codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty first Session
Coronado Hotel, San Diego, United States of America

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, Czech Republic, Denmark, Finland, France, Germany, Japan, Norway, Poland, Slovenia, Spain, Thailand, FAO, Codex secretariat and CIAA.

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Guidelines at Step 3 (see Appendix) 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, Seventeenth Edition*) to: Ms Barbara McNiff, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-690-4719, or email Barbara.McNiff@fsis.usda.gov with a copy to: Secretary, 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 September 2009.**

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. 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. The Committee requested that the working group should consider the most appropriate title and presentation of this work (ALINORM 09/32/13, paras 138-141).

Following the request of the Committee, the 32nd Session of the Commission (29 June – 4 July 2009) approved this new work.

APPENDIX

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 food-borne disease. Viruses require special attention because they behave differently from bacteria, and because currently used *control measures* typically have not been validated for the effect on viral contamination and there is not a good understanding of their efficacy towards controlling virus contamination of foods. Data from recent studies have shown that food-borne 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 Viruses in Food in 2007[1], attention was given to the threat of viruses as a risk to public health when 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 in diameter, whereas bacteria generally range in size from 0.5 to 5 micrometers. In addition to size, other structural and biological properties differ between viruses and bacteria. Unlike bacteria, which are free living, viruses use the host cells to replicate. Each group of viruses has its 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, surfaces or food.

The viruses *most frequently involved in food-borne infections* are norovirus (NoV) and hepatitis A virus (HAV), but other viruses such as human rotavirus (HRV), hepatitis E virus (HEV), astrovirus, Aichi virus, sapovirus, enterovirus, coronaviruses, parvovirus and adenovirus can also be transmitted by food, and anecdotal evidence suggests the list of food-borne viruses may be even longer. Based on the symptoms of infection, 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 food-borne viruses are those that infect via the gastrointestinal tract and are excreted in faeces and for some viruses, in vomitus, which are infectious for humans when ingested via the oral route. Asymptomatic infections and shedding are common.

Noteworthy *characteristics* of food-borne viruses *and the associated infections/illnesses* are the following:

- Viruses need to enter living cells in order to be able to multiply (replicate). Unlike bacteria, they will never replicate in food. Consequently, viruses will never 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 vomits, only a few viral/infectious particles (1 to 100) are needed to cause infection and produce illness.

- Viruses transmitted by the faecal-oral route have been shown to be hardy and to persist in the environment for weeks to months in water, marine sediments or bivalve molluscs or on various inanimate surfaces. Most food-borne viruses are non-enveloped and are therefore less susceptible to intrinsic and extrinsic parameters commonly used in food preservation, e.g. refrigeration, freezing, pH (as low as 3-4 and as high as 9-10), drying, UV radiation, heat and pressure, disinfectants, etc.

- Freezing and refrigeration temperatures preserve viruses and are believed to be the single most important parameter that increases the persistence of food-borne 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 food matrix can influence relative survival to heat and desiccation.

[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.

- 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 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 hygienic hand washing practices. Moreover the majority of chemical disinfectants used do not effectively inactivate non-enveloped viruses, as was shown e.g. for HAV.

- The transmission of zoonotic viruses via food, with the possible exception of HEV, is not as common as is the case for many bacterial pathogens, e.g. *Salmonella* and *Campylobacter*.

During the FAO/WHO Expert meeting on "Viruses in Food"[1], NoV and HAV were determined to be the viruses of *greatest concern from food safety perspective* based on the incidence of reported food-borne disease, the severity of disease, including mortality, and having the potential for transmission via foods. Estimates of the burden of disease due to NoV range from 11-3067 cases per 100 000 persons per year. 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 the major food-borne viruses that cause severe disease and significant mortality. Emerging viruses of a zoonotic nature, such as HEV, Nipah, HPAI H5N1, have been linked to food or postulated to be transmitted via food, but to date too little data is present to elaborate on these emerging viruses in this context.

NoV Norovirus infections occur all year round, and cause gastroenteritis 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. Clear seasonal peaks have been observed when looking at reported outbreaks but these are particularly associated with healthcare infections rather than food-borne infections. The incubation period, i.e. the period between exposure to the virus and onset of symptoms, is relatively short; 12-72 hours, on average around 24-30 hours. The onset of symptoms after NoV infection is often characterised by sudden start of one or several episodes of projectile vomiting, followed by several days with diarrhoea. A NoV infected person sheds a large amount of infectious virus particles while having symptoms, but also before the onset of symptoms and may continue to shed up to 3 weeks after resolution of symptoms even in immuno-competent persons. The shedding period may be longer in the case of immunosuppressed individuals. Some NoV infections occur without resulting in apparent symptoms. No vaccine against NoV is 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 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 are immune. In developed countries, however, HAV infections are less common as a result of increased standards of living. 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 number ($>10^6$ particles/g) in faeces from the latter 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 for zoonotic viruses, although combinations of these routes have also been described. The meeting sought to prioritize the *virus-commodity combinations* of greatest public health concern, based on knowledge known in 2007, which was acknowledged as being incomplete. Prioritization was done according to the following criteria: disease severity, incidence/prevalence, probability of exposure, trade impact, public health cost, and ability to control food borne infections. The virus-commodity combinations selected were NoV and HAV in shellfish, NoV and HAV in fresh produce and NoV and HAV in prepared (ready-to-eat) foods. For these combinations, separate Annexes with specific recommendations have been written, accompanying this

document. It should be kept in mind that mitigation of one virus would probably help in preventing other viruses too as they often have a common sources, 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 practicing poor personal hygiene during food preparation and serving. Alternatively, via viral contaminated inanimate surfaces or when viral contaminated ingredients are used. Food handlers can contaminate food either with particles from vomits (NoV) or from faeces (NoV/HAV) when practicing 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.

