

DAIRY



**GUIDELINE
TO FACILITATE INTRA-REGIONAL
TRADE IN THE CARIBBEAN**

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REGIONAL GUIDELINES FOR
SANITARY MEASURES

GUIDELINE TO FACILITATE INTRA- REGIONAL TRADE IN DAIRY PRODUCTS

Produced by the Caribbean Agricultural
Health and Food Safety Agency (RPPO)
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ADOPTION

This guideline was adopted by the Council of Trade and Economic Development (COTED) in June 2022.

APPLICATION

These SPS compliant guidelines may be used in providing the conditions necessary to allow for trade of dairy within the region. These guidelines are intended for use by exporters and importers while assisting in the development of the national production systems for trade.

BACKGROUND/INTRODUCTION

To ensure SPS compliancy, conditions from the farm to the table must be taken into consideration. This includes conditions in which the dairy cattle are housed and raised; the conditions in which the cattle are milked, the conditions in which the milk¹ is collected, processed and stored; the conditions in which the milk and milk products are transported.

Product testing will also be considered, testing assesses the performance of an export registered establishment's food safety management system (approved arrangement) in producing SPS compliant dairy products. A regular program of product testing provides the importing governments with a level of assurance, which allows the exporting country to issue records (ie: Export Health Certificate) showing that the milk and milk products are free of contaminants.

SCOPE

These guidelines apply to dairy products (milk and milk products) and are in compliance with the SPS Agreement, of which the OIE is considered the standard setting body.

The importation of animal products involves a certain level of disease risk to the importing country. This risk may be represented by one or several diseases, infections or infestations. Therefore, the importing country may wish to perform their own risk analyses. According to OIE, the principal aim of an import risk analysis is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of animal products.

The risk analysis should be transparent, meaning the comprehensive documentation and communication of all data, information, assumptions, methods, results, discussion and conclusions used in the risk analysis. This is necessary so that the exporting country and all interested parties are provided with clear reasons for the imposition of import conditions or refusal to import. The components of risk analysis are hazard identification, risk assessment, risk management and risk communication.

An importing country may decide to permit the importation using the appropriate sanitary standards recommended in the OIE Terrestrial Animal Health Code, therefore, eliminating the need for a risk assessment. These guidelines provide details as to the appropriate standards

¹ 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. **General Standard for the Use of Dairy Terms – CXS 206-1999**

recommended within the OIE Terrestrial Animal Health Code with respect to the production of dairy products.

PROCESS

1. Application: For milk and milk products to be imported from Country X, an application must be made to the Veterinary Authority of the importing country by the importer:
 - The general public, importers and custom brokers can apply for the permit
 - The process to apply for an import permit varies from country to country but some common methods of application are via online government websites, via completion of government issued forms, via email, in person etc.
2. Import Risk Analysis (see Appendix): The Veterinary Authority of the importing country may carry out a risk analysis of milk production, collection, processing, storage and transportation within the exporting country (Country X).
3. If the dairy products are produced, collected, processed, stored and transported according to OIE standards, then risks should be low. Elements of these standards may be found under the section MANAGEMENT OF DAIRY PRODUCTS FROM FARM TO TABLE.
4. If testing for contaminants is done regularly at various points in the production process these results should be easily accessed by the Veterinary Authority in the importing country, then the risk of importing may be considered low.
5. Import Permit: If risk is low an Import Permit may be issued by the Veterinary Authority. If the risk is high, the Veterinary Authority may refuse to issue an Import Permit.
6. Requirements of the Import Permit:
 - The importer provide an Official Sanitary Certificate issued by the Veterinary Authority of the exporting country prior to the importation of the dairy products. An Official Sanitary Certificate which shall certify that:
 - The dairy products are produced from animals originating in country of export (Country X)

During the 12 months immediately prior to export no outbreak of disease of export significance has occurred in Country X (e.g. Brucellosis, Tuberculosis, Foot and Mouth Disease, Lumpy Skin Disease etc) See

- OIE LISTED DISEASES OF IMPORTANCE TO INTERNATIONAL TRADE RELATED TO DAIRY AND THE OIE RECOMMENDATIONS FOR TRADE.
- Dairy products are produced, collected, handled, processed, stored and transported according to OIE and CODEX best practices and certified by a representative of the Veterinary Authority
- Dairy products are acceptable for human consumption
- The Veterinary Authority will conduct a Veterinary Inspection of the dairy products once landed at the port of the importing country to determine if the products are fit for human consumption.

CONTENTS

This section presents the general standards recommended within the OIE Terrestrial Animal Health Code and CODEX Alimentarius Code for Hygienic Practice for Milk and Milk Products with respect to the production of dairy products. This is followed by a list of plans, programmes, documentation and record keeping that should be in place. General contaminants of dairy products are also included. Finally, the OIE list of diseases important for trade along with recommendations for trade are provided.

MANAGEMENT OF DAIRY PRODUCTS FROM FARM TO TABLE

Commercial Dairy Cattle Production Systems (Article 7.11.3, Chap 7.11 – OIE Terrestrial Animal Health Code)

Dairy cattle may be kept housed, in pastured system or a combination of both. Within the housed system, cattle are kept on a formed surface and all food, shelter and water are provided by humans. Within this system, the cattle may be kept tethered or without any restraints. Within the pastured systems, the cattle live completely outdoors and have some autonomy over access to food, water and shelter. No housing is present, with the exception of that required for milking. The combination system includes any combination of housed and pasture production systems.

