

# GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF VIRUSES IN FOOD

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## INTRODUCTION

1. In recent years, viruses have been increasingly recognized as important causes of foodborne diseases. Viruses are microorganisms that differ in size, structure and biological characteristics from 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. Human viruses can be transmitted directly from person-to person, but also indirectly via virus-contaminated water, air, soil, surfaces or food. Some viruses (zoonotic viruses) are transmitted from animals to humans. 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 mainly targeted at reducing bacterial contamination.

2. The human enteric viruses most frequently reported as involved in foodborne outbreaks are norovirus (NoV) and hepatitis A virus (HAV). Other viruses such as rotavirus, 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 gastroenteritis (e.g., NoV), enterically transmitted hepatitis (e.g., HAV, that replicates in the liver), and a third group which replicates in the human intestine, but only causes illness after they migrate to other organs such as the central nervous system (e.g., 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.

3. Noteworthy aspects of foodborne viruses and the associated infections/illnesses that determine management strategies to be different from management strategies for bacterial pathogens:

- Viruses need to enter living host cells in order to be able to multiply (replicate). Unlike bacteria, they do not replicate in food. Consequently, viruses do not cause deterioration of the product and the organoleptic properties of the food are not affected due to viral contamination.
- Even though high numbers of viral particles are shed in the stools of symptomatic or asymptomatic infected persons (e.g., exceeding  $10^6$  particles per gram of stool) or in vomit, only a few viral/infectious particles (less than 100) are needed to cause infection that may lead to illness.
- 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.
- Non-enveloped viruses, such as NoV and HAV, are covered in a protein-based structure called a capsid. Enveloped viruses, such as influenza, have a capsid and are further coated in a biological membrane derived from the host cell. Both the capsid and envelope structures influence environmental persistence and resistance to cleaning and disinfection interventions. However, the non-enveloped viruses tend to be more resistant to inactivation from solvents (e.g., chloroform) and desiccation.
- Viruses transmitted by the faecal-oral route can persist for months in foodstuffs or in the environment (e.g., in soil, water, sediments, bivalve molluscs or on various inanimate surfaces). Most foodborne viruses are more resistant than bacteria to commonly used control measures, (e.g., refrigeration, freezing, pH, drying, UV radiation, heat, 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 resistance to heat and drying.
- Traditional hand washing practices may be more effective for infectious virus reduction as compared to the use of hand sanitizing-agents. The majority of chemical disinfectants used in food establishments do not effectively inactivate non-enveloped viruses, such as NoV or HAV.
- Zoonotic foodborne transmission of viruses is not commonly reported as is the case for many bacterial pathogens, such as *Salmonella* and *Campylobacter*, however, it does occur, e.g., for HEV.
- In general, testing of foods for foodborne viruses is challenging and requires matrix-dependent extraction and concentration techniques and is based on detection of viral nucleic acids.
- There is a current lack of methods for assessing the level of inactivation of foodborne viruses in food. This has led to the use of surrogate viruses, e.g., the use of feline calicivirus and murine norovirus in place of NoV. When evaluating risk management options, the use of a surrogate will not always mimic the resistance of the intended foodborne viruses.

4. During the FAO/WHO Expert meeting on "Viruses in Food"<sup>1</sup>, 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

<sup>1</sup> 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.

of around 5% for HAV and 12-47% for NoV<sup>1</sup>. Data from at least 4 continents show that this is a major public health issue worldwide, although data from many countries are sparse. HAV and rotavirus were identified as the major foodborne viruses that cause severe disease and significant mortality. The primary mode of transmission for rotavirus is person-to-person spread, but in areas with poor hygienic situations waterborne and foodborne spread may play a role. Like HAV and NoV, HEV is transmitted by the faecal-oral route. HEV has been found to be responsible for sporadic and epidemic acute hepatitis, especially in some areas. HEV infection is usually associated with contaminated drinking water, but has also been linked to eating raw deer meat, undercooked pork liver or wild boar meat.

5. NoV: Norovirus, formerly Norwalk-like virus, 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 wintertime peaks in incidence have been observed when looking at reported outbreaks, but other than in the case of bivalve molluscs these are particularly associated with infections spread through person-to person contact or contaminated environmental surfaces (e.g., outbreaks in healthcare facilities) rather than foodborne infections. The incubation period is 12-72 hours; 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 ( $10^6$ - $10^{10}$  particles/g) in their stool while having symptoms, but this may also occur before the onset of symptoms, and shedding may continue on average for 2 or more weeks after resolution of symptoms even in immuno-competent persons. The disease and shedding period may be longer in the case of immuno-suppressed individuals. Some NoV infections occur without resulting in apparent symptoms. A vaccine against NoV is not available at present.

6. HAV: Hepatitis A virus is a cause of acute viral hepatitis. The incidence of HAV infection varies considerably among and within countries. In countries where HAV infection is highly 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 countries, where HAV infections are less common as a result of increased standards of public health such as access to safe drinking water, sanitation and hygiene, very few persons are infected in early childhood, and the majority of adults remain susceptible to infection by HAV. Later in life (persons over 40 years), 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 hepatitis A 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 the 2 weeks preceding the onset of jaundice, i.e., the presence of yellow colouring of the skin and/or mucous membranes. The virus is shed in large numbers ( $10^6$ - $10^9$  particles/g) in faeces from the final 2 weeks of the incubation period up to 5 weeks into the symptomatic phase. In HAV endemic areas, children may be an important risk factor in the spread of HAV during primary production or food preparation activities. Some HAV infections occur without symptoms. Vaccines against HAV are available.

