne pathogens are minimised to the greatest extent practicable;
- holding of animals so that their physiological condition is not compromised and ante-mortem inspection can be effectively carried out, e.g., animals should be adequately rested and not overcrowded and protected from weather where necessary;

- separation of different classes and types of slaughter animals as appropriate, e.g., separation of animals with special dressing requirements, and separation of "suspects" that have been identified as having the potential to transfer specific food-borne pathogens to other animals (refer to 6.3);
- systems to ensure that only animals that are sufficiently clean are slaughtered;
- systems to ensure that feed has been appropriately withdrawn before slaughter;
- maintenance of identification of animals (either individually, or as lots, e.g., poultry) until the time of slaughter and dressing; and
- conveying of relevant information on individual animals or lots of animals to facilitate ante- and post-mortem inspection.

The competent authority or the competent body should take into account QA systems properly implemented by the establishment operator, in setting the frequency and intensity of verification activities necessary to determine that the conditions of lairage are in accordance with regulatory requirements.

6.3 Ante-mortem inspection

All animals presented for slaughter should be subjected to ante-mortem inspection, by a competent person whether on an individual or a lot basis. Inspection should include confirmation that the animals are properly identified, so that any special conditions pertaining to their place of primary production are considered in the ante-mortem inspection, including relevant public and animal health quarantine controls.

Ante-mortem inspection should support post-mortem inspection by application of a specific range of procedures and/or tests that consider the behaviour, demeanour and appearance, as well as signs of disease in the live animal.

Animals described below should be subject to special controls, procedures or operations imposed by the competent authority (which may include denial of entry to the abattoir) when:

- animals are not sufficiently clean;
- animals have died in transit;
- a zoonotic disease posing an immediate threat to either animals or humans is present, or suspected;
- an animal health disease subject to quarantine restrictions is present, or suspected;
- animal identification requirements are not met; or
- declarations from the primary producer, if required by the competent authority (including compliance with good veterinary practice in the use of animal medicines), are absent or inadequate.

6.3.1 **Design of ante-mortem inspection systems**

Ante-mortem inspection should be included as an integral component of an overarching risk-based system for the production of meat, with systems for process control (refer to Section 9) incorporating appropriate components. Relevant information on the slaughter population, e.g., animal class, health status, geographical region of origin, should be utilised in both the design and implementation of ante-mortem inspection systems.

Ante-mortem inspection, including procedures and tests, should be established by the competent authority according to a science and risk-based approach. In the absence of a risk-based system, procedures will have to be based on current scientific knowledge and practice.

Ante-mortem procedures and tests may be integrated and implemented together so as to achieve public health and animal health objectives. In such cases all aspects of ante-mortem inspection should be science-based and be tailored to the relevant risks.

Where indicated by public health concerns, measures additional to routine ante-mortem inspection may be required.

Characteristics of a risk-based ante-mortem inspection programme are:

- procedures for confirmation of proper animal identification in accordance with national legislation;
- design and application of organoleptic procedures and tests that are relevant and proportional to meat-borne risks associated with clinical signs of illness and grossly-detectable abnormalities;
- tailoring of procedures to the spectrum and prevalence of diseases and defects reasonably likely to be present in the slaughter population, taking into account the type of animal, geographical origin and primary production system;
- integration with HACCP-based process control to the extent practicable, e.g., application of objective criteria for ensuring appropriate cleanliness of animals presented for slaughter;
- on-going tailoring of procedures to information received from the primary production unit, where practicable;
- use of laboratory tests for hazards that are unaddressed by organoleptic inspection when their presence is suspected, e.g., chemical residues and contaminants; and
- return of information to the primary producer so as to seek continuous improvement in the safety and suitability status of animals presented for slaughter (refer to 6.4).

6.3.2 **Implementation of ante-mortem inspection**

The competent authority should determine how ante-mortem inspection is to be implemented, including identification of the components that may be applied at primary production rather than the abattoir, e.g., in the case of intensively-raised poultry.[31] The competent authority should establish the training, knowledge, skills and ability requirements of all personnel involved, and the roles of the official inspector, including the veterinary inspector (refer to 9.2). Verification of inspection activities and judgements should be undertaken as appropriate by the competent authority or competent body. The final responsibility for verifying that all regulatory requirements are met should lie with the competent authority.

The responsibilities of the establishment operator in respect of ante-mortem inspection include:

- providing verifiable information required by the competent authority with respect to ante-mortem inspection carried out at primary production;
- segregation of animals if, for example, they have recently given birth during transport or in lairages, or have recently aborted and/or show retained foetal membranes;
- applying identification systems for individual animals or lots of animals until the time of slaughter that document the outcome of ante-mortem inspection, and after slaughter in the case of "suspect" animals;
- presentation of animals that are sufficiently clean; and
- prompt removal of animals that have died in the lairage, e.g., from metabolic disease, stress, suffocation, with the permission of the competent person undertaking ante-mortem inspection.

Ante-mortem inspection at the abattoir should occur as soon, as is practicable after delivery of slaughter animals. Only animals that are judged to be sufficiently rested should proceed to slaughter, but should not be withheld from slaughter any longer than necessary. If ante-mortem inspection has occurred and there is a delay of more than 24 hours before slaughter, ante-mortem inspection should be repeated.

[31] In some cases the competent authority may allow slaughter on the farm for particular classes of animal, e.g., farmed game, and in such cases the slaughter animals should be subject to ante-mortem inspection and other hygiene controls as determined by the competent authority.

Ante-mortem inspection systems required by the competent authority should include the following:

- all relevant information from the level of primary production should be taken into account on an on-going basis, e.g., declarations from the primary producers relating to the use of veterinary drugs, information from official hazard control programmes;
- animals suspected as being unsafe or unsuitable for human consumption should be identified as such and handled separately from normal animals (refer to 6.2 and 8.2);
- results of ante-mortem inspection are made available to the competent person undertaking post-mortem inspection before animals are inspected at the post-mortem stations so as to augment final judgement. This is particularly important when a competent person undertaking ante-mortem inspection, judges that a suspect animal can proceed to slaughter under special hygiene conditions.;
- in more equivocal situations, the competent person undertaking ante-mortem inspection may hold the animal (or lot) in special facilities for more detailed inspection, diagnostic tests, and/or treatment;
- animals condemned as unsafe or unsuitable for human consumption should be immediately identified as such and handled in a manner that does not result in cross-contamination of other animals with food-borne hazards (refer to 8.2); and
- the reason for condemnation should be recorded, with confirmatory laboratory tests being carried out if deemed necessary. Feed back of this information to the primary producer should take place.

Slaughter of animals under an official or officially-recognised programme for the eradication or control of a specific zoonotic disease, e.g., salmonellosis, should only be carried out under the hygiene conditions specified by the competent authority.

6.3.3 Ante-mortem judgement categories

Ante-mortem judgement categories include:

- passed for slaughter;
- passed for slaughter subject to a second ante-mortem inspection, after an additional holding period, e.g., when animals are insufficiently rested, or are temporarily affected by a physiological or metabolic condition;
- passed for slaughter under special conditions i.e. deferred slaughter as “suspects”, where the competent person undertaking ante-mortem inspection suspects that post-mortem inspection findings could result in partial or total condemnation;

- condemned for public health reasons i.e. due to: meat-borne hazards, occupational health hazards, or likelihood of unacceptable contamination of the slaughter and dressing environment following slaughter;[32]
- condemned for meat suitability reasons;
- emergency slaughter, when an animal eligible for being passed under special conditions could deteriorate if there was a delay in slaughter; and
- condemned for animal health reasons, as specified in relevant national legislation.

6.4 Information on animals presented for slaughter

Information provided on animals presented for slaughter may be an important determinant of optimal slaughter and dressing procedures and is a prerequisite for effective design and implementation of process control by the establishment operator. The competent authority should analyse relevant information and take it into account when setting hygiene requirements for risk-based hygiene systems throughout the entire food chain (refer to 9.2).

The competent authority may require monitoring of animals presented for slaughter to establish baseline information on the prevalence of hazards in the slaughter population, e.g., specified meat-borne pathogens, chemical residues greater than maximum residue limits. The competent authority should design and implement these monitoring activities according to national public health goals. Scientific analysis and dissemination of results to interested parties is the responsibility of the competent authority.

So as to facilitate science- and risk-based meat hygiene throughout the entire food chain, systems should be in place that provide:

- on-going information on animals presented for slaughter for incorporation into HACCP plans and/or quality assurance (QA) programmes that are part of process control;
- information back to the primary producer on the safety and suitability status of animals presented for slaughter; and
- information to the competent authority that facilitates on-going review.

[32] The competent person may judge, after post-mortem inspection in special facilities, that edible parts of the animal can be salvaged for a particular purpose e.g. pet-food.

7. PRESENTATION OF KILLED WILD GAME FOR DRESSING

Killed wild game presented at an establishment have been subject to different harvesting, handling and transportation arrangements compared to live animals presented for slaughter. Killed wild game should undergo an appropriate inspection before dressing and full post-mortem inspection commences, so as to prevent undue contamination of the dressing environment and wastage of resources.

7.1 Principles of meat hygiene applying to inspection of killed wild game presented for dressing

i. Inspection of killed wild game for safety and suitability prior to dressing should be risk-based to the extent practicable, and should take into account relevant information available from the field.

7.2 Inspection of killed wild game presented for dressing

The inspection should determine to the extent possible whether hygienic practice for field-harvested animals has been appropriately applied, including an assessment of cleanliness sufficient for hygienic dressing. Special measures required by the competent authority to facilitate post-mortem inspection, e.g., correct identification and attachment of viscera separated from the animal body (refer to 5.3), should be confirmed at this time.

The inspection should take into account any information available from harvesting in the field, e.g., presence of abnormalities at the time of death, geographical location. Where practicable, the results should be returned to hunters or other people involved in harvesting of wild game so as to improve their knowledge of and contribution to meat hygiene.

Inspection of killed wild game for safety and suitability prior to dressing should be risk-based to the extent practicable, given that the entire animal may not be presented for dressing, e.g., the gastrointestinal tract of large killed wild game will most likely have been discarded in the field. Inspection procedures prior to dressing and post-mortem inspection, will be necessarily limited in nature. They should be focused on detecting abnormalities intrinsic to field harvesting of wild game, e.g. signs of natural death or the animal being moribund at the time of death, the effects of a misplaced or expanding bullet, decomposition, and any evidence of intoxication with poisons or environmental contaminants. Systems for the implementation of inspection procedures and judgements should be based on those used for ante-mortem inspection of other classes of animals (refer to 6.3).

Identity of the body of the animal along with those parts required for post-mortem inspection, should be maintained until final post-mortem judgement.

8. ESTABLISHMENTS: DESIGN, FACILITIES AND EQUIPMENT

The principles and guidelines presented in this section are supplemental to the objectives and guidelines in Section IV of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

The competent authority should allow variations in the design and construction of game depots and establishments processing killed wild game, and their facilities, where they are by necessity impermanent, as long as meat hygiene is not compromised.

8.1 Principles of meat hygiene applying to establishments, facilities and equipment

i. Establishments should be located, designed and constructed so that contamination of meat is minimised to the greatest extent practicable.
ii. Facilities and equipment should be designed, constructed and maintained so that contamination of meat is minimised to the greatest extent practicable.
iii. Establishments, facilities and equipment should be designed to allow personnel to carry out their activities in a hygienic manner.
iv. Facilities and equipment that are in direct contact with edible parts of animals and meat, should be designed and constructed so that they can be effectively cleaned and monitored for their hygiene status.
v. Suitable equipment should be available for control of temperature, humidity and other factors as appropriate to the particular processing system for meat.
vi. Water should be potable except where water of a different standard can be used without leading to contamination of meat.

Each establishment should have appropriate facilities and equipment for competent persons to properly carry out their meat hygiene activities.

Laboratory facilities necessary to support meat hygiene activities may be located in the establishment or provided at a separate location.

8.2 Design and construction of lairages

Lairages should be designed and constructed so that they do not lead to undue soiling of the animal, cause undue stress of the animal, or otherwise adversely impact on the safety and suitability of meat derived from animals held therein.

Lairages should be designed and constructed so that:

- animals can be held without overcrowding or injury, and are not exposed to climatic stress;[33]
- there are appropriate layout and facilities for cleaning and/or drying of animals;
- ante-mortem inspection is facilitated;
- floors are paved or slatted and allow good drainage;
- there is an adequate supply and reticulation of clean water for drinking and cleaning, and facilities are provided for feeding where necessary;
- there is a physical separation between lairages and areas of an abattoir where edible material may be present;
- "suspect" animals can be segregated and inspected in separate areas.[34] These areas should include facilities that are capable of secure holding of "suspect" animals pending slaughter under supervision, in a manner that precludes contamination of other animals; and
- there is an adjacent area with adequate facilities for cleaning and sanitation of transport vehicles and crates, unless there are facilities within close distance that are approved by the competent authority.

Special facilities may be required to handle condemned animals.

These facilities should be:

- constructed so that all parts, gut contents and faeces from condemned animals can be held under secure containment as appropriate to the circumstances; and
- constructed and equipped so as to facilitate effective cleaning and sanitation (refer to Section 10).

8.3 Design and construction of slaughter areas

Stunning and bleeding areas should be separated from dressing areas (either physically or by distance), so that cross-contamination of animals is minimised.

Areas for scalding, dehairing, defeathering, scraping and singeing (or similar operations) should also be appropriately separated from dressing areas.

Where slaughter is carried out the processing line should be designed so that there is constant progress of animals in a manner that does not cause cross-contamination.

[33] In the case of poultry and farmed game birds, facilities should be available to park transport vehicles in areas that are well ventilated, and are protected from direct sunlight, inclement weather and extremes of temperature.

[34] In the case of poultry and farmed game birds, "suspect" birds are usually slaughtered on the slaughter line under special hygiene provisions.

Special facilities may be required to slaughter and dress "suspect" or injured animals.

Where these facilities exist they should be:

- easily accessed from pens containing "suspect" or injured animals;
- constructed with suitable facilities for hygienic storage of parts derived from "suspect" or injured animals; and
- constructed and equipped so as to facilitate effective cleaning and sanitising (refer to Section 10).

8.4 Design and construction of areas where bodies of animals are dressed or meat may otherwise be present

All areas and facilities where bodies of animals are dressed or meat may be present should be designed and constructed so that they facilitate GHP,[35] and contamination of meat is minimised to the greatest extent practicable.

Rooms and other areas in which bodies of animals are dressed or meat may be present should be designed and constructed so that:

- cross-contamination during operations is minimised to the greatest extent practicable;
- effective cleaning, sanitation and maintenance can be carried out during and between periods of operation; (refer to Section 10);
- floors in areas where water is present slope sufficiently to grilled or otherwise protected outlets so as to ensure continual drainage;
- exterior doors do not open directly into the area;
- chutes separately conveying different parts of animals are fitted with inspection and cleaning hatches where these are necessary for sanitation;
- separate rooms or separated areas are used for skin-on dressing of pigs or other animals, when other classes of animals are being dressed at the same time;
- separate rooms are used for:
  - emptying and cleansing of alimentary tracts, and further preparation of clean alimentary tracts, unless such separation is deemed unnecessary;
  - handling of meat and inedible parts of animals after they have been so designated, unless these products are otherwise separated by time or distance;
  - storage of inedible animal parts such as hides, horns, hooves, feathers and inedible fats;

[35] *Recommended International Code of Practice: General Principles of Food Hygiene* (CAC/RCP 1-1969).

- there is adequate natural or artificial lighting for hygienic process control;
- there are appropriate facilities for the preparation and storage of edible fats;
- access and harbouring of pests are effectively restricted; and
- adequate facilities are provided for secure storage of chemicals, (e.g., cleaning materials, lubricants, branding inks) and other hazardous substances so as to prevent accidental contamination of meat.

Appropriately designed and insulated rooms should be available as necessary for cooling, chilling and freezing of meat.

Establishments that de-bone or otherwise cut up meat should have for this purpose:

- facilities that allow constant progress of operations or that ensure separation between different production batches;
- a room or rooms, capable of being temperature-controlled; and
- separation of the boning, cutting and primary wrapping area from the packaging area, unless hygiene measures are in place to ensure that packaging does not contaminate meat.

Wood may be used in rooms for curing, smoking, maturing, pickling, storage and dispatch of meat preparations and manufactured meat when essential for technological reasons, as long as meat hygiene requirements are not compromised.

Drainage and waste disposal systems should not be a source of contamination of meat, the potable water supply or the processing environment. All lines should be watertight and adequately trapped and vented, with catch basins, traps and sumps that are isolated from any area where bodies of animals are dressed or meat may be present.

Establishments should have an appropriate area, sufficiently protected from environmental contamination and capable of preventing adverse temperature variations, for dispatching meat.

8.5 Design and construction of equipment where bodies of animals are dressed or meat may be present

All equipment used in areas where bodies of animals are dressed or meat may be present should facilitate good hygienic practices (GHP). Equipment and containers in rooms and other areas where bodies of animals are dressed or meat may be present should be designed and constructed so that contamination is minimised. Meat should not be allowed to contact the floor and walls, or fixed structures not designed for such contact.

Where slaughter lines are operated, they should be designed so that there is constant progress of animal bodies, carcasses and other parts, in a manner that prevents cross-contamination between different parts of the slaughter line and between different slaughter lines. In establishments where meat preparations and manufactured meat are circulating, the layout and equipment should be designed to prevent cross contamination between products of different status and products at different production stages.

All rooms and other areas in which animals are dressed or meat may be present should be equipped with adequate facilities for washing hands, and should be equipped with adequate facilities for cleaning and sanitation of implements where required (refer to Section 10).

Facilities for cleaning and sanitation of equipment should:
- be designed to effectively clean and sanitise the particular equipment;
- be located convenient to work stations; and
- have waste water ducted to drains.

Equipment and implements for use with inedible or condemned parts of animals should be distinctively identified.

Establishments should be provided with adequate means of natural or mechanical ventilation so as to prevent excessive heat, humidity and condensation, and ensure that air is not contaminated with odours, dust or smoke.

Ventilation systems should be designed and constructed so that:
- air-borne contamination from aerosols and condensation droplets is minimised;
- ambient temperatures, humidity and odours are controlled; and
- air flow from contaminated areas, (e.g., slaughter and dressing areas) to clean areas, (e.g., chilling rooms for carcasses) is minimised.

Equipment used for heat treatment of manufactured meat and meat preparations should be fitted with all control devices necessary to ensure that an appropriate heat treatment is applied.

8.6 Water supply[36]

Adequate facilities should be provided for monitoring and maintaining potability, storage, temperature control, distribution of water and for the disposal of waste water.

[36] *Recommended International Code of Practice – General Principles of Food Hygiene, Section 5.5* (CAC/RCP 1-1969).

Equipment should be installed that provides:

- an adequate and easily accessible supply of hot and cold potable water at all times;
- hot potable water for effective sanitising of equipment, or an equivalent sanitation system;
- potable water at a temperature appropriate for hand-washing; and
- sanitising solution used according to manufacturers' specifications supplied as and where necessary.

Where non-potable water is supplied for various uses e.g., fire fighting, steam production, refrigeration, reticulation systems should be designed and identified so that cross-contamination of the potable water supply is prevented.

8.7 Temperature control

In the absence of suitable temperature, humidity and other environmental controls, meat is particularly vulnerable to survival and growth of pathogens and spoilage micro-organisms.

Facilities and equipment should be adequate for:

- Cooling, chilling and/or freezing of meat according to written specifications;
- Storage of meat at temperatures that achieve the safety and suitability requirements; and
- Monitoring of temperature, humidity, air flow and other environmental factors so as to assure that process control regimes are achieved.

Where steam is generated in the cooking of meat, it should be properly vented out of the area in order to minimise the potential for condensation and not be allowed to permeate into adjoining rooms.

8.8 Facilities and equipment for personal hygiene

Slaughter and dressing of animals and animal parts, and further handling of meat preparations and manufactured meat presents many opportunities for cross-contamination of meat by food handlers (refer to Section 11). Appropriate personal hygiene facilities are needed to minimise cross-contamination of meat from this source.

Facilities and equipment should be provided, designed and located so that meat safety is not compromised. Where necessary, separate amenities should be provided e.g. for staff handling live animals, condemned products (refer Section 11).

Facilities for personal hygiene should include:

- changing rooms, showers, flush toilets, hand-washing and hand-drying facilities in the appropriate locations, and separate areas for eating; and
- protective clothing that can be effectively cleaned and minimises accumulation of contaminants.

All areas in which exposed meat may be present, should be equipped with adequate facilities for washing hands that:

- are located convenient to work stations;
- have taps that are not operable by hand;
- supply water at an appropriate temperature, and are fitted with dispensers for liquid soap or other hand cleansing agents;
- include hand drying equipment where necessary, and receptacles for discarded paper towels; and
- have waste water ducted to drains.

8.9 Means of transport

Vehicles or shipping containers in which unprotected meat is transported should:

- be designed and equipped so that the meat does not contact the floor;
- have joint and door seals that prevent entry of all sources of contamination; and
- where necessary, be equipped so that temperature control and humidity can be maintained and monitored.

9. PROCESS CONTROL

An extensive range of hazards are associated with meat, e.g., *Salmonella* spp. and veterinary drug residues; the processing environment, e.g., *Listeria monocytogenes;* and food handlers themselves, e.g., *Staphylococcus aureus* and hepatitis viruses. Effective process control, that includes both GHP and HACCP, is necessary to produce meat that is safe and suitable for human consumption.

The principles and guidelines presented in this section should satisfy the general objectives and guidelines in Section V of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969). They are developed in this section in respect of hazards in meat however they are equally applicable to suitability characteristics.

Many aspects of slaughter and dressing procedures have the potential to result in significant contamination of meat, e.g., hide/feather removal, evisceration, carcass washing, post-mortem inspection, trimming, and further handling in the cold chain. Systems for process control should limit microbial cross-contamination in these circumstances to as low as practicably achievable, and reflect the proportional contribution of these controls in reducing meat-borne risks to human health.

Ready-to-eat (RTE) products may require specific microbiological testing regimes that incorporate microbiological criteria.[37]

9.1 Principles of meat hygiene applying to process control

i. Production of meat that is safe and suitable for human consumption requires that detailed attention be paid to the design, implementation, monitoring and review of process control.
ii. The establishment operator has the primary responsibility for implementing systems for process control. Where such systems are applied, the competent authority should verify that they achieve all meat hygiene requirements.
iii. Process control should limit microbiological contamination to the lowest level practicable, according to a risk-based approach.
iv. HACCP should be applied wherever practicable as the system of choice for process control, and should be supported by prerequisite GHP that includes sanitation standard operating procedures (SSOPs).
v. Process control should reflect an integrated strategy for control of hazards throughout the food chain, with information available from primary production and pre-slaughter being taken into account wherever possible and practicable.
vi. All bodies of animals should be subjected to post-mortem inspection that is science- and risk-based, and is tailored to the hazards and/or defects that are reasonably likely to be present in the bodies of animals presented for inspection.[38]
vii. The competent authority should determine the procedures and tests to be used in post-mortem inspection, how that inspection is to be implemented, and the necessary training, knowledge, skills and ability required of personnel involved (including the role of veterinarians, and personnel employed by the establishment operator).
viii. Post-mortem inspection should take into account all relevant information from primary production, ante-mortem inspection, and from official or officially-recognised hazard control programmes.
ix. Post-mortem judgements should be based on: food-borne risks to human health, other human health risks, e.g., from occupational exposure or

[37] *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).
[38] Where risk assessment capability is not available, post-mortem inspection carried out according to current scientific knowledge and practice should be capable of achieving the level of consumer protection required.

handling of meat in the home, food-borne risks to animal health as specified in relevant national legislation, and suitability characteristics.

x. Performance objectives or performance criteria for the outcome of process control and post-mortem inspection activities should be established by the competent authority wherever practicable, and should be subject to verification by the competent authority.

xi. Where appropriate, microbiological testing, for verification purposes, should be included in meat preparation and manufactured meat HACCP plans. Such testing should be relevant to the type of product and the likely risks to consumers, including vulnerable sub-populations.

xii. Competent bodies or competent persons may be engaged by the establishment operator to undertake prescribed process control activities[39], including ante-[40] and post-mortem inspection, as approved by the competent authority.

xiii. Handling of ready-to-eat (RTE) products up until the point of sale to the consumer should ensure that there is no contact with non- ready-to-eat (RTE) products, and any other exposure to potential sources of microbiological contamination is minimised to the greatest extent practicable.

xiv. Voluntary or officially recognised quality assurance (QA) systems may be implemented by the establishment operator where they enhance meat hygiene activities, and they may be taken into account in the verification of regulatory requirements by the competent authority.

9.2 Process control systems

Effective process control requires design and implementation of appropriate systems. Industry has the primary responsibility for applying and supervising process control systems to ensure the safety and suitability of meat, and these should incorporate prerequisite GHP and HACCP plans as appropriate to the circumstances.

A documented process control system should describe the meat hygiene activities applied (including any sampling procedures), performance objectives or performance criteria (if set), verification activities, and corrective and preventative actions.

Competent bodies or competent persons suitably recognised by the competent authority may be engaged by the establishment operator to undertake prescribed process control activities, including post-mortem inspection. These activities should be part of HACCP or QA systems as appropriate to the circumstances.

Process control systems relating to food safety should incorporate a risk-based approach. Application of HACCP principles in the design and implementation of process control

[39] Prescribed process control activities *may include "Officially recognised inspection systems" (CAC*/GL 20-1995).

[40] Ante-mortem inspection as covered in Section 6.3.

systems should be according to The Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application (CAC/RCP 1-1969). The *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) provide general requirements for control of operations for food as they relate to international trade.

9.2.1 **Sanitation Standard Operating Procedures (SSOPs)**

Pre-operational and operational sanitation standard operating procedures (SSOPs) should minimise direct and indirect contamination of meat to the greatest extent possible and practicable. A properly implemented SSOP system should ensure that facilities and equipment are clean and sanitised prior to start of operations, and appropriate hygiene is maintained during operations. SSOP guidelines may be provided by the competent authority, which may include minimum regulatory requirements for general sanitation.

Characteristics of sanitation standard operating procedures (SSOPs) are:

- development of a written SSOP programme by the establishment that describes the procedures involved and the frequency of application;
- identification of establishment personnel responsible for implementing and monitoring SSOPs;
- documentation of monitoring and any corrective and/or preventative actions taken, which is made available to the competent authority for purposes of verification;
- corrective actions that include appropriate disposition of product; and
- periodic evaluation of the effectiveness of the system by the establishment operator.

Microbiological verification of SSOPs can utilise a range of direct or indirect methods. Establishment operators should use statistical process control or other methods to monitor sanitation trends.

In the case of ready-to-eat (RTE) products, microbiological verification of SSOPs for food contact and non-food contact surfaces is likely to be of higher intensity than for other types of product.

9.2.2 **HACCP**

HACCP systems for production of meat are a proactive means of process control for food safety purposes.[41] Validation of a HACCP plan for meat should ensure that it is effective in meeting performance objectives or performance criteria (refer 9.2.3), taking into account the degree of variability in presence of hazards that is normally associated with different lots of animals presented for processing.

[41] Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application, (Annex to CAC/RCP 1-1969).

Verification frequency may vary according to the operational aspects of process control, the historical performance of the establishment in application of the HACCP plan, and the results of verification itself. The competent authority may choose to approve HACCP plans and stipulate verification frequencies.

Microbiological testing for verification of HACCP systems, e.g. for verification of critical limits and statistical process control, is an important feature of HACCP for many products.

Guidelines for the development of HACCP programmes to achieve pre-determined process criteria stipulated by the competent authority should be provided to establishment operators so as to guide development of process and product-specific HACCP plans. Guidelines should be developed in consultation with industry and other interested stakeholder organisations, and may be differentiated according to processing category, e.g.:

- Raw ground or comminuted e.g. pork sausage
- Meat with secondary inhibitors / non-shelf stable e.g. cured corned beef
- Heat treated / not fully cooked, non-shelf stable e.g. partially-cooked patties
- Fully cooked / non-shelf stable e.g. cooked ham
- Non-heat treated / shelf stable e.g. dry salami
- Heat treated / shelf stable e.g. beef jerky
- Thermally processed / commercially sterile e.g. canned meat
- Specific ethnic processes, e.g. tandoori

When developing HACCP plans for heat-treated meat preparations and manufactured meat, the establishment operator should fully document as appropriate to the process, all thermal process parameters, post-heat treatment handling, and additional preservation treatments appropriate to the intended process outcome e.g. a pasteurised product. Process parameters for cooling of heat-treated products may incorporate as appropriate to the product, rapid cooling, slow cooling, or interrupted cooling. Previously heated products should not be packaged above a minimum temperature, e.g. 4° C, unless it can be demonstrated that cooling after packaging does not compromise product safety.

HACCP plans for meat preparations and manufactured meat that are cooked should include monitoring and documentation of parameters that ensure appropriate internal temperatures are reached. Internal temperatures of product should be taken as necessary to verify the adequacy of the cook.

9.2.3 Outcome-based parameters for process control

In a risk-based meat hygiene system, verification of process control is greatly strengthened by establishment of performance objectives or performance criteria for the outcome of specified activities. In most cases these will be established by the competent authority. When performance objectives or performance criteria are established, industry can use them to readily demonstrate adequate process control for food safety characteristics of meat.

The establishment should have a documented process control system for implementing corrective actions that will allow it to consistently meet performance objectives or performance criteria. Process review and any other corrective and preventative actions required as a result of non-compliance with performance objectives or performance criteria should be properly recorded. The competent authority should implement a system for collecting and analysing results from all establishments to the greatest extent possible, and periodically review process control trends in relation to national meat hygiene goals.

Where possible, performance objectives or performance criteria should objectively express the level of hazard control as derived from the application of risk analysis principles. In the absence of sufficient knowledge of risks to human health, performance objectives or performance criteria can initially be established from baseline surveys of current performance, and subsequently modified as appropriate to reflect public health goals. Where outcome-based parameters have been established for suitability characteristics of meat, outcomes should be practically achievable and reflect consumer expectations.

Organoleptic parameters may also be established.

Performance objectives or performance criteria for outcomes of process control systems act to:

- facilitate validation of process control systems;
- facilitate derivation of process parameters at various steps in the food production system;
- allow maximum flexibility and technical innovation in the way the establishment operator achieves the required level of performance;
- facilitate industry-wide consistency in performance;
- provide an objective basis for outcome-driven regulatory guidelines and standards, e.g., statistical process control requirements, prevalence of *Salmonella* spp.;
- improve hazard control over time so as to enhance the level of consumer protection; and
- facilitate determination of the equivalence of sanitary measures.

Microbiological performance objectives or performance criteria, process criteria and microbiological criteria for ready-to-eat (RTE) products should be risk-based according to the category of product e.g. not heat treated and shelf stable, heat treated and shelf stable, fully cooked and not shelf stable. Microbiological verification tests should be undertaken by the establishment at a frequency appropriate to the circumstances. The competent authority may also implement testing to verify that appropriate control is maintained by industry. HACCP plans applied by the establishment should document corrective and preventative measures to be taken in the event of positive tests for pathogens or toxins.

Where performance objectives or performance criteria are established as regulatory requirements e.g., guidelines for allowable levels of generic *E. coli*, standards for absence of *E. coli* O157:H7, maximum residue limits for chemicals with acute toxicity, explanation of the linkage to an appropriate level of consumer protection should be provided to all interested parties,.

In some circumstances a performance criterion may be established as a microbiological criterion that defines the acceptability of a production lot, e.g. based on the presence/absence or number of microbes, and/or the quantity of their toxins or metabolites according to a specified sampling plan.[42]

The competent authority should, wherever practicable, recognise different risk-based meat hygiene activities within its competence, which have been demonstrated to meet at least the same risk-based meat hygiene outcomes.

9.2.4 **Regulatory systems**

The competent authority should have the legal power to set and enforce regulatory meat hygiene requirements, and has the final responsibility for verifying that all regulatory requirements are met. The competent authority should:

i. Establish regulatory systems (e.g. recall, traceback, product tracing, etc., as appropriate) and requirements, e.g. training, knowledge, skills and ability of personnel (generally at a national level).
ii. Undertake specified meat hygiene controls that are designated activities of the competent authority, e.g., official sampling programmes, those aspects of ante and post-mortem activities specified by the competent authority, or official certification.
iii. Verify that process control systems implemented by the establishment operator meet regulatory requirements e.g. GHP, SSOPs, HACCP, as appropriate.
iv. Verify that competent bodies are carrying out functions as required.
v. Carry out enforcement actions as necessary.

The competent authority should verify compliance with:

- GHP requirements for: animals presented for slaughter (and killed wild game presented for dressing), establishments, facilities and equipment, process control, transport, and hygiene of personnel;
- SSOPs;
- HACCP plans;
- all regulatory requirements relating to ante- and post-mortem inspection;
- microbiological performance objectives or performance criteria, process criteria or microbiological criteria that are regulatory requirements";
- chemical residue and contaminant levels that are below maximum limits as described in relevant legislation and national sampling plans;

[42] *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

- official or "officially-recognised" zoonoses control programmes, e.g., microbiological tests for *E. coli* O157:H7; and
- additional risk management measures as specified by the competent authority.

Verification activities may include assessment of processing activities carried out by establishment personnel, documentary checks, organoleptic inspection of edible parts and meat, taking of samples for laboratory tests and testing for pathogens, indicator organisms, residues, etc. Approval/registration/listing of an establishment may facilitate the ability of the competent authority to verify that it is operating in compliance with regulatory requirements.

The competent authority(s) should conduct appropriate monitoring of verification activities performed by the operator, and the nature and intensity of that monitoring should be based on risk and performance. The distribution and retail sale of products should be included in this monitoring to an extent that the risks to the consumer are mitigated.

The official inspector (including the veterinary inspector) should verify compliance with the regulatory requirements and may use additional documentary checks, procedures and tests in this role. Rules governing the presence of the official inspector during ante- and post-mortem inspection, and during processing, cutting, and storage of meat, should be determined by the competent authority in relation to deployment of other competent persons, and in relation to potential risks to human health associated with the classes of animals and meat involved.

A national meat hygiene programme should be subject to verification by the competent authority.

Where the establishment operator does not comply with regulatory requirements, the competent authority should carry out enforcement actions that may include:

- slowing of production while the operator regains process control;
- stopping production, and withdrawing certification for meat deemed to be unsafe or unsuitable for its intended use;
- withdrawing official supervision, or accreditation of competent persons;
- ordering specified treatment, recall or destruction of meat as necessary; and
- withdrawing or suspending all or part of the approval/registration/listing of the establishment if process control systems are invalid or repeatedly non-compliant.

9.2.5 **Quality assurance (QA) systems**

Whenever there are verifiable quality assurance (QA) systems in place in the industry, the competent authority should take them into account.[43]

9.3 General hygiene requirements for process control

Process control should meet the general hygiene requirements of the *Recommended International Code of Practice – General Principles of Food Hygiene*.[44]

General hygiene requirements for process control should include for example:

- water for cleaning and sanitising of a standard that is appropriate for the specific purpose, and used in a manner that does not directly or indirectly contaminate meat;
- cleaning of facilities and equipment that involves disassembly where necessary, removal of all debris, rinsing of parts, application of an approved cleaner, repeat rinsing, reassembly, and further sanitizing and rinsing as appropriate;
- handling and storage of containers and equipment in a way that minimises the potential for contamination of meat;
- assembly of containers or cartons in rooms or areas where meat may be present in such a manner that there is minimal possibility of contamination; and
- controlled access of personnel to processing areas.

The competent authority and industry should utilise appropriately accredited or otherwise recognised laboratories when verifying process control and carrying out other meat hygiene activities. Testing of samples should utilise validated analytical methods.[45]

Laboratory testing may be required for:

- verification of process control;
- Monitoring achievement of performance objectives or performance criteria;
- residue monitoring;
- diagnosis of disease conditions affecting individual animals; and
- monitoring of zoonoses.

[43] *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* – Section 4 "Quality Assurance" (CAC/GL 26-1997).

[44] Note that general requirements for control of incoming materials, use of water, packaging, documentation and records, and recall procedures are described in the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

[45] *Guidelines for the Assessment of the Competence of Testing Laboratories involved in the Import and Export Control of Food* (CAC/GL 27-1997).

9.4 Hygiene requirements for slaughter and dressing

Only live animals intended for slaughter should be brought into an abattoir, with the exception of animals that have undergone emergency slaughter outside the slaughterhouse and have appropriate veterinary documentation.

No animal other than an animal intended for slaughter should enter an abattoir, with the exception of animals used for stock handling provided these animals stay in the live animal handling area of the abattoir.

An animal should only be slaughtered or dressed in an abattoir if a competent person is available to undertake ante- and post-mortem inspection. In cases of emergency slaughter where a competent person is not available, special provisions established by the competent authority will apply to ensure that the meat is safe and suitable for human consumption.

All animals brought to the slaughter floor should be slaughtered without delay, and stunning, sticking and bleeding of animals should not proceed at a rate faster than that at which bodies of animals can be accepted for dressing.

During initial dressing operations, and with due consideration to minimising contamination:

- slaughtered animals that are scalded, flamed or similarly treated should be scoured of all bristles, hair, scurf, feathers, cuticles and dirt;
- the trachea and oesophagus should remain intact during bleeding, except in the case of ritual slaughter;
- bleeding should be as complete as possible; if blood is intended for food, it should be collected and handled in a hygienic manner;
- exposure of the tongue should be done in such a way that the tonsils are not cut;
- skinning of the head may not be required for some classes of animals e.g. goats, calves, sheep, provided that heads are handled in such a way as to avoid undue contamination of meat;
- before the removal from the head of any parts intended for human consumption, the head should be clean and, except in the case of animal bodies that are scalded and dehaired, skinned to an extent sufficient to facilitate inspection and the hygienic removal of specified parts;
- lactating or obviously-diseased udders should be removed from animal bodies at the earliest opportunity;

- removal of udders should be done in such as way that the contents do not contaminate the animal bodies;
- gas skinning or dehiding (pumping of air or gas between the skin or hide and the underlying tissue to facilitate skinning) should only be permitted if it can meet required criteria for process control; and
- hides/fleeces should not be washed, de-fleshed or left to accumulate in any part of an abattoir or establishment that is used for slaughter or dressing.

Poultry and farmed game birds, following de-feathering, can only be effectively cleaned of dust, feathers and other contaminants by the application of potable water. Washing of the animal bodies at multiple steps in the dressing process, and as soon as possible after each contaminating step, reduces the adherence of bacteria to the skin which can minimise overall carcass contamination. (Washing after evisceration and post-mortem is also necessary for technological reasons, as this is the only method available to routinely clean carcasses before entry to the chilling process). Washing may be carried out by several methods e.g., spraying, immersion washing.

Farmed ratites may have an excessive amount of dust and dirt trapped in their feathers, and this has the potential for significant contamination of the dressing area unless there is adequate separation by distance, physical barrier, or other means, e.g., positive ventilation.

Once the removal of the hide/fleece has commenced, or dehairing has occurred, animal bodies should be separated from each other to avoid contact, and this should be maintained until each carcass has been inspected and judged by a competent person undertaking post-mortem inspection. (Note: While full separation of carcasses is more difficult in the case of poultry and farmed game birds, such contact should be minimised).

During dressing, and with due consideration to minimising contamination:

- where bodies of animals are skinned, this process should be completed before evisceration;
- water in scalding tanks should be managed so that it is not excessively contaminated;
- evisceration should be carried out without delay;
- discharge or spillage of any material from the oesophagus, crop, stomach, intestines, cloaca or rectum, or from the gall bladder, urinary bladder, uterus or udder, should be prevented;
- intestines should not be severed from the stomach during evisceration and no other opening should be made into an intestine, unless the intestines are first effectively tied to prevent spillage, except in the case of poultry and game birds;

- stomachs and intestines and all inedible material derived from the slaughtering and/or dressing of bodies of animals should be removed as soon as possible from the dressing area, and processed in a manner that does not cause cross-contamination of meat;
- methods used to remove visible and microbial contamination should be demonstrated to be effective and meet other requirements as specified by the competent authority; and
- faecal and other material should be trimmed or otherwise removed from carcasses in a manner that does not result in further contamination, and which achieves appropriate performance objectives or performance criteria for process control.

Animal bodies and carcasses should not come into contact with surfaces or equipment unless practically unavoidable. Where use of equipment involves contact by design, e.g., in the case of automatic eviscerating machines, the hygiene of the equipment should be appropriately maintained and monitored.

Where a competent person undertaking post-mortem inspection, considers that the manner in which animals are being slaughtered or dressed, or meat is further handled, will adversely affect the safety and suitability of meat, that competent person should enforce a reduction in the rate of production or the suspension of operations or other appropriate measures, as deemed necessary (refer to 9.2.4).

Establishment operators should meet the requirements of the competent authority in terms of presentation of edible parts of bodies of animals for post-mortem inspection. Parts of slaughtered animals that have been removed before post-mortem inspection is performed should remain identifiable, as belonging to a single carcass (or a group of carcasses) when required for post-mortem judgement.

Facilities and equipment for slaughtering and/or dressing may be used for other purposes, e.g. for animal health emergency slaughter, provided appropriate cleaning and sanitation requirements are met.

The competent authority should encourage development and adoption of innovative technologies and procedures at the establishment level that reduce cross-contamination and enhance food safety, e.g., enclosing the terminal rectal intestine in a bag and tying off.

9.5 Post-mortem inspection

All carcasses and other relevant parts should be subjected to post-mortem inspection, which preferably should be part of an overarching, risk-based system for the production of meat.

Post-mortem inspection of carcasses and other relevant parts should utilise information from primary production and ante-mortem inspection, together with the findings from organoleptic inspection of the head, carcass and viscera, to make a judgement on the safety and suitability of parts intended for human consumption. Where the results of organoleptic inspection are insufficient to accurately judge carcasses and other relevant parts as safe or suitable for human consumption, the parts should be set aside and followed up with confirmatory inspection procedures and/or tests.

9.5.1 Design of post-mortem inspection systems

Post-mortem inspection procedures and tests should be established by the competent authority according to a science- and risk-based approach. The competent authority has responsibility for establishing judgement criteria and verifying the post-mortem inspection system. In the absence of a risk-based system, procedures will have to be based on current scientific knowledge and practice.

Post-mortem procedures and tests may be integrated and implemented together so as to achieve public health and animal health objectives. In such cases, all aspects of post-mortem inspection should be science-based and be tailored to the relevant risks.

Relevant information on the animal population, e.g., animal type, health status, geographical region of origin, should be utilised in both the design and implementation of post-mortem inspection systems.

Where indicated by public health concerns, routine screening of carcasses and other relevant parts by methods other than organoleptic inspection may be required for suspected hazards, e.g., testing for *Trichinella* spp.

Characteristics of a risk-based post-mortem inspection programme are:

- design and application of organoleptic procedures and tests that are relevant and proportional to meat-borne risks associated with grossly-detectable abnormalities;
- tailoring of procedures to the spectrum and prevalence of diseases and defects reasonably likely to be present in the particular slaughter population, taking into account the type (age), geographical origin and primary production system of the slaughter animals, e.g., multiple incisions of relevant muscles in all pigs from geographical regions where *Taenia solium* is present;
- procedures that minimise cross-contamination through handling to the greatest extent practicable, and may include procedures that are limited to visual observation of carcasses and other relevant parts in the first instance if justified by risk assessment;
- inspection of non-edible parts of animals where they may play an indicator role in the judgement of edible parts;

- modification of traditional procedures where scientific investigation has shown them to be ineffective, or, of themselves, hazardous to food, e.g., routine incision of lymph nodes of young animals to detect granulomatosus abnormalities;
- application of more intensive organoleptic procedures on a routine basis when a disease or condition capable of general distribution is found in a single part of a carcass and other relevant parts, e.g., cysts of *Taenia saginata* in cattle, xanthosis;
- application of additional risk-based inspection procedures on a routine basis when live animals are positive to a diagnostic test, e.g., tuberculin test in cattle, mallein test in horses;
- use of laboratory tests for hazards that are unaddressed by organoleptic inspection, e.g., *Trichinella* spp., chemical residues and contaminants;
- application of measurable outcomes of organoleptic inspection that reflect a risk-based approach;
- integration with HACCP plans for other process control activities;
- on-going tailoring of procedures to take into consideration information received from the primary producer on a lot-by-lot basis; and
- return of information to the primary producer so as to seek continuous improvement in the safety and suitability status of animals presented for slaughter (refer to 6.4).

9.5.2 **Implementation of post-mortem inspection**

Post-mortem inspection should occur as soon as is practicable after slaughter of animals, or delivery of killed wild game animals. Inspection should take into account all relevant information from the level of primary production and ante-mortem inspection, e.g. information from official or officially-recognised hazard control programmes, information on animals slaughtered as "suspects".

The competent authority should determine: how post-mortem inspection is to be implemented, the training, knowledge, skills and ability required of personnel involved (including the role of the official inspector, the veterinary inspector, and any personnel not employed by the competent authority), and the frequency and intensity of verification activities (refer to 9.2.4). The final responsibility for verifying that all post-mortem inspection and judgement requirements are met should lie with the competent authority.

Carcasses and other relevant parts condemned by the competent person undertaking post-mortem inspection, as unsafe or unsuitable for human consumption should be identified as appropriate and handled in a manner that does not result in cross-contamination of meat from other carcasses and relevant parts. The reason for condemnation should be recorded, and confirmatory laboratory tests may be taken if deemed necessary.

The responsibilities of the establishment operator in respect of post-mortem inspection include:

- maintenance of the identity of a carcass and other relevant parts (including blood as appropriate) until inspection is complete;
- skinning and dressing of heads to the extent necessary to facilitate inspection, e.g., partial skinning to allow access to sub-maxillary lymph nodes, detaching of the base of the tongue to allow access to the retropharyngeal lymph nodes;
- skinning of heads to the extent necessary to allow hygienic removal of edible parts, when this is a processing option;
- presentation of a carcass and other relevant parts for inspection according to the requirements of the competent authority;
- a prohibition on establishment personnel intentionally removing or modifying any evidence of a disease or defect, or animal identification mark, prior to post mortem inspection;
- prompt removal of foetuses from the evisceration area, for rendering or other processes as allowed by the competent authority, e.g., collection of foetal blood;
- retention in the inspection area of all carcasses and other relevant parts required for inspection, until inspection and judgement has been completed;
- provision of facilities for identifying and retaining all carcasses and other relevant parts that require more detailed inspection and/or diagnostic tests before a judgement on safety and suitability can be made, in a manner that prevents cross-contamination of meat from other carcasses and other relevant parts;
- condemnation of parts of the carcass trimmed from the region of the sticking wound;
- routine condemnation of the liver and/or kidneys from older animals where the competent authority has determined that there may be accumulation of heavy metals to an unacceptable level;
- use of health marks (as specified by the competent authority) that communicate the outcome of post-mortem inspection; and
- co-operation with competent persons undertaking post-mortem inspection, in all other ways necessary to facilitate effective post-mortem inspection, e.g., access to processing records, and easy access to all carcasses and other relevant parts.

Post-mortem inspection systems, should include:

- procedures and tests that are risk-based to the extent possible and practicable (refer to 9.5.1);
- confirmation of proper stunning and bleeding;

- availability of inspection as soon as is practicable after completion of dressing;
- visual inspection of the carcass and other relevant parts, including inedible parts, as determined by the competent authority;
- palpation and/or incision of the carcass and other relevant parts, including inedible parts, as determined by the competent authority according to a risk-based approach;
- additional palpation and/or incisions, as necessary to reach a judgement for an individual carcass and other relevant parts, and under appropriate hygiene control;
- more detailed inspection of edible parts intended for human consumption compared with inspection of those parts for indicator purposes alone, as appropriate to the circumstances;
- systematic, multiple incisions of lymph nodes where incision is necessary;
- other organoleptic inspection procedures, e.g., smell, touch;
- where necessary, laboratory diagnostic and other tests carried out by the competent authority or by the establishment operator under instruction;
- performance objectives or performance criteria for the outcomes of organoleptic inspection, if available;
- regulatory authority to slow or halt processing so as to allow adequate post-mortem inspection at all times;
- removal of specified parts if required by the competent authority, e.g., "specified risk materials" for BSE; and
- proper use and secure storage of equipment for health marking.

The competent authority and industry should record and disseminate the results of post-mortem inspection as appropriate. Notifiable human or animal health diseases and cases of non-complying residues or contaminants should be reported to national competent authorities as well as to the owner of the animal(s). Analysis of the results of post-mortem inspection over time is the responsibility of the competent authority, and the results of such analyses should be made available to all interested parties.

9.6 Post-mortem judgement

Post-mortem judgement of edible parts as safe and suitable for human consumption should primarily be based on food-borne risks to human health. Other risks to human health, e.g., from occupational exposure or from handling of meat in the home, also are an important consideration. Judgements in relation to suitability characteristics of meat should reflect consumer acceptability requirements appropriate to intended end-use. [46]

[46] The competent authority may take into account varying needs of different consumer populations so that suitability judgements do not distort the economics of the food supply.

