CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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Agenda Item 4 **CX/FH 11/43/4**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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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 Electronic Working Group led by Netherlands

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Guidelines at Step 3 (see Appendix I) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission*) **to**: Ms Barbara McNiff, US Department of Agriculture, Food Safety and Inspection Service, US Codex Office, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720 3157, or email Barbara.McNiff@fsis.usda.gov with a copy **to**: The Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by 15 October 2011.**

Format for submitting comments: In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers, which are not yet doing so, are requested to provide their comments in the format outlined in the Annex to this document.

BACKGROUND

1. The 42nd Session of the Committee on Food Hygiene agreed to circulate the proposed draft Guidelines for comments at Step 3 and to establish an electronic working group led by The Netherlands to prepare revised proposed draft Guidelines based on the written comments at Step 3 and the recommendations and discussions during the 42nd Session of CCFH.

WORKING GROUP REPORT

2. During the period March – June 2011 the participants of the Electronic Working (see Appendix II) discussed the proposed draft Guidelines departing from the document as presented in the report of the 42nd Session of CCFH (REP 11/FH, Appendix IV) and prepared revised proposed draft Guidelines (Appendix I).

3. The working group further refined the document by many editorial changes and deleting parts that are already covered in the General Principles. The main proposed changes made in the different sections of the draft guidelines are listed below.

Introduction

4. Although this section is rather extensive and repeats information from the FAO/WHO Expert meeting on viruses, the working group considers this background information very important when measures have to be taken to control viruses in food and the working group agreed on not to shorten this section.

5. Additional statements on the value of molecular detection methods, the use of surrogate viruses for the evaluation of control measures and on the relevance of rotavirus have been introduced.

6. The proposed change of ‘developing countries’ into ‘some area’ was supported by a majority of the working group.

Section 2 – Scope, Use and Definitions

7. As these Guidelines should be read and used in conjunction with the General Principles it was decided to remove the references to the General Principles in the different sections to improve the readability of the Guidelines.

Section 3 – Primary Production/Harvesting Area

8. Additional text on aquaculture and reference to the 'WHO Guidelines for the safe use of waste water, excreta and grey water. Volume 3: Waste water and excreta use in aquaculture' has been introduced.

Section 5 – Control of Operation

9. Section 5.1 has been changed to a chapeau paragraph as suggested during the 42nd Session of CCFH.

10. The working group agreed on a better description of the effects of heat treatment on viruses in food in subsection 5.2.1.

11. In subsection 5.2.2 additional paragraphs on 'Washing', 'Gamma irradiation', the combination of process procedures and the validation of new virucidal technologies have been introduced.

12. The working group discussed the maintenance of statements on the presence of children in production fields and premises. As stated in the Introduction children may be an important risk factor in the spread of HAV in endemic area. Therefore the working group agreed on the insertion of statements on the exclusion of children (subsections 5.6, 7.5, 10.2 and Annex II, 7.5)

Section 6 – Establishment: Maintenance and Sanitation

13. In subsection 6.1.1 a general statement has been introduced on the procedures to be followed after vomiting/diarrhoea events.

14. In subsection 6.1.2 statements on the use of absorbent material to remove contamination with faeces or vomit and on the use of vaporized hydrogen peroxide treatment for the disinfection of surfaces have been inserted.

Section 7 – Establishment: Personal Hygiene

15. The 42nd Session of CCFH decided to delete detailed descriptions of hand washing procedures. As following proper hand washing procedures by food handlers is very essential for the control of viruses in foods the working group proposes to include a statement to encourage the use of disposable hand towels and non-hand operable taps, wherever possible.

16. A more detailed description on the use of gloves in food handling has been added.

Section 9 – Product Information and Consumer Awareness

17. Additional statements on consumer information and lot identification have been inserted.

Section 10 – Training

18. In subsection 10.1 the responsibilities of food business operators, managers and personnel have been introduced.

Annex I – HAV and Nov in Bivalve Molluscs

19. The working group agreed on some changes and additional text regarding sanitary survey of harvesting water (Section 3).