7. During the FAO/WHO Expert meeting on "Viruses in Food"<sup>1</sup>, three major sources of viral contamination of foods were identified: 1) human sewage/faeces, 2) infected food handlers and 3) animals harbouring zoonotic viruses, although combinations of these have also been described. The virus-commodity combinations of greatest public health concern selected were NoV and HAV in prepared (ready-to-eat) foods, bivalve molluscs, and fresh produce.

8. There are currently no effective, realistic and validated risk management options to eliminate viral contamination of both bivalve molluscs and fresh produce prior to consumption without changing the normally desired characteristics of the food. 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 (fresh fruits and vegetables) and at the post-harvest phase for others (prepared, ready-to-eat foods).

9. Evidence of viral contamination is primarily based on the detection of viral RNA/DNA since many foodborne viruses cannot be reliably cultured *in vitro*. Quantitative and semi-quantitative real time reverse transcription polymerase chain reaction (real time RT-PCR) methods have been developed for various food/virus combinations that are sensitive and specific. Detection of viral RNA/DNA does not discriminate between infectious and non-infectious virus particles and test results are subject to variability depending on the food product, the distribution of virus within the food matrix and the presence of PCR inhibitors. Importantly, there is a degree of uncertainty as to how the lower limits of detection relate to product safety. Molecular technologies should be fully validated and the intended use and interpretation clearly defined. Ideally, the testing laboratory should be accredited.

## SECTION 1 - OBJECTIVES

10. The primary purpose of these guidelines is to give guidance on how to prevent or minimize the presence of human enteric viruses in foods, and more specifically of NoV and HAV in foods. The guidelines provide advice to governments on a framework for the control of human enteric viruses in food, especially NoV and HAV, 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 2 - SCOPE, USE AND DEFINITION

### 2.1 SCOPE

#### 2.1.1 Food chain

11. These guidelines are applicable to all foods, with a focus on ready-to-eat food, from primary production through to consumption, for the control of human enteric viruses, in particular NoV and HAV, in foods. They should complement controls in place for any other pathogens.

## 2.2 USE

12. These guidelines follow the format of the *General Principles of Food Hygiene* (CAC/RCP 1-1969)<sup>2</sup> and should be used in conjunction with it and other relevant Codes of Practice, such as the *Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering* (CAC/RCP 39-1993), the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003). The annex on the *Control of Hepatitis A Virus (HAV) and Norovirus (NoV) in Bivalve Molluscs* (Annex I) and the annex on the *Control of Hepatitis A Virus (HAV) and Norovirus (NoV) in Fresh Produce* (Annex II) are supplements to these guidelines and provide additional recommendations for these specific virus-commodity combinations.

## 2.3 DEFINITIONS

**Human enteric virus** – a virus that replicates in the gastro-intestinal tract or in the liver and is excreted in faeces and/or vomitus from humans. It is transmitted mainly by the faecal-oral route and is infectious to humans.

**Fresh produce** – fresh fruit and vegetables grown in the field (with or without cover) or in protected facilities (hydroponic systems or greenhouses).

**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, that is normally eaten without further steps, which could remove viruses or eliminate their infectivity.

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

## SECTION 3 - 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 become contaminated at the primary production area by water, soil, harvesting containers or utensils contaminated by faeces or vomit or by food handlers.

### 3.1 ENVIRONMENTAL HYGIENE

13. Potential sources of viral contamination of the environment should be identified prior to production activities. Sources of viral contamination of food at the primary production site include water, soil, manures (not properly treated), sludge or fertilizers contaminated by faeces of human origin or proximity to other production activities which could result in run-off or flooding with virus-contaminated waters. Primary food production should not be carried out in areas where the presence of viruses may lead to the viral contamination of food. Assessment of environmental conditions is particularly important because subsequent control steps during production may not be adequate to remove contamination.

### 3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

14. Food sources should be protected from faecal contamination and vomit or vomit-derived aerosols.

15. The source of water used for primary 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. Water for primary production of fresh produce should be suitable for its intended use and not compromise food safety and should be applied using an appropriate method. Also during harvesting of foods, clean water, such as for washing, should be used. (Refer to *WHO Guidelines for the safe use of wastewater, excreta and grey water. Volume 2: Wastewater use in agriculture* (World Health Organization 2006 ISBN 92 4 154683 2, v.2; [www.who.int/water\\_sanitation\\_health/wastewater/gsuweg2/en/index.html](http://www.who.int/water_sanitation_health/wastewater/gsuweg2/en/index.html)) and *WHO Guidelines for the safe use of wastewater, excreta and grey water. Volume 3 Waste water and excreta use in aquaculture* ([http://whqlibdoc.who.int/publications/2006/9241546840\\_eng.pdf](http://whqlibdoc.who.int/publications/2006/9241546840_eng.pdf)).

16. Natural fertilizers may contain human pathogenic viruses that persist for weeks or months. Proper treatment such as application of heat, chemical or biological treatments of biosolids, manures and waste by-products will reduce the risk of potential human virus survival. Growers should seek appropriate guidance on the use and treatment of biosolids, manures and waste by-products.

17. Aquaculture operations should not be established in areas susceptible to sewage contamination, in particular those for production of products intended for consumption without further treatment.

### 3.3 HANDLING, STORAGE AND TRANSPORT

18. 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.

19. Harvesting equipment, utensils and containers should be in a clean condition and in good working order.

### 3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

20. Refer to Section 6 (Sanitation) and 7 (Personal hygiene) of this document for aspects of sanitation and personnel hygiene in primary production.

<sup>2</sup> Section numbers correspond to those in the *General Principles of Food Hygiene* (CAC/RCP 1-1969).

## SECTION 4 - ESTABLISHMENT: DESIGN AND FACILITIES

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

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

### 4.4 FACILITIES

#### 4.4.4 *Personnel hygiene facilities and toilets*

##### 4.4.4.1 *Changing facilities and toilets*

21. Hygienic and sanitary facilities should be available to ensure that an appropriate and acceptable degree of personal hygiene can be maintained.

