CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CX/FH 10/42/5**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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Kampala, Uganda, 29 November – 3 December 2010

PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF VIRUSES IN FOOD (At Step 3)

Prepared by the Netherlands with the assistance of Belgium, Canada, Denmark, Finland, France, Germany, Japan, Poland, Spain, Thailand, United Kingdom, United States of America, FAO, WHO and CIAA.

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Guideline at Step 3 (see Appendix I) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission*) **to**: Ms Barbara McNiff, US Department of Agriculture, Food Safety and Inspection Service, US Codex Office, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720 3157, or email Barbara.McNiff@fsis.usda.gov with a copy **to**: Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by 15 October 2010.**

BACKGROUND

Based on the recommendations of the working group, the 40th Session of the Codex Committee on Food Hygiene agreed to start new work on viruses in food and asked the 32nd Session of the Commission to approve new work on the Code of Hygienic Practice for the Control of Viruses in Food. Following the request of the Committee, the 32nd Session of the Commission (29 June – 4 July 2009) approved this new work (N07-2009).

The Committee also agreed to establish a physical working group led by The Netherlands, open to all interested parties, working in English only, to meet in March 2009 to develop the Code of Hygienic Practice for Control of Viruses in Food for circulation at Step 3 for comments and consideration by the next session of the Committee. During the 41st Session of the Codex Committee on Food Hygiene the document *Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food* was introduced by The Netherlands. The Committee concluded that additional work was necessary on the development of the Guidelines and agreed to establish a physical working group, led by The Netherlands, working in English only, to revise the proposed draft Guidelines taking into account comments received and additional information to be gathered. This working group meeting was held in The Netherlands, 25-26 March 2010 and prepared the Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food for circulation at Step 3 for comments (see Appendix I). The list of participants is provided in Appendix II

APPENDIX I

PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF VIRUSES IN FOOD
(At Step 3)

INTRODUCTION

In recent years, viruses have been increasingly recognized as important causes of foodborne diseases. Viruses require special attention because they behave differently from bacteria. Furthermore currently used *control measures* have not been validated for their efficacy towards controlling virus contamination of foods. Data from recent studies have shown that foodborne viral infections are very common in many parts of the world, despite the measures already in place to reduce bacterial contamination. During the FAO/WHO Expert meeting on Viruses in Food in 2007[1], attention was given to the threat of human enteric viruses as a risk to public health when these viruses are present in food. Moreover specific virus-commodity combinations of greatest public health significance were determined.

Viruses are very small micro-organisms, ranging in size from 18 to 400 nanometers, whereas bacteria generally range in size from 0.5 to 5 micrometers. In addition to size, other structural and biological differences exist between viruses and bacteria. Viruses are strictly host-dependent for their replication and have their own typical host range and cell preference (tropism). Viruses can be transmitted in different ways, e.g., via the respiratory or faecal-oral routes. Some human viruses can be transmitted directly from person-to person, but also indirectly via virus-contaminated water, air, soil, surfaces or food.

The human enteric viruses *most frequently involved in foodborne outbreaks* are norovirus (NoV) and hepatitis A virus (HAV), but other viruses such as rotavirus (RV), hepatitis E virus (HEV), astrovirus, Aichi virus, sapovirus, enterovirus, coronavirus, parvovirus and adenovirus can also be transmitted by food, and anecdotal evidence suggests the list of foodborne viruses may be even longer. Based on the symptoms of disease, these viruses can be grouped into those that cause *gastro-enteritis* (e.g. NoV), enterically transmitted *hepatitis* (e.g. HAV, that migrates to the liver where it manifests disease), and a third group which replicates in the human intestine, but only cause illness after they migrate to *other organs* such as the central nervous system (enterovirus). The major foodborne viruses are those that infect via the gastrointestinal tract and are excreted in faeces and/or vomit, and are infectious for humans when ingested via the oral route. Asymptomatic infections and shedding are common and have to be considered in food production.

Noteworthy *characteristics* of foodborne viruses *and the associated infections/illnesses* are the following:

- Viruses need to enter living host cells in order to be able to multiply (replicate). Unlike bacteria, they will not replicate in food. Consequently, viruses will not cause deterioration of the product and the organoleptic properties of the food will not be affected due to viral contamination.
- Even though high numbers of viral particles are shed in the stools of asymptomatic or infected persons (e.g., exceeding 10^7 particles per gram of stool) or in vomit, only a few viral/infectious particles (1 to 100) are needed to cause infection that may lead to illness.
- Viruses transmitted by the faecal-oral route can persist in foodstuffs or in the environment in soil, water, marine sediments or bivalve molluscs or on various inanimate surfaces for months. Most foodborne viruses are more resistant than bacteria to commonly used control measures, e.g., refrigeration, freezing, pH (as low as 3-4 and as high as 9-10), drying, UV radiation, heat and pressure, disinfection, etc.
- Freezing and refrigeration temperatures preserve viruses and are believed to be important factors that increase the persistence of foodborne viruses in the environment. Heat and drying can be used to inactivate viruses, but there are virus-to-virus differences in resistance to these processes. The presence of organic matter, such as faecal material and the food matrix can influence relative survival to heat and drying.
- Human enteric viruses, such as NoV and HAV, are very infectious and person-to-person spread is the most common transmission route. Secondary spread of these viruses after primary introduction by, for example, food-related contamination, is common and often results in larger prolonged outbreaks.
- Hand disinfectants may not be as effective for virus inactivation as compared to traditional hand washing practices. Moreover, the majority of chemical disinfectants used do not effectively inactivate non-enveloped viruses, as has been shown for HAV.
- Zoonotic foodborne transmission of viruses is not as common as is the case for many bacterial pathogens, such as *Salmonella* and *Campylobacter,* however, it does occur, e.g., for HEV.

[1] FAO/WHO [Food and Agriculture Organization of the United Nations/World Health Organization]. 2008. Viruses in Food: Scientific advice to support risk management activities: meeting report. Microbiological Risk Assessment Series. No. 13.

During the FAO/WHO Expert meeting on "Viruses in Food"[1], NoV and HAV were determined to be the viruses of *greatest concern from a food safety perspective* based on the incidence of reported foodborne disease, the severity of disease, including mortality, and their potential for transmission via foods. Estimates of the proportion of viral illness attributed to food are in the range of around 5% for HAV and 12-47% for NoV[1]. Data from at least 4 continents show that this is a major public health issue worldwide, although data from developing countries are sparse. HAV and rotavirus were identified as the major foodborne viruses that cause severe disease and significant mortality. Even though NoV is typically less virulent, it has caused significant mortality in the elderly and immuno-compromised patients. Emerging viruses of a zoonotic nature, such as the Severe Acute Respiratory Syndrome (SARS)-coronavirus, Nipah virus and Highly Pathogenic Avian Influenzavirus (HPAI) H5N1, and HEV, have been linked to food or postulated to be transmitted via food, but currently there is not sufficient data to elaborate on these emerging viruses in this context.

NoV Norovirus infections occur year-round, and cause gastro-enteritis in people of all ages. Overall, illness is relatively mild, but can be more severe and may result in death in high-risk groups such as the elderly or people with underlying disease. The greatest public health impact from NoV outbreaks has been reported in institutions such as hospitals and nursing homes, where NoV outbreaks commonly occur due to the close proximity of patients in an enclosed environment. Clear seasonal peaks have been observed when looking at reported outbreaks, but these are particularly associated with healthcare infections rather than foodborne infections. The incubation period, i.e., the period between exposure to the virus and onset of symptoms, is 12-72 hours, but in most cases symptoms appear between 24-30 hours. The onset of symptoms after NoV infection is often characterised by sudden onset of one or several episodes of projectile vomiting and/or by one to several days with diarrhoea. NoV-infected persons shed large amounts of infectious virus particles in their stool while having symptoms, but this may also occur before the onset of symptoms, and may continue to shed up to 8 weeks after resolution of symptoms even in immuno-competent persons. The disease and shedding period may be longer in the case of immunosuppressed individuals. Some NoV infections occur without resulting in apparent symptoms. A vaccine against NoV is not available at present.