Although outside the mandate of Codex, post-mortem inspection programmes may be utilised to identify and judge carcasses and other relevant parts according to risks to animal health, as specified in relevant national legislation.

Judgement of edible parts as safe and suitable should take into account information from the following sources:

- information from primary production (refer to Section 6);
- observations made of animals in the lairage;
- ante-mortem inspection; and
- post-mortem inspection, including diagnostic tests, where required.

Judgements should be based on science and risks to human health to the greatest extent possible, with guidelines being provided by the competent authority. Judgements should only be made by competent persons. The level of training, knowledge, skills and ability required for judgement may be less in situations where edible parts demonstrating a specific abnormality are always judged to be unsafe or unsuitable for human consumption and appropriately disposed of.

Where the initial results of post-mortem inspection are insufficient to accurately judge edible parts as safe or suitable for human consumption, a provisional judgement should be followed up with more detailed inspection procedures and/or tests. Pending the outcome of more detailed inspection and/or diagnostic tests, all parts of the animal that are required for further investigation should be held under the control of the competent person undertaking these activities.

Judgement categories for edible parts include:

- safe and suitable for human consumption;
- safe and suitable for human consumption, subject to application of a prescribed process, e.g., cooking, freezing;[47]
- held on suspicion of being unsafe or unsuitable, pending the outcome of further procedures and/or tests.
- unsafe for human consumption but able to be used for some other purpose, e.g., pet-food, feed and feed ingredients, industrial non-food use, providing there are adequate hygiene controls to prevent any transmission of hazards, or illegal re-entry to the human food chain;
- unsafe for human consumption and requiring condemnation and destruction;

[47] The competent person can instruct that following post-mortem inspection, edible parts held under suitable inventory control can be designated as safe and suitable when subjected to a particular process e.g. freezing, cooking, canning.

- unsuitable for human consumption, but able to be used for some other purpose, e.g., pet-food, feed and feed ingredients, industrial non-food use, providing there are adequate controls to prevent illegal re-entry to the human food chain;
- unsuitable for human consumption, and requiring condemnation and destruction; and
- unsafe for animal health reasons as specified in national legislation, and disposed of accordingly.[48]

When edible parts are judged to be safe and suitable for human consumption subject to application of a prescribed process, the specifications for that process should be verified by the competent authority as sufficient to eliminate/reduce or adequately remove the hazard or condition of concern, e.g., specifications for retorting, high temperature rendering and freezing.

9.7 Hygiene requirements for process control after post-mortem inspection

Operations following post-mortem inspection include all procedures until the point of retail sales, e.g. chilling of carcasses, de-boning and cutting, further preparing, processing, packaging, freezing, storing, and distribution to the point of retail sale. Particular attention needs to paid to temperature control, with temperatures of freshly slaughtered and dressed carcasses and other edible parts being reduced as rapidly as possible to a temperature that minimise the growth of micro-organisms or the formation of toxins that could constitute a risk to human health. It is also important that the cold chain is not interrupted except to the minimal extent necessary for practical operations, e.g., handling during transportation.

In the case of poultry and farmed game birds, viscera or parts of viscera, apart from kidneys, should be entirely removed as soon as possible, unless otherwise permitted by the competent authority.

Meat passed as safe and suitable for human consumption should be:

- removed without delay from the dressing area;
- handled, stored and transported in a manner that will protect it from contamination and deterioration;
- held under conditions that reduce its temperature and/or water activity as quickly as possible, unless cut up or de-boned pre-rigor; and
- held at temperatures that achieve safety and suitability objectives.

[48] In some circumstances, edible parts may be judged as suitable for human consumption but subject to restricted distribution because the animals were sourced from geographical areas under quarantine for animal health reasons.

In the case of poultry or farmed game birds undergoing immersion chilling:

- the immersion chilling process should meet hygiene criteria as specified by the competent authority;
- the reduction in carcass temperature should be as rapid as possible;
- carcasses emerging from the process should have a lesser microbiological count for indicator organisms and pathogens than those entering the process; and
- sanitation requirements should include complete emptying, cleaning and sanitation of tanks as appropriate.

An official health mark applied to meat, wrapping or packaging, should provide recognition that the product has been produced in accordance with regulatory requirements, and should assist with trace-back to the establishment of origin if required. When used as part of an official meat hygiene programme, the health mark should include the approval/registration/listing number of the establishment, be applied in such a way that it cannot be re-used, and be legible. Other marks may denote conformance with commercial specifications, or unacceptability for human consumption, e.g., distinctive brands for pet-food.

Official health marks may be applied directly to the product, wrapping or packaging, or be printed on a label affixed to the product, wrapping or packaging. In circumstances of bulk transport to another establishment for further handling, processing or wrapping, health marks may be applied to the external surface of the container or packaging.

Where carcasses, parts of carcasses or other meat is placed in a holding room:

- all requirements for hygienic control of operations must be adhered to e.g., chiller loading rates, stock rotation, specifications for temperature and relative humidity;
- carcasses and parts of carcasses, whether hung or placed in racks or trays, should be held in a manner permitting adequate circulation of air;
- the potential for cross-contamination via dripping of fluids should be prevented; and
- water dripping from overhead facilities and condensation should be controlled to the extent practicable, to prevent contamination of meat and food contact surfaces.

Rooms and equipment for cutting, mincing, mechanical separation, meat preparation and the manufacturing of meat should be designed such that activities can be carried out separately, or in such a manner that does not led to cross contamination.

Fresh meat intended for cutting or de-boning should be brought into work rooms progressively as needed, and should not accumulate on work tables. If fresh meat is

cut or de-boned prior to reaching temperatures that are appropriate for storage and transport, it should be immediately reduced in temperature to prescribed levels.

When fresh meat is cut or de-boned pre-rigor:

- it should be transported directly from the dressing area to the cutting up or de-boning room;
- the cutting up or de-boning room should be temperature-controlled and directly linked to the dressing areas, unless the competent authority approves alternative procedures that provide an equivalent level of hygiene; and
- cutting up, de-boning and packing should be done without delay and should meet all requirements for hygienic process control.

When raw meat is minced:

- it should be obtained only from parts of animals as approved by the competent authority e.g. striated muscle and adherent fatty tissues[49];
- it should not contain bone fragments or skin;
- any grossly abnormal tissues and / or post-dressing contamination should be removed before mincing; and
- the competent authority may specify compositional criteria.

When raw meat is mechanically separated, the competent authority should:

- restrict the type of animal parts that can be used e.g. non-use of skulls;
- set compositional standards for maximum calcium content; and
- require specific labelling of the final product.

When raw meat is minced, mechanically separated or used in meat preparations:

- the competent authority can specify maximum time/temperature schedules for process control at each step of production e.g. maximum times and temperatures from chilling or freezing of raw material to the time of preparation, maximum temperatures during production, maximum times before chilling or freezing;

[49] Striated muscles from affected animal species should have undergone an examination from Trichinella as specified by the competent authority.

- unless used directly as an ingredient for meat preparations and manufactured meat, it should be immediately wrapped and/or packaged, followed by immediate refrigeration;
- the competent authority may specify microbiological performance objectives, performance criteria, process criteria or microbiological criteria for raw materials and final product;
- establishments should have in-line magnets or other means of detecting contamination with metal fragments as appropriate; and
- it should not be refrozen after thawing.

When meat preparations or manufactured meat are handled:

- the process flow of raw meat awaiting processing and during processing should ensure uniform turnover of accumulated product and avoid possible cross-contamination, e.g. between raw materials and ready-to-eat products;
- supply and addition of non-meat ingredients should be subject to good hygienic practice and HACCP as appropriate and practicable, and may involve decontamination treatments e.g. for herbs and spices;
- products that include non-meat protein products (as defined or standardised by Codex) should be appropriately labelled[50];
- process control for non-commercially sterile products should prevent pathogen growth and toxin production during all processing activities e.g. during fermentation, partial heat treatment, drying, maturing and curing. Process criteria may include for example, correct pH after fermentation, correct time/temperature schedules during and after heating or smoking, correct moisture / protein ratio after drying, correct formulation and application of nitrite as a cure ingredient;
- if heat and/or other processing treatments are not sufficient to ensure the stability of the product, the product should be cooled to an appropriate storage temperature and in a manner that ensures product safety is not compromised as a result of germination and subsequent growth of pathogenic sporeformers;
- product formulations e.g. distribution of antibacterial ingredients throughout cooked sausage emulsions, addition of cultures, adjustment of pH, should achieve required levels of pathogen control;
- microbiological contamination of raw meat used to produce fermented products should be as low as possible, and similarly, mechanically separated meat should only be used if appropriate time / temperature schedules to achieve product safety requirements of the competent authority are used;

[50] *General Standard for the Labelling of Prepackaged Food* (CODEX STAN 1-1985).

- processing of shelf-stable products in hermetically sealed rigid containers should be according to Codex guidelines;[51]
- cooked products should achieve time / internal temperatures that are validated as achieving appropriate pathogen reduction, including meeting specified performance objectives, performance criteria and microbiological criteria;
- pasteurisation values or other heat processes should be validated for all heat treated chilled products in hermetically sealed containers so as to ensure that product safety is maintained to the end of shelf life, taking into account all preservation factors that may be present;
- unless the absence of trichinellae can be assured by testing or other means, process treatments for products containing striated muscle from affected animal species, either alone or in combination, should be sufficient to destroy *Trichinella* spp.;
- contamination with *L. monocytogenes* of heat treated / non-shelf stable and non-heat treated / shelf stable products should be prevented by use of SSOPs and GHPs that are subject to routine microbiological verification;
- dried products should be protected from environmental contamination and from reabsorption of moisture; and
- processes for products containing minced, comminuted or mechanically separated meat should have in-line magnets or other means of detecting contamination with metal fragments.

Where meat is packaged or wrapped:

- packaging material should be suitable for use, stored and used in a hygienic manner; and
- cases or cartons should have a suitable inner liner or other means of protecting the meat, except that the liner or other protection may not be required if pieces of meat, such as cuts, are individually wrapped before packing.

Where meat is placed in a room for freezing:

- meat that is not in cartons should be hung or placed on racks or trays in a manner that allows adequate circulation of air;
- meat that is not in cartons should be held in a manner whereby the potential for cross-contamination via dripping of liquids is prevented;
- cartons containing meat should be stacked so as to permit adequate circulation of air; and

[51] *Recommended International Code of Hygienic Practice for Low-Acid Canned Foods* (CAC/RCP 23-1979).

- meat held on trays should be placed so as to avoid contact with the base of an upper tray.

Where meat is held in a freezer room or storage facility:

- the temperature of the meat should have been reduced to an acceptable level before placement;
- exposed meat must be stored in such a way that the hygiene cannot be compromised by the presence of packaged meat or packaging material;
- meat, whether in carcass form or in cartons, should not be stacked directly on the floor and should be positioned so that there is adequate air circulation;
- the freezer store should be operated and maintained under conditions appropriate to maintaining the safety and suitability of meat;
- temperatures should be continuously recorded and monitored; and
- adequate inventory control should be maintained.

Where raw meat is thawed for further processing, hygiene controls should be such that thawing will not result in growth of micro-organisms or the formation of toxins to the extent that they may constitute a risk to human health. Hygiene controls should include adequate drainage of liquid run-off.

The establishment operator should establish and implement a procedure for determining and validating the shelf life of manufactured meat and meat preparations.

In some circumstances ready-to-eat (RTE) products that do not meet microbiological performance objectives, performance criteria, process criteria, or microbiological criteria, may be re-processed, condemned or treated as inedible. Where appropriate, follow-up sampling should verify that re-processed ready-to-eat (RTE) products comply with regulatory microbiological requirements. When ready-to-eat (RTE) products have been contaminated subsequent to cooking and/or other preservation treatment with pathogens such that they could pose a risk to public health, the products should be reworked or condemned without compromise.

Where establishments are approved, registered and/or listed for different animal species, all operations must be controlled in terms of space or time so that there is no possibility of accidental mixing of meat from different slaughter species, and no mis-identification at the time of packaging.

9.8 Hygiene requirements for parts of animals deemed unsafe or unsuitable for human consumption

Special hygiene measures should be applied to operations involving parts of animals deemed unsafe or unsuitable for human consumption. These measures should prevent cross-contamination to other edible parts and meat, and prevent any possibility of substitution.

Parts of animals deemed unsafe or unsuitable for human consumption should be:

- placed without delay into specifically identified chutes, containers, trolleys, or other handling facilities;
- identified by means as appropriate to the type and end use of the tissue;
- in the case of condemned material, handled in rooms reserved for that purpose and conveyed in a secure manner to a place of disposal (e.g. rendering station).

9.9 Systems for removing products that are in circulation

Establishments should have adequate systems that enable removal of products that are in circulation. The competent authority should verify that the systems are adequate. The competent authority should be notified when an establishment operator removes product for public health reasons. Consumers and interested parties should be notified as appropriate in these cases.

Removal of product requires systems that are capable of:

- Withdrawal, where measures are applied by the establishment operator to prevent the distribution, display or offer of a product that is not safe or suitable for human consumption;
- Recall, where measures are applied to return unsafe or unsuitable product that has already been supplied or made available to consumers;
- Detention, where measures are applied by the competent authority to ensure that the product is not moved or tampered with pending a decision on its disposition; it includes storage by the establishment operator in accordance with instructions from the competent authority.

The particular systems that are enacted in the case of a removal will depend on the specific situation and the likely risks to human health.

Where removal of product is necessary, the amount of product involved may be more than that from a single production or sampled lot. The competent authority should verify to the extent practicable, that the establishment has taken all steps necessary to ensure all affected product or potentially affected product is included in the removal.

Product removal systems designed by the establishment operator should:

- Incorporate identification, management and operational procedures that facilitates the rapid and complete removal of implicated lots;
- Provide for records that facilitate trace-back to the origin of the problem;
- Provide for records that facilitate investigation of any processing inputs that may be implicated;
- Be reviewed and tested periodically; and
- Include provision for communication where appropriate to the competent authority, consumers and other interested stakeholders particularly where public health issues are involved.

10. ESTABLISHMENTS: MAINTENANCE AND SANITATION

The principles and guidelines presented in this section are supplemental to the objectives and guidelines in Section VI of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

10.1 Principles of meat hygiene applying to maintenance and sanitation of establishments, facilities and equipment

i. Establishments, facilities and equipment should be maintained and sanitised in such a manner that contamination of meat is minimised to the greatest extent practicable.
ii. Documented programmes for effective and appropriate maintenance and sanitation should be in place (refer to 9.2.1).
iii. Monitoring of the effectiveness of maintenance and sanitation should be included as a basic component of meat hygiene programmes (refer to 9.2.1).
iv. Special sanitation requirements should be applied to the slaughter and dressing of animals that are condemned or designated as "suspects".

10.2 Maintenance and sanitation

Establishments, facilities and equipment should be kept in an appropriate state of repair and condition to facilitate all sanitation procedures and prevent contamination of meat, e.g., from metal shards, flaking plaster and chemical contaminants.

Sanitation standard operating procedures (SSOPs) should specify the scope of the cleaning programme, cleaning specifications, persons responsible, and monitoring and record keeping requirements.

Cleaning procedures and programmes should:

- be specified in SSOPs as appropriate to the circumstances;
- provide for removal and storage of waste;
- ensure that there is no consequential contamination of meat with detergents or sanitising agents, unless allowable under conditions of use; and
- be monitored for their effectiveness, e.g., organoleptic checks and microbiological sampling of meat contact surfaces, and be redesigned if and when necessary.

Particular cleaning programmes are required for equipment used in the slaughter and dressing of carcasses e.g., knives, saws, machine cutters, evisceration machines and flushing nozzles.

Such equipment should be:

- clean and sanitised before each new period of work;
- cleaned, and sanitised, by immersion in hot water or alternative methods, with appropriate frequency during and/or between periods of work;
- immediately cleaned and sanitised when coming into contact with abnormal or diseased tissue that may harbour food-borne pathogens; and
- stored in designated areas in such a manner that it will not become contaminated.

Containers and equipment should not pass from an "inedible" area to an "edible" area before being cleaned and sanitised.

Pest control programmes are an essential part of maintenance and sanitation and should follow GHP as described in the *Recommended International Code of Practice – General Principles of Food Hygiene*.[52]

In particular:

- the programme should be properly documented and verified by the establishment operator;
- treatment of areas, rooms, facilities and equipment, with an approved pesticide should be carried out according to the conditions of use; and
- pesticides and other pest control chemicals should be kept in secure storage, with access being limited to authorised persons.

[52] *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

11. PERSONAL HYGIENE

Slaughter and dressing of animals, and handling and inspection of meat, presents many opportunities for cross-contamination. Personal hygiene practices should prevent undue general contamination, and prevent cross-contamination with human pathogens that may cause food-borne disease. The guidelines presented in this section are supplemental to the objectives and guidelines in Section VII of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

Persons moving from rooms or areas containing raw meat to rooms or areas used for meat preparations and manufactured meat (especially when these products are cooked) should thoroughly wash, change and/or sanitise their protective clothing as appropriate, and otherwise limit the possibility of cross-contamination to the lowest level practicable.

11.1 Personal cleanliness

Persons who come into direct or indirect contact with edible parts of animals or meat in the course of their work should maintain appropriate personal cleanliness and behaviour, and should not be clinically affected by communicable agents likely to be transmitted by meat.

Persons who come into direct or indirect contact with edible parts of animals or meat should:

- maintain an appropriate standard of personal cleanliness;
- wear protective clothing appropriate to the circumstances, and ensure that non-disposable protective clothing is cleaned before and during work;
- if wearing gloves during the slaughter and dressing of animals and the handling of meat, ensure that they are of an approved type for the particular activity, e.g., chain-mail stainless steel, synthetic fabric, latex, and they are used according to specifications, e.g., washing of hands before use, changing or sanitising gloves when contaminated;
- immediately wash and sanitise hands and protective clothing when there has been contact with abnormal animal parts that are likely to harbour food-borne pathogens;
- cover cuts and wounds with waterproof dressings; and
- store protective clothing and personal effects in locations that are separate from areas where meat may be present.

11.2 Personal health status

The establishment should maintain relevant personal health records of personnel.

Persons who come into direct or indirect contact with edible parts of animals or meat in the course of their work should:

- where necessary, have a medical examination prior to and during employment;
- not work while clinically affected by, or suspected to be carrying, communicable agents likely to be transmitted through meat; and
- be aware of and comply with reporting requirements to the establishment operator in respect of communicable agent.

12. TRANSPORTATION

The guidelines presented in this section are supplemental to the objectives and guidelines in Section VIII of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

Due to the potential for growth of pathogenic and spoilage micro-organisms under conditions of inadequate temperature control, meat should be transported at temperatures that achieve safety and suitability objectives. Equipment for continuous monitoring and recording of temperatures should accompany transport vehicles and bulk containers wherever appropriate. Additionally, the conditions of transport should provide adequate protection from exogenous contamination and damage, and should minimise growth of pathogenic and spoilage micro-organisms.

If meat is inadvertently exposed to adverse temperature conditions or sources of contamination that may affect safety and suitability, an inspection should be carried out by a competent person before further transport or distribution is allowed.

13. PRODUCT INFORMATION AND CONSUMER AWARENESS

Appropriate product information and adequate knowledge of food hygiene is necessary to prevent mishandling at later stages in the food chain. Pre-packaged foods should be labelled with clear instructions to enable the next person in the food chain to handle, display, store and use the product safely. Principles and guidelines for product information and consumer awareness in the context of safety and suitability of meat are described in general terms in Section IX of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

The conditions of storage of meat preparations and manufactured meat should be clearly presented on the packaging.

Meat preparations and manufactured meat should, where appropriate, be specifically labelled so as to provide safe handling, refrigeration and storage instructions for consumers. Foods containing meat that have not received an adequate biocidal treatment for pathogens (e.g. containing raw meat, partially cooked meat, or products with secondary inhibitors) should be labelled with handling, refrigeration, storage, cooking and preparation statements that have been validated as sufficiently biocidal.

14. TRAINING

Adequate training of competent personnel is of fundamental importance in the production of meat that is safe and suitable for human consumption. The principles and guidelines presented in this section are supplemental to the objectives and guidelines in Section X of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

14.1 Principles of training in meat hygiene

Persons engaged in meat hygiene activities should be trained, and/or instructed to a required level of training, knowledge, skills, and ability. Training specified or recognised by the competent authority, should be:

i. appropriate to the activities and operations;
ii. proportional to the potential of the particular meat hygiene activity to impact on food-borne risks to human health;
iii. properly documented, including records of training programme delivery;
iv. verified as appropriate; and
v. subject to recognition by the competent authority where delivered by third parties.

14.2 Training programmes

Training programmes should:

- provide personnel with the training, knowledge, skills and ability to carry out specified meat hygiene tasks, e.g., post-mortem inspection, verification of statistical process control, HACCP;
- provide practical training to the extent required;
- where necessary, arrange for formal testing of personnel;
- ensure that personnel involved in supervisory roles have appropriate skills;
- recognise and build on professional qualifications; and
- provide for the continuing education of competent persons.

ANNEX I

RISK-BASED EVALUATION OF ORGANOLEPTIC POST-MORTEM INSPECTION PROCEDURES FOR MEAT

1. INTRODUCTION

Post-mortem meat inspection procedures are a set of food hygiene measures that are unique to the production of meat. Such procedures are regarded as a component of overall process control, which is defined as "all conditions and measures applied during the production process that are necessary to achieve safety and suitability of meat".

The *General Principles of Food Hygiene* state that "in deciding whether a (food control) requirement is necessary or appropriate, an assessment of the risk should be made, preferably within the framework of the HACCP approach". [53] Many long-standing post-mortem meat inspection procedures are often complex, labour-intensive, undifferentiated for different classes of slaughtered livestock, and poorly evaluated in terms of their relative contribution to reducing food-borne risks to public health. For these reasons, competent authorities in a number of countries are carrying out investigations into the scientific basis of current procedures.[54]

This Annex generally applies to the evaluation of routine on-line organoleptic inspection procedures. The performance of other inspection technologies, e.g. tissue imaging, relative to organoleptic procedures, may also be considered.

While risk-based evaluation of organoleptic post-mortem inspection procedures should be based on risk assessment for hazards of concern and development of performance objectives, currently few such risk assessments are available. In their absence, other sources of scientific knowledge on food-borne risks to human health e.g. human surveillance data, risk ranking processes, can be used to develop risk-based post-mortem inspection procedures.

The principles and guidelines presented in this Annex could also be adapted to evaluation of organoleptic post-mortem inspection procedures for determining the suitability of meat.

2. OBJECTIVES OF RISK-BASED POST-MORTEM INSPECTION PROCEDURES FOR MEAT

A risk-based approach to post-mortem inspection for meat can achieve the following objectives:

[53] *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

[54] Competent authorities have different approaches to defining the respective roles of industry and competent authority personnel in delivering meat hygiene activities, and this issue is not covered in this Annex.

- Determination of the level of consumer protection provided by specified post-mortem inspection procedures;
- Relative measurement of the contribution of post-mortem inspection to the overall level of control of hazards in meat (and risks to consumers), thereby allowing risk managers to allocate meat hygiene resources proportionate to their greatest benefit in reducing risk by preventing exposure to meat-borne hazards;
- Comparison of the effectiveness of different inspection procedures applied for the same purpose and in the same context, e.g. positive predictive value;
- Provision of information that allows appropriate evaluation of different risk management options e.g. regionalisation of inspection programmes, feasibility and comparative costs of different post-mortem inspection procedures, potential for cross-contamination;
- Full integration of post-mortem inspection procedures into a "production-to-consumption" approach to meat hygiene.

3. RISK ANALYSIS

3.1. Risk management framework

Development and implementation of risk-based post-mortem inspection procedures should utilise a risk management framework.[55] The four components are: preliminary risk management activities, evaluation of risk management options, implementation of management decisions, and monitoring and review of decision taken. All components require effective risk communication among risk assessors, risk managers and other interested parties as necessary. Utilisation of a risk management framework is the subject of on-going work within the Codex system, and is described in a number of Codex documents.

3.2. Risk assessment

If required, a risk assessment is commissioned during preliminary risk management activities. A risk assessment consists of four steps: hazard identification, hazard characterisation, exposure assessment, and risk characterisation. The output of this process should be qualitatively integrated with all other factors relating to post-mortem meat inspection to make risk management decisions on appropriate procedures for control of hazards.

In the ideal situation, risk estimates will be quantified in terms of risks to human health, and risk management decisions on an appropriate level of protection (ALOP) will dictate the nature and intensity of the post-mortem inspection procedures to be applied. However, risk assessment of microbiological hazards in meat is currently limited by a lack of quantitative risk assessment models. Nevertheless, appropriate assembly of scientific information and qualitative risk characterisation as to the probable impacts on human health can provide an objective basis for decision-making. In any case, risk management decisions will revolve around the acceptability of the likely human health impact of differences in hazard levels brought about by different inspection procedures.

[55] *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (Procedural Manual of the Codex Alimentarius Commission).

4. GENERAL PRINCIPLES FOR DEVELOPMENT OF RISK-BASED POST-MORTEM MEAT INSPECTION PROCEDURES

i. Risk-based post-mortem inspection procedures should be derived from the application of risk analysis principles.

ii. Development of risk-based post-mortem inspection procedures should:
- Involve application of a risk management framework;
- Include quantitative risk assessment where appropriate and practicable;
- Take into account all relevant information available from the food chain;
- Take into account disease prevalence;
- Take into account all relevant information from primary production and ante-mortem inspection of the animals.

iii. Inspection procedures should be evaluated for application within a specific context e.g. species and class of slaughtered animal, defined geographical region, defined animal husbandry system.

iv. Where different inspection procedures that have the same purpose and context are being evaluated:
- An objective basis for comparison of the level of control of hazards associated with these procedures, should be established;
- The efficacy of each inspection procedure in detecting abnormalities and visible contamination affecting the safety of meat should be taken into account;
- Other risk management factors should be taken into account as appropriate e.g. potential for inadvertent cross-contamination, feasibility, and practicality.

v. Where needed, representative and sufficiently large field trials should be undertaken to determine the performance attributes of specified inspection procedures e.g. sensitivity, specificity, and non-detection rates for abnormalities.

vi. Where appropriate, laboratory investigations should be designed to detect the range of hazards of possible public health importance that have been described in hazard identification.

vii. Routine application of post-mortem inspection procedures should not inadvertently increase cross-contamination with microbiological hazards.

viii. Irrespective of inspection delivery systems, the competent authority should be responsible for defining the role of personnel involved in post-mortem inspection procedures, and verifying that any risk-based regulatory requirements are met.

ix. Alternative inspection procedures (e.g. serology) may be utilised to complement post-mortem inspection, which might be reduced to visual inspection.

5. GUIDELINES FOR THE DEVELOPMENT OF RISK-BASED POST-MORTEM INSPECTION PROCEDURES

5.1. Identification of the meat hygiene issues

A hazard identification process should be undertaken to determine the likely range of hazards of public health significance that may be present in the abnormalities or visible contamination that are the target of the inspection procedure(s) being evaluated. Following this, field trials should be undertaken to determine the performance attributes of specified inspection procedures or new technologies relative to the hazards that may be present.

5.2. Field trials

Once the likely range of hazards has been established, field trials may be an appropriate means to establish the prevalence of these hazards in the animal population, the potential exposure of consumers to these hazards and the potential impact of different inspection procedures on this exposure. Field trials should be carried out under competent authority supervision and employing competent personnel. The number of animals inspected by the inspection procedures under evaluation should give a statistically valid estimate of the detection rate of abnormalities achieved by specific post-mortem inspection procedures.

Sampling plans should be representative of the slaughter population, and cater for known biological variation in respect of the type and prevalence of abnormalities e.g. influence of animal age, geographical region, farming type and season. Different trial designs may be employed, depending on the prevalence of abnormalities in the slaughter population, and the logistics of detailed inspection.

Where different post-mortem inspection procedures are being compared: all procedures should be applied to the same animals, each inspection station should be designed to provide independent results, and the trial should include enough samples so as to allow definite conclusions as to the consequences of changing inspection procedures. The possibility of target tissues acting as "indicators" for detection of abnormalities in other tissues and/or disposition of other tissues may be included in the design of field trials. Detailed recording of trial results is necessary, including appropriate pathological descriptions of all abnormalities detected.

Laboratory investigations e.g. microbiological examination and histology, should be designed to identify the range of hazards of possible public health importance that have been identified in the hazard identification process. A representative number and range of samples should be taken from abnormalities, so as to confirm the outcome of the hazard identification process and provide as much information as possible on the prevalence (and concentration) of hazards in target tissue. Trial design should include representative surveying of the prevalence (and concentration) of hazards in target tissues that are organoleptically normal, so as to provide a comparison with the prevalence (and concentration) of hazards in those tissues that are organoleptically abnormal.

5.3 Sensitivity

An understanding of the level of consumer protection that is achieved by particular inspection procedures requires knowledge of the level of control of hazards that is attained by their application. The sensitivity of post-mortem inspection procedures should be determined to establish their contribution to achieving overall public health goals.

The sensitivity of a post-mortem inspection procedure is the probability of identifying bodies or parts thereof that contain grossly detectable abnormalities likely to contain hazards of concern.

The sensitivity of an inspection procedure e.g. visual inspection, palpation, and/or incision, should be determined within appropriate statistical limits established by the competent authority. The intended end-use of the target tissues has an important influence on the development of risk-based post-mortem inspection procedures. When selecting post-mortem inspection procedures, priority should be given to those procedures with high correlation between the detection of a specified abnormality and the presence of the hazard of concern.

5.4 Risk management decisions

Risk management decisions on the acceptability or otherwise of specified post-mortem inspection procedures will generally be based on the worst case of non-detection of abnormalities included in an appropriate statistical confidence interval. Decisions should take into account the comparative public health risks associated with:

- The prevalence (and concentration) of hazards in target tissues that are organoleptically abnormal;
- The prevalence (and concentration) of hazards in target tissues that are organoleptically normal;
- The overall prevalence (and concentration) of hazards being transmitted by all pathways throughout the production of meat.

In the general case, new or alternative inspection procedures should provide a level of consumer protection that is at least equivalent to that provided by existing procedures, unless there are strong mitigating factors that may influence a different risk management choice e.g. unacceptable introduction of new hazards, undue risks from occupational exposure.

Required regulatory outcomes for post-mortem inspection may include performance attributes expressed as limits on non-detection rates for particular abnormalities. Those performance attributes may be derived quantitatively from risk assessment models, or qualitatively from baseline surveys of current performance.

Where detailed information on the health status of slaughtered animals is available from primary production, risk-based post-mortem inspection procedures may be modified on a lot-by-lot basis, with the competent authority having responsibility for determining the frequency and extent of the procedures.

The competent authority should regularly analyse results of post-mortem inspection at both the establishment and national level, and provide appropriate feedback to establishments and other interested parties on the performance of risk-based post-mortem inspection procedures. The competent authority could consider an incentive for improving the system, e.g. recognition of performance, decreased farm inspection frequency, additional change of inspection procedures, etc.

The competent authority may change presentation requirements and the sequence of inspection procedures as a result of scientific evaluation of different post-mortem inspection procedures, and allow introduction of new inspection tools e.g. mirrors. Alternative technologies for detecting abnormalities e.g. tissue imaging, should be acceptable to the competent authority if validated as being as effective as current procedures.

ANNEX II

VERIFICATION OF PROCESS CONTROL OF MEAT HYGIENE BY MICROBIOLOGICAL TESTING

1. INTRODUCTION

Microbiological testing at specific points in the food chain is an important tool for verifying a risk-based approach to food safety. Specification of food safety microbiological outcomes establishes appropriate levels of consumer protection, while providing maximum flexibility to industry in terms of the detailed process control systems that are employed.

The *General Principles of Food Hygiene*[56] state that "in deciding whether a (food control) requirement is necessary or appropriate, an assessment of the risk should be made, preferably within the framework of the HACCP approach", and any microbiological specifications "should be based on sound scientific principles and state, where appropriate, procedures, analytical methods and action limits"[57]. Process control is defined as "all conditions and measures applied during the production process that are necessary to achieve safety and suitability of meat".

Where appropriate, microbiological performance objectives or performance criteria should be included in verification of process control.

As described in this Annex, microbiological performance objectives or performance criteria are different from microbiological criteria. The latter are used for judging the acceptability of a product or food lot.[58] Although not included in the scope of this Annex, microbiological testing of meat may also be used to assess suitability.

2. VERIFICATION OF PROCESS CONTROL BY MICROBIOLOGICAL TESTING

A preventative, HACCP-based approach should be regarded as the most effective means of ensuring microbiological process control. Once process control has been validated, verification by microbiological testing can be important to assure that required food safety outcomes are being met on an on-going basis. Verification by microbiological testing for process control purposes should be implemented where meaningful in terms of consumer protection.

Verification of process control of meat by microbiological testing provides a tool for:

- Assessing the adequacy and efficacy of establishment process control in relation to faecal and other contamination;
- Assuring the level of control of specified hazards of public health importance;

[56] *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

[57] Specifications for microbiological testing in relation to the outcome of SSOPs are not regarded as microbiological performance objectives or performance criteria for process control.

[58] *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

- Facilitating development of process criteria at a specified step or combination of steps that achieve microbiological performance objectives or performance criteria;
- Identifying the need for review and redesign of HACCP plans;
- Objective comparison of the outcome of different process control systems in different situations;
- Provision of assurances by competent authorities.

3. PRINCIPLES FOR THE ESTABLISHMENT OF MICROBIOLOGICAL TESTING REQUIREMENTS

i. Establishment of microbiological testing requirements should take into account all information available throughout the food chain, including the health status of live animals relative to public health.
ii. Microbiological testing requirements should be: hazard-, product- and process-specific, reasonably achievable, and applied only at those points in the food chain specified. When validating the testing requirements, account should be taken of the likelihood of uneven distribution of micro-organisms in the sampled unit and the inherent variability of the analytical procedure.
iii. Microbiological testing requirements should be based on scientific analysis and advice, and, where sufficient data is available, developed from risk analysis. Where a food safety objective based on the required level of consumer protection has been established, the relationship between the food safety objective (FSO) and performance objectives (POs) or performance criteria (PCs) should be specified.
iv. The stringency of microbiological testing requirements should be proportional to human health risk.
v. In the absence of sufficient knowledge of risks to human health, microbiological testing requirements should initially be established from baseline surveys of current industry performance, and subsequently be modified as appropriate to reflect public health goals. Sampling plans for baseline surveys should be representative of the slaughter population, and cater for known biological variation in respect of hazards in the raw material supply e.g. influence of geographical region, farming type and season.
vi. Microbiological testing requirements should be based on micro-organisms that are indices of the presence of hazards to human health, or the pathogen itself, in the food specified.
vii. Establishment of microbiological testing requirements, including performance objectives or performance criteria should be the responsibility of competent authorities, in consultation with relevant interested parties, and may consist of guidelines or regulatory standards.
viii. The competent authority should verify compliance with microbiological testing requirements where they are specified in regulation e.g., microbiological statistical process control requirements, standards for *Salmonella* spp.

4. IMPLEMENTATION OF A PROGRAMME FOR VERIFICATION OF PROCESS CONTROL BY MICROBIOLOGICAL TESTING

4.1 Specifications

A standardised random sampling plan should be developed, including specification of the process step, product, size and type of sample, time and date of sampling, collection methods and transport. Sampling and testing at multiple steps in the food chain may provide greater information on process control and allows for a more targeted response to non-compliance by the establishment and the competent authority.

Sampling of tissue may be destructive e.g. by excision, or non-destructive e.g. by swabbing or sponging. No method will recover all the flora present on the surface. As non-destructive sampling will recover only a proportion of those recovered by the destructive method, microbiological testing requirements specified in this manner should be established in relation to the type of sampling used.

For practical reasons, microbiological testing requirements are unlikely to be verified on an on-going basis as part of a HACCP plan. However, microbiological verification should be conducted with sufficient frequency to ensure effectiveness of any process criteria that are part of a HACCP plan. These criteria should be measurable in real time, will most likely constitute critical limits at critical control points in HACCP plans, and may be subject to microbiological verification as appropriate.

In the case of indicator micro-organisms e.g. generic *Escherichia coli*, Enterobacteriaciae and total viable counts (aerobic plate counts), the presence and / or concentration of these indicator organisms should reflect states or conditions that indicate process control or lack of process control. In the case of specific hazards[59] (e.g. *Salmonella* spp. on carcasses, *Listeria monocytogenes* in ready-to-eat products), the prevalence will generally be reflective of hazards arising pre-slaughter (e.g. *Salmonella* present on hides of incoming animals) and at specific steps during product processing.

The competent authority should provide flexibility in regulation so that the most effective verification systems can be established at the establishment level e.g. provision for alternative carcass sampling sites if an establishment can identify that they are equally as effective in assessing carcass contamination than those specified. Similarly, flexibility should be provided by the competent authority with regard to the number of units comprising the sample or testing against alternative indicator micro-organisms as long as the procedure can provide equivalent guarantees.

Alternative approaches to microbiological testing that are properly validated should be established where they offer practical advantages.

[59] Ongoing work in CCFH and JEMRA with respect to foodborne pathogens should also be taken into account.

4.2 Frequency of sampling

There is no single method for determining the frequency of sampling. For slaughter and dressing establishments frequency of sampling may be fixed in relation to the particular process or may be based on throughput of animals. In addition to ensuring randomness, variables to be taken into account at the establishment level include: source of raw materials, type and nature of the meat process, and volume of production.

Sampling frequency should be increased or decreased according to performance. Once results show that the HACCP-based procedures are providing a consistent level of acceptable performance, subsequent microbiological testing must be sufficient to ensure that process control is maintained.

4.3 Laboratory analysis

Methods for detection and enumeration should be practical, accurate, reproducible, sensitive and selective. Only methods for which the reliability and reproducibility have been validated should be used. Inter-laboratory testing should be a feature of a microbiological verification programme. In cases of dispute, recognised reference methods should be used.

To allow meaningful analysis and to permit objective comparison of different control systems, methods for the computation of results should be specified, including handling of pooled/individual results, calculation of mean results (e.g. log means) from groups of samples from the same carcass or different carcasses.

4.4 Regulatory application

Regulatory requirements in terms of microbiological testing may be specified in several ways. For indicator organisms, two or three class attribute sampling plans that specify limits for numbers of micro-organisms (m and M) may be useful, in other situations variable sampling plans may be useful. Two class plans should be applied for pathogen criteria. Where requirements are set according to current industry performance, percentile values may be used e.g. 80th percentile for m and 98th percentile for M, a variety of statistical approaches can be used.

Effective systems should be in place for distribution and sharing of information from the establishment to all interested parties, as appropriate, so as to maintain and improve process control of meat.

The competent authority should regularly analyse results at both the establishment and national level, and provide appropriate feedback to establishments and other interested parties.

Additional to verification of process control, the results of microbiological testing may be used to establish on-farm controls e.g. intensive measures to reduce the prevalence of *Salmonella* spp. in fattening pigs.

In situations of non-compliance with microbiological requirements, actions should be specified. Regulatory and/or establishment responses should be proportional to test results as well as the public health impact of specific pathogens. Where detailed information on the status in relation to public health, of animals destined for slaughter, is available from primary production, e.g. in the case of *Salmonella* spp. in fattening pigs and broiler chickens in some intensive production systems, responses in relation to process control at the establishment level, may include consideration of pre-slaughter levels of hazards.

The competent authority should consider microbiological results in conjunction with public health and other relevant information when taking regulatory action. Regulatory intervention and/or sanctions may be necessary when validated controls are not being properly implemented.

In cases of repeated non-compliance, the competent authority in addition to other actions, should require the establishment operator to review and revise the HACCP plan and may specify an increased sampling frequency to verify that the required level of process control is restored.

CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS

CAC/RCP 57-2004

Adopted 2004. Amendments 2007, 2009.

CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS

CAC/RCP 57-2004

INTRODUCTION

Milk and milk products are a rich and convenient source of nutrients for people in many countries and international trade of milk-based commodities is significant. The purpose of this Code is to provide guidance to ensure the safety and suitability of milk and milk products to protect consumers' health and to facilitate trade. The Code satisfies the food hygiene provisions in the Codex Alimentarius *Procedural Manual* under "Relations Between Commodity Committees and General Committees" for use in the various dairy standards.

All foods have the potential to cause food borne illness, and milk and milk products are no exception. Dairy animals may carry human pathogens. Such pathogens present in milk may increase the risk of causing food borne illness. Moreover, the milking procedure, subsequent pooling and the storage of milk carry the risks of further contamination from man or the environment or growth of inherent pathogens. Further, the composition of many milk products makes them good media for the outgrowth of pathogenic micro-organisms. Potential also exists for the contamination of milk with residues of veterinary drugs, pesticides and other chemical contaminants. Therefore, implementing the proper hygienic control of milk and milk products throughout the food chain is essential to ensure the safety and suitability of these foods for their intended use. It is the purpose of this Code to provide guidance to countries so that their appropriate level of public health protection for milk and milk products may be achieved. It is also the purpose of this code to prevent unhygienic practices and conditions in the production, processing, and handling of milk and milk products, as in many countries milk and milk products form a large portion of the diet of consumers especially infants, children, and pregnant and lactating women. This document is formatted in accordance with the *Recommended International Code of Practice – General Principles of Food Hygiene*, CAC/RCP 1-1969. This Code presents principles for the hygienic production and manufacture of milk and milk products and guidance on their application. This Code takes into consideration, to the extent possible, the various production and processing procedures as well as the differing characteristics of milk from various milking animals used by member countries. It focuses on acceptable food safety outcomes achieved through the use of one or more validated food safety control measures, rather than mandating specific processes for individual products.

1. OBJECTIVES

The objective of this Code is to apply the recommendations of the *Recommended Code of Practice – General Principles of Food Hygiene* to the particular case of milk and milk products. It also provides guidance on how to achieve the general requirements contained in the hygiene sections of the Codex commodity standards for milk products.

2. SCOPE AND USE OF THE DOCUMENT

2.1 Scope

This Code applies to the production, processing and handling of milk and milk products as defined in the *General Standard for the Use of Dairy Terms*[1](CODEX STAN 206-1999). Where milk products are referred to in the code it is understood that this term also includes composite milk products. The scope of this Code does not extend to the production of raw drinking milk.

This Code applies to products in international trade. It may also serve as a basis for national legislation.

2.2 Use of the document

The provisions of this document are supplemental to and must be used in conjunction with, the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1-1969.

This document consists of a series of principles, explanatory narratives and guidelines. Over-arching principles that are applicable to all phases of production, processing and handling of milk and milk products are given in Section 2.3.

Specific principles and their associated explanatory narratives and guidelines are given in the appropriate section.

Principles, shown in **bold text**, are a statement of the goal or objective that is to be achieved. *Explanatory narratives*, shown in *italicized text,* serve to explain the purpose of the stated principle. Guidelines for the application of the stated principle are shown in normal text.

The annexes are an integral part of this Code. They provide guidelines for different approaches to the application of the principles. The purpose of the guidelines contained in the annexes is to explain and illustrate how principles in the main body of this code may be met in practice. Thus, the *Recommended International Code of Practice – General Principles of Food Hygiene*, the main body of this Code and its annexes must be used together to obtain complete guidance on the hygienic production of milk and milk products.

[1] This code applies to the milk and milk products obtained from all milking animals.

2.3 Overarching principles applying to the production, processing and handling of all milk and milk products

The following overarching principles apply to the production, processing and handling of all milk and milk products.

- **From raw material production to the point of consumption, dairy products produced under this Code should be subject to a combination of control measures, and these control measures should be shown to achieve the appropriate level of public health protection.**

- **Good hygienic practices should be applied throughout the food chain so that milk and milk products are safe and suitable for their intended use.**
  No part of this Code should be used without consideration of what takes place in the chain of events prior to the particular measure being applied or what will take place subsequent to a particular step. The Code should only be used within the context of an understanding that there is a continuum of controls that are applied from production to consumption.

- **Wherever appropriate, hygienic practices for milk and milk products should be implemented within the context of HACCP as described in the Annex to the *Recommended International Code of Practice – General Principles of Food Hygiene.***
  This principle is presented with the recognition that there are limitations to the full application of HACCP principles at the primary production level. In the case where HACCP cannot be implemented at the farm level, good hygienic practices, good agricultural practices and good veterinary practices should be followed.

- **Control measures should be validated as effective.** The overall effectiveness of the system of control measures should be subject to validation. Control measures or combinations thereof should be validated according to the prevalence of hazards in the milk used, taking into consideration the characteristics of the individual hazards(s) of concern and established Food Safety Objectives and/or related objectives and criteria. Guidance on validating control measures should be obtained from the Codex *Guidelines for the Validation of Food Hygiene Control Measures* (CAC/GL 69-2008).

2.4 Relative roles of milk producers, manufacturers, distributors, retailers, transporters, consumers, and competent authorities

Although the responsibility lies with the manufacturer for ensuring that the foods manufactured are safe and suitable, there is a continuum of effective effort or controls needed by other parties, including milk producers, to assure the safety and suitability of milk products. It is important to recognize that distributors, competent authorities and consumers also have a role in ensuring the safety and suitability of milk and milk products.

The interrelationship and impact of one segment of the food chain on another segment is important to ensure that potential gaps in the continuum are dealt with through communication and interaction between the milk producer, the manufacturer, the distributor and the retailer. While it is principally the responsibility of the manufacturer to conduct the hazard analysis within the context of developing a control system based on HACCP and thus to identify and control hazards associated with the incoming raw materials, the milk producer should also have an understanding of the hazards associated with milk, so as to assist in minimizing their presence in the raw material.

To achieve an effective continuum, the various parties should pay attention, in particular, to the following responsibilities.

- Producers should ensure that good agricultural, hygienic and animal husbandry practices are employed at the farm level. These practices should be adapted, as appropriate, to any specific safety-related needs specified and communicated by the manufacturer.
- Manufacturers should utilize good manufacturing and good hygienic practices, especially those presented in this Code. Any needs for additional measures with regard to controlling hazards during primary production should be effectively communicated to suppliers to enable the milk producer to adapt their operations to meet them. Likewise, the manufacturer may have to implement controls or adapt their manufacturing processes based on the ability of the milk producer to minimize or prevent hazards associated with the milk. Such additional needs should be supported by an adequate hazard analysis and should, where appropriate, take into consideration technological limitations during processing, and/or market demands.
- Distributors, transporters and retailers should assure that milk and milk products under their control are handled and stored properly and according to the manufacturer's instructions.
- Consumers should accept the responsibility of ensuring that milk and milk products in their possession are handled and stored properly and according to the manufacturer's instructions.
- In order to effectively implement this Code, competent authorities should have in place legislative framework (e.g., acts, regulations, guidelines and requirements), an adequate infrastructure and properly trained inspectors and personnel. For food import and export control systems, reference should be made to the *Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997). Control programmes should focus on auditing relevant documentation that shows that each participant along the chain has met their individual responsibilities to ensure that the end products meet established food safety objectives and/or related objectives and criteria.

It is important that clear communications and interactions exist between all parties to help assure good practices are employed, that problems are identified and resolved in an expeditious manner, and that the integrity of the entire food chain is maintained.

2.5 Definitions

Definitions contained in the *Codex General Standard for the Use of Dairy Terms* (CODEX STAN 206- 1999) are incorporated into this document by reference. Definitions relevant to a particular annex (e.g., heat treatment definitions) will be contained in the relevant annex.

Avoid – To keep away from, to the extent reasonably practicable. This term will be used when it is possible, in theory, to have no contamination or to constrain a particular practice.

Control measure – Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.[2]

Food safety objective[3]

Minimize – To reduce the likelihood of occurrence or the consequence of an unavoidable situation such as microbiological growth.

Process criteria[4] – The process control parameters (e.g. time, temperature) applied at a processing step.

Raw milk – Milk (as defined in *Codex General Standard for the Use of Dairy Terms*) which has not been heated beyond 40°C or undergone any treatment that has an equivalent effect.

Shelf life – The period during which the product maintains its microbiological safety and suitability at a specified storage temperature and, where appropriate, specified storage and handling conditions.

Validation[5]

2.6 Suitability

Food Suitability as defined in the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1-1969 is: "Assurance that food is acceptable for human consumption according to its intended use".

For the purposes of this Code, Suitability includes:

- The concept of wholesomeness and soundness.
- Only matters relating to hygiene. Matters relating to grade, commercial quality or compliance to standards of identity are not included.

Additionally:

- Suitability of milk and milk products may be achieved by observing good hygienic practice as outlined in the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1-1969 and specified in

[2] For purposes of this Code, a control measure encompasses any action or activity used to eliminate a hazard or reduce it to an acceptable level. In addition the term refers to any action or activity taken to reduce the likelihood of the occurrence of a hazard in milk or milk products. Thus, control measures include both process controls such as heating, cooling, acidification, etc., as well as other activities such as general hygiene and pest control programmes, etc.