22. Harvest and production may be subject to seasonal influx of workers to meet the needs of producers and may vary for different products. An inherent danger at the farm and production level is an under-supply of suitable toilet and hand washing facilities to meet this influx. Food business operators should ensure that suitable facilities are provided, are readily accessible and meet appropriate hygiene standards.

23. Hygienic and sanitary facilities should:

- be located in proximity to the production area;
- be located in areas adjacent to the processing area, but without direct access to it;
- be in sufficient numbers to accommodate personnel;
- be of appropriate design to ensure hygienic removal of wastes;
- be designed so that there is no seepage into underground water or enter the agricultural field;
- have adequate means for washing and drying hands;
- be maintained under sanitary conditions and good repair;
- be appropriately cleaned and disinfected (see 6.2 cleaning programmes); and
- be separate for guests and personnel of the establishment, when feasible.

##### 4.4.4.2 *Hand washing facilities*

24. Hand washing facilities should be supplied with hand cleanser (soap). Where possible, hand washing facilities should have non-hand operable taps and single-use towels to help prevent the re-contamination of clean hands. Hand washing and drying instructions should be visibly present for all users of these facilities.

25. Hand washing and drying facilities should be suitably located in food preparation or production areas to ensure food handlers have ready access to them. There should be hand washing facilities within close proximity to the toilets and positioned so that the personnel must pass by them before returning to the food handling area.

## SECTION 5 - 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

26. Control of human enteric viruses such as NoV and HAV in food will typically require a stringent application of hygiene control systems, which could be referred to as, e.g., Good Hygienic Practices (GHPs) and sanitation standard operation procedures (SSOPs). These prerequisite programs, together with validated interventions, e.g., as part of a HACCP-based system, provide a framework for the control of enteric viruses.

### 5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

#### 5.2.1 *General Control Programs*

27. Any food possibly contaminated by vomit particles or by aerosols containing vomit particles should be disposed of. Any food handled by an ill person should be evaluated to determine the need to dispose of it. Food handled by someone with NoV during that day (or the day before) should be considered a risk and disposal of implicated products should be considered. For foods handled by someone with HAV, consider what other foods were handled at least two weeks before the illness occurred, because HAV viruses may be shed at peak levels at least two weeks before symptoms appear. In this situation, disposal of the implicated food also should be considered.

28. 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.

#### 5.2.2 *Process-Specific Control Systems*

##### 5.2.2.1 *Time and temperature control*

- Cooling and freezing: Cooling and freezing processes should not be considered suitable for the control of foodborne viruses as they do not reduce virus infectivity to levels considered safe.

- **Heat treatment:** The effects of heat treatment on virus infectivity in foods are highly dependent on virus (sub)-type, food matrix and the initial level of viral contaminants. Cooking procedures in which an internal temperature of the food reaches at least 90 °C for 90 seconds are considered adequate treatments to destroy viral infectivity in most foods. However, light cooking, e.g., steaming, searing, may not be adequate to inactivate viral infectivity leading to unsafe foods. Conventional pasteurization (e.g. 63 °C for 30 min or 70 °C for 2 min) is more effective than High Temperature Short Time (HTST; 72 °C for 15–20 seconds) pasteurization, and likely yields at least a 3 log<sub>10</sub> inactivation of NoV. However, given the potential for contamination with millions of viral particles and an infectious dose as low as a few viral particles, even conventional pasteurization may not adequately inactivate NoV in a contaminated food. Commercial canning is considered an adequate treatment to destroy viral infectivity in foods.

### 5.2.2.2 Specific process steps

29. Various processes have been shown to reduce virus load in selected food items but are subject to substantial variability depending on virus type and subtype, food matrix and location of virus on food matrix. As such, these processes by themselves will be inadequate to protect the consumer, but when the processes are combined, the additive effect of the processes may enhance the level of inactivation of viruses present. Processing combinations should be subject to rigorous validation to ensure consumer protection.

- **Washing:** The washing of food ingredients or products in water, either treated (UV, ozone, chlorine, etc.) or untreated, may not be effective if the food surface is rough, broken or pitted or when viruses are internalized.
- **Reduce pH:** Human enteric viruses are very stable at low pH levels. More than 3 log<sub>10</sub> inactivation of HAV may occur only at pH < 3, a pH that is not always acceptable for the sensorial quality of foods.
- **Reducing water activity (RA<sub>w</sub>):** RA<sub>w</sub> may accelerate degradation or inactivation rates of viruses, but its effect on virus infectivity in foods (or on fomites) is highly dependent on virus (sub)type and food matrix and thus RA<sub>w</sub> cannot be considered an effective generic measure to reduce viral loads at present. The drying/desiccation of human enteric viruses on processing equipment surfaces may reduce virus titers.
- **High hydrostatic pressure (HHP):** The effects of HHP on virus infectivity in foods are highly dependent on virus (sub)type and food matrix, but may be considered a measure to reduce viral loads for some virus(types) present in specified matrices.
- **Ultraviolet (UV) Irradiation:** 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.

30. When new virucidal technologies or treatment combinations are being developed, they should be validated with the appropriate hazard/food combination prior to their implementation in the food production chain. Their effectiveness should be evaluated using virus infectivity assays where possible. When such assays do not exist for the specific virus, use of suitable surrogate viruses, or molecular assays, which can evaluate decline in virus genome copies, should be considered. The results should be evaluated with caution as the surrogates will not always mimic the resistance of the intended foodborne viruses. Some treatments might be subject to prior approval by the competent authority.