Welfare Aspects of Dairy Cattle Production (Article 7.11.4, Chap 7.11 – OIE Terrestrial Animal Health Code)

Animal welfare must be optimal for milk production to be optimal. The following animal-based criteria can be useful indicators of animal welfare.

- Behavior
- Morbidity rate
- Mortality and culling rates
- Changes in body weight, body condition and milk yield
- Reproductive efficiency
- Physical appearance
- Handling responses
- Complications from common procedures

Ensuring good welfare of dairy cattle hinges on several management factors. Serious problems can arise in any system if one or more of these elements are lacking. These management factors include system design, environmental management and animal management practices inclusive of responsible husbandry and provision of appropriate care.

When planning of refurbishing existing facilities, the system design and physical environment should be taken into consideration as these factors can have a direct impact on animal welfare and health. The factors of concern include the thermal environment, air quality, lighting, noise, flooring, bedding, resting surfaces and outdoor areas, location, construction and equipment and emergency plans (Article 7.11.6, Chap 7.11 – OIE Terrestrial Animal Health Code).

Biosecurity and Disease Prevention (Article 7.11.7, Chap 7.11 – OIE Terrestrial Animal Health Code)

Biosecurity plans should be designed, implemented, and maintained to ensure the best herd health status, with consideration of available resources, infrastructure and current disease risk. These plans should address the control of the major sources and pathways for spread of pathogenic agents which include: cattle, introductions to the herd, calves coming from different sources, other domestic animals, wildlife and pests, sanitation practices, equipment, tools and facilities, vehicles, air supply, water supply, feed and bedding, manure, waste and dead stock disposal, semen and embryos.

Animal Health Management Programme should optimize the physical and behavioral health and welfare of the dairy herd. It includes the prevention, treatment and control of diseases and conditions affecting the herd (mastitis, lameness, reproductive and metabolic diseases) in consultation with a veterinarian, where appropriate. This programme should include the recording of production data, morbidities, mortalities, culling rate and medical treatments. These records should be kept up to date as they can quickly indicate problem areas that require immediate intervention. The Animal Health Management programme should include ecto and endo parasite monitoring, control and treatment to manage parasitic burdens; monitoring of foot health to reduce the incidence of lameness; monitoring of early signs of disease or distress to reduce illness; vaccination programme where appropriate; and emergency plans for disease outbreaks.

Other Factors (Article 7.11.7, Chap 7.11 – OIE Terrestrial Animal Health Code)

Other factors that affect the welfare of dairy cattle include the following:

- **Nutrition:** The nutrient requirements of dairy cattle have been well defined. Energy, protein, mineral and vitamin content of the diet are major factors determining milk production and growth, feed efficiency, reproductive efficiency, and body condition. All cattle, including unweaned calves, need an adequate supply and access to palatable water that meets their physiological requirements and is free from contaminants hazardous to cattle health.
- **Social Environment:** Management of cattle should take into account their social environment as it relates to animal welfare, particularly in housed systems. Problem areas include: agonistic and oestrus activity, mixing of heifers and cows, feeding cattle of different size and age in the same pens, decreased space allowance, insufficient space at the feeder, insufficient water access and mixing of bulls.

- **Space Allowance:** Cattle in all production systems should be offered adequate space for comfort and socialisation. Insufficient and inadequate space allowance may increase the occurrence of injuries and have an adverse effect on growth rate, feed efficiency, and behaviour such as locomotion, resting, feeding and drinking.
- **Protection from predators:** All efforts should be made to protect cattle in both housed and pastured systems from predators.
- **Genetic selection:** Welfare and health considerations, in addition to productivity, should be considered when choosing a breed or subspecies for a particular location or production system.
- **Artificial insemination, pregnancy diagnosis and embryo transfer:** Semen collection, artificial insemination, pregnancy diagnosis, and embryo transfer should be performed by a competent operator in a manner that does not cause any pain or distress.
- **Dam and sire selection and calving management.**
- **Newborn calves:** Animal handlers should ensure that calves receive colostrum of a satisfactory quality, within 24 hours of birth, and in sufficient quantity, to provide passive immunity. Colostrum is most beneficial if received during the first six hours after birth. When there is risk of disease transfer from the dam, colostrum from a healthy cow should be used.
- **Cow-calf separation and weaning:** Different strategies to separate the calf from the cow are utilised in dairy cattle production systems. These include early separation (usually within 48 hours of birth) or a more gradual separation (leaving the calf with the cow for a longer period so it can continue to be suckled). Separation is stressful for both cow and calf.
- **Rearing of replacement stock:** Young calves are at particular risk of thermal stress. Special attention should be paid to management of the thermal environment (e.g. provision of additional bedding, nutrition or protection to maintain warmth and appropriate growth).
- **Milking management:** Milking, whether by hand or machine, should be carried out in a calm and considerate manner in order to avoid pain and distress. Special attention should be paid to the hygiene of personnel, the udder and milking equipment. All cows should be checked for abnormal milk at every milking. Milking machines, especially automated milking systems, should be used and maintained in a manner which minimises injury to teats and udders. Manufacturers of such equipment should provide operating instructions that consider animal welfare. A regular milking routine should be established relevant to the stage of lactation and the capacity of the system. Animal handlers should regularly check the information provided by the milking system and act accordingly to protect the welfare of the cows. Special care should be paid to animals being milked for the first time. They should be familiarised with the milking facility prior to giving birth. Long waiting times before and after milking can lead to health and welfare problems (e.g. lameness, reduced time to eat). Management should ensure that waiting times are minimised.
- **Painful husbandry procedures:** Husbandry practices are routinely carried out in cattle for reasons of management, animal welfare and human safety. Those practices that have the potential to cause pain should be performed in such a way as to minimise any pain and stress to the animal. Such procedures should be performed at as early an age as possible or using anaesthesia or analgesia under the recommendation or supervision of a veterinarian.
- **Inspection and Handling:** Dairy cattle should be inspected at intervals appropriate to the production system and the risks to the health and welfare of the cattle. Lactating cows should be inspected at least once a day. Some animals should be inspected more frequently,

for example, neonatal calves, cows in late gestation, newly weaned calves, cattle experiencing environmental stress and those that have undergone painful husbandry procedures or veterinary treatment.