• *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 surrounding of the growing areas.

• *for fresh produce:* through contaminated water (used for irrigation, or fertilizer application, or wash water); through the use of human sewage as fertilizer and through manual (human) handling by infected food handlers during and post-harvest. However, the relative contribution of each is not known.

The *persistence* of viruses in 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. 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, whereas depuration processes used to reduce bacterial contamination of bivalves cannot be relied upon for complete virus removal.

There are *no realistic post-harvest risk management* options except cooking adequately to reduce viral contamination of both bivalves and fresh produce. Because of concerns about virus persistence in food processing, effective control strategies need to focus on *prevention* of contamination. Such prevention will have to occur at the pre-harvest level for some products (bivalve molluscs, fresh produce for raw consumption) and at the post-harvest phase for others (prepared and ready-to-eat foods). If viruses contaminate foods at the end of the food chain, acid resistance and the ability to infect the gastro-intestinal tract are more important.

It is now known that some commonly used methods for *sewage treatment* may not be sufficient to effectively remove or inactivate viruses. Moreover, *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. As is the case for hand disinfection, most surface *disinfectants* lack efficacy (i.e. cause less than a 1000 fold reduction in infectivity) against enteric viruses at manufacturers recommended concentrations. In fact, it is well recognized that the majority of chemical disinfectants used in both institutional and domestic environments do not effectively inactivate HAV.

Recently, the number of available *detection methods* for food-borne viruses in food matrices other than bivalve molluscs has increased reflecting the recognition of significance of food-borne viral disease. Standardised sensitive methods for NoV and HAV detection in selected food matrices (soft fruits, leafy greens and bottled water) are presently being validated in the CEN/TAG4 committee of the European Union. Furthermore, Health Canada has listed select validated methods in it's Compendium of Analytical Methods (http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/index-eng.php) for virus detection in foods.

Since most food-borne 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 as compared to *classic* PCR methods. 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 enteric viruses, among which norovirus (NoV) and hepatitis A virus (HAV) in specific, in foods. The guidelines provide advice to governments on a framework for the control of enteric viruses, especially hepatitis A virus (HAV) and norovirus (NoV), 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.

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 throughout the food chain, from primary production through consumption and are necessary to control viruses in foods 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, Rev. 4 (2004) (abbreviated in this document as General Principles of Food Hygiene) and other applicable codes such as Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993, sections 4.3; 5.2; 5.7-5.8; 6.5-6.9; 7.2 and 7.3); 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, Rev 4 (2003).*

2.2 USE

This Guidelines follow the format of the Codex *Recommended International Code of Practice - General Principles of Food Hygiene*- CAC/RCP 1-1969, Rev 4 (2003). The major issues are covered in Sections 3, 6 and 7. Some of the sections in this document state both the objectives to be achieved and the rationale behind those objectives in terms of safety and suitability of food. The *Annex for hygienic practice by food handlers for control of hepatitis A virus (HAV) and norovirus (NoV) in ready to eat foods (ANNEX I), Annex to the control of hepatitis A virus (HAV) and norovirus (NoV) in bivalve molluscs (ANNEX II)* and *Annex to the control of hepatitis A virus (HAV) and norovirus (NoV) in fresh produce (ANNEX III)* are supplements to this code and include additional recommendations.

2.3 DEFINITIONS

For the purpose of this Code, refer to definitions of the "Recommended International Code of Practice – General Principles of Food Hygiene- CAC/RCP 1-1969, Rev 4 (2004)" and "Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)". In addition the following expressions have the meaning stated:

Enteric virus –enteric viruses are viruses that replicate in the gastro-intestinal tract or in the liver, are excreted in faeces and are transmitted mainly by the faecal-oral route.

Fresh produce – including leafy products

Food worker – any person who touches or handles unpackaged food.

HAV – hepatitis A virus

Ingredient - any substance, including a food additive, used in the manufacture or preparation of a food and present in the final product although possibly in a modified form.

NoV- norovirus, formally known as norwalk-like virus.

Primary production - those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing.

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.

Shellfish – Filter feeding animals such as bivalve molluscs (e.g. clams, cockles, oysters, and mussels) that have a shell or shell-like skeleton.

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 faecal contaminated water or soil or by contagious food handlers.