## 5.3 INCOMING MATERIAL REQUIREMENTS

31. Raw ingredients contaminated with viruses may lead to contamination of food handlers' hands, other foods, or food contact surfaces. Preferably, use raw ingredients from suppliers or production plants with an adequate food safety management system.

## 5.4 PACKAGING

32. Various types of packaging that are aimed at inhibiting bacterial or fungal growth are not effective against human viruses because human viruses do not grow in foods.

## 5.6 MANAGEMENT AND SUPERVISION

33. Managers and supervisors should understand the importance of applying good hygiene practices and personnel health and hygiene, in aspects such as:

- the availability of adequate hygiene facilities;
- compliance with hand washing instructions;
- exclusion from the premises of food handlers or any persons, including children, with symptoms of gastroenteritis or acute hepatitis or those recovering from these infections (see Section 7.2);
- how to clean and disinfect surfaces when contaminated.

## 5.7 DOCUMENTATION AND RECORDS

34. It is recommended that control procedures used for viruses be monitored to ensure their continuing effectiveness.

## 5.8 RECALL PROCEDURES

35. Based on the determined level of risk associated with the presence of viruses in a given food product, a decision may be taken to recall the contaminated product from the market. The need for public information and communicated warnings should be considered.

## SECTION 6 – ESTABLISHMENT: MAINTENANCE AND SANITATION

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

**RATIONALE:** Vomiting/diarrhoea events and persons shedding viruses are likely to cause widespread contamination of food production premises, and measures to eliminate this contamination should be taken.

## 6.1 MAINTENANCE AND CLEANING

### 6.1.1 General

36. A food establishment shall have a set of procedures to be followed by employees when responding to vomiting or diarrhoea events that involve the discharge of vomitus or faecal matter onto surfaces and that address the specific actions employees must take to minimize the potential for the spreading of contamination and for increasing exposure of employees, food, and surfaces to vomitus or faecal matter.

### 6.1.2 Cleaning procedures and methods

#### *Cleaning and disinfection:*

37. Each establishment should have documented regular cleaning and disinfection procedures. Disinfection should always be preceded by cleaning. It is also recommended that establishments have a procedure for the disinfection of surfaces possibly contaminated with enteric viruses, such as NoV or HAV. Cleaning and disinfection should take place immediately after each vomiting event in premises or rooms, after reported symptoms of gastroenteritis or symptoms indicative of hepatitis of any personnel. Cleaning and disinfection should include all surfaces suspected to be contaminated with viruses, both in the hygiene facilities and toilets and (as a preventive measure) in food production areas (e.g., equipment, utensils, telephones, keyboards, door handles, etc.), as viruses in vomit, aerosols and faecal matter are persistent and can stay infectious for a long period.

38. Ideally, because of the exposure to highly infectious substances, disposable materials such as gloves, facemasks and aprons or smocks should be worn during cleaning and disinfection by a person trained in cleaning-up infectious material. Any spillage or contamination with faeces or vomit should be dealt with immediately, and food handling in the same area(s) should be stopped. Absorbent material such as paper towels and tissues may be used to limit the spread of contaminated fluids but should then be properly disposed of, e.g., in closed plastic bags, so as not to be a vehicle for further contaminating foods, surfaces or personnel.

#### *Surface disinfection:*

39. Surfaces should always be cleaned prior to disinfection to ensure effective disinfection. For surface disinfection, solutions of  $\geq 1000$  ppm free chlorine applied for 5 to 10 min at room temperature consistently show  $> 3 \log_{10}$  reduction in viral infectivity. Freshly constituted hypochlorite solutions are preferable. Alternatively, chlorine dioxide solutions at concentrations of 200 ppm may be used. The solutions are corrosive, and need to be thoroughly rinsed from food contact surfaces afterwards, e.g., by washing with clean water. 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.

40. Experiments have demonstrated that a vaporized hydrogen peroxide (VHP) treatment at  $>100$  ppm for 1 h is effective against bacteria, bacterial spores and a range of viruses including poliovirus, rotavirus, adenovirus, and murine norovirus. This treatment can be applied to whole rooms, including kitchens, and results in disinfection of various surfaces such as stainless steel and framing panel and is a less labour-consuming alternative to manual disinfection using chlorine solutions.

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

42. Most other surface disinfectants lack efficacy (i.e., consistently cause less than a  $3 \log_{10}$  reduction in infectivity) against enteric viruses at manufacturer's recommended concentrations and exposure times. It is well recognized that the majority of chemical disinfectants currently used in institutional and domestic environments and in the food industry do not effectively inactivate NoV and HAV. New compounds and/or methods can be considered if they show virucidal activity of  $> 3 \log_{10}$  for non-enveloped viruses in standardized carrier tests and are approved for use on food contact surfaces. Interpretation of results from the use of human NoV surrogates, specifically feline calicivirus and murine NoV, in the evaluation of disinfectants should be made with caution as these surrogates exhibit different physiochemical properties as compared to NoV.

## 6.2 CLEANING PROGRAMMES

43. Cleaning and disinfection programs should include disinfectant agents and specific cleaning (including manual and automatic dishwashing) and disinfection procedures that are able to inactivate enteric viruses and include a checklist of which surfaces should be disinfected (see Section 6.1.2). These 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). When cleaning and disinfection is needed for potential virus contamination, accurate documentation and monitoring of the cleaning and disinfection are recommended.

## 6.4 WASTE MANAGEMENT

44. 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.

**SECTION 7 – 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 personal hygiene of food handlers, particularly in relation to the prevention of NoV and/or HAV, contamination.

**7.1 HEALTH STATUS**

45. Diarrhoea and vomiting may be caused by infectious (e.g., NoV, *Salmonella*) or non-infectious (e.g., toxins) 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 of hepatitis, which should also be regarded as an infectious condition. Persons with 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.