- **Personnel Training:** All people responsible for dairy cattle should be competent in accordance with their responsibilities and should understand cattle husbandry, animal handling, milking routines, reproductive management techniques, behaviour, biosecurity, signs of disease, and indicators of poor animal welfare such as stress, pain and discomfort, and their alleviation.
- **Disaster Management:** Plans should be in place to minimise and mitigate the effect of disasters (e.g. earthquake, fire, drought, flooding, blizzard, hurricane). Such plans may include evacuation procedures, identifying high ground, maintaining emergency feed and water stores, destocking (reducing cattle numbers) and humane killing when necessary.
- **Humane Killing:** For sick and injured cattle a prompt diagnosis should be made to determine whether the animal should be treated or humanely killed. The decision to kill an animal humanely and the procedure itself should be undertaken by a competent person.

Principles Applied to the Primary Production of Milk (Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004)

The following three principles must be considered and managed during the process of milk production. These principles are as follows:

- The milk should not contain any contaminant at a level that jeopardizes the appropriate level of public health protection, when presented to the consumer.
- Contamination of milk from animal and environmental sources during primary production should be minimized.
- The microbial load of milk should be as low as achievable, using good milk production practices, considering the technological requirements for subsequent processing.

Environmental Hygiene (Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004)

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

Hygienic production of milk (Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004)

Areas and Premises for Milk Production (Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004) 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.

Animal Health (Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004) 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 finished product.

General Hygienic practice (Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004)

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.

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.

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

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

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.

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 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.

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.

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.

Collection, transport and delivery procedure and equipment: 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. 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.

Documentation and record keeping: Records should be kept, as necessary, to enhance the ability to verify the effectiveness of the control systems.

Establishment: Design and Facilities (Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004)

Equipment: Equipment should be designed and installed so that when possible, dead ends or dead spots in milk pipelines do not occur.

Control of Operation (Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004)

Control of Food Hazards: The combination of control measures should effectively control the identified hazards in milk and milk products.

Hazard Identification and Evaluation: All potential hazards should be identified. Each potential hazard should be evaluated to determine the severity of its adverse health effects and reasonable likelihood of occurrence.

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

- Microbiocidal control measures that reduce the microbial load, by killing, inactivation or removal. These may be applied 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.

Examples of typical microbiostatic control measures include the following:

Carbon dioxide (CO₂): 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 : 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 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.

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 cytoplasm of microorganisms, 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: Lowering of product temperature to limit microbial activity.

Time: 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: Control of the water activity (a_w) 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 a_w 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 a_w below 0.90–0.95 also results in an antimicrobial effect, depending on the type of sugar (synergy).

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 is 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 high intensity broadband light pulses of wavelengths in the ultraviolet, visible and infrared spectrum (~20 000 times sunlight) to destroy micro-organisms (e.g: packaging material, equipment and water). 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 specified time, temperature and conditions that 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 microorganisms. 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) causes 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 measure is to ensure adequate cooling rates of packaged products to minimize potential for *B. cereus* growth.

Establishment of process criteria: Process criteria for control measures should be established to ensure the process will be applied in a manner that will meet the performance required to assure the adequate delivery of the control measure.

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.

Key aspects of Hygiene control systems (Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004)

Temperature and time controls: From milk production through to finished products, products should be stored at appropriate temperatures and for appropriate times so growth or development of a food safety hazard will be minimized and the product’s suitability will not be adversely affected.

Management of products within the plant: The principle of “first arrived, first processed” should apply. 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. There should be adequate stock rotation, based on the principle of “first in, first out”.

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.

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

Specific process steps: The processes used during the manufacture of milk products that can control hazards that are reasonably likely to occur. (See microbiocidal and microbiostatic control measures above). 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.

Microbiological and other specifications

Incoming milk: Manufacturers should establish incoming milk criteria that consider the end use of the milk and the conditions under which the milk was produced. Corrective action taken for non-compliance with incoming milk

criteria should be commensurate with the potential risks presented by the non-compliance.

Microbiological criteria: It may be necessary to establish microbiological criteria 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.

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. There should be adequate separation of areas with different levels of contamination risk.

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.

Water: (Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004)

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. Appropriate safety and suitability criteria that meet the intended outcomes should be established for any water used in dairy processing. Reconditioning of water for reuse and use of reclaimed, recirculated and recycled water should be managed in accordance with HACCP principles.

Establishment Maintenance and cleaning: (Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004)

Processing areas should be kept as dry as possible. 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. A routine programme to verify the adequacy of cleaning should be in place.

Transportation: (Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004)

Dairy products should be transported at time/temperature combinations that will not adversely affect the safety and suitability of the product. In the case of refrigerated products, the vehicle product compartment should be cooled prior to loading and the product compartment should be always kept at an appropriate temperature, including during unloading.

Labelling: (Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004)

Milk products should be labelled in accordance with the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), the 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. Raw milk products should be labelled to indicate they are made from raw milk according to national requirements in the country of retail sale.

Training Programmes: (Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004)

- 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.