3.1 ENVIRONMENTAL HYGIENE

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*. One of the sources of viral contamination of food at the primary production site is due to the use of water or soil that is contaminated by faeces of human or animal origin. Currently used control measures are not effective in controlling viral contamination. During primary production, efforts should therefore be made to restrict contact of food, e.g. bivalve molluscs and fresh produce, with high quality water only.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*. In addition to faecal contamination, food should also be protected from vomits or vomiting derived aerosols, since products exposed to vomits or faecal matter in primary production areas could be a risk to human health, especially if the products do not undergo a treatment that ensures the elimination of virus infectivity before consumption.

3.3 HANDLING, STORAGE AND TRANSPORT

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003).*

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, Rev 4 (2003)*. 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 also be excluded to be present in the primary production area to reduce the likelihood of transmission of enteric viruses, such as NoV and HAV, that may be the underlying cause of the symptoms of gastroenteritis or hepatitis, respectively. A person should leave the primary production area directly after vomiting or on the first event of diarrhoea. A person with symptoms of acute hepatitis should seek medical advice. In case of gastroenteritis, allow returning of persons only after a period

without symptoms of diarrhoea and vomiting (e.g. period of 48 hours which is an accepted practice) or in case of hepatitis, allow returning of persons after disappearance of jaundice and medical examination and medical advice. As shedding of viruses, such as NoV or HAV, may continue post-symptomatically (e.g. the NoV continues to be present in the stool for as long as 2 to 3 weeks after recovery), these persons should comply with strict hand hygiene instructions (i.e. thorough hand washing with soap and running water and preferably drying hands with disposable (paper) towels.) and preferably use a separate bathroom. When one of the staff members 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. Compliance to hand hygiene remains important at all times. In case of complaints of acute hepatitis, the whole staff should seek medical advice. Vaccination against hepatitis A might be used to immunize food workers to reduce the risk of viral contamination of the food, taking into account the epidemiological situation and/or immune status.

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 or contamination of food.

4.1 LOCATION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*

4.2 PREMISES AND ROOMS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*

4.3 EQUIPMENT

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*

4.4 FACILITIES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003),* in addition:

4.4.4 Personnel hygiene facilities and toilets

4.4.4.1 Changing facilities and toilets

Refer to the Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993, see Section 4.3.15). Hygienic and sanitary facilities should be available to ensure that an appropriate degree of personal hygiene can be maintained. These should be located in close proximity to the production area, in sufficient number to accommodate personnel, be of appropriate design to ensure hygienic removal of wastes, have adequate means of hygienically washing and drying hands, be maintained under sanitary conditions and good repair, and be included in disinfection programmes (for the latter see 6.2). In addition: A reminder of the hand wash 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

Refer to the Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993, see 4.3.16). In addition: Hand washing facilities should be within close vicinity of the toilets. Hand washing with soap and running water should be encouraged as this 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. Hands should be dried preferably with disposable (paper) towels.

SECTION V - CONTROL OF OPERATION

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

RATIONALE: Preventive measures against the identified 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

- Each time food is being in contact with faecal material of either human or animal sources or faecal contaminated water during the production phase (irrigation, washing, freezing/icing).

- Each time that a food worker handles (ingredients for) food without compliance to strict hygienic practice while being contagious with viruses. 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, other food or surfaces.

5.1.2 Implement effective control procedures at those steps

- Only water in compliance with the WHO "Guidelines for Drinking Water Quality" should be used for the production of food to avoid food to be contaminated with faecal material of human or animal sources.

- Personal hygiene of food handler 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 aware of the importance to adhere to hand wash instructions at all times. Training should be provided to food handlers and managers (see Section 10).

- 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 to be present in the primary production area. A person should be excluded from the primary production or preparation area directly after vomiting or the first event of diarrhoea. A person with symptoms of hepatitis should seek medical advice.

- 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) could 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 should therefore also comply with strict hand hygiene, 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.

- Allow returning of recovered persons only after a period without symptoms of diarrhoea and vomiting in case of gastroenteritis (e.g. period of 48 hours which is an accepted practice) or in case of hepatitis allow returning of persons after disappearance of jaundice and medical examination and advise under the condition of strict hand hygiene instructions.

- Vaccination against HAV infection can be considered as a preventive measure, taking into account the epidemiological situation and/or immune status.

- Have disinfection programmes, disinfectant agents able to disinfect enteric viruses and equipment available at all time, including a checklist which surfaces should be disinfected.

- Preferably only use raw ingredients from sources with adequately trained personnel, high personnel hygiene and controlled health and from production plants that use water in compliance with the WHO "Guidelines for Drinking Water Quality" only.

5.1.3 Monitor control procedures to ensure their continuing effectiveness

Not applicable yet.

5.1.4 Review control procedures periodically, and whenever the operations change

Not applicable yet.

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, Rev 4 (2003)*. Note that cooling or freezing will not affect virus infectivity.

5.3 INCOMING MATERIAL REQUIREMENTS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003).* Preferably only use raw ingredients from sources with adequately trained personnel, high personnel hygiene and controlled health and from production plants that use water in compliance with the WHO "Guidelines for Drinking Water Quality" only (see also Annex II and III.)

5.4 PACKAGING

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*

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, Rev 4 (2003)*. Only water in compliance with the WHO "Guidelines for Drinking Water Quality" should be used. Raw fruits and vegetables to be used in meals should be thoroughly washed in potable water before addition to the meals.