46. Refer to the Introduction section of these guidelines for the incubation and contagious periods of NoV and HAV viruses.

**7.2 ILLNESS AND INJURIES**

47. Food handlers with clinical symptoms of gastroenteritis or with symptoms of acute hepatitis should be excluded from the handling of food, food contact surfaces and food equipment and should not be present in the area where food is exposed, 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 any diarrhoea event and in any case directly after these events. Any person with symptoms of acute hepatitis should seek medical advice.

48. Persons who have had gastroenteritis should only be allowed to return to work after a period without symptoms of diarrhoea and vomiting. Persons, who have had hepatitis, should only be allowed to return to work after disappearance of jaundice.

49. As shedding of viruses, such as NoV or HAV, may continue for several weeks after symptoms have subsided (e.g., NoV may be post-symptomatically present on average for 2 or more weeks in the stools of recently infected persons), training and instructions should be given to all personnel on the infectivity, transmission and disinfection of foodborne viruses, and the importance of following strict hand hygiene instructions at all times.

50. When one of the staff members has symptoms of gastroenteritis or hepatitis, other staff members may be or become (asymptomatically) infected at that point. Similarly, when a family/house member of a staff member has symptoms of gastroenteritis or hepatitis, the staff member may be (asymptomatically) infected, and/or serve as a vector carrying infectious virus on their person. In these specific situations, in particular, compliance with strict hand hygiene measures is important to reduce the risk of further spread of the illness.

51. Vaccination of food handlers against hepatitis A should be recommended 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, e.g., where HAV is endemic or the population has low immunity. Where feasible and appropriate, checking for HAV immune status of food handlers could be useful.

**7.3 PERSONAL CLEANLINESS**

52. Personal hygiene of food handlers is critical. Food handlers should be aware of the infectious nature and transmission routes of enteric viruses, such as NoV and HAV. As asymptomatic shedding can occur, food handlers should adhere to hand washing instructions at all times. Training should be provided for food handlers, managers and other company personnel (see Section 10).

53. Hands should be washed and dried before handling of food. The most effective way of preventing spread of viruses is thorough hand washing. Hands should be lathered with soap and then washed with clean running water<sup>3</sup>. The use of disposable hand towels and non-hand operable taps should be encouraged wherever possible. Hands should be washed in sinks dedicated to such a purpose and not washed in dishwashing sinks or food preparation sinks, to the extent possible.

54. 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/nappies, cleaning toilets), or after being in contact with vomit.

55. If gloves are used, a procedure for glove use should be developed and followed. If gloves are used in the handling of food products, they should be in a sound, clean and sanitary condition. If disposable gloves are used, they should be discarded when they become torn, soiled, or otherwise contaminated and replaced. When gloved hands have been in contact with potentially contaminated items, new gloves should be put on before preparing food. The wearing of gloves or the use of hand sanitizers does not exempt the person from having thoroughly washed hands before putting on gloves.

56. Clothes of food handlers who have been infected, or suspected to have been infected, should be washed. It has been shown that conventional household washing detergents have a good virucidal efficiency at 40 °C.

**7.4 PERSONAL BEHAVIOUR**

57. Items such as money, tickets, etc., should not be handled at the same time as food. After any contact with potentially virus-contaminated material, hands should be thoroughly washed. If gloves are used in the handling of food, new gloves should be put on before handling or preparing food.

**7.5 VISITORS**

58. Non-authorized persons and, to the extent possible, children should not be present in food handling areas where food is grown, harvested, stored or prepared.

<sup>3</sup> 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](http://whqlibdoc.who.int/hq/2005/WHO_EIP_SPO_QPS_05.2.pdf)

## SECTION 9 – PRODUCT INFORMATION AND CONSUMER AWARENESS

### 9.1 LOT IDENTIFICATION

59. NoV and HAV can persist for long periods of time in food. As distribution of food between areas and countries complicates traceability, lot identity and integrity should be maintained to facilitate trace back.

### 9.4 CONSUMER EDUCATION

60. Countries should develop educational programs to make consumers more alert to the risk of viruses in certain ready-to-eat foods, such as raw bivalve molluscs harvested near areas of human habitation, (e.g., presence of sewage plants).

## SECTION 10 – TRAINING

**OBJECTIVES:** Those food handlers engaged in food growing, harvesting 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:** Food handlers may be less familiar with controls specific to enteric viruses.

### 10.1 AWARENESS AND RESPONSIBILITIES

61. Food business operators (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. There is a need to increase awareness of stakeholders on foodborne disease outbreaks due to viral infection.

62. It is the responsibility of the managers to educate and train their personnel, to keep control of the level of awareness of the training content, and to have both cleaning and disinfection programmes operational.

63. It is the responsibility of the managers and employers to carry out monitoring to ensure that personnel are undertaking good hygienic practices. Monitoring includes regular observation of personnel hand washing prior to entry into food handling areas.

64. It is the responsibility of the personnel to inform the supervisor or employer when ill with diarrhoea or vomiting, or when having complaints or symptoms indicative of hepatitis or gastrointestinal illnesses. It is also the responsibility of all personnel to adhere to strict hand washing instructions after returning from the toilet or after being in contact with faecal or vomit matter.