HAV The hepatitis A virus is a cause of acute viral hepatitis. The incidence of HAV infection varies considerably among and within countries. In most developing countries, where hepatitis A infection is often endemic, the majority of people are infected in early childhood, when the infection is asymptomatic in over 90% of children under 5 years of age. Virtually all adults in these areas are immune. In developed countries, however, HAV infections are less common as a result of increased standards of public health as defined by access to safe drinking water, sanitation and hygiene in these countries. Very few persons are infected in early childhood, and the majority of adults remain susceptible to infection by HAV. Later in life, HAV infection is symptomatic in over 80% of the infected persons and may result in a more severe disease outcome. As a result, the potential risk of outbreaks of HAV is increased in these regions. The incubation period for HAV is at least 2 weeks, to a maximum of 6 weeks, with an average of 28 days. The peak infectivity occurs in 2 weeks preceding the onset of jaundice. The virus is shed in large numbers (10^6-10^8 particles/g) in faeces from the final 2 weeks of the incubation period up to 5 weeks into the illness. A vaccine against HAV is available. Some HAV infections occur without symptoms.

During the FAO/WHO Expert meeting on "Viruses in Food"[1], three major routes of viral contamination of foods were identified to be: 1) human sewage/faeces, 2) infected food handlers and 3) animals harbouring zoonotic viruses, although combinations of these routes have also been described. Based on the available knowledge in 2007, the meeting sought to prioritize the *virus-commodity combinations* of greatest public health concern. Prioritization was done according to the following criteria: disease severity, incidence/prevalence, probability of exposure, trade impact, public health costs, and ability to control foodborne infections. The virus-commodity combinations selected were NoV and HAV in shellfish, fresh produce and prepared (ready-to-eat) foods. It should be kept in mind that mitigation of the contamination by one virus would probably help in preventing contamination by other viruses too, as they often have a common source, i.e., human faeces.

The *transmission routes* for the introduction of NoV and HAV in the selected commodities are:

- *for prepared ready-to-eat foods*: via infected food handlers practising poor personal hygiene during food preparation and serving. Food handlers can contaminate food either with particles from vomit (NoV) or from faeces (NoV/HAV) when practising insufficient personal hygiene especially when shedding viruses themselves, e.g., after using toilets, but also after taking care of infected persons (e.g., changing of diapers) or cleaning toilet areas used by infected persons. Food handlers can also contaminate food by transferring viruses from contaminated surfaces to hands during preparation of ready-to-eat food or by

transferring viruses from contaminated food to other ready-to-eat foods. Inanimate surfaces include contaminated utensils, e.g., chopping equipment, such as dicers; cutting knives, and serving utensils.

- *for bivalve molluscs* that are consumed raw or lightly cooked: through faecal contamination of waters in which they are growing. The contamination most commonly occurs through sewage discharge, run off from agriculture and point source contamination of the immediate surroundings of the growing areas. Sewage discharge from boats, harvesting vessels, on site sewage management systems, and sewage treatment plants has been documented to contaminate bivalve molluscs. Vomiting events in harvesting areas have also been reported as a cause of contamination of bivalve molluscs. Since bivalve molluscs are filter-feeders, they bioaccumulate viruses in the gut to a concentration, which is much higher than present in the surrounding seawater.
- *for fresh produce:* through contaminated water (used for irrigation, or fertiliser application, or wash water); through the use of human sewage as fertiliser; through contaminated soil (used for primary cultivation) and through manual (human) handling by infected food handlers during and post-harvest. Fresh produce can also become contaminated after being in contact with contaminated surfaces and contaminated utensils, e.g., chopping equipment, such as dicers, cutting knives, and serving utensils. However, the relative contribution of each is not known.

The *persistence* of viruses in soil, water, on inanimate surfaces or in foods is well documented. Viruses may persist for extended periods (1 – 60 days with around 100-fold reduction in infectivity) on several types of materials commonly found in institutional and domestic environments. In addition, enteric viruses can persist on fresh produce for periods exceeding the shelf life of the product itself, and can particularly persist on contaminated produce that is stored frozen, such as contaminated berries. In (artificially) contaminated water, viruses may survive for prolonged periods of time. Enteric viruses can persist in bivalve molluscs and marine sediments for several weeks or months, and depuration processes used to reduce bacterial contamination of bivalves cannot be relied upon for complete virus removal.

There are currently no effective, realistic and validated *post-harvest risk management* options except cooking adequately to reduce viral contamination of both bivalves and fresh produce. Because of concerns about virus persistence during food processing, effective control strategies need to focus on *prevention* of contamination. Such prevention will have to occur primarily at the pre-harvest level for some products (bivalve molluscs, fresh produce for raw consumption), at the harvest level (manual handling during picking fresh fruits and vegetables) and at the post-harvest phase for others (prepared and ready-to-eat foods).

It is now known that some commonly used methods for *sewage treatment* may not be sufficient to effectively remove or inactivate viruses.

Hand sanitizing-agents have not been shown to be able to completely eliminate enteric virus infectivity from hands. Consequently, it is conceivable that considerable numbers of infectious viruses will remain when hand sanitizers are used instead of traditional hygienic hand washing with streaming water and soap, followed by drying using disposable towels.

For *surface disinfection*, many disinfection agents recommended for use in food establishments are not effective against the non-enveloped viruses, such as NoV or HAV. One effective method is the use of sodium hypochlorite, for which the effectiveness is determined by the concentration used or more correctly the availability of free chlorine and the exposure time. The recommended treatment for clean surfaces are solutions of $\geq$ 1000 ppm free chlorine for at least 5 min to inactivate HAV, and presumably also NoV. This is different from that required for the inactivation of bacteria. New chemicals and methods with virucidal claims are currently being validated for their efficacy to disinfect viral contaminated surfaces.

Recently, the number of available *detection methods* for foodborne viruses in food matrices other than bivalve molluscs has increased, reflecting the recognition of the significance of foodborne viral disease. Standardization of methods for NoV and HAV detection in selected food matrices (soft fruits, leafy greens and bottled water) is part of the program of the European Committee for Standardization (CEN). Furthermore, Health Canada has listed select validated methods in its Compendium of Analytical Methods for virus detection in foods.

Since most foodborne viruses cannot be cultured *in vitro*, detection methods are based on molecular amplification techniques, even though they are unable to discriminate between infectious and non-infectious viruses. Molecular methods, such as *real-time* reverse transcription polymerase chain reaction methods (real time RT-PCR) are less time- and labour intensive, and have facilitated the analysis of large numbers of samples. They can also be designed to be quantitative or semi-quantitative. Once validated, these methods will be useful in outbreak investigations as well as in auditing and monitoring of control systems.

SECTION I- OBJECTIVES

The primary purpose of these guidelines is to minimize the risk of illness arising from the presence of human enteric viruses in foods, and more specifically from norovirus (NoV) and hepatitis A virus (HAV) in foods. The guidelines provide advice to governments on a framework for the control of human enteric viruses, especially NoV and HAV and, with a view towards protecting the health of consumers and ensuring fair practices in food trade. The guidelines also provide information that will be of interest to the food industry, consumers and other interested parties. Information provided in these guidelines may also assist in minimizing the risks of foodborne illness from new and emerging viruses in foods.

SECTION II - SCOPE, USE AND DEFINITION

2.1 SCOPE

2.1.1 Food chain

These guidelines are intended for all kind of foods and are applicable to all foods throughout the food chain, from primary production through consumption, with a focus on ready-to-eat-food, and are necessary to control human enteric viruses in foods. These should not compromise controls in place for any other pathogens. These guidelines should be used in conjunction with Good Hygienic Practices (GHPs), as specified in the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* and other applicable codes such as *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP53-2003) and *Code of Practice for Fish and Fishery Products* (CAC/RCP52-2003, section 7).