[3] *Codex Procedural Manual*.

[4] This term is described in Annex 2 of the *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CAC/GL 63-2007).

[5] This term is defined in *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008).

detail in this Code. The use of a management system based on HACCP principles is an effective way of ensuring suitability and demonstrating that suitability is achieved.

- Milk and milk products may not be suitable if the milk or milk product, for example:
  - Is damaged, deteriorated or perished to an extent that makes the milk or milk product unfit for its reasonable intended use; or
  - Contains any damaged, deteriorated or spoiled substance that makes the milk or milk product unfit for its reasonable intended use; or
  - Contains a biological or chemical agent, or other matter or substance, that is foreign to the nature of the food and that makes the milk or milk product unfit for its reasonable intended use.
- The "intended use" is the purpose for which the product is specifically stated or could reasonably be presumed to be intended having regard to its nature, packaging, presentation and identification.

3. PRIMARY PRODUCTION

These principles and guidelines supplement those contained in Section 3 of the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1-1969 and the general principles presented in Section 2.3 above. Details on specific approaches to the production of milk are given in Annex I of this Code.

PRINCIPLES APPLYING TO THE PRIMARY PRODUCTION OF MILK

Milk should not contain any contaminant at a level that jeopardizes the appropriate level of public health protection, when presented to the consumer.

Because of the important influence of primary production activities on the safety of milk products, potential microbiological contamination from all sources should be minimized to the greatest extent practicable at this phase of production. It is recognized that microbiological hazards can be introduced both from the farm environment and from the milking animals themselves. Appropriate animal husbandry practices should be respected and care should be taken to assure that proper health of the milking animals is maintained. Further, lack of good agricultural, animal feeding and veterinary practices and inadequate general hygiene of milking personnel and equipment and inappropriate milking methods may lead to unacceptable levels of contamination with chemical residues and other contaminants during primary production.

Contamination of milk from animal and environmental sources during primary production should be minimized.

*Note: A contaminant is "any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability" (*Recommended International Code of Practice – General Principles of Food Hygiene*).*

The microbial load of milk should be as low as achievable, using good milk production practices, taking into account the technological requirements for subsequent processing.

Measures should be implemented at the primary production level to reduce the initial load of pathogenic micro-organisms and micro-organisms affecting safety and suitability to the extent possible to provide for a greater margin of safety and/or to prepare the milk in a way that permits the application of microbiological control measures of lesser stringency than might otherwise be needed to assure product safety and suitability.

USE OF THIS SECTION

Guidelines for applying the principles in this section are contained in Annex I. The guidelines are intended to result in raw material that is acceptable for further processing and that will ultimately result in the level of protection required for the particular finished milk product.

Annex I provides details of the general approach that should be used for the primary production of milk intended for further processing of an unspecified nature. Additional provisions to be used in the production of milk intended for the manufacture raw milk products are identified in relevant sections of the annex. Flexibility in the application of certain aspects of the primary production of milk for small holder dairy farms is also provided for. Milk produced according to the provisions of this section should be subjected to the application of control measures described in Annex II.

3.1 Environmental hygiene

Water and other environmental factors should be managed in a way that minimizes the potential for the transmission, directly or indirectly, of hazards into the milk.

Contaminated water, and for example pests (such as insects and rodents), chemicals and the internal and external environments where the animals are housed and milked, may contaminate feed, equipment or milking animals leading to the introduction of hazards into milk.

Water used in primary production operations should be suitable for its intended purpose and should not contribute to the introduction of hazards in milk.

3.2 Hygienic production of milk

3.2.1 Areas and premises for milk production

Areas including premises used for the production of milk should be designed, situated, maintained and, to the extent practicable, used in a manner that minimizes the introduction of hazards into milk.

Improperly protected and maintained premises for the holding and milking of dairy animals have been shown to contribute to the contamination of milk.

3.2.2 Animal health

The health status of milking animals and herds should be managed in a manner that addresses the hazards of concern for human health.

Milk should come from animals in good health so that, considering the end use, it does not adversely affect the safety and suitability of the end product.

It is important to prevent the spread of zoonotic diseases among animals and from animals (including milking animals) to milk. Milk and milk products produced from milk obtained from certain diseased animals has been known to be neither safe nor suitable for human consumption.

Maintenance of healthy milking animals has been shown to reduce the likelihood that human pathogens will be introduced into the milk via the mammary gland or from the faeces.

3.2.3 General hygienic practice

3.2.3.1 Feeding

With consideration given to the end use of the milk, forage and feed for lactating animals should not introduce, directly or indirectly, contaminants into milk in amounts that present an unacceptable health risk to the consumer or adversely affect the suitability of milk or milk products.

It has been shown that improper procurement, manufacturing and handling of animal feed can result in the introduction of pathogens and spoilage organisms to milking animals and the introduction of chemical hazards such as pesticide residues, mycotoxins and of other contaminants which can affect the safety and suitability of milk or milk products.

3.2.3.2 Pest control

Pests should be controlled, and in a way that does not result in unacceptable levels of residues, such as pesticides, in the milk.

Pests such as insects and rodents are known vectors for the introduction of human and animal diseases into the production environment. Improper application of pest control chemicals used to control these pests may introduce chemical hazards into the production environment.

3.2.3.3 Veterinary drugs

Animals should only be treated with veterinary drugs authorized by the competent authority for the specific use and in a manner that will not adversely impact on the safety and suitability of the milk, including adherence to the withdrawal period specified.

Milk from animals that have been treated with veterinary drugs that can be transferred to milk should be discarded appropriately until the withdrawal period specified for the particular veterinary drug has been achieved.

Residues of veterinary drugs in milk should not exceed levels that would present an unacceptable risk to the consumer.

The improper use of veterinary drugs has been shown to result in potentially harmful residues in milk and milk products, and may affect the suitability of milk intended for the manufacture of cultured products.

3.2.4 Hygienic milking

Milking should be carried out in such a manner that minimizes contamination of the milk being produced.

Effective hygienic practice during milking is an important element of the system of controls necessary to produce safe and suitable milk and milk products. Failure to maintain adequate sanitation and employee practices has been shown to contribute to the contamination of milk with undesirable or pathogenic micro-organisms or chemical or physical hazards.

3.3 Handling, storage and transport of milk

With consideration given to the end use of the milk, handling, storage and transport of milk should be conducted in a manner that will avoid contamination and minimize any increase in the microbiological load of milk.

Proper handling, storage and transport of milk are important elements of the system of controls necessary to produce safe and suitable milk and milk products. Contact with unsanitary equipment and foreign materials are known causes of milk contamination. Temperature abuse is known to increase the microbiological load of milk.

3.3.1 Milking equipment

Milking equipment should be designed, constructed, installed, maintained and used in a manner that will avoid the introduction of contaminants into milk.

Milking equipment is normally designed and constructed according to recognized standards that avoid the introduction of contaminants into milk. Equipment selected for installation on dairy farms should meet recognized design and construction standards. Recognized guidelines also exist for the proper use, cleaning and maintenance of milking equipment; such guidelines should be followed to avoid transfer of disease between animals through milking equipment and to help ensure obtaining milk that is safe and suitable.

Milking equipment should be operated in a manner that will avoid damage to udder and teats and that will avoid the transfer of disease between animals through the milking equipment.

It is important to prevent any damage to udder and teats by milking equipment since such damage can lead to infections and consequently adversely affect the safety and suitability of milk and milk products.

3.3.2 Storage equipment

Milk storage tanks and cans should be designed, constructed, maintained and used in a manner that will avoid the introduction of contaminants into milk and minimize the growth of micro-organisms in milk.

3.3.3 Premises for, and storage of, milk and milking-related equipment

Premises for the storage of milk and milking-related equipment should be situated, designed, constructed, maintained and used in a manner that avoids the introduction of contaminants into milk.

Whenever milk is stored, it should be stored in a manner that avoids the introduction of contaminants into milk and in a manner that minimizes the growth of micro-organisms.

3.3.4 Collection, transport and delivery procedures and equipment

This section also covers the activities of personnel involved in the transport of milk.

Milk should be collected, transported and delivered without undue delay, and in a manner that avoids the introduction of contaminants into milk and minimizes the growth of micro-organisms in the milk.
Note: See Section 10 for provisions on the training of personnel involved in the collection, transport and delivery of milk.

Milk transport tankers and cans should be designed, constructed, maintained and used in a manner that will avoid the introduction of contaminants into milk and minimize the growth of micro-organisms in milk.

3.4 Documentation and record keeping

Records should be kept, as necessary, to enhance the ability to verify the effectiveness of the control systems.

4. ESTABLISHMENT: DESIGN AND FACILITIES

These principles and guidelines are supplemental to those contained in Section 4 of the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1-1969, and to the general principles presented in Section 2.3 above.

4.1 Equipment

Equipment should be designed and installed such that as far as possible dead ends or dead spots in milk pipelines do not occur.
Where dead ends or dead spots occur, special procedures should ensure they are effectively cleaned or otherwise do not permit a safety hazard to occur.

5. CONTROL OF OPERATION

These principles and guidelines are supplemental to those contained in Section 5 of the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1-1969 (including the Annex on *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application)* and to the overarching principles presented in Section 2.3 above.

USE OF THIS SECTION

This section contains principles for the control of operation that are intended to be applied in such a manner as to result in meeting acceptable levels of relevant hazards specified as Food Safety Objectives and/or related objectives and criteria, or end product criteria that have been established to express the level of protection for the specific situation. Guidelines for applying the principles with respect to physical, chemical and microbiological hazards are provided in this section as well. Details given in Annex II provide guidance on the establishment and management of control measures used to achieve safety and suitability during and after processing.

For the effective implementation of the provisions in this Section, milk should be produced in accordance with Section 3 and Annex I of this Code.

5.1 Control of food hazards

The combination of control measures should effectively control the identified hazards in milk and milk products.

The combination of control measures should be designed in a systematic way, and the chosen combination should be adapted to the hygiene status of the milk and raw materials used with consideration given to the relevant microbiological, chemical and physical hazards of concern and to the establishment of Food Safety Objective(s) and/or related objectives and criteria.

Where appropriate control measures and/or control measure combinations are chosen to control hazards that are reasonably likely to occur, the procedures described in sections 5.1.1 to 5.1.3 and corresponding guidelines contained in Annex II should be implemented in order to minimize or prevent the likelihood of a health risk to the consumer.

The following procedures are intended to enhance and supplement those aspects of the HACCP Annex to the *International Recommended Code of Practice – General Principles of Food Hygiene,* which are critical to the successful design of a system of food safety controls.

5.1.1 Hazard identification and evaluation

All potential hazards should be identified.

This should be done before control measures are selected and is the first step in the hazard analysis.

The identification should be based on the initial descriptions developed during preliminary steps and on experience, external information, as well as epidemiological and other historical data that have been associated with the type of food under consideration, the type of raw materials and ingredients used, and that may be introduced during processing and distribution. To insure a comprehensive approach, the various step(s) in the manufacturing process, from material selection through processing and distribution, where a hazard may occur or be introduced should be identified.

Each potential hazard should be evaluated to determine the severity of its adverse health effects and reasonable likelihood of occurrence.
Potential hazards that are determined to have severe adverse health effects and/or are reasonably likely to occur should be subject to control by the system of control measures.

5.1.2 Control measure selection

Following hazard evaluation, control measures and control measure combinations should be selected that will prevent, eliminate, or reduce the hazards to acceptable levels.
The next step in the hazard analysis process is to select control measures that will be effective in controlling those hazards. A number of such control measures are further described in Annex II, Parts A and B.
Guidance on how to provide reference validations of individual control measures or control measure combinations against individual hazards in various media is given in *Guidelines for the Validation of Food Hygiene Control Measures* (CAC/GL 69-2008).

5.1.3 Establishment of process criteria

Process criteria for control measures should be established in order for the process to be applied in a manner that will meet the performance required, i.e., assure the adequate delivery of the control measure.
Process criteria should be established at such intensities that the control measures actually deliver the expected performance, taking into account normal process deviations.

5.2 Key aspects of hygiene control systems

5.2.1 Temperature and time controls

From milk production through to finished products, products should be stored at appropriate temperatures and for appropriate times such that the growth or development of a food safety hazard will be minimized and the product's suitability will not be adversely affected.
Because milk and many milk products have a sufficient moisture content to support the growth of pathogens, temperature and time controls represent key microbiological control measures to control growth throughout the manufacturing process, from the handling of milk to the distribution and storage of perishable milk products (e.g., pasteurized drinking milk, desserts, and soft cheeses, depending on shelf life). For instance, for liquid milk, increased storage temperature will decrease the shelf life.

5.2.1.1 Management of products within the plant

Incoming milk

When arriving at the dairy plant, and provided that further processing does not allow otherwise, the milk should be cooled and maintained at such temperatures as necessary to minimize any increase of the microbial load of the milk.

The principle of "first arrived, first processed" should apply.

Intermediate products

Intermediate products that are stored prior to further processing should, unless further processing does not allow it, be kept under such conditions that limit/prevent microbial growth or be further processed within a short time period.

The ultimate safety and suitability of milk and milk products, as well as the intensity of the control measures that need to be applied during processing, depends not only on the initial microbial load upon receipt at the dairy plant but also on preventing the growth of micro-organisms. Application of proper storage temperatures and management of raw materials is an essential factor in minimizing microbial growth. The ability of a product to meet intended Food Safety Objectives and/or related objectives and criteria is dependent upon the proper application of the control measures, including time and temperature controls.

There should be adequate stock rotation, based on the principle of "first in, first out".

5.2.1.2 Distribution of finished products

It is essential that milk and milk products be kept at an appropriate temperature in order to maintain their safety and suitability from the time it is packaged until it is consumed or prepared for consumption.

While the storage temperature should be sufficient to maintain the product's safety and suitability throughout the intended shelf life, the appropriate storage temperature will vary depending upon whether the product is perishable or non-perishable. For perishable products, the distribution system should be designed to maintain adequate low-temperature storage to ensure both safety and suitability. For non-perishable products designed to be shelf-stable at ambient temperature, extremes of temperature should be avoided, primarily to assure maintaining suitability. Reasonably anticipated temperature abuse should be taken into account in designing the normal patterns of distribution and handling.

5.2.1.3 Establishment of shelf life

It is the responsibility of the manufacturer to determine the shelf life of the product and the conditions for storage.

Limitation of shelf life is a control measure that, in many cases, is decisive for the safety and suitability of the product. The corresponding storage conditions are an integral aspect of product shelf life.

5.2.2 Specific process steps

Annex II, Appendices A and B contain examples of processes used during the manufacture of milk products that can control hazards that are reasonably likely to occur. These processes include both extrinsic and intrinsic factors that influence the growth of micro-organisms.

Extrinsic factors *refer to factors impacting the product from the environment in which the food is placed. Examples include temperature, time, and relative humidity of the air.*

Intrinsic factors *refer to internal factors in the product itself (food matrix), influenced by or as consequence of extrinsic factors, that have an impact on the growth and/or survival of micro-organisms. Examples include water activity, pH, nutrient availability, competition of micro-organisms, and bacteriocins or other growth inhibitors.*

5.2.3 Microbiological and other specifications

Where they are employed, microbiological criteria, including those used to verify the effective application of control measures within the framework of HACCP principles, should be developed in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods*, CAC/GL 21-1997, including the use of a risk assessment approach as specified in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment,* CAC/GL 30-1999.

5.2.3.1 Incoming milk

Manufacturers should establish incoming milk criteria that take into account the end use of the milk and the conditions under which the milk was produced.

Depending upon the end use of the milk, particularly for milk used in the production of raw milk products, certain specific microbiological criteria may be appropriate to verify the microbiological quality of the milk used as raw material.

Corrective action taken for non-compliance with incoming milk criteria should be commensurate with the potential risks presented by the non-compliance.

Incoming milk that is out of compliance with established criteria indicates that the control measure system is not working properly and corrective action should be taken to identify and resolve causative problems.

5.2.3.2 Microbiological criteria

Microbiological criteria may be necessary to be established at different points in the process for carrying out the design of control measure combinations and for the verification that the control system has been implemented correctly.

In some cases, for example where more comprehensive control measures are put into place to ensure the safety and suitability of milk (such as may be the case for raw milk intended to be used in the production of raw milk products), it may be necessary to establish criteria for in-process product, intermediate product or finished product in order to verify that the more comprehensive set of control measures have been properly carried out.

5.2.4 Microbiological cross contamination

The flow of the product and of the ingredients within equipment and through the processing facility should maintain a forward progression from raw material receipt to finished product packaging so as to avoid cross contamination.

The flow of the water, air, effluents, and milk should be carefully evaluated to ensure that the potential for cross-contamination does not occur. Similarly, the flow of personnel should be evaluated to ensure that their actions couldn't contaminate milk.

There should be adequate separation of areas with different levels of contamination risk.
Milk products that have been returned from other locations should be identified, segregated and stored in a clearly designated area.

Where there is the potential for cross-contamination between end products and raw materials or intermediate products, and from contaminated areas such as construction and rebuilding areas, consideration should be given to a physical separation, such as by the application of barrier hygiene (the application of physical or mechanical barriers to prevent or minimize the transfer of contaminants or potential sources of contaminants) and wet/dry area segregation.

5.2.5 Physical and chemical contamination

Preventive measures should be implemented to minimize risks of contaminating milk and milk products with physical and chemical hazards and foreign substances.
Avoiding physical and chemical contamination of milk and milk products during processing requires the effective control of equipment maintenance, sanitation programmes, personnel, monitoring of ingredients and processing operations.
Preventive measures should include those that will minimize the potential for cross contamination of allergenic components and/or ingredients that may present in other products to a milk product in which these components and/or ingredients are not supposed to be present.

5.3 Incoming material (other than milk) requirements

Ingredients used for the processing of milk products should be purchased according to specifications, and their compliance with these specifications should be verified.
Contaminated ingredients have been known to lead to unsafe/unsuitable milk products, since these ingredients are often added during processing where no further control measures are applied.
Preferably, specifications for raw materials should be established such that their use will result in a safe and suitable product. No raw material should be accepted if it is known to contain chemical, physical or microbiological contaminants that would not be reduced to an acceptable level by normal sorting and/or processing. Raw materials should, where appropriate, be inspected and sorted before processing. Any claims that raw materials meet safety and suitability specifications should be verified periodically.

5.4 Water

Dairy processing establishments should have potable water available, which prior to its first use, should meet the criteria specified by the competent authorities having jurisdiction and should be regularly monitored.

Water recirculated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use.
Proper maintenance of water conditioning systems is critical to avoid the systems becoming sources of contamination. For example, filter systems can become sources of

bacteria and their metabolites if bacteria are allowed to grow on the organic materials that have accumulated on the filter.

Appropriate safety and suitability criteria that meet the intended outcomes should be established for any water used in dairy processing.
These criteria depend upon the origin and the intended use of the water. For example, reuse water intended for incorporation into a food product should at least meet the microbiological specifications for potable water.

Reconditioning of water for reuse and use of reclaimed, recirculated and recycled water should be managed in accordance with HACCP principles.
Any reuse of water should be subject to a hazard analysis including assessment of whether it is appropriate for reconditioning. Critical control point(s) should be identified, as appropriate, and critical limit(s) established and monitored to verify compliance.

6. ESTABLISHMENT: MAINTENANCE AND SANITATION

These principles and guidelines are supplemental to those contained in Section 6 of the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1-1969.

6.1 Maintenance and cleaning

Processing areas should be kept as dry as possible.
Use of dry cleaning methods, and limiting the use of water in processing areas, helps to avoid the spread of contamination by water. Wet cleaning (other than Cleaning-in-Place) has been known to lead to milk product contamination due to the production of aerosols.

All food product contact surfaces in piping and equipment, including areas that are difficult to clean such as by-pass valves, sampling valves, and overflow siphons in fillers should be adequately cleaned.

6.2 Cleaning programmes

A routine programme to verify the adequacy of cleaning should be in place.
All equipment and utensils used in processing should, as necessary, be cleaned and disinfected, rinsed with water which is safe and suitable for its intended purpose (unless the manufacturer's instructions indicate rinsing is not necessary), then drained and air dried where appropriate.

7. ESTABLISHMENT: PERSONAL HYGIENE

No specific requirements beyond those contained in the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1-1969 are needed.

8. TRANSPORTATION

These principles and guidelines are supplemental to those set forth in Section 8 of the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1-1969 and, as appropriate, those set forth in *Code of Hygienic Practice for the Transport of Foodstuffs in Bulk and Semi-Packed Foodstuffs*. (CAC/RCP 47-2001).

8.1 Requirements

Products covered under this Code should be transported at time/temperature combinations that will not adversely affect the safety and suitability of the product.

8.2 Use and maintenance

In the case of refrigerated products, the vehicle product compartment should be cooled prior to loading and the product compartment should be kept at an appropriate temperature at all times, including during unloading.

9. PRODUCT INFORMATION AND CONSUMER AWARENESS

These principles and guidelines are supplemental to those contained in Section 9 of the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1-1969.

9.1 Labelling

Milk products should be labelled in accordance with the Codex *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985), the Codex *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999) and the relevant labelling section of Codex commodity standards for individual milk products.

Unless the product is shelf stable at ambient temperatures, a statement regarding the need for refrigeration or freezing should be included on the label of the product.

Additional provision for raw milk products

Raw milk products should be labelled to indicate they are made from raw milk according to national requirements in the country of retail sale.

10. TRAINING

These principles and guidelines are supplemental to those contained in Section 10 of the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1-1969.

10.1 Training programmes

Milk producers and personnel involved in the collection and transport and retail of milk should be trained as necessary and have appropriate skills in the areas listed below:

- health of animals and use of veterinary drugs;
- manufacturing and use of feeds (more specifically fermented feeds);
- herd management;
- hygienic milking;
- storage, handling, collection and transport of milk (cleaning of storage tanks, temperature requirements, sampling procedures, etc.);
- microbiological, chemical and physical hazards and their control measures.

ANNEX I

GUIDELINES FOR THE PRIMARY PRODUCTION OF MILK

INTRODUCTION AND OBJECTIVES

The detailed information contained in this annex should be implemented in order to reduce the likelihood of milk contamination through inadequate primary production practices. This information will enable the implementation of the principles laid down in Section 3 of the main body of the Code by providing guidelines for their application.

These measures, in combination with microbiological control measures found in Annex II, should be used to effectively control the microbiological hazards in milk products. There is a close relationship between the hygienic conditions found in primary production and the safety and suitability of processed milk products based on the control measures presented in Annex II.

SCOPE

This Annex provides details of the approaches that should be used for the primary production of milk intended for further processing of an unspecified nature. The milk should be subjected to the application of microbiological control measures described in Annex II.

The degree to which on-farm practices control the likelihood of occurrence of food safety hazard in milk will have an impact on the nature of controls needed during the subsequent processing of the milk. Under normal circumstances, milk will be subjected to control measures sufficient to address any hazards that may be present. Where the subsequent processing of milk does not involve the application of control measures necessary to address any hazards that may be present, the focus then becomes preventative in nature in order to reduce the likelihood that such hazards will occur during the primary production phase of the continuum. Likewise, in certain primary production situations, the occurrence of food safety hazards may be less avoidable, which will mandate the application of more stringent control measures during subsequent processing in order to insure the safety and suitability of the finished product.

USE OF ANNEX I

The information in Annex I is organized to correspond with the relevant sections in the main part of the Code and the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1-1969. Where a particular principle has been identified in the main body of the Code, guidelines for the application of that principle will be located in the corresponding section of this Annex.

Additional provisions for the production of milk used for raw milk products

When milk is intended to be used for the manufacture of raw milk products, the hygienic conditions used at the primary production are one of the most important public health control measures, as a high level of hygiene of the milk is essential in order to obtain milk with a sufficiently low initial microbial load in order to enable the manufacturing of raw milk products that are safe and suitable for human consumption. In such situations, additional control measures may be necessary. Where applicable, these additional measures are provided at the end of each sub-section.

Compliance with these additional hygienic provisions is important, and is considered mandatory in certain circumstances (where the nature of the finished product or national legislation requires), throughout the milk production process, up to the manufacture of the particular raw milk product. In addition, increased emphasis in certain aspects of the production of milk for raw milk products (animal health, animal feeding, milk hygiene monitoring) are specified and are critical to the production of milk that is safe and suitable for the intended purpose. To reflect the greater emphasis on the compliance needed on certain provisions, the word "should" has been substituted with the word "shall" where applicable.

As is the case with the rest of this code, this section also does not mandate or specify the use of any one set of controls to be used, but leaves it up to those responsible for assuring the safety of the finished product to choose the most appropriate set of control measures for the particular situation.

There are a wide variety of raw milk products, most of which are cultured products such as cheeses. The range of moisture content, pH and salt content (among other parameters) in these products will have varying degrees of impact on any potential microbiological hazards that may be present in the milk used for their manufacture. The degree to which the inherent characteristics of the product (or process used to manufacture the product) will control the hazard should guide the extent to which these potential hazards need to be prevented or controlled during primary production.

A wide range of food safety approaches exist for the production of raw milk products. As is the case with the rest of this code, the approach taken in this section is intended to be flexible enough to take into account the different approaches used in different countries regarding the manufacture and marketing of raw milk products.

Special provisions for the production of milk on small holder dairy farms

In the context of this Code, the expression "Small Holder Dairy Farm" refers to farms where the number of animals per farmer or per herd usually does not exceed 10, milking machines are not generally used, milk is not chilled at the producer's level and/or the milk is transported in cans.

Flexibility in the application of certain requirements of the primary production of milk in small holder dairy farms can be exercised, where necessary, provided that the milk is received by dairy plants and will be subjected to a combination of microbiological

control measures sufficient to obtain a safe and suitable milk product. Such flexibility is indicated throughout this annex by the use of a parenthetical statement "if used" or "if applicable" placed next to the particular provision where the flexibility is needed.

Flexibility as above may also apply to farms with larger number of animals but having similar economic constraints or limited water and/or power supplies, preventing investment in technological facilities and infrastructure.

3. PRIMARY PRODUCTION

3.1 Environmental hygiene

When water is used for the cleaning of the udder and for cleaning equipment used for the milking and storage of milk it should be of such quality that it does not adversely affect the safety and suitability of the milk.

Precautions should be adopted to ensure that milking animals do not consume or have access to contaminated water or other environmental contaminants likely to cause diseases transmissible to humans or contaminate milk.

3.2 Hygienic production of milk

3.2.1 Areas and premises for milk production

3.2.1.1 Animal holding areas

- The design, layout and provision of holding areas should not adversely affect the health of animals. In particular, holding areas should be kept clean and maintained in a manner that minimizes the risk of animal infection or contamination of the milk.
- Access to the animal holding area, including the stable and attached premises, if used, should preclude the presence of other species that would adversely affect the safety of the milk.
- The holding area should, as far as practicable, be kept clean and free of accumulations of manure, mud or any other objectionable materials.
- If used, stable and stalls should be designed and constructed to keep them free of accumulations of manure, feed residues, etc.
- Animal holding areas should be designed such that animals with contagious diseases can be separated to prevent the transmission of disease to healthy animals.
- Animal holding areas should not adversely affect the health of animals. In particular, the litter and the stabling area should be maintained in a manner that minimizes the risk of teat injuries and udder diseases.

3.2.1.2 Milking areas and related facilities

- Premises where milking is performed should be situated, constructed (if applicable) and maintained in a manner that will minimize or prevent contamination of the milk.

- Milking areas should be kept free of undesirable animals such as pigs, poultry and other animals whose presence may result in the contamination of milk.
- Premises where milking is performed should be easy to clean, especially in areas subject to soiling or infection, e.g., they should have:
  - flooring constructed to facilitate draining of liquids and adequate means of disposing of waste;
  - adequate ventilation and lighting;
  - an appropriate and adequate supply of water of a suitable quality for use when milking and in cleaning the udder of the animals and equipment used for milking;
  - effective separation from all sources of contamination such as lavatories (if used) and manure heaps; and
  - effective protection against vermin.

Additional provisions for the production of milk used for raw milk products

Only potable water can be used in milking areas, product storage areas and other critical areas.

3.2.2 Animal health

Adequate management measures should be implemented to prevent animal diseases and to control drug treatment of diseased animals or herds in an appropriate way. In particular, preventive measures should be taken to prevent disease including:

- Eradication of animal diseases or control of risk of transmission of the diseases, according to the specific zoonosis;
- Management of other animals in the herd and other farmed animals present (including the segregation of diseased animals from healthy animals);
- Management of new animals in the herd.

The milk should originate from herds or animals that are officially free of brucellosis and tuberculosis, as defined by the *OIE International Animal Health Code*. If not officially free, then milk should originate from herds or animals that are under official control and eradication programmes for brucellosis and tuberculosis. If controls for brucellosis and tuberculosis were not sufficiently implemented, it would be necessary for the milk to be subjected to subsequent microbiological control measures (e.g., heat treatment) that will assure the safety and suitability of the finished product.

Milk should be drawn from animals that:

- are identifiable to facilitate effective herd management practices;
- do not show visible impairment of the general state of health; and
- do not show any evidence of infectious diseases transferable to humans through milk including but not limited to diseases governed by the *OIE International Animal Health Code*.

Adequate measures should be implemented in order to prevent udder infections, especially:

- the correct use of milking equipment (e.g. daily cleaning, disinfection and disassembling of equipment);
- the hygiene of milking (e.g. udder cleaning or disinfection procedures);
- the management of the animal holding areas (e.g. cleaning procedures, design and size of areas);
- the management of dry and lactation periods (e.g., treatment for the drying off).

Additional provisions for the production of milk used for raw milk products

The milk cannot carry unacceptable levels of zoonotic agents. Therefore, the milk shall originate from individual animals:

- that are identifiable such that the health status of each animal can be followed. To this effect:
  - the herd shall be declared to the competent authorities and registered;
  - each animal shall be identified with a steadfast device and registered by the competent authorities.
- that do not show visible impairment of the general state of health and which are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or recognizable inflammation of the udder;
- that do not show any evidence (signs or analytical results) of infectious diseases caused by human pathogens (e.g., Listeriosis) that are transferable to humans through milk including but not limited to such diseases governed by the OIE International Animal Health Code;
- that, in relation to brucellosis and tuberculosis, shall comply with the following criteria:
  - cows milk shall be obtained from animals belonging to herds that are officially free of tuberculosis and brucellosis in accordance with the relevant chapters of the OIE International Animal Health Code;
  - sheep or goat milk shall be obtained from animals belonging to sheep or goat herds that are officially free or free of brucellosis as per the OIE International Animal Health Code;
  - when a farm has a herd comprised of more than one species, each species shall comply with sanitary conditions that are mandatory for each particular species ;
  - if goats are in the same environment with cows, goats shall be monitored for tuberculosis.

In addition, it is necessary that the milk also be checked for other relevant aspects in accordance with point 5.2.3.1. (microbiological and other specifications) which can have an impact on the safety and suitability of raw milk products; these results may provide information regarding the health status of the animals.

In particular, preventive measures are needed to prevent disease including:

- animals of unknown health status shall be separated, before being introduced in the herd, until such time that their health status has been established. During that separation period, milk from those animals shall not be used for the production of milk for the manufacture of raw milk products;
- the owner shall keep a record of relevant information, e.g., results of tests carried out to establish the status of an animal just being introduced, and the identity for each animal either coming or leaving the herd.

3.2.3 General hygienic practice

3.2.3.1 Feeding

The relevant aspects of the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004) should be applied to minimize or prevent the introduction of contaminants through feed or feeding practices.

Additional provisions for the production of milk used for raw milk products

When using fermented feed, it is necessary that the feed be prepared, stored and used in a manner that will minimize microbial contamination. Particular attention shall be given to compliance with good practices concerning the following aspects:

- the design of silos;
- good production practices of silage;
- regular check of the quality of the fermented feed (organoleptic inspection or pH).

The owner shall keep a record of relevant information concerning feed.

3.2.3.2 Pest control

- Before pesticides or rodenticides are used, all efforts should be made to minimize the presence of insects, rats and mice. Although stables and milking parlours (if used) attract such pests, good preventive measures such as proper building construction and maintenance (if applicable), cleaning, and removal of faecal waste can minimize pests.
- Accumulations of manure should not be allowed to develop close to milking areas.
- Mice and rats are also attracted to animal feed stores. Hence, any such feed stores should be located at a suitable place and feed kept in containers that provide adequate protection against such pests.
- If it is necessary to resort to chemical pest control measures, such products should be approved officially for use in food premises and used in accordance with the manufacturer's instructions.
- Any pest control chemicals should be stored in a manner that will not contaminate the milking environment. Such chemicals should not be stored in wet areas or close to feed stores. It is preferable to use solid baits, wherever possible.
- No pesticides should be applied during milking.

3.2.3.3 Veterinary drugs[6]

- The relevant aspects of the *Guidelines on the Control of Veterinary Drug Residues in Milk and Milk Products* (under development) should be applied to minimize or prevent the introduction of drug residues in milk or milk products.
- Good husbandry procedures should be used to reduce the likelihood of animal disease and thus reduce the use of veterinary drugs.
- Only those medicinal products and medicinal premixes that have been authorized by competent authority for inclusion in animal feed should be used.
- Milk from animals that have been treated with veterinary drugs that can be transferred to milk should be discarded until the withdrawal period specified for the particular veterinary drug has been achieved. Established MRLs for residues of veterinary drugs in milk may serve as a reference for such verification.
- The veterinarian and/or the livestock owner or the collection centre should keep a record of the products used, including the quantity, the date of administration and the identity of animals. Appropriate sampling schemes and testing protocols should be used to verify the effectiveness of on-farm controls of veterinary drug use and in meeting established MRLs.

3.2.4 Hygienic milking

Minimizing contamination during milking requires that effective hygienic practices be applied in respect of the skin of the animal, the milking equipment (whenever used), the handler and the general environment e.g. faecal sources of contamination.

Milking should be carried out under hygienic conditions, including:

- good personal hygiene of the milking personnel;
- clean udders, teats, groins, flanks and abdomens of the animal;
- clean and disinfected milking vessels/equipment; and
- avoidance of any damage to the tissue of the teat/udder.

In particular, during any milking, consideration should be given to minimizing and/or preventing contamination from the milk production environment and maintaining personal hygiene.

Animals showing clinical symptoms of disease should be segregated and/or milked last, or milked by using separate milking equipment or by hand, and such milk should not be used for human consumption.

Operations such as feeding the animals or placement/removal of litter should be avoided prior to milking in order to reduce the likelihood of contamination of the milking equipment and the milking environment from manure or dust.

[6] Treatment with veterinary drugs should be consistent with the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005).

The milking animals should be maintained in an as clean state as possible. Prior to any milking, teats should be clean. The milker should monitor by appropriate means that the milk appears normal, for example by careful observation of the condition of milking animals, by checking the milk of each animal for organoleptic or physicochemical indicators, and by using records and identification of treated animals. If the milk does not appear normal, the milk should not be used for human consumption. The producer should take appropriate precautions to minimize the risk of infections to teats and udders, including the avoidance of damage to tissue. Foremilk (initially drawn small quantity of milk) from each teat should be discarded or collected separately and not used for human consumption unless it can be shown that it does not affect the safety and suitability of the milk.

3.2.4.1 Environmental contamination

Milking operations should minimize the introduction of food-borne pathogens and foreign matter from the skin and general milking environment as well as chemical residues from cleaning and disinfection routines.

3.2.4.2 Milking equipment design

- Milking equipment, utensils and storage tanks should be designed, constructed and maintained in such a way that they can be adequately cleaned and do not constitute a significant source of contamination of milk.
- Milking equipment should be designed such that it does not damage teats and udders during normal operation.

3.2.4.3 Milking equipment cleaning and disinfection

- Milking equipment and storage tanks (and other vessels) should be thoroughly cleaned and disinfected following each milking, and dried when appropriate.
- Rinsing of equipment and storage tanks following cleaning and disinfection should remove all detergents and disinfectants, except in those circumstances where the manufacturer instructions indicate that rinsing is not required.
- Water used for cleaning and rinsing should be appropriate for the purpose, such that it will not result in contamination of the milk.

Additional provisions for the production of milk used for raw milk products

- Only potable water can be used in contact with milking equipment and other milk contact surfaces.

3.2.4.4 Health and personal hygiene of milking personnel

- Milking personnel should be in good health. Individuals known, or suspected to be suffering from, or to be a carrier of, a disease likely to be transmitted to the milk, should not enter milk handling areas if there is a likelihood of their contaminating the milk. Medical examination of a milk handler should be carried out if clinically or epidemiologically indicated.
- Hands and forearms (up to elbow) should be washed frequently and always washed before initiating milking or handling of milk.

- Milking should not be performed by persons having exposed abrasions or cuts on their hands or forearms. Any injury on hands or forearms must be covered with a water-resistant bandage.
- Suitable clothing should be worn during milking and should be clean at the commencement of each milking period.

3.3 Handling, storage and transport of milk

Time and temperature control is important during storage and transport of milk and depends highly on the type and effectiveness of the control measures applied during and after processing. Therefore, the needs for time/temperature control at farm level should be clearly communicated by the manufacturer of the milk products.

3.3.1 Milking equipment

The design of milking equipment, where used, and cans, should ensure there are no crevices or recesses that can interfere with proper cleaning.

Milking equipment should be installed and tested (if applicable) in accordance with manufacturer's instructions and in accordance with any available technical standards that have been established by appropriate technical standards setting organizations for such equipment (e.g., IDF, ISO, 3A) in order to assist in assuring that the equipment is functioning properly.

Milking equipment and cans should be cleaned and disinfected regularly and with sufficient frequency to minimize or prevent contamination of milk.

There should be a periodic verification process to ensure that milking equipment is in good working condition.

Milking equipment and utensils which are intended to come into contact with milk (e.g., containers, tanks, etc.) should be easy to clean and disinfect, corrosion resistant and not capable of transferring substances to milk in such quantities as to present a health risk to the consumer.

Between inspections, milking equipment should be maintained in proper working condition.

3.3.2 Milk storage equipment

Milk storage tanks and cans should be so designed to ensure complete drainage and constructed to avoid contamination of the milk when it is stored.

Milk storage equipment should be properly installed, maintained and tested in accordance with manufacturer's instructions and in accordance with any available technical standards that have been established by appropriate technical standards setting organizations for such equipment (e.g., IDF, ISO, 3A) in order to assist in assuring that the equipment is functioning properly.

Surfaces of milk storage tanks, cans and associated equipment intended to come into contact with milk should be easy to clean and disinfect, corrosion resistant and not capable of transferring substances to milk in quantities that will present a health risk to the consumer.

Milk tanks and cans should not be used to store any harmful substance that may subsequently contaminate milk. If milk storage tanks and cans are used to store foods other than milk, precautions should be taken to prevent any subsequent milk contamination.

Storage tanks and cans should be cleaned and disinfected regularly and with sufficient frequency to minimize or prevent contamination of milk.

Storage tanks or portions of storage tanks that are outdoors should be adequately protected or designed such that they prevent access of insects, rodents and dust in order to prevent contamination of milk.

There should be a periodic verification process to ensure that milk storage equipment is properly maintained and in good working condition.

Additional provisions for the production of milk used for raw milk products

Milk tanks and cans can be used only to store milk and milk products.

It is necessary to verify, at least once a year, that milk storage equipment is maintained and in good working order.

3.3.3 Premises for, and storage of, milk and milking-related equipment

Premises for the storage of milk should be situated and constructed to avoid risk of contamination of milk or equipment.

Premises for the storage of milk should have:

- suitable milk refrigeration equipment, when appropriate;
- a sufficient supply of water of a suitable quality of for use in milking and in cleaning of equipment and instruments;
- protection against vermin;
- easily cleanable floors, if applicable; and
- adequate separation between milking areas and any premises where animals are housed in order to prevent contamination of milk by animals. Where separation is not possible, adequate measures should be taken to ensure that the milk is not contaminated.

Immediately after milking, the milk should be stored in properly designed and maintained tanks or cans in a clean place.

Storage temperatures and times should be such that minimizes any detrimental effect on the safety and suitability of milk. The time and temperature conditions for milk storage at the farm should be established taking into account the effectiveness of the control system in place during and after processing, the hygienic condition of the milk and the intended duration of storage. In situations where the milk cannot be chilled on the farm, collection and delivery of this milk to a collection centre or processing facility within certain time limits may be required. These conditions may be specified in legislation, in Codes of Practice, or by the manufacturer receiving the milk in collaboration with the milk producer and the competent authority.

Additional provisions for the production of milk used for raw milk products

When milk for further processing is not collected or used within 2 hours after milking, it shall be cooled:

- to a temperature equal to or below 6°C when collected on a daily basis; or
- to a temperature equal to or below 4°C when not collected every day.

Deviations from those temperatures may be acceptable if those deviations will not result in an increased risk of microbiological hazards, have been approved by the manufacturer receiving the milk, have been approved by the competent authority, and the end product will still meet the microbiological criteria established in accordance with 5.2.3.2.

3.3.4 Collection, transport and delivery procedures and equipment

3.3.4.1 Collection, transport and delivery procedures

- Personnel and vehicular access to the place of collection should be adequate for the suitable hygienic handling of milk. In particular, access to the place of collection should be clear of manure, silage, etc.
- Prior to collection, the milk hauler or collection/chilling centre operator should check the individual producer's milk to ensure that the milk does not present obvious indications of spoilage and deterioration. If the milk shows indications of spoilage and deterioration, it should not be collected.
- Collection and chilling centres, if employed, should be designed and operated in such a manner that minimizes or prevents the contamination of milk.
- Milk should be collected under hygienic conditions to avoid contamination of milk. In particular, the milk hauler or collection centre operator should, where appropriate, take samples in such a way to avoid contamination of the milk and should ensure that the milk has the adequate storage/in-take temperature prior to collection.
- The milk hauler should receive adequate training in the hygienic handling of raw milk.
- Milk haulers should wear clean clothing.
- Milk hauling operations should not be performed by persons at risk of transferring pathogens to milk. Appropriate medical follow-up should be done in the case of an infected worker.

- Milk haulers should perform their duties in a hygienic manner so that their activities will not result in contamination of milk.
- The driver should not enter the stables or other places where animals are kept, or places where there is manure.
- Should driver clothing and footwear be contaminated with manure, the soiled clothes and footwear should be changed or cleaned before work is continued.
- The tanker driver should not enter the processing areas of the dairy plant. Conditions should be arranged to allow necessary communication with the staff of the dairy, delivery of milk samples, dressing, rest breaks, etc. without direct contact taking place with the dairy processing areas or with staff members involved with processing milk and milk products.

Additional provisions for the production of milk used for raw milk products

- Milk to be used for the manufacture of raw milk products shall be collected separately. Mixing, or cross-contamination with milk which does not comply with the quality (including microbiological) expected for the processing of raw milk products shall not be allowed.
  For example:
  - organize collection pick-ups in such a way that milk for the manufacture of raw milk products be collected separately; or
  - use milk transport tankers with compartments that will allow the separation of the milk for raw milk products from milk to be heat processed combined with the pick-up of milk for raw-milk products before milk for other products.

3.3.4.2 Collection, transport and delivery equipment

- Guidance on the bulk transport of foods is given in the *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (CAC/RCP 47-2001).
- Milk transport tankers and cans should be designed and constructed such that they can be effectively cleaned and disinfected.
- Milk transport tankers and cans should be designed and constructed to ensure complete drainage.
- Milk transport tankers and cans should not be used to transport any harmful substance. If milk transport tanks and cans are used to transport foods other than milk, precautions such as the implementation of adequate cleaning protocols should be taken to prevent any subsequent milk contamination.
- Surfaces of milk transport tankers, cans and associated equipment intended to come into contact with milk should be easy to clean and disinfect, corrosion resistant and not capable of transferring substances to the milk in such quantities as to present a health risk to the consumer.
- Milk cans and transport tankers (including the milk discharge area, valves, etc.) should be cleaned and disinfected with sufficient frequency in order to minimize or prevent contamination of milk.
- After disinfection, tankers and cans should be drained.
- Lorries, trucks or other vehicles which carry the tank or cans should be cleaned whenever necessary.

3.3.4.3 Transport time and temperature

- Transport temperature and time should be such that milk is transported to the dairy or to the collection/chilling centre in a manner that minimizes any detrimental effect on the safety and suitability of milk.
- The time and temperature conditions for the collection and transport of milk from the farm should be established taking into account the effectiveness of the control system in place during and after processing, the hygienic condition of the milk and the intended duration of storage. In situations where the milk cannot be chilled on the farm, collection and delivery of this milk to a collection centre or processing facility within certain time limits may be required. These conditions may be specified in legislation, in Codes of Practice, or by the manufacturer receiving the milk in collaboration with the milk producer, collector and transporter and the competent authority.

Additional provisions for the production of milk used for raw milk products

- The temperature of the milk to be used for the manufacture of raw-milk products shall not exceed 8°C, unless the milk has been collected within 2 hours after milking.
- Deviations from this temperature may be acceptable if these deviations will not result in an increased risk of microbiological hazards, have been approved by the manufacturer receiving the milk, have been approved by the competent authority and the end product will still meet the microbiological criteria established in accordance with 5.2.3.2.

3.4 Documentation and recordkeeping

With respect to food safety, records should be kept where necessary on:

- Prevention and control of animal diseases with an impact on public health;
- Identification and movement of animals;
- Regular control of udder health;
- Use of veterinary drugs and pest control chemicals;
- Nature and source of feed;
- Milk storage temperatures;
- Use of agricultural chemicals;
- Equipment cleaning.

ANNEX II

GUIDELINES FOR THE MANAGEMENT OF CONTROL MEASURES DURING AND AFTER PROCESSING

INTRODUCTION AND OBJECTIVES

The detailed information contained in this annex should be implemented in order to prevent, eliminate or reduce hazards associated with incoming materials to acceptable levels and to reduce the likelihood of milk contamination resulting from inadequate control of manufacturing operations. This information will enable the implementation of the principles laid down in Section 5 of the main body of the Code by providing guidelines for their application.

These measures should be used in combination with guidelines on primary production found in Annex I in order to effectively control the microbiological hazards in milk products. There is a close relationship between the control of manufacturing operations and the safety and suitability of processed milk products based on the control measures presented in Annex II.

SCOPE

The provisions in this Annex reinforce and supplement the principles and guidelines specified in Section 5 of the Code (Control of Operation), in particular Section 5.1, and should apply to the manufacture of any milk product. The principles in Section 5, Control of Operation, as well as the hazard identification provisions of this annex apply not only to the control of microbial hazards but also to the control of chemical and physical hazards.

The most common microbiological control measures are addressed in further detail in Part A (microbiostatic control measures) and Part B (microbiocidal control measures), respectively. However, this does not preclude in any way the use of additional and/or alternative microbiological control measures, provided that the general guidance provided in this Annex is followed.

USE OF ANNEX II

The information in Annex II is organized to correspond with the relevant sections in the main part of the Code and the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1-1969. Where a particular principle has been identified in the main body of the Code, guidelines for the application of that principle will be located in the corresponding section of this part of the Annex.

These guidelines are supplemental to those contained in Section 5 of the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1-1969

(including the Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application Annex) and to the overarching principles presented in Section 2.3 of the base document.

The guidelines presented in this annex are intended to enhance and supplement those aspects of the *Recommended International Code of Practice – General Principles of Food Hygiene* HACCP Annex which are critical to the successful design of a system of food safety controls. The users of this document are encouraged to implement the guidelines contained in the HACCP Annex when designing a HACCP system and to refer to those Annex II guidelines for further details on the hazard analysis, control measure selection and critical limit determination.

DEFINITIONS

The definitions below apply for the purpose of this Annex, and in addition to those definitions contained in Section 2.5 of the main body of this Code.

Microbiocidal treatments are control measures that substantially reduce or practically eliminate the number of micro-organism present in a food.

Microbiostatic treatments are control measures that minimize or prevent the growth of micro-organisms present in a food.

Pasteurization is a microbiocidal heat treatment aimed at reducing the number of any pathogenic micro-organisms in milk and liquid milk products, if present, to a level at which they do not constitute a significant health hazard. Pasteurization conditions are designed to effectively destroy the organisms *Mycobacterium tuberculosis* and *Coxiella burnettii*.