### 10.2 TRAINING PROGRAMMES

65. Training programmes 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 potential for persistence of infectious virus in/on contaminated foods and food production settings.
- The incubation periods of foodborne viruses, specifically NoV and HAV.
- The duration of virus shedding during and even after recovery from clinical symptoms and the possibility of pre- and post-symptomatic shedding.
- The infectivity of vomit.
- Procedures for cleaning and disinfection of contaminated surfaces.
- Proper hand washing practices and the importance of strict compliance with hand washing instructions at all times, particularly after being in contact with faecal or vomit matter. It is advisable to have documentation of the hand-washing instructions given to each new starting personnel.
- The possibility that if one staff member or household member has a viral illness, other staff members or household members may also be infected.
- The need to stay away from work and not to have direct contact with any ready-to-eat food when having symptoms of gastroenteritis or infectious hepatitis.
- The need to keep children away from food growing fields and food preparation areas, to the extent possible, in HAV endemic areas (since in endemic areas children are a primary source of the virus).
- Procedures for the disposal of contaminated food items.

### 10.3 INSTRUCTION AND SUPERVISION

66. Extensive training and instructions should be given to all new personnel on the infectivity, transmission and management of foodborne viruses. Incorporation of these instructions into the National codes of hygienic practice would be advisable.

67. Also inspectors or other relevant authorities who inspect fields, post harvest processing plants, and eating facilities should be provided with the above training, and be aware of the instructions.

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

### INTRODUCTION

1. For bivalve molluscs, the major, well-documented route of contamination is via human 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 digestive tissue of bivalve molluscs. Recent evidence has shown that some NoV genotypes bind specifically to bivalve molluscs' tissue receptor sites, which could explain why some viruses persist after depuration procedures as currently practiced in the industry. Long-term relay of bivalve molluscs to clean environmental waters can be effective for eliminating the risk of illness from viruses, but often this is impractical due to added costs or lack of clean areas in reasonable proximity to contaminated harvest sites. Furthermore, studies indicate that there may even be a risk of infection if contaminated bivalve molluscs are consumed after insufficient heat treatment. 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 difficult. Therefore, measures should be taken to prevent viral contamination of bivalve molluscs by improving environmental conditions (particularly water quality) in production and harvesting areas.

### SECTION 1- OBJECTIVES

2. 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 2 - SCOPE, USE AND DEFINITION

#### 2.1 SCOPE

3. 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.

#### 2.2 USE

4. This annex on the *Control of Hepatitis A Virus (HAV) and Norovirus (NoV) in Bivalve Molluscs* (Annex I) is a supplement to the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food* and provides additional recommendations for this specific virus-commodity combination. This annex should also be used in conjunction with Sections 2 and 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

#### 2.3 DEFINITIONS

**Clean water** – See Section 2.1 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

**Depuration** – See Section 2.3 of CAC/RCP 52-2003.

**Growing areas** – See Section 2.3 of CAC/RCP 52-2003.

**Relaying** – See Section 2.3 of CAC/RCP 52-2003.

**Relaying areas** - See Section 2.3 of CAC/RCP 52-2003.

### SECTION 3 - PRIMARY PRODUCTION

5. 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, raw or partially treated. Since bivalve molluscs are filter-feeders, they concentrate microbiological contaminants to a much higher concentration than is present in the surrounding seawater. The potential for 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.

6. It is important to ensure the seawater quality of growing areas to prevent or minimize viral contamination of bivalve molluscs growing areas. A sanitary survey of growing areas should be conducted prior to the commencement of growing and/or harvesting operations and when climatic conditions such as heavy rainfall warrant. The sanitary survey of growing areas should include an assessment of possible human faecal contamination sources.

7. The following are examples of factors that should be addressed during the sanitary survey and where possible supplemented by a practical shoreline survey:

- location and extent of the bivalve mollusc fishery;
- type of shellfishery (species, method of harvest, seasonality of harvest);
- location, type and volume of sewage discharges;
- location of river inputs and other potentially contaminated water courses (from maps/nautical charts);
- location of harbours and marinas (from maps/nautical charts);
- hydrographic and hydrometric data;

- existing microbiological data from water quality or shellfish monitoring undertaken in the same area or adjacent areas; and
- areas of recreational bathing.

8. The level of faecal contamination may indicate the potential for the presence of human enteric viruses. To control the hazards, identification and monitoring of growing areas is very important for bivalve molluscs safety. *E. coli*/faecal coliforms are used as indicators of faecal contamination. Monitoring data should be interpreted within the context of the sanitary survey, as viruses may be present in the absence of these bacterial indicators.

9. When there has been a bivalve mollusc-borne outbreak caused by an identified pathogen such as NoV or HAV and the area has been closed, viral testing of the bivalve molluscs or an approach consistent with the requirements of the competent authority should be used as part of the process of reopening the affected area to ensure product safety using either standardized methods or alternative validated methods. Other conditions, including meeting the sanitary survey requirements, should also have been satisfied as a condition of reopening the area. Ideally they should include the identification of sources of pollution/contamination and prevention of future contamination events.

### 3.1 ENVIRONMENTAL HYGIENE

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

- Growing areas that are contaminated by sewage discharge or disposal of faecal matter from ships, recreational boats and bivalve molluscs harvesting vessels.
- Overflow from sewage treatment plants that may contaminate the growing waters after heavy rainfall.
- Quality of sewage collecting network and private septic tanks.

11. Every effort should be made to eliminate the overflow of untreated or partially treated sewage into growing waters.

12. Sewage treatments should ensure adequate reduction of viral loads and aim to achieve significant reduction of NoV and HAV (Refer to *WHO Guidelines for the safe use of wastewater, excreta and grey water. Volume 3 Waste water and excreta use in aquaculture* ([http://whqlibdoc.who.int/publications/2006/9241546840\\_eng.pdf](http://whqlibdoc.who.int/publications/2006/9241546840_eng.pdf)). Whenever possible, sewage treatment should involve a tertiary treatment step such as UV or ultra-filtration treatment. The use of a prohibition zone for the harvest of bivalve molluscs near a wastewater treatment plant is another option the competent authority may use. Treatment plants should be designed to minimize storm overflows that may affect the fishery. Systems should be put in place to monitor sewage spills and provide prompt notification to the appropriate competent authority as well as the bivalve molluscs industry so that appropriate action (i.e., cessation of harvesting) can be taken.