20. In subsection 5.2.2 a better description of the effects of heat treatment and HHP on viruses in bivalve molluscs has been given.

21. Additional statements on lot identification and labelling have been introduced in section 9.

Annex II – HAV and Nov in Fresh Produce

22. The working group agreed on the addition of more information on the possible contamination by sewage.

23. A paragraph (5.2.2) on washing of fresh produce has been added.

Recommendations

24. The 43rd Session of the CCFH is invited to consider the revised Proposed Draft Guidelines on the Application of General Principles to the control of Viruses in Food as presented in Appendix I.

25. Comments submitted will be considered by a physical working group, led by The Netherlands, meeting immediately prior to the 43rd Session of the CCFH.

APPENDIX I

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

(At Step 3 of the Procedure)

SECTION 5 - CONTROL OF OPERATION

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.2 Specific process steps

5.2.2.1 Chemical treatment

SECTION 7 – ESTABLISHMENT: PERSONAL HYGIENE

SECTION 10 – TRAINING

10.2 TRAINING PROGRAMMES

INTRODUCTION

1. In recent years, viruses have been increasingly recognized as important causes of foodborne diseases. Viruses are micro-organisms, ranging in size from 18 to 400 nanometers, whereas bacteria generally range in size from 0.5 to 5 micrometers. In addition to size, other structural and biological differences exist between viruses and bacteria. Viruses are strictly host-dependent for their replication and have their own typical host range and cell preference (tropism). Viruses can be transmitted in different ways, e.g., via the respiratory or faecal-oral routes. 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, adenovirus can also be transmitted by food, and anecdotal evidence suggests the list of foodborne viruses may be even longer. Based on the symptoms of disease, these viruses can be grouped into those that cause gastro-enteritis (e.g. NoV), enterically transmitted hepatitis (e.g. HAV, that 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.
- 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 and pressure, disinfection, etc).
- Freezing and refrigeration temperatures preserve viruses and are believed to be important factors that increase the persistence of foodborne viruses in the environment. Heat and drying can be used to inactivate viruses, but there are virus-to-virus differences in resistance to these processes. The presence of organic matter, such as faecal material and the food matrix can influence relative 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 as common 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" [1], NoV and HAV were determined to be the viruses of *greatest concern from a food safety perspective* based on the incidence of reported foodborne disease, the severity of disease, including mortality, and their potential for transmission via foods. Estimates of the proportion of viral illness attributed to food are in the range of around 5% for HAV and 12-47% for NoV[1]. Data from at least 4 continents show that this is a major public health issue worldwide, although data from 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 are likely to play a role. Like HAV and NoV, HEV is transmitted by the fecal-oral route. HEV has been found to be responsible for sporadic and epidemic acute hepatitis, especially in developing countries. 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. Other emerging viruses, such as the Severe Acute Respiratory Syndrome (SARS)-coronavirus, Nipah virus and Highly Pathogenic Avian Influenza virus (HPAI) H5N1, all of zoonotic nature, have been linked to food or postulated to be transmitted via food, but currently there is not sufficient data to elaborate on these emerging viruses in this context.

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 healthcare infections rather than foodborne infections. The incubation period, i.e., the period between exposure to the virus and onset of symptoms is 12-72 hours, 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 up to 8 weeks after resolution of symptoms even in immuno-competent persons. The disease and shedding period may be longer in the case of 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 (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 (10^6-10^8 particles/g) in faeces from the final 2 weeks of the incubation period up to 5 weeks into the illness. 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"[1], 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

[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.