2.1.2 Roles of governments, industry and consumers

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

2.2 USE

These guidelines follow the format of the Codex *Recommended International Code of Practice - General Principles of Food Hygiene*- CAC/RCP 1-1969). The major issues are covered in Sections 3, 6 and 7. Some of the sections in this document state both of the objectives to be achieved and the rationale behind those objectives in terms of safety and suitability of food. The annex to the control of hepatitis A virus (HAV) and norovirus (NoV) in bivalve molluscs (ANNEX I) and the annex to the control of hepatitis A virus (HAV) and norovirus (NoV) in fresh produce (ANNEX II) are supplements to these guidelines and include additional recommendations.

2.3 DEFINITIONS

For the purpose of these guidelines, refer to definitions of the *Recommended International Code of Practice – General Principles of Food Hygiene- CAC/RCP 1-1969)* and *Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)* and *Code of Hygienic Practice for fresh Fruits and Vegetables* (CAC/RCP 53 –2003). In addition the following expressions have the meaning stated:

Clean water - water that does not compromise food safety in the circumstances of its use.

Human enteric virus –viruses that replicate in the gastro-intestinal tract or in the liver and are excreted in faeces from humans. They are transmitted mainly by the faecal-oral route and are infectious to humans.

Fresh produce – fresh fruit and vegetables, including leafy vegetables, grown in the field (with or without cover) or in protected facilities.

Food handler - any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements.

HAV – hepatitis A virus.

NoV - norovirus, formerly known as Norwalk-like virus or small round structured virus (SRSV).

Potable water - water which meets the quality standards of drinking water such as described in the WHO Guidelines for Drinking Water Quality.

Ready-to-eat food (RTE-food) - any food that is normally eaten in its raw state or any food handled, processed, mixed, cooked, or otherwise prepared into a form, which is normally eaten without further virucidal steps, e.g. by processing.

SECTION III - PRIMARY PRODUCTION/HARVESTING AREA

OBJECTIVES: To describe the setting in which the primary production occurs and to identify different aspects of production processes that should be controlled to reduce the chance of viral contamination of food.

RATIONALE: Food may be contaminated already at the primary production area by faecally contaminated water or soil or by contagious food handlers or other infected persons.

3.1 ENVIRONMENTAL HYGIENE

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969), Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)" and Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 –2003).*

Potential sources of environmental contamination should be identified prior to production activities. Sources of viral contamination of food at the primary production site include the use of water, soil, manures or fertilizers contaminated by faeces of human or animal origin. Sites that have potential to contaminate the production site via run-off, faecal material, (vomit-derived) aerosols, or organic waste, for example, should be evaluated. During primary production, efforts should be made to ensure that food, e.g. bivalve molluscs and fresh produce, has contact with clean water only. Assessment of environmental conditions is particularly important because subsequent steps during production may not be adequate to remove contamination.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).*

Ill workers should not be present at food production sites (e.g. those with symptoms of gastroenteritis or acute hepatitis). In addition to faecal contamination, food should also be protected from vomit or vomit-derived aerosols, since products exposed to vomit or faecal matter in primary production areas could become contaminated and pose a risk to human health, especially if the products do not undergo a treatment that ensures the elimination of virus infectivity before consumption. Hygiene and health requirements should be followed to ensure that personnel who come directly into contact with food during production are not likely to contaminate the product.

The source of water used for production and the method of delivery of the water can affect the risk of contamination of food during production. Growers should seek appropriate guidance on water quality and delivery methods to minimize the potential for contamination by viruses. Irrigation water should come from a source determined to be safe. Also during harvesting of foods intended to be eaten raw, clean water should be used.

Natural fertilizers may contain human pathogens that persist for weeks or months. Proper treatments such as heat, chemical or biological treatments of biosolids, manures and by-products using treatments will reduce the risk of potential human pathogen survival.

3.3 HANDLING, STORAGE AND TRANSPORT

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).*

Harvesting methods vary depending on the characteristics of the product. Specific control measures should be implemented to minimize the risk of contamination from viruses associated with the method.

Harvesting containers should be in whole and in clean condition, and used only the specified number of times (e.g. single use containers).

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*. In addition, the following aspects of personal hygiene in primary production area are of major importance for food safety:

Food handlers with clinical symptoms of gastroenteritis (diarrhoea and/or vomiting) or with symptoms of acute hepatitis (fever, headache, fatigue combined with dark urine and light stools, or jaundice), should be excluded from food handling and should not, be present in the primary production area, so as to reduce the likelihood of transmission of the human enteric viruses, NoV and HAV. Worker(s) should leave the primary production area, if possible, before the onset of vomiting or the first diarrhea event and in any case directly

after these events. Any person with symptoms of acute hepatitis should seek medical advice. In the case of gastroenteritis, staff should only be allowed to return to work after a period without symptoms of diarrhoea and vomiting (e.g., period of 48 hours) or in the case of hepatitis, staff should only be allowed to return to work after disappearance of jaundice, having had a complete medical examination. As shedding of viruses such as NoV or HAV, may continue after their symptoms have subsided (post-symptomatically) (e.g., NoV can be present in the stool on average for 4 weeks up to 8 weeks), persons should have education of contagiousness and should comply with strict hand hygiene instructions at all times (i.e., thorough hand washing with soap and running water, and preferably drying hands with disposable (paper) towels). When one of the staff members presents or calls in with symptoms of gastroenteritis or hepatitis, other staff members may also be (asymptomatically) infected and all staff members should comply with strict hand hygiene measures. Compliance with acceptable standards of hand hygiene practice remains important at all times. Moreover in the case that one or more staff members complains of /or is diagnosed with acute hepatitis, the whole staff should seek medical advice. Vaccination against hepatitis A should be recommended to immunize food handlers where necessary to reduce the risk of viral contamination of the food, taking into account the epidemiological situation and/or immune status of the local population.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

OBJECTIVES: Equipment and facilities should be designed, constructed and laid out to ensure that surfaces can be cleaned and if needed disinfected.

RATIONALE: Inability to properly clean and disinfect may result in persistence of the virus leading to potential contamination of food.

4.1 LOCATION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*

4.2 PREMISES AND ROOMS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*

4.3 EQUIPMENT

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*

4.4 FACILITIES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969),* in addition:

4.4.4 Personnel hygiene facilities and toilets

4.4.4.1 Changing facilities and toilets

Hygienic and sanitary facilities should be available to ensure that an appropriate and acceptable degree of personal hygiene can be maintained. These should be located in close proximity to the production area, in sufficient numbers to accommodate personnel, be culturally appropriate and separate facilities may be required for men and women in some countries, be of appropriate design to ensure hygienic removal of wastes, have adequate means for hygienically washing and drying hands, be maintained under sanitary conditions and good repair, and following cleaning and disinfection programs (see 6.2 cleaning programs). In addition: a reminder of the hand washing instructions should be visibly present for all users of these facilities. Preferably, separate toilets for guests and employees of the establishment should be available. Toilet areas should not be open directly to food handling areas.

4.4.4.2 Hand washing facilities

In addition: Hand washing facilities should be within close vicinity of the toilets and positioned so that the employee must pass them returning to the food handling area.. Hands should be lathered with soap then washed for a minimum of 20 seconds with running water. Hands should be dried

preferably with disposable (paper) towels for a further 20 seconds[2]. This should be encouraged, as it is the most effective way to eliminate viruses and where possible, non-hand operable taps should be available to help prevent re-contamination of clean hands.

SECTION V - CONTROL OF OPERATION

OBJECTIVES: Processing operations should be controlled to prevent contamination of food with viruses.

RATIONALE: Preventive measures against the identified hazards or risks may help to reduce virus contamination.