5.5.2 *As an ingredient*

Only water in compliance with the WHO "Guidelines for Drinking Water Quality" 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, Rev 4 (2003)*. Ice should be made from water in compliance with the WHO "Guidelines for Drinking Water Quality" 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 contain no substance, 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, as described in Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993, see Section 4.3.12.5).

5.6 MANAGEMENT AND SUPERVISION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)* and to the Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993), see Section 5.6). All employees and managers should know the importance of personnel hygiene to reduce the chance of viral contamination of food, i.e. importance of compliance to hand wash instructions, exclusion of food handlers or any persons to be present in the premises with symptoms of gastroenteritis or acute hepatitis or recovering, and how to disinfect surfaces when contaminated. It is advisable to have documentation of given hand-wash instructions during settling in into the new job of each new employee as well as a reminder of hand-wash instructions on 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, Rev 4 (2003)* and to the Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993, see Section 5.7).

5.8 RECALL PROCEDURES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*.and to the Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993, see 5.8).

SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION

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

RATIONALE: Many disinfection agents 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, Rev 4 (2003)*.

6.1.2 Cleaning procedures and methods

Each establishment should have a regular cleaning procedure. Refer to General Principles of Food Hygiene and to the Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993, see 5.2). In addition, establishments should also have a procedure for the disinfection of surfaces possibly contaminated with enteric viruses, such as NoV or HAV. Cleaning and disinfection should take place after each vomiting event in premises or rooms, after reported symptoms of gastroenteritis (diarrhoea and/or vomiting) or symptoms indicative for 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 bathroom and (as a preventive measure) in food production areas (e.g. equipment, utensils, telephones, keyboards etc.), as viruses in vomits, aerosols and faecal matter are persistent and will stay infectious for a long period.

Ideally disposable (or rubber) gloves and a disposable apron should be worn during cleaning and disinfection, 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 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. Absorbent material such as paper towels, tissues may be used to limit the spread of liquid soiling and be disposed. Surfaces should be cleaned before disinfection can take place appropriately.

Many disinfection agents recommended for use in food establishments are not effective against the non-enveloped viruses, such as NoV or HAV. One of the effective methods is e.g. the use of sodium hypochlorite (1000 ppm) for at least 5 min. Freshly constituted hypochlorite solutions (e.g. using tablets) are preferable. 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 thoroughly disinfection has taken place.

6.2 CLEANING PROGRAMMES

For normal cleaning programmes refer to the General Principles of Food Hygiene. The programmes should take into account the specific cleaning and disinfection procedures that must be applied to ensure elimination of virus infectivity. These cleaning and disinfection programmes 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 reportage of illness (gastro-enteritis, hepatitis) of food workers. The disinfection should be thorough on all surfaces (e.g. equipment, utensils, telephones, keyboards etc.) that may have been contaminated by the ill person 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, Rev 4 (2003)*.

6.4 WASTE MANAGEMENT

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*. Food possibly contaminated with virus particles should be discarded in a manner that contact between this food and any person, food or surfaces is prevented.

6.5 MONITORING EFFECTIVENESS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*.

SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE

OBJECTIVES: To prevent food handlers to contaminate food due to poor hygienic practice

RATIONALE: Food handlers may shed virus and the infectious dose is very low

7.1 HEALTH STATUS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)* and to the Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993, see Sections 6.1 and 6.2 and 6.3).

Diarrhoea and vomiting can be caused by infectious (e.g. NoV) or non-infectious agents. 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 for hepatitis, which should also be regarded as infectious. Persons reporting the above symptoms should therefore be excluded to handle food or to be 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/this document for the incubation and contagious periods for NoV and HAV, respectively.

7.2 ILLNESS AND INJURIES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*. Food handlers with clinical symptoms of gastroenteritis (diarrhoea and/or vomiting) or with symptoms of hepatitis (fever, headache, fatigue combined with dark urine and light stools, or jaundice), should be excluded from food handling and should also be excluded from being present in the food handling area to reduce the likelihood of transmission of enteric viruses, such as NoV and HAV, that may be the underlying cause of the symptoms of gastroenteritis or hepatitis, respectively. A person should leave the food handling area directly after vomiting or on the first event of diarrhoea. A person with symptoms of hepatitis should seek medical advice. In case of gastroenteritis, allow returning of persons only after a period without symptoms of diarrhoea and vomiting (e.g. period of 48 hours which is an accepted practice) or in case of hepatitis, allow returning of persons after disappearance of jaundice and medical examination and advice. As shedding of NoV or HAV may continue post-symptomatically, these persons should comply with strict hand hygiene instructions (i.e. thorough hand washing with soap and running water) and preferably use a separate bathroom. When one of the staff members 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. Compliance to hand hygiene remains important at all times. Moreover, in case of complaints of hepatitis, the whole staff should seek medical advice. Vaccination against hepatitis A could be used to immunise food workers to reduce the risk of viral contamination of the food.

7.3 PERSONAL CLEANLINESS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)* and to the Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993), see Section 6.6.

