

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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Agenda Item 8

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty first Session

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

**Comments submitted at Step 3 by: Australia, Costa Rica, Cuba, Jamaica, Malaysia, Mexico,
New Zealand, Peru, United States of America**

AUSTRALIA

Introduction

Page 6, paragraph 4, dot point 1:

Some viruses do cause deterioration of food. For example herpes virus commonly infects some shellfish species and causes significant deterioration of the shellfish and mortality. While viruses such as herpes virus cause deterioration of food they are not a food safety issue for humans, as their host range is limited to the animals that they infect. Consideration should be given to more clearly defining 'viruses' in the introductory section, so that it is clear that the use of the term viruses throughout the document refers to human enteric viruses transmitted via food, not viruses giving rise to disease in other animals. This could be achieved by defining the use of the word 'viruses' in the Introduction section and in Section 2.3, and amending the 'Scope' (Section 2.1) to include the words 'human enteric'.

Page 7, paragraph 6:

The 6th sentence could be modified as "... a result of increased standards of sanitation and hygiene".

Page 8, paragraph 4:

Consideration should be given to expanding the following text to give some specific examples of the types of sewage discharge that lead to virus contamination of bivalve molluscs; this will add strength to the recommended mitigation steps included later in the document. *"for bivalve molluscs that are consumed raw or lightly cooked: through faecal contamination of waters in which they are growing. The contamination most commonly occurs through sewage discharge, run off from agriculture and point source contamination of the immediate surrounding of the growing areas.* Addition of "Sewage discharge from boats, harvesting vessels, on site sewage management systems, sewage treatment plants have been documented to contaminate bivalve molluscs"

Page 8, paragraph 6:

It is suggested that the 3rd sentence be modified to include frozen fresh produce such as berries that have been an issues, e.g. ... shelf-life of the product itself, particularly for contaminated frozen produce such as berries.

Page 8, paragraph 7:

The 3rd sentence of this paragraph seems to have missed the risk at harvest, e.g. manual handling during picking of fresh fruits and vegetables.

Section I – OBJECTIVES

Page 9, paragraph 2:

It is suggested to amend the text as follows: “The primary purpose of these Guidelines is to minimize the risk of illness arising from the presence of *human enteric* viruses, among which norovirus (NoV) and hepatitis A virus (HAV) *are commonly found in some foods.*”

Section II – SCOPE, USE AND DEFINITION

2.1 SCOPE

2.1.1 Food Chain

See comment made under ‘Introduction, Page 6 above’. Consideration should be given to amending the text as follows:

“These guidelines are intended for all kind of foods and are applicable throughout the food chain, from primary production through consumption and are necessary to control *human enteric* viruses in foods in conjunction with Good Hygienic Practices (GHPs) as specified in the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4 (2004)).”

2.2 Use

Suggest amending the text as follows:

“This Guideline follows the format of the Codex Recommended International Code of Practice – General Principles of Food Hygiene- CAC/RCP 1-1969, Rev 4 (2003).”

2.3 DEFINITIONS

See comment made under ‘Introduction, Page 6 above’. Consideration should be given to including a definition for ‘viruses’ as used in this document e.g. ‘human enteric viruses’.

We seek clarification for specifying leafy products in the definition of fresh produce and suggest the standard JEMRA/CCFH wording be used e.g. produce that is marketed fresh and often ready-to-eat. This may include produce that has been peeled, cut or otherwise physically altered from their original form, but remains in a fresh state and is intended for consumption raw.

Definition of Primary production appears to be the same as that of the Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003). To minimise duplications, it is suggested to leave this definition out.

Section III – PRIMARY PRODUCTION/HARVESTING AREA

3.1 Environmental Hygiene

It is not certain what control measures are actually referred in the 3rd sentence as ‘currently used control measures...’.

We suggest rewording to “During primary production, efforts should therefore be made to restrict contact of food, e.g. bivalve molluscs and fresh produce, to high quality water”.

It is unclear what is “high quality water”. Perhaps it refers to “uncontaminated water” or water meets the WHO standard for human consumption.