UHT (ultra-high temperature) ***treatment*** of milk and liquid milk products is the application of heat to a continuously flowing product using such high temperatures for such time that renders the product commercially sterile at the time of processing. When the UHT treatment is combined with aseptic packaging, it results in a commercially sterile product.[7]

5. CONTROL OF OPERATIONS

5.1 Control of food hazards

It is important that control measures are applied during both primary production and processing to minimize or prevent the microbiological, chemical or physical contamination of milk. In addition, special attention should be given during the processing of different milk products so that inadvertent cross-contamination does not occur, including with respect to ingredients that may contain allergenic substances. *Note: A distinction can be drawn between the types of control measures used for microbiological hazards and those used for chemical and physical hazards. The control*

[7] The concepts of aseptic packaging and commercially sterile can be found in the Codex documents on Low Acid and Acidified Canned Foods (CAC/RCP 23-1979) and Aseptic Processing (CAC/RCP 40-1993).

measures used for chemical and physical hazards in food are generally preventive in nature, i.e., they focus on avoiding the contamination of food with chemical or physical hazards in the first place rather than on reducing or eliminating such hazards once they have been introduced into the product. It should be noted however that there are some exceptions to this type of distinction, e.g., the use of filters, screens and metal detectors to remove certain physical hazards.

Microbiological food hazards are controlled by appropriate selection of control measures applied during primary production in combination with control measures applied during and after processing. The result of applying any microbiocidal control measure depends significantly on the microbial load (including the concentration of microbiological hazards) in the material subjected to it. It is therefore important that preventive measures are applied in primary production to reduce the initial load of pathogenic micro-organisms as well as during processing to avoid contamination within the processing environment. The initial microbial load significantly impacts the performance needed for the microbiological control measures applied during and after processing as well as the performance required for suitability. The safety and suitability of the end product depends not only on the initial microbiological load and the efficiency of the process, but also on any post-process growth of surviving organisms and post-process contamination.

Individual control measures should be selected and applied in such combination as to achieve a sufficient performance as to result in end products with acceptable levels of hazards.

Acceptable levels of contaminants in the end product should be identified and be based upon:

- Food safety objectives, end product criteria and similar regulatory requirements, as applicable;
- Acceptable levels derived from the purchaser constituting the subsequent link of the food chain; and/or
- The maximum levels found acceptable by the manufacturer, taking into account acceptable levels agreed with the customer and/or regulatory measures established by public health authorities.

The guidelines contained in sections 5.1.1 to 5.1.3 are intended to be supplemental to the *Recommended International Code of Practice – General Principles of Food Hygiene* HACCP Annex.

5.1.1 Hazard identification and evaluation

Hazard identification can be separated into two distinctly different parts, the identification of all potential hazards and the evaluation of the identified potential hazards to determine which are considered to have severe adverse health effects and/or are reasonably likely to occur and therefore need to be controlled through the implementation of effective control measures.

The hazard identification should be based on the initial descriptions developed during preliminary steps contained in the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1-1969, HACCP Annex and on experience, external information, as well as epidemiological and other historical data that have been associated with the type of food under consideration, the type of raw materials and ingredients used, and that may be introduced during the processing distribution. To insure a comprehensive approach, the various step(s) in the manufacturing process, from material selection through processing and distribution, where a hazard may occur or be introduced should be identified.

The potential hazards for such consideration should be listed in relation to the identified acceptable levels, including established FSO(s), where available.

For microbiological hazards, the likelihood of occurrence will depend on the actual prevalence in the milk and raw materials used. Factors influencing the prevalence are climatic conditions, animal species, prevalence of animal disease (sub-clinically or clinically) caused by the organism, prevalence of mastitis including the relative distribution of causing organisms, the adequacy of primary production practices including the potential of environmental contamination (feeding practices, water quality, milking hygiene level), and the potential for human contamination. Consultation of the competent authorities having jurisdiction in relation to the herds is appropriate.

When evaluating potential microbiological hazards, consideration should be given to which of the organisms are likely to be present in the milk. For instance, microbiological hazards that are not relevant in the geographical area of concern (e.g. because the prevalence is insignificant or zero) can be ruled out at an early stage. Also, where it can be verified that specific sanitary measures are successfully applied during primary production to prevent or significantly reduce introduction of a pathogen into the herd, including efficient eradication programmes, the pathogen in question may be ruled out. The manufacturer or other appropriate party is responsible for documenting the conditions that support such a determination. This can be accomplished by documenting the OIE status (e.g. disease-free area), the effectiveness of national programmes, the effectiveness of individual producer screening programmes, on the basis of documented historical evidence, and through the development of epidemiological evidence.

Regular analysis of the milk (including but not restricted to microbiological analyses) received at the manufacturing establishment producing milk products can be used to verify the implementation of control measures affecting the likelihood of occurrence of a hazard, depending upon the technology used and the kind of milk product being made.

Hazard identification should take into consideration the allergenic nature of some foods. Milk products may contain ingredients such as nuts, eggs and cereal grains that are known to be allergens.

Further, any additional hazards that can be introduced into the milk product during and after processing (e.g. environmental contamination, human contamination) should also be considered. During such considerations, the effectiveness of preventive measures taking place in the manufacturing environment (e.g., environmental and equipment sanitation programmes, employee practices, pest control programmes, etc.) should be evaluated to determine the likelihood of occurrence of potential hazards.

5.1.2 Control measure selection

Note: While the following guidelines are focused on the control of microbiological hazards, the concepts presented herein can be applied as well to the control of chemical and physical hazards.

The next step in the hazard analysis process is to select control measures that will be effective in controlling those hazards. A number of such control measures are further described in Appendices A and B of Annex II.

Selection of individual control measures

Individual microbiological control measures can be grouped according to primary function as follows:

- *Microbiocidal control measures* that reduce the microbial load, for instance by killing, inactivation or removal. These may be applied during processing as processing steps (e.g. microfiltration, thermization, pasteurization) or after the processing as intrinsic factors (e.g. ageing).
- *Microbiostatic control measures* that prevent, limit or retard the growth of micro-organisms by chemical or physical means. These are used to stabilize the product against activity of pathogens and spoilage organisms and may apply after milk production, during processing (e.g. in between processing steps) and after processing. Microbiostatic control measures still imply some probability of growth. Microbiostatic control measures that are efficient after processing may be applied towards the product (e.g. temperature/time control) as extrinsic factors or be built into the product as intrinsic factors (e.g. preservatives, pH).
- *Microbiostatic control measures that prevent direct contamination* of product, for instance by closed circuits or by appropriate packaging to protect the product. These are used to physically prevent contamination, in particular, during packaging and/or after processing.

The use of a single processing step may have subsequent microbiological effects (e.g. reduction of pH, water content), while other microbiological control measures only reduce the number of micro-organisms at the point in the manufacturing process, where it is applied.

Combination of microbiological control measures

More than one microbiological control measure is usually needed to control microbial content, to retard or prevent spoilage and to help prevent food borne diseases. Suitable combinations can be devised in order that specific organisms of concern can

be reduced in number and/or no longer grow/survive in the product. Such suitable combinations are sometimes referred to by the dairy industry as "hurdle technology". The combination of control measures has two main objectives:

- During processing: Providing assurance that the levels of the pathogens (and/or spoilage organisms) of concern, where present, are kept at or reduced to acceptable levels.
- After processing (packaging, distribution and storage): Providing assurance that the acceptable levels of the pathogens (and/or spoilage organisms) of concern that have been achieved during processing are kept under control throughout shelf life.

It may be necessary to ensure that growth of micro-organisms is kept to a minimum prior to processing, in between different processing steps, and after processing. The microbiostatic control measures used should be adapted to the need of the particular product in the particular situation. The resulting outcome in terms of the safety and suitability of the end product does not depend only on the initial microbial load and the effectiveness of the process, but also on any post-process growth of surviving organisms and post-process contamination. Therefore, all microbiological control measure combinations should be supported by appropriate preventive measures prior to and after the process, as deemed necessary.

Depending on the source and possible routes of contamination, the hazard(s) may be kept under control by preventive measures implemented at primary production level and/or in processing environments. When evaluating microbiological preventive measures, it is particularly important to know which of the hazards are affected by the preventive measure and to what extent the measure reduces the probability of the hazard contaminating the milk product during milking, processing and/or distribution. Those microbiological hazards that are not managed adequately by preventive and microbiostatic control measures need to be managed and controlled by adequate microbiocidal control measures with sufficient combined performance.

Microbiological control measures having effect only at the point of application must be applied in appropriate combinations with other microbiological control measures.

The combination of microbiological control measures is most efficient when it is *multi-targeted*, that is, when various individual measures are selected so that different factors effecting microbial survival are targeted, e.g., pH, A_w, availability of nutrients, etc. In many cases, a multi-targeted combination using microbiological control measures with low intensity may be more effective than one single measure with high intensity. The presence of a number of microbiological control measures inhibiting or reducing the number of micro-organisms may be *synergistic*, that is that interaction occurs between two or more measures so that their combined effect is greater than the sum of their individual effects. Therefore, the utilization of synergistic effects can allow for combining microbiological control measures of less intensity than would be otherwise expected from each measure individually.

Where flexibility from provisions in Annex I is granted for small holder dairy farms, particular attention should be paid to the nature of the granted deviations and their potential consequences in terms of hazard levels in the milk.

Attention should be paid to the application of microbiocidal control measures with such performance that they effectively eliminate any risks associated with the transfer of additional zoonotic hazards to the milk. Similarly, where certain animal diseases are present in herds producing the milk, particular attention should be drawn to the recommendations in the *OIE International Animal Health Code*, as specific microbiocidal control measures or performances thereof may be necessary to eliminate the animal health risks associated with these diseases.

5.1.3 Establishment of process criteria

From the performance required, the corresponding process criterion or criteria (as appropriate to the nature of the microbiological control measure) should be established. They are intended for the appropriate implementation (set-up) of a processing step and for application in practical process control (e.g. filter size, pH, concentration of preservative, time/temperature combinations). In the context of HACCP, process criteria may or may not constitute critical limits.

The performance of control measures and control measure combinations selected should be validated using procedures outlined in the *Guidelines for the Validation of Food Hygiene Control Measures* (CAC/GL 69-2008). The validation of control measures or control measure combinations is especially important when establishing the effectiveness of new or developing technologies. validation may not be necessary in situations where well established control measures or technologies are considered to be acceptable.

If the performance required cannot be achieved by the control measure(s) or if it is estimated and/or monitoring shows that the hazards are not under sufficient control by the selected combination of microbiological control measures, modification of the control system design is necessary.

Examples of some of the modifications that can be made until the hazard of concern is considered under control include:

- Increase of the intensities of the microbiological control measure(s) applied.
- Identification of additional microbiological control measure(s) that target the hazard of concern.
- Implementation of more stringent on-farm control measures.
- Introduction of specifically targeted measures at farm level that reduce the prevalence of the hazard of concern in the milk used.
- Reduction of the intended shelf life and/or amendments of the intended storage conditions.

Additional provisions for the manufacture of raw milk products

It is critical for a dairy farm, when producing milk intended for the manufacturing of raw milk product, to comply with the provisions (including the identified additional

provisions) detailed in Annex I and in section 5.2.3.1 of this Annex, and these activities should be frequently monitored and evaluated for their effective implementation. This evaluation may lead to the identification of needed improvements at the primary production level (practices, equipment, environment, etc.) or in the classification of dairy farms according to their ability to provide milk for the processing of raw milk products.

Any non-compliance detected either at the farm level or at the milk reception of a manufacturing plant should result in immediate action that may affect the farm, the manufacturing establishment or both. For this reason, there should be clear communication between the manufacturer and the farm and, if necessary, technical assistance should be provided to the primary producer by the manufacturer.

5.2 Key aspects of hygiene control systems

5.2.1 Time and temperature control

5.2.1.2 Distribution of finished products

Perishable products

- The storage temperature should be sufficient to maintain product safety and suitability throughout the intended shelf life. If the temperature of the product is the principal means of preservation, it is essential that the product be maintained at the appropriate temperature. Validation of the selected temperature should be carried out except in situations where well established storage temperatures are considered acceptable.
- Regular and effective monitoring of temperatures of storage areas, transport vehicles and store display cases should be carried out where:
  - the product is stored, and
  - the product is being transported, within the product load, which could be done by using temperature indicating and recording systems;
  - the product is being presented for retail sale.
- Particular attention should be paid throughout storage and distribution to:
  - periods of defrosting of refrigeration units;
  - temperature abuse; and
  - overloading the cold storage facility.

Products stable at ambient temperatures

Products that can be stored at ambient temperatures, should be protected against external agents and contamination, e.g., direct sun radiation, excessive heating, moisture, external contaminants, etc. from rapid temperature changes which could adversely affect the integrity of the product container or the safety and suitability of the product.

5.2.1.3 Establishment of shelf life

- Product shelf life is influenced by a number of factors, such as:
  - applied microbiological control measures, including storage temperatures;

- cooling methods applied to product;
- type of packaging (e.g., hermetically sealed or not, modified atmosphere packaging);
- likelihood of post-process contamination and type of potential contamination.

— The shelf life of milk products may be limited by microbial changes (e.g., deterioration and growth of pathogenic and spoilage micro-organisms to unacceptable levels).

— When establishing product shelf life, it is the responsibility of the manufacturer to assure and, as necessary, to demonstrate, that the safety and suitability of the milk product can be retained throughout the maximum period specified, taking into consideration the potential for reasonably anticipated temperature abuse during manufacture, storage, distribution, sale and handling by the consumer.

— These temperature abuses may allow the growth of pathogenic micro-organisms, if present, unless appropriate intrinsic factors are applied to prevent such growth.

Explanatory note: Reasonably anticipated temperature abuse takes into account the normal period of transporting of purchased products to appropriate consumer storage facilities and normal patterns of handling during consumption, for instance, the number and length of periods in which the product is removed from the refrigerator and subjected to ambient temperatures until the whole package has been consumed.

— The possible reactivation of pathogens with time should be taken into account when determining the shelf life.

— Shelf life determination can be carried out at the plant level by testing products subjected to the storage conditions specified or by predicting microbial growth in the product under the specified storage conditions. Reasonable anticipated temperature abuse can be integrated into the study or be taken into account by applying an appropriate safety factor (e.g., by shortening the maximum durability specified in the labelling or by requiring lower storage temperatures).

5.2.2 Microbiological and other specifications

5.2.2.1 Milk

— The milk used for the manufacture of products covered by this Code should be evaluated based on sampling of milk from individual farms or milk collection centres.

— Upon receiving, the milk should be subject to olfactory and visual inspection. Other criteria (e.g., temperature, titratable acidity, microbiological and chemical criteria) should be used to detect unacceptable conditions.

— Any-non-compliance with the above mentioned criteria, and in particular with regards to pathogens, should result in immediate corrective actions at the farm level and in the manufacturing establishment, for example: rejection of the milk for the processing of raw milk products; corrective actions on the milking procedure (cleaning and sanitation procedures of the milking equipment, cleaning or sanitation procedures of the udder, etc.,); quality of feed; the hygienic quality of the water supply; practices in animal holding areas; individual

check of animals to find the animal(s) that may be the carrier; isolation of that animal from the herd as necessary. Corrective actions should be identified and implemented, and specific assistance to the dairy farm may need to be provided.

- In some cases, where more comprehensive control measures are put into place to ensure the safety and suitability of milk, as may be the case for raw milk intended to be used in the production of raw milk products, it may be necessary to classify farms into two categories: those acceptable for use in raw milk products and those that are not.

Additional provisions for milk used in the manufacture of raw milk products

- Depending on the hazard analysis performed by the manufacturer and the combination of microbiological control measures applied during and after processing of milk products, specific microbiological criteria regarding pathogens (for example: *Salmonella* spp., *Listeria monocytogenes*) may need to be established.

APPENDIX A
MICROBIOSTATIC CONTROL MEASURES

Note: The control measures described in this appendix are presented as descriptive examples only and require validation prior to use with respect to their effectiveness and safe use.

Microbial growth is dependent upon many conditions in the organism's environment such as: ingredients, nutrients, water activity, pH, presence of preservatives, competitive micro-organisms, gas atmosphere, redox-potential, storage temperature and time. Control of these conditions can therefore be used to limit, retard, or prevent microbial growth.

Such microbiological control measures as well as microbiological control measures protecting the product against direct microbial contamination from the surroundings have microbiostatic functions.

Many microbiostatic control measures act by interfering with the homeostasis[8] mechanisms that micro-organisms have evolved in order to survive environmental stresses.

Maintaining a constant internal environment requires significant energy and material resources of the micro-organism, and when a microbiological control measure disturbs the homeostasis there will be less energy left for the micro-organism to multiply. Consequently, the organisms will remain in the lag phase and some may even die out before the homeostasis is re-established.

[8] Homeostasis is the constant tendency of micro-organisms to keep their internal environment stable and balanced. For instance, micro-organisms spend considerable efforts keeping their internal pH and osmotic pressure within narrow limits.

Examples of typical microbiostatic control measures include the following:

Carbon dioxide (CO_2):	The addition and/or formation of carbonic acid to obtain a multiple inhibitory effect, including the creation of anaerobic conditions by replacing oxygen, reducing pH, inhibiting certain intracellular enzymes (decarboxylation), and inhibiting the transport of water-soluble nutrients across the membrane (by dehydrating the cellular membrane). The efficiency depends mainly on the point of application. In ripened cheese, the emission of carbon dioxide from the cheese to the outside environment is often utilized to provide (almost) anaerobic conditions in the headspace of cheese packaging
Coatings:	The introduction of a physical barrier against contamination, with or without antimicrobial substances implemented into it (immobilized) to obtain a slow migration of these from the surface.
Freezing:	The lowering of temperature below the freezing point of the product combined with a reduction of the water activity. Freezing has microbiostatic as well as microbiocidal effects.
Lactoferrins:	Retardation through the utilization of naturally present glycoproteins (highest concentration in colostrum) to prolong the lag phases of bacteria for 12–14 hours, by binding iron in the presence of bicarbonates.
Lactoperoxidase system[9]:	The activation of the lactoperoxidase/thiocyanate/hydrogen peroxide system (indigenous system in milk) to inactivate several vital metabolic bacterial enzymes, consequently blocking their metabolism and ability to multiply. Guidance for application is provided in the *Codex Guidelines for Preservation of Raw Milk by the Use of the Lactoperoxidase System* (CAC/GL 13-1991).
Modified atmosphere:	The establishing of a gaseous environment (either low in oxygen and/or high in carbon dioxide or nitrogen) to limit growth of aerobic micro-organisms by impairing biochemical pathways. Modified atmosphere packaging (MAP) means that a modification of the gas atmosphere in the packaging is created. Establishing anaerobic environment to limit growth of aerobic micro-organisms may proliferate certain anaerobic pathogenic micro-organisms.

[9] These microbiostatic control measures should only be used as a last resort in countries where infrastructure does not permit cooling of milk at farm level or at collection centres. Whenever used, chemical methods should never replace nor delay implementing good hygienic practices in milk production. Any trade in milk treated by the lactoperoxidase system should only be on the basis of mutual agreement between countries concerned, and without prejudice to trade with other countries.

Packaging:	Packaging provides a physical barrier that protects against access of micro-organisms from the surroundings.
pH reduction:	The creation of extra-cellular acid conditions that enables hydrogen ions to be imported into the cytoplasma of micro-organisms, thus disturbing the homeostasis mechanism of the intracellular pH responsible for maintaining functionality of key cell components vital for continuing growth and viability. Low pH values are obtained by fermentation or addition of acids (inorganic or organic). The pH value for preventing growth depends on the pathogen, but lies typically between pH 4.0–5.0. Micro-organisms become more sensitive to other microbiological control measures at lower pH. Synergy occurs with salt, water activity, organic acids, the LP-system, and antimicrobial substances.
(Use of) preservatives:	The addition of certain additives to enhance keeping quality and stability through direct or indirect antimicrobial and/or fungicidal activity. Most preservatives are rather specific and have effect only on certain micro-organisms.
Redox potential control:	The redox potential (Eh) is a measure of the oxidizing or reducing potential of food systems that determines whether aerobic or anaerobic micro-organisms are able to grow. Eh is influenced by removal of oxygen and/or addition of reducing substances (e.g. ascorbic acid, sucrose, etc.).
Refrigeration:	The lowering of product temperature to limit microbial activity
Time:	The practice of applying very short collection/storage periods, limiting the shelf life of products, or immediate processing of raw milk to ensure that all micro-organisms present are in the lag phase, and therefore not active and more susceptible to other microbiological control measures.
Water activity control:	The control of the water activity (aw) in the product (the accessibility of water for micro-organisms, not the water content in the food), expressed as the ratio of water vapour pressure of the food to that of pure water. The aw value for preventing growth depends on the pathogen, but lies typically between 0.90 and 0.96. Water activity can be controlled by: • concentration, evaporation and drying, which also increase the buffering capacity of milk (synergy); • salting (addition of sodium chloride), which also reduces the cell resistance against carbon dioxide and in the solubility of oxygen (synergy); and • sweetening (addition of sugars), which at aw below 0.90–0.95 also results in an antimicrobial effect, depending on the type of sugar (synergy).

APPENDIX B
MICROBIOCIDAL CONTROL MEASURES

Note: the control measures described in this appendix are presented as descriptive examples only and require validation prior to use with respect to their effectiveness and safe use.

Microbiocidal or practical elimination control measures act by reducing the microbial load, for instance through killing, inactivation or removal.

Many microbiological control measures have multiple functions. Some microbiostatic control measures also have microbiocidal effects, the degree often depending upon the intensity at which they are applied (e.g. pH reduction, refrigeration, freezing, preservatives and indigenous antimicrobial systems).

Pasteurization and other heat treatments of milk that have at least an equivalent efficiency are applied at such intensities (sufficient time/temperature combinations) that they practically eliminate specific pathogens. They have therefore been traditionally used as key microbiocidal control measures in the manufacture of milk products. Non-thermal microbiocidal control measures with similar efficiencies are not yet applied at such intensities that will render the milk product safe at the point of application.

Examples of typical microbiocidal control measures include the following:

Centrifugation:	The removal of microbial cells of high density from milk using high centrifugal forces. Most efficient against microbial cells of high density, notably bacterial spores and somatic cells
Commercial sterilization:	The application of heat at high temperatures for a time sufficient to render milk or milk products commercially sterile, thus resulting in products that are safe and microbiological stable at room temperature.
Competitive microflora:	The reduction of the number of undesirable micro-organisms by lowering the pH, consumption of nutrients, and production of bacterial antimicrobial substances (such as nisin, other bacteriocins and hydrogen peroxide). Usually, this microbiological control measure is applied by choice of starter cultures. The efficiency is determined by many factors, including the speed and level of pH-reduction and variations in the pH level.
"Cooking" of cheese curd:	The application of heat to cheese curd, mainly for technical purposes. The heat treatment has a lower intensity than thermization but stresses micro-organisms to become more susceptible to other microbiological control measures.

Electromagnetic energy treatment:	Electromagnetic energy results from high voltage electrical fields, which alternate their frequency millions of times per second (< 10^8 MHz). Examples are microwave energy (thermal effect), radio-frequency energy (non-thermal effects) or high electric field pulses (10–50 kV/cm, non-thermal effects). The treatment destroys cells by establishing pores in the cell walls due to the build up of electrical charges at the cell membrane.
High-pressure treatment:	Application of high hydrostatic pressures to irreversibly damage the membranes of vegetative cells.
Microfiltration:	Removal of microbial cells, clumps and somatic cells by recirculation over a microfilter. Normally, a pore size of ~0.6–1.4 μm is sufficient to separate most bacteria. Synergy in combination with heat treatment.
Pasteurization:	The application of heat to milk and liquid milk products aimed at reducing the number of any pathogenic micro-organisms to a level at which they do not constitute a significant health hazard.
Pulsed high-intensity light:	The application of (on e.g. packaging material, equipment and water) high intensity broadband light pulses of wavelengths in the ultraviolet, visible and infrared spectrum (~20 000 times sunlight) to destroy micro-organisms. Due to the inability to penetrate in-transparent substances, the technology is only effective against surfaces, for instance, in the removal of biofilm and can therefore prevent cross contamination
Ripening (ageing):	The holding for such time, at such temperature, and under such conditions as will result in the necessary biochemical and physical changes characterizing the cheese in question. When applied as a microbiocidal control measure, the multifactoral, complex system developing in cheese (pH, antagonistic flora, decreased water activity, metabolism of bacteriocins and organic acids) is utilized to influence the microenvironment in and on the food and consequently the composition of the microflora present.
Thermization:	The application to milk of a heat treatment of a lower intensity than pasteurization that aims at reducing the number of micro-organisms. A general reduction of log 3–4 can be expected. Micro-organisms surviving will be heat-stressed and become more vulnerable to subsequent microbiological control measures.

Ultrasonication:	The application of high intensity ultrasound (18-500 MHz) that cause cycles of compression and expansion as well as cavitation in microbial cells. Implosion of microscopic bubbles generates spots with very high pressures and temperatures able to destroy cells. More effective when applied in combination with other microbiological control measures. When applied at higher temperatures, the treatment is often referred to as "thermosonication".
Warm sealed packaging:	The application of heat (80 to 95 °C) to a solid end product in connection with the packaging process, for instance to maintain the product at a viscosity suitable for packaging. Such process can be done in a continuous flow system or in batch processes. The product is sealed at the packaging temperature and chilled for storage/distribution purposes afterwards. When combined with low pH in the product, e.g. below 4.6, the warm sealed product may be commercially sterile as any surviving micro-organisms may not be able to grow. A supplementary microbiostatic control measures is to ensure adequate cooling rates of packaged products to minimize potential for *B. cereus* growth.

1. Pasteurization of milk and fluid milk products

1.1 Description of process

Pasteurization can either be carried out as a batch operation ("batch pasteurization" or "LTLT-pasteurization" (low temperature, long time)), with the product heated and held in an enclosed tank, or as a continuous operation ("HTST-pasteurization" (high temperature, short time)) with the product heated in a heat exchanger and then held in a holding tube for the required time.

Currently, the most common method of pasteurization is by means of heat exchangers designed for the HTST process (high temperature short time). This process involves heating of the milk to a certain temperature, holding at that temperature under continuous turbulent flow conditions for a sufficiently long time, to ensure the destruction and/or inhibition of any hazardous micro-organisms that may be present. An additional outcome is the delay of the onset of microbiological deterioration, extending the shelf life of milk.

To save energy, heat is regenerated, i.e. the chilled milk feeding the exchangers is heated by the pasteurized milk leaving the pasteurization unit. The effect of this pre-heating is cumulative, and should be taken into account when simulating pasteurization conditions at laboratory scale.

Pasteurization carried out in a batch-process involves the heating of milk placed in a container to a certain temperature for sufficiently long time to achieve equivalent

effects as in the case of the HTST process. The heat can be supplied externally or internally in heat exchangers or within a pasteurizer. Due to the non-continuous flow conditions, heating and cooling takes longer and will add to the effect (cumulative).

1.2 Process management

Performance criteria

As *C. burnettii* is the most heat-resistant non-sporulating pathogen likely to be present in milk, pasteurization is designed to achieve at least a 5 log reduction of C. *burnettii* in whole milk (4% milkfat).

Process criteria

According to validations carried out on whole milk, the minimum pasteurization conditions are those having bactericidal effects equivalent to heating every particle of the milk to 72 °C for 15 seconds (continuous flow pasteurization) or 63 °C for 30 minutes (batch pasteurization). Similar conditions can be obtained by joining the line connecting these points on a log time versus temperature graph.[10]

Processing times necessary rapidly decrease with minimal increase in temperature. Extrapolation to temperatures outside the range of 63 to 72 °C, in particular, processing at temperatures above 72°C must be treated with the utmost caution as the ability for them to be scientifically [validated] is beyond current experimental techniques.

For example, it would be extremely difficult if not impossible to determine pasteurization efficiency at 80°C given the extrapolated processing time would be around 0.22 seconds to achieve at least a 5 log reduction.

To ensure that each particle is sufficiently heated, the milk flow in heat exchangers should be turbulent, i.e. the Reynolds number should be sufficiently high.

When changes in the composition, processing and use of the product are proposed, the necessary changes to the scheduled heat treatment should be established and a qualified person should evaluate the efficiency of the heat treatment.

For instance, the fat content of cream makes it necessary to apply minimum conditions greater than for milk, minimum 75 °C for 15 seconds.

Formulated liquid milk products with high sugar content or high viscosity also require pasteurization conditions in excess of the minimum conditions defined for milk.

[10] Note**:** The time/temperature combinations for HTST pasteurization were established many years ago on the basis of the hygiene status at that time (quality of raw milk and of hygiene management levels). With time, the hygiene status has increased considerably. However, the tradition to specify the minimum time/temperature combinations in regulatory texts has not enabled the elevation of the hygiene status to be converted into the application of microbiocidal control measures of less intensity. Instead, it has been (and still is) converted into extension of the product shelf life.

Verification of process

The products subjected to pasteurization should show a negative alkaline phosphatase reaction immediately after the heat treatment as determined by an acceptable method. Other methods could also be used to demonstrate that the appropriate heat treatment has been applied.

Alkaline phosphatase[11] can be reactivated in many milk products (cream, cheese, etc.). Also, micro-organisms used in the manufacture may produce microbial phosphatase and other substances that may interfere with tests for residual phosphatase. Therefore, this particular verification method must be performed immediately after the heat treatment in order to produce valid results. *Note: Low residual alkaline phosphatase levels in heat-treated milk (below 10 μg p-nitro-phenol equivalent/ml) are taken as assurance that the milk has been correctly pasteurized and that it has not been contaminated by raw milk. However, although this measure is still considered as being the most appropriate method of verification, the factors listed below influence the residual levels and should be taken into account when interpreting the results:*

Initial concentration in milk: the "pool" of alkaline phosphatase present in milk varies widely between different species and within species. Typically, raw cow's milk shows an activity much higher than goats milk. As pasteurization results in a log reduction of the initial level, the post-pasteurization residual level will vary with the initial level in the raw milk. Consequently, different interpretation according to origin of the milk is necessary and in some cases, the use of alkaline phosphatase testing to verify pasteurization may not be appropriate.

Fat content of the milk: Phosphatase is readily absorbed on fat globules, thus the fat content in the product subjected to pasteurization influence the result (typical concentrations in cows milk: skim 400 μg/ml; whole 800 μg/ml, and 40% cream 3500 μg/ml).

Application of pre-heating: The level of alkaline phosphatase is decreased with heat, such as at temperatures typically applied in separation and in thermization.

1.3 Application of pasteurization

Numerous manuals recognized by competent authorities exist for the correct layout, designs and constructions of suitable pasteurizing equipment as well as for practical operation and monitoring. Such manuals should be available and consulted whenever necessary.

[11] Milk from different species of milking animals normally contains different levels of alkaline phosphatase. These differences should be taken into account when establishing criteria for phosphatase analysis and when establishing the effectiveness of alkaline phosphatase testing as a means to verify that pasteurization conditions have been properly applied.

2. Commercial sterilization of milk and milk products

Details on the establishment of thermal processes designed to render milk or milk products commercially sterile can be found in the Codex document on Low-Acid Canned Foods (CAC/RCP 23-1979) and the Codex document on Aseptic processing (CAC/RCP 40–1993).

2.1 Description of process

Commercial sterilization is a microbiocidal control measure that can be obtained by various heat treatments, the most common and [validated] methods being UHT (ultra high temperature) processing in combination with aseptic packaging or In-container Sterilization.

UHT treatment is a continuous operation that can either be carried out by direct mixing of steam with the product to be sterilized, or by indirect heating by means of a heat exchanging surface, followed by further aseptic processing (eventual) and aseptic packaging/filling. Thus the UHT plant are constituted by heating equipment in conjunction with appropriate packaging equipment and, eventually, additional treatment equipment (e.g. homogenization).

In-container sterilization may be a batch or continuous process.

2.2 Process management

Performance criteria

Thermal processes necessary to obtain commercially sterile products are designed to result in the absence of viable micro-organisms and their spores capable of growing in the treated product when kept in a closed container at normal non-refrigerated conditions at which the food is likely to be held during manufacture, distribution and storage.

Process criteria

For products at risk of contamination with *Clostridium botulinum* such as certain composite milk products (as identified as likely to occur by a hazard analysis), the minimum thermal process should be established in consultation with an official or officially recognized authority. Where the risk of contamination with *Clostridium botulinum* is lower, alternative thermal processes may be established by an official or officially recognized authority, provided that the end products are microbiologically shelf stable and verified.

The combined effects of two or more treatments may be considered additive provided they comprise a single continuous process.

UHT treatment

UHT treatment is normally in the range of 135 to 150 °C in combination with appropriate holding times necessary to achieve commercial sterility. Other equivalent conditions can be established through consultation with an official or officially recognized authority.

Validation of milk flow and holding time is critical prior to operation.

See CAC/RCP 40–1993 for aspects of aseptic processing and packaging not already covered by this code.

Verification of process

The products subjected to commercial sterilization must be microbiologically stable at room temperature, either measured after storage until end of shelf life or incubated at 55 °C for 7 days (or at 30 °C for 15 days) in accordance with appropriate standards. Other methods could also be used to demonstrate that the appropriate heat treatment has been applied.

2.3 Application of commercial sterilization

Numerous manuals exist for the establishment of thermal processes needed to achieve commercial sterility, for the proper layout, designs and constructions of suitable sterilization equipment and for practical operation and monitoring of thermal processing equipment. Such manuals should be available and consulted whenever necessary.

Also, see CAC/RCP 23-1979 for aspects of in-container sterilization not already covered by this code.

CODE OF HYGIENIC PRACTICE FOR EGGS AND EGG PRODUCTS

CAC/RCP 15-1976

Adopted in 1966. Amendments 1978, 1985. Revision 2007.

CODE OF HYGIENIC PRACTICE FOR EGGS AND EGG PRODUCTS

CAC/RCP 15-1976

INTRODUCTION

This *Code of Hygienic Practice for Eggs and Egg Products* is intended to provide guidance for the safe production of eggs and egg products. A hazard analysis approach was used in determining the controls presented in this Code. The FAO/WHO document below was used to provide a risk-based foundation for the revised Code.

- *Risk assessments of* Salmonella *in eggs and broiler chickens*. Microbiological Risk Assessment Series 1. FAO/WHO 2002 (ISBN 92-5-104873-8). http://www.fao.org/DOCREP/005/Y4393E/Y4393E00.HTM

This *Code of Hygienic Practice for Eggs and Egg Products* takes into consideration, to the extent possible, the differing egg and egg product production systems and processing procedures used by countries. This Code focuses primarily on eggs produced from domesticated chickens. The principles may also be applied to the hygienic practices for egg production from other domesticated egg producing bird species (e.g. duck, quail and goose). Therefore, the code is, of necessity, a flexible one to allow for different systems of control and prevention of contamination of eggs and egg products.

This Code addresses the two main sources of contamination of eggs:

1. internally during egg formation, and
2. externally, at any point at or after laying.

It takes into consideration the possibility of illness in the general population due to the consumption of eggs or egg products contaminated by *Salmonella* species, other enteric pathogens or other contaminants, as well as the susceptibility to illness of sectors of the population such as the elderly, children, and immunocompromised individuals. For microbiological contamination, this approach is consistent with the approach identified by the Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods (Rome, Italy, 30 April – 4 May 2001).

1. OBJECTIVES

The objective of this Code is to ensure the safety and suitability[1] of eggs and egg products by applying the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969) to the particular case of eggs and egg products. The

[1] Safety and suitability as defined in the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

document describes the specific considerations for food hygiene and safety associated with all methods of primary production and processing of eggs and egg products, including the adequate measures for small-scale producers and processors.

2. SCOPE AND USE OF THE DOCUMENT

2.1 Scope

This Code applies to the primary production, sorting, grading, storing, transport, processing, and distribution of eggs in shell and egg products of such eggs produced by domesticated birds and intended for human consumption. Traditional delicacy eggs (e.g. Balut, 1 000-year-old eggs) are not within the scope of this Code.

2.2 Use of the document

The provisions of this document are supplemental to and should be used in conjunction with, the Recommended *International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

The Code also references other Codex Standards, Codes or Guidelines, including the labelling standards and the Codex *Code of Hygienic Practice for the Transport of Foods in Bulk and Semi-Packed Food* (CAC/RCP 47-2001), when they apply to the hygienic production of eggs and egg products.

This document consists of a series of principles, explanatory narratives and guidelines.

Principles, shown in **bold text**, are a statement of the goal or objective that is to be achieved. *Explanatory narratives*, shown in *italicized text,* serve to explain the purpose of the stated principle. Additional information to assist in the application of the stated principle is shown in normal text.

Principles that are applicable to all phases of production, handling and processing of eggs and egg products are given in Section 2.3.

This Code is flexible to allow for different productions systems, size of operation and different systems of control of hazards during production, handling and processing of eggs and egg products.

Recognition of the production and processing of eggs by small-scale/less developed egg producers/businesses

In the context of this Code, the expression "small-scale egg producer" refers to production systems based on the number of birds, or where automated collecting and sorting/grading machines are not generally used, or where water and other requirements are in poor supply thus limiting the number of birds that can be kept. The maximum number of birds permitted in small-scale establishments may be set down in national legislation, codes of practice or other guidelines.

Flexibility in the application of these requirements in this Code may apply to less developed egg producers, i.e. those producers with larger flocks that have less developed systems, and/or economic, water and/or power supply constraints, preventing investment in modern grading and packaging processes and infrastructure.

Flexibility in the application of requirements on the primary production of eggs by small-scale and/or less developed egg producers can be exercised, where necessary. However, any microbiological or other control measures used should be sufficient to obtain safe and suitable eggs and egg products.

Such flexibility is indicated throughout the Code by the use of a parenthetical statement "where practicable" placed next to the particular provision where the flexibility is needed.

Further guidance on the issues facing small and less developed businesses, particularly in relation to implementing HACCP is under development and can be found in FAO/WHO *Guidance to Governments on the Application of HACCP in Small and/or Less Developed Businesses* (FAO/WHO, October 2006)

2.3 Principles applying to the production, handling and processing of all eggs and egg products

The following principles should apply, where appropriate and practicable, to the production, handling and processing of all eggs and egg products.

- **From primary production to the point of consumption, eggs and egg products should be subject to control measures intended to achieve the appropriate level of public health protection.**
  The Code is aimed at encouraging the safe production of eggs and egg products for human consumption, and gives relevant guidance to producers and processors, large and small, on the application of control measures throughout the entire food chain. It recognizes that there is a need for continuous, effective effort or controls, which should be applied, by primary producers in addition to processors, in assuring the safety and suitability of eggs and egg products.
  Good hygienic, agricultural and manufacturing practices should be identified during primary production, shell egg processing and egg product processing. Such practices should be applied throughout the food production chain so that eggs and egg products are safe and suitable for their intended use.
  Both the relationship and impact of one part of the food production chain on another part should be identified to ensure that potential gaps in the chain are dealt with through communication and interaction between those in the production chain. Information should be obtained to cover one step forward and one step back through to final food preparation.
  No part of this Code should be used without consideration of what takes place in the production chain prior to the particular measure being applied or what will take place subsequent to a particular step. The Code should only be used within the context of an understanding that there is a continuous system of controls

that are applied from the breeding flock and sourcing of the laying flock to consumption of the end product. Good hygienic practice should also apply when handling eggs during food preparation.

- **Wherever appropriate, hygienic practices for eggs and egg products should be implemented within the context of HACCP systems as described in the Annex to the *Recommended International Code of Practice – General Principles of Food Hygiene.***
  There should be an understanding of the hazards associated with eggs, at each stage in egg production, handling, grading, packaging, transporting and processing so as to minimize contamination. It is principally the responsibility of the producer, where practicable, to conduct a hazard analysis within the context of developing a control system based on HACCP and thus to identify and control hazards associated with flock management and egg production. Similarly it is principally the responsibility of the processor to conduct a hazard analysis to identify and control hazards associated with egg processing.
  This principle is presented with the recognition that there are limitations to the full application of HACCP principles at the primary production level of eggs. In the case where HACCP is not implemented at the producer level, good hygienic, agricultural and animal husbandry practices should be followed.

- **Control measures should be effective and validated, where practicable.**
  The overall effectiveness of the control measures should be validated according to the prevalence of hazards in the egg, taking into consideration the characteristics of the individual hazards(s) of concern, established Food Safety Objectives/Performance Objectives and level of risk to the consumer.
  Small and less developed businesses that do not have resources to validate the effectiveness of their control measures should implement appropriate control measures required by their country. Where there are no legal requirements, such businesses should follow recommendations in industry-recognized guidelines or follow practices established as safe, where practicable.

2.4 Relative roles of egg producers, processors and transporters

All parties involved in the egg production chain share responsibility for food safety. This can include those involved in primary production, handling, grading, packaging, processing, supplying, distributing and commercial cooking of eggs and egg products for human consumption. In order to achieve this common goal, respective parties should pay attention to the following responsibilities:

- Good communication and interaction should exist between egg producers, processors and others in the chain so that an effective chain of controls is maintained from breeding of the laying flock to production of eggs to consumption. This can help to ensure that appropriate and complementary hygiene practices are applied at each stage of the chain and that appropriate and timely action is taken to resolve any food safety problems that may arise.

- Primary producers should apply good hygienic, agricultural and animal husbandry practices consistent with food safety, and adapt their operations as appropriate and practicable to meet any specifications for specific hygiene controls to be applied and/or any standards to be achieved as may be agreed with the processor, distributor, transporter or warehouser.
- Processors should follow good manufacturing and good hygienic practices, especially those presented in this Code and in the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969) or those required by the competent authority. The processor may have to implement controls, or adapt their manufacturing processes, based on the ability of the egg producer to minimize or prevent associated hazards.
- Producers and/or processors should communicate any recommendations for safe handling and storage of eggs and egg products during distribution and transportation, and their subsequent use by food businesses.
- Distributors and transporters, wholesalers, retailers and those involved in food preparation at any facility should ensure that eggs and egg products under their control are handled and stored properly and according to the producers and/or processors instructions.
- Information to consumers should include advice on safe handling, storage and preparation of eggs.

2.5 Definitions

Definitions of general expressions are included in the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969). For the purpose of this Code, the following terms have the definition stated:

Breaking – the process of intentionally cracking the egg shell and separating its pieces to remove the egg contents.

Breeding flock – a group of birds kept for the purpose of production of the laying flock.

Broken/leaker egg – an egg showing breaks of both the shell and the membrane, resulting in the exposure of its contents.

Candling – examining the interior condition of an egg and the integrity of the shell by rotating or causing the egg to rotate in front of or over a light source that illuminates the contents of the egg.

Cracked egg – an egg with a damaged shell, but with intact membrane

Dirty egg – an egg with foreign matter on the shell surface, including egg yolk, manure or soil.

Domesticated birds – members of the Class Aves that are kept for the production of eggs intended for human consumption.

Egg laying establishment – the facilities and the surrounding area where primary production of eggs takes place.

Egg product – all, or a portion of, the contents found inside eggs separated from the shell, with or without added ingredients, intended for human consumption.

Incubator egg – an egg that has been set in an incubator.

Microbiocidal treatment is a control measure that practically eliminates the number of micro-organisms, including pathogenic micro-organisms present in a food or reduces them to a level at which they do not constitute a health hazard.

Pasteurization – a microbiocidal control measure where eggs or egg products are subjected to a process, using heat to reduce the load of pathogenic micro-organisms to an acceptable level to ensure safety.

Shelf life – the period during which the egg or egg product maintains its safety and suitability.

Table egg – an egg destined to be sold to the end consumer in its shell and without having received any treatment significantly modifying its properties.

3. PRIMARY PRODUCTION

It is recognized that some of the provisions in this Code may be difficult to implement in areas where primary production is conducted in small holdings in both developed and developing countries and also in areas where traditional farming is practised. Therefore, the Code is, of necessity, a flexible one to allow for different systems of control and prevention of contamination of eggs during primary production.

These principles and narratives supplement those contained in Section 3 of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969) and the general principles presented in Section 2.3 above.

Egg producers should take all reasonable measures to reduce the likelihood of hazards occurring in or on eggs during primary production.
Primary production activities can significantly impact on the safety of eggs and egg products. Bacterial contamination of eggs can occur during formation, thus the practices used at this phase of production are a key factor in reducing the potential for micro-organisms to be present in or on eggs.

It is recognized that microbiological hazards can be introduced both from the primary production environment and from the breeding and laying flocks themselves. Pathogens such as Salmonella *Enteritidis (SE) can be transmitted vertically from breeder flocks to commercial laying flocks, and horizontally from other layers, feed and/or environment and hence to eggs. Importantly, the presence of* Salmonella *in the laying and/or breeding flock increases the possibility of* Salmonella *in the egg.*

Thus the preventative role of good hygienic and agricultural practice in the primary production of eggs is critically important. Appropriate animal husbandry practices should be respected and care should be taken to assure that proper health of the breeding and laying flocks is maintained. Further, lack of good agricultural, animal feeding and veterinary practices and inadequate general hygiene by personnel and equipment during egg handling, and/or collection may lead to unacceptable levels of bacterial and other contamination (such as physical and chemical) during primary production.

The focus for primary producers is to reduce the likelihood that such hazards will occur during the primary production phase of the chain. Likewise, in certain primary production situations, the occurrence of food safety hazards may be less avoidable which may result in the application of more stringent control measures during subsequent processing in order to ensure safety and suitability of the finished product. The degree to which primary production practices control the likelihood of occurrence of a food safety hazard in or on eggs will have an impact on the nature of controls needed during the subsequent processing of eggs.

Contamination of eggs during primary production should be minimized.
Producers should obtain domesticated birds from breeding stock that have been subject to control measures to reduce and, if possible eliminate, the risk of introducing into laying flocks, poultry diseases and pathogenic organisms transmissible to humans. The breeding flock should be subject to a programme which will monitor the effect of the control measures.

Laying flock management is key to safe primary production of eggs. Laying flocks are managed under a wide range of climatic conditions using various agricultural inputs and technologies, and on farms of various sizes. However in backyard poultry farms and small scale producers, the number of birds maintained is very small and, accordingly, the systems and hygienic conditions of production may vary. Hazards may vary between one type of production system and another. In each egg laying establishment, it is necessary to consider the particular agricultural practices that promote the safe production of eggs, the type of products (e.g., unsorted eggs, eggs for the table egg market, eggs strictly for breaking) and production methods used.

The microbial load of eggs should be as low as achievable, using good egg production practices, taking into account the requirements for subsequent processing. Measures should be implemented at the primary production level to reduce as far as possible the initial load of pathogenic micro-organisms affecting safety and suitability. Such measures would permit the application of microbiological control measures of lesser stringency and still ensure product safety and suitability.

3.1 Environmental hygiene

The egg laying establishment should be appropriate for the primary production of eggs such that sources of potentially harmful substances are minimized and are not present at unacceptable levels in or on eggs.
Where practicable, producers could identify and evaluate the immediate surroundings and previous use (indoor and outdoor) of the egg laying establishment in order to identify hazards. Potential sources of contamination from the egg laying establishment including the immediate environment should be identified. This could include contamination associated with previous uses of the land, presence of contaminants, polluted surface water, potential microbial and chemical hazards from contamination by faeces, and other organic waste that could be introduced into the egg laying establishment. This is particularly relevant in the case of free range foraging by domesticated birds.

Primary production should not be carried out in areas where the presence of potentially harmful substances in the egg laying establishment would lead to an unacceptable level of such substances in or on eggs. The potential for contamination from, for example, agricultural chemicals, hazardous wastes, etc. should be considered. The potential for the introduction of disease from wild birds and animals should also be considered.

The evaluation process could include the following:

- Identification of previous and present usage of the primary production area and the adjoining sites to determine potential microbial, chemical and physical hazards and determine sources of environmental contamination, for example by faeces or other organic waste, that could be introduced into the egg laying establishment.
  - Sites/uses of concern can include crops grown, feed lot, animal production, hazardous waste site, sewage treatment site, and mining extraction site.
- Identification of points of access to the site by domesticated and wild animals, including access to water sources used in primary production, to determine potential faecal and other contamination of the soils and water and the likelihood of contamination of eggs.
  - Existing practices should be reviewed to assess the prevalence and likelihood of uncontrolled deposits of animal faeces coming into contact with eggs.
  - As much as possible, domestic and wild animals, including wild birds as well as rodents should be prevented from entering egg laying establishments.
- Identification of the potential for contamination of egg laying establishments by leaking, leaching or overflowing manure storage sites and flooding from polluted surface waters.

If previous uses cannot be identified, or the evaluation leads to the conclusion that hazards exist, where practicable, the sites should be tested for contaminants of concern. Additionally, periodic monitoring of the environment and forage, and judicious selection and use of fertilizers and agricultural chemicals should occur.

If contaminants are present at levels which may result in the egg or egg product being harmful to human health, and corrective or preventive actions have not been taken to minimize identified hazards, the sites should not be used until such actions have been applied.

Care should be taken to minimize access to contaminated water or to environmental contaminants to the extent practicable in order to avoid diseases transmissible to birds or to humans or the likelihood of contamination of eggs.

3.2 Hygienic production of eggs

Provisions in this section are equally relevant to all egg producers.

3.2.1 Flock management and animal health

Eggs should come from flocks (both breeding and laying) in good health so that flock health does not adversely affect the safety and suitability of the eggs.