The most effective way of preventing spread of the virus is thorough hand washing with soap in running water and drying[2]. Everyone should always wash his or her hands after returning from the toilet or being in contact with faecal matter (also after changing diapers, cleaning toilets) or vomit. The use of disposable hand towels should be encouraged.

7.4 PERSONAL BEHAVIOUR

[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

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)* and to the Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993, see 6.5, 6.7).

7.5 GLOVES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)* and Cooked Foods in Mass Catering (CAC/RCP 39-1993, see 6.8). In addition, money, tickets etc. and food should not be handled at the same time when wearing gloves. When this is not possible, new gloves should be put on before preparing food.

7.6 VISITORS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)* or to the Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993, see Section 6.9). Visitors should preferably use separate personal hygiene provisions.

SECTION VIII – TRANSPORTATION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*.

SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENESS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*. Consumers should be made aware of the risk of infection when consuming raw or lightly cooked ready to eat food that may be contaminated with viruses during production, via labelling of the products (see Annex II).

SECTION X – TRAINING

OBJECTIVES: Those engaged in food operation that 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, Rev 4 (2003)*. In addition, it is the responsibility of the employee to call in when ill with diarrhoea or vomiting complaints or symptoms indicative for hepatitis. It is also the responsibility of the employee to adhere to strict hand wash instructions after returning from toilet or being in contact with faecal or vomit matter. It is the responsibility of the managers to educate and train their employees, to keep control on the level of awareness of the training content, and have both cleaning and disinfection programs operational.

10.2 TRAINING PROGRAMMES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*. Training programmes should contain information on the following: viruses can be contaminants of food, knowledge on the incubation periods of viruses, and on NoV and HAV in specific, on duration of virus shedding even after recovery from clinical symptoms, on possibility of a-symptomatic shedding, on the infectivity of vomits, on cleaning and disinfection of contaminated surfaces, on the need for compliance to hand wash instructions[2] , need for washing of hands after being in contact with faecal or vomit matter; be aware that if a staff member calls in, probably other members may be (asymptomatically) infected too, and in addition if a household member is ill, probably the staff member may be (asymptomatically) infected too.

10.3 INSTRUCTION AND SUPERVISION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*. Extent training and instructions to knowledge on infectivity, transmission and disinfection of viruses should be given to all new employees. 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, Rev 4 (2003).

ANNEX I

HYGIENIC PRACTICE BY FOOD HANDLERS FOR CONTROL OF HEPATITIS A VIRUS (HAV) AND NOROVIRUS (NOV) IN READY TO EAT FOODS

INTRODUCTION

Infected food handlers are the main source of viral contamination of ready-to-eat foods. In all instances in which a person carrying a virus comes in contact with food, contamination might occur and, due to the stability of these pathogens, they are likely to survive in many foods that do not receive a terminal heating step prior to consumption.

When viral contamination occurs because of poor personal hygiene of a food handler having direct contact with the food, the contamination will be localized in spots (focally). Infections caused by focally contaminated foodstuffs are most likely to be recognized as food-borne when the contamination has occurred at the end of the food chain (i.e. at retail or in the home). Prepared foods are at greatest risk of contamination by this route and include delicacies and bakery products, salads and other ready-to-eat foods. NoV and HAV outbreaks associated with these products have been reported. Surface contamination, either by faecal deposition or by aerosolized vomit (NoV) may also cause food-borne outbreaks. Since vomiting is a symptom of NoV infection in 70-80% of the cases, it can be an efficient mode of virus spread, directly via aerosols or indirectly via contamination of food items or via contamination of the environment or surfaces, and subsequent cross-contamination of foods.

SECTION I- OBJECTIVES

These guidelines provide advice to governments on a framework for the reduction of HAV and NoV in ready to eat foods, with a view towards protecting the health of consumers. The guidelines also provide information that will be of interest to the food industry, consumers, and other interested parties.

SECTION II - SCOPE, USE AND DEFINITION

2.1 SCOPE

2.1.1 The food chain

This Annex is intended for ready-to-eat foods and is applicable throughout the food chain, from primary production through consumption and are necessary to control viruses in ready-to-eat foods 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, Rev 4 (2003)*) and other applicable codes such as "Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering" (CAC/RCP 39-1993, sections 4.3; 5.2; 5.7-5.8; 6.5-6.9; 7.2 and 7.3).

2.2 USE

This Annex follows the format of the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003).* Although most of the issues covered in the General part of these "Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food" are also of major importance in the Annex for Hygienic Practice by Food Handlers for the Control of HAV and NoV in Ready-to-Eat Food", this separate Annex was written to stress the importance of control measures in the reduction of contamination of ready to eat food with NoV and HAV by food handlers, in particular.

2.3 DEFINITIONS

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.