3.4 Cleaning, Maintenance and Personnel Hygiene at Primary Production

Hepatitis virus excretion begins during the incubation period before symptoms. See 5.1.1. Therefore it is not just a matter of excluding ill or convalescing workers. Indiscriminate defaecation by children in produce growing fields in areas where the disease is endemic and is high in children is a problem as they are difficult to control. Also for workers with no toilet facilities. The latter e.g. older workers may be more of a problem in non-endemic areas. Casual visitors should be excluded from fields etc”

It is noted in the draft Guideline that shedding of viruses may continue post-symptomatically for as long as 2 – 3 weeks. Shedding of norovirus for many weeks after infection is also well documented in the scientific literature. A person who is shedding norovirus should not be involved in the production or preparation of food. Clinical testing for norovirus in humans is widely available and the methods are highly developed and standardised in most countries. It is feasible that employees involved in the handling of food could undergo diagnostic tests for norovirus following bouts of gastroenteritis before undertaking commercial food preparation activities again. Consideration should be given to amending the text as follows:

“In the case of gastroenteritis, allow returning of persons only after a period without symptoms of diarrhoea and vomiting (e.g. period of 48 hours which is an accepted practice), *consideration should also be given to requiring a negative clinical diagnostic test for norovirus following episodes of gastroenteritis*”

Section IV – ESTABLISHMENT: DESIGN AND FACILITIES

4.4. FACILITIES

4.4.4.1 Changing facilities and toilets

It is suggested to add “be culturally appropriate and separate facilities may be required for men and women in some countries” into the 3rd sentence, and replace ‘...adequate means of hygienically...’ with ‘... adequate means for hygienically ...’.

4.4.4.2 Hand Washing Facilities

Consideration should be given to including a recommended time frame for both washing and drying hands. The New Zealand Food Safety Authority recommend following the ‘20-20 rule’ by which hands should be lathered with soap then washed for 20 seconds with warm water, then hands should be dried for 20 seconds with a dry, clean towel or paper towel. Suggest amending the text as follows:

“Hands should be lathered with soap then washed for 20 seconds with warm running water. Hands should then be dried preferably with disposable (paper) towels for a further 20 seconds. This should be encouraged as this it is the most effective way to eliminate viruses and, where possible non-hand operable taps should be available to help prevent re-contamination of clean hands.

Section V – CONTROL OF OPERATION

5.1.1 Identification of steps critical to the safety of food

This section would benefit from some editing to remove confusion - it is hard to understand the meaning and then the connection with next section.

5.1.2 Implement effective control procedures at those steps

1st dot point Does this include growing? Depuration water re-cycled and sanitised by UV etc would not meet drinking water guidelines if it is seawater.

(i) The following text should be amended as follows:

“- Any food possibly contaminated by vomit particles or aerosols containing vomit particles should be disposed of. Any food handled by the ill person during that day (or the day before) *should* be considered a risk.”

(ii) See comment in Section 3.4 above. Suggest amending text in this section as follows:

“Allow returning of recovered persons only after a period without symptoms of diarrhoea and vomiting in case of gastroenteritis (e.g. period of 48 hours which is an accepted practice), consideration should also be given to requiring a negative clinical diagnostic test for norovirus following episodes of gastroenteritis”

(iii) There is a grammatical error in the second to last point, suggest amending as follows:

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

5.3 Incoming Material Requirements

The text repeats text in last dash point at top of page 13.

5.5.1 In contact with food

We seek clarification of the last sentence on page 13 - What does this achieve? Pre-cut and packaged produce many have already been washed and sanitised.

Management and Supervision

We suggest rewording the last sentence to “provide new employees with hand-washing instructions in addition to displaying hand washing instructions on each of the personal hygiene facilities and toilets”.

Section VI – ESTABLISHMENT: MAINTENANCE AND SANITATION

6.1.2 Cleaning Procedures and Methods

(i) Suggest amending text in second paragraph as follows:

“Any food handled by the ill person during that day (or the day before (NoV), or longer (HAV)) could be a risk *and disposal of implicated product should be considered*”

(ii) Suggest amending text in third paragraph as follows:

“One of the effective methods is e.g. *the use of contact with* sodium hypochlorite (1000 ppm) for at least 5 min.”

Section VII – ESTABLISHMENT: PERSONAL HYGIENE

7.2 ILLNESS AND INJURIES

See comment in Section 3.4 above. Suggest amending text in this section as follows:

In *the case of gastroenteritis*, allow returning of persons only after a period without symptoms of diarrhoea and vomiting (e.g. period of 48 hours which is an accepted practice), *consideration should also be given to requiring a negative clinical diagnostic test for norovirus following episodes of gastroenteritis*”

Section X – TRAINING

10.1 AWARENESS AND RESPONSIBILITIES

The responsibilities of employers and managers to carry out some monitoring to ensure that employees are undertaking good hygienic practise should be included in this section.

10.2 Training Programs

It is suggested to change “... virus can be contaminants of food,...” to “... food can carry viruses if contaminated...”.

It is suggested to add “keep children away from food growing fields and food preparation areas in HAV endemic areas” to the end of the paragraph.

ANNEX 1 – HYGIENIC PRACTICE BY FOOD HANDLERS FOR CONTROL OF HEPATITIS A VIRUS (HAV) AND NOROVIRUS (NOV) IN READY TO EAT FOODS

INTRODUCTION

Second paragraph on page 19

For the 2nd sentence, it is suggested that the sentence be modified and take into consideration of virus caused outbreaks due to orange juice provided by an airline, green onions from Mexico, frozen berries in the EU. In addition, vomitus could be more of a risk of person to person transmission than foodborne transmission.