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. Recently, the number of *analytical methods* available for the detection of foodborne viruses in food matrices has increased, reflecting the recognition of the significance of foodborne viral disease. Since many foodborne viruses cannot be cultured *in vitro*, detection methods are based on molecular amplification techniques. Molecular methods, such as *real-time* reverse transcription polymerase chain reaction methods (real time RT-PCR) are rapid, have good sensitivity and specificity, are not labour intensive, and have facilitated the analysis of large numbers of samples. They can also be designed to be quantitative or semi-quantitative. Molecular detection methods, once validated for the intended purpose and widely available, will be useful in outbreak investigations as well as in auditing and monitoring of control systems. However, it is important to note that low levels of viruses may not be detected due to low extraction efficiency and/or the presence of PCR-interfering substances. Moreover these methods cannot be used to distinguish between infectious and non-infectious viruses, which would allow an exact determination of whether the food poses a risk to human health.

SECTION 1 - OBJECTIVES

10. The primary purpose of these guidelines is to give guidance on how to minimize the risk of illness arising from the presence of human enteric viruses in foods, and more specifically from 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) throughout the food chain, from primary production through 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 *Code of Practice - General Principles of Food Hygiene*- (CAC/RCP 1-1969) 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, which is normally eaten without further steps, which could remove viruses or eliminate their infectivity.

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 faecally contaminated water or soil 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. Primary food production should not be carried on 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, since products exposed to vomit or faecal matter in primary production areas could become contaminated and pose a risk to human health. Hygiene and health requirements should be followed to ensure that personnel who come directly into contact with food during production do not contaminate the product.

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; 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).

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.

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 utensils and containers should be in a clean condition and should not be damaged.

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

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

- be located in proximity to the production or processing areas,

- not open directly to food handling areas,
- be in sufficient numbers to accommodate personnel,
- be culturally appropriate,
- be of appropriate design to ensure hygienic removal of wastes,
- have adequate means for hygienically washing and drying hands,
- be maintained under sanitary conditions and good repair,
- be appropriately cleaned and disinfected (see 6.2 cleaning programmes) and
- preferably be separate for guests and personnel of the establishment.

4.4.4.2 Hand washing facilities

21. Hand washing facilities should be supplied with hand cleanser (soap) and be within close proximity to the toilets and positioned so that the personnel must pass by them before returning to the food handling area. Where possible, hand washing facilities should have non-hand operable taps to help prevent the re-contamination of clean hands and single-use disposable paper towels. Hand washing and drying instructions should be visibly present for all users of these facilities.

22. Hand washing sinks and drying facilities should be suitably located in food preparation or production areas to ensure food handlers have ready access to them.

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 IN RELATION TO VIRAL CONTAMINATION

23. Control of human enteric viruses such as NoV and HAV in food will typically require a stringent application of good hygienic practice, and other supportive programs. These prerequisite programs, together with HACCP provide a framework for the control of enteric viruses.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

24. 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 considered a risk and should be discarded.

25. 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.

5.2.1 Time and temperature control

- Cooling and freezing: Processes aimed at inhibition of microbial growth, such as cooling or freezing, will not affect virus infectivity enough to yield safe foods. For HAV there is less than 1 $\log_{10}$ reduction in infectious units after 5 cycles of freezing and thawing and less than 1 $\log_{10}$ reduction after storage at refrigerator temperatures for 1 week. For NoV freezing tends to preserve infectivity, however, there may be an initial loss in virus titre with each freeze-thaw cycle.
- 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 commonly used in food preparation, where an internal temperature of the food reaches at least 90 ºC 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; 71.7°C for 15–20 seconds) pasteurization, and likely yields at least a 3 $\log_{10}$ 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 (e.g., 113ºC for 55 minutes) is considered an adequate treatment to destroy viral infectivity in foods.

5.2.2 Specific process procedures

- Washing: The washing of food ingredients or products in wash 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 $\log_{10}$ 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 (RWA): RWA 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 RWA can not 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.
- Gamma (γ) Irradiation: γ-irradiation may reduce virus infectivity, depending in part on irradiation dose, virus type and food matrix, but it cannot be considered an effective measure to reduce viral loads on or in food.