13. After heavy rainfall, during risk periods (e.g., untreated or partially treated sewage that has or is suspected to have entered a growing area) and/or after overflow from sewage treatment plants, harvesting of bivalve molluscs should cease for a period, until the water and/or bivalve molluscs quality of the harvesting area has been assessed and has been returned to normal background levels for the area. If there is evidence that the area has been impacted by human sewage, testing of water or bivalve molluscs for the presence of indicators of faecal contamination and/or NoV or HAV, as determined by the competent authority or an equivalent approach to ensure safety, may be an option prior to re-opening.

14. When untreated or partially treated sewage is known or suspected to have entered a growing area it is recommended that bivalve molluscs already harvested from this area should be designated exclusively for virucidal heat treatment (see Section 5.2.2, main document) by the processor before release to retail sales. Another option is long term relaying or a combination of depuration and relaying as determined by the competent authority.

15. In addition, suitable precautions should be taken to protect bivalve molluscs from being contaminated by human faecal material, in particular:

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

### 3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

16. Efforts should be made to restrict the growing and harvesting of bivalve molluscs to areas of clean water only.

17. Records regarding the history of contamination of bivalve 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 for contamination levels in risk areas should be reinforced.

18. In addition to the use of clean water during primary production, other possible control measures for enteric viruses, such as NoV and HAV, include long term relaying or a combination of depuration and relaying.

19. If using short-term or long-term relaying as a means to reduce microbial contaminants, the effectiveness of the treatment is dependent upon the water quality and conditions of the location to which the bivalve molluscs are relayed. The time used for relaying bivalve molluscs should be verified as appropriate by the competent authority having jurisdiction, using standardized protocols for specific virus/molluscs species pairings. The holding time and minimum temperature during long term relaying should be based on the degree of contamination before relaying, the temperature of the water, the bivalve mollusc species involved and local geographic or hydrographic conditions to ensure that contamination levels will be adequately reduced to ensure that virus is not present using validated testing methods. A short-term depuration process commonly reduces low levels of bacterial

contamination, and thus contributes to the safety of bivalve molluscs but depuration alone is inadequate in the elimination of viruses.

20. When there is a likelihood or evidence of virus contamination through epidemiological information, environmental events or direct detection of virus or viral RNA, closure of the area, destruction of contaminated bivalve molluscs and/or virucidal heat treatment (see Section 5.2.2, main document) before consumption of already harvested bivalve molluscs is recommended. Another option, if verified by the competent authority, is long term relaying or a combination of depuration and relaying.

## SECTION 5 - CONTROL OF OPERATION

### 5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

#### 5.2.2 *Specific process steps*

- **Heat Treatment:** Heat treatments of bivalve molluscs should be validated for their ability to inactivate viruses. An internal temperature of 85 to 90 °C for at least 90 seconds is considered to be a virucidal treatment. However, this degree of cooking would probably render specific bivalve molluscs, such as oysters, unpalatable to consumers. Even though cooking temperatures typically used by consumers may not achieve 90 °C for at least 90 seconds and thus ensure inactivation of viruses, any cooking would reduce viral levels and depending on the initial level of contamination possibly would reduce the risk of causing foodborne infection. For example, it has been reported that an internal temperature of steamed shellfish maintained at 85 to 90 °C for 1 min reduced titers of HAV in cockles by more than 4 log. The possible inability of home or restaurant cooking to provide adequate assurance of consumer protection from consuming virally contaminated bivalve molluscs in certain circumstances or forms of consumption underlines the importance of harvesting bivalve molluscs from clean water growing areas.

- **High Hydrostatic Pressure (HHP):** HHP may reduce virus titers in bivalve molluscs with relatively small effects on the character of the meat. The HHP conditions for inactivation depend upon pressure as well as time, temperature and the salinity of the water, e.g., a pressure of 600 MPa applied at 6 °C for five minutes can completely inactivate NoV in oysters. The use of HHP alone or in combination with other inactivation procedures should be validated for the virus of concern in the specific bivalve mollusc species prior to its application.

## SECTION 9 – PRODUCT INFORMATION AND CONSUMER AWARENESS

### 9.1 LOT IDENTIFICATION

21. NoV and HAV can persist for long periods of time in bivalve molluscs. As movements between growing areas and countries complicate traceability of bivalve molluscs, lot identity, harvest site and date, and integrity should be maintained to facilitate trace back to all the growing areas. Because of viral persistence, it is recommended that growing areas be registered for a two month period prior to harvest and that harvest areas also be registered.

### 9.3 LABELLING

22. Refer to the *General Standard for Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and to the labelling provisions of the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008). Where appropriate, product labels should include information on safe handling practices and storage recommendations.

23. In addition, countries should give consideration to labelling of unpackaged live or raw bivalve molluscs, so that consumers are adequately informed with respect to the safety and true nature (alive or not alive) of these products. In particular, bivalves that are at a high risk of being contaminated with NoV or HAV, should be labelled to alert at-risk consumers to avoid or cook these products, in line with the legislation in the countries where these products are retailed or sold.

### 9.4 CONSUMER EDUCATION

24. Each country has specific consumption habits; therefore communication programmes pertaining to viruses in relation to the consumption of bivalve molluscs are most effective when established by national governments. Consumers should be made aware of the risk of becoming infected with NoV or HAV after consuming raw or treated bivalve molluscs.