SECTION III - PRIMARY PRODUCTION/HARVESTING AREA

3.4 PERSONNEL HYGIENE AT PRIMARY PRODUCTION

Refer to General Part of these Guidelines on enteric viruses in general (Section 3.4). Aspects of personnel hygiene that are of major importance to reduce the likelihood of food to become contaminated with NoV or HAV are the exclusion of persons with clinical symptoms of gastroenteritis (diarrhoea and/or vomiting) or with symptoms of hepatitis (fever, headache, fatigue combined with dark urine and light stools, or jaundice) from food handling or to be present in food handling area, the awareness of the possibility of a-symptomatic or post-symptomatic virus shedding of HAV or NoV, compliance to strict hand hygiene instructions and the possibility of vaccination against HAV.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.4.4.1 Changing facilities and toilets

Refer to the General Part of these Guidelines on enteric viruses in general (section 4.4.4.1) for facilities required to ensure that an appropriate degree of personal hygiene can be maintained to reduce the risk of transmission of NoV or HAV in food preparation areas. Preferably separate toilets for guests and employers of the establishment should be available. Toilet areas should not be open directly to food handling areas.

4.4.4.2 Hand washing facilities

Refer to the General Part of these Guidelines on enteric viruses in general (section 4.4.4.2). Hand washing facilities should be within close vicinity of the toilets. Hand washing with soap and running water should be encouraged, where possible non-hand operable taps should be available to help prevent re-contamination of clean hands. Hands should be dried preferably with disposable (paper) towels.

SECTION V - CONTROL OF OPERATION

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 identified steps, as presented in the General Part of these Guidelines on enteric viruses in general (section 5.1.1), that may also lead to contamination of food or surfaces in the food handling area with faecal or vomit particles containing NoV or HAV.

5.1.2 Implement effective control procedures at those steps

Refer to the effective control procedures at the identified steps, as presented in the General Part of these Guidelines on enteric viruses in general (Section 5.1.2), that may also prevent contamination of ready-to-eat food with NoV or HAV.

5.6 MANAGEMENT AND SUPERVISION

Refer to the issues, summarized in the General Part of these Guidelines on enteric viruses in general (section 5.1.1), which also apply for the commodities NoV and HAV in ready to eat food. These issues should be acknowledged by all employees and managers working in food handling areas producing ready to eat foods.

SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION

6.1 MAINTENANCE AND CLEANING

6.1.2 Cleaning procedures and methods

Refer to the General Part of these Guidelines on enteric viruses in general (section 6.1.2). Each establishment should have both a regular cleaning and disinfection procedure. For the effective disinfection of NoV and HAV contaminated surfaces, it is important that it is acknowledged when disinfection should take place, which surfaces should be disinfected, how disinfection can be safely be performed and which agents should be applied (section 6.1.2 and 6.2). Food preparation should only begin after thoroughly disinfection has taken place.

SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE

7.1 HEALTH STATUS

Refer to the General Part of these Guidelines on enteric viruses in general (section 7.1). All cases of gastroenteritis should be regarded as infectious unless good evidence suggests otherwise. Fever, headache, fatigue combined with dark urine and light stools, or jaundice are indicative for hepatitis, which may be caused by HAV.

7.2 ILLNESS AND INJURIES

In order to reduce the likelihood of food to become contaminated with NoV or HAV, refer to the General Part of these Guidelines on enteric viruses in general (section 7.2) regarding information on which persons should be excluded from food handling or to be present in the food handling area, and after which period such persons are allowed to return to work. This information applies for infections with NoV or HAV, in particular. Compliance to strict hand hygiene procedures is important because of the occurrence of a-symptomatic and post-symptomatic shedding of NoV or HAV. Vaccination against hepatitis A could be used to immunize food workers to reduce the risk of viral contamination of the food taking into account the epidemiological situation and/or immune status.

7.3 PERSONAL CLEANLINESS

Refer to the General Part of these Guidelines on enteric viruses in general (section 7.3) on the most effective way of preventing spread of viruses by thorough hand washing with soap in running water and drying[3], which also applies for NoV and HAV. Everyone should always wash his or her hands after returning from the toilet or being in contact with faecal matter or vomit. The use of disposable hand towels should be encouraged.

7.6 VISITORS

Refer to the General Part of these Guidelines on enteric viruses in general (section 7.6). Visitors should preferably use separate personal hygiene provisions.

SECTION X – TRAINING

10.2 TRAINING PROGRAMMES

Personnel and managers involved in the production of ready to eat food should have appropriate training in the importance of reporting clinical symptoms of gastroenteritis or hepatitis and should act appropriately here upon. Personnel and managers should also be aware of the low infectious dose of NoV and HAV and the occurrence of a- symptomatic and post-symptomatic shedding of NoV or HAV, should therefore acknowledge the importance to comply with hand hygiene, and finally know when and how to clean and disinfect surfaces possibly contaminated with NoV or HAV.

10.3 INSTRUCTION AND SUPERVISION

[3] 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

Refer to the General Part of these Guidelines on enteric viruses in general (section 10.3). Extent training and instructions on infectivity, transmission and disinfection of NoV or HAV should be given to all new employees. Incorporation of these instructions into the National Hygiene Codes would be advisable.

ANNEX II

ANNEX TO THE 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 at least 8 to 10 weeks in contaminated live bivalve molluscs and can be detected in bivalve molluscs gut tissue. Recent evidence has shown that norovirus (NoV) binds specifically to bivalve molluscs tissue receptor sites, which could explain why 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 have occurred, removal or disinfection 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 coastal water qualities in bivalve molluscs harvesting areas.