Good animal husbandry practices should be used to help maintain flock health and resistance to colonization by pathogenic organisms. These practices should include timely treatment for parasites, minimizing stress through proper management of human access and environmental conditions and use of appropriate preventive measures for example, veterinary medicines and vaccines.

The Salmonella *Enteritidis Risk Assessment has shown that reducing the prevalence of* Salmonella *Enteritidis infected flocks is anticipated to result in a reduction in the risk of human illness from the consumption of* Salmonella *Enteritidis positive eggs.*[2]

Flock management is critical in reducing the risk of human illness from the consumption of eggs. Good husbandry practices should also be used to reduce the likelihood of pathogens (i.e. avian disease) and thus reduce the use of veterinary drugs. Where drug treatment occurs, its use should be appropriate and should consider possible antimicrobial resistance.[3] In particular, measures to prevent disease could include:

- Evaluating the health status of domesticated birds relative to avian diseases and where practicable, colonization by pathogenic organisms transmissible to humans and always taking action to ensure only healthy birds are used.
- Taking preventive measures, including managing human access, to reduce the risk of transferring micro-organisms that may impact on food safety to, or from, or between, flocks.
- Using, where permitted, appropriate vaccines as part of an overall flock management programme, including as measures when introducing new birds.
- Regularly checking the flock and removing dead and diseased birds, isolating sick birds, and investigating suspicious or unknown causes of illness or death to prevent further cases.
- Disposing of dead birds in a manner that prevents recycling of diseases to the laying flock by either pests or handlers.
- Treating birds only with veterinary drugs where permitted, prescribed by a veterinarian and in a manner that will not adversely impact on the safety and suitability of eggs, including adhering to the withdrawal period specified by the manufacturer or veterinarian.
  - Only those medicinal products and medicinal premixes that have been authorized by the relevant authority for inclusion in animal feed should be used.
  - Where birds/flocks have been treated with veterinary drugs that can be transferred to eggs, their eggs should be discarded until the withholding period for the particular veterinary drug has been achieved. Established

[2] *Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods*, FAO Headquarters, Rome, Italy 30 April – 4 May 2001, page 13.

[3] *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005).

maximum residue levels (MRLs), including those established by Codex, for residues of veterinary drugs in eggs, may be used to verify such measures.
  - The veterinarian and/or the producer/layer establishment owner/manager or the collection centre should keep a record of the products used, including the quantity, the date of administration, the identity of the flock and withdrawal period.
  - Appropriate sampling schemes and testing protocols should be used to verify the effectiveness of on-farm controls of veterinary drug use and in meeting established MRLs.
  - Veterinary drugs should be stored appropriately and according to manufacturer's instructions.
- Particularly for countries where *Salmonella* Enteritidis has been associated with poultry or eggs, monitoring for SE through faecal testing and the use of a vaccination protocol may reduce the risk of human illness.[4] If a vaccine is used, it should be approved by the competent authority. Monitoring for SE can also include environmental testing of litter, dust, ventilation fans etc.
- Disposing of eggs from infected flocks still in production that represent a risk to human or flock health, in a safe manner or specifically diverting them to a process that ensures elimination of a hazard.
- Where practicable, destruction of *Salmonella* Enteridis positive flocks or slaughter in accordance with country requirements.
- Ensuring visitors, where necessary, wear appropriate protective clothing, footwear and head covering to reduce the risk of introducing hazards or spreading hazards between flocks. Visitor movement should be controlled to minimize likelihood of transfer of pathogens from other sources.

3.2.2 Areas and establishments for egg laying systems

Egg laying areas and establishments should, to the extent practicable, be designed, constructed, maintained and used in a manner that minimizes exposure of domesticated birds or their eggs to hazards and pests.

Improperly protected and maintained areas and premises for the housing of flocks and laying of eggs, particularly for free range and barn production systems may contribute to the contamination of eggs.

Taking into account climatic conditions, production systems including those used to provide feed, water, shelter, control temperature and predators and manage interactions between birds should be designed, constructed, maintained and used in a manner to minimize the likelihood of transfer of foodborne pathogens to the egg, either directly or indirectly.[5]

[4] *Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods,* FAO Headquarters, Rome, Italy 30 April – 4 May 2001, page 17.

[5] Although evaluation of the importance of such interventions for reducing the risk of human illness based on existing data was inconclusive. *Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods*, FAO Headquarters, Rome, Italy 30 April – 4 May 2001, page 17.

The following should be considered, where practicable, in the assessment of areas and establishments used for egg laying:

- The internal design and layout of housing should not adversely affect the health of the birds and should permit compliance with good hygienic practices.
- The facilities used to house flocks should be cleaned and disinfected in a way that reduces the risk of transfer of pathogens to the next flock. An 'all-in, all-out' step for each poultry house should be followed, where feasible, taking into consideration multi-aged poultry houses. Such a process would give the opportunity to eliminate rodents and insects before the next flock is introduced.
- A plan should be in place to detect any failure in cleaning and disinfection programmes and ensure that corrective actions are taken.
- Use of litter should be managed to reduce the risk of introducing or spreading hazards.
- Water delivery systems should be protected, maintained and cleaned, as appropriate, to prevent microbial contamination of water.
- Drainage systems and systems for storing and removal of manure should be designed, constructed and maintained so as to prevent the likelihood of contaminating the water supply or eggs.

Access to egg laying establishments by other animal species (i.e. dogs, cat, wild animals and other birds) that may adversely affect the safety of the eggs should be minimized.

The egg laying establishments should, as far as practicable, be kept clean. Accumulations of broken eggs, manure, or any other objectionable materials should be minimized in order to reduce the likelihood of contact with eggs and to minimize attracting pests into the establishment.

3.2.3 General hygienic practice

3.2.3.1 Watering

Water should be managed in a way that minimizes the potential for the transmission of hazards, directly or indirectly, into or on the egg.

Water used in primary production operations should be suitable for its intended purpose and should not contribute to the introduction of microbiological or chemical hazards into or on eggs.
Contaminated water may contaminate feed, equipment or laying birds leading to the potential introduction of hazards in or on eggs.
As water can be a source of contamination, treatment of drinking water to reduce or eliminate pathogens including *Salmonella* should be considered.

- Potable water should be used, or if potable water is not available for some or all purposes, water should be of a quality that does not introduce hazards

to humans consuming the eggs.[6] Access to surface water, where it introduces hazards, should be denied.

- Potential sources of contamination of water from chemical runoff or improperly managed faeces should be identified and controlled to the extent practicable to minimize the likelihood of contaminating eggs.
- Appropriate safety and suitability criteria that meet the intended outcomes should be established for any water used in egg production.
- Where practicable, good purchasing practices for water could be used to minimize the risk associated with hazards in the water and may include using vendor assurances or contractual agreements.
- Where possible, water should be regularly tested to ensure that water supplied to the birds is of a quality that does not introduce hazards in or on the egg.

Any reuse of water should be subject to a hazard analysis including assessment of whether it is appropriate for reconditioning. Critical control point(s) should be identified, as appropriate, and critical limit(s) established and monitored to verify compliance.

- Water recirculated or recycled for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of eggs results from its use.
- Reconditioning of water for reuse and use of reclaimed, recirculated and recycled water should be managed in accordance with HACCP principles.

3.2.3.2 Feeding[7]

Feed for the laying and/or breeding flock should not introduce, directly or indirectly, microbiological or chemical contaminants into eggs that present an unacceptable health risk to the consumer or adversely affect the suitability of eggs and egg products.

The improper procurement, manufacturing and handling of animal feed may result in the introduction of pathogens and spoilage organisms to the breeding and laying flock and the introduction of chemical hazards, such as pesticide residues and other contaminants, which can affect the safety and suitability of eggs and egg products.

Producers should take care where appropriate, during production, transportation, preparation, processing, procurement, storage, and delivery of feed to reduce the likelihood of introducing hazards into the production system.

- To minimize the risk associated with hazards in the feed, good purchasing practices for feed and feed ingredients should be employed. This may include using vendor assurances, contractual agreements and/or purchasing batches of feed that have had microbiological and chemical analysis and are accompanied by certificates of analysis.

[6] *Safe Use of Wastewater, Excreta and Greywater. Volume II, Wastewater Use in Agriculture.* WHO/FAO/UNEP, 2006 and the *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005).

[7] *Code of Practice on Good Animal Feeding* (CAC/RCP 54 – 2004).

- Feed should be managed so that it does not become mouldy or contaminated from waste including faeces.
- As feed can be a source of contamination, heat or other treatment of feed to reduce or eliminate pathogens including *Salmonella* should be considered.
- When the egg producer processes their own feed, information should be kept about its composition, the origin of the ingredients, relevant processing parameters and where practicable, the results of any analyses of the finished feed.
- The owner should keep a record of relevant information concerning feed.

3.2.3.3 Pest control

Pests should be controlled using a properly designed pest control programme as they are recognized as vectors for pathogenic organisms.

Any pest control measures should not result in unacceptable levels of residues, such as pesticides, in or on eggs.

Pests such as insects and rodents are known vectors for the introduction of human and animal pathogens into the production environment. Improper application of chemicals used to control these pests may introduce chemical hazards into the production environment.

A properly designed pest control programme should be used, that considers the following:

- Before pesticides or rodenticides are used, all efforts should be made to minimize the presence of insects, rats and mice and reduce or remove places which could harbour pests.
  - As cages/pens/enclosures/coops (if used) attract such pests, measures such as proper design, construction and maintenance of buildings (if applicable), effective cleaning procedures and removal of faecal waste should be used to minimize pests.
  - Mice, rats and wild birds are attracted to stored feed. Any feed stores should be located, designed, constructed and maintained so as to be, where practicable, inaccessible to pests. Feed should be kept in pest proof containers.
- Bait should always be placed in "bait stations" so that they are obvious, cannot be accessed by animals or insects they are not intended for and can be identifiable and found easily for checking.
- If it is necessary to resort to chemical pest control measures, the chemicals should be approved for use in food premises and used in accordance with the manufacturer's instructions.
- Any pest control chemicals should be stored in a manner that will not contaminate the laying environment. Such chemicals should be stored in a safe manner. They should not be stored in wet areas or close to feed stores or be accessible by birds. It is preferable to use solid baits, wherever possible.

3.2.3.4 Agricultural and veterinary chemicals

Procurement, transport, storage and use of agricultural and veterinary chemicals should be undertaken in such a way that they do not pose a risk of contaminating the eggs, flock or the egg-laying establishment.

- Transport, storage and use of agricultural and veterinary chemicals should be in accordance with the manufacturer's instructions.
- Storage and use of agricultural and veterinary chemicals on the egg laying establishment should be evaluated and managed, as they may represent a direct or indirect hazard for the eggs and flock.
- Agricultural and veterinary chemical residues should not exceed limits established by the Codex Alimentarius Commission or as per national legislation.
- Workers that apply agricultural and veterinary chemicals should receive training in the proper application procedures.
- Agricultural and veterinary chemicals should be kept in their original containers. Labels should have the name of the chemical substances and the instructions for their application.
- Equipment used to apply or administer agricultural and veterinary chemicals should be stored or disposed of in a manner that does not represent a direct or indirect hazard for the eggs and flock
- Empty agricultural and veterinary containers should be disposed of according to applicable regulation and/or the manufacturer's directions and should not be used for other purposes.
- Where possible and practicable, producers should keep records of agricultural and veterinary chemical applications. Records should include information on the date of application, the chemical used, the concentration, method and frequency of application, the purpose for using the chemical applications and where it was applied.

3.3 Collection, handling, storage and transport of eggs

Eggs should be collected, handled, stored and transported in a manner that minimizes contamination and/or damage to the egg or egg shell, and with appropriate attention to time-temperature considerations, particularly temperature fluctuations.

Appropriate measures should be implemented during disposal of unsafe and unsuitable eggs to protect other eggs from contamination.
Proper collection, whether using manual or automated methods, handling, storage and transport of eggs are important elements of the system of controls necessary to produce safe and suitable eggs and egg products. Contact with unsanitary equipment and foreign materials or methods that cause damage to the shell, may contribute to egg contamination.

Whether manual or automated methods are used to collect eggs, producers should minimize the time between egg laying and further handling or processing. In particular, the time between egg laying and controlled temperature storage should be minimized.

Methods used to collect, handle, store and transport eggs should minimize damage to the shell, and avoid contamination and practices should reflect the following points:

- Cracked and/or dirty eggs should be excluded from the table egg trade.
- Cracked and/or dirty eggs should be directed to a processing or packing establishment, as appropriate, as soon as possible after collection (see Section 5.1).
- Hygienic practices, which take into account time and temperature factors, should be used to protect the egg from surface moisture in order to minimize microbial growth.
- Where appropriate, broken and/or dirty eggs should be segregated from clean and intact eggs.
- Broken eggs and incubator eggs should not be used for human consumption and be disposed of in a safe manner.

Egg processors should communicate any specific requirements at farm level (i.e. time/temperature controls) to the egg producer.

Selection

Eggs from different species of poultry and/or farm production systems (e.g. free range, barn and caged eggs) should be segregated as appropriate.

3.3.1 Egg collection equipment

Collection equipment should be made of materials that are non-toxic and be designed, constructed, installed, maintained and used in a manner to facilitate good hygiene practices.

It is important to prevent any damage to the eggshells by collecting equipment since such damage can lead to contamination and consequently adversely affects the safety and suitability of eggs and egg products. It is also important that the equipment is maintained to a standard of cleanliness adequate to prevent contamination of the eggs.

Where used, egg collecting equipment and containers should be cleaned and disinfected regularly, or if necessary replaced, and with sufficient frequency to minimize or prevent contamination of eggs.

Single use containers should not be reused.

Egg collecting equipment should be maintained in proper working condition and this should be periodically verified.

3.3.2 Packaging and storage

Egg packaging and packaging equipment should be designed, constructed, maintained and used in a manner that will minimize damage to the eggshell and avoid the introduction of contaminants in or on eggs.

Wherever eggs are stored, it should be in a manner that minimizes damage to the eggshell and avoids the introduction of contaminants, or growth of existing micro-organisms in or on eggs, giving consideration to time and temperature conditions.
Any egg packaging, storage or associated equipment should not transfer substances to eggs that will present a health risk to the consumer.
Where permanent equipment is used, it should be corrosion resistant and easy to clean and disinfect or if necessary able to be dismantled and reassembled.

Storage temperatures, times and humidity should not have a detrimental effect on the safety and suitability of eggs. The time and temperature conditions and humidity for egg storage at the farm should be established taking into account the hygienic condition of the eggs, the hazards that are reasonably likely to occur, the end use of the eggs, and the intended duration of storage.

3.3.3 Transport, delivery procedures and equipment

Whenever eggs are transported, it should be in a manner that minimizes damage to the egg or eggshell and avoids the introduction of contaminants in or on eggs.
Personnel and vehicular access should be adequate for the hygienic handling of eggs, such that contamination is not introduced onto the farm and thus in or on eggs.

Lorries, trucks or other vehicles or equipment, which carry the eggs, should be cleaned at a frequency necessary to prevent contamination flow between farms or premises and thus of eggs.

The time and temperature conditions for the transport and delivery of eggs from the producer should be established taking into account the hygienic condition of the eggs, the hazards that are reasonably likely to occur, the end use of the eggs, and the intended duration of storage.

- These conditions may be specified in legislation, in codes of practice, or by the processor receiving the eggs in collaboration with the egg producer and transporter and the relevant authority.

Delivery procedures should be adequate for the hygienic handling of eggs.

3.4 Cleaning, maintenance and personnel hygiene at primary production

3.4.1 Cleaning and maintenance of egg laying establishments

Egg laying establishments should be cleaned and maintained in a manner that ensures the health of flocks and safety and suitability of eggs.
Cleaning and disinfection programmes should be in place, and their efficacy should be periodically verified and an environmental monitoring programme implemented where possible and practicable.

These programmes should include procedures for routine cleaning while birds are in the poultry house. Full cleaning and disinfection programmes should be applied when poultry houses are empty.

De-populated poultry house cleaning procedures should cover cleaning and/or sanitizing nest boxes/cages, poultry houses, disposing of contaminated litter, nesting materials and faeces from diseased birds and, where necessary, safe disposal of eggs from infected flocks and dead or diseased birds.

The egg-laying establishment should be safe for the re-entry of new stock.

3.4.2 Personnel hygiene, health, and sanitary facilities

3.4.2.1 Personnel hygiene

Hygiene and health requirements should be followed to ensure that personnel who come directly into contact with eggs are not likely to contaminate them.

Hygiene and health requirements should be followed to ensure that personnel who come directly into contact with birds are not likely to transmit illness between birds.
Personnel should understand and follow preventative measures specifically relating to the handling of birds and/or eggs, so as to prevent introducing hazards from one to the other, from other facilities or from cross contamination of birds from personnel.

Personnel should be adequately instructed and/or trained to handle eggs and domesticated birds to ensure the use of good hygienic practices that will minimize the risk of egg or flock contamination.

3.4.2.2 Health status

Personnel should be in good health and not introduce diseases or illness likely to affect flock health or the safety and suitability of eggs.
People known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted to birds or through eggs should not be allowed to enter any bird facility or egg collection or handling area, if there is a likelihood of their contaminating the birds or the eggs. Any person so affected should immediately report illness or symptoms of illness to the management.

3.4.2.3 Personal cleanliness

Personnel who have direct contact with eggs should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, footwear and head covering that is not likely to introduce contamination into egg laying areas.
Personnel should wash their hands before starting work that involves the handling of eggs, each time they return to handling areas after a break, immediately after using the toilet, and after handling anything which may contaminate eggs.

3.4.2.4 Sanitary facilities

Facilities should be available to ensure that an appropriate degree of personal hygiene can be maintained.
Facilities should:

- Be located in close proximity to wherever eggs or domesticated birds are handled;
- Be constructed to facilitate hygienic removal of wastes and avoid contamination of facilities, equipment, raw materials and the immediate environment;
- Have adequate means for hygienically washing and drying hands and disinfecting footwear; and
- Be maintained under sanitary conditions and in good repair at all times.

3.5 Documentation and record keeping

Records should be kept, as necessary and where practicable, to enhance the ability to verify the effectiveness of the control systems. Documentation of procedures can enhance the credibility and effectiveness of the food safety control system.
With respect to food safety, records should be kept on:

- Prevention and control of avian diseases with an impact on public health;
- Identification and movement of birds and eggs;
- Use of agricultural and pest control chemicals;
- Nature and source of feed, feed ingredients and water;
- Use of veterinary drugs/medicines;
- Results of testing where testing is performed;
- Health status of personnel;
- Cleaning and disinfection; and
- Traceability/product tracing[8] and recall.

4. ESTABLISHMENT: DESIGN AND FACILITIES

Section 4 of the *Recommended International Code of Practice – General Principles of Food Hygiene* applies to both the processing of eggs for the table egg market and the processing of egg products.

The following guidelines are supplemental to Section 4 of the *Recommended International Code of Practice – General Principles of Food Hygiene* for establishments that produce egg products.

Where practicable, separate areas should be allocated for:

- Storage of egg and untreated egg product;
- Breaking and microbiocidal treatment of eggs;

[8] Refer to *Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System* (CAC/GL 60-2006)

- Packing of microbiocidally treated egg product;
- Storage of microbiocidally treated liquid and frozen egg products and other liquid or frozen ingredients as appropriate;
- Storage of microbiocidally treated dried egg product and other dry ingredients as appropriate; and
- Storage of cleaning and sanitizing materials.

Work areas for raw and treated product should be separated via physical barriers.

5. CONTROL OF OPERATION

These guidelines are supplemental to those set forth in Section 5 of the *Recommended International Code of Practice – General Principles of Food Hygiene*.

This section refers to control measures that should be taken to prevent, eliminate or reduce hazards when processing eggs for the shell egg market (i.e. table eggs) and when producing egg products. These measures should be used in conjunction with good hygienic and animal husbandry practices for the primary production of eggs as per Section 3 in order to provide an effective system of control of microbiological and other hazards that can occur in or on eggs and egg products.

These principles are also intended to enhance and supplement those aspects of the *Recommended International Code of Practice – General Principles of Food Hygiene HACCP* Annex (CAC/RCP 1-1969), which are essential to the successful design of a system of food safety controls for shell eggs and egg products. The users of this document are encouraged to implement the guidelines contained in the HACCP Annex when designing a HACCP system.

5.1 Control of food hazards

Eggs and egg products should be safe and suitable.

Table egg

Unsafe or unsuitable eggs[9] include:

- Incubator eggs;
- Broken/leaker eggs;
- Eggs with bacterial or fungal rots;
- Eggs contaminated with faeces;
- Eggs stored for hatching for sufficient time to adversely affect the safety and suitability.

[9] Refer to definition of food safety and food suitability in the *Recommended Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 2.3 Definitions.

Table eggs should be clean and intact.
All efforts should be made to avoid production of dirty eggs. However, dirty eggs may be used for table eggs if permitted by the relevant authorities, in accordance with country requirements, and if cleaned appropriately.

Egg products

- *Cracked or dirty eggs that are not suitable for human consumption as table eggs should be directed to processing (e.g. washing and breaking followed by a microbiocidal treatment) or be disposed of in a safe manner.*
- *Broken/leaker eggs should not be used to produce egg products and should be disposed of in a safe manner.*
- *Cracked eggs may be used in egg products, but should be processed with minimum delay.*
- *Dirty eggs should be visibly clean prior to breaking and processing.*
- *Other unsafe or unsuitable eggs should not be used for egg products and should be disposed of in a safe manner.*

Control measures based on risk should be in place to ensure that process and product specifications are met and the hazards in or on eggs and egg products are effectively identified and controlled.
Control measures used should achieve an appropriate level of public health protection. Where possible, measures should be based on HACCP principles.

These measures should allow the identification and removal of eggs and egg products that are not suitable for human consumption. They should also address the need to control pathogen growth throughout handling, cleaning, sorting and grading, packaging, processing, storage and distribution and have a sound basis in good hygiene practice. It is important that control measures are applied during primary production and processing to minimize or prevent the microbiological, chemical or physical contamination of eggs.

Processors should only use eggs that have been produced in accordance with the Code.

5.2 Key aspects of hygiene control systems

5.2.1 Temperature and time issues

From receipt of eggs, through handling, sorting and grading, washing, drying, treatment, packing, storage and distribution to point of consumption, consideration should be given to time and temperature and humidity conditions for eggs such that the growth of pathogenic micro-organisms will be minimized and the safety and suitability of the eggs will not be adversely affected.

Temperature fluctuations should be minimized as much as possible.
Storage and handling conditions, including those during cleaning, grading and packaging should be such that moisture on the shell surface is minimized.

As eggs are perishable products, particular attention should be paid to temperature conditions throughout storage and distribution, noting that lower storage and distribution temperatures lend themselves to longer shelf life and minimize microbial growth, for example of *Salmonella* Enteritidis.

From receipt of raw/untreated egg product, through processing, treatment, packaging, storage and distribution to point of consumption, consideration should be given to time and temperature conditions for egg products such that the growth of pathogenic micro-organisms will be minimized and the safety and suitability of the egg products will not be adversely affected.
Storage conditions should be such that the potential for microbial contamination, the growth of microbial pathogens and the risk to human health is minimized.

5.2.2 Specific process steps

5.2.2.1 Handling of table eggs

Eggs should be handled during all stages of cleaning, sorting, grading, packing, storing and distribution in a manner that avoids damage, minimizes moisture on the shell surface and prevents contamination.
Handling of shell eggs can result in damage to eggs. Eggs should be handled in a manner that avoids damage and contamination, including minimizing moisture on the egg shell surface.
Activities involved in shell eggs handling may be done by the primary producer, the processor or others involved in the egg production chain. Wherever in the production chain these activities are done, they should be done in accordance with this Code.

Eggs intended for the table egg market should be visibly clean prior to grading and packing.
Sorting, grading, and where appropriate, washing processes should result in clean eggs.

(i) Sorting, grading and packing
Sorting, grading and packing of the egg refers to the stage between primary production and retail or further processing, where the whole egg may undergo one or more activities to prepare it for either the table egg market or for processing into egg products.

Cracked, dirty, and unsafe/unsuitable eggs should be segregated from clean and intact eggs.
Cracked eggs should be segregated (for example, by candling) and sent for processing (see Section 5.2.2) or disposed of in a safe manner.

Dirty eggs may be cleaned and if appropriately cleaned, used for the table egg market or the egg product industry in accordance with country requirements. Dirty eggs sent for processing should be clearly labelled that they are not suitable as table eggs.

The cleaning process used should not damage or contaminate the eggs. Incorrect cleaning of eggs can result in a higher level of contamination of eggs than existed prior to cleaning.

Broken/leaker and other unsuitable eggs should be segregated from eggs suitable for human consumption.
Broken/leaker and other unsuitable eggs should be identified in such a way that they cannot be used for human consumption, for example, by appropriate labelling or the use of a de-characterizing agent (an additive that makes it clearly visible that the eggs should not be processed into human food, e.g. a denaturing agent).

Cleaning

- Where permitted by the relevant authority, a cleaning process may be used to remove foreign matter from the shell surface, but this should be carried out under carefully controlled conditions so as to minimize damage to the shell surface.
- Cleaning can be used to reduce the bacterial load on the outside of the shell.
- If dry cleaning is undertaken, the methods used should minimize damage to the protective cuticle and, where appropriate, be followed by oiling of the shell using a suitable food grade oil.

Washing, disinfection and drying
Where washing is permitted by the relevant authority, it should be carried out under carefully controlled conditions so as to minimize damage to the shell and prevent contamination of the egg contents.

- Eggs should not be soaked prior to or during washing.
- Water used for washing should be suitable and not adversely affect the safety and suitability of the egg, giving consideration to appropriate water temperature, pH, and quality, and egg temperature.
- If cleaning compounds such as detergents and sanitizers are used, they should be suitable for use on eggs and not adversely affect the safety of the egg.
- If eggs are washed, they should be dried to minimize moisture on the surface of the shell that can lead to contamination or growth of mould.
- Washing should be followed by effective sanitizing of the shell and, where appropriate, with subsequent oiling of the shell using a suitable food grade oil.

(ii) In shell treatment

Where table eggs are treated to eliminate pathogens (e.g. in-shell pasteurization) the treatment should not adversely affect the safety or suitability of the egg.

(iii) Storage and distribution

Eggs should be stored and transported under conditions that will not adversely affect the safety and suitability of the egg.
Eggs are perishable products.

- Storage conditions should minimize moisture on the shell surface.
- Lower temperatures minimize microbial growth and extend shelf life of the eggs.
- Temperature fluctuations during storage and distribution should be minimized.

(iv) Shelf life for table eggs[10]

The growth of pathogenic and/or spoilage micro-organisms to unacceptable levels may affect the shelf life of eggs.

The shelf life of eggs is influenced by a number of factors, such as:

- Storage conditions including temperature, temperature fluctuation and humidity;
- Methods and treatments;
- Type of packaging.

Shelf life of table eggs should be established by the grader/packer, consistent with requirements of relevant authorities, based on:

- information from the producer on the time since lay, time and temperature in storage and transport;
- type of packaging;
- likelihood of microbial growth, due to reasonably anticipated temperature abuse during storage, distribution, retail, sale and handling by the consumer under reasonably foreseeable conditions of distribution, storage and use.

Where processors clearly advise on egg packaging that eggs are to be refrigerated, others in the food chain, including retailers should follow the processors' advice, unless it is expressly made as a recommendation to the consumer (e.g. that the conditions of refrigeration should be fulfilled after purchasing).

5.2.2.2 Egg product processing

Processors should be satisfied that the egg products they produce are safe and suitable for human consumption.

Eggs for processing should be visibly clean prior to breaking and separating.

Cracked eggs may be processed. Broken eggs should not be processed and should be disposed of in a safe manner.
Dirty eggs should be disposed of in a safe manner or may be cleaned in accordance with 5.2.2.1.

[10] *Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods*, FAO Headquarters, Rome, Italy 30 April – 4 May 2001, page 14.

Separating the egg contents from the shell should be done in a manner that will, as far as possible, avoid cross-contamination between the shell and egg contents, avoid contamination by personnel or from equipment, and that permits examination of egg contents.

(i) Treatments

Egg products should be subjected to a microbiocidal treatment to ensure the products are safe and suitable.

All operations subsequent to the treatment should ensure that the treated product does not become contaminated.
Hygienic manufacturing and personnel practices should be in place to manage the risk of contamination from the food contact surfaces, equipment, and personnel, packaging material and between raw egg and processed egg products.
Microbiocidal treatments, including heat treatment, should be validated to show they achieve the desired reduction in the number of pathogenic micro-organisms and result in a safe and suitable product.

Where heat treatment is used, consideration should be given to time and temperature combinations.
Pasteurized liquid egg products should be cooled rapidly immediately after pasteurization and maintained under refrigeration.

(ii) Untreated egg products

Egg products that have not had a microbiocidal treatment should only be directed to further processing to ensure their safety and suitability.
Where untreated egg products leave a grading/processing premises, they should be labelled that the product has not been treated.

(iii) Storage and distribution

Egg products should be stored and transported under conditions that will not adversely affect the safety and suitability of the product.
Egg products, including those that can be stored at ambient temperatures, should be protected against external agents and contamination, e.g. direct sun light, excessive heating, moisture, external contaminants, and from rapid temperature changes which could adversely affect the integrity of the product packaging or the safety and suitability of the product.

(iv) Shelf life for egg products

The shelf life of egg products is influenced by a number of factors, such as:

- Storage conditions including temperature, temperature fluctuation and humidity;
- Processing methods and treatments;
- Type of packaging.

Shelf life of egg products should be established by the processor, consistent with requirements of relevant authorities, based on:

- Applied microbiological control measures, including storage temperatures, e.g. storage under refrigeration, freezing or ambient;
- Methods and treatments applied to product;
- Type of packaging;
- Likelihood of post process contamination and type of potential contamination under reasonably foreseeable conditions.

The safety and suitability of the egg product should be assured and, where necessary, demonstrated that it would be retained throughout the maximum period specified.

Shelf life determination may be done at the plant level by testing products subjected to the storage conditions specified or by predicting microbial growth in the product under the specified storage conditions. Reasonably anticipated temperature abuse should be integrated into the study or be taken into account by applying an appropriate safety factor (e.g., by shortening the maximum durability specified in the labelling or by requiring lower storage temperatures).

5.2.3 Microbiological and other specifications

Refer to the *Recommended International Code of Practice – General Principles of Food Hygiene* (*Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997)).

Information that may be useful for establishing specifications could include:

- Flock health status (including pathogen status);
- Pathogen load in/on eggs;
- Agricultural and veterinary chemical status;
- Age of eggs;
- Handling methods; and
- Microbiocidal treatments.

Particular attention should be given to specific indicating control of pathogens such as *Salmonella* Enteritidis.

5.3 Incoming material requirements

Refer to the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

Depending upon the end use of the egg, certain specific microbiological criteria for incoming ingredients may be appropriate to verify that the control systems have been implemented correctly.

5.4 Packaging

Refer to the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

5.5 Water

Refer to the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969).

5.6 Management and supervision

Refer to the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

5.7 Documentation and records

Refer to the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

5.8 Recall procedures

Refer to the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

6. ESTABLISHMENT: MAINTENANCE AND SANITATION

These guidelines are supplemental to those set forth in Section 6 of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

6.1 Maintenance and cleaning

Refer to the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

6.2 Cleaning programmes

Handling, packaging and processing of eggs uses a variety of equipment with sensitive electronic controls. Where wet cleaning may damage or result in the contamination of the equipment, alternative cleaning programmes should be considered.

6.3 Pest control systems

Refer to the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

6.4 Waste management

Refer to the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

6.5 Monitoring effectiveness

Refer to the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

7. ESTABLISHMENT: PERSONAL HYGIENE

Refer to the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

8. TRANSPORTATION

These principles and guidelines are supplemental to those set forth in Section 8 of the *Recommended International Code of Practice – General Principles of Food Hygiene* and, as appropriate, those set forth in *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (CAC/RCP 47 – 2001).

Eggs and egg products should be transported in a manner that will minimize breakage, damage and contamination.

Mobile containers and tankers should be cleaned and disinfected prior to being refilled.
Egg haulers (driver or individual in charge of transport to and from packing facility) should use vehicles suitable for transporting eggs, which permit easy and thorough cleaning.

Piping, connectors and valves used for filling and discharge of liquid egg should be of a suitable design and be cleaned, disinfected and stored as appropriate.

Eggs should be transferred between establishments promptly. Eggs should be maintained at an appropriate temperature, including avoiding fluctuations in temperatures that will result in condensation of water on the shell surface.

9. PRODUCT INFORMATION AND CONSUMER AWARENESS

These principles and guidelines are supplemental to those contained in Section 9 of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

9.1 Lot identification

Refer to the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

Documentation can enhance the credibility and effectiveness of the food safety control system, especially when it includes measures that permit a client to refer to their supplier on the history of a product. Labelling and record keeping also aid in the implementation of other emergency and corrective actions.

Where appropriate and practicable, a system should be in place that allows the identification of the egg layer establishment, transporter, grading/packing premises and processor where eggs and egg products were produced.

The system should be easy to audit. Records should be kept for a period of time sufficient to permit efficient traceback investigations of the eggs and/or egg products. It is important to ensure that all parties involved in this system are adequately informed and trained in its implementation.

9.2 Product information

Refer to the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

9.3 Labelling

Egg and egg products should be labelled in accordance with the Codex *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985).

Processors and food manufacturers awareness

Processors and food manufacturers that use egg products should follow labelling instructions.

9.4 Consumer education

Where appropriate, advice should be made available to consumers on the safe handling, use, preparation and consumption of eggs.

10. TRAINING

Refer to the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

GUIDELINES FOR THE DESIGN AND IMPLEMENTATION OF NATIONAL REGULATORY FOOD SAFETY ASSURANCE PROGRAMMES ASSOCIATED WITH THE USE OF VETERINARY DRUGS IN FOOD-PRODUCING ANIMALS

CAC/GL 71-2009

GUIDELINES FOR THE DESIGN AND IMPLEMENTATION OF NATIONAL REGULATORY FOOD SAFETY ASSURANCE PROGRAMMES ASSOCIATED WITH THE USE OF VETERINARY DRUGS IN FOOD-PRODUCING ANIMALS

CAC/GL 71-2009

INTRODUCTION

1. Modern food production systems should be designed and managed to ensure that the exposure of food-producing animals to veterinary drugs does not pose a risk to human health.

2. The commercial entities involved in the production and marketing of food have the primary responsibility for ensuring food safety. The role of competent authorities is to control the use of veterinary drugs and to verify that appropriate practices are being applied and effective measures are in place within the veterinary drug distribution and food production systems to provide effective protection for consumer health and ensure fair practice in the food trade, consistent with the goals of the Codex Alimentarius. All parties also have a responsibility to provide consumers with information and education to facilitate sound choice of food products of animal origin.

3. The application of a programme based on risk to all food types should provide the controls and verification consistent with the risk that the food type may pose to consumers. The application of an approach based on risk across all food groups and hazard classes should allow a more focused application of resources to those areas that are most likely to generate real human health protection gains.

4. Risk profiles for different hazards may vary by country, region, species and/or production system. The application of a control and verification assurance programme based on risk should provide the necessary basis for exporting countries to certify the safety of exported food, and for importing countries to have the confidence to accept such consignments.

5. It is recognized that developing countries in particular may need a transition period and/or technical assistance regarding the full implementation of these Guidelines.

SCOPE

6. This guide is intended to provide the overarching principles and guidance for governments on the design and implementation of national and trade-related food safety assurance programmes for residues of veterinary drugs. The current and future appendixes to this

guide may provide a further refinement of guidance on issues that may be relevant to the control and verification programmes for products from certain species. These appendixes should be read in conjunction with the principles outlined in this guide.

GENERAL PRINCIPLES

7. Programmes for the control of residues of veterinary drugs in foods should:

   i. be based on risk using realistic risk profiles assessed as reasonably likely to be associated with food derived from the relevant productions system(s);
   ii. be prevention-focused, based on the realistic risk profiles associated with the probable or known use of approved, non-approved and prohibited veterinary drugs in the production system;
   iii. include regulatory measures proportionate to the relative human health risk associated with these hazards compared with other food-associated hazards;
   iv. ensure all parties involved in the production, marketing and processing system of the animals and/or the food products derived from them are held accountable to ensure that unsafe animal products will not be sold as a result of their action or inaction;
   v. recognize that pre-harvest controls and practices are the primary means for ensuring safe food;
   vi. recognize that the primary role of audits and sampling programmes is to verify the implementation and effectiveness of the pre-harvest controls and practices;
   vii. focus on system- and population-based assurances; and
   viii. be cost-effective and have the support of stakeholders.

8. It should be recognized that veterinary drugs are regulated in many countries for a variety of reasons, such as animal health, animal welfare and protection of the environment. Where these uses and the related standards do not fall under the mandate of the Codex Alimentarius Commission, they should be clearly identified and justified where, for reason of efficiency, they form part of the competent authority's residue control programme.

9. The Codex Alimentarius Commission's recommended sampling procedures for residues of veterinary drugs in food are exempted from the general sampling procedures of food commodities developed by the Codex Committee on Methods of Analysis and Sampling. Accordingly, these Guidelines include sampling procedures relevant for the entire control programme.

10. The safety of foods is achieved by the implementation of appropriate rules applied from primary production or import to retail or export and requires the participation of all parties involved. Competent authorities should verify correct implementation of programmes and, where necessary, if action has been taken.

11. The reliability of laboratory results is important for the decision-making of competent authorities. Thus, official laboratories should use methods validated as fit for purpose and work under internationally accepted (e.g. ISO 17025) quality management principles.

12. A control programme designed and implemented according to these Guidelines provide reassurance for importing countries to accept consignments certified as safe by the exporting country.

APPROACH BASED ON RISK

13. An approach based on risk applied across the entire production chain and on all food groups and potential hazards will allow competent authorities to focus application of resources to areas of highest risk that are most likely to have an impact on consumer health protection.

14. Continuous application of good practices and regular control contribute more significantly to food safety than end-product testing.

15. Residues may exert an adverse effect on consumers in a number of ways, such as:
    (a) chronic toxicological adverse effects;
    (b) acute pharmacological effects on consumers and on the microflora of the gastrointestinal tract of consumers;
    (c) allergic reactions.

16. Different types of controls and monitoring programme may be justified where the risk assessment identifies one or more of these other end-points as being significant for human health. Detections of non-compliant residues (e.g. those exceeding applicable maximum residue levels [MRLs]) justify regulatory follow-up.

17. Animals and/or production systems can be exposed to a variety of veterinary drugs and other chemicals that may as a result be present in the products derived from them. Their importance for consumer health protection, however, varies with type and source.

18. An understanding of the circumstances required for each veterinary drug input actually to pose a risk to consumers of animal products, along with an estimate of the relative likelihood of this occurring, is essential to determine the appropriate controls and verification programmes that should be included in the design of national residue control and verification programmes.

19. The application of a control and verification programme based on risk should provide the necessary basis for exporting countries to certify, where required, the safety of exported food, and for importing countries, subject to any additional assessment they deem necessary, to accept such consignments.

20. The same principles should apply to export assurance programmes as are applied to the design and implementation of national assurance programmes.

DEFINITIONS (FOR THE PURPOSES OF THESE GUIDELINES)

Competent authority (authorities) means the official government organization or agency (agencies) having jurisdiction.[1]

Approved means officially authorized or recognized by a competent authority.

Based on risk means focused on and proportionate to an estimate of the probability and severity of an adverse effect occurring in consumers.

Risk profiles are defined in the *Procedural Manual*. For veterinary drugs, they relate a production system to a potential consumer health risk. They are the basis for approvals and use restrictions.

System verification means obtaining overall information on the extent of application of the practices and controls.

Risk-targeted verification programmes means inspection/audit and/or sampling/laboratory analysis of specific suppliers or products aimed at the detection of non-compliance.

Non-biased sampling refers to the random sampling of specified populations to provide information about the occurrence of residue non-compliances, typically on an annual, national basis. Compounds selected for non-biased sampling are usually based on risk profiles and the availability of laboratory methods suitable for regulatory purposes. The results of non-biased sampling are a measure of the effectiveness and appropriateness of the controls and practices within a wider segment of the production system.

Survey refers to the collection of additional data aimed at the investigation of residues linked to a specific veterinary drug use or production type.

Withdrawal time/withholding time (food harvest restriction) are defined in the *Glossary of terms and definitions (residues of veterinary drugs in foods)* (CAC/MISC 5-1993). A period of time may also be represented by a combination of events or other factors.

Production system means the methods or activities used to produce food for human consumption.

Quality control (in residue laboratories) means monitoring those factors associated with the analysis of a sample by a tester.

Quality assurance (in residue laboratories) means independent review to ensure that the analytical programme is performing in an acceptable manner.

Quality management system ensures that a laboratory is managed and operated in a manner that meets the requirements of an internationally recognized quality standard to produce quality data and results (e.g. ISO/IEC 17025:2005).

[1] Definition used in the *Guidelines for the production, processing, labelling and marketing of organically produced foods* (CAC/GL 32-1999).

REGULATORY FRAMEWORK

Roles

21. Business operators/commercial entities involved in the production, processing and marketing of food have the primary responsibility for ensuring food safety.

22. Competent authorities regulate the use of veterinary drugs, verify that appropriate practices are applied and that effective measures are in place within the veterinary drug distribution and food production system to provide effective protection of consumers and facilitate trade, consistent with the goals of the Codex Alimentarius.

23. The competent authority responsible for providing consumer assurances for foods must ensure that it has sufficient knowledge of and control over veterinary drugs that are being sold and used within the production systems and that it has sufficient knowledge of food safety.

Approval by competent authority

Criteria

24. Appropriate official approval criteria should be established. These criteria may include the acceptance of the assessments of other recognized competent authorities where use patterns are likely to be similar.

25. Approval systems should:
(a) require an evaluation of the human safety of residues of the veterinary drug relying on a risk analysis and establishing, where appropriate, MRLs;
(b) take into account the needs of the producers in order to reduce the temptation to use unapproved veterinary drugs or prohibited substances.

26. Approval systems should take into account that risk profiles and management options may vary substantially among production systems and regions.

Approval restrictions

27. The conditions for the approval of veterinary drugs should be specified in the appropriate national regulations.

28. To mitigate potential risk, restrictions may be imposed on:
(a) formulations;
(b) criteria of use (e.g. time, species) and route of administration;
(c) indications for use; and
(d) withdrawal time/withholding time/food harvest restriction.

National register

29. All formulations of veterinary drugs approved in a country should be recorded in a national register.

Information on veterinary drugs

30. Information and/or education programmes on suitable use to provide effective treatment while affording protection of consumers should be provided for each approved veterinary product formulation.

Sale and use

31. National/regional regulations should establish which veterinary drugs may be sold domestically and how these may be used. Formulations not recorded in the national register should not be used and sanctions should be in place to act as a deterrent against such use.

32. It may be appropriate, where justified by a relevant risk profile for competent authorities, to impose additional conditions on the sale and use of certain veterinary drugs to ensure appropriate use and to prevent misuse or abuse.

33. Sale and use conditions may include:
(a) requiring all sales to be subject to a prescription from a veterinarian or other professional with approved competencies;
(b) restricting administration to individuals or professionals with approved competencies;
(c) requiring all treated animals/production systems to be identified in specified ways;
(d) requiring all uses to be recorded and/or notified to a unified database(s).

34. Efficacy and the necessity of use conditions should be regularly reviewed against the local risk profile. In doing this, it should be considered that the non-availability of necessary treatments may encourage use of non-approved veterinary drugs or prohibited substances.

35. Competent authorities may establish legislation/regulation that allows, as an exception, the use of non-approved veterinary drugs off-label/extra label in accordance with direct and written veterinary advice and oversight. Such legislation should be consistent with national and/or international guidance and technical information on this issue.

36. In animals from which milk, eggs or honey, respectively, are collected for human consumption, only veterinary drugs specifically approved for use in lactating animals, laying birds and honey bees should be used. Specific exemptions may be made for off-label/extra label use.

Responsibilities of business operators (best practice guidance)

37. Producers should only use veterinary drugs that have been approved for use in food-producing animals. Non-approved veterinary drugs should not be used. Veterinary drugs should be used strictly in accordance with the officially approved/recognized instructions. Off-label use of veterinary drugs should only be permitted in accordance with direct and written advice from a veterinarian in accordance with national authorities' laws and regulations. Such advice should be consistent with national and/or international guidance documents and technical information on this issue.

38. Producers should be encouraged to seek the advice of veterinarians or other competent professionals on the application of the correct withdrawal time where the label direction for use may not be available or may not be clear.

39. Records should be kept of all details of the treatment and the withdrawal time/withholding time required before the animal or product from the animal can be harvested for human consumption.

40. Business operators (whether primary producers or others) should be required to communicate food harvesting restrictions (withdrawal/withholding times) still in place on the animal or animal product at the time of sale to subsequent purchasers of the animal(s).

41. Processors should be required to ensure that they only purchase and/or process animals and/or animal products from suppliers (whether primary producers or others) that can credibly attest to the suitability/safety of the animal or animal product for the purpose intended.

42. Producers should have appropriate on-farm food safety assurance measures in place with respect to the use of, and/or exposure of food-producing animals to, veterinary drugs. All workers directly involved with the animals should be familiar with these measures.

43. Producers should be able to identify all food-producing animals, or lots of these animals, that have been treated with or exposed to veterinary drugs to ensure compliance with withdrawal/withholding times.

44. Continuous food safety assurance measures such as record-keeping should ensure that products (e.g. milk, eggs, honey) are harvested only if appropriate withdrawal/withholding times have been followed.

45. Treated or exposed animals for which the withdrawal time/withholding time has not elapsed should be kept separate from animals that have not been treated, or be positively identified to reduce the potential for mistakes.

46. Products from animals under harvest restrictions should be handled in such a way that ensures their product does not mix with that being harvested for human consumption. Any equipment likely to be contaminated should be adequately cleaned prior to being used on other animals.

VERIFICATION PROGRAMMES

Purpose

47. A verification programme that combines audits/inspection of various control points and point-of-harvest testing should be implemented. This approach will reduce reliance on chemical analyses and provide a higher degree of assurance.

48. The overall objective of the verification programme is to provide an appropriate degree of confidence that the practices and controls in place are adequate and being applied to the extent necessary to ensure the health of consumers of animal products. It will therefore attempt to ensure that exposure to residues in excess of the acceptable daily intake (ADI) rarely occurs.

49. Verification programmes may contribute to the:
(a) verification of assumptions made in the registration process;
(b) identification of unacceptable production, marketing and/or chains of advice;
(c) evaluation of the effectiveness of veterinary drug label information as it relates to food safety;
(d) evaluation of the effectiveness of education or risk reduction programmes;
(e) evaluation of quality management systems;
(f) verification of implementation and effectiveness of corrective actions.

General design principles

50. Verification programmes should cover, as appropriate, the entire food chain. A combined system of inspection/audits and sampling/laboratory analysis should be implemented. To provide the most effective control, the frequency, point and type of activity should be based on an assessment of the risk.

51. Verification programmes can be classified as follows according to objective and criteria applied to the sample selection:
(a) system verification programmes;
(b) risk-targeted verification programmes;
(c) surveys;
(d) port-of-entry testing programmes.

52. Verification programmes may focus on assessing the:
(a) effectiveness of a control system; and/or
(b) compliance by individuals or groups.

System and targeted verification programme design

53. Verification programmes should:
(a) define their purpose;
(b) identify the population being sampled;
(c) state whether the sampling is non-biased or targeted (directed), and
- base the number of samples for non-biased sampling protocols on statistics,
- pre-determine targeting criteria to direct sampling;

(d) pre-determine the criteria to be applied to the analysis of the results;
(e) define sampling and identification procedures that allow tracing each sample back to its origin and independent confirmation of the finding in case of dispute.

Risk profiling

54. It is the responsibility of the competent authorities to determine the risk profiles for their country and/or production system.

55. The frequency and intensity of verification or inspection/audit of each drug residue chosen to be monitored under the system verification programme should depend on the veterinary drug and use profile.

56. Risk profile considerations concerning veterinary drugs include:
(a) the type of hazard presented;
(b) the class and severity of the adverse human health effect associated with the residue (e.g. chronic toxicity, acute pharmacological, allergic reaction or microbiological disturbance);
(c) the use and/or production circumstances required to produce residues and the likelihood of these occurring in foods derived from the production system at concentrations and in frequencies presenting a risk to consumer health;
(d) the dietary consumption required for the residue to give rise to a realistic consumer health risk.

57. Competent authorities should attempt to make realistic estimates of the types, quantities and use patterns of veterinary drugs in their jurisdiction.

58. Subsequently, the following should be considered:
(a) circumstances required for each veterinary drug to cause an adverse health impact on consumers;
(b) likelihood of such circumstances occurring.

59. When considering and ranking the residues associated with the veterinary drugs likely to be present at some stage in the production system, potential sources and exposure pathways should be described.