PLANS, PROGRAMMES, DOCUMENTATION AND RECORDS

Records should be kept, as necessary and where practicable to enhance the ability to verify the effectiveness of the control systems. Documentation of plans, programmes and procedures can enhance the credibility and effectiveness of the food safety control system.

A summary of records as recommended under the section “MANAGEMENT OF DAIRY PRODUCTS FROM FARM TO TABLE” which are important for food safety are as follows:

- Evidence of a Biosecurity Plan: This plan should address the control of the major sources and pathways for spread of pathogenic agents. An application of Good Hygienic Practices (GHP) and Hazard Analysis Critical Control Points (HACCP) should also be included.
 - The major sources and pathways include cattle, including introductions to the herd; calves coming from different sources; other domestic animals, wildlife and pests; people including sanitation practices; equipment, tools and facilities; vehicles; air; water supply, feed and bedding; manure, waste and dead stock disposal; semen and embryos.
- Evidence of Animal Health Management Programme: This programme should aim to optimize health and welfare of the dairy herd. The following records should be kept within the programme:
 - procedures for monitoring, prevention, treatment and control of diseases and conditions affecting the herd (mastitis, lameness, reproductive and metabolic diseases);
 - other illnesses, injuries, morbidities, mortalities;
 - medical treatments and evidence of adherence to withdrawal periods;
 - nature and source of feed, feed ingredients and water;
 - production data, culling rate;
 - ecto and endo parasite monitoring, control and treatment to manage parasitic burdens;
 - vaccination programmes where appropriate; and
 - emergency plans for disease outbreaks.
- Records of animal identification practices to allow trace-back to place of origin
- Personnel (staff) hygiene records
- Transportation of dairy products records:

- records of temperatures kept during transportation
- records of conditions of transportation
- evidence of mitigation practices in place if the temperatures and conditions are adverse
- Records of dairy product storage:
 - records of temperatures kept during storage
 - records of storage conditions
 - evidence of mitigation practices in place if temperatures and conditions are adverse
- Records of training programmes for staff in:
 - 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.
- Records of Quality Assurance Systems in place
- Records of Risk Assessment and Risk Management
 - Results of microbiological, serological or other testing at single-animal and herd level used to support surveillance, as well as risk assessment of prioritised foodborne hazards.
 - Results of microbiological, pesticide, veterinary drug residue testing of milk and milk products to ensure that these contaminants do not exceed levels that would present a risk to the consumer.

CONTAMINANTS (PATHOGENS) GENERALLY ASSOCIATED WITH DAIRY PRODUCTS

(Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004)

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.

Hygienic milk production practices, proper handling and storage of milk, and mandatory pasteurization has decreased the threat of milkborne diseases such as tuberculosis, brucellosis, and typhoid fever. There have been a number of foodborne illnesses resulting from the ingestion of raw milk, or dairy products made with milk that was not properly pasteurized or was poorly handled causing post-processing contamination. The following bacterial pathogens are still of concern today in raw milk and other dairy products:

- *Bacillus cereus*
- *Listeria monocytogenes*
- *Yersinia enterocolitica*
- *Salmonella spp.*
- *Escherichia coli O157:H7*
- *Campylobacter jejuni*

It should also be noted that moulds, mainly of species of *Aspergillus*, *Fusarium*, and *Penicillium* can grow in milk and dairy products. If the conditions permit, these moulds may produce mycotoxins which can be a health hazard. (<https://www.uoguelph.ca/foodscience/book-page/pathogenic-microorganisms-milk>)

OIE LISTED DISEASES OF IMPORTANCE TO INTERNATIONAL TRADE RELATED TO DAIRY AND THE OIE RECOMMENDATIONS FOR TRADE

OIE Listed Diseases and other Diseases of importance to international trade 2021 and the OIE Recommendations for Trade	
Bovine (Beef and Dairy)	
Anthrax	<p>Recommendations for the importation of milk and milk products intended for human consumption – Article 8.1.7, Chapter 8.1, OIE Terrestrial Animal Health Code</p> <p>Veterinary authorities of importing countries should require the presentation of an international veterinary certificate attesting that the products originate from animals that:</p> <ol style="list-style-type: none"> 1. Show no clinical sign of anthrax at the time of milking; 2. If the milk originates from herds or flocks that have had a case of anthrax within the previous 20 days, it has been chilled promptly and processed using a heat treatment at least equivalent to pasteurisation.
Infection with Aujeszky’s Disease Virus (AD)	<p>Pigs are the natural host for Aujeszky’s disease (AD) virus, although it can infect cattle, sheep, cats, dogs and rats causing fatal disease (Article 8.2.1, Chapter 8.2, OIE Terrestrial Animal Health Code).</p> <p>Safe Commodities – Article 8.2.1, Chapter 8.2, OIE Terrestrial Animal Health Code</p> <p>When authorising import or transit of products of animal origin not containing offal (head, and thoracic and abdominal viscera) and any products made from these, veterinary authorities should not require any AD-related conditions, regardless of the AD status of the exporting country or zone.</p>
Infection with Bluetongue Virus	<p>OIE recommended Safe Commodities – Article 8.3.2, Chapter 8.3 OIE Terrestrial Animal Health Code</p> <p>When authorising the import or transit of milk and milk products, Veterinary Authorities should not require any bluetongue-related conditions regardless of the bluetongue status of the exporting country.</p>
Bovine Anaplasmosis	No provisions provided for trade in dairy
Bovine Babesiosis	No provisions provided for trade in dairy
Bovine Genital Campylobacteriosis	No provisions provided for trade in dairy
Bovine Spongiform Encephalopathy	<p>General Provisions (Article 11.4.1, Chapter 11.4 OIE Terrestrial Animal Code)</p> <p>These recommendations are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (<i>Bos taurus</i> and <i>B. indicus</i>) only.</p>