SECTION I- OBJECTIVES

These guidelines provide advice to governments on a framework for the reduction of hepatitis A virus (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 these guidelines is to minimise the likelihood of illness arising from the presence of HAV and NoV in bivalve molluscs. The guidelines also provide information that will be of interest to the food industry, consumers, and other interested parties.

SECTION II - SCOPE, USE AND DEFINITION

2.1 SCOPE

These guidelines are intended for bivalve molluscs and will focus on control measures that can be used, where appropriate, to minimize and/or prevent the contamination of HAV and NoV. These guidelines are based on the results of the FAO/WHO risk assessment, other available risk assessments and epidemiological evaluations. They highlight key 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 hepatitis and gastroenteritis.

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 control of food borne 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 Raw bivalve Molluscs (Codex Stan 292-2008)”. 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.

Good Hygienic Practices (GHPs) as specified in the “Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)” and the other applicable codes of hygienic practice should be suitable to control viruses in foods. However, the additional measures described in the following guidelines should be consulted and implemented, as necessary to control HAV and NoV in bivalve molluscs.

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, Rev 4 (2003). The major issues are covered in Section III.

2.3 DEFINITIONS

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

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.

SECTION III - PRIMARY PRODUCTION

The main hazard known for the production of bivalve molluscs is microbiological contamination of waters in which they grow, especially as the bivalve molluscs are intended to be eaten live or raw. Since molluscs are filter feeders they concentrate contaminants to a much higher concentration than present in the surrounding seawater. The 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 increase the seawater quality of growing areas by increasing sewage treatment efficiency for virus removal/inactivation and avoid discharge of untreated sewage in the surroundings of the bivalve molluscs growing areas. The assessment of the microbiological quality of harvesting and/or growing water for NoV and HAV risks should include an assessment of possible human faecal contamination sources of the water (sanitary survey). To control the hazards, identification and monitoring of growing areas is very important for bivalve molluscs safety. *E. coli* is the preferred indicator for the possibility of faecal contamination, although faecal coliforms are also used as such. A short-term depuration process commonly reduces low levels of bacterial contamination, and thus contributes to 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 or environmental events or direct detection through virological analysis, long term relaying for at least two months is recommended or destination for exclusively heat treatment before consumption. When there has been a shellfish borne outbreak caused by an identified pathogen, such as NoV or HAV, monitoring the bivalve molluscs using referenced validated methods may be appropriate as part of the process of closure and reopening the affected harvesting area. Other conditions including the sanitary surveys requirements should also have been satisfied as a condition of reopening the area.

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*. In addition:

3.1 ENVIRONMENTAL HYGIENE

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)* and Code of Practice for Fish and Fishery Products, section 7 (CAC/RCP 52-2003). In spite of classification of the growing and harvesting areas based on sanitary surveys and bacteriological monitoring, viruses may be present. Efforts should be made to restrict growing and harvesting of bivalve molluscs to areas of high 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)*. In addition:

5.1 CONTROL OF FOOD HAZARDS

5.1.1 Identification of steps critical to the safety of foods

- Safe growing water during the whole production process, until the day of harvest.
- Growing water that is free from sewage discharges or disposal of faecal matter from ships.
- Prevention of overflow from sewage platforms after heavy rainfall that may contaminate the growing waters.

5.1.2 Implement effective control procedures at those steps

- Efforts should be made to restrict growing and harvesting of bivalve molluscs to areas of high water quality only.

- Sewage treatments should be improved to obtain maximal reduction of viral loads of the effluents.

- After heavy rainfall, harvesting of bivalve molluscs (especially oysters) should be halted for a period, until the water quality of the harvesting area has been checked. Testing of water or bivalve molluscs by RT-PCR may be an option prior to re-opening. Relaying is another possibility, although new contaminations may occur during the relaying period, as the area involved is susceptible for new contamination events.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Specific process steps

The country's competent authority should approve commercial heat treatment processes, e.g. the UK heat cook parameters of raising the internal temperature of bivalve molluscs meats to 90 °C for 1.5 min[4]. The degree of cooking required to reliably inactivate NoVs would, however, probably render oysters unpalatable to consumers. Also the inability of home or restaurant cooking to provide adequate guarantees of consumer protection against viral contamination for bivalve shellfish emphasis the reliance on harvesting from virus safe water growing areas.

5.8 RECALL PROCEDURES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)* 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, Rev 4 (2003)*. In addition:

9.1 LOT IDENTIFICATION

NoV and HAV show a long persistence in bivalve molluscs. Movements between various growing waters and trade often accompany the production of bivalve molluscs. For traceability (e.g. outbreak investigation), lot identification should therefore enable identification of all recent growing waters. It is therefore important to register all growing areas of a batch and not only the area of harvest.

9.3 LABELLING

Consumers should be made aware of the possibility to become infected with NoV or HAV after consumption of bivalve molluscs, either raw or lightly cooked. Cooking does not guarantee total inactivation of these viruses, but cooking may reduce the risk of a food-borne infection. A recommended end-point treatment of the bivalves prior to consumption should therefore be on the package label.