5.1 CONTROL OF FOOD HAZARDS IN RELATION TO VIRAL CONTAMINATION

5.1.1 Identification of steps critical to the safety of food

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969), in addition with regard to risks for virus contamination some of the specific areas to be addressed are as follows:

- Each time food comes in contact with faecal material of either human or animal sources or faecally contaminated water during the production phase (irrigation, washing, freezing/icing).
- Each time that a food handler handles (ingredients for) food without compliance with strict hygienic practice while being contagious with viruses or after being in contact with faecal material or vomit matter, or after being in contact with other infected staff members. This is especially important when food is intimately handled by bare hands instead of utensils, such as commonly practiced in food service establishments. Please note that a person can be contagious prior, during or after illness or even without experiencing symptoms.
- Each time that a person vomits within the food production or preparation area.
- Cleaning and disinfection after a vomiting event in the production or food preparation area by an employee, visitor or guests of the establishment.
- Cleaning and disinfection after an event of diarrhoea of an employee, visitor or guests of the establishment.
- Each time that raw ingredients contaminated with viruses are introduced into the premises, as this may lead to contamination of food handler's hands, or other food or surfaces.

5.1.2 Implement effective control procedures

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969), in addition with regard to procedures to control viruses in food some of the specific areas to be addressed are as follows:

- Only potable water should be used as an ingredient to food and in operations involving food contact surfaces for the production of food to avoid food becoming contaminated with faecal material of human or animal origin.
- Personal hygiene of food handlers is critical. Food handlers should be aware of the high infectivity and transmission routes of enteric viruses, such as NoV and HAV. As asymptomatic shedding occurs, food handlers should be adhering to hand wash instructions at all times. Training should be provided to food handlers and managers (see Section 10). Food handlers should reduce direct bare hand contact with ready-to-eat foods by using utensils to handle food.
- Exclusion of food handlers, or any person, with clinical symptoms of gastroenteritis (diarrhoea and/or vomiting) or with symptoms of acute hepatitis (fever, headache, fatigue combined with dark urine and light stools, or jaundice), from food handling, or from being present in the primary production area. A person should be excluded from the primary production or preparation area, if possible, before the onset of vomiting or the first diarrhoea event and in any case directly after these events. Any person with symptoms of hepatitis should seek medical advice.

[2] WHO Guideline on hand hygiene in health care. WHO/EIP/SPO/QPS/05.2. http://whqlibdoc.who.int/hq/2005/WHO_EIP_SPO_QPS_05.2.pdf

- Any food possibly contaminated by vomit particles or aerosols containing vomit particles should be disposed of. Any food handled by the ill person during that day (or the day before) should be considered a risk.
- Acknowledge the fact that when one of the staff members calls in with symptoms of gastroenteritis or hepatitis, other staff members may also be (asymptomatically) infected. These other staff members should therefore also comply with strict hand hygiene at all times, or in case of hepatitis, should seek medical advice.
- Acknowledge the fact that when a family/house member of one of the staff members has symptoms of gastroenteritis or hepatitis, the staff member may also be (asymptomatically) infected, and/or serve as a vector carrying infectious virus on their person. Such staff members should, therefore, also comply with strict hand hygiene at all times, or in the case of hepatitis also seek medical advice.
- Allow recovered persons to return to work only after a period without symptoms of diarrhoea and vomiting in case of gastroenteritis (e.g., period of 48 hours) and under the condition that they comply with strict hand hygiene instructions, and preferably to activities not directly involving food handling. In the case of hepatitis, allow individuals to return to work only after disappearance of jaundice, under the condition that they comply with strict hand hygiene plus a medical examination and advice.
- Vaccination against HAV infection can be considered as a preventive measure, taking into account the epidemiological situation and/or immune status of the local population.
- Having cleaning, disinfection programs and disinfectant agents able to inactivate enteric viruses and disinfect equipment readily available, and include a checklist of which surfaces should be disinfected (see 6.1.2).
- Preferably only use raw ingredients from production plants that use clean or potable water only as well as from sources with adequately trained personnel, high personnel hygiene and good health.
- Avoid presence of non-authorized persons during food handling or on premises where food is grown, harvested, stored or prepared.
- Regular check up for HAV infection of workers of food service establishment is recommended especially in endemic areas.

5.1.3 Monitor control procedures to ensure their continuing effectiveness

- After having recovered from gastro-enteritis or hepatitis, check that staff members returning to work have been instructed and comply with strict hand hygiene practices at all times. All staff should be fully aware of the need to comply with strict hand hygiene measures.
- Verify that other staff members have not been infected or in the case of hepatitis have been vaccinated as a preventive measure.

5.1.4 Review control procedures periodically, and whenever the operations change

If an outbreak has been traced back to an establishment, the necessary steps should be taken to find the source, to eliminate the virus, and to avoid future outbreaks.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

5.2.1 Time and temperature control

Note that processes aimed at inhibition of microbial growth, such as cooling or freezing, will not affect virus infectivity enough to yield safe foods (e.g., for NoV and HAV less than 1 log reduction after 5 cycles of freezing and thawing and less than 1 log after storage at refrigerator temperatures for 1 week).

The effects of heat treatment on virus infectivity in foods are highly dependent on virus (sub)-type and food matrix. Commonly used cooking procedures for rice, pastas, or potatoes are considered adequate treatments to destroy viral infectivity. Conventional pasteurization (e.g. 63°C for 30 min, or 70°C for 2 min) is more effective than High Temperature Short Time (HTST; 71.7 °C for 15–20 seconds) pasteurization, but NoV and HAV are unlikely to be completely inactivated at those treatments. For shellfish, it has been shown that HAV can be inactivated when an internal temperature of 90°C is reached for at least 90 seconds. This could also be true for NoV.

5.2.2 Specific process steps

NoV and HAV are very stable at low pH and over 3 log inactivation may occur only at pH < 3, a pH that is often unacceptable for the sensorial quality of foods. Information on virus infectivity after long term storage, or cooling or freezing in combination with acidification is lacking.

Reducing water activity (RWA): The effects of RWA on virus infectivity in foods (or on fomites) are highly dependent on virus (sub)type and food matrix and can not be considered an effective generic measure to reduce viral loads.

High hydrostatic pressure (HHP): The effects of HHP on virus infectivity in foods are highly dependent on virus (sub)type and food matrix and may be considered a measure to reduce viral loads for some virus(types) present in specified matrices. As an example, infectious HAV titers could be reduced > 3 log at a HHP of 500MPa for 5 min in salty water and >3 log in oysters at a HHP of 400 MPa for 1 min.

Irradiation: Studies on the effect of irradiation (gamma or UV) on virus infectivity in foods are limited. UV-irradiation does reduce virus infectivity but its effectiveness is highly dependent on the presence of the virus on the surface of the food, the virus (sub)-type and the food matrix. It cannot be considered an effective generic measure to reduce viral loads on or in food. UV irradiation can be effective for the inactivation of viruses on surfaces for food preparation and for the inactivation of viruses in water and aerosols.

Prior to implementation in the food production chain virucidal treatments should be validated with the hazard/food combination to ensure that they are effective and can be applied consistently.

5.3 INCOMING MATERIAL REQUIREMENTS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).*

Preferably only use raw ingredients from production plants that use clean or potable water only (see also annex I and II) as well as from sources with adequately trained personnel, high personnel hygiene and good health.

5.4 PACKAGING

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).*

Modified atmosphere packaging (MAP) is a method that aims at inhibition of microbial growth. Since human viruses per definition do not grow in foods, this method is unlikely to be a suitable strategy to reduce virus infectivity.

5.5 WATER

5.5.1 *In contact with food*

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).*

Only potable water should be used for food that has not been washed or sanitized yet and that requires washing before adding to meals.

5.5.2 *As an ingredient*

Only potable water should be used.

5.5.3 *Ice and steam*

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).*

Ice should be made from potable water and should be manufactured, handled and stored so as to protect it from contamination. Steam used in direct contact with food or food contact surfaces should not contain any substances, which may be hazardous to health or may contaminate the food.

5.5.4. *Non-potable water*

Non-potable water used for steam production, refrigeration, fire control and other similar purposes not connected with food should be carried in completely separate lines, identifiable preferably by colour, and with no cross-connection with or back-siphonage into the system carrying potable water.