ANNEX II - ANNEX TO THE CONTROL OF HEPATITIS A VIRUS (HAV) AND NOROVIRUS (NOV) IN BIVALVE MOLLUSCS

SECTION III – PRIMARY PRODUCTION

(i) There is very little cohesive international guidance on what types of sewage treatment processes are effective for human enteric viruses or what level of virus reduction through a sewage treatment plant is satisfactory. The Guideline should suggest what types of sewage treatment are most appropriate to inactivate NoV and HAV and the level of virus reduction that is acceptable.

The following text in the first paragraph should be expanded to include this guidance:

“It is important to increase the seawater quality of growing areas by increasing sewage treatment efficiency for virus removal/inactivation and avoid discharge of untreated sewage in the surroundings of the bivalve molluscs growing areas. *Sewage treatment plants should aim to achieve at least 4 log reduction of NoV and HAV through the treatment process and the process should when ever possible involve a tertiary treatment step such as UV sterilisation*”.

(ii) “*When there is a likelihood or evidence of virus contamination through epidemiological information or environmental events or direct detection through virological analysis, long term relaying for at least two months is recommended or destination for exclusively heat treatment before consumption.*”

While NoV has been shown to persist in shellfish for up to several months it is unlikely that the viruses are still viable within the shellfish tissue for more than four weeks. Supporting this scientific evidence suggests

that HAV in oysters was able to be detected by PCR methods for up to six weeks, however the HAV was not found to be viable by plaque assay after three weeks*. Further evidence from the United States also suggests that re-opening times could be shortened. Consideration should be given to shortening the length of time that relaying is recommended for or placing this judgement in the hands of the Competent Authority.

* Kingsley, D. H., and G. P. Richards. 2003. Persistence of Hepatitis A virus in oysters. *Journal of Food Protection* 66:331-334.

(iii) With regards to using ‘*referenced validated methods*’. Ideally a method which has undergone validation via a full inter laboratory study should be used e.g. a CEN, ISO, or AOAC standard method. It is recognised that at the current time such a method for NoV or HAV in shellfish does not exist (though there is a method that is currently undergoing such a validation through CEN). If methods are to be used in the management of impacted production areas they should also be ISO 17025 accredited. Guidance should also be given in the Draft Guideline as to how many samples should be analysed for the purposes of re-opening and the number of shellfish that a sample should comprise.

The text should be expanded to state the following:

...‘monitoring the bivalve molluscs using *methods that have been validated through inter-laboratory studies and are accredited to ISO 17025* may be appropriate as part of the process of closure and reopening the affected harvesting area. *Methods that have undergone extensive single laboratory validation and are accredited to ISO 17025 may be acceptable until a fully validated (inter laboratory study) and standardised method is available.*’

SECTION V – CONTROL OF OPERATION

5.1 CONTROL OF FOOD HAZARDS

5.1.1 Identification of steps critical to the safety of foods

We suggest reviewing this section for example, dot point 1 under 5.1.1 “Safe growing water ...” is a control measure but not an identification step. So is dot point 1 under 5.1.2.

(i) With regards to the second point in this section. Outbreaks of gastroenteritis have been linked to ill harvesters contaminating production areas via defecation directly into the area while undertaking harvesting activities*. Suggest amending the wording as follows:

‘Growing water that is free from sewage discharges or disposal of faecal matter from ships, *recreational boats and shellfish harvesting vessels*’.

* Berg, D. E., M. A. Kohn, T. A. Farley, and L. M. McFarland. 2000. Multi-state outbreaks of acute gastroenteritis traced to fecal-contaminated oysters harvested in Louisiana. *The Journal of Infectious Diseases* 181:S381-S386.

(ii) With regards to the third point in this section. Prevention of overflow from sewerage systems is unavoidable for most systems that are in place world wide. Suggest amending the wording as follows:

“*Prevention of overflow from sewage platforms after heavy rainfall that may contaminate the growing Waters. Every effort should be made to minimize the overflow of untreated or partially treated sewage into growing waters.*”

5.1.2 Implement effective control procedures at those steps

(i) With regards to the second point in this section. There is very little cohesive international guidance on what types of sewage treatment processes are effective for human enteric viruses or what level of virus reduction through a sewage treatment plant is satisfactory. The Guideline should suggest what types of sewage treatment are most appropriate to inactivate NoV and HAV and the level of virus reduction that is acceptable. The following text should be expanded to:

“*Sewage treatments should be improved to obtain maximal reduction of viral loads of the effluents. Sewage treatment processes should aim to achieve at least 4 log reduction of NoV and HAV through the treatment process and the process should when ever possible involve a tertiary treatment step such as UV sterilisation*”.