26. Often 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.

27. When new virucidal technologies or treatment combinations are being developed, they should be validated with the 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

28. Raw ingredients contaminated with viruses may lead to contamination of food handlers' hands, other foods, or food contact surfaces. Preferably only use raw ingredients from suppliers or production plants with an adequate food safety management system; this includes the use of clean or potable water, adequately trained personnel, high personnel hygiene standard, availability of adequate hygiene facilities, and a good health supervision system.

5.4 PACKAGING

29. Various types of packaging that are aimed at inhibiting bacterial or fungal growth, e.g. modified atmosphere packaging (MAP) are not effective as human viruses do not grow in foods.

5.6 MANAGEMENT AND SUPERVISION

30. All managers and supervisors should understand the importance of good hygiene practices and personnel health and hygiene, such as the following:

- the importance of the availability of adequate hygiene facilities,
- the importance of 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) and
- how to clean and disinfect surfaces when contaminated.

5.7 DOCUMENTATION AND RECORDS

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

5.8 RECALL PROCEDURES

32. 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

33. 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 other than those inside a toilet bowl 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:

34. Each establishment should have a documented regular cleaning and disinfection procedure. 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.

35. 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 then should be properly disposed of, e.g., in closed plastic bags, so as not to be a vehicle for further contaminating foods, surfaces or personnel.

36. Dispose of any food possibly contaminated by vomit particles or by vomit-derived aerosols. An evaluation should be undertaken to determine the need to dispose of a food handled by an ill person. 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.

Surface disinfection:

37. Surfaces should always be cleaned prior to disinfection to ensure effective disinfection. For surface disinfection, solutions of ≥ 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 (e.g., using tablets) are preferable. The solution is corrosive, and needs to be thoroughly removed afterwards. Adequate precautions should be taken during cleaning or disinfection of rooms, equipment or utensils to prevent food

being contaminated by wash water, detergents and disinfectants. Food preparation should only begin after thorough disinfection has taken place.

38. A vaporized hydrogen peroxide (VHP) treatment at >100 ppm for 1 h has been shown to be effective against bacteria, bacteria 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 different surfaces such as stainless steel and framing panel and is a less labour-consuming alternative to manual disinfection using chlorine solutions.

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

40. 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. In fact, 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. As noted earlier, 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

41. Cleaning and disinfection programs should include disinfectant agents and specific cleaning (including manual 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

42. 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 hygiene control by food handlers, particularly in relation to the prevention of NoV and/or HAV, contamination.

7.1 HEALTH STATUS

43. 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 (section 3.4).

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

7.2 ILLNESS AND INJURIES

45. Food handlers with clinical symptoms of gastroenteritis or with symptoms of acute hepatitis should be excluded from handling 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.

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

47. As shedding of viruses, such as NoV or HAV, may continue for several weeks after symptoms have subsided (e.g., NoV can post-symptomatically be present in the stool of recently infected persons on average for 4 weeks and for up to 8 weeks), 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.

48. 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.

49. 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

50. 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).

51. Hands should be washed and dried before handling of food. The most effective way of preventing spread of viruses is thorough handwashing. Hands should be lathered with soap and then washed with clean running water[2].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.

52. 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.

53. 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.

7.4 PERSONAL BEHAVIOUR

54. 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 put on before handling or preparing food.

7.5 VISITORS

55. Avoid presence of non-authorized persons, such as children, to the extent possible, during food handling or on premises where food is grown, harvested, stored or prepared.

SECTION 9 – PRODUCT INFORMATION AND CONSUMER AWARENESS

56. Countries should give consideration to 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.

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[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

9.1 LOT IDENTIFICATION

57. 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.

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

58. 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.

59. 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.

60. 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.

61. 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

62. 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 disposition of contaminated food items.

10.3 INSTRUCTION AND SUPERVISION

63. 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.

64. 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.