5.6 MANAGEMENT AND SUPERVISION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

All employees and managers should understand the importance of personnel hygiene to reduce the chance of viral contamination of food, i.e., importance of compliance with hand wash instructions, exclusion from the premises of food handlers or any persons with symptoms of gastroenteritis or acute hepatitis or those recovering from these symptoms, and how to disinfect surfaces when contaminated. It is advisable to have documentation of given hand-wash instructions for each new starting employee, in addition to displaying hand-washing instructions in each of the personnel hygiene facilities and toilets.

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)*.

SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION

OBJECTIVES: To provide specific guidance on preventive maintenance and sanitation procedures after an event of vomiting, diarrhoea and/or notification of hepatitis.

RATIONALE: Many disinfectants recommended for use in food establishments are not effective against enteric viruses, such as the non-enveloped NoV or HAV.

6.1 MAINTENANCE AND CLEANING

6.1.1. General

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

6.1.2 Cleaning procedures and methods

Cleaning: Each establishment should have a documented regular cleaning procedure. Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-196)*.

Disinfection: In addition, establishments should also have a procedure for the disinfection of surfaces possibly contaminated with enteric viruses, such as NoV or HAV. Disinfection, preceded by cleaning, should take place after each vomiting event in premises or rooms, after reported symptoms of gastroenteritis (diarrhoea and/or vomiting) or symptoms indicative of hepatitis (fever, headache, fatigue combined with dark urine and light stools, or jaundice) of one or more of the employees. Cleaning and disinfection should include all surfaces both in the bathroom and (as a preventive measure) in food production areas (e.g., equipment, utensils, telephones, keyboards, etc.), as viruses in vomit, aerosols and faecal matter are persistent and can stay infectious for a long period.

Ideally, disposable gloves, a disposable facemask and a disposable apron should be worn during cleaning and disinfection by a person trained in cleaning-up infectious material, because of the exposure to highly infectious pathogens. Any spillage or contamination with faeces or vomit should be dealt with immediately**,** and food handling in the same area(s) should be stopped. Dispose of any food possibly contaminated by vomit particles or by aerosols containing vomit particles. Any food handled by the ill person during that day (or the day before (NoV), or longer (HAV)) could be a risk and disposal of implicated product should be considered. Absorbent material such as paper towels and tissues may be used to limit the spread of liquid soiling and then be disposed of. Surfaces should be cleaned to ensure effective disinfection.

For *surface disinfection*, solutions of ≥ 1000 ppm free chlorine consistently show > 3 log reduction in viral infectivity within 5 min at room temperature. Freshly constituted hypochlorite solutions (e.g., using tablets) are preferable. The solution is corrosive, and needs to be thoroughly removed afterwards. Adequate precautions should be taken during cleaning or disinfection of rooms, equipment or utensils to prevent food being contaminated by wash water, detergents and disinfectants. Food preparation should only begin after thorough disinfection has taken place.

UV irradiation at >40 mWs/cm^2 (=mJ/cm^2) causes > 3 log 10 reduction of feline calicivirus (FCV) and murine norovirus (MNV), which have been used as models for human NoV and HAV, and this treatment can be considered for reducing viral infectivity on surfaces, in aerosols and in water.

Most other surface ***disinfectants*** lack efficacy (i.e., consistently cause less than a 3 log reduction in infectivity) against enteric viruses at manufacturer's recommended concentrations and exposure times. In fact, it is well recognized that the majority of chemical disinfectants currently used in both institutional, domestic environments, and in the food industry do not effectively inactivate HAV. New compounds and/or methods can be considered if they show virucidal activity of >3 log for non-enveloped viruses in standardized carrier tests.

6.2 CLEANING PROGRAMMES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* for normal cleaning programs.

The programs should take into account the specific cleaning and disinfection procedures that should be applied to ensure elimination of virus infectivity. These cleaning and disinfection programs should be in place (including the name, volume and concentration of disinfectants, time, temperature and/or pH to be applied and equipment to be used), and immediately be applied after a vomiting event or after notification of illness (gastro-enteritis, hepatitis) of food handlers. The disinfection should be thorough on all surfaces (e.g., equipment, utensils, telephones, keyboards, etc.) that may have been contaminated by ill persons or vomit particles, using effective disinfection agents (see also above, 6.1.2.).

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)*.

Food possibly contaminated with virus particles should be discarded in a manner such that contact between this food and any person, food or food contact surfaces is prevented.

6.5 MONITORING EFFECTIVENESS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE

OBJECTIVES: To prevent food handlers from contaminating food with viruses, in particular NoV and/or HAV due to poor personal hygiene

RATIONALE: Food handlers may shed virus and the infectious dose is very low. There is a need for strict hygiene control by food handlers, particularly in relation to the prevention of NoV and HAV contamination.

7.1 HEALTH STATUS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

Diarrhoea and vomiting can be caused by infectious (e.g., NoV) or non-infectious agents (e.g., toxins). All cases of gastroenteritis should, however, be regarded as infectious unless good evidence suggests otherwise. Fever, headache, fatigue combined with dark urine and light stools, or jaundice are indicative of hepatitis, which should also be regarded as infectious. Persons reporting the above symptoms should therefore be excluded from handling food or from being present in the premises, to reduce the likelihood of transmission of any infectious agents via food (see below at 7.2). The most important examples of enteric viruses related to gastroenteritis and hepatitis that can be transmitted via food (handlers) are NoV and HAV, respectively. Refer to the Introduction-Section of these guidelines for the incubation and contagious periods of both of these viruses.

7.2 ILLNESS AND INJURIES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

Food handlers with clinical symptoms of gastroenteritis (diarrhoea and/or vomiting) or with symptoms of acute hepatitis (fever, headache, fatigue combined with dark urine and light stools, or jaundice), should be excluded from food handling and should not be present in the food handling area, so as to reduce the likelihood of transmission of the human enteric viruses, NoV and HAV. Worker(s) should leave the food handling area, if possible, before the onset of vomiting or the first diarrhea event and in any case directly after these events. Any person with symptoms of acute hepatitis should seek medical advice. In the case of gastroenteritis, staff should only be allowed to return to work after a period without symptoms of diarrhoea and vomiting (e.g., period of 48 hours) or in the case of hepatitis, staff should only be allowed to return to work after disappearance of jaundice, having had a complete medical examination. As shedding of viruses such as NoV or HAV, may continue after their symptoms have subsided (post-symptomatically) (e.g., NoV can be present in the stool on average for 4 weeks up to 8 weeks), persons should have education of contagiousness and should comply with strict hand hygiene instructions at all times (i.e., thorough hand washing with soap and running water, and preferably drying hands with disposable (paper) towels). When one of the staff members presents or calls in with symptoms of gastroenteritis or hepatitis, other staff members may also be (asymptomatically) infected and all staff members should comply with strict hand hygiene measures. Compliance with acceptable standards of hand hygiene practice remains important at all times. Moreover in the case that one or more staff members complains of /or is diagnosed with acute hepatitis, the whole staff should seek medical advice. Vaccination against hepatitis A should be recommended to immunize food handlers where necessary to reduce the risk of viral contamination of the food, taking into account the epidemiological situation and/or immune status of the local population.

7.3 PERSONAL CLEANLINESS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

Hands should be washed before handling of food. The most effective way of preventing spread of viruses is thorough handwashing. Hands should be lathered with soap then washed for a minimum of 20 seconds with running water. Hands should be dried preferably with disposable (paper) towels for a further 20 seconds[2]. Everyone should always wash his or her hands especially before handling food, after using the toilet or after being in contact with faecal matter (also after changing diapers, cleaning toilets) or after being in contact with vomit. The use of disposable hand towels should be encouraged.

7.4 PERSONAL BEHAVIOUR

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

In addition, money, tickets etc., should not be handled at the same time as food when wearing gloves. When this is not possible, new gloves should be put on before preparing food.

7.5 VISITORS

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

SECTION VIII – TRANSPORTATION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENESS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*. Countries should give consideration to labelling of certain ready-to-eat foods so that consumers can make an informed choice with regard to these products and are adequately informed about the risks associated with the consumption of these products, raw or lightly cooked, that may be contaminated with viruses during production.