OIE Listed Diseases and other Diseases of importance to international trade 2021 and the OIE Recommendations for Trade	
Bovine (Beef and Dairy)	
	<p>For the purposes of official BSE risk status recognition, BSE excludes 'atypical BSE' as a condition believed to occur spontaneously in all cattle populations at a very low rate.</p> <p>OIE recommended Safe Commodities When authorising import or transit of the milk and milk products and containing no other tissues from cattle, Veterinary Authorities should not require any BSE-related conditions, regardless of the BSE risk status of the cattle population of the exporting country, zone or compartment.</p>
<p>Brucellosis Infection with <i>B. abortus</i>; <i>B. melitensis</i></p>	<p>Recommendations for the importation of milk and milk products – Article 8.4.20, Chapter 8.20 OIE Terrestrial Animal Health Code</p> <p>Veterinary Authorities of importing countries should require the presentation of an International Veterinary Certificate attesting that the milk and milk products:</p> <ol style="list-style-type: none"> 1. Have been derived from animals in a country, zone, herd or flock free from infection with <i>Brucella</i> as relevant; OR 2. Were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.
<p>Infection with <i>Echinococcus granulosus</i></p>	<p>OIE Recommended Safe Commodities – Article 8.5.2, Chapter 8.5 OIE Terrestrial Animal Health Code</p> <p>When authorising import or transit of the milk and milk products of livestock, Veterinary Authorities should not require any <i>E. granulosus</i>-related conditions regardless of the status of the animal population of the exporting country or zone.</p>
<p>Infection with Epizootic Hemorrhagic Disease (EHD) Virus</p>	<p>OIE recommended Safe Commodities – Article 8.7.2, Chapter 8.7 OIE Terrestrial Animal Health Code</p> <p>When authorising import or transit of milk and milk products, Veterinary Authorities should not require any EHD-related conditions regardless of the EHD status of the ruminant population of the exporting country.</p>
<p>Infection with Foot and Mouth Disease Virus</p>	<p>Recommendations for importation from FMD free countries or zones where vaccination either is or is not practised or FMD free compartments – Article 8.8.24, Chapter 8.8 OIE Terrestrial Animal Health Code</p> <p>For milk and milk products intended for human consumption</p> <p>Veterinary Authorities should require the presentation of an International Veterinary Certificate attesting that these products come from animals</p>

OIE Listed Diseases and other Diseases of importance to international trade 2021 and the OIE Recommendations for Trade	
Bovine (Beef and Dairy)	
	<p>which have been kept in a FMD free country, zone or compartment, or which have been imported in accordance with:</p> <p style="padding-left: 40px;">a. Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments (Article 8.8.10, Chapter 8.8 OIE Terrestrial Animal Health Code) – For FMD susceptible animals</p> <p>Veterinary Authorities should require the presentation of an International Veterinary Certificate attesting that the dairy and dairy products come from animals that:</p> <ul style="list-style-type: none"> i. Showed no clinical sign of FMD on the day of shipment; ii. Were kept since birth or for at least the past three months in a FMD free country or zone where vaccination is not practised or a FMD free compartment; iii. If transiting an infected zone, were not exposed to any source of FMDV during transportation to the place of shipment. <p style="text-align: center;">OR</p> <p style="padding-left: 40px;">b. Recommendations for importation from FMD free countries or zones where vaccination is practised (Article 8.8.11, Chapter 8.8 OIE Terrestrial Animal Health Code) – For domestic ruminants</p> <p>Veterinary Authorities should require the presentation of an International Veterinary Certificate attesting that the dairy and dairy products come from animals that:</p> <ul style="list-style-type: none"> iv. Showed no clinical sign of FMD on the day of shipment; v. Were kept since birth or for at least the past three months in a FMD free country or zone where vaccination is practised; vi. Were subjected to a test for FMD with negative results; vii. If transiting an infected zone, were not exposed to any source of FMDV during transportation to the place of shipment. <p style="text-align: center;">OR</p> <p style="padding-left: 40px;">c. Recommendations for importation from FMD infected countries or zones where an official control programme exists –Article 8.8.12, Chapter 8.8 OIE Terrestrial Animal Health Code - For domestic ruminants</p> <p>Veterinary Authorities should require the presentation of an International Veterinary Certificate attesting that the meat and meat products come from animals that:</p> <ul style="list-style-type: none"> i. The animals showed no clinical sign of FMD on the day of shipment;

OIE Listed Diseases and other Diseases of importance to international trade 2021 and the OIE Recommendations for Trade	
Bovine (Beef and Dairy)	
	<p>ii. Prior to isolation, the animals were kept in the establishment of origin:</p> <ol style="list-style-type: none"> 1. for 30 days, or since birth if younger than 30 days, if a stamping-out policy is applied to control FMD in the exporting country or zone, 2. for three months, or since birth if younger than three months if a stamping-out policy is not applied to control FMD in the exporting country or zone, <p>iii. FMD has not occurred within the establishment of origin for the relevant period as defined in points 2(a) and 2(b) above;</p> <p>iv. The animals were isolated in an establishment for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic virological and serological tests for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period, and that FMD did not occur within a 10 kilometre radius of the establishment during that period, or the establishment is a quarantine station;</p> <p>v. The animals were not exposed to any source of FMDV during their transportation from the establishment to the place of shipment.</p> <p>Recommendations for importation from FMD infected countries or zones where an official control programme exists – Article 8.8.25, Chapter 8.8 OIE Terrestrial Animal Health Code</p> <p>For Milk and Milk Products</p> <p>Veterinary Authorities should require the presentation of an International Veterinary Certificate attesting that:</p> <ol style="list-style-type: none"> 1. These products: <ol style="list-style-type: none"> a. Originate from establishments which were not infected or suspected of being infected with FMD at the time of milk collection; b. Have been processed to ensure the destruction of FMDV in accordance with one of the procedures; <p>Procedures for the inactivation of FMDV in milk and cream for human consumption – Article 8.8.35, Chapter 8.8 OIE Terrestrial Animal Health Code</p> <p>For the inactivation of FMDV present in milk and cream for human consumption, one of the following procedures should be used:</p>