60. The following sources of veterinary drug residues should be considered:
(a) veterinary drugs authorized in the jurisdiction of the competent authority;
(b) veterinary drugs that are known to be, or suspected of being, misused.

61. The exposure pathways of veterinary drug residues should be considered:
(a) intended, e.g. direct administration to the animals;
(b) indirect administration to the animals through addition to feed or water;
(c) unintended contamination via e.g. feed, water or the environment.

62. Competent authorities should, as appropriate to the risk profiles in the country and/or production system, consider the following potential pre-harvest control points for audit/inspection in the verification programme:
(a) the sellers and purchasers of veterinary drugs, to verify what is being sold and how it is being marketed;
(b) the users of veterinary drugs (including farmers, veterinarians and feed compounders), to verify how drugs are actually being used in the production systems, e.g. according to label, what records are being kept and how the treatment status of animals is identified;

(c) the animal and animal product distributors, to verify that any food harvest restrictions associated with the animal or product are effectively communicated;
(d) the assurance systems used by processors and/or producers, to ensure the suitability of the animals or product they are being supplied with for the purposes they intend using it for.

CHOICE OF VERIFICATION PROGRAMME

System verification programmes

63. In setting up system verification programmes, the following should be considered:
(a) examination of the relevant control points of the control system;
(b) non-biased sampling of a specified population with broadly similar attributes so that the results can be used to derive a statistical confidence as to the extent of control present in that population as a whole.

64. System verification programmes can focus on the degree of application of specific controls in the process or can focus on monitoring the residues in the animals/products at or close to the point of harvest.

65. Non-biased sampling programmes should be used in order to find out whether one of the controls within the system needs adjusting. They should not be relied upon for product evaluation.

66. Where the competent authority has linked the approval of a veterinary drug to particular use conditions/restrictions in order to avoid misuse or abuse, the appropriateness of the use conditions/use restrictions should be regularly verified with risk-targeted verification programmes as to their efficacy and necessity to manage the risk posed by the use of the veterinary drug.

67. Generally, non-biased sampling protocols are not efficient in detecting low incidences of non-compliance. Where such incidences are a potential significant risk to human health, other assurance programmes should be employed.

Risk-targeted verification programmes

68. In setting up risk-targeted verification programmes the following should be considered:
(a) previous performance, history of non-compliance;
(b) the quality management components usually relied on;
(c) potential risk factors that may be correlated with an increased use of veterinary drugs such as:
- high somatic cell counts in milk, or
- significant ante- or post-mortem findings, e.g. injection site lesions or resolving pathology;

(d) any other information linked to non-compliance and drug use.

69. Competent authorities may complement the risk-targeted pre-harvest verification programmes with established risk-targeted post-harvest verification programmes.

Surveys

70. Surveys may be performed to:
(a) assess the initial situation before a verification programme is started;
(b) evaluate the efficiency and appropriateness of specific aspects of control programmes;
(c) monitor the impact that variables, such as location, season or age, may have on the presence, absence or concentration of a residue.

Review

71. Control and verification programmes should be regularly reviewed to ensure their continued efficacy and/or necessity, as well as to review the potential impact of changes to the risk profiles.

72. Where a significant incidence of non-compliance is identified in any one year and consequent changes to the control programme implemented, a higher standard of verification may be appropriate until the effectiveness of the corrective actions has been demonstrated. Some of the selected lower risk profile veterinary drugs should be considered for rotation in and out of the programme based on history of compliance to ensure that the scope is as wide as possible.

SAMPLE TAKING

General principles

73. Appropriate mechanisms to prevent possible bias occurring in both the selection and taking of samples should be put in place.

74. Ideally, samples should be taken before animals and/or products are commingled with animals or product from other suppliers.

Traceability/product tracing

75. Competent authorities should ensure that all samples can, throughout the sampling, storing, shipping, analysis and reporting, be traced back to their origin.

76. Each sample needs to be clearly identified so that appropriate follow-on actions can be applied in case of non-compliant results.

77. If subunits of a consignment are sampled, care should be taken to identify those subunits clearly. Sufficient samples should be taken to allow for unprocessed subunits to be retained, allowing possible independent confirmation of the findings.

STATISTICAL CONSIDERATIONS

General

78. The number of samples for system verification programmes can be statistically predetermined (see Appendix A for additional guidance).

79. In designing a sampling protocol, it is essential to define both the purpose of the programme and the population of interest. It is also important to define the criteria to be applied when analysing the results with respect to the need/desirability for any further action, and especially how such criteria and actions directly relate to the protection of human health.

80. Ultimately, "a population" made up of "units of food consumed" is the most relevant to human health. However, as it is the application of appropriate pre-harvest practices and controls that ensures food safety, a sampling strategy that verifies both the appropriateness and extent of compliance of these pre-harvest practices and controls can be used to provide appropriate assurances that the health of consumers is unlikely to be negatively affected. Generally, the population of interest for targeting pre-harvest compliance/appropriateness verification information will be those population units to which common practices and controls should be applied such as:
(a) the seller of the veterinary drug input into the production system;
(b) the producer;
(c) the supplier of the animals or animal product to the processor; or
(d) the processor.

81. However, because the potential consequences to human health are much larger when large production units (farms) are out of control, the usual pre-harvest population randomly sampled is a standardized unit of production sold at any one time, e.g. individual animal, vat of milk, barrel of honey, or defined weight of aquaculture product. In this way, the larger producers/suppliers should effectively have a greater probability of being sampled while still maintaining the randomness of the sampling protocol.

82. Generally, conclusions will be drawn from the prevalence, or lack thereof, of non-complying results in the units sampled during the production season or calendar year. However, where problems are found during the course of the production season, corrective actions may have already been applied and have started to have a positive effect well before the end of production season or calendar year. For small populations, or for either low risk or reasonably stable exposure scenarios, several production seasons or calendar years may be used/needed to collect the number of samples statistically determined to give the required confidence.

83. Where it is possible to further refine and describe the affected population associated with defined risk factors such as season, region or specific type of production, then a correlation of the sampling protocol to such a co-variable may be justified.

84. The point at which a sample is taken depends on the objective of the specific programme. Where the objective is to verify the effectiveness of controls at the supplier stage, samples are generally taken at the point of sale/harvest in order to correlate the unit sampled with a supplier or producer.

85. On-farm sampling may also be used as part of a pre-harvest quality assurance programme or where there are concerns associated with the possible use of substances prohibited by the competent authority.

86. Where the objective is to verify the overall effectiveness of a system at ensuring the general population's exposure is less than the ADI, then multiple sample units can be combined before analysis, or commingled product sampled and analysed.

87. Where the objective is to verify the credibility and effectiveness of the control and verification programmes present in an exporting country, samples may be taken from standardized units of export at the port of entry. Such secondary verification programmes have quite different design considerations with respect to their objective, the population of interest and the type of response to any identified incidence of non-compliance. The statistical tables in Appendix A are not relevant to such programmes and the number of samples should reflect the importing country's confidence in the performance of the exporting country.

Retention of consignments during laboratory analysis

88. Competent authorities should not routinely retain lots of production associated with randomly selected samples pending the availability of the analytical results. Competent authorities may routinely retain lots of production where it is considered likely that a risk-targeted test will produce non-compliant results that present a potential risk for consumer health.

Result interpretation

89. A greater degree of assurance is achieved if verification programmes such as statistically based systems involving non-biased sampling and risk-targeted verification programmes (e.g. specific suppliers or products) are operated in parallel.

90. The results of risk-targeted verification programmes alone do not allow conclusions on the exposure of the general population with residues of veterinary drugs.

91. Conclusions on the exposure of the general population can be drawn from the combining the results of:
(a) statistically based system verification programmes involving non-biased sampling; and
(b) risk-targeted verification programmes.

Port-of-entry testing programmes (specific requirements)

92. Competent authorities should consider port-of-entry testing programmes only as a secondary system verification tool.

93. The matrices used in port-of-entry programmes may vary from those used for national verification programmes.

94. Except where a risk to health is suspected or detected, certified product should be subjected to non-biased sampling and release programmes at a frequency determined by the importing country based on the exporting country's record of compliance. Consignments of animal products tend to be heterogeneous by nature and will often be made up from a variety of animals, farms and processing dates. Results will reflect

the performance of the national control and verification system as a whole and should not be extrapolated to specific judgements on other units within the consignment except where a common pre-harvest risk factor is shared and a direct health threat is indicated.

95. The application of directed or targeted sampling in port-of-entry sampling programmes is only appropriate where it is known or suspected that products share the same risk profile.

96. However, following the detection of non-compliant results during port-of-entry programmes, importing countries may increase the overall frequency of testing of directly related food of animal origin from the exporting country for a period as an added verification of the effectiveness of any additional controls being implemented by the exporting country.

97. In the interpretation of laboratory results of consignments of animal products, it should be considered that these are made up of commingled product from a variety of animals, farms and processing dates and, therefore, heterogeneous. Because of this, results should not be taken to judge other units of a consignment except where units share a common pre-harvest risk factor and where a direct risk to health is suspected or detected.

98. Results of port-of-entry testing programmes should only be communicated if confirmed with methods fully validated for the specific matrix and analyte.

99. Laboratory reports on non-compliant results should include:
(a) a description of the method used;
(b) performance characteristics of the method of analysis (including the confidence interval of the result).

100. Laboratory reports on non-compliant results should be distributed to all parties affected by the result (e.g. the owner of the consignment and the certifying competent authority of the exporting country).

101. Competent authorities of importing countries should regularly provide exporting countries with the results of their verification programmes, including information for purposes of traceability/product tracing.

102. In cases of non-compliance with the food safety parameters, competent authorities from the exporting country should conduct a trace-back, apply appropriate corrective actions and then provide a summary of these to the importing country.

103. Where the type, incidence and/or frequency of non-compliance detected raises concerns as to whether the imports are meeting the standard of human health protection required by the importing country, then additional assurances may be requested.

104. The importing country may also choose to increase the frequency of port-of-entry verification to confirm that the assurances given are in fact addressing the problem.

105. Where residues of substances that should not be used in food-producing animals in either the exporting or the importing country are detected in port-of-entry testing, both competent authorities should cooperate in order to identify potentially similarly affected food of animal origin and to resolve any potential wider control problem.

106. Resolution of such problems will require the originating country to conduct an analysis to determine the possible source of such residues, the identification of deficiencies within the country's own control and monitoring system, and subsequent application of appropriate additional controls and measures to address the situation.

107. In cases where the exporting country is a less-developed country, consideration should be given by the importing country to the provision of technical assistance to help resolve the issue.

108. The application of new sampling and testing methods may reveal the presence of types and concentrations of residues previously unknown to exist by one or both parties. The determination of the source of such residues and their significance may take some time.

109. Where the presence of such residues is associated with previously accepted production practices, the implementation of changes, should these be deemed necessary, may require an extended period of time for capacity building.

REGULATORY ACTION

Investigation of non-compliances

110. Competent authorities should investigate each non-compliant result to ascertain the contributing factors that led to its occurrence and the systemic significance of the identified case.

111. An attempt should be made to identify the substances and the consumer health significance of their occurrence in food.

112. When an animal tissue/food contains residues in excess of the relevant MRL at the point of harvest, the following possibilities should be considered:

(a) the veterinary drug was not used according to label or prescription instructions;
(b) a non-authorized veterinary drug or formulation was used;
(c) the recommended withholding time was not observed or is not appropriate;
(d) treated and non-treated animals were commingled;
(e) unintended exposure to feed, water or contaminated environment occurred;
(f) the food is part of the statistically predictable small percentage of animals with residues in excess of the MRL even when the required withdrawal period has elapsed;
(g) sample contamination, analytical method problems or analytical error.

113. Laboratories should report all suspect positive samples that they have not been able to confirm positively using established confirmation criteria. This will allow the competent authority to identify possible patterns of non-compliance.

Measures in case of non-compliance: conduct

114. Competent authorities should adjust the scale and type of response to identified non-compliances to the relative importance that the respective hazard has for consumer health protection.

115. Competent authorities should take proportionate action when considering whether the non-compliance is the result of negligence or intent.

116. Competent authorities should, in cases of isolated mistakes due to ignorance or negligence, require that appropriate advice and training measures be followed.

117. In the case of proven negligence or intent, punitive measures in line with the Codex member's penal system should be considered (e.g. condemnations, fines, movement controls, etc.) to act as a deterrent.

118. Competent authorities should, in cases of widespread non-compliance, advise stakeholders and motivate the respective business sector to initiate the necessary changes.

119. Competent authorities should verify that appropriate corrective action is taken and monitor the success of these measures through inspection/audits and/or sampling/ laboratory analysis.

Measures in case of non-compliance: product

120. Unsafe product should not be passed as fit for human consumption and should be disposed of appropriately.

121. Where the results of samples taken on-farm for risk-targeted verification programmes do not provide the necessary confidence that the rest of the lot has been produced using appropriate practices and controls, the lot should not be passed for human consumption until sufficient information can be generated to provide the required degree of assurance as to its safety.

122. Where the results indicate there is a direct risk to consumer health, an attempt should be made to trace and remove all similarly affected products.

123. In non-biased sampling programmes, the unidentified proportion may represent a much greater potential threat to consumers than the identified proportion. Accordingly, any actions taken with respect to the identified non-compliant lot are less significant than the actions taken on the system as a whole.

124. When pre-harvest controls are not carried out or are unreliable owing to a high incidence of misuse of veterinary drugs, more frequent post-harvest verification may be appropriate to provide the required degree of consumer assurance. This should be regarded as an interim measure only until the appropriate corrective actions to the control programme have been put in place and subsequently demonstrated to be effective.

Corrective action in cases of non-compliance

125. Depending on the results of such investigations, local and/or systemic corrective actions may be considered appropriate to prevent reoccurrence.

126. Where the investigation of non-compliances indicates that use and distribution provisions for the substance(s) are inappropriate, competent authorities should take appropriate corrective action by modifying approval and distribution rules.

127. Where the investigation of non-compliances identifies local or systemic control failures, competent authorities should ensure that appropriate corrective action is taken at the relevant points.

128. The competent authority should verify that the measures are taken. Respective action should be proportionate in time and intensity to the consumer health hazard, scale and frequency of the non-compliance.

129. In cases where the failure lies outside the direct control of the business operator, the competent authority should prevent repetition of the failure by applying appropriate measures at the relevant control point.

INTERACTION BETWEEN THE CONTROL PROGRAMMES OF TWO COMPETENT AUTHORITIES

130. Competent authorities should cooperate to ensure that consumer health in all countries is protected.

131. This cooperation aims at achieving greater assurance than can be achieved through sole reliance on port-of-entry inspection programmes.

132. Trading countries should exchange copies of their control and verification programmes along with the results of these programmes from preceding years on a regular basis.

133. In order to facilitate trade from developing countries, longer transition periods and technical assistance regarding all aspects of a residue control programme should be considered.

ANALYTICAL METHODS FOR RESIDUE CONTROL

GENERAL CONSIDERATIONS ON ANALYTICAL METHODS FOR RESIDUE CONTROL

Introduction

134. Analytical methods used to determine compliance with the maximum residue limit for veterinary drugs (MRLVD) should be suitable for routine use by competent authorities of member governments for their testing programmes for all residues of veterinary drugs and substances that may be used as veterinary drugs. This includes certain pesticides that have veterinary uses and that may be present as residues in commodities. These methods may be used for the analysis of randomly selected survey samples in a national regulatory control programme to determine compliance with established MRLVDs, for the analysis of targeted samples when there is reason to suspect non-compliance with MRLVDs, or for the collection of data for use in estimation of intake.

135. Methods may also be required in regulatory control programmes for the detection of residues of substances for which ADIs and MRLVDs have not been established by the Codex Alimentarius Commission. For some substances, the toxicological evaluation leads to the conclusion that an ADI or MRLVD should not be established. For such substances, the determination of the lowest concentration at which the residue can be detected and the identity confirmed in a food is a primary concern in the method validation. Performance characteristics related to quantitative analyses may be less critical for such substances, where detection and confirmation of the presence of the substance as a residue is the major issue. Confirmation of identity of a residue is generally based on the comparison of a set of characteristics of a detected substance with those of a known standard of the suspected residue.

136. Suitably validated methods are not always available for all possible combinations of veterinary drug residues and foods. Competent authorities responsible for designing national residue control programmes should ensure that appropriate residue methods of analysis are used to ensure compliance with Codex MRLVDs. This may sometimes require the development and validation of a new analytical method or the extension of the validation of an existing analytical method to include a new combination of analyte and matrix. Appropriate regulatory action may then be taken against adulterated products, consistent with the reliability of the analytical data.

Integrating analytical methods for residue control

137. Analytical methods for veterinary drug residues in foods must reliably detect the presence of an analyte of interest, determine its concentration and correctly identify the analyte. When residues resulting from the use of approved veterinary drugs are detected at concentrations above an established MRLVD, the results should be confirmed before regulatory enforcement actions are taken. In the case of substances that have been banned from use in food-producing animals by a competent authority, or for which an ADI and MRLVDs have not been established for toxicological reasons, the confirmed presence of residues at any concentration in a food may result in regulatory action.

138. The principal performance attributes of analytical methods used in residue control programmes are dependent on whether a method is intended simply to detect, to quantify or to confirm the presence of a target residue. Completion of a full collaborative study[2] is not a requirement for recognition of a method to be placed in one of these three categories.

139. Screening methods are qualitative or semi-quantitative in nature and are used as screening methods to identify the presence (or absence) of samples from a herd or lot that may contain residues that exceed an MRLVD or other regulatory action limit established by a competent authority. These methods may not provide adequate information to define accurately the concentration present or to confirm the structure of a residue but may be used to determine quickly which products require further testing and which can be released. They may be applied to a sample at the point of entry into the food chain, site of inspection or on receipt of a sample at the laboratory to determine if the sample contains residues that may exceed a regulatory limit. Such methods usually provide greater analytical efficiency, can sometimes be performed in non-laboratory environments and may be less expensive for use in regulatory control programmes than tests conducted within a laboratory. Use of screening methods allows the laboratory resources to be focused on analysis of the presumptive positive (suspect) samples identified using this test. These methods, which should have a defined and low false negative rate, should not be used alone for residue control purposes on official samples without the availability of suitably validated quantitative and/or confirmatory methods to apply to any samples identified as potentially not in compliance with an MRLVD.

140. Quantitative methods provide quantitative information that may be used to determine if residues in a particular sample exceed an MRLVD or other regulatory action limit, but do not provide unequivocal confirmation of the identity of the residue. Such methods that provide quantitative results must perform in good statistical control within the analytical range that brackets the MRLVD or regulatory action limit.

141. Confirmatory methods provide unequivocal confirmation of the identity of the residue and may also confirm the quantity present. Confirmatory methods are the most definitive and are frequently based on combined chromatographic and mass spectrometric techniques, such as liquid chromatography–mass spectrometry (LC/MS). When used for confirmation of residue identity, such methods should provide reliable structural information within established statistical limits. When the confirmatory method does not provide quantitative information, the quantification result of the original quantitative method should be verified by analysis of replicate test portions using the original quantitative method or a suitably validated alternative quantitative method.

142. These three categories of methods – screening, quantitative and confirmatory – often share some performance characteristics. In addition, each category has other specific

[2] Horwitz, W. 1995. Protocol for the design, conduct and interpretation of method performance studies. *Pure and Applied Chemistry*, 67: 331–343.

considerations. Understanding the relationship between these three categories of methods is important in the development and operation of a balanced residue control programme. These three categories of methods may be applied sequentially in a residue control programme.

143. Samples that test "positive" with the screening method are considered suspect and are usually designated for further laboratory testing using more definitive methods. This could include repeat testing of replicate test portions with a screening method, but typically quantitative and/or confirmatory methods are used in the laboratory to establish that the sample does contain residues in excess of the regulatory limit. Such tests should be conducted on new test portions of the sample material used in the initial screening test to confirm that the analyte detected in the initial test is definitely the suspected compound and that the MRLVD (or other regulatory action limit established by the competent authority) has indeed been exceeded. The performance attributes, or characteristics, that must be determined during method validation for each type of method – screening, quantitative, confirmatory – are presented in the section "Attributes of analytical methods for residues of veterinary drugs in foods" (below).

Consideration for selection and validation of analytical methods

Identification of method requirements

Method scope

144. The intended purpose of the method is usually defined in a statement of *scope* that defines the analytes (residues), the matrices (tissues, milk, honey, etc.) and the concentration range to which the method applies. It also states whether the method is intended for screening, quantitative or confirmatory use. The competent authority must establish an appropriate *marker residue* for each drug for which an MRLVD has been established and should also designate a preferred *target tissue* to be sampled for testing.

Marker residue

145. The MRLVD is expressed in terms of the marker residue, which may be the parent drug, a major metabolite, a sum of parent drug and/or metabolites or a reaction product formed from the drug residues during analysis. In some cases, the parent drug or the metabolite may be present in the form of a bound residue that requires chemical or enzymatic treatment or incubation to be released for analysis. It is important that the marker residue should, whenever possible, provide unequivocal evidence of exposure to the drug. In rare situations, it is necessary to use compounds as marker residues that may also result from sources other than exposure to the drug. In such cases, additional information is required in order to ascertain that the probable source of the residue is exposure to the drug. An example of such a situation is the use of semi-carbazide, which may occur from other sources, as a marker residue for the drug nitrofurazone.

Target tissue

146. The usual target tissue selected by competent authorities to be tested for veterinary drug residues in a residue control programme is the edible tissue in which residues of the marker residue occur at the highest concentrations and are most persistent. For lipophilic substances, the usual target tissue is fat. For most other substances, the target tissue is liver or kidney, depending on the primary route of elimination. One of these tissues is usually the target tissue designated for use in testing of domestically produced foods of animal origin. The organ tissues may not be available for testing imported products, so muscle tissue may be the target tissue for testing of these commodities. In some cases, such as drugs that are normally administered as injectable formulations, testing of muscle tissue from suspected injection sites may be required. The regulatory programme manager and the laboratory managers need to identify clearly the testing objectives and the analytical requirements required in terms of target tissues, marker residues and concentration ranges to ensure suitable methods are used in the regulatory control programme. In certain situations, competent authorities may also use biological fluids such as urine or serum to indicate the presence or absence of residues of interest.

Implementing other Codex Alimentarius Commission guidelines

147. The Codex Alimentarius Commission has issued guidelines for laboratories involved in the import/export testing of foods,[3] which recommend that such laboratories should:

(a) use internal quality control procedures, such as those described in the "Harmonized guidelines for internal quality control in analytical chemistry laboratories";[4]
(b) participate in appropriate proficiency testing schemes for food analysis that conform to the requirement laid out in "The international harmonized protocol for proficiency testing of chemical analytical laboratories";[5]
(c) Comply with the general criteria for testing laboratories laid down in ISO/IEC Guide 17025:2005 "General requirements for the competence of calibration and testing laboratories"; and
(d) Whenever available, use methods that have been validated according to the principles laid down by the Codex Alimentarius Commission.

148. Methods used for analyses of veterinary drug residues in foods should be capable of detecting the compounds included in the residue control programme. The analytical recovery and precision for the target foodstuffs should meet the criteria stated elsewhere in this document. The methods should be used within an established laboratory quality management system that is consistent with the principles in the document on internal quality control referenced above. When methods that have not been subjected to a multilaboratory performance trial are used in a regulatory programme for control of veterinary drug residues in foods, the quality control and

[3] *Guidelines for the assessment of the competence of testing laboratories involved in the import and export control of food* (CAC/GL 27-1997).

[4] Thompson, M. & Wood, R. 1995. Harmonized guidelines for internal quality control in analytical chemistry laboratories. *Pure and Applied Chemistry*, 67(4): 649–666.

[5] Thompson, M., Ellison, S.L.R. & Wood, R. 2006. The international harmonized protocol for proficiency testing of chemical analytical laboratories. *Pure and Applied Chemistry*, 78(1): 145–196.

quality assurance procedures applied with these methods require careful definition, implementation and monitoring. In the case of methods that have been through multilaboratory trials, performance characteristics, such as recovery and precision, are defined through the results obtained during the study. For a method validated within a single laboratory, data must be generated to define the performance characteristics expected of the method when used by analysts within that laboratory. The ongoing performance must be monitored through the quality management system in place in the laboratory.

Method validation and fitness for purpose

149. The process of method validation is intended to demonstrate that a method is *fit for purpose*. This means that in the hands of a properly trained analyst using the specified equipment and materials, and following the procedures described in the method, reliable and consistent results can be obtained within specified statistical limits for the analysis of a sample. The validation should address the issues of marker residue, target tissue and concentration range identified by the laboratory in consultation with the residue programme manager. When the method protocol is followed, using suitable analytical standards, results within the established performance limits should be obtained on the same or equivalent sample material by a trained analyst in any experienced residue control laboratory.

150. Multilaboratory method performance studies generally satisfy the analytical requirements for use in a regulatory programme. These methods are subjected to a properly designed interlaboratory study with analysts in independent laboratories, so that different sources of reagents, materials and equipment are used by the participants.

151. Quantitative methods studied collaboratively according to the revised harmonized protocol adopted in 1995 by AOAC International, the International Union of Pure and Applied Chemistry (IUPAC) and the International Organization for Standardization (ISO) have been evaluated in a minimum of eight laboratories, unless highly complex equipment or other unusual requirements were identified (in such cases, a minimum of five participating laboratories is required).[5] Collaborative studies of qualitative methods currently require a minimum of ten participating laboratories. Collaborative studies conducted prior to 1995 completed method evaluation in a minimum of six laboratories in an acceptable, statistically designed study. These multilaboratory method performance studies generally satisfy the analytical requirements for use in a regulatory programme, as information on method performance in the hands of different analysts in different laboratories is obtained through these studies. However, relatively few of the analytical methods currently used in residue control programmes for veterinary drug residues in foods have been validated by such a multilaboratory study. Collaborative study designs are based on the analyses of coded duplicate test materials that represent the combinations of analytes, matrices and concentrations included in the scope of the method and include an independent peer review of both the study design and the results. In some situations, multilaboratory studies may be conducted that do not have the minimum number of laboratories required to qualify as a collaborative study. Such studies, when conducted using the same scientific

principles of design, evaluation and review as are applied in collaborative studies, can provide useful information on method performance in the hands of multiple analysts in different laboratories, but do not provide the same degree of statistical confidence obtained from the results of a collaborative study.

152. Multilaboratory and collaborative studies of methods usually do not encompass all possible combinations of residue, tissue and species to which the method may subsequently be applied. Methods may be extended to include related analytes, additional tissues, species or products (or combinations of these not included in the original multilaboratory study) by completing additional within-laboratory studies. Analytical results from method extension studies may require additional review before use in a regulatory programme. Whenever possible, analytical results obtained using methods that have not been validated by traditional interlaboratory study should be compared with results obtained using a method that has been validated through a collaborative or multilaboratory study or tested using sample materials from a recognized proficiency programme. The comparison should be based on a statistically acceptable study design using portions of the same (homogeneous) samples. The data from such studies should be independently reviewed by a qualified third party (such as a quality assurance [QA] unit, a peer group of regulatory scientists, auditors of national accreditation body) to determine the comparability of method performance.

153. Some residue control methods that have been demonstrated to be suitable for determining compliance with MRLVDs have a history of use in one or more expert laboratories, but have not been subjected to a formal multilaboratory study. These methods were demonstrated to be suitable at the time of initial regulatory use and have continued in use over an extended period of time either in the absence of alternative validated methods, or because they remain a preferred choice for reasons that may include use of available technology, cost, reliability and suitability for use within the constraints of a national programme. Although evidence of a formal collaborative or multilaboratory method trial is lacking, the method performance has been demonstrated through successful use and from quality control data in one or more laboratories over time.

154. Most regulatory laboratories rely on the use of veterinary drug residue methods that have not have been subjected to a multilaboratory study. Factors that have contributed to this situation include a requirement for specialized expertise or equipment, cost of such studies, lack of suitable collaborating laboratories, analyte and/or sample instability and rapidly changing technologies. While for many years the focus on equivalency of analytical results was based on the use of standardized methods that had performance characteristics defined on the basis of collaborative study, accredited laboratories now operate in an environment where it is the responsibility of the individual laboratory to demonstrate that the methods used and the analytical results produced meet performance criteria established in consultation with a client. In the absence of methods validated through interlaboratory method trials, regulatory laboratories must frequently use analytical methods that have been subjected to studies conducted within their own laboratory to characterize the method performance.

Single laboratory validation – the criteria approach

155. A guidance document on single laboratory validation of methods, "Harmonized guidelines for single-laboratory validation of methods of analysis", has been published as a technical report by the IUPAC.[6] The *Procedural Manual*[7] recognizes that interlaboratory validated methods are not always available or applicable, particularly for multianalyte/multisubstrate methods and new analytes. In such cases, methods may be validated in a single laboratory to meet the general criteria for the selection of methods of analysis, as well as the additional criteria:

(a) the method is validated according to an internationally recognized protocol (for example, the IUPAC guidelines, referenced above);

(b) use of the method is embedded in a quality management system in compliance with the ISO/IEC 17025:2005 standard or with the principles of good laboratory practice;

(c) the method should be complemented with information on accuracy, demonstrated for example by:

- regular participation in proficiency schemes, where available,
- calibration using certified reference materials, where applicable,
- recovery studies performed at the expected concentration of the analytes,
- verification of result with other validated method, where available.

156. The criteria approach, which combines a single laboratory validation model with a requirement that methods meet specific performance specifications, has been adopted by some regulatory authorities.

ATTRIBUTES OF ANALYTICAL METHODS FOR RESIDUES OF VETERINARY DRUGS IN FOODS

Introduction

157. The performance characteristics of analytical methods used to determine compliance with MRLVDs must be defined and proposed methods evaluated accordingly. This will ensure reliable analytical results and provide a secure basis for determining residues of veterinary drugs in foods for commodities in international trade. The section "General considerations of analytical methods for residue control" (above) presents a discussion of general types or categories of regulatory methods, and provides a scheme for using these analytical methods based upon their intended purpose in a regulatory framework. In the discussion below, attributes common to the three categories of methods (referred to as confirmatory, quantitative and screening methods) for determining compliance with Codex MRLVDs are presented. The additional attributes that are applicable to only one or two categories of methods are also discussed.

Method development considerations

158. The development of an analytical method requires analysts experienced in the analytical techniques to be used, as well as appropriate laboratory space, equipment and financial

[6] Thompson, M., Ellison, S.L.R. & Wood, R. 2002. Harmonized guidelines for single-laboratory validation of methods of analysis. *Pure and Applied Chemistry* 74(5): 835–855.

[7] FAO/WHO Codex Alimentarius Commission *Procedural Manual*.

support. Before initiating method development activities, the intended use and need for a method in a residue control programme should be established, including the required performance parameters. Other considerations include the required scope of the method (compound or class of compounds of interest and types of sample materials), potential interfering substances, the required performance characteristic of the measurements system, the pertinent physical and chemical properties that may influence method performance, the specificity of the desired testing system and how it will be determined, analyte and reagent stability data and purity of reagents, the acceptable operating conditions for meeting method performance factors, sample preparation guidelines, environmental factors that may influence method performance, safety considerations, and any other specific information pertinent to programme needs. In particular, stability of standards, both under normal conditions of storage and use and during processing of samples, should be assessed. Analyte stability in samples during typical conditions of sample storage prior to analysis should also be determined, including any period for which a sample may be held pending a potential re-analysis for confirmatory purposes.

159. Establishing method performance attributes is essential, as these provide the necessary information for food safety agencies to develop and manage their public health programmes. Performance attributes for analytical methods also provide a basis for good management decisions in future planning, evaluation and product disposition. For the animal health care industry, it provides a guideline for knowing exactly what performance must be achieved in developing analytical procedures. All will benefit by having well-defined analytical method performance factors. Method performance requirements will vary depending on whether the method is used for the screening, quantification or confirmation of a residue for which MRLs have been established, or for residues of a drug for which an ADI and MRLVDs have not been recommended. In the latter case, the competent authority may establish a minimum performance standard that must be met by analytical methods used for regulatory control purposes. However, when no safe concentrations of these compounds in foods have been established, the competent authority may review such limits periodically to ensure they reflect improvements in technology and analytical capability. When such limits have not been formally established by the competent authority, they are usually established de facto by the detection capabilities of the methods used in the regulatory laboratories.

Analytical performance characteristics

Performance characteristics of screening methods

160. Screening methods are usually either qualitative or semi-quantitative in nature, with the objective being to discriminate samples that contain no detectable residues above a threshold value ("negatives") from those that may contain residues above that value ("positives"). The validation strategy therefore focuses on establishing a threshold concentration above which results are "positive", determining a statistically based rate for both "false positive" and "false negative" results, testing for interferences and establishing appropriate conditions of use.

161. For screening tests, particularly those involving test kit technologies, the term "*sensitivity*" refers to the lowest concentration at which the target analyte may be reliably detected within defined statistical limits. In the AOAC Performance Tested Methods℠ Program for test kits, this is determined experimentally by testing a minimum of 30 residue-free sample materials fortified with the analyte at the target concentration. The sample materials should be from at least six different sources (that is, at least five replicates from each of at least six sources), all of which should yield a positive result when fortified at the target concentration. Three or more negative results constitute a failure of the sensitivity test. If one or two of the results are negative, the experiment should be repeated and two negative results would then constitute failure. The experiment should be repeated with known incurred material at the target concentration, if such material is available.

162. The "*selectivity*" of a screening method refers to the ability of the test to determine that samples that give a negative response are truly negative. The test must also be able to distinguish the presence of the target compound, or group of compounds, from other substances that may be present in the sample material. It is normally not as great as that of a quantitative method, because screening methods often take advantage of a structural feature common to a group or class of compounds. These methods, which generally fit into the screening methods category, are often based on microbiological growth inhibition, immunoassays or chromogenic responses that may not unambiguously identify a compound. The selectivity of a screening method may be increased when it is used as a detection system after chromatographic or other separation technique. To demonstrate a selectivity rate of at least 90 percent with 95 percent confidence (which is recommended for screening tests), 30 replicate analyses are conducted on representative blank sample matrix materials from a minimum of six different sources. All results should be negative. Additional tests for potential interferences and cross-reactivity may then be conducted by testing blank matrix material fortified with potential interfering substances, such as other drugs that might be used in animal treatment, potential environmental contaminants, drug metabolites, or chemically related compounds. Again, responses should be negative when these compounds are present at concentrations that might reasonably be expected to be present in a sample.

163. The "cut-off" or threshold for the test for a particular compound is established by conducting concentration-response experiments, typically using 30 replicates (from at least six sources) fortified at each of a series of increasing concentrations. Once the concentrations have been established where all 30 replicates give a negative response and all 30 replicates give a positive response, the experiment is repeated using the blank matrix materials fortified at four evenly spaced concentrations between the "all negative" and "all positive" concentrations. An additional set is tested at a concentration 20 percent above the "all positive" concentration. Statistical analysis of the results enables the user to establish a reliable detection concentration at the required confidence level (usually 95 percent).[8]

[8] Finney, D.J. 1978. *Statistical method in biological assay.* 3rd edition. New York, USA, MacMillan Publishing Co.

Performance characteristics for quantitative methods

164. *Selectivity*, the ability of an analytical method to detect and discriminate the signal response from a compound in the presence of other compounds that may be present in the sample material, is of particular importance in defining the performance characteristics of methods used in regulatory control programmes for veterinary drug residues in foods. There are two aspects that must be considered – the ability of the method to provide a signal response that is free from interferences from other compounds that may be present in a sample or sample extract, and the ability of the method to identify unequivocally a signal response as being exclusively related to a specific compound. For a quantitative method, the requirement is that the signal used for quantification should relate only to the target analyte and not contain contributions for coextracted materials. Chromatographic analyses based on peaks that are not fully resolved provide less reliable quantitative results. Use of element-specific detectors or detection wavelengths or mass-selective detectors that are more specific to a particular compound or structure, combined with chromatographic separation, improves the selectivity of quantitative methods for veterinary drug residues in foods.

165. In addition to the selectivity of a method, the ability of the method to provide a quantitative result that is reliable must be demonstrated. This consists of two factors:
(a) the closeness of the result to the true or accepted value for the concentration of analyte present in the sample material, expressed in terms of *accuracy*, *trueness* or *bias*; and
(b) the ability of the method to provide consistent results on replicate determinations, expressed in terms of *precision* (*repeatability* and *reproducibility*).

166. It is recommended that methods used to support Codex MRLVDs should meet the performance standards for trueness and precision listed in Table 1, where CV_A refers to the coefficient of variation determined by test portions of blank matrix fortified prior to extraction and CV_L is the overall laboratory variability, which includes a 10 percent estimate for variability of sample processing.[9]

[9] Alder, L., Holland, P.T., Lantos, J., Lee, M., MacNeil, J.D., O'Rangers, J., van Zoonen, P. & Ambrus, A. 2000. *Guidelines for single-laboratory validation of analytical methods for trace-level concentrations of organic chemicals* (available at http://www.iaea.org/trc/pest-qa_val2.htm).

TABLE 1

Performance criteria that should be met by methods suitable for use as quantitative analytical methods to support MRLVDs for residues of veterinary drugs in foods[10]

Concentration	Coefficient of variation (CV)				Trueness
	Repeatability (within-laboratory, CV_A)	Repeatability (within-laboratory, CV_L)	Reproducibility (between-laboratory, CV_A)	Reproducibility (between-laboratory, CV_L)	Range of mean % recovery
(µg/kg)	*Percentage*				
≤ 1	35	36	53	54	50–120
1 to 10	30	32	45	46	60–120
10 to 100	20	22	32	34	70–120
100 to 1 000	15	18	23	25	70–110
≥ 1 000	10	14	16	19	70–110

167. The *accuracy* of a method may be determined by analysis of a certified reference material, by comparison of results with those obtained using another method for which the performance parameters have previously been rigorously established (typically, a collaboratively studied method) or, in the absence of reference materials or methods validated by interlaboratory trial, by determination of the *recovery* of analyte fortified into known blank sample material. The determination of accuracy as recovery is frequently used in validation of methods for veterinary drug residues in foods, as both certified reference materials and methods validated by interlaboratory trial are often not available. The accuracy of a measurement is closely related to *systematic error* (analytical method bias) and analyte recovery (measured as percent recovery). The accuracy requirements of methods will vary depending upon the planned regulatory use of the results. The accuracy should be carefully characterized at concentrations near the MRLVD or target concentration for regulatory action (typically at concentrations from 0.5 to 2.0 times the target concentration) to ensure that regulatory action is only taken on samples containing residues that can be demonstrated to exceed the regulatory action limit with a defined statistical confidence.

168. *Recovery* is usually expressed as the percentage of analyte experimentally determined after fortification of sample material at a known concentration and should be assessed over concentrations that cover the analytical range of the method. In interpreting recoveries, it is necessary to recognize that analyte added to a sample may not behave in the same manner as the same biologically incurred analyte (veterinary drug residue). In many situations, the amount of an incurred residue that is extracted (the yield or recovered fraction) is less than the total incurred residues present. This may be due to losses during extraction, intracellular binding of residues, the presence of conjugates, or other factors that are not fully represented by recovery experiments conducted with analyte-fortified blank tissues. At relatively high concentrations, analytical recoveries

[10] *Harmonized IUPAC Guidelines for the use of recovery information in analytical measurement* (CAC/GL 37-2001); see also Thompson, M., Ellison, S.L.R., Fajgelj, A., Willetts, P. & Wood, R. 1999. Harmonized guidelines for the use of recovery information in analytical measurement. *Pure Applied Chemistry*, 71(2): 337–348.

are expected to approach 100 percent. At lower concentrations, particularly with methods involving extensive extraction, isolation and concentration steps, recoveries may be lower. Regardless of what average recoveries are observed, recovery with low variability is desirable so that a reliable correction for recovery can be made to the final result, when required. Recovery corrections should be made consistent with the guidance provided by the Codex Alimentarius Commission.[10]

169. *Precision*, which quantifies the variation between replicated measurements on test portions from the same sample material, is also an important consideration in determining when a residue in a sample should be considered to exceed an MRLVD or other regulatory action limit. Precision of a method is usually expressed in terms of the within-laboratory variation (*repeatability*) and the between-laboratory variability (*reproducibility*) when the method has been subjected to a multilaboratory trial. For a single laboratory method validation, precision should be determined from experiments conducted on different days, using a minimum of six different tissue pools, different reagent batches, preferably different equipment, etc. and preferably by different analysts. Precision of a method is usually expressed as the standard deviation. Another useful term is relative standard deviation, or coefficient of variation (the standard deviation divided by the absolute value of the arithmetic mean). It may be reported as a percentage by multiplying by 100.

170. Method variability, achieved in a laboratory developing a method, is usually less than the variability achieved by another laboratory that may later use the method. If a method cannot achieve a suitable standard of performance in the laboratory where it was developed, it cannot be expected to do any better in other laboratories.

171. Quantitative methods are usually based on a comparison of the response from an analyte in a sample with the response from standards of the analyte in solution at known concentrations. In method development and validation, the calibration curve should first be determined to assess the detector response to standards over a range of concentrations. These concentrations (a minimum of five, plus blank) should cover the full range of analytical interest and the resultant curve should be statistically expressed. However, although it is recommended practice to include a suitable blank with the calibration samples, this does not imply that it is acceptable to extrapolate into the region of the curve below the low standard to obtain a quantitative result. The analytical function relates the response for the analyte recovered from sample material at various concentrations throughout the range of analytical interest. For analytes for which an MRLVD or regulatory action limit has been established in a particular sample material (matrix), response is typically determined for known blank sample material and for blank sample material fortified at a range of concentration above and below the MRLVD (use of six different sources of blank materials is recommended).

172. The analytical function experiment data can also be used to calculate the analytical recovery at each concentration and are of particular importance when the presence of matrix coextractives modifies the response of the analyte as compared with analytical

standards. The *linearity* is determined from the analytical function experiments and is the statistical expression of the curve obtained for the analysis of sample materials fortified at the target concentrations. It is typically determined from a linear regression analysis of the data, assuming there is a linear response. It is increasingly common in methods for veterinary drug residues in foods to base the quantitative determination on a standard curve prepared by addition of standard to known blank representative matrix material at a range of appropriate concentrations that bracket the target value (the analytical function). Use of such a "tissue standard curve" for calibration incorporates a recovery correction into the analytical results obtained.

173. It is also necessary to establish the lower limits at which reliable detection, quantification or confirmation of the presence of an analyte may be performed using a particular analytical method. The *detection limit* may be described in practical terms as the lowest concentration where the analyte can be identified in a sample. It can be estimated using the standard deviation ($s_{y/x}$) from the linear regression analysis of the standard curve generated in the analytical function experiment described above.[11] Using this approach, the limit of detection is calculated using the y-intercept (assuming a positive value) of the curve plus three times $s_{y/x}$. This approach provides a conservative estimate of the detection limit. The detection limit can also be estimated by measurements on representative test materials as the weakest relevant response of the analyte in the blank plus three times its standard deviation. It is often necessary to fortify test materials at a concentration resulting in a barely detectable response to obtain an approximation of the standard deviation of the blank when using this approach.

174. The *limit of quantification* (LOQ), also referred to as quantification limit, may be established from the same experiments using the y-intercept of the curve plus ten times $s_{y/x}$. For methods used to support MRLVDs established by the Codex Alimentarius Commission, the LOQ should meet the criteria for precision and accuracy (recovery) in Table 1 and should be equal to or less than one-half the MRLVD. However, when the LOQ of a method is lower than the actual concentrations monitored for compliance with an MRLVD, the validation and subsequent application of the method should be based on a *lowest calibrated level* (LCL), which is typically 0.5 × the MRLVD. For use in a regulatory programme, the limits of detection and quantification are important parameters when the method will be applied to estimate exposures to residues, where there may be an interest in monitoring residues at concentrations below the MRLVD, or when conducting residue analyses for substances that do not have ADIs or MRLVDs. For monitoring compliance with an MRLVD, it is important that an LCL be included in the analysis that adequately demonstrates that the MRL concentration may be reliably determined. The LCL of a method used to support an MRLVD should not be less than the LOQ. The *Procedural Manual* recommends the term *determination limit* under "Terms to be used in the criteria approach".[7]

[11] Miller, J.C. & Miller, J.N. 1993. *Statistics for analytical chemistry*. 3rd Edition. Chichester, UK, Ellis Horwood Ltd.

Performance characteristics for confirmatory methods

175. *Selectivity*, the ability of the method to identify unequivocally a signal response as being exclusively related to a specific compound, is the primary consideration for confirmatory methods. Certain instrumental techniques such as Fourier transform infrared spectroscopy or mass spectrometry may be sufficiently selective to provide unambiguous identification. These are often the techniques on which confirmatory methods are based.

176. Typically, a minimum of four identification points is required to meet accepted performance criteria for regulatory methods. Methods based on high-resolution mass spectrometry are considered to give a higher reliability through more precise measurement of mass than can be obtained using low-resolution mass spectrometry techniques. Method performance requirements for confirmatory methods based on low resolution gas chromatography mass/spectrometry (GC/MS) and liquid chromatography/mass spectrometry (LC/MS), as recently published by an international expert body,[12] are given in Table 2.

TABLE 2
Performance requirements for relative ion intensities (sample compared to standard) using various mass spectrometric analytical techniques[9]

Relative ion intensity (% of base peak)	GC-MS (EI) (relative)	GC-MS (CI), GC-MS/MS LC-MS, LC-MS/MS (relative)
Percentage	*Percentage*	*Percentage*
> 50	≤ 10	≤ 20
20–50	≤ 15	≤ 25
10–20	≤ 20	≤ 30

177. It is considered that one identification point should be assigned to each structurally significant ion fragment detected using a low-resolution mass spectrometric method. When a tandem low-resolution instrument, such as a "triple quadrupole" mass spectrometer is used, secondary fragments are detected from a primary fragment that is isolated in the first stage of the spectrometer. The fact that these structurally significant fragments are produced from the fragmentation of a major fragment (parent or precursor ion) associated with the molecule provides greater confidence, and each such daughter or product ion is assigned a value of 1.5 identification points. A combination of a precursor ion and two product ions provides the four required identification points when low-resolution MS/MS instruments are used in a confirmatory method.

178. Additional confidence is provided when high-resolution mass spectrometers are used in a confirmatory method, as the high resolution provides more precise identification of the mass and may be used to predict the elemental composition of each fragment. For a single high-resolution mass spectrometer, each structurally significant fragment detected is

[12] Bethem, R., Boison, J.O., Gale, J., Heller, D., Lehotay, S., Loo, J., Musser, S., Price, P. & Stein, S. 2003. Establishing the fitness for purpose of mass spectrometric methods. *Journal of the American Society for Mass Spectrometry*, 14(5): 528–541.

assigned a value of 2 identification points, while product ions generated in high-resolution MS/MS experiments are assigned an identification point value of 2.5 each. In addition, at least one ion ratio must also be measured to eliminate the potential for fragments of the same mass arising from isobaric compounds of similar structure.

179. Other techniques, when they are used in combination, may be capable of achieving a comparable degree of selectivity as confirmatory techniques. For example, identification may be verified by combinations of methods such as:
(a) thin layer chromatography;
(b) element-specific gas-liquid chromatography and accompanying detection systems;
(c) formation of characteristic derivatives followed by additional chromatography; or
(d) determining compound-specific relative retention times using several chromatographic systems of differing polarity.

180. Such procedures must be applicable at the designated MRLVD of the analyte. When a confirmatory method such as mass spectrometry is not available, information on the selectivity associated with the analysis of a particular veterinary drug residue in a sample may be developed from various sources.[13] This information may be captured in a structured logging document of all the information that leads to the conclusion a method has detected a particular compound in a sample, at a measured concentration as reported. While no single measurement or analysis may provide the unequivocal proof of compound identity and/or quantity present that is desired, the combined information that has been compiled provides evidence that the analyst has made a conscientious effort to arrive at a logical result consistent with the data and other information available. Examples of analytical techniques that may be suitable to meet criteria for confirmatory analytical methods are summarized in Table 3.

TABLE 3
Examples of detection methods suitable for the confirmatory analysis of substances, as recommended by the Miskolc Consultation[9]

Detection method	Criterion
LC or GC and mass spectrometry	If sufficient number of fragment ions are monitored
LC-DAD	If the UV spectrum is characteristic
LC – fluorescence	In combination with other techniques
2-D TLC – (spectrophotometry)	In combination with other techniques
GC-ECD, NPD, FPD	Only if combined with two or more separation techniques[a]
Derivatization	If it was not the first choice method
LC-immunogram	In combination with other techniques
LC-UV/VIS (single wavelength)	In combination with other techniques

[a] Other chromatographic systems (applying stationary and/or mobile phases of different selectivity) or other techniques.

[13] Stephany, R.W. 2003. *SPECLOG – the specificity log*. CRD-9, Codex Committee on Residues of Veterinary Drugs in Foods, 14th Session, Arlington, USA, 4–7 March.