SECTION X – TRAINING

OBJECTIVES: Those workers engaged in food growing or processing who come directly or indirectly in contact with foods should be trained and/or instructed in the control of enteric viruses to a level appropriate to the operations they are to perform.

RATIONALE: Controls specific to enteric viruses are generally more stringent than routine good hygiene practices.

10.1 AWARENESS AND RESPONSIBILITIES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

In addition, it is the responsibility of the employee to call in sick when ill with diarrhoea or vomiting complaints or symptoms indicative of hepatitis. It is also the responsibility of the employee to adhere to strict hand washing instructions after returning from the toilet or after being in contact with faecal or vomit matter. It is the responsibility of the managers to educate and train their employees, to keep control of the level of awareness of the training content, and to have both cleaning and disinfection programs operational. It is the responsibility of employers and managers to carry out some monitoring to ensure that employees are undertaking good hygiene practice.

10.2 TRAINING PROGRAMMES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

Training programs should contain information on the following: the potential for food to be a vehicle of virus transmission if contaminated; the potential sources and routes of transmission of human enteric viruses; the incubation periods of foodborne viruses, specifically NoV and HAV; the duration of virus shedding even after recovery from clinical symptoms; the possibility of asymptomatic shedding; the infectivity of vomit, procedures for cleaning and disinfection of contaminated surfaces; the need for strict compliance with hand washing instructions at all times and the need for washing of hands after being in contact with faecal or vomit matter. Training should also emphasize that if a staff member calls in sick, it is likely that other members may be (asymptomatically) infected too, and, in addition, if a household member is ill, it is likely that the staff member may be (asymptomatically) infected too and strict hand hygiene is required. Staff members should also be taught to stay away from work and not to have direct contact with any ready-to-eat food if they have symptoms of gastroenteritis or hepatitis. Moreover training should also emphasize the need to keep children away from food growing fields and food preparation areas in HAV endemic areas.

10.3 INSTRUCTION AND SUPERVISION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

Extensive training and instructions should be given to all new employees on the infectivity, transmission and disinfection of foodborne viruses. Incorporation of these instructions into the National Hygiene Codes would be advisable.

10.4 REFRESHER TRAINING

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

ANNEX I

CONTROL OF HEPATITIS A VIRUS (HAV) AND NOROVIRUS (NoV) IN BIVALVE MOLLUSCS

INTRODUCTION

For bivalve molluscs, the major, well-documented route of contamination is via faecal contamination in growing or harvesting areas. Viruses have been observed to persist for 8 to 10 weeks in contaminated live bivalve molluscs and can be detected in the gut tissue of bivalve molluscs. Recent evidence has shown that norovirus (NoV) binds specifically to bivalve molluscs tissue receptor sites, which could explain why some viruses persist after depuration. Furthermore, studies indicate that there may even be a risk of infection if contaminated bivalve molluscs are consumed (lightly) cooked. Thus, once viral contamination of bivalve molluscs has occurred, removal or inactivation of the viruses by processes that retain the sensory characteristics of the live molluscs is currently unfeasible. Therefore, measures should be taken to prevent viral contamination by increasing the water quality in bivalve molluscs harvesting areas.

SECTION I- OBJECTIVES

This annex provides advice to governments on a framework for the reduction of HAV and NoV in bivalve molluscs, with a view towards protecting the health of consumers and ensuring fair practices in food trade. The primary purpose of this annex is to minimize the likelihood of human illness arising from the presence of HAV and NoV in bivalve molluscs. This annex also provides information that will be of interest to the food industry, consumers, and other interested parties.

SECTION II - SCOPE, USE AND DEFINITION

2.1 SCOPE

This annex is applicable to bivalve molluscs and focuses on control measures to minimize and/or prevent contamination of bivalve molluscs with HAV and NoV with the aim of preventing or reducing human illness. This annex is based on the results of the FAO/WHO Expert Meeting, held on 21-25 May 2007 (in Bilthoven, the Netherlands)[1], as well as other available risk assessments and epidemiological evaluations. They highlight critical control measures that affect key factors that influence the frequency and extent of contamination of bivalve molluscs with HAV and NoV and thus the risk of developing hepatitis and gastroenteritis through consumption.

In many instances, these control measures are articulated in a general manner in the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* as part of the general strategy for the control of foodborne pathogens in all foods. More specific control measures for bivalve molluscs can be found in the *Code of Practice for Fish and Fishery products (CAC/RCP 52-2003*, Section 7)" and the "*Standard for Live and RawBivalve Molluscs (CODEX STAN 292-2008)* and the WHO Guidelines for the safe use of wastewater, excreta and grey water. Volume 3: Wastewater and excreta use in aquaculture (World Health Organization 2006 ISBN 92 4 154684 0; www.who.int/water_sanitation_health/wastewater/gsuweg3/en/index.html). In providing these guidelines, it is assumed that these General Principles of Food Hygiene are being implemented. Those principles that are restated reflect the need for special attention for the control of viruses.

2.2 USE

This annex follows the format of the Codex *Recommended International Code of Practice - General Principles of Food Hygiene- CAC/RCP 1-1969)*. The major issues are covered in Section III.

2.3 DEFINITIONS

Definitions of the *Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007)*" and "*Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)* apply.

Clean water - Clean water means water from any source where harmful microbiological contamination, substances and/or toxic plankton are not present in such quantities that may affect the safety of fish, shellfish and their products intended for human consumption.

Depuration – The reduction of micro-organisms to a level acceptable for direct consumption by the process of holding live bivalve molluscs for a period of time under approved, controlled conditions, in natural or artificial seawater suitable for the process, which may be treated or untreated.

Relaying – the removal of bivalve molluscs from a microbiologically contaminated growing area to an acceptable growing or holding area under the supervision of the agency having jurisdiction and holding them

there for the time necessary for the reduction of contamination to an acceptable level for human consumption.

SECTION III - PRIMARY PRODUCTION

The main hazard known for the production of bivalve molluscs is microbiological contamination of the waters in which they grow, especially as the bivalve molluscs are often consumed live or raw. Since molluscs are filter-feeders, they concentrate contaminants to a much higher concentration than is present in the surrounding seawater. Contamination with bacteria and viruses in the growing area is therefore critical for the end product specification and determines the process requirements for further processing. It is important to ensure the seawater quality of growing areas by increasing sewage treatment efficiency for virus removal/inactivation and avoid discharging of untreated sewage in the surroundings of the bivalve molluscs growing areas. Sewage treatment plants should aim to achieve at least a 4 log reduction of NoV and HAV through the treatment process and the process should when-ever possible involve a tertiary treatment step such as UV treatment. The sanitary survey of harvesting and/or growing water should include an assessment of possible human faecal contamination sources. To control the hazards, identification and monitoring of growing areas is very important for bivalve molluscs safety. *E. coli* and/or faecal coliforms are used as indicators for faecal contamination. Monitoring data should be interpreted within the context of the sanitary survey, as viruses may be present in the absence of *E.coli/* faecal coliforms/total coliforms. A short-term depuration process commonly reduces low levels of bacterial contamination, and thus contributes to the safety of bivalve molluscs but depuration, as usually performed, is ineffective in the removal of viruses. When there is a likelihood or evidence of virus contamination through epidemiological information, environmental events or direct detection through virological analysis, closure of the area, destination for exclusively virucidal heat treatment (see 5.2.1, main document) before consumption or long term relaying is recommended. The holding time and minimum temperature during long term relaying is determined by the official agency having jurisdiction, according to the degree of contamination before relaying, the temperature of the water, the bivalve molluscs species involved and local geographic or hydrographic conditions to ensure that contamination levels will be adequately reduced. When there has been a shellfish-borne outbreak caused by an identified pathogen such as NoV or HAV and the area has been closed, viral testing of the bivalve molluscs may be used as part of the process of reopening the affected harvesting area depending on the requirements of the official agency, using either standardized methods or alternative validated methods performed by accredited laboratories. Other conditions, including meeting the sanitary surveys requirements, should also have been satisfied as a condition of reopening the area. Ideally they include the identification of sources of pollution/contamination.