OIE Listed Diseases and other Diseases of importance to international trade 2021 and the OIE Recommendations for Trade	
Bovine (Beef and Dairy)	
	<ol style="list-style-type: none"> 1. A process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or 2. If the milk has a pH less than 7.0, a process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]), or 3. If the milk has a pH of 7.0 or greater, the HTST process applied twice. <p>Procedures for the inactivation of FMDV in milk for animal consumption – Article 8.8.36, Chapter 8.8 OIE Terrestrial Animal Health Code</p> <p>For the inactivation of FMDV present in milk for animal consumption, one of the following procedures should be used:</p> <ol style="list-style-type: none"> 1. The HTST process applied twice; or 2. HTST combined with another physical treatment, e.g. maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with desiccation; or 3. UHT combined with another physical treatment referred to in point 2 above. 4. The necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.
Infection with <i>Mycoplasma mycoides</i> subsp. <i>mycoides</i> SC (Contagious bovine pleuropneumonia)	OIE recommended Safe Commodities According to Article 11.5.2, Chapter 11.5, OIE Terrestrial Animal Health Code, when authorising import or transit of milk and milk products, Veterinary Authorities should not require any contagious bovine pleuropneumonia (CBPP) related conditions, regardless of the CBPP status of the domestic bovids and water buffalo population of the exporting country, zone or compartment.
Enzootic Bovine Leukosis	No provisions provided for trade in dairy
Heartwater	OIE recommends prohibition of trade (Article 8.9.2, Chapter 8.9 OIE Terrestrial Animal Health Code)
Haemorrhagic Septicaemia (<i>Pasteurella multocida</i> serotypes 6:b and 6:e)	OIE recommends prohibition of trade in commodities (Article 11.7.5, Chapter 11.7 OIE Terrestrial Animal Health Code)
Infectious Bovine Rhinotracheitis / Infectious Pustular Vulvovaginitis	No provisions provided for trade in dairy

OIE Listed Diseases and other Diseases of importance to international trade 2021 and the OIE Recommendations for Trade	
Bovine (Beef and Dairy)	
Infection with Lumpy Skin Disease Virus	<p>OIE recommendations for the importation of milk and milk products - Article 11.9.11, Chapter 11.9, OIE Terrestrial Animal Health Code</p> <p>Veterinary Authorities of importing countries should require the presentation of an International Veterinary Certificate attesting that the milk or milk products:</p> <ol style="list-style-type: none"> 1. Have been derived from animals in a country or zone free from LSD; OR 2. Were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the CODEX Alimentarius Code of Hygienic Practice for Milk and Milk Products.
Infection with <i>Mycobacterium Tuberculosis</i>	<p>Recommendations for the importation of milk and milk products of bovids – Article 8.11.13, Chapter 8.11 OIE Terrestrial Animal Health Code</p> <p>Veterinary Authorities of importing countries should require the presentation of an International Veterinary Certificate attesting that the milk or milk products:</p> <ol style="list-style-type: none"> 1. Have been derived from bovins in a herd free from infection with <i>M. tuberculosis</i> complex; OR 2. Were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the CODEX Alimentarius Code of Hygienic Practice for Milk and Milk Products.
New World Screwworm (<i>Cochliomyia hominivorax</i>) and Old World Screwworm (<i>Chrysomya bezziana</i>)	Restrictions on these products are not considered necessary. (Article 8.12.4, Chapter 8.12 OIE Terrestrial Animal Health Code)
Paratuberculosis	No provisions provided for trade in dairy
Rabies	No provisions provided for trade in dairy
Infection with Rinderpest	<p>Recommendations for international trade in livestock products – Article 8.16.4., Chapter 8.16 OIE Terrestrial Animal Health Code</p> <p>When authorising import or transit of livestock and their products, Veterinary Authorities should not require any rinderpest-related conditions.</p>
Theileriosis	No provisions provided for trade in dairy
Trichomonosis	No provisions provided for trade in dairy

OIE Listed Diseases and other Diseases of importance to international trade 2021 and the OIE Recommendations for Trade	
Bovine (Beef and Dairy)	
<p>Infection with <i>Trypanosoma brucei</i>, <i>T. congolense</i>, <i>T. simiae</i> and <i>T. vivax</i></p>	<p>OIE Recommended Safe Commodities – Article 8.18.2, Chapter 18 OIE Terrestrial Animal Health Code</p> <p>When authorising the import or transit of pasteurised milk and pasteurised milk products from susceptible animals, Veterinary Authorities should not require conditions related to infection with <i>T. brucei</i>, <i>T. congolense</i>, <i>T. simiae</i> and <i>T. vivax</i> regardless of the status of the exporting country or zone.</p>

KEY RELEVANT DOCUMENTS/REFERENCES

All references and sources of information consulted for the development of the guideline:

Bahamas Dairy Import Requirements

<https://www.bahamas.gov.bs/wps/portal/public/gov/government/services>

Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57 2004

https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B57-2004%252FCXC_057e.pdf

Food Safety - Milk & Milk Products – European Commissions

https://ec.europa.eu/food/animals/animals-products-trade-imports/milk-milk-products_en

Guidelines for preservation of raw milk by use of the Lactoperoxidase system – CAC/GL 13-1991

http://files.foodmate.com/2013/files_1757.html

Model Export Certificate for Milk and Milk Products CAC/GL 67-2008

General Standard for the use of Dairy Terms, CXS 206-1999

<http://www.fao.org/dairy-production-products/products/codex-alimentarius/en/>

OIE Terrestrial Animal Health Code – Chapter 3.2, 7.11, 8, 11

<https://www.oie.int/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/>

Pathogenic Microorganisms in Milk

<https://www.uoguelph.ca/foodscience/book-page/pathogenic-microorganisms-milk>

Step-by-Step guide to exporting dairy products

<https://www.agriculture.gov.au/export/controlled-goods/dairy/step-by-step>

WTO International: Dairy Agreement

https://www.wto.org/english/res_e/booksp_e/analytic_index_e/dairy_01_e.htm

APPENDIX – OIE TERRESTRIAL CODE IMPORT RISK ANALYSIS

SECTION 2

CHAPTER 2.1

IMPORT RISK ANALYSIS

Article 2.1.1.

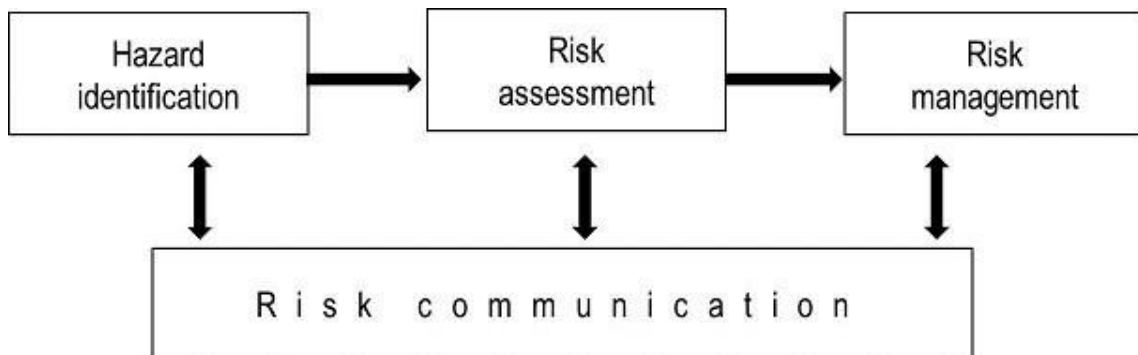
The importation of *animals* and animal products involves a certain level of disease *risk* to the *importing country*. This *risk* may be represented by one or several diseases, *infections* or *infestations*.

The principal aim of import *risk analysis* is to provide *importing countries* with an objective and defensible method of assessing the disease *risks* associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, biological products and *pathological material*. The analysis should be transparent. Transparency means the comprehensive documentation and communication of all data, information, assumptions, methods, results, discussion and conclusions used in the *risk analysis*. This is necessary so that the *exporting country* and all interested parties are provided with clear reasons for the imposition of import conditions or refusal to import.

Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

This chapter provides recommendations and principles for conducting transparent, objective and defensible *risk analyses* for *international trade*. The components of *risk analysis* are *hazard identification*, *risk assessment*, *risk management* and *risk communication* (Figure 1).

Fig. 2. The four components of risk analysis



The *risk assessment* is the component of the analysis which estimates the *risks* associated with a *hazard*. *Risk assessments* may be qualitative or quantitative. For many diseases, particularly for those diseases listed in this *Terrestrial Code* where there are well developed internationally agreed standards, there is broad agreement concerning the likely *risks*. In such cases it is more likely that a qualitative assessment is all that is required. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making. No single method of import *risk assessment* has proven applicable in all situations, and different methods may be appropriate in different circumstances.

The process of import *risk analysis* usually needs to take into consideration the results of an evaluation of *Veterinary Services*, zoning, compartmentalisation and *surveillance* systems in place for monitoring of animal health in the *exporting country*. These are described in separate chapters in the *Terrestrial Code*.

Article 2.1.2.

Hazard identification

The *hazard* identification involves identifying the pathogenic agents which could potentially produce adverse consequences associated with the importation of a *commodity*.

The *hazards* identified would be those appropriate to the species being imported, or from which the *commodity* is derived, and which may be present in the *exporting country*. It is then necessary to identify whether each *hazard* is already present in the *importing country*, and whether it is a *notifiable disease* or is subject to control or eradication in that country and to ensure that import measures are not more trade restrictive than those applied within the country.

Hazard identification is a categorisation step, identifying biological agents dichotomously as *hazards* or not. The *risk assessment* may be concluded if *hazard* identification fails to identify *hazards* associated with the importation.

The evaluation of the *Veterinary Services*, *surveillance* and control programmes and zoning and compartmentalisation systems are important inputs for assessing the likelihood of *hazards* being present in the animal population of the *exporting country*.

An *importing country* may decide to permit the importation using the appropriate sanitary standards recommended in the *Terrestrial Code*, thus eliminating the need for a *risk assessment*.

Article 2.1.3.