181. Although confirmatory methods are generally instrumental procedures, observation of a pathologic or other morphologic change that specifically identifies exposure to a class of veterinary drugs could potentially be a confirmatory method, if it has sufficient sensitivity and precision.

General performance characteristics for methods for use in a regulatory control programme

182. There are some additional considerations for selection of suitable methods for use in a regulatory control programme for veterinary drug residues in foods. Methods should be rugged (robust), cost-effective, relatively uncomplicated, portable and capable of simultaneously handling a set of samples in a time-effective manner. The stability of analytes must also be established.

183. *Ruggedness* testing should be conducted using the standard factorial design approach to determine any critical control points.[14] Typical factors to include in a design include variations in reagent volumes or concentrations, pH, incubation or reaction time and temperature, reagent quality, and different batch or source of a reagent or chromatographic material. Ruggedness testing of a confirmatory method may be required if the method differs significantly from the quantitative method previously validated (if the method uses different extraction or derivatization procedures than are used in the quantitative method).

184. *Cost-effectiveness* is the use of reagents and supplies that are readily available in the required purity from local suppliers and equipment for which parts and service are also readily available. The *method efficiency* is increased when multiple samples can be analysed at the same time. This reduces the analytical time requirements per sample and usually reduces the cost per sample, as there are certain fixed costs associated with the analysis of samples whether done singly or in larger sets. The ability of a method to accommodate multiple samples in a batch is important when large numbers of samples must be analysed in short or fixed time frames. *Portability* is the analytical method characteristic that enables it to be transferred from one location to another without loss of established analytical performance characteristics.

185. *Analyte stability* during analysis must be established for both standards and analyte in the presence of sample material, during processing through the complete analysis for all methods used in a regulatory control programme and for typical conditions of storage while a sample is awaiting analysis. The period chosen for stability during storage should cover the expected time when sample material may be stored for all required analyses, including the use of the screening, quantitative and confirmatory methods. It is prudent to conduct the storage study for a period that extends to at least 90 days beyond the expected time for all screening, quantitative and confirmatory analyses to be completed and the results reported in case there is a challenge and a request for re-analysis.

[14] Youden, W.J. & Steiner, E.H. 1975. *Statistical Manual of the Association of Official Analytical Chemists*. Gaithersburg, USA, AOAC International.

Method development and validation considerations for residue control methods

Selection of appropriate test material for validation

186. Laboratories must demonstrate that the methods in use for analysis of regulatory samples have been suitably validated. Traditionally, the multilaboratory method validation study has been the preferred approach to provide analytical data to define method performance characteristics. However, other models have been developed that include multilaboratory trials with smaller numbers of laboratories than are required to conduct a full collaborative study and single laboratory validation based on rigorous in-house evaluation of method performance, supported by a quality management system, independent audits and analysis of proficiency or reference materials, when available.

187. In developing and validating a residue control method, data should be derived from three types of sample material. Control test material from non-treated animals provides information about analytical background and matrix interferences. Fortified test material, containing known amounts of the analyte added to the control material, yields information about the method's ability to recover the analyte of interest under controlled conditions. Tissues should be obtained from multiple sources to cover the variations resulting from factors such as different diets, husbandry practices, sex and breed of animals. A minimum of six different sources of material is recommended.

188. In some instances, known drug-free sample materials may not be available for use in residue control laboratories. In these instances, an equivalent sample material may be used. Equivalent sample materials may consist of either the same matrix as the test sample matrix from an unknown source, or a different matrix from a known drug-free source that closely matches the sample matrix. In all cases, the residue control laboratory must demonstrate that the equivalent sample material is free from interferences for the drug and exhibits satisfactory recovery for fortified samples. Additionally, when a material is used from an unknown source for quantitative or screening methods, it is recommended that a second method be used to demonstrate that the matrix does not contain residues of the drug. It is the responsibility of the residue control laboratory to demonstrate fitness for purpose of the equivalent sample material.

189. Finally, analysis of biologically incurred tissue from food-producing animals that have been treated with the drug provides information about biological or other interactions that may occur when analysing residue control samples.

Measurement uncertainty

190. Laboratories should provide their customers on request with information on the measurement uncertainty or statement of confidence associated with the quantitative results produced by each quantitative method. Guidance on estimation of measurement uncertainty is being developed by the IUPAC and has been published by other independent scientific bodies.[15]

[15] Ellison, S.L.R., Roslein, M. & Williams, A. 2000. *Quantifying uncertainty in analytical measurement*. EURACHEM/CITAC Guide CG 4 (available at http://www.measurementuncertainty.org/mu/QUAM2000-1.pdf).

Use of internal standards

191. Residue methods are sometimes designed using internal standards for analytical control. A properly used internal standard will compensate for some of the analytical variability of an analysis, improving precision. However, an improperly used internal standard may obscure variables that are an important part of the analytical measurement. If an internal standard is used, it should be added to a sample as early as possible in the procedure, preferably to the test material before analysis begins. The internal standard must reflect the recovery of the target analyte in a uniform and predictable fashion. An internal standard that does not mirror the behaviour of the target analyte in the method will lead to significant errors in calculation of the final result. Caution must be taken in the choice of internal standards to ensure that they do not alter the percent recovery of the analyte of interest or interfere with the measurement process. It is important to know the extent and predictability of the effects of the internal standard on an analytical method. Internal standards can greatly enhance method performance when used properly.

Environmental considerations

192. If residue control methods may be subjected to widely variable physical test environments, this should be taken into account in the development and validation of these methods. Addressing these issues may help improve method ruggedness. Warmer environments may require reagents to be more thermally stable, while solvents used in the analysis will have to be less volatile and test sample requirements to be more tolerant. Cooler environments may require reagents and solvents to have different physical properties, such as lower freezing point and greater solvating characteristics, to provide effective extraction of an analyte. Environmental temperatures may influence the time required to perform an analysis, as well as influencing reaction rates, gravitational separations and colour development. These considerations may strain efforts to standardize methods for use in broadly differing environments because of the need to adapt methods to compensate for these factors. When considering the physical environment in which a method will be used, it is important to remember that volumetric glassware and many analytical instruments are calibrated to be used at specific temperatures, or within a controlled range of temperature. Operation outside these temperatures may compromise test results.

Choice of validation model

193. An analytical method developed and used in only one laboratory may have limited use in a residue control programme unless care is taken to meet the rigorous expectations for single laboratory method validation associated with accreditation under ISO/IEC 17025 or equivalent accreditation procedures for testing laboratories. The reliability of reported values may be a concern even though strong quality control procedures may have been employed, unless supported by data from an ongoing proficiency programme, comparison with a suitable method validated in an interlaboratory trial or other forms of interlaboratory comparison of results. Ideally, a method should be validated by at least three laboratories. Methods that have been carefully validated in a single laboratory with inclusion of properly designed ruggedness tests should be able to undergo successfully a collaborative study involving at least eight different laboratories.

194. The principles for conducting a single laboratory method validation, a multilaboratory method trial or a collaborative study of a residue control method are the same. Samples for evaluating method performance should be unknown to the analyst, in randomized replicates, containing the residue near the MRLVD or other target concentration, as well as samples with the analyte above and below the concentration of interest, and test material blanks. A minimum of three individual datasets should be generated over three analysis periods, on at least three separate occasions (at least one day apart), preferably with replicate analysis, to improve statistical evaluation of method performance and provide an estimate of interday variability. It should be noted that these are only minimal requirements. The establishment of statistically based performance standards for methods is enhanced by increasing the number of independent analysts and laboratories testing the method, as well as by the number of samples tested. In a single laboratory validation, it is recommended that the method should be tested by multiple analysts to provide appropriate measures of within-laboratory performance. Expanding the validation to include other laboratories, preferably to the number required for a collaborative study, is recommended. Analyses of blind duplicates, as required in the collaborative study protocol,[7] in only eight laboratories, with one or two animal species and tissues, yields limited quality estimates for overall repeatability and reproducibility. The validation of a collaboratively studied method can be extended to include additional tissues and species in a subsequent study conducted by a single expert laboratory, as required.

Quality management systems

195. A quality management system is an essential component of residue analysis. It both monitors those factors associated with the analysis of a sample by an analyst and provides the oversight by independent reviewers to ensure that the analytical programme is performing in an acceptable manner. The use of an accredited quality management system is invaluable to support decision-making for residue control agencies, improving the reliability of analytical results, and providing quality data for residue control programmes to demonstrate food safety to consumers, producers and law-making bodies regarding residues of veterinary drugs in food. The establishment of quality measures consistent with the principles published by the IUPAC is recommended for regulatory control laboratories.

APPENDIX A
SAMPLING STRATEGIES

NON-BIASED SAMPLING

Purpose

1. Non-biased sampling is designed to provide profile information, especially as to the extent of application or performance of a control or assurance system for a specified animal/food population over a defined period.

Statistical considerations on sampling population size

2. The number of samples for non-biased sampling protocols should be statistically based and may be influenced by the size of the population (where less than 5 000), the prevalence of non-compliance determined to be significant, the confidence to be placed in the results as well as economic considerations.

3. The number of samples based on the binomial distribution will always be equal to or greater than the required number of samples based on the hypergeometric distribution.[1]

4. If the size of the population is small, the effect of sampling without replacement is significant and the sampling distribution should be based on the hypergeometric distribution.

5. In populations larger than 5 000 units, the effect of sampling without replacement is negligible. Thus, the binomial distribution can be used to determine an appropriate number of samples.

6. The number of samples for a defined confidence will be effectively constant for populations exceeding 5 000 units.

Sampling confidence reporting

7. Where non-compliant results are detected, it is possible to derive a crude estimate of the likely prevalence in the general population.

8. However, where no non-compliant results are found, then any statements about prevalence need to be stated with a defined confidence that the prevalence of non-compliant results does not exceed a specified percentage.

9. The number of samples required to give a required statistical assurance can be read from Table 1. Other scientifically based statistical protocols may also be used.

[1] In probability theory and statistics, the *hypergeometric distribution* is a discrete (consisting of unconnected distinct parts) probability distribution that describes the number of successes in a sequence of *n* draws from a finite population without replacement.

TABLE 1

Number of samples required to detect at least one non-compliant result with pre-defined probabilities (90, 95 and 99 percent) in a population having a known non-compliance prevalence

Non-compliant prevalence (% in a population)	Minimum number of samples required to detect a non-compliant result with a confidence level of:		
	90%	95%	99%
35	6	7	11
30	7	9	13
25	9	11	17
20	11	14	21
15	15	19	29
10	22	29	44
5	45	59	90
1	230	299	459
0.5	460	598	919
0.1	2 302	2 995	4 603

TABLE 2

Probability of failing to detect a non-compliance

Prevalence (%)	Number of animals/units of product in sample tested									
	5	10	25	50	75	100	200	250	500	1 000
1	0.951	0.904	0.779	0.605	0.471	0.366	0.134	0.081	0.007	0.000
2	0.904	0.817	0.603	0.364	0.220	0.133	0.018	0.006	0.000	
3	0.859	0.737	0.467	0.218	0.102	0.048	0.002	0.000		
4	0.815	0.665	0.360	0.130	0.047	0.017	0.000			
5	0.774	0.599	0.277	0.077	0.021	0.006				
6	0.734	0.539	0.213	0.045	0.010	0.002				
7	0.696	0.484	0.163	0.027	0.004	0.001				
8	0.659	0.434	0.124	0.015	0.002	0.000				
9	0.590	0.389	0.095	0.009	0.001					
10	0.528	0.349	0.072	0.005	0.000					
12	0.470	0.279	0.041	0.002						
14	0.418	0.221	0.023	0.001						
16	0.371	0.175	0.013	0.000						
18	0.328	0.137	0.007							
20	0.254	0.107	0.004							
24	0.193	0.064	0.001							
28	0.193	0.037	0.000							
32	0.145	0.021								
36	0.107	0.012								
40	0.078	0.006								
50	0.031	0.001								
60	0.010	0.000								

10. The probability of failing to detect a specified prevalence of non-compliant results associated with a specified targeting mechanism can be read from Table 2. Because of the low efficacy of sampling protocols in detecting low prevalences of non-compliance, other assurance mechanisms are more important where a low prevalence of non-compliance is expected.

DIRECTED OR TARGETED SAMPLING

Purpose

11. Directed or targeted sampling protocols are designed to place a greater intensity of inspection/audit on suppliers or product considered to have possibly a greater potential than the general population of being non-compliant.

12. It is not possible to extrapolate from non-compliant results to draw conclusions about the general population because a subpopulation that is considered to have greater chance of non-compliance is being sampled (biased sampling).

13. However, if compliant results confirm non-biased programme results, they provide increased assurance that the system is working effectively.

APPENDIX B

SAMPLING OF COMMODITIES

SCOPE

1. This Appendix applies to the following commodities: primary food commodities of animal origin and processed products of animal origin made from primary food appearing in Table A and Table B of this Appendix, and honey of the following origins and/or processing methods:
   (a) blossom or nectar honey that comes mainly from nectaries of flowers;
   (b) honeydew honey that comes mainly from secretions of or on living parts of plants;
   (c) comb honey stored by bees in the cells of freshly built broodless combs, and sold in sealed whole combs or sections of such combs;
   (d) extracted honey obtained by centrifuging decapped broodless combs;
   (e) pressed honey obtained by pressing broodless combs with or without the application of moderate heat.

DEFINITIONS

Lot means an identifiable group of animals or quantity of animal product intended for food use and determined to have common characteristics, such as origin variety, type of packing, packer or consignor, or markings, by the sampling official. Several lots may make up a consignment.

Consignment means an identifiable group of animals or quantity of animal product intended for food use as described on a particular contractor's shipping document. Lots in a consignment may have different origins or may be delivered at different times.

Primary sample means a quantity of representative biological material taken from a single animal (or group of animals) or from one place in the lot. When the quantity is inadequate for residue analysis, samples from more than one animal (or group of animals) or more than one location in the lot can be combined for the primary sample (such as poultry organs).

Bulk sample means the combined total of all the primary samples taken from the same lot.

Final laboratory sample means the primary or bulk sample, or a representative portion of the primary or bulk sample, intended for laboratory analysis.

Final laboratory test portion means the representative portion of the final laboratory sample on which an analysis is conducted. The entire laboratory sample may be used for analysis in some cases but typically will be subdivided into representative test portions for analysis. It is prepared by combining and thoroughly mixing the primary samples.

Lot of honey means a discrete quantity of honey delivered for distribution at one time, and determined to have common characteristics, such as origin, variety, type of packing, packer or consignor, or markings, by the sampling official.

Consignment of honey means a discrete quantity of honey as described on a particular contractor's shipping document. A consignment may be made up of different lots.

Primary honey sample means a quantity of honey taken from one place in the lot, unless this quantity is inadequate for the residue analysis. When the quantity is inadequate, samples from more than one location can be combined for the primary sample.

SAMPLING PROCEDURES

2. Samples must be collected by those officially authorized for this purpose.

3. Each lot to be examined must be sampled separately.

4. During collection and processing, care must be taken to prevent contamination or other changes in the samples that would alter the residue, affect the analytical determination, or make the laboratory test portion not representative of the bulk or laboratory sample.

5. Guidance on sample type and quantity for different commodities is provided in Table A (meat and poultry products) and Table B (milk, eggs and dairy products). The following are general instructions:
   (a) Each primary sample should be taken from a single animal (or group of animals) or unit in a lot, and when possible, be selected randomly.
   (b) When several animals are required for adequate sample size of the primary sample (e.g. poultry liver), the samples should be collected consecutively after initial random selection.
   (c) Frozen product should not be thawed before sampling.
   (d) Canned or packaged product should not be opened for sampling unless the unit size is at least twice the amount required for the final laboratory sample. The final laboratory sample should contain a representative portion of juices surrounding the product.
   (e) Unopened cans or packages that constitute a final laboratory sample should be sent unopened and intact to the laboratory for analysis.
   (f) The contents of cans or packages opened by the authorized inspector should be frozen as described in paragraph 23(d) (below) before dispatch to the laboratory for analysis.
   (g) Large, bone-containing units of product (i.e. prime cuts) should be sampled by collecting edible product only as the primary sample.
   (h) When portions of single unit are less than described as a primary sample, additional sample units need to be taken to satisfy bulk sample requirements.
   (i) Portions remaining of final laboratory samples should be frozen and stored in conditions that will maintain the sample integrity.

6. The number of primary samples collected will depend on whether a lot is considered suspect.

7. A lot is suspect if there is:
   (a) a history of non-compliance with the maximum residue limit for veterinary drugs (MRLVD);
   (b) evidence of contamination during transport;
   (c) signs of toxicosis (systemic poisoning) observed during ante- or post-mortem inspection; or
   (d) other relevant information available to the authorized inspection official.

8. A minimum of 6 to a maximum of 30 primary samples should be collected from a suspect lot. When the suspected residues are expected to occur throughout the lot, the smaller number of samples is sufficient.

9. Imports from countries that do not run verification programmes for compliance with MRLVDs should be sampled as suspect lots.

SPECIFIC SAMPLE PREPARATION INSTRUCTIONS FOR HONEY

   (a) Collect 250 ml of liquid or strained honey after the following preparations as applicable.
   (b) Liquidize comb honey: Cut across top of comb, if sealed, and separate completely from comb by straining through a sieve, the meshes of which are made by so weaving wire as to form square openings of 0.500 mm by 0.500 mm (ISO 565:1990).[1]
   (c) If foreign matter, such as wax, sticks, bees, particles of comb, etc., is present, heat sample to 40 °C in water bath and strain through cheesecloth in hot-water-funnel before sampling.

10. When a sample is free from granulation, mix thoroughly by stirring or shaking; if granulated, place closed container in water-bath without submerging, and heat for 30 minutes at 60 °C; then, if necessary, heat at 65 °C until liquefied. Occasional shaking is essential. Mix thoroughly and cool rapidly as soon as the sample liquefies.

STATISTICAL CONCERNS

11. For non-suspect lots, a statistically based, non-biased sampling programme is recommended. Any of the following types of sampling can be used.

Stratified random sampling

12. Where consignments are commingled, simple random criteria cannot be applied and stratified random sampling should be considered.

13. In stratified random sampling, the consignment is divided into non-overlapping groups or strata, e.g. geographical origin, genders, time. A sample is taken from each stratum.

[1] Such sieve could be replaced by US sieve with No. 40 standard screen (size of openings = 0.420 mm).

14. Homogeneity within each stratum is better than in the whole population. Countries or geographic regions are considered natural strata based on uniformity in agricultural practices.

15. Time strata (e.g. month, quarter) are commonly used for convenience, efficiency and detection of seasonal variability. Random number tables[2] or other objective techniques should be used to ensure that all elements of a population have an equal and independent chance of being included in the sample.

Systematic sampling

16. In systematic sampling, units are selected from the population at a regular interval (e.g. once an hour, every other lot, etc.).

17. It may be applied when there is reliable information on product volumes to determine the sampling interval that will provide the desired number of samples over time. However:
(a) If the sampling system is too predictable, it may be abused.
(b) Consignments need to be homogeneous, because systematic sample units are uniformly distributed over the population.

Biased or estimated worst case sampling

18. In biased or estimated worst case sampling, investigators use their judgement and experience regarding the population, lot or sampling frame to decide which primary samples to select.

19. The population group anticipated to be at greatest risk may be identified, but no general conclusion should be made about the population sampled from the data collected (non-random samples).

PREPARATION OF LABORATORY SAMPLES

20. The final laboratory sample is sent for analysis.

21. Some national/regional legislation/regulation may require that the final laboratory sample is subdivided into two or more portions for separate analyses. Each portion should be representative of the final laboratory sample. Precautions indicated under *sampling procedures* should be observed.

22. The laboratory test portion should be prepared from the final laboratory sample by an appropriate method of reduction.

[2] Random number tables consist of a randomly generated series of digits (0–9). To improve readability, there are spaces e.g. after every fourth digit and after every tenth row. Reading can begin anywhere (at random), but having started, has to continue across the line or down a column and NOT jump about. Example: extract from a table of random sampling numbers: 3680 2231 8846 5418 0498 5245 7071 2597.

SHIPMENT OF LABORATORY SAMPLES

23. Final laboratory samples should be prepared as follows:
   (a) Each sample should be placed in a clean, thermally insulating, chemically inert container to protect the sample from contamination, defrosting and damage in shipping.
   (b) The container should be sealed so that unauthorized opening is detectable.
   (c) The container should be sent to the laboratory as soon as possible, after taking precautions against leakage and spoilage.
   (d) For shipping, all perishable samples should be frozen to minus 20 °C immediately after collection and packed in a suitable container that retards thawing. Freezer packs or other suitable refrigerants should be used to maintain freezer temperatures during shipment. Samples and freezer packs should be fully frozen to minus 20 °C prior to dispatch.
   (e) Replicate portions of the final laboratory sample that may be retained as required by national/regional legislation or as an administrative policy should be placed in a clean, chemically inert container to protect the sample from contamination, sealed so that unauthorized opening is detectable and stored under suitable conditions to prevent a change in the product or any residues it may contain in case future analysis is required for comparison with analytical results obtained on the sample material submitted to the laboratory.

RESULT INTERPRETATION IN THE LABORATORY

24. For purposes of control, the MRLVD is applied to the residue concentration found in each laboratory sample taken from a lot.

25. Lot compliance with an MRLVD is achieved when the mean result for analysis of the laboratory test portions does not indicate the presence of a residue that exceeds the MRLVD.

SAMPLING RECORDS

26. Each primary or bulk sample and each final laboratory sample should be uniquely linked to a record with the type of sample, analyses required, its origin (e.g. country, state or town), its location of collection, date of sampling, and additional information required for follow-up action if necessary.

27. If there is a deviation from recommended sampling procedures, records accompanying the sample should describe procedures actually followed in detail.

GUIDANCE ON SAMPLE TYPE AND QUANTITY FOR DIFFERENT COMMODITIES

TABLE A

Meat and poultry products

Commodity	Instructions for collection	Minimum quantity required for laboratory sample
I. Group 030 (Mammalian meats)		
A. Whole carcass or side, unit weight normally 10 kg or more	Collect diaphragm muscle, supplement with cervical muscle, if necessary, from one animal.	500 g
B. Small carcass (e.g. rabbit)		500 g after removal of skin and bone
C. Fresh/chilled parts		
1. Unit minimum weight of 0.5 kg, excluding bone (e.g. quarters, shoulders, roasts)	Collect muscle from one unit.	500 g
2. Unit weighing less than 0.5 kg (e.g. chops, fillets)	Collect the number of units from selected container to meet laboratory sample size requirements.	500 g after removal of bone
D. Bulk frozen parts	Collect a frozen cross-section from selected container, or take muscle from one large part.	500 g
E. Retail packaged frozen/chilled parts, or individually wrapped units for wholesale	For large cuts, collect muscle from one unit or take sample from number of units to meet laboratory sample size requirements.	500 g after removal of bone
Ia. Group 030 (Mammalian meats where MRL is expressed in carcass fat)		
A. Animals sampled at slaughter	See instructions under II. Group 031.	
B. Other meat parts	Collect 500 g of visible fat, or sufficient product to yield 50–100 g of fat for analysis. (Normally, 1.5–2.0 kg of product is required for cuts without trimmable fat.)	Sufficient to yield 50–100 g of fat
II. Group 031 (Mammalian fats)		
A. Large animals sampled at slaughter, usually weighing at least 10 kg	Collect kidney, abdominal or subcutaneous fat from one animal.	500 g
B. Small animals sampled at slaughter[1]	Collect abdominal and subcutaneous fat from one or more animals.	500 g
C. Bulk fat tissue	Collect equal size portions from 3 locations in container.	500 g
III. Group 032 (Mammalian edible offal)		
A. Liver	Collect whole liver(s) or portion sufficient to meet laboratory sample size requirements.	400–500 g

(continued)

TABLE A (continued)

Meat and poultry products

Commodity	Instructions for collection	Minimum quantity required for laboratory sample
B. Kidney	Collect one or both kidneys, or kidneys from more than one animal, sufficient to meet laboratory sample size requirement. Do not collect from more than one animal if size meets the low range for sample size.	250–500 g
C. Heart	Collect whole heart or ventricle portion sufficient to meet laboratory sample size requirement.	400–500 g
D. Other fresh/chilled or frozen, edible offal product	Collect portion derived from one animal unless product from more than one animal is required to meet laboratory sample size requirement. A cross-section can be taken from bulk frozen product.	500 g
IV. Group 036 (Poultry meats)		
A. Whole carcass of large bird, typically weighing 2–3 kg or more (e.g. turkey, mature chicken, goose, duck)	Collect thigh, leg, and other dark meat from one bird.	500 g after removal of skin and bone
B. Whole carcass of bird, typically weighing between 0.5–2.0 kg (e.g. young chicken, duckling, guinea fowl)	Collect thigh, legs, and other dark meat from 3–6 birds, depending on size.	500 g after removal of skin and bone
C. Whole carcasses of very small birds, typically weighing less than 500 g (e.g. quail, pigeon)	Collect at least 6 whole carcasses	250–500 g of muscle tissue
D. Fresh/chilled or frozen parts		
1. Wholesale package		
a. Large parts	Collect an interior unit from a selected container.	500 g after removal of skin and bone
b. Small parts	Collect sufficient parts from a selected layer in the container	500 g after removal of skin and bone
2. Retail packaged	Collect a number of units from selected container to meet laboratory sample size requirement.	500 g after removal of skin and bone
IVa. Group 036 (Poultry meats where MRLVD is expressed in carcass fat)		
A. Birds sampled at slaughter	See instructions under V. Group 037	
B. Other poultry meat	Collect 500 g of fat or sufficient product to yield 50–100 g of fat. (Normally, 1.5–2.0 kg is required.)	500 g of fat or enough tissue to yield 50–100 g of fat
V. Group 037 (Poultry fats)		
A. Birds sampled at slaughter	Collect abdominal fat from 3–6 birds, depending on size.	Sufficient to yield 50–100 g of fat
B. Bulk fat tissue	Collect equal size portions from 3 locations in container.	500 g

(continued)

TABLE A (continued)

Meat and poultry products

Commodity	Instructions for collection	Minimum quantity required for laboratory sample
VI. Group 038 (Poultry edible offal)		
A. Liver	Collect 6 whole livers or a sufficient number to meet laboratory sample requirement.	250–500 g
B. Other fresh/chilled or frozen edible offal product	Collect appropriate parts from 6 birds. If bulk frozen, take a cross-section from container.	250–500 g
VII. Class E – Type 16 (Secondary meat and poultry products)		
A. Fresh/chilled or frozen comminuted product of single species origin	Collect a representative fresh or frozen cross-section from selected container or packaged unit.	500 g
B. Group 080 (Dried meat products)	Collect a number of packaged units in a selected container sufficient to meet laboratory sample size requirements.	500 g, unless fat content is less than 5% and MRLVD is expressed on a fat basis. Then, 1.5–2.0 kg is required.
VIII. Class E – Type 18 (Manufactured, single ingredient product of animal origin)		
A. Canned product (e.g. ham, beef, chicken), unit size of 1 kg or more	Collect one can from a lot. When unit size is large (greater than 2 kg), a representative sample including juices may be taken.	500 g, unless fat content is less than 5% and MRLVD is expressed on a fat basis. Then 1.5–2.0 kg is required.
B. Cured, smoked, or cooked product (e.g. bacon slab, ham, turkey, cooked beef), unit size of at least 1 kg	Collect portion from a large unit (greater than 2 kg), or take whole unit, depending on size.	500 g, unless fat content is less than 5% and MRLVD is expressed on a fat basis. Then 1.5–2.0 kg is required.
IX. Class E – Type 19 (Manufactured, multiple ingredient, product of animal origin)		
A. Sausage and luncheon meat rolls with a unit size of at least 1 kg	Collect cross-section portion from a large unit (greater than 2 kg), or whole unit, depending on size.	500 g

[1] When adhering fat is insufficient to provide a suitable sample, the sole commodity without bone is analysed and the MRL will apply to the sole commodity.

TABLE B

Milk, eggs, dairy products

Commodity	Instructions for collection	Minimum quantity required for laboratory sample
I. Group 033 (Milks)		
Whole liquid milk raw, pasteurized, UHT & sterilized	In bulk: Mix thoroughly and immediately take a sample by means of a dipper. In retail containers: Take sufficient units to meet laboratory sample size requirements.	500 ml
II. Group 082 (Secondary milk products)		
A. Skimmed milk – skimmed and semi-skimmed	As for whole liquid milk. Bulk containers (barrels, drums): Mix the contents carefully and scrape adhering material from the sides and bottom of the container. Remove 2–3 litres, repeat the stirring and take a 500 ml sample.	500 ml
B. Evaporated milk – evaporated full-cream & skimmed milk	Small retail containers: Take sufficient units to meet laboratory sample size requirements.	500 ml
C. Milk powders		
1. Whole	Bulk containers: Pass a dry borer tube steadily through the powder at an even rate of penetration. Remove sufficient bores to make up a sample of 500 g. Small retail containers: Take sufficient units to meet laboratory sample size requirements.	500 g
2. Low-fat	As for whole milk powders.	500 g
III. Group 087 (Derived milk products)		
A. Cream – fresh, frozen & UHT; single, whipping, whipped, double & clotted	Bulk containers: Plunge to ensure thorough mixing, moving the plunger from place to place, avoiding foaming, whipping and churning. Take a 200 ml sample by means of a dipper. Small containers: Take sufficient units to meet laboratory sample size requirements.	200 ml
B. Butter – including whey butter and low-fat spreads containing butterfat	In bulk: Take two cores or more of butter so that the minimum total sample weight is not less than 200 g. In pats or rolls: For units weighing over 250 g, divide into four and take opposite quarters. For units weighing less than 250 g, take one unit as sample.	200 g
C. Butter oil – including anhydrous butteroil and anhydrous milk fat	Mix thoroughly and take a 200 g sample.	200 g
IV. Group 090 (Manufactured milk products – single ingredient)		
A. Yoghurt – natural, low-fat through to full-cream	Select number of units sufficient to meet laboratory requirements.	500 g

(continued)

TABLE B (continued)
Milk, eggs, dairy products

Commodity	Instructions for collection	Minimum quantity required for laboratory sample
B. Cheeses – all varieties	Make two cuts radiating from the centre of the cheese if the cheese has a circular base, or parallel to the sides if the base is rectangular. The piece removed should meet the laboratory sample size requirements. For small cheeses and wrapped portions of cheese, take sufficient units to meet laboratory sample requirements.	200 g
■ **V. Group 092** (Manufactured milk products – multi-ingredient)		
A. Dairy ice cream – only ice cream containing 5% or greater of milk fat	Select block or units sufficient to meet laboratory sample size requirements.	500 ml
B. Processed cheese preparations	Select units sufficient to meet laboratory sample size requirements.	200 g
C. Flavoured yoghurt	As for natural yoghurt.	500 g
D. Sweetened condensed milk	As for evaporated milk.	500 ml
■ **VI. Group 039** (Eggs and egg products)		
A. Liquid and frozen eggs	Use sample schedule. Subsample size will be 250 ml liquid or 500 ml packed shavings from aseptic drillings into containers.	500 g
B. Dried egg products	Use sample schedule. For containers of 500 g or less or 25 ml or less, collect a minimum of 2 units per subsample. For containers of 500 g to 10 kg, select 1 unit per subsample. For containers of 10 kg or more, collect 1 kg from each unit sampled. Collect with aseptic technique.	500 g
C. Shell eggs		
1. Retail packages	Use sample schedule. Subsample size is 12 eggs.	500 g or 10 whole eggs
2. Commercial cases	For 15 cases or less, collect 12 eggs from each case, minimum of 24 eggs. For 16 or more cases, collect 12 eggs from 15 random cases.	500 g or 10 whole eggs

CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE

CAC/RCP 61-2005

CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE

CAC/RCP 61-2005

INTRODUCTION

This document provides additional guidance for the responsible and prudent use of antimicrobials in food-producing animals, and should be read in conjunction with the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes associated with the Use of Veterinary Drugs in Food-producing Animals* (CAC/GL 71-2009). Its objectives are to minimize the potential adverse impact on public health resulting from the use of antimicrobial agents in food-producing animals, in particular the development of antimicrobial resistance. It is also important to provide for the safe and effective use of veterinary antimicrobial drugs in veterinary medicine by maintaining their efficacy. This document defines the respective responsibilities of authorities and groups involved in the authorization, production, control, distribution and use of veterinary antimicrobials such as the national regulatory authorities, the veterinary pharmaceutical industry, veterinarians, distributors and producers of food-producing animals.

The marketing authorization procedure has a significant role in establishing the basis for prudent use of veterinary antimicrobial drugs in food-producing animals through clear label indications, directions and warning statements.

A number of codes of practice relating to the use of veterinary antimicrobial drugs and the conditions thereof have been developed by different organisations. These codes were taken into consideration and some elements were included in the elaboration of this *Code of Practice to Minimize and Contain Antimicrobial Resistance*.

In keeping with the Codex mission, this Code focuses on antimicrobial use in food–producing animals. It is recognized that antimicrobial resistance is also an ecological problem and that management of antimicrobial resistance may require addressing the persistence of resistant microorganisms in the environment. Although this issue is most relevant for CCRVDF with respect to food-producing animals, the same principles apply to companion animals, which also harbor resistant microorganisms.

AIMS AND OBJECTIVES

It is imperative that all who are involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in food-producing animals act legally, responsibly and with the utmost care in order to limit the spread of resistant microorganisms among animals so as to protect the health of consumers.

Antimicrobial drugs are powerful tools for the management of infectious diseases in animals and humans. This Code and existing guidelines for the responsible use of antimicrobial drugs in food-producing animals include recommendations intended to prevent or reduce the selection of antimicrobial resistant microorganisms in animals and humans in order to:

- Protect consumer health by ensuring the safety of food of animal origin intended for human consumption.
- Prevent or reduce as far as possible the direct and indirect transfer of resistant microorganisms or resistance determinants within animal populations and from food-producing animals to humans.
- Prevent the contamination of animal derived food with antimicrobial residues which exceed the established MRL.
- Comply with the ethical obligation and economic need to maintain animal health.

This Code does not address environmental issues related to antimicrobial resistance from the use of veterinary antimicrobial drugs but it encourages all those involved to consider the ecological aspects when implementing the Code. Efforts should be made to ensure that environmental reservoirs of veterinary antimicrobial drugs, antimicrobial resistant organisms and resistance determinants are kept to a minimum. In particular:

- Regulatory authorities should assess the impact of proposed veterinary antimicrobial drug use on the environment in accordance with national guidelines or recognized international guidelines[1].
- Research should be conducted on resistant microorganisms in the environment and the magnitude of resistance determinant transfer among microorganisms in the environment.

The responsible use of veterinary antimicrobial drugs in food-producing animals:

- is controlled by the veterinary profession or other parties with the required expertise.
- is part of good veterinary and good animal husbandry practice and takes into consideration disease prevention practices such as the use of vaccination and improvements in husbandry conditions.
- aims to limit the use of veterinary antimicrobial drugs according to their approved and intended uses, and takes into consideration on-farm sampling and testing of isolates from food-producing animals during their production, where appropriate, and makes adjustments to treatment when problems become evident.
- should be based on the results of resistance surveillance and monitoring (microbial cultures and antimicrobial sensitivity testing), as well as clinical experience.

[1] VICH (2000). *Guidelines on Environmental Impact Assessment for Veterinary Medicinal Products, Phase I.* http://vich.eudra.org/pdf/2000/Gl06_st7.pdf

- does not include the use for growth promotion of veterinary antimicrobial drugs that belong to or are able to cause cross resistance to classes of antimicrobial agents used (or submitted for approval) in humans in the absence of a risk analysis. This risk analysis should:
  - be undertaken by the appropriate national regulatory authority;
  - be based on adequate scientific evidence; and.
  - focus on the potential to impact resistance to antimicrobials used in human medicine.
- is aimed at all the relevant parties, such as:
  - regulatory and scientific authorities;
  - the veterinary pharmaceutical industry;
  - distributors and others handling veterinary antimicrobial drugs;
  - veterinarians, pharmacists and producers of food-producing animals.

RESPONSIBILITIES OF THE REGULATORY AUTHORITIES

The national regulatory authorities, which are responsible for granting the marketing authorisation for antimicrobials for use in food-producing animals, have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian through product labelling and/or by other means, in support of prudent use of veterinary antimicrobial drugs in food-producing animals. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of veterinary antimicrobial drug applications. National governments in cooperation with animal and public health professionals should adopt a proactive approach to promote prudent use of antimicrobials in food-producing animals as an element of a national strategy for the containment of antimicrobial resistance. Other elements of the national strategy should include good animal husbandry practices, vaccination policies and development of animal health care at the farm level, all of which should contribute to reduce the prevalence of animal disease requiring antimicrobial treatment. Use of veterinary antimicrobial drugs for growth promotion that belong to classes of antimicrobial agents used (or submitted for approval) in humans and animals should be terminated or phased out in the absence of risk-analysis, as described in the section "Aims and objectives".

It is the responsibility of the pharmaceutical company or sponsor[2] to submit the data requested by the regulatory authorities for granting marketing authorisation.

The use of antimicrobial agents in food-producing animals requires a marketing authorisation, granted by the competent authorities when the criteria of safety, quality and efficacy are met.

- The examination of dossiers/drug applications should include an assessment of the risks to both animals and humans resulting from the use of antimicrobial agents in food-producing animals. The evaluation should focus on each individual veterinary antimicrobial drug but take into consideration the class of antimicrobials to which the particular active principle belongs.

[2] As defined in the VICH Good Clinical Practice Guideline, http://vich.eudra.org/pdf/2000/Gl09_st7.pdf

- The safety evaluation should include consideration of the potential impact of the proposed use in food-producing animals on human health, including the human health impact of antimicrobial resistance developing in microorganisms found in food-producing animals and their environment associated with the use of veterinary antimicrobial drugs.

If dose ranges or different durations of treatment are indicated, the national authorities should give guidance on the approved product labelling regarding the conditions that will minimize the development of resistance, when this information is available.

The relevant authorities should make sure that all the antimicrobial agents used in food-producing animals are prescribed by a veterinarian or other suitably trained person authorized in accordance with national legislation or used under conditions stipulated in the national legislation. (See OIE Guidelines for Antimicrobial Resistance: Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine (*Terrestrial Animal Health Code*, Appendix 3.9.3).

No veterinary antimicrobial drug should be administered to animals unless it has been evaluated and authorized for such use by the relevant authorities or the use is allowed through off-label guidance or legislation. Regulatory authorities should, where possible, expedite the market approval process of new veterinary antimicrobial drug formulations considered to have the potential to make an important contribution in the control of antimicrobial resistance.

Countries without the necessary resources to implement an efficient authorisation procedure for veterinary antimicrobial drugs and whose supply of veterinary antimicrobial drugs mostly depends on imports from foreign countries should:

- ensure the efficacy of their administrative controls on the import of these veterinary antimicrobial drugs,
- seek information on authorizations valid in other countries, and
- develop the necessary technical cooperation with experienced authorities to check the quality of imported veterinary antimicrobial drugs as well as the validity of the recommended conditions of use. Alternatively, a national authority could delegate a competent institution to provide quality certification of veterinary antimicrobial drugs.

All countries should make every effort to actively combat the manufacture, advertisement, trade, distribution and use of illegal and/or counterfeit bulk active pharmaceutical ingredients and products. Regulatory authorities of importing countries could request the pharmaceutical industry to provide quality certificates or, where feasible, certificates of Good Manufacturing Practices prepared by the exporting country's national regulatory authority.

Quality control of antimicrobial agents

Regulatory authorities should ensure that quality controls are carried out in accordance with international guidance and in compliance with the provisions of good manufacturing practices, in particular:

- to ensure that the quality and concentration (stability) of veterinary antimicrobial drugs in the marketed dosage form(s) is maintained and properly stored up to the expiry date, established under the recommended storage conditions.
- to ensure the stability of veterinary antimicrobial drugs when they are mixed with feed or drinking water.
- to ensure that all veterinary antimicrobial drugs are manufactured to the appropriate quality and purity.

Assessment of efficacy

Preclinical data should be generated to establish an appropriate dosage regimen necessary to ensure the efficacy of the veterinary antimicrobial drug and limit the selection of microbial resistant microorganisms. Such preclinical trials should, where applicable, include pharmacokinetic and pharmacodynamic studies to guide the development of the most appropriate dosage regimen.

Important pharmacodynamic information may include:

- mode of action;
- the spectrum of antimicrobial activity of the substance;
- identification of bacterial species that are naturally resistant relevant to the use of the veterinary antimicrobial drugs;
- antimicrobial minimum inhibitory and/or bactericidal concentrations;
- determination of whether the antimicrobial exhibits time or concentration-dependent activity or co-dependency,
- evaluation of activity at the site of infection.

Important pharmacokinetic information may include:

- bio-availability according to the route of administration;
- concentration of the veterinary antimicrobial drug at the site of infection and its distribution in the treated animal;
- metabolism which may lead to the inactivation of veterinary antimicrobial drugs;
- excretion routes.

The use of fixed combinations of veterinary antimicrobial drugs should be justified taking into account:

- pharmacodynamic (additive or synergistic effects towards the target microorganism);
- pharmacokinetics (maintenance of the concentrations of associated antimicrobials responsible for additive or synergistic effects at the site of infection throughout the treatment period).

Clinical data should be generated to confirm the validity of the claimed indications and dosage regimens established during the preclinical phase.

Criteria to be considered include:

- parameters for qualitatively and quantitatively assessing efficacy;
- diversity of the clinical cases met when carrying out clinical trials;
- compliance of the protocols of clinical trials with good clinical practice, such as VICH guidelines[3];
- eligibility of the studied clinical cases based on appropriate clinical and microbiological criteria.

Assessment of the potential of veterinary antimicrobial drugs to select for resistant microorganisms

Where applicable, data from preclinical or clinical trials should be used to evaluate the potential for target microorganisms, foodborne and/or commensal microorganisms to develop or acquire resistance.

Appropriate information should be provided to support an adequate assessment of the safety of veterinary antimicrobial drugs being considered for authorisation in food-producing animals. The regulatory authorities should develop criteria for conducting such assessments and interpreting their results. Existing guidelines for antimicrobial resistance risk assessment, such as the OIE Guideline[4] may be used for more comprehensive information. The type of information to be evaluated in these assessments may include, but is not limited to, the following:

- the route and level of human exposure to food-borne or other resistant microorganisms;
- the degree of cross resistance within the class of antimicrobials and between classes of antimicrobials;
- the pre-existing level of resistance, if available, in pathogens causing gastrointestinal infections in humans (baseline determination);
- the concentration of active compound in the gut of the animal at the defined dosage level.

Establishment of ADIs (acceptable daily intake), MRLs (maximum residue limit), and withdrawal periods for veterinary antimicrobial drugs

When setting ADIs and MRLs for veterinary antimicrobial drugs, the safety evaluation is carried out in accordance with international guidelines and should include the determination of microbiological effects (e.g., the potential biological effects on the human intestinal flora) as well as toxicological and pharmacological effects.

An acceptable daily intake (ADI) and a maximum residue limit (MRL) for appropriate food stuffs (i.e., meat, milk, eggs, fish and honey) should be established for each antimicrobial agent. MRLs are necessary in order that officially recognised control laboratories can monitor that the veterinary antimicrobial drugs are being used as

[3] VICH Good Clinical Practice Guideline, http://vich.eudra.org/pdf/2000/GI09_st7.pdf

[4] *Antimicrobial resistance: risk analysis methodology for the potential impact on public health of antimicrobial resistant bacteria of animal origin*, http://www.oie.int/eng/publicat/rt/2003a_r20314.htm

approved. Withdrawal periods should be established for each veterinary antimicrobial drug, which make it possible to produce food in compliance with the MRLs.
Withdrawal periods have to be established for each veterinary antimicrobial drug by taking into account:

- the MRLs established for the considered veterinary antimicrobial drug;
- the pharmaceutical form;
- the target animal species;
- the dosage regimen and the duration of treatment;
- the route of administration.

Establishment of a summary of product characteristics for each veterinary antimicrobial drug for food-producing animals

The summary of product characteristics contains the information necessary for the appropriate use of veterinary antimicrobial drugs. It constitutes, for each veterinary antimicrobial drug, the official reference of the content of its labelling and package insert. This summary contains the following items:

- pharmacological properties;
- target animal species;
- indications;
- target microorganisms;
- dosage and administration route;
- withdrawal periods;
- incompatibilities;
- shelf-life;
- operator safety;
- particular precautions before use;
- instructions for the return or proper disposal of un-used or out-of-date products;
- any information on conditions of use relevant to the potential for selection of resistance should be included, for the purpose of guidance on prudent use;
- class and active ingredient of the veterinary antimicrobial drug.

Surveillance programmes

The relevant authorities should develop a structured approach to the investigation and reporting of the incidence and prevalence of antimicrobial resistance. For the purposes of this Code, priority should be given to the evaluation of antimicrobial resistance in foodborne microorganisms.

For reasons of efficiency, the methods used to establish such programmes (laboratory techniques, sampling, choice of veterinary antimicrobial drug(s) and microorganism(s)) should be harmonized as much as possible at the international level (e.g. OIE documents on *Harmonisation of National Antimicrobial Resistance Monitoring and Surveillance Programmes in Animals and Animal Derived Food* http://www.oie.int/eng/publicat/rt/2003/a_r20318.htm and *Standardisation and Harmonisation of Laboratory Methodologies Used for the Detection and Quantification of Antimicrobial Resistance* http://www.oie.int/eng/publicat/rt/2003/a_r20317.htm).

Preferably, epidemiological surveillance of antimicrobial resistance should be accompanied by data on the amounts of veterinary antimicrobial drugs used by veterinarians and other authorized users in food-producing animals. These data could be collected using one or more of the following sources:

- production data from manufacturers;
- importers and exporters;
- if possible, data on intended and actual usage from manufacturers, wholesale and retail distributors including feed mills, and veterinary prescription records;
- surveys of veterinarians, farmers and producers of food-producing animals.

Regulatory authorities should have in place a pharmacovigilance programme for the monitoring and reporting of adverse reactions to veterinary antimicrobial drugs, including lack of the expected efficacy related to microbial resistance. The information collected through the pharmacovigilance programme should form part of the comprehensive strategy to minimize microbial resistance.

In cases, where the assessment of data collected from pharmacovigilance and from other post-authorization surveillance including, if available, targeted surveillance of antimicrobial resistance, suggests that the conditions of use of the given veterinary antimicrobial drug should be reviewed, regulatory authorities shall endeavour to achieve this re-evaluation.

Distribution of veterinary antimicrobial drugs in veterinary medicine

The relevant authorities should make sure that all veterinary antimicrobial drugs used in food-producing animals are, to the extent possible:

- prescribed by a veterinarian or other suitably trained person authorized in accordance with national legislation or used under conditions stipulated in the national legislation;
- supplied only through licensed/authorized distribution systems;
- administered to animals by a veterinarian or, under the supervision of a veterinarian or other suitably trained person authorized in accordance with national legislation; and that
- proper records are kept of their administration (see Responsibilities of Veterinarians: Recording section).

Control of advertising

Advertising of veterinary antimicrobial drugs should be done in a manner consistent with prudent use guidelines and any other specific regulatory recommendation for the product.

All advertising of veterinary antimicrobial drugs should be controlled by the relevant authorities.

- The authorities should ensure that advertising of veterinary antimicrobial drugs:
  - complies with the marketing authorisation granted, in particular with the content of the summary of product characteristics; and
  - complies with each country's national legislation.

Training of users of veterinary antimicrobial drugs

Training should be undertaken to assure the safety to the consumer of animal derived food and therefore the protection of public health. Training should involve all the relevant professional organisations, regulatory authorities, the pharmaceutical industry, veterinary schools, research institutes, professional associations and other approved users such as farmers and producers of food animals and should focus on:

- information on disease prevention and management strategies to reduce the need to use veterinary antimicrobial drugs;
- relevant pharmacokinetic and pharmacodynamic information to enable the veterinarian to use veterinary antimicrobial drugs prudently;
- the ability of veterinary antimicrobial drugs to select for resistant microorganisms in food- producing animals that may contribute to animal or human health problems; and
- the need to observe responsible use recommendations and using veterinary antimicrobial drugs in animal husbandry in agreement with the provisions of the marketing authorisations and veterinary advice.

Development of research

The relevant authorities should encourage public and private research to:

- improve the knowledge about the mechanisms of action of antimicrobials in order to optimise the dosage regimens and their efficacy;
- improve the knowledge about the mechanisms of selection, emergence and dissemination of resistance determinants;
- develop practical models for applying the concept of risk analysis to assess the public health concern precipitated by the development of resistance;
- further develop protocols to predict, during the authorisation process, the impact of the proposed use of the veterinary antimicrobial drugs on the rate and extent of resistance development; and
- develop and encourage alternative methods to prevent infectious diseases.