(ii) Suggest altering the text in the third point in this section to:

“After heavy rainfall, harvesting of bivalve molluscs (especially oysters) should be halted for a period, until the water quality of the harvesting area has been checked *and has returned to normal background levels for the area.*”

(iii) With respect to the third point in this Section. This clause should apply equally to all bivalve molluscs (oysters should not be prioritized, outbreaks of NoV and HAV related to the consumption of other species such as mussels are well documented). Unless there is a belief that rainfall has caused the area to be impacted by human sewage then testing of water or shellfish for viruses by PCR is not necessary. Suggest altering the text to:

“After heavy rainfall, harvesting of bivalve molluscs (*especially oysters*) should be halted for a period, until the water quality of the harvesting area has been checked. *If there is a belief that the area has been impacted by human sewage* testing of water or bivalve molluscs by RT-PCR may be an option prior to re-opening.

(iv) Suggest adding the following points into Section 5.1.2:

(a) “*Systems must be put in place to detect sewage spills and provide prompt notification to the appropriate competent authority as well as the shellfish industry so that appropriate action (i.e. cessation of harvesting) can be taken.*”

(b) “*When raw or partially treated sewage is known or suspected to have entered a growing area shellfish harvesting must immediately cease. Shellfish growing areas must remain closed to harvest for a minimum of 21 days* or until testing of representative shellfish sample(s) by referenced and validated methods have demonstrated that the shellfish are free of NoV and HAV. Absence of faecal indicator bacteria in shellfish or growing waters does not demonstrate absence of NoV or HAV.*”

*Note that the mandatory sewage closure time should be longer for areas with cold water and for certain species. The minimum closure time should be determined by the relevant Competent Authority with regard for water temperature and species harvested.

(v) Suggest adding a new section into part 5.1 of the document as follows:

“*5.1.3 Guidance for areas involved in a virus related shellfish borne outbreak. When a shellfish growing area has been confirmed as the source of an outbreak it is recommended that the following re-opening procedure be followed. If the steps in this procedure cannot be fulfilled the area should cease operation as a shellfish harvest area and alternative arrangements such as relay for at least 60 days should be considered.*

The procedure for re-opening a shellfish growing area involved in a virus related shellfish borne outbreak should be:

- *Systematically identify, assess and where necessary remediate all potential sources of human effluent.*
- *Testing by RT-PCR confirms that there is no on-going contamination of the harvest area by NoV or HAV. (Recommend at least three rounds of testing which include adverse periods such as rainfall or holiday times).*
- *Confirm that the area meets the normal criteria for the commencement of harvest.”*

(vi) Outbreaks of gastroenteritis have been linked to ill harvesters contaminating production areas via defecation directly into the area while undertaking harvesting activities*. Suggest adding a new section into part 5.1 of the document as follows:

* Berg, D. E., M. A. Kohn, T. A. Farley, and L. M. McFarland. 2000. Multi-state outbreaks of acute gastroenteritis traced to

fecal-contaminated oysters harvested in Louisiana. The Journal of Infectious Diseases 181:S381-S386.

“*5.1.4 Disposal of human sewage from harvest vessels*

- *Human sewage should not be discharged overboard from a harvest vessel, or vessel assisting a harvest vessel unless the discharge occurs more than 500 metres from the production area boundary.*
- *An acceptable marine sanitation device, portable toilet or other acceptable sewage disposal receptacle (e.g. a sealed bucket) should be provided on each harvest vessel to contain human sewage.*
- *Portable toilets and other acceptable sewage disposal receptacles should —*

(a) be secured while on board and located to prevent contamination of bivalve molluscs by spillage or leakage; and

(b) be maintained in a sanitary manner; and

(c) be constructed of impervious, cleanable material and have a tight fitting lid.

- Harvest operators should ensure that acceptable hand washing and sanitising facilities (e.g. potable water and soap) are provided on harvest vessels.

- All persons on board a harvest vessel should wash and sanitise their hands after using the toilet.

SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENESS

9.1 LOT IDENTIFICATION

A definition of ‘recent’ should be included in the Guideline. Due to the length of time that viruses can persist in shellfish (e.g. several months) the lot identification should enable identification of growing waters for a two month period prior to harvest. “For traceability (e.g. outbreak investigation), lot identification should therefore enable identification of all *recent* growing waters *for a two month period prior to harvest.*”

9.3 LABELLING

Some bivalve molluscs are produced in areas which are remote from human habitation and sources of human sewage. When bivalves are produced in areas such as these the risk of consumers becoming infected with NoV and HAV after consumption is significantly reduced and similar to all other food types. Therefore the recommendation of labelling all molluscs as requiring end product treatment is unwarranted. Suggest the removal of this section as it is not appropriate for all molluscs.