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* and *the Standard for Live and Raw Bivalve Molluscs (CODEX STAN 292-2008)*. In addition:

3.1 ENVIRONMENTAL HYGIENE

Refer to the *Code of Practice for Fish and Fishery Products, section 7 (CAC/RCP 52-2003).*

In spite of the classification of the growing and harvesting areas based on sanitary surveys and bacteriological monitoring, viruses may be present. Efforts should be made to restrict the growing and harvesting of bivalve molluscs to areas of clean water quality.

SECTION V - CONTROL OF OPERATION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003, Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)* and *the Standard for Live and Raw Bivalve Molluscs (CODEX STAN 292-2008).* In addition:

5.1 CONTROL OF FOOD HAZARDS IN RELATION TO VIRAL CONTAMINATION

5.1.1 Identification of steps critical to the safety of foods

With regard to risks for virus contamination some of the specific areas to be addressed are as follows:

- Growing area that is contaminated by sewage discharge or disposal of faecal matter from ships, recreational boats and shellfish harvesting vessels.
- Overflow from sewage treatment forms that may contaminate the growing waters after heavy rainfall.
- Quality of sewage collecting network and private septic tanks.
- Inadequate heat-treatment of products.

5.1.2 Implement effective control procedures

With regard to procedures to control viruses in food some of the specific areas to be addressed are as follows:

- Every effort should be made to minimize the overflow of untreated or partially treated sewage into growing waters.
- Efforts should be made to restrict the growing and harvesting of bivalve molluscs to areas of clean water only.
- Records regarding the history of contamination of molluscs harvesting areas by NoV and HAV should be reviewed in order to determine whether risk periods can be identified for each area; during such periods, the monitoring of areas should be reinforced.
- Sewage treatments should ensure adequate reduction of viral loads. Sewage treatment processes should aim to achieve at least 4 log reduction of NoV and HAV through the treatment process and the process should when ever possible involve a tertiary treatment step such as UV treatment.
- After heavy rainfall, during risk periods and/or after overflow from sewage treatment plants, harvesting of bivalve molluscs should be halted for a period, until the water and/or shellfish quality of the harvesting area has been checked and has been returned to normal backgrounds levels for the area. If there is a belief that the area has been impacted by human sewage, testing of water or bivalve molluscs for the presence of NoV or HAV may be an option prior to re-opening. Relaying is another possibility, although new contamination may occur during the relaying period, as the area involved is likely to be susceptible to new contamination events. Additionally, since shellfish are frequently eaten raw, without cooking, it is vital that they be harvested only from clean waters. Shellfish safety programs achieve the necessary safety and quality by classifying shellfish harvest areas and controlling the harvest activities. Bivalve molluscs intended for further treatment, which has been harvested from contaminated areas, should follow a appropriate control measures including post harvest treatment, e.g. heat treatment.
- Systems should be put in place to monitor sewage spills and provide prompt notification to the appropriate official agency as well as the shellfish industry so that appropriate action (i.e. cessation of harvesting) can be taken.
- When raw or partially treated sewage is known or suspected to have entered a growing area, shellfish harvesting must immediately cease and destination for exclusively virucidal heat treatment (see 5.2.1, main document) before consumption or long term relaying for already harvested shellfish from this area is recommended. The holding time and minimum temperature during relaying is determined by the official agency having jurisdiction according to the degree of contamination before relaying, the temperature of the water, the bivalve molluscs species involved and local geographic or hydrographic conditions to ensure that contamination levels will be adequately reduced.
- Heat treatments should be validated with respect to viral inactivation.

5.1.3 Guidance for areas involved in a virus-related-shellfish-borne-outbreak.

When there has been a shellfish-borne outbreak caused by an identified pathogen such as NoV or HAV and the area has been closed, testing of the bivalve molluscs may be used as part of the process of reopening the affected harvesting area depending on the requirements of the official agency, using either standardized methods or alternative validated methods performed by accredited laboratories. Other conditions, including meeting the sanitary surveys requirements, should also have been satisfied as a condition of reopening the area. Ideally they should include the identification of sources of pollution/contamination.

5.1.4 Disposal of human sewage from harvest vessels

Suitable precautions should be taken to protect bivalve molluscs from being contaminated by human faecal materials:

- No overboard discharge of human faecal material should occur from harvest (or assisting) vessels around shellfish growing areas
- All necessary measures should be taken to prevent contamination on board of bivalve molluscs by faecal materials.
- Personal hygiene and facilities should be such to ensure that an appropriate degree of personal hygiene can be maintained.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.2 Specific process steps

Heat treatments of bivalve molluscs should be validated for their ability to inactivate viruses (see 5.2.1, main document). Even though cooking may not guarantee total inactivation of viruses, it would reduce their levels and reduce the risk of causing foodborne infection. The degree of cooking required to reliably inactivate NoV and HAV would, however, probably render oysters unpalatable to consumers. Also the inability of home or restaurant cooking to provide adequate guarantees of consumer protection from consuming virally contaminated bivalve shellfish underlines the importance of harvesting bivalve molluscs from clean water growing areas meeting the control measures as listed in 5.1.

5.8 RECALL PROCEDURES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* and *Code of Practice for Fish and Fishery Products, section 7 (CAC/RCP 52-2003)*.

In addition, based on the determined level of risk associated with the presence of NoV and HAV in a given food product, a decision may be taken to recall the contaminated product from the market. The need for public warnings should be considered.

SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENESS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*. In addition:

9.1 LOT IDENTIFICATION

NoV and HAV can persist for long periods of time in bivalve molluscs. Movements between growing areas and countries complicate traceability of bivalve molluscs. Lots should be identified with information from areas where molluscs were grown and such areas should be registered. It is therefore important not only to register the area of harvest, but also all growing areas for a two month period prior to harvest.

9.3 LABELLING

Refer to *the General Standard for the Labelling of Prepackaged Foods* (*CODEX STAN 1-1985*).

Where appropriate, product labels should include information on safe handling practices and storage recommendations. In addition, countries should give consideration to labelling of unpackaged live or raw seafood, so that consumers are adequately informed with respect to the safety and true nature (alive or not alive) of these products.

9.4 CONSUMER EDUCATION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* and *Code of Practice for Fish and Fishery Products, (CAC/RCP 52-2003, section 7)*.

In addition, each country has specific consumption habits, therefore communication programs pertaining to viruses are most effective when established by individual governments. Consumers should be made aware of the risk of becoming infected with NoV or HAV after consumption of bivalve molluscs, either raw or lightly cooked.

SECTION X – TRAINING

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

10.1 AWARENESS AND RESPONSIBILITIES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* and *Code of Practice for Fish and Fishery Products, (CAC/RCP 52-2003, section 7)*.

In addition, industry (primary producers, manufacturers, distributors, retailers and food service/ institutional establishments) and trade associations have an important role in providing specific instructions and training for control of viruses.

10.2 TRAINING PROGRAMMES

In addition to the training content mentioned in the Guidelines on the application of general principles of food hygiene to the control of viruses in food (section 10.1), appropriate personnel involved in the growing and harvesting of bivalve molluscs should have appropriate training in:

- The general characteristics of HAV and NoV and their resistance to various environmental conditions, e.g. sewage treatment, temperature;
- Control measures to prevent faecal contamination of growing and harvesting areas;
- The availability of methods appropriate to analyse shellfish for the presence of viruses; including the interpretation of negative or positive viral test results.

ANNEX II

CONTROL OF HEPATITIS A VIRUS (HAV) AND NOROVIRUS (NoV) IN FRESH PRODUCE

INTRODUCTION

Fresh produce is now grown on a large scale in many countries and is transported globally. Outbreaks of viral disease associated with contaminated green onions and raspberries, as well as other produce items are well documented[1]. The contamination of fresh produce may occur at any stage from production (sources include contaminated water or soil and infected food handlers) through the use by the consumer.