Collection and destruction of unused veterinary antimicrobial drugs

The relevant authorities should develop effective procedures for the safe collection and destruction of unused or out-of-date veterinary antimicrobial drugs.

RESPONSIBILITIES OF THE VETERINARY PHARMACEUTICAL INDUSTRY

Marketing authorisation of veterinary antimicrobial drugs for food-producing animals

It is the responsibility of the veterinary pharmaceutical industry:

- to supply all of the information requested by the national regulatory authority in order to establish objectively the quality, safety and efficacy of veterinary antimicrobial drugs; and
- to ensure the quality of this information on the basis of the implementation of procedures, tests and trials in compliance with the provisions of good manufacturing, good laboratory and good clinical practices.

Marketing and export of veterinary antimicrobial drugs

Only officially licensed/authorized veterinary antimicrobial drugs should be marketed, and then only through approved distribution systems.

- Only veterinary antimicrobial drugs meeting the quality standards of the importing country should be exported from a country in which the products were produced;
- The information necessary to evaluate the amount of veterinary antimicrobial drugs marketed should be provided to the national regulatory authority.

Advertising

It is the responsibility of the veterinary pharmaceutical industry to advertise veterinary antimicrobial drugs in accordance with the provisions of the Responsibilities of the Regulatory Authorities**,** Control of Advertising and to not inappropriately advertise antimicrobials directly to the food animal producer.

Training

It is the responsibility of the veterinary pharmaceutical industry to participate in the training of users of veterinary antimicrobial drugs as defined in the section "Training of users of veterinary antimicrobial drugs".

Research

It is the responsibility of the veterinary pharmaceutical industry to contribute to the development of research as defined in the section "Development of research".

RESPONSIBILITIES OF WHOLESALE AND RETAIL DISTRIBUTORS

Retailers distributing veterinary antimicrobial drugs should only do so on the prescription of a veterinarian or other suitably trained person authorized in accordance with national legislation and all products should be appropriately labelled.

Distributors should encourage compliance with the national guidelines on the responsible use of veterinary antimicrobial drugs and should keep detailed records of all antimicrobials supplied according to the national regulations including:

- date of supply
- name of prescribing veterinarian
- name of user
- name of medicinal product
- batch number
- quantity supplied

Distributors should participate in the training of users of veterinary antimicrobial drugs as defined in the section "Training of users of veterinary antimicrobial drugs".

RESPONSIBILITIES OF VETERINARIANS[5]

The veterinarian is responsible for identifying recurrent disease problems and developing alternative strategies to prevent or treat infectious disease. These may include changes in husbandry conditions and vaccination programs where vaccines are available.

Veterinary antimicrobial drugs should only be prescribed for animals under his/her care, which means that:

- the veterinarian has been given responsibility for the health of the animal or herd/flock by the producer or the producer's agent;
- that responsibility is real and not merely nominal;
- that the animal(s) or herd/flock have been seen immediately before the prescription and supply, or
- recently enough for the veterinarian to have personal knowledge of the condition of the animal(s) or current health status of the herd or flock to make a diagnosis and prescribe; and
- the veterinarian should maintain clinical records of the animal(s) or the herd/flock.

It is recommended that veterinary professional organizations develop for their members species-specific clinical practice guidelines on the responsible use of veterinary antimicrobial drugs.

Veterinary antimicrobial drugs should only be used when necessary and in an appropriate manner:

- A prescription for veterinary antimicrobial drugs must precisely indicate the treatment regimen, the dose, the dosage intervals, the duration of the treatment, the withdrawal period and the amount of antimicrobial to be delivered depending on the dosage, the number, and the weight of the animals to be treated;
- All veterinary antimicrobial drugs should be prescribed and used according to the conditions stipulated in the national legislation.

The appropriate use of veterinary antimicrobial drugs in practice is a clinical decision which should be based on the experience and local expertise of the prescribing veterinarian, and the accurate diagnosis, based on adequate diagnostic procedures. There will be occasions when a group of animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing in order to prevent the development of clinical disease and for reasons of animal welfare.

Determination of the choice of a veterinary antimicrobial drug by:

- The expected efficacy of the treatment based on:

[5] Under some circumstances, this may refer to a suitably trained person authorized in accordance with national legislation.

  - the clinical experience of the veterinarian;
  - the spectrum of the antimicrobial activity towards the pathogens involved;
  - the epidemiological history of the rearing unit particularly in regards to the antimicrobial resistance profiles of the pathogens involved. Ideally, the antimicrobial profiles should be established before the commencement of treatment. Should a first antimicrobial treatment fail or should the disease recur, the use of a second veterinary antimicrobial drug should be based on the results of microbiological tests;
  - the appropriate route of administration;
  - results of initial treatment;
  - known pharmacokinetics/tissue distribution to ensure that the selected veterinary antimicrobial drug is active at the site of infection;
  - prognosis.
- The need to minimize the adverse health impact from the development of microbial resistance based on:
  - the choice of the activity spectrum of the veterinary antimicrobial drug;
  - the targeting of specific microorganism;
  - known or predictable susceptibilities using antimicrobial susceptibility testing;
  - optimized dosing regimens;
  - the use of effective combinations of veterinary antimicrobial drugs;
  - the importance of the antimicrobial drugs to veterinary and human medicine; and,
  - the route of administration.

If the label conditions allow for some flexibility, the veterinarian should consider a dosage regimen that is long enough to allow an effective recovery of the animal but is short enough to limit the selection of resistance in foodborne and/or commensal microorganisms.

Off-label use

The off-label use of a veterinary antimicrobial drug may be permitted in appropriate circumstances and should be in agreement with the national legislation in force including the administrative withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of responsible use in such a case including the therapeutic regimen, the route of administration, and the duration of the treatment. Off-label use of antimicrobial growth promoters should not be permitted.

Recording

Records on veterinary antimicrobial drugs should be kept in conformity with national legislation. Veterinarians may refer to recording information as covered in the relevant national legislation.[6] In particular, for investigation of antimicrobial resistance, veterinarians should:

[6] Veterinarians can also refer to the *Guidelines for the Design and Implementation of National Regulatory Food Safety Programmes associated with the Use of Veterinary Drugs in Food-Producing Animals* (CAC/GL 71-2009).

- record the antimicrobial susceptibility testing results;
- investigate adverse reactions to veterinary antimicrobial drugs, including lack of expected efficacy due to antimicrobial resistance, and report it, as appropriate, to the regulatory authorities.

Veterinarians should also periodically review farm records on the use of veterinary antimicrobial drugs to ensure compliance with their directions.

Training

Veterinary professional organizations should participate in the training of users of veterinary antimicrobial drugs as defined in Paragraph 36.

RESPONSIBILITIES OF PRODUCERS

Producers are responsible for preventing disease outbreaks and implementing health and welfare programmes on their farms. They may, as appropriate, call on the assistance of their veterinarian or other suitably trained person authorized in accordance with national legislation. All people involved with food-producing animals have an important part to play in ensuring the responsible use of veterinary antimicrobial drugs.

Producers of food-producing animals have the following responsibilities:

- to use veterinary antimicrobial drugs only when necessary and not as a replacement for good management and farm hygiene, or other disease prevention methods such as vaccination;
- to implement a health plan in cooperation with the veterinarian in charge of the animals that outlines preventative measures (e.g. mastitis plan, worming and vaccination programmes, etc.);
- to use veterinary antimicrobial drugs in the species, for the uses and at the doses on the approved labels and in accordance with the prescription, product label instructions or the advice of a veterinarian familiar with the animals and the production site;
- to isolate sick animals and dispose of dead or dying animals promptly under conditions approved by relevant authorities;
- to comply with the storage conditions of veterinary antimicrobial drugs according to the approved product labelling;
- to address hygienic conditions regarding contacts between people (veterinarians, breeders, owners, children) and the animals treated;
- to comply with the recommended withdrawal periods to ensure that residue levels in animal derived food do not present a risk for the consumer;
- to not use out-of-date veterinary antimicrobial drugs and to dispose of all unused veterinary antimicrobial drugs in accordance with the provisions on the product labels;
- to inform the veterinarian in charge of the unit of recurrent disease problems;
- to maintain all clinical and laboratory records of microbiological and susceptibility tests if required by the national regulatory authority. These data

should be made available to the veterinarian in charge of treating the animals in order to optimize the use of veterinary antimicrobial drugs.

- To keep adequate records of all veterinary antimicrobial drugs used, including the following:
  - name of the veterinary antimicrobial drug/active substance and batch number;
  - name of supplier;
  - date of administration;
  - identification of the animal or group of animals to which the veterinary antimicrobial drug was administered;
  - clinical conditions treated;
  - quantity and duration of the antimicrobial agent administered;
  - withdrawal periods;
  - result of laboratory tests;
  - result of treatment;
  - name of the prescribing veterinarian or other suitably trained person authorized in accordance with national legislation.
- To ensure sound management of animal wastes and other materials to avoid dissemination of antimicrobial agents and resistance determinants into the environment;
- To prevent the unnecessary contact with and transmission of resistant bacteria to all personnel, including farm workers;
- To assist the relevant authorities in surveillance programs related to antimicrobial resistance.

CONCLUSIONS

Veterinary antimicrobial drugs are very important tools for controlling a great number of infectious diseases in both animals and humans. It is vital that all countries put in place the appropriate systems to ensure that veterinary antimicrobial drugs are manufactured, marketed, distributed, prescribed and used responsibly, and that these systems are adequately audited.

This document is designed to provide the framework that countries may implement in accordance with their capabilities but within a reasonable period of time. A stepwise approach may be appropriate for a number of countries to properly implement all of the elements in this document.

The continued availability of veterinary antimicrobial drugs, which are essential for animal welfare and animal health and consequently human health, will ultimately depend on the responsible use of these products by all those involved in the authorisation, production, control, distribution and use of antimicrobials in food-producing animals.

ENDNOTES

1 A. Franklin, J. Acar, F. Anthony, R. Gupta †T. Nicholls, Y. Tamura, S. Thompson, E.J. Threlfall, D. Vose, M. van Vuuren, D.G. White, H. C. Wegener & M.L. Costarrica. Antimicrobial resistance: harmonisation of national antimicrobial resistance monitoring and surveillance programmes in animals and in animal-derived food. *Rev. sci. tech. Off. Int. Epiz.*, 2001, 20 (3), 859–870. http://www.oie.int/eng/publicat/rt/2003/a_r20318.htm

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LIST OF ABBREVIATIONS USED IN THIS CODE

ADI	Acceptable Daily Intake
CAC	Codex Alimentarius Commission
CAC/RCP	Codex Alimentarius Commission/Recommended Code of Practice
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
FAO	Food and Agriculture Organization of the United Nations
MRL	Maximum Residue Limit
OIE	Office International des epizooties/International Office of Epizooties
VICH	International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organization

GLOSSARY AND DEFINITIONS OF TERMS

Veterinary antimicrobial drug

Veterinary antimicrobial drug(s) refers to naturally occurring, semi-synthetic or synthetic substances that exhibit antimicrobial activity (kill or inhibit the growth of microorganisms). Where anticoccidial products have antibacterial activity, they should be considered as veterinary antimicrobial drugs, except where this is precluded by national legislation.

Disease treatment/therapeutic use

Treatment/Therapeutic Use refers to use of an antimicrobial(s) for the specific purpose of treating an animal(s) with a clinically diagnosed infectious disease or illness.

Disease prevention/prophylactic use

Prevention/Prophylactic Use refers to use of an antimicrobial(s) in healthy animals considered to be at risk of infection or prior to the onset of clinical infectious disease. This treatment includes:

- control of the dissemination of a clinically diagnosed infectious disease identified within a group of animals, and
- prevention of an infectious disease that has not yet been clinically diagnosed.

Growth promotion

Growth Promotion refers to the use of antimicrobial substances to increase the rate of weight gain and/or the efficiency of feed utilization in animals by other than purely nutritional means. The term does NOT apply to the use of antimicrobials for the specific purpose of treating, controlling, or preventing infectious diseases, even when an incidental growth response may be obtained.

CODE OF PRACTICE ON GOOD ANIMAL FEEDING

CAC/RCP 54-2004

CODE OF PRACTICE ON GOOD ANIMAL FEEDING

CAC/RCP 54-2004

SECTION 1. INTRODUCTION

This Code is to establish a feed safety system for food producing animals which covers the whole food chain, taking into account relevant aspects of animal health and the environment in order to minimize risks to consumers' health. This Code applies in addition to the principles of food hygiene already established by the Codex Alimentarius Commission[1], taking into account the special aspects of animal feeding.

SECTION 2. PURPOSE AND SCOPE

The objective of this Code is to help ensure the safety of food for human consumption through adherence to good animal feeding practice at the farm level and good manufacturing practices (GMPs) during the procurement, handling, storage, processing and distribution of animal feed and feed ingredients for food producing animals.

This Code of Practice applies to the production and use of all materials destined for animal feed and feed ingredients at all levels whether produced industrially or on farm. It also includes grazing or free-range feeding, forage crop production and aquaculture.

Those issues of animal welfare other than food safety related animal health are not covered. Environmental contaminants should be considered where the level of such substances in the feed and feed ingredients could present a risk to consumers' health from the consumption of foods of animal origin.

While recognizing that, in its totality, a feed safety system would address animal health and environmental issues, in addition to consumers' health, this Code of Practice, in fulfilling the Codex mandate of consumer protection, only addresses food safety. Notwithstanding this, best efforts have been made to ensure that the recommendations and practices in this Code of Practice will not be detrimental to the more general animal health and environmental aspects of animal feeding.

[1] *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969).

SECTION 3. DEFINITIONS

For the purpose of this Code:

Feed (Feedingstuff): Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food producing animals.

Feed Ingredient: A component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animal's diet, including feed additives. Ingredients are of plant, animal or aquatic origin, or other organic or inorganic substances.

Feed Additive[2]: Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, which affects the characteristics of feed or animal products.

Medicated Feed: Any feed which contains veterinary drugs as defined in the Codex Alimentarius Commission Procedural Manual.

Undesirable Substances: Contaminants and other substances which are present in and/or on feed and feed ingredients and which constitute a risk to consumers' health, including food safety related animal health issues.

SECTION 4. GENERAL PRINCIPLES AND REQUIREMENTS

Feed and feed ingredients should be obtained and maintained in a stable condition so as to protect feed and feed ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during production, handling, storage and transport. Feed should be in good condition and meet generally accepted quality standards. Where appropriate, good agricultural practices, good manufacturing practices (GMPs) and, where applicable, Hazard Analysis and Critical Control Point (HACCP) principles[3] should be followed to control hazards that may occur in food. Potential sources of contamination from the environment should be considered.

Parties that produce feed or feed ingredients, those that rear animals for use as food and those that produce such animal products need to collaborate to identify potential hazards and their levels of risk to consumers' health. Such collaboration will enable the development and maintenance of appropriate risk management options and safe feeding practices.

4.1 Feed ingredients

Feed ingredients should be obtained from safe sources and be subject to a risk analysis where the ingredients are derived from processes or technologies not hitherto evaluated from a food safety point of view. The procedure used should be consistent

[2] Micro-organisms, enzymes, acidity regulators, trace elements, vitamins and other products fall within the scope of this definition depending on the purpose of use and method of administration.

[3] Hazard Analysis and Critical Control Point, as defined in the Annex to the *Recommended International Code of Practice on General Principles of Food Hygiene* (CAC/RCP 1-1969).

with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.*[4] Manufacturers of feed additives in particular should provide clear information to the user to permit correct and safe use. Monitoring of feed ingredients should include inspection and sampling and analysis for undesirable substances using risk-based protocols. Feed ingredients should meet acceptable and, if applicable, statutory standards for levels of pathogens, mycotoxins, pesticides and undesirable substances that may give rise to consumers' health hazards.

4.2 Labelling

Labelling should be clear and informative as to how the user should handle, store and use feed and feed ingredients. Labelling should be consistent with any statutory requirements and should describe the feed and provide instructions for use. Labelling or the accompanying documents should contain, where appropriate:

- information about the species or category of animals for which the feed is intended;
- the purpose for which the feed is intended;
- a list of feed ingredients, including appropriate reference to additives, in descending order of proportion;
- contact information of manufacturer or registrant;
- registration number if available;
- directions and precautions for use;
- lot identification;
- manufacturing date; and
- "use before" or expiry date.

This sub-section does not apply to labelling of feed and feed ingredients derived from modern biotechnology.[5]

4.3 Traceability/product tracing and record keeping of feed and feed ingredients

Traceability/product tracing of feed and feed ingredients, including additives, should be enabled by proper record keeping for timely and effective withdrawal or recall of products if known or probable adverse effects on consumers' health are identified. Records should be maintained and readily available regarding the production, distribution and use of feed and feed ingredients to facilitate the prompt trace-back of feed and feed ingredients to the immediate previous source and trace-forward to the next subsequent recipients if known or probable adverse effects on consumers' health are identified.[6]

[4] Procedural Manual of the Codex Alimentarius Commission.

[5] Whether and how to label animal feed and feed ingredients derived from modern biotechnology awaits developments on food labelling, being considered by the Codex Committee on Food Labelling.

[6] Development of detailed measures on traceability/product tracing should take into the account: *Principles for Traceability/Product Tracing as a tool within a Food Inspection and Certification System* (CAC-GL 60-2006).

4.3.1 **Special conditions applicable to emergency situations**

Operators should, as soon as reasonable, inform the competent authorities in the country if they consider that a feed or feed ingredient does not satisfy the feed safety requirements established in this Code. The information should be as detailed as possible and should at least contain a description of the nature of the problem, a description of the feed or feed ingredients, the species for which it is intended, the lot identifier, the name of the manufacturer and the place of origin. The competent authorities and operators should immediately take effective measures to ensure that those feed or feed ingredients do not pose any danger to consumers' health.

As soon as it becomes likely that a particular feed or feed ingredient is to be traded internationally and may pose a danger to consumers' health, the competent authorities of the exporting countries should notify, at least, the competent authorities of the relevant importing countries. The notification should be as detailed as possible and should at least contain the particulars indicated in the previous paragraph.

4.4 Inspection and control procedures

Feed and feed ingredients manufacturers and other relevant parts of industry should practice self-regulation/auto-control to secure compliance with required standards for production, storage and transport. It will also be necessary for risk-based official regulatory programmes to be established to check that feed and feed ingredients are produced, distributed and used in such a way that foods of animal origin for human consumption are both safe and suitable. Inspection and control procedures should be used to verify that feed and feed ingredients meet requirements in order to protect consumers against food-borne hazards.[7] Inspection systems should be designed and operated on the basis of objective risk assessment appropriate to the circumstances.[8] Preferably the risk assessment methodology employed should be consistent with internationally accepted approaches. Risk assessment should be based on current available scientific evidence.

Monitoring of feed and feed ingredients, whether by industry or official inspection bodies, should include inspection and sampling and analysis to detect unacceptable levels of undesirable substances.

4.5 Health hazards associated with animal feed

All feed and feed ingredients should meet minimum safety standards. It is essential that levels of undesirable substances are sufficiently low in feed and feed ingredients that their concentration in food for human consumption is consistently below the level of concern. Codex Maximum Residue Limits and Extraneous Maximum Residue Levels set for feed should be applied. Maximum residue limits set for food, such as those established by the Codex Alimentarius Commission, may be useful in determining minimum safety standards for feed.

[7] *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995).

[8] *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997).

4.5.1 **Feed additives and veterinary drugs used in medicated feed**

Feed additives and veterinary drugs used in medicated feed should be assessed for safety and used under stated conditions of use as pre-approved by the competent authorities.

Veterinary drugs used in medicated feed should comply with the provisions of the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes associated with the Use of Veterinary Drugs in Food-producing Animals* (CAC/GL 71-2009).

Borderlines between feed additives and veterinary drugs used in medicated feed may be set to avoid misuse.

Feed additives should be received, handled and stored to maintain their integrity and to minimise misuse or unsafe contamination. Feed containing them should be used in strict accordance with clearly defined instructions for use.

Antibiotics should not be used in feed for growth promoting purposes in the absence of a public health safety assessment.[9]

4.5.2 **Feed and feed ingredients**

Feed and feed ingredients should only be produced, marketed, stored and used if they are safe and suitable, and, when used as intended, should not represent in any way an unacceptable risk to consumers' health. In particular, feed and feed ingredients contaminated with unacceptable levels of undesirable substances should be clearly identified as unsuitable for animal feed and not be marketed or used.

Feed and feed ingredients should not be presented or marketed in a manner liable to mislead the user.

4.5.3 **Undesirable substances**

The presence in feed and feed ingredients of undesirable substances such as industrial and environmental contaminants, pesticides, radionuclides, persistent organic pollutants, pathogenic agents and toxins such as mycotoxins should be identified, controlled and minimised. Animal products that could be a source of the Bovine Spongiform Encephalopathy (BSE) agent[10] should not be used for feeding directly to, or for feed manufacturing for, ruminants. Control measures applied to reduce unacceptable level of undesirable substances should be assessed in terms of their impact on food safety.

[9] *WHO Global Principles for the Containment of Antimicrobial Resistance in Animals Intended for Food*, June 2000, Geneva, Switzerland.

[10] Joint WHO/FAO/OIE Technical Consultation on BSE: public health, animal health and trade, OIE Headquarters, Paris, 11–14 June 2001.

The risks of each undesirable substance to consumers' health should be assessed and such assessment may lead to the setting of maximum limits for feed and feed ingredients or the prohibition of certain materials from animal feeding.

SECTION 5. PRODUCTION, PROCESSING, STORAGE, TRANSPORT AND DISTRIBUTION OF FEED AND FEED INGREDIENTS

The production, processing, storage, transport and distribution of safe and suitable feed and feed ingredients is the responsibility of all participants in the feed chain, including farmers, feed ingredient manufacturers, feed compounders, truckers, etc. Each participant in the feed chain is responsible for all activities that are under their direct control, including compliance with any applicable statutory requirements.

Feed and feed ingredients should not be produced, processed, stored, transported or distributed in facilities or using equipment where incompatible operations may affect their safety and lead to adverse effects on consumers' health. Due to the unique characteristics of aquaculture, the application of these general principles must consider the differences between aquaculture and terrestrial-based production.

Where appropriate, operators should follow GMPs and, where applicable, HACCP principles to control hazards that may affect food safety. The aim is to ensure feed safety and in particular to prevent contamination of animal feed and food of animal origin as far as this is reasonably achievable, recognising that total elimination of hazards is often not possible.

The effective implementation of GMPs and, where applicable, HACCP-based approaches should ensure, in particular, that the following areas are addressed.

5.1 Premises

Buildings and equipment used to process feed and feed ingredients should be constructed in a manner that permits ease of operation, maintenance and cleaning and minimises feed contamination. Process flow within the manufacturing facility should also be designed to minimise feed contamination.

Water used in feed manufacture should meet hygienic standards and be of suitable quality for animals. Tanks, pipes and other equipment used to store and convey water should be of appropriate materials which do not produce unsafe levels of contamination.

Sewage, waste and rain water should be disposed of in a manner which avoids contamination of equipment, feed and feed ingredients.

5.2 Receiving, storage and transportation

Chemical fertilizers, pesticides and other materials not intended for use in feed and feed ingredients should be stored separately from feed and feed ingredients to avoid the potential for manufacturing errors and contamination of feed and feed ingredients.

Processed feed and feed ingredients should be stored separately from unprocessed feed ingredients and appropriate packaging materials should be used. Feed and feed ingredients should be received, stored and transported in such a way so as to minimize the potential for any cross-contamination to occur at a level likely to have a negative impact on food safety.

The presence of undesirable substances in feed and feed ingredients should be monitored and controlled.

Feed and feed ingredients should be delivered and used as soon as possible. All feed and feed ingredients should be stored and transported in a manner which minimizes deterioration and contamination and enables the correct feed to be sent to the right animal group.

Care should be taken to minimize deterioration and spoilage at all stages of handling, storage and transport of feed and feed ingredients. Special precautions should be taken to limit fungal and bacterial growth in moist and semi-moist feed. Condensation should be minimized in feed and feed ingredient manufacturing and processing facilities. Dry feed and feed ingredients should be kept dry in order to limit fungal and bacterial growth.

Waste feed and feed ingredients and other material containing unsafe levels of undesirable substances or any other hazards should not be used as feed, but, should be disposed of in an appropriate manner including compliance with any applicable statutory requirements.

5.3 Personnel training

All personnel involved in the manufacture, storage and handling of feed and feed ingredients should be adequately trained and aware of their role and responsibility in protecting food safety.

5.4 Sanitation and pest control

Feed and feed ingredients, processing plants, storage facilities and their immediate surroundings should be kept clean and effective pest control programmes should be implemented.

Containers and equipment used for manufacturing, processing, transport, storage, conveying, handling and weighing should be kept clean. Cleaning programmes should be effective and minimise residues of detergents and disinfectants.

Machinery coming into contact with dry feed or feed ingredients should be dried following any wet cleaning process.

Special precautions should be taken when cleaning machinery used for moist and semi-moist feed and feed ingredients to avoid fungal and bacterial growth.

5.5 Equipment performance and maintenance

All scales and metering devices used in the manufacture of feed and feed ingredients should be appropriate for the range of weights and volumes to be measured, and be tested regularly for accuracy.

All mixers used in the manufacture of feed and feed ingredients should be appropriate for the range of weights or volumes being mixed and be capable of manufacturing suitable homogeneous mixtures and homogeneous dilutions, and be tested regularly to verify their performance.

All other equipment used in the manufacture of feed and feed ingredients should be appropriate for the range of weights or volumes being processed, and be monitored regularly.

5.6 Manufacturing controls

Manufacturing procedures should be used to avoid cross-contamination (for example flushing, sequencing and physical clean-out) between batches of feed and feed ingredients containing restricted or otherwise potentially harmful materials (such as certain animal by-product meals, veterinary drugs). These procedures should also be used to minimise cross-contamination between medicated and non-medicated feed and other incompatible feed. In cases where the food safety risk associated with cross-contamination is high and the use of proper flushing and cleaning methods is deemed insufficient, consideration should be given to the use of completely separate production lines, transfer, storage and delivery equipment.

Pathogen control procedures, such as heat treatment or the addition of authorised chemicals, should be used where appropriate, and monitored at the applicable steps in the manufacturing process.

5.7 Recalls

Records and other information should be maintained as indicated in sub-section 4.3 of this Code to include the identity and distribution of feed and feed ingredients so that any feed or feed ingredient considered to pose a threat to consumers' health can be rapidly removed from the market and that animals exposed to the relevant feed can be identified.

SECTION 6. ON-FARM PRODUCTION AND USE OF FEED AND FEED INGREDIENTS

This section provides guidance on the cultivation, manufacture, management and use of feed and feed ingredients on farms and in aquaculture.

This section should be used in conjunction with the applicable requirements of Sections 4 and 5 of this Code.

To help ensure the safety of food used for human consumption, good agricultural practices[11] should be applied during all stages of on-farm production of pastures, cereal grain and forage crops used as feed or feed ingredients for food producing animals. For aquaculture the same principles should apply, where applicable. Three types of contamination represent hazards at most stages of on-farm production of feed and feed ingredients, namely:

- Biological, such as bacteria, fungi and other microbial pathogens;
- Chemical, such as residues of medication, pesticides, fertilizer or other agricultural substances; and
- Physical, such as broken needles, machinery and other foreign material.

6.1 Agricultural production of feed

Adherence to good agricultural practices is encouraged in the production of natural, improved and cultivated pastures and in the production of forage and cereal grain crops used as feed or feed ingredients for food producing animals. Following good agricultural practice standards will minimize the risk of biological, chemical and physical contaminants entering the food chain. If crop residuals and stubbles are grazed after harvest, or otherwise enter the food chain, they should also be considered as livestock feed. Most livestock will consume a portion of their bedding. Crops that produce bedding material or bedding materials such as straw or wood shavings should also be managed in the same manner as animal feed ingredients. Good pasture management practices, such as rotational grazing and dispersion of manure droppings, should be used to reduce cross-contamination between groups of animals.

6.1.1 Site selection

Land used for production of animal feed and feed ingredients should not be located in close proximity to industrial operations where industrial pollutants from air, ground water or runoff from adjacent land would be expected to result in the production of foods of animal origin that may present a food safety risk. Contaminants present in runoff from adjacent land and irrigation water should be below levels that present a food safety risk.

6.1.2 Fertilizers

Where manure fertilization of crops or pastures is practised, an appropriate handling and storage system should be in place and maintained to minimize environmental contamination, which could negatively impact on the safety of foods of animal origin. There should be adequate time between applying the manure and grazing or forage harvesting (silage and hay making) to allow the manure to decompose and to minimize contamination.

Manure, compost and other plant nutrients should be properly used and applied to minimize biological, chemical and physical contamination of foods of animal origin which could adversely affect food safety.

[11] Guidelines on this definition are under development by FAO.

Chemical fertilizers should be handled, stored and applied in a manner such that they do not have a negative impact on the safety of foods of animal origin.

6.1.3 **Pesticides and other agricultural chemicals**

Pesticides and other agricultural chemicals should be obtained from safe sources. Where a regulatory system is in place, any chemical used must comply with the requirements of that system.

Pesticides should be stored according to the manufacturer's instructions and used in accordance with Good Agricultural Practice in the Use of Pesticides (GAP)[12]. It is important that farmers carefully follow the manufacturer's instructions for use for all agricultural chemicals.

Pesticides and other agricultural chemicals should be disposed of responsibly in a manner that will not lead to contamination of any body of water, soil, feed or feed ingredients that may lead to the contamination of foods of animal origin which could adversely affect food safety.

6.2 Manufacturing of feed on-farm

6.2.1 **Feed ingredients**

On-farm feed manufacturers should follow the applicable guidelines established in sub-section 4.1 of this Code when sourcing feed ingredients off the farm.

Feed ingredients produced on the farm should meet the requirements established for feed ingredients sourced off the farm. For example, seed treated for planting should not be fed.

6.2.2 **Mixing**

On-farm feed manufacturers should follow the applicable guidelines established in Section 5 of this Code. Particular attention should be given to sub-section 5.6 of this Code.

In particular, feed should be mixed in a manner that will minimize the potential for cross-contamination between feed or feed ingredients that may have an effect on the safety or withholding period for the feed or feed ingredients.

6.2.3 **Monitoring records**

Appropriate records of feed manufacturing procedures followed by on-farm feed manufacturers should be maintained to assist in the investigations of possible feed-related contamination or disease events.

Records should be kept of incoming feed ingredients, date of receipt and batches of feed produced in addition to other applicable records set out in sub-section 4.3 of the Code.

[12] See Definitions for the Purposes of the Codex Alimentarius (Procedural Manual of the Codex Alimentarius Commission).

6.3 Good animal feeding practice

Good animal feeding practices include those practices that help to ensure the proper use of feed and feed ingredients on-farm while minimising biological, chemical and physical risks to consumers of foods of animal origin.

6.3.1 Water

Water for drinking or for aquaculture should be of appropriate quality for the animals being produced. Where there is reason to be concerned about contamination of animals from the water, measures should be taken to evaluate and minimise the hazards.

6.3.2 Pasture grazing

The grazing of pastures and crop lands should be managed in a way that minimises the avoidable contamination of foods of animal origin by biological, chemical and physical food safety hazards.

Where appropriate, an adequate period should be observed before allowing livestock to graze on pasture, crops and crop residuals and between grazing rotations to minimise biological cross-contamination from manure.

Where agricultural chemicals are used, operators should ensure that the required withholding periods are observed.

6.3.3 Feeding

It is important that the correct feed is fed to the right animal group and that the directions for use are followed. Contamination should be minimised during feeding. Information should be available of what is fed to animals and when, to ensure that food safety risks are managed.

Animals receiving medicated feed should be identified and managed appropriately until the correct withholding period (if any) has been reached and records of these procedures must be maintained. Procedures to ensure that medicated feed are transported to the correct location and are fed to animals that require the medication should be followed. Feed transport vehicles and feeding equipment used to deliver and distribute medicated feed should be cleaned after use, if a different medicated feed or non-medicated feed or feed ingredient is to be transported next.

6.4 Stable feeding and lot/intensive feeding units

The animal production unit should be located in an area that does not result in the production of food of animal origin that poses a risk to food safety. Care should be taken to avoid animal access to contaminated land, and to facilities with potential sources of toxicity.

6.4.1 Hygiene

The animal production unit should be designed so that it can be adequately cleaned. The animal production unit and feeding equipment should be thoroughly cleaned regularly to prevent potential hazards to food safety. Chemicals used should be

appropriate for cleaning and sanitising feed manufacturing equipment and should be used according to instructions. These products should be properly labelled and stored away from feed manufacturing, feed storage and feeding areas.

A pest control system should be put in place to control the access of pests to the animal production unit to minimise potential hazards to food safety.

Operators and employees working in the animal production unit should observe appropriate hygiene requirements to minimise potential hazards to food safety from feed.

6.5 Aquaculture[13]

Aquaculture includes a wide range of species of finfish, molluscs, crustaceans, cephalopods, etc. The complexity of aquaculture is reflected in the wide range of culturing methods ranging from huge cages in open seas to culturing in small freshwater ponds. The diversity is further reflected by the range of stages from larvae to full grown size, requiring different feed as well as different culture methods. Nutritional approaches range from feeding only naturally occurring nutrients in the water to the use of sophisticated equipment and scientifically formulated compound feed.

To ensure food safety, necessary precautions should be taken regarding culturing methods, culturing sites, technologies, materials and feed used to minimize contamination in order to reduce food hazards.

SECTION 7. METHODS OF SAMPLING AND ANALYSIS

7.1. Sampling

Sampling protocols should meet scientifically recognized principles and procedures.

7.2 Analysis

Laboratory methods developed and validated using scientifically recognized principles and procedures should be used.[14] When selecting methods, consideration should also be given to practicability, with preference given to those methods which are reliable and applicable for routine use. Laboratories conducting routine analyses of feed and feed ingredients should ensure their analytical competency with each method used and maintain appropriate documentation.[15]

[13] Aquaculture producers should refer to relevant sections of the Code of Practice for Fish and Fishery Products for additional information (CAC/RCP 52-2003).

[14] *General Criteria for the Selection of Methods of Analysis Using the Criteria Approach* (Procedural Manual of the Codex Alimentarius Commission).

[15] For example, through quality assurance systems such as ISO 17025.

CODE OF PRACTICE FOR THE REDUCTION OF AFLATOXIN B_1 IN RAW MATERIALS AND SUPPLEMENTAL FEEDINGSTUFFS FOR MILK PRODUCING ANIMALS

CAC/RCP 45-1997

1. BACKGROUND

1.1 Aflatoxin B_1 contamination of animal feedingstuffs can be a very serious problem, occurring in part due to inadequate storage conditions. Contamination may also occur at the preharvest stage and be exacerbated by inadequate storage conditions. Good cropping practices, use of seed varieties bred for resistance to seed-infecting fungi and insect pests as well as the use of appropriate approved pesticides represent reasonable preventive measures to control contamination in the field. Even with application of these practices, conditions created by the environment and/or traditional agricultural procedures may defeat any preventative measures.

1.2 Practices that reduce aflatoxin B_1 contamination in the field and after harvest should be an integral part of animal feedingstuff production, particularly for the export market because of the additional handling and transport steps required to get the product to the final destination. The factors most amenable for prevention of fungal infection and aflatoxin B_1 production involve proper drying and storage of the feedingstuff prior to transport. The problems created by too much moisture are magnified greatly by deficient post-harvest crop handling techniques.

1.3 Investigations concerning the biological fate of aflatoxin B_1 (AFB_1) in lactating dairy cattle have demonstrated the transmission of residues into milk, occurring as the metabolite aflatoxin M_1 (AFM_1). Although AFM_1 is considered to be less carcinogenic than AFB_1 by at least an order of magnitude, its presence in dairy products should be limited to the lowest level practicable. The amount of daily ingested AFB_1 which is transferred into milk is in the range of 0.17 to 3.3%.

1.4 To ensure the lowest possible level of AFM_1 in milk, attention should be given to residues of AFB_1 in the lactating dairy animal's daily feed ration.

1.5 To date there has been no widespread government acceptance of any decontamination treatment intended to reduce aflatoxin B_1 levels in contaminated animal feedingstuffs. Ammoniation appears to have the most practical application for the decontamination of agricultural commodities, and has received limited regional (state, country) authorization for its use with animal feed under specified conditions (i.e. commodity type, quantity, animal). Also, research suggests that the addition of the anticaking/binding agent "hydrated sodium calcium aluminosilicate" to aflatoxin contaminated

feeds may reduce AFM_1 residues in milk, depending on the initial concentration of AFB_1 in the feed.

2. RECOMMENDED PRACTICES

2.1 Crop production

2.1.1 Prepare seed bed for new crop by destroying or removing the seed heads or fruits (e.g. corn ears, peanuts, etc.) of aflatoxin susceptible crops.

2.1.2 Utilize soil tests if possible to determine fertilizer needs and apply fertilizer and soil conditioners to assure adequate soil pH and plant nutrition to avoid plant stress, especially during seed development.

2.1.3 When feasible, use seed varieties bred for fungal resistance and field tested for resistance to *Aspergillus flavus*.

2.1.4 As far as practicable, sow and harvest crops at times which will avoid high temperature and drought stress during the period of seed development/maturation.

2.1.5 Minimize insect damage and fungal infection by the proper use of appropriate approved insecticides and fungicides and other appropriate practices within an integrated pest management program.

2.1.6 Use good agronomic practice, including measures which will reduce plant stress. Such measures may include: avoidance of overcrowding of plants by sowing at the recommended row and intra-plant spacings for the species/varieties grown; maintenance of a weed free environment in the growing crop by the use of appropriate approved herbicides and other suitable cultural practices; elimination of fungal vectors in the vicinity of the crop; and crop rotation.

2.1.7 Minimize mechanical damage to crops during cultivation.

2.1.8 Irrigation is a valuable method of reducing plant stress in some growing situations. If irrigation is used ensure that it is applied evenly and individual plants have an adequate supply of water.

2.2 Harvest

2.2.1 Harvest crops at full maturity unless allowing the crop to continue to full maturity would subject it to extreme heat, rainfall or drought conditions.

2.2.2 As much as possible avoid mechanical damage during harvest.

2.2.3 Where applicable dry crops to a minimum moisture content as quickly as possible.

2.2.4 If crops are harvested at high moisture levels dry immediately after harvest.

2.2.5 Avoid piling or heaping wet freshly harvested commodities for more than a few hours prior to drying or threshing to lessen the risk of fungal growth.

2.2.6 Ensure adequate protection from rain during sun drying.

2.3 Storage

2.3.1 Practice good sanitation for storage structures, wagons, elevators and other containers to ensure that stored crops will not be contaminated. Proper storage conditions include dry, well ventilated structures that provide protection from rain or seepage of ground water.

2.3.2 For bagged commodities, ensure that bags are clean and dry and stack on pallets or incorporate a water impermeable layer between the sacks and the floor.

2.3.3 Ensure that crops to be stored are free of mould and insects and are dried to safe moisture levels (ideally crops should be dried to a moisture content in equilibrium with a relative humidity of 70%).

2.3.4 Prevent insect infestation by the use of appropriate approved insecticides.

2.3.5 Ensure that the storage facilities are free of insects and mould by good housekeeping and/or the use of appropriate approved fumigants.

2.3.6 Prevent access by rodents and birds.

2.3.7 Store at as low a temperature as possible. Where possible aerate commodities stored in bulk through continuous circulation of air through the storage vessel to maintain proper temperature and moisture.

2.3.8 Use of a suitable authorized preservative e.g. an organic acid such as proprionic acid, may be beneficial in that such acids are effective in killing moulds and fungi and preventing the production of mycotoxins. If organic acids are used, it is important that the amounts added are sufficient to prevent fungal growth and is consistent with the products end use.

2.4 Transport

2.4.1 Make sure that transport containers and vehicles are free of mould, insects and any contaminated material by thoroughly cleaning before use or re-use. Periodic disinfestation with appropriate approved fumigants or other pesticides may be useful.

2.4.2 Protect shipments from moisture by appropriate means such as airtight containers, covering with tarpaulins, etc. Care must be taken in the use of tarpaulins to avoid sweating of the commodity that could lead to local moisture and heat build up which are prime conditions for fungal growth.

2.4.3 Avoid insect and rodent infestation during transport by the use of insect resistant containers or insect and rodent repellent chemical treatments.

2.5 Feed production and disposition of AFB_1 contaminated animal feeds

2.5.1 Ensure that milling equipment is kept clean, free of dust and feed accumulation.

2.5.2 Use an appropriate sampling and testing program to monitor outbound and inbound shipments for the presence of AFB_1. Because AFB_1 concentration in shipments may be extremely heterogeneous refer to FAO recommendations for sampling plans. Adjust frequency of sampling and testing to take into account conditions conducive to aflatoxin B_1 formation, the regional source of the commodity and prior experience within the growing season.

2.5.3 If aflatoxin B_1 is detected, consider one or more of the following options. In all cases ensure that the aflatoxin B_1 level of the finished feed is appropriate for its intended use (i.e. maturity and species of animal being fed) and is consistent with national codes and guidelines or qualified veterinary advice.

2.5.3.1 Consider the restriction of AFB_1 contaminated feed to a percentage of the daily ration such that the daily amount of AFB_1 ingested would not result in significant residues of AFM_1 in milk.

2.5.3.2 If feed restriction is not practical, divert the use of highly contaminated feedingstuffs to non-lactating animals only.

GLOSSARY OF TERMS AND DEFINITIONS (Residues of veterinary drugs in foods)

CAC/MISC 5-1993

FOREWORD

The Glossary of Terms and Definitions has been elaborated by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) with a view towards providing information and guidance to the Committee, and is intended for internal Codex use only.

The Glossary is intended to be an open list which is subject to review by the CCRVDF in order to update, modify or add to the list of terms. Relevant terms elaborated by other Codex Committees are included. Attention is drawn to the Notes following.

1. ***Acceptable Daily Intake (ADI):*** An estimate by JECFA of the amount of a veterinary drug, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man = 60 kg) (See Note 3).

2. ***Bioavailable Residues:*** Those residues that can be shown, by means of an appropriate method (e.g. Gallo-Torres method) to be absorbed into systemic circulation when fed to laboratory animals (See Note 3).

3. ***Bound Residue:*** Residues derived from the covalent binding of the parent drug or a metabolite of the drug and a cellular biological soluble or insoluble macromolecule. These residues are not extractable from the macromolecule by exhaustive extraction, denaturation or solubilization techniques. They do not result from the incorporation of metabolized, radiolabelled fragments of the drug into endogenous compounds, or the same macromolecule by normal biosynthetic pathways. Information concerning the calculation of bound residues may be found in Annex 3 of the 34th Report of JECFA (pages 58–61, WHO TRS 788).

4. ***Egg:*** The fresh edible portion of the spheroid body produced by female birds, especially domestic fowl.
Portion of the commodity to which the MRL applies: The edible portion of the egg including the yolk and egg white after removal of the shell

5. ***Extractable Residue:*** Those residues extracted from tissues or biological fluids by means of aqueous acidic or basic media, organic solvents and/or hydrolysis with enzymes (e.g. sulfatase or glucuronidase) to hydrolyze conjugates. The extraction conditions must be such that the compounds of interest are not destroyed (See Note 2).

6. ***Fat:*** The lipid-based tissue that is trimmable from an animal carcass or cuts from an animal carcass. It may include subcutaneous, omental or perirenal

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fat. It does not include interstitial or intramuscular carcass fat or milk fat. *Portion of the commodity to which the MRL applies:* The whole commodity. For fat-soluble compounds the fat is analysed and MRLs apply to the fat. For those compounds where the trimmable fat is insufficient to provide a suitable test sample, the whole commodity (muscle and fat but without bone) is analysed and the MRL applies to the whole commodity (e.g., rabbit meat).

7. ***Fish:*** Means any of the cold-blooded aquatic vertebrate animals commonly known as such. This includes Pisces, Elasmobranchs and Cyclostomes. Aquatic mammals, invertebrate animals and amphibians are not included. It should be noted, however, that this term may also apply to certain invertebrates, particularly Cephalopods.

8. ***Good Practice in the Use of Veterinary Drugs (GPVD):*** Is the official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions (See Note 1).

9. ***Marker Residue:*** A residue whose concentration decreases in a known relationship to the level of total residues in tissues, eggs, milk or other animal tissues. A specific quantitative analytical method for measuring the concentration of the residue with the required sensitivity must be available (See Note 3).

10. ***Maximum Residue Limit for Veterinary Drugs (MRLVD):*** Is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or ìg/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food (See Note 1). It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technological aspects. When establishing an MRL, consideration is also given to residues that occur in food of plant origin and/or the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available.

11. ***Meat:*** The edible part of any mammal.

12. ***Milk:*** Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing.
Portion of the commodity to which the MRL applies:–Codex MRLs for fat-soluble compounds in milk are expressed on a whole commodity basis.

13. ***Muscle***: Muscle is the skeletal tissue of an animal carcass or cuts of these tissues from an animal carcass that contains interstitial and intramuscular fat. The muscular tissue may also include bone, connective tissue, tendons as well as nerves and lymph nodes in natural portions. It does not include edible offal or trimmable fat.

Portion of the commodity to which the MRL applies: The whole commodity without bones.

14. ***Non-Extractable Residues*** (See Note 2): These residues are obtained by subtracting the extractable residues from the total residues and comprise:
    i) Residues of the drug incorporated through normal metabolic pathways into endogenous compounds (e.g. amino acids, proteins, nucleic acid). These residues are of no toxicological concern.
    ii) Chemically-bound residues derived by interaction of residues of parent drug or its metabolites with macromolecules. These residues may be of toxicological concern.

15. ***Poultry***: Means any domesticated bird including chickens, turkeys, ducks, geese, guinea-fowls or pigeons.

16. ***Regulatory Method of Analysis*****:** A method that has been legally enacted and/or validated in a multi-laboratory study and can be applied by trained analysts using commercial laboratory equipment and instrumentation to detect and determine the concentration of a residue of a veterinary drug in edible animal products for the purpose of determining compliance with the MRL.

17. ***Residues of Veterinary Drugs***: Include the parent compounds and/or their metabolites in any edible portion of the animal product, and include residues of associated impurities of the veterinary drug concerned (See Note 1).

18. ***Screening Method:*** A rapid, relatively inexpensive, and rugged field method used for testing for a specific substance or closely related group of substances which are sufficiently selective and sensitive to allow at least semi-quantitative detection of residues in contents in accordance with the established maximum limit.

19. ***Temporary Acceptable Daily Intake (TADI)***: Used by JECFA when data are sufficient to conclude that use of the substance is safe over the relatively short period of time required to generate and evaluate further safety data, but are insufficient to conclude that use of the substance is safe over a lifetime. A higher-than-normal safety factor is used when establishing a temporary ADI and an expiration date is established by which time appropriate data to resolve the safety issue should be submitted to JECFA (See Note 2).

20. ***Tissue***: All edible animal tissue, including muscle and by-products (See Note 2).

21. ***Tissue, Control:*** Tissue from animals not treated with veterinary drugs of the same species, sex, age and physiological status as the target species.

22. ***Tissue, Dosed***: Tissue from animals of the test species that have been treated with the drug according to its intended use.

23. ***Tissue, Spiked or Fortified***: Tissue containing known concentrations of the analyte added to the sample of control tissue.

24. ***Total Residue***: The total residue of a drug in animal derived food consists of the parent drug together with all the metabolites and drug based products that remain in the food after administration of the drug to food producing animals. The amount of total residues is generally determined by means of a study using the radiolabelled drug, and is expressed as the parent drug equivalent in mg/kg of the food (See Note 2).

25. ***Validated Method***: An analytical method which has been subjected to a multi-laboratory study for accuracy, precision, reproducibility performance and ruggedness. Concise written procedures for sample selection, preparation and quantitative analysis are provided for inter-laboratory quality assurance and consistency of results, on which an appropriate regulatory method of analysis can be established.

26. ***Veterinarian Client-Patient Relationship***: The relationship is recognized when the livestock enterprise, premises and husbandry practices are known to the veterinarian as a result of a recent professional visit to the site and the veterinarian is available for emergency on site consultation and is responsible for preventative medicine programmes.

27. ***Veterinary Drug***: Any substance applied or administered to any food-producing animal, such as meat or milk producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic, or diagnostic purposes, or for modification of physiological functions or behaviour (See Note 1).

28. ***Withdrawal Time and Withholding Time***: This is the period of time between the last administration of a drug and the collection of edible tissue or products from a treated animal that ensures the contents of residues in food comply with the maximum residue limit for this veterinary drug (MRLVD).

Notes

1. Definitions adopted by the Codex Alimentarius Commission as **Definitions for the Purpose of the Codex Alimentarius**. See *Procedural Manual*.
2. Definitions established and adopted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
3. Definitions previously established and adopted by the JECFA, which have been modified by the Codex Committee on Residues of Veterinary Drugs in Foods.

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