COSTA RICA

Costa Rica appreciates the opportunity to comment on this document and also would like to congratulate this working group for addressing such an important topic. Costa Rica presents the following comments:

1. In each of its sections, the new code of practice proposal includes references to the content of Codes of Practice that have already been developed within Codex. Therefore, Costa Rica considers the development of a new document unnecessary if this topic can be included in existing ones.

In this regard, Costa Rica proposes that the topic of viruses in food be included, where appropriate, in the following documents:

- Codex Recommended International Code of Practice - General Principles of Food Hygiene - CAC/RCP 1-1969, rev. 4 (2003).
 - Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003, section 7).
 - Standard for Live and Raw Bivalve Molluscs (Codex Stan 292-2008).
 - Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003).
 - Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007).
 - Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993).
2. Also, Costa Rica proposes to include in the review and update of the codes of practice, where appropriate, the vaccination against the HAV infection as a preventive measure, taking into account the epidemiological situation and/or immune status.
 3. In addition, the revision and update of the codes of practice should include as a preventive measure, where appropriate, the use of suitable disinfecting agents to eliminate viruses, as these are not specified in the document proposal.

CUBA

Cuba endorses the content of the above mentioned document and highlights the importance of continuing to examine it in order to ratify its support at the Session of the CCFH and at the 33rd Session of the Codex Alimentarius Commission.

JAMAICA

Section 2.3

There is a definition for food worker, however, the preferred term would be food Handler because elsewhere in the code the word Food Handler is used. The definition of food handler could be stated as “*any individual who is involved in the handling, preparation, storage, distribution of food for the intended purpose of human consumption*”.

Section 3.1

This sentence is not clear “*During primary production, efforts should therefore be made to restrict contact of food, e.g. bivalve molluscs and fresh produce, with high quality water only.*”

During primary production, efforts should therefore be made to restrict contact of food, e.g. bivalve molluscs and fresh produce, with high quality water. It would be better worded “During primary production, where Food e.g. Bivalve molluscs and fresh produce have to make contact with water, that is, water is of potable quality”.

Section 3.2

We suggest deleting “*especially if the products do not undergo a treatment that ensures the elimination of virus infectivity before consumption*” because we believe that this is granting permission for the product to be exposed to these contaminants if they intend to put same through treatment that may destroy them”.

Section 3.4

The words “In case of complaints of acute hepatitis ...” need to be replaced as no person ever complains of acute hepatitis. Persons complain of **symptoms** of acute hepatitis.

Is it necessary to list all symptoms of viral infection in the code? It might be more all inclusive to make a broad statement that would cover all illnesses because as a rule no sick person should be involved with the handling of food at any stage of the production process, if a food handlers becomes ill he or she should report to their supervisor and be removed from the food handling area.....

MALAYSIA

Malaysia notes the following terms which is defined by Codex:

Food worker – any person who touches or handles unpackaged food

(Note: As in the draft document)

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

(Note: As in *Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003)*)

The definition of food worker excludes the direct handling of unpackaged food, food equipment and utensils, or food contact surfaces. We suggest the use of the term **food handler** in the document for consistency with the document *CAC/RCP 1-1969*. Furthermore, transmission of virus is possible via handling of packaged food, food equipment and utensils, or food contact surfaces.

Specific Comment

SECTION III - PRIMARY PRODUCTION/HARVESTING AREA

3.1 ENVIRONMENTAL HYGIENE

This section states that contact with food is only with *high quality water*. The use of the term “high quality water” needs to be defined in section 2.3 if *high quality water* is water quality other than of potable water.

MEXICO

Mexico reaffirms its commitment to the Codex Alimentarius and thanks the Committee for the opportunity to comment on the Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food at Step 3.

General comments:

- We ask for clarification of the term “enteric virus”, which for the purposes of this document refers to both Norovirus and the Hepatitis A virus, even though the latter is not specifically enteric.
- We consider that Annexes I, II and III are very repetitive with regard to the main document. We propose stipulating in more detail the hygienic practices that contribute to reducing the risk of viral contamination, specifically for the products addressed by each Annex.