Direct contact with human sewage can be a cause of pre-harvest contamination of fresh produce items through the use of sewage-contaminated waters in irrigation, washing, as fertiliser or for fertiliser/pesticide application or through contaminated sewage seeping into the soil. (Surface) water may become contaminated with viruses, as it is known that sewage treatments applied are not always sufficient to effectively remove or inactivate viruses.

Fresh produce may also become contaminated by viruses via contaminated hands of food handlers due to not practising appropriate personal hygiene if they are shedding viruses themselves with or without symptoms, after visiting the toilet, after changing diapers, or after cleaning toilet areas. A second important factor in food-handler associated spread of viruses is vomiting. Infections with norovirus (NoV) will often lead to projectile vomiting with a very abrupt onset. The formation of aerosols in an area where a person has vomited can lead to widespread contamination of the environment.

SECTION I- OBJECTIVES

This annex provides advice to governments on a framework for the control of NoV and hepatitis A virus (HAV) in fresh produce, with a view towards protecting the health of consumers and ensuring fair practices in food trade. The primary purpose of this annex is to minimise the likelihood of illness arising from the presence of NoV and HAV in fresh produce. The annex also provides information that will be of interest to the food industry, consumers, and other interested parties.

SECTION II – SCOPE, USE AND DEFINITION

2.1 SCOPE

This annex covers general hygienic practices for the primary production, farm processing and packing of fresh produce cultivated for human consumption in order to produce a safe and wholesome product, particularly for those intended to be consumed raw. Specifically, this annex is applicable to fresh produce grown in the field (with or without cover) or in protected facilities (hydroponic systems, greenhouses). It concentrates on NoV and HAV in fresh produce and how to prevent fresh produce from becoming contaminated by these viruses during primary production.

Although it is important for the safety of fresh produce, this annex does not provide recommendations for handling practices to maintain the safety of fresh produce at wholesale, retail, food services or in the home, since those are covered in the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969),* the *Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003)* and the present document 'Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food'.

2.2 USE

This annex follows the format of the Codex *Recommended International Code of Practice - General Principles of Food Hygiene*- CAC/RCP 1-1969). The major issues are covered in Section III.

2.3 DEFINITIONS

For the purpose of these guidelines, the following definitions apply:

Definitions in the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53 – 2003).

Clean water - water that does not compromise food safety in the circumstances of its use

SECTION III - PRIMARY PRODUCTION

Fresh produce is grown and harvested under a wide range of climatic and diverse geographical conditions, using various agricultural inputs and technologies, under varying socioeconomic, hygienic and epidemiological circumstances, and on farms of different sizes. Viral hazards may therefore vary

considerably from one type of production to another. In each primary production area, it is necessary to consider the particular agricultural practices that promote the production of safe fresh fruits and vegetables, taking into account the conditions that are specific to the primary production area, type of products, and methods used. Procedures associated with primary production should be conducted under good hygienic conditions and should minimize potential risks from fresh produce contaminated with NoV and HAV.

Potential sources of contamination include:

- Sewage-contaminated surface waters which can be a cause of pre-harvest contamination of fresh produce items through the use of sewage-contaminated waters in irrigation, washing, as fertilizer or for fertilizer/pesticide applications or through contaminated sewage seeping into the soil.
- During growth, harvest and packing fresh produce may be contaminated by infected food pickers directly through handling with contaminated hands or vomiting in the field, and also by the presence of young children in the fields.

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* and *Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003) and Annex on Fresh Leafy Vegetables*.

3.1 ENVIRONMENTAL HYGIENE

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* and *Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003)* and *WHO Guidelines for the safe use of wastewater, excreta ad grey water. Volume 2: Wastewater use in agriculture (World Health Organization 2006 ISBN 92 4 154683 2,v.2) and Annex on Fresh Leafy Vegetables*

In the case of NoV and HAV in fresh produce, the main (human) sources of contamination of the production sites that should be specifically regarded are sewage treatment plants, human excreta used as fertilizer, agricultural workers and the sanitary facilities on-site. If these sources contaminate water and soil that come into contact with fresh produce, there is a potential risk of contamination with NoV and HAV. NoV and HAV are persistent in the environment, as well as on fresh produce, where they can sometimes survive the shelf life of the products.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53 – 2003). *Annex on Fresh Leafy Vegetables*

3.2.1 Water for irrigation and harvesting

The assessment of the microbial quality of the sources of water used on the farm for the presence of NoV and HAV should include an assessment of possible human faecal contamination sources of the water (sanitary survey) and, if, deemed necessary, testing. In the case of identified contamination sources of the water used on the farm, corrective actions should be taken to minimize the NoV and HAV risks. It needs to be verified if the corrective actions were effective.

Testing for *E. coli and/or faecal coliforms* is useful to determine the level of faecal contamination of the water. *E. coli* originates from human and animal sources, however, currently it is assumed that NoV and HAV originate from human sources only. The level of faecal contamination may indicate the potential for the presence of NoV and HAV, however these viruses may be present in the absence of faecal indicators. The frequency of testing should be established according to the source of the water (ground water, surface water, wells) and the conditions of the irrigation system.

With water delivery techniques that result in exposure of the edible portion of fresh fruits and vegetables directly to irrigation water, the risk of NoV and HAV contamination is considered to be higher as compared with other types of irrigation.

SECTION V - CONTROL OF OPERATION

Refer to *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* and *Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003)* and *WHO Guidelines for the safe use of wastewater, excreta ad grey water. Volume 2: Wastewater use in agriculture (World Health Organization 2006 ISBN 92 4 154683 2,v.2)*. In addition:

The control of NoV and HAV in fresh produce should focus on the prevention of contamination of fresh produce with human faecal material, as limited effective post-harvest treatments are available at the present time.

5.1 CONTROL OF FOOD HAZARDS

5.1.1 Identification of steps critical to the safety of foods

- Use of contaminated water during the whole production process.
- Irrigation water that is not free from sewage discharges.
- Overflow from sewage and septic tank systems after heavy rainfall that may contaminate the surface water used for production of fresh produce.
- Seepage of sewage into soil.
- Land contaminated with pathogenic human viruses.
- Bare hand contact with produce.

5.1.2 Implement effective control procedures

- Efforts should be made to use only clean water and soil for the production of food.
- Sewage treatments should ensure adequate (maximal) reduction of viral loads in treated sewage.
- Avoid presence of non-authorized persons, including children, on premises where food is grown, harvested, washed or stored.
- Presence of (portable) sanitary facilities, including appropriate hand washing facilities, in close vicinity of the fields.
- Compliance with personal hygiene practice.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.2 Specific process steps

5.2.2.1. Post harvest water use

Antimicrobial agents, effective for bacteria, may not be effective for the reduction of NoV and HAV in fresh produce. Any (new) antiviral treatment should be validated prior to its use in the production phase. It should be clearly stated for which viruses it has been shown to be virucidal. If applicable, antiviral treatments should be approved by the competent authorities.

5.8 RECALL PROCEDURES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

Based on the determined level of risk associated with the presence of NoV and HAV in a given fresh produce, corrective actions may be taken and/or a decision may be taken to recall the contaminated product from the market. The need for public warnings should be considered.

SECTION X – TRAINING

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*. In addition:

10.1 AWARENESS AND RESPONSIBILITIES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* and *Code of Hygienic Practice for Fruits and Vegetables (CAC/RCP 53-2003)*.

In addition, industry (primary producers, manufacturers, distributors, retailers and food service/ institutional establishments) and trade associations have an important role in providing specific instructions and training for control of viruses.

10.2 TRAINING PROGRAMMES

Personnel involved in handling of fresh produce should have appropriate training in:

- The general characteristics of NoV and HAV and their resistance to various environmental conditions, e.g. sewage treatment, temperature;
- Personal hygiene (see Section 7, Main document);
- Control measures to prevent faecally contaminated water to be used in primary production;
    - Control measures to prevent fresh produce to be contaminated by contagious food handlers.

APPENDIX II

Codex Virus meeting – 25-26 March 2010, Utrecht, The Netherlands
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