ANNEX I

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. Furthermore, studies indicate that there may even be a risk of infection if contaminated bivalve molluscs are consumed after 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 the *Code of Practice for Fish and Fishery Products* (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 by improving sewage treatment efficiency for virus removal/inactivation and avoid discharging of inadequately treated sewage in the surroundings of the bivalve molluscs growing areas. The sanitary survey of harvesting and/or growing water should include an assessment of possible human faecal contamination sources and the intensity of the survey should be in agreement with the occurrence of viral diseases in the human domain and weather conditions, e.g. after heavy rain fall. 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/total coliforms are used as indicators for faecal contamination. Monitoring data should be interpreted within the context of the sanitary survey, as viruses may be present in the absence of these bacterial indicators. A short-term depuration process commonly reduces low levels of bacterial contamination, and thus contributes to the safety of bivalve molluscs but depuration, as usually performed, is inadequate in the elimination of viruses.

7. When there is a likelihood or evidence of virus contamination through epidemiological information, environmental events or direct detection through virological analysis, closure of the area, destruction of

contaminated bivalve molluscs, virucidal heat treatment (see section 5.2.2) before consumption or long term relaying for already harvested bivalve molluscs is recommended. The holding time and minimum temperature during long term relaying are determined by the competent authority having jurisdiction, according to the degree of contamination before relaying, the temperature of the water, the bivalve molluscs species involved and local geographic or hydrographic conditions, to ensure that contamination levels will be adequately reduced. Another option is a combination of depuration and relaying as determined by the competent authority.

8. When there has been a bivalve molluscs-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 equivalent approach to ensure safety should be used as part of the process of reopening the affected harvesting area depending on the requirements of the competent authority, 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

9. 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.

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

11. 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 ad grey water. Volume 3 Waste water and excreta use in aquaculture* (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 per year 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.

12. 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 backgrounds levels for the area. If there is a presumption that the area has been impacted by human sewage, testing of water or bivalve molluscs for the presence of NoV or HAV, as determined by the competent authority or an equivalent approach to ensure safety, may be an option prior to re-opening. Relaying of the implicated bivalve molluscs is another possibility, although new contamination may occur during the relaying period, as the area involved is likely to be susceptible to new contamination events.

13. 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) by the processor before release to retail sales. Alternatively long term relaying or depuration is recommended and should be validated with respect to viral inactivation or removal.

14. 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

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

16. 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 of areas should be reinforced.

17. In addition to the use of clean water during primary production, other control measures for enteric viruses, such as NoV and HAV, include bivalve molluscs depuration and relaying, which should be validated with respect to viral inactivation or removal.

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 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. 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

18. 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 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

19. Refer to the *General Standard for Labelling of Prepackaged Foods (CODEX STAN 1-1985)*. Where appropriate, product labels should include information on safe handling practices and storage recommendations.

20. The competent authority should give consideration to labelling of bivalve molluscs, so that the consumers are adequately informed with respect to their safety regarding possible viral contaminations and true nature (raw or treated) of these products.

9.4 CONSUMER EDUCATION

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

SECTION 10 – TRAINING

10.2 TRAINING PROGRAMMES

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

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

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.

SECTION 4 - ESTABLISHMENT: DESIGN AND FACILITIES

4.4 FACILITIES

4.4.4 Personnel hygiene facilities and toilets

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.

SECTION 5 - CONTROL OF OPERATION

16. 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 as the surface topography 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. Any (new) antiviral treatment should be validated prior

to its use in the production phase. It should be clearly stated for which viruses it has been shown to be virucidal.

SECTION 7 –ESTABLISHMENT: PERSONAL HYGIENE

7.5 VISITORS

17. 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

18. 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.

APPENDIX II

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Annex

GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS

In order to facilitate the compilation and prepare a more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

(i) General Comments

(ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in **underlined/bold font** and deletion in ~~strikethrough font~~.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied / pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.