Principles of risk assessment

- 1) *Risk assessment* should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. *Risk assessment* should be able to accommodate the variety of animal *commodities*, the multiple *hazards* that may be identified with an importation and the specificity of each disease, detection and *surveillance* systems, exposure scenarios and types and amounts of data and information.
- 2) Both *qualitative risk assessment* and *quantitative risk assessment* methods are valid.
- 3) The *risk assessment* should be based on the best available information that is in accord with current scientific thinking. The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion.
- 4) Consistency in *risk assessment* methods should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.
- 5) *Risk assessments* should document the uncertainties, the assumptions made, and the effect of these on the final *risk estimate*.
- 6) *Risk* increases with increasing volume of *commodity* imported.
- 7) The *risk assessment* should be amenable to updating when additional information becomes available.

Article 2.1.4.

Risk assessment steps

1. Entryassessment

Entry assessment consists of describing the biological pathways necessary for an importation activity to introduce pathogenic agents into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitatively (as a numerical estimate). The entry assessment describes the probability of the “entry” of each of the *hazards* (the pathogenic agents) under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures. Examples of the kind of inputs that may be required in the entry assessment are:

- a) Biological factors
 - species, age and breed of *animals*
 - agent predilection sites
 - *vaccination*, testing, treatment and quarantine. b)

Country factors

- incidence or prevalence
- evaluation of *Veterinary Services*, *surveillance* and control programmes and zoning and compartmentalisation systems of the *exporting country*.

c) Commodity factors

- quantity of *commodity* to be imported
- ease of contamination
- effect of processing
- effect of storage and transport.

If the entry assessment demonstrates no significant *risk*, the *risk assessment* does not need to continue.

2. Exposure assessment

Exposure assessment consists of describing the biological pathways necessary for exposure of *animals* and humans in the *importing country* to the *hazards* (in this case the pathogenic agents) from a given *risk* source, and estimating the probability of the exposures occurring, either qualitatively (in words) or quantitatively (as a numerical estimate).

The probability of exposure to the identified *hazards* is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure, such as ingestion, inhalation or insect bite, and the number, species and other characteristics of the animal and human populations exposed. Examples of the kind of inputs that may be required in the exposure assessment are:

- a) Biological factors
 - properties of the agent. b)

Country factors

- presence of potential *vectors*
- human and animal demographics
- customs and cultural practices
- geographical and environmental characteristics. c)

Commodity factors

- quantity of *commodity* to be imported
- intended use of the imported *animals* or products
- disposal practices.

If the exposure assessment demonstrates no significant *risk*, the *risk assessment* may conclude at this step.

3. Consequence assessment

Consequence assessment consists of describing the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process should exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring. This estimate may be either qualitative (in words) or quantitative (a numerical estimate). Examples of consequences include:

- a) Direct consequences

- animal *infection*, disease and production losses
- public health consequences. b)

Indirect consequences

- *surveillance* and control costs
- compensation cost
- potential trade losses
- adverse consequences to the environment.

4. Riskestimation

Risk estimation consists of integrating the results from the entry assessment, exposure assessment, and consequence assessment to produce overall measures of *risks* associated with the *hazards* identified at the outset. Thus *risk* estimation takes into account the whole of the *risk* pathway from *hazard* identified to unwanted outcome.

For a quantitative assessment, the final outputs may include:

- estimated numbers of *herds*, *flocks*, *animals* or people likely to experience health impacts of various degrees of severity over time;
- probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates;
- portrayal of the variance of all model inputs;
- a sensitivity analysis to rank the inputs as to their contribution to the variance of the *risk* estimation output;
- analysis of the dependence and correlation between model inputs.

Article 2.1.5.

Principles of risk management

- 1) *Risk management* is the process of deciding upon and implementing measures to address the *risks* identified in the *risk assessment*, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage *risk* appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of disease incursions and their consequences and its desire to import *commodities* and fulfil its obligations under *international trade* agreements.
- 2) The international standards of the OIE are the preferred choice of *sanitary measures* for *risk management*. The application of these *sanitary measures* should be in accordance with the intentions in the standards.

Article 2.1.6.

Risk management components

- 1) Risk evaluation - the process of comparing the *risk* estimated in the *risk assessment* with the reduction in *risk* expected from the proposed *risk management* measures.
- 2) Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the *risk* associated with an importation. The efficacy is the degree to which an option reduces the likelihood or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the *risk assessment* and then comparing the resulting level of *risk* with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the *risk management* options.
- 3) Implementation - the process of following through with the *risk management* decision and ensuring that the *risk management* measures are in place.
- 4) Monitoring and review - the ongoing process by which the *risk management* measures are continuously audited to ensure that they are achieving the results intended.

Article 2.1.7.

Principles of risk communication

- 1) *Risk communication* is the process by which information and opinions regarding *hazards* and *risks* are gathered from potentially affected and interested parties during a *risk analysis*, and by which the results of the *risk assessment* and proposed *risk management* measures are communicated to the decision-makers and interested parties in the *importing* and *exporting countries*. It is a multidimensional and iterative process and should ideally begin at the start of the *risk analysis* process and continue throughout.
- 2) A *risk communication* strategy should be put in place at the start of each *risk analysis*.
- 3) The *communication of the risk* should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.

- 4) The principal participants in *risk communication* include the authorities in the *exporting country* and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups.
- 5) The assumptions and uncertainty in the model, model inputs and the *risk* estimates of the *risk assessment* should be communicated.
- 6) Peer review is a component of *risk communication* in order to obtain scientific critique and to ensure that the data, information, methods and assumptions are the best available.

NB: FIRST ADOPTED IN 1998; MOST RECENT UPDATE ADOPTED IN 2018