| | Location in the text | Comment |
|----|--|--|
| 1. | INTRODUCTION Page 8, paragraph 7 of English version | To improve clarity, we suggest substituting the text “acid resistance” with “resistance to gastric juices”. |
| 2. | 2.3 DEFINITIONS <i>Fresh produce</i> | The definition is unclear because it does not define whether it refers to food that is eaten raw (with no heat treatment). If this is the case, it is necessary to mention that there is food of animal and vegetable origin that is eaten raw. Therefore, we propose the following definition: <i>Fresh produce: products that are not heat treated prior to consumption.</i> |
| 3. | Item 3.1 ENVIRONMENTAL HYGIENE Last line of the paragraph where a reference is made to “high quality water”. | We ask for a definition of the term “high quality water”, since other documents use the term “potable water” or “clean water”. Mexico asks for a clarification of the difference that exists relative to the term “potable water”. |
| 4. | 3.2 HYGIENIC PRODUCTION OF FOOD SOURCES In regards to the last paragraph, where it states: “...that ensures the elimination of virus infectivity before consumption.” | We suggest changing the term “virus infectivity” to “viruses” as this is more accurate. Likewise, we suggest ensuring that this term is deleted throughout the document. |
| 5. | 3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION | The [second] paragraph is very long. We suggest summarizing it or dividing it. We recommend emphasizing the personnel aspects of hygiene and disinfection in order to avoid the risk of viral contamination. |
| 6. | 5.1.1 <i>Identification of steps critical to the safety of food</i> | There is a lack of coherence between the title and the bulleted points of item 5.1.1. The title refers to the steps within the production process, and the bulleted points refer to the activities or recommendations to be carried out for food safety. |

NEW ZEALAND

New Zealand would like to thank the Working Group led by the Netherlands for preparing a draft document and welcomes the opportunity to provide comments on the “Proposed Draft Guidelines on Application of General Principles of Food Hygiene to The Control of Viruses in Food at Step 3”.

General Comments

New Zealand supports the development of Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food and provides the following comments in preparation for the 41st session of the Codex Committee on Food Hygiene (CCFH) in November 2009.

New Zealand notes that the document contains some repetition/duplication of information and grammatical irregularities, but recognises this is likely to be rectified in future versions of the document. Furthermore some sections contain a large amount of information that is presented in paragraph form where listing this as bullet points would enhance clarity and accessibility.

New Zealand asks if a separate ANNEX (Annex I) “Hygienic Practice By Food Handlers For Control Of Hepatitis A Virus (HAV) And Norovirus (NoV) In Ready To Eat Foods” is required as the content is generic and already covered in the General Guidelines. Recommend instead that a statement is included in the general guidelines in Section VII – Establishment of Personal Hygiene, OBJECTIVE, (see specific comments) that emphasises the need for strict hygiene control by food handlers, particularly in relation to the prevention of HAV and NOV.

Specific Comments:

Paragraph 3 bullet point 3. The sentence does not state what is being compared to foodborne viruses. New Zealand proposes change to “Most food-borne viruses are non-enveloped and are therefore less susceptible ~~to~~ than bacteria to inactivation by intrinsic and extrinsic parameters commonly used in food preservation.

SECTION I - OBJECTIVES

New Zealand notes that while specific hazard food combinations have been identified this should not exclude the general section from covering risks from emerging foodborne viruses e.g. Hepatitis E Virus, as the general controls should also be applicable to these.

New Zealand proposes that the following sentence be included:

“Information provided in this guideline may assist in minimising the risks of foodborne illness from new and emerging zoonotic viruses in foods.”

SECTION II – SCOPE, USE AND DEFINITIONS

2.1.1 Food chain

Paragraph 1. New Zealand suggests that in order to define the scope further the first paragraph be rewritten as

“These guidelines are intended for all kind of foods and are applicable from primary production and processing through consumption and are necessary to control viruses in foods. These should not compromise controls in place for any other pathogens. These guidelines should be used in conjunction with Good Hygienic Practices (GHPs) as specified in the Recommended International Code of Practice ...”

2.3 Definitions

New Zealand notes that the definitions provided in the Code of Hygiene Practice for Fresh Fruit and Vegetables are also applicable and should be referred to here. New Zealand proposes

“For the purpose of this Code, refer to definitions of the “Recommended International Code of Practice – General Principles of Food Hygiene- CAC/RCP 1-1969, Rev 4 (2004), Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003) and) and Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003)”.

Fresh produce – New Zealand recommends this definition is amended to include the words –fresh fruit and vegetables to reflect terminology used in other Codex documents (e.g. Code of Hygiene Practice for Fruits and Vegetables (CAC 53-2003). Propose

~~“Fresh produce – including leafy products~~ fresh fruit and vegetables”

Food worker – New Zealand notes Annex III refers to “food handlers” and “food-handlers and personnel”, “food handlers” seems a more appropriate term for this document since its referring to viruses – and the association with the physical aspect of ‘handling’. New Zealand proposes *“Food worker-handler – any person who touches or handles unpacked food”*

SECTION III – PRIMARY PRODUCTION/HARVESTING AREA

New Zealand notes the document should refer to the following guidelines that are applicable to this section and subsequent subsections. Propose

“Refer to the “Recommended International Code of Practice – General Principles of Food Hygiene-CAC/RCP 1-1969, Rev 4 (2004), Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003) and Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003)”.

3.1 ENVIRONMENTAL HYGIENE

Sentence 2. New Zealand suggests rewriting the sentence to account for the use of manures or use of human waste as fertilizer.

~~“One of the sources of viral contamination of food at the primary production site is due~~

~~to the use of water or soil that is contaminated by faeces of human or animal origin~~ *Sources of viral contamination of food at the primary production site include the use of water, soil, manures or fertilizers contaminated by faeces of human or animal origin.”*

Sentence 3. New Zealand considers this sentence ambiguous as it talks about restricting contact of food **with** high quality water, although water is a growing medium for bivalve molluscs and used in irrigation for fresh produce. New Zealand proposes the sentence *“During primary production, efforts should ~~therefore~~ be made to ensure that food, e.g. bivalve molluscs and fresh produce, ~~with~~ only has contact with high quality water.”*

SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION

Section 6.1.2 Cleaning procedures and methods

Paragraph 2 sentence 6. The statement “can take place appropriately” is unclear. New Zealand proposes *“Surfaces should be cleaned ~~before disinfection can take place appropriately~~ to ensure effective disinfection”*

Paragraph 3 sentence 5. New Zealand notes that disinfection is more effective after a surface has been cleaned and debris has been removed and proposes the sentence read *“Food preparation should only begin after ~~thoroughly disinfection~~ cleaning and disinfection has taken place.”*

SECTION V - CONTROL OF OPERATION

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

New Zealand believes that the draft proposed guidelines should refer here to further processing that could be used to mitigate the risk from viruses e.g. irradiation, heat-pressure processing, heating to a temperature of 90°C for 90 seconds, and proposes

“The use virucidal processes e.g. heat treatment (temperature of 90°C for 1.5 minutes), irradiation, high-pressure processing, may under certain circumstances be useful to mitigate the risk from viruses present in food. These virucidal processes should be validated for the hazard food combination to ensure that the treatments are effective and can be applied consistently. It should be noted that either cooling or freezing will not affect virus activity.”*

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

SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE

OBJECTIVES: New Zealand notes the statement is unclear and proposes *“OBJECTIVES: To prevent food handlers ~~to contaminate~~ contaminating food with viruses (in particular HAV and NoV) due to poor personal hygiene”*

SECTION X – TRAINING

OBJECTIVE: New Zealand suggests expanding and clarifying the term “operation” and proposes

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

10.2 TRAINING PROGRAMMES

Sentence 2. New Zealand believes that training programmes should also provide information on the potential sources and transmission of viruses, resistant nature of viruses and the persistence of viruses in the environment and proposes

“Training programmes should contain information on the following: viruses as

contaminants of food, the potential sources and routes of transmission of viruses, the resistant nature of foodborne viruses the persistence of these viruses in the environment, knowledge on the incubation periods of viruses, ~~and on~~ specifically NoV and HAV ~~in specific~~, on the duration of virus shedding even after recovery from clinical symptoms, on possibility of a-symptomatic shedding, on the infectivity of vomits,...”

10.3 INSTRUCTION AND SUPERVISION

Sentence 2. New Zealand proposes this sentence be phrased to improve clarity

“~~Extent~~ Extensive training and instructions should be given to new all employees on the infectivity, transmission and disinfection of foodborne viruses ~~to knowledge on infectivity, transmission and disinfection of viruses should be given to all new employees.~~”

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

10.3 INSTRUCTION AND SUPERVISION

Sentence 2. New Zealand proposes this sentence be phrased to improve clarity

“~~Extent~~ Extensive training and instructions should be given to new all employees on the infectivity, transmission and disinfection of NoV and HAV viruses ~~to knowledge on infectivity, transmission and disinfection of viruses should be given to all new employees.~~”

ANNEX II ANNEX TO THE CONTROL OF HEPATITIS A VIRUS (HAV) AND NOROVIRUS (NOV) IN BIVALVE MOLLUSCS

Section II –Scope, Use and definition

Paragraph 2 sentence 2. New Zealand notes that the WHO “Guidelines for the safe use of wastewater, excreta and greywater. Volume 3: Wastewater and excreta use in aquaculture” (World Health Organization 2006 ISBN 92 4 154684 0; www.who.int/water_sanitation_health/wastewater/gsuweg3/en/index.html) is also a useful source of protection measures.

Propose *“More specific control measures for bivalve molluscs can be found in the “Code of Practice for Fish and Fishery products (CAC/RCP 52-2003, Section 7)”, the “Standard for Live and Raw bivalve Molluscs (Codex Stan 292-2008) and the WHO “ Guidelines for the safe use of wastewater, excreta and greywater. Volume 3: Wastewater and excreta use in aquaculture (World Health Organization 2006 ISBN 92 4 154684 0; www.who.int/water_sanitation_health/wastewater/gsuweg3/en/index.html)”*

SECTION III- PRIMARY PRODUCTION

Paragraph 2. New Zealand notes that the Code of Practice for Fish and Fishery products should also be referenced and proposes

“Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003), Code of Practice for Fish and Fishery products (CAC/RCP 52-2003, Section 7)” and the “Standard for Live and Raw bivalve Molluscs (Codex Stan 292-2008)”

SECTION V - CONTROL OF OPERATION

Sentence 1. New Zealand notes that the Code of Practice for Fish and Fishery products should also be referenced and proposes

“Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003), Code of Practice for Fish and Fishery products (CAC/RCP 52-2003, Section 7)” and the “Standard for Live and Raw bivalve Molluscs (Codex Stan 292-2008)”

Section 5.1.2 Implement effective control procedures at those steps

Bullet point 3 sentence 2. RT-PCR is a general technique not a specific test. New Zealand proposes *“Testing of water or bivalve molluscs for NoV and/or HAV by RT-PCR may be an option prior to re-opening”*

5.2.1 Specific process steps

Sentence 1. New Zealand notes that other processes in addition to cooking, such as high pressure processing may be available and should be considered. Propose the sentence read

“The country’s competent authority should approve commercial heat treatment or other effective and validated virucidal processes...”

ANNEX III CONTROL OF HEPATITIS A VIRUS (HAV) AND NOROVIRUS (NOV) IN FRESH PRODUCE

Introduction sentence 3. New Zealand believes this statement needs to have a broader scope and proposes the sentence be rewritten. *“The contamination of ~~the~~ fresh produce may occur ~~either at the pre-harvest stage (sewage contaminated water, infected pickers) or at the post-harvest phase (infected food handlers)~~ at any stage from production (sources include contaminated water or soil and infected food handlers) through to use by the consumer”*

2.1 Scope

Paragraph 1 sentence 2. New Zealand suggests that the term “fresh produce” should be used consistently in the document and replace the term “fresh fruits and vegetables”. Proposes *“Specifically, this Annex is applicable to fresh produce ~~fruits and vegetables~~ grown in the field ...”*

Paragraph 2 sentence 1. New Zealand suggests that the term “fresh produce” be used consistently in the document and replace the term “fresh fruits and vegetables”. Proposes *“Although it is important for the safety of NoV and HAV in fresh produce, this annex does not provide recommendations for handling practices to maintain the safety of fresh produce ~~fruits and vegetables~~ at wholesale,*

2.3 DEFINITIONS: Fresh produce

To maintain consistency with other CODEX documents New Zealand proposes the definition of Fresh produce be amended to **“Fresh produce** – fresh fruit and vegetables

Section III – PRIMARY PRODUCTION

Paragraph 1 sentence 1. New Zealand suggests that the term “fresh produce” be used consistently in the document and replace the term “fresh fruits and vegetables”. Proposes *“Fresh produce ~~fruits and vegetables~~ are grown and harvested under a wide range of climatic and diverse geographical...”*

Paragraph 1 sentence 4. New Zealand suggests that the term “fresh produce” be used consistently in the document and replace the term “fresh fruits and vegetables”. Proposes *“...health due to the contamination of fresh produce ~~fruits and vegetables~~.”*

Section 3.1 ENVIRONMENTAL HYGIENE

SENTENCE 1. NEW ZEALAND NOTES THE INCREASING GLOBAL USE OF WASTEWATER, EXCRETA AND GREY WATER AS A RESOURCE IN AGRICULTURE AND CONSIDERS IT IMPORTANT THAT THIS SECTION REFER TO THE 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; [HTTP://WWW.WHO.INT/WATER_SANITATION_HEALTH/WASTEWATER/WWUVOL2CHAP1.PDF](http://www.who.int/water_sanitation_health/wastewater/WWUVOL2CHAP1.PDF)).

Proposes “*Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP1-1969, Rev 4 (2003), Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003) and WHO Guidelines for the safe use of wastewater, excreta and greywater. Volume 2: Wastewater use in agriculture (World Health Organization 2006 ISBN 92 4 154683 2, v. 2).*

Page 28 3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

New Zealand asks if this Annex is expected to cover risks from zoonotic viruses. New Zealand notes that in the Introduction to the general guidelines the text states, “During the FAO/WHO Expert meeting on “Viruses in Food”¹, three major routes of viral contamination of foods were identified to be: 1) human sewage/faeces, 2) infected food handlers and 3) animals for zoonotic viruses...” If zoonotic virus infections are to be addressed New Zealand proposes including the sentence “*To minimise the potential risk of contamination of fresh produce posed by zoonotic viruses measures should taken to restrict access of wild and domestic animals to fresh produce production sites.*”