## SECTION 10 – TRAINING

### 10.2 TRAINING PROGRAMMES

25. In addition to the training content mentioned in the main part of this document (Section 10.2), appropriate personnel involved in the growing and harvesting of bivalve molluscs should have appropriate training in:

- Control measures to prevent faecal contamination of growing and harvesting areas. Awareness of the lack of correlation between bacterial indicators and viral contamination should also be ensured.
- Control measures to prevent bivalve molluscs from becoming contaminated by contagious food handlers.

## ANNEX II

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

1. Fresh produce is now grown on a large scale in many countries and is transported globally. Outbreaks of viral disease associated with contaminated raspberries, green onions, and leafy greens as well as other produce items are well documented. The contamination of fresh produce may occur at any stage from production to consumption.
2. Fresh produce may become contaminated with viruses through contact with human sewage, e.g., through the use of sewage-contaminated waters for irrigation, washing, or in the application of fertilisers and agrichemicals, or through the seepage of untreated or partially treated sewage into the soil.
3. Fresh produce may also become contaminated by viruses via contaminated hands of food handlers especially if they do not practise appropriate personal hand hygiene (i.e., hand washing). A second important factor in food-handler associated spread of viruses is vomiting that can lead to widespread contamination of the environment.
4. In countries where HAV infection is endemic, children in and around produce production fields may be an important risk factor in the spread of viruses during primary production. Children who are asymptomatic or have unsuspected HAV infection (shedding virus) and are working in the production field or being cared for by a food handler also increase the risk of contaminating fresh produce.

**SECTION 1- OBJECTIVES**

5. 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 2 – SCOPE, USE AND DEFINITION****2.1 SCOPE**

6. This annex covers general hygienic practices for the production, harvesting, processing, packing and storage of fresh produce for human consumption particularly for fresh produce intended to be consumed raw or partially treated. 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.
7. Recommendations for handling practices to maintain the safety of fresh produce at wholesale, retail, food services or in the home are covered in *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 main part of this document.

**2.2 USE**

8. This Annex on the *Control of Hepatitis A Virus (HAV) and Norovirus (NoV) in Fresh Produce* (Annex II) is a supplement to the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food* and provides additional recommendations for this specific virus-commodity combination.

**2.3 DEFINITION**

**Clean water** - See Section 2.3 of the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003).

**SECTION 3 - PRIMARY PRODUCTION**

9. 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. Primary production activities should be conducted following good hygienic practices in order to minimize potential risks of contamination of fresh produce with NoV and HAV.

**3.1 ENVIRONMENTAL HYGIENE**

10. 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 effluents, untreated human excreta used as fertilizer, agricultural workers and the personnel hygiene and toilet facilities on-site (Refer to *WHO Guidelines for the safe use of wastewater, excreta and grey water. Volume 2: Wastewater use in agriculture* (World Health Organization 2006 ISBN 92 4 154683 2,v.2; [www.who.int/water\\_sanitation\\_health/wastewater/gsuweg2/en/index.html](http://www.who.int/water_sanitation_health/wastewater/gsuweg2/en/index.html)). 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. Infectious NoV and HAV can persist in the environment, as well as on fresh produce, and it can sometimes survive the shelf life of the products.

11. Sewage treatments should ensure adequate (maximal) reduction of viral loads in treated sewage, as the following could be potential sources of contamination:

- Water contaminated with untreated or partially treated sewage discharges, by overflow from sewage and septic tank systems or from run-off associated with a heavy rainfall that is used for irrigation, washing of produce, or application of fertilizers and agrichemicals.

- Seepage of untreated or partially treated sewage onto/into agricultural soil.

### **3.2 HYGIENIC PRODUCTION OF FOOD SOURCES**

#### **3.2.1 Water for primary production**

12. Efforts should be made to use only clean water for the production of food. 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 for faecal contamination. 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. The effectiveness of corrective actions should be verified.

13. Testing for *E. coli* / 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 for indicators of faecal contamination should be established according to the source of the water (ground water, surface water, wells) and the conditions of the irrigation system.

14. With water delivery techniques that result in exposure of fresh fruits and vegetables (particularly the edible portion) directly to irrigation water, such as with use of overhead sprinklers, the risk of NoV and HAV contamination is considered to be higher as compared to other types of irrigation, such as drip irrigation.

#### **3.2.2 Personnel health, hygiene and sanitary facilities**

##### **3.2.3.1 Personnel hygiene and sanitary facilities**

15. Personnel hygiene facilities and toilets (permanent or portable), including appropriate hand washing facilities, should be present in close vicinity of the fields where agricultural workers are working.

### **3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION**

16. Refer to Section 6 (Sanitation) and Section 7 (Personal hygiene) of the main document for aspects of sanitation and personnel hygiene in primary production.

## **SECTION 5 - CONTROL OF OPERATION**

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

### **5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS**

#### **5.2.2 Specific process steps**

- Washing: The washing of fresh produce is not a suitable method to eliminate viruses as the surface type may allow viruses to remain present.
- Chemical treatment: Antimicrobial agents, effective for bacteria, may not be effective for the reduction of NoV and HAV in fresh produce.

## **SECTION 7 –ESTABLISHMENT: PERSONAL HYGIENE**

### **7.5 VISITORS**

18. Non-authorized persons and, to the extent possible, children, should not be on the premises where fresh produce is grown, harvested, washed, packed or stored.

## **SECTION 10 – TRAINING**

### **10.2 TRAINING PROGRAMMES**

19. Personnel involved in growing, harvesting, processing and storage of fresh produce should have appropriate training in:

- The general characteristics of NoV and HAV and their resistance to various environmental conditions, e.g., conditions of sewage treatment, temperature.
- Personal hygiene (see Section 7, main document).
- Control measures to prevent faecally contaminated water being used in primary production and processing.
- The risks associated with the use of human waste excreta as a fertilizer.
- Control measures to prevent fresh produce becoming contaminated by contagious food handlers.