9.4 CONSUMER EDUCATION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)* 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.

SECTION X – TRAINING

[4] Council Decision of 11th December 1992 approving certain heat treatments to inhibit the development of pathogenic micro-organisms in bivalve molluscs and marine gastropods (93/25/EEC). *Off. J. Eur. Communities*. 16, 22-23

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*. In addition:

10.1 AWARENESS AND RESPONSIBILITIES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)* 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), personnel involved in the growing and harvesting of bivalve molluscs should have appropriate training in:

- The biology of HAV and NoV, and its resistance to various environmental conditions, e.g. sewage treatment, temperature;

- Control measures to prevent faecal contamination of growing and harvesting areas;

- The possibility of viral analysis; meaning of negative or positive test results.

ANNEX III

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. Viral outbreaks associated with contaminated green onions and raspberries, as well as other produce items are well documented[5]. The contamination of the produce may occur either at the pre-harvest stage (sewage-contaminated water, infected pickers) or at the post-harvest phase (infected food handlers).

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 fertilizer or for fertilizer/pesticide application. (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 the hands of food handlers if they are shedding viruses themselves with or without symptoms after changing diapers of others, after cleaning toilet areas, and not practicing appropriate personal hygiene. A second important factor in food-handler associated spread of viruses is vomiting. NoV infections often lead to projectile vomiting with 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 hepatitis A virus (HAV) and norovirus (NoV) 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 HAV and NoV 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 fruits and vegetables grown in the field (with or without cover) or in protected facilities (hydroponic systems, greenhouses). It concentrates on hazards from NoV and HAV in fresh produce and how to prevent fresh produce to become contaminated by these viruses during primary production phase.

Although it is important for the safety of NOV and HAV in fresh produce, this annex does not provide recommendations for handling practices to maintain the safety of fresh fruits and vegetables 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, Rev 4 (2003),* 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'. Moreover, reference will be made to other documents such as the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003),* and Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003).

[5] 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.

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, Rev 4 (2003). 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, Rev 4 (2003)) and Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003).

Fresh produce – including leafy greens.

SECTION III - PRIMARY PRODUCTION

Fresh fruits and vegetables are 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 varying sizes. Viral hazards may therefore vary significantly 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 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 hazards from NoV and HAV to health due to the contamination of fresh fruits and vegetables.

Sewage-contaminated surface waters 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 application. Fresh produce items can be handled by contaminated human hands during growth, harvest, packing, distribution, and at retail establishments or homes. In addition, fresh produce may be contaminated by food pickers directly through vomiting in the field. On the other hand, retail food handlers and food preparers in the home can contaminate highly handled “prepared” foods with viruses immediately prior to consumption.

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)*. In addition:

3.1 ENVIRONMENTAL HYGIENE

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)* and Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003). In case of NoV and HAV in fresh produce, the main sources of contamination (human sources) of the production sites that should be specifically regarded are sewage treatment, human excreta used as fertilizer, agricultural workers and the sanitary facilities. If these sources contaminate water and soil that come into contact with fresh produce, there is a potential hazard of NoV and HAV. NoV and HAV are persistent in the environment, also on fresh produce, sometimes exceeding 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).

The assessment of the microbial quality of the sources of water used on the farm for NoV and HAV risks should include an assessment of possible human fecal contamination sources of the water (sanitary survey) and if, deemed necessary, testing. In 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 have taken effect.

Testing for *E. coli* is useful to determine the level of fecal contamination of the water. The level of fecal contamination may indicate the probability for NoV and HAV risks. *E. coli* originates from human and animal sources, however, currently it is assumed that NoV and HAV originate from human sources only. The frequency of testing should be established according to the source of the water (ground water, surface water, wells) and to the condition of the irrigation system.

3.2.1 Water for irrigation and harvesting

In case of NoV and HAV, that are known to be very persistent viruses, the risk of water delivery techniques that expose the edible portion of fresh fruits and vegetables directly to irrigation water is considered to be higher as compared with other types of irrigation.

SECTION V - CONTROL OF OPERATION

The control of NoV and HAV in fresh produce should be focusing on prevention of contamination of fresh produce with human faecal contamination, as no effective post-harvest treatments are available at the present time.

Refer to General Principles of Food Hygiene. In addition:

5.1 CONTROL OF FOOD HAZARDS

5.1.1 Identification of steps critical to the safety of foods

- Use of water of high quality during the whole production process, until the day of harvest.
- Irrigation water that is free from sewage discharges.
- Prevention of overflow from sewage platforms after heavy rainfall that may contaminate the surface water used for production of fresh produce.

5.1.2 Implement effective control procedures at those steps

- Efforts should be made to use water of high quality only for the production of fresh produce.
- Sewage treatments should be improved to obtain maximal reduction of viral loads of the effluents.

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 the non-enveloped NoV and HAV viruses 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 validated to be virucidal.

5.8 RECALL PROCEDURES

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, Rev 4 (2003)*. In addition:

10.1 AWARENESS AND RESPONSIBILITIES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)* 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 instruction and training for control of viruses.

10.2 TRAINING PROGRAMMES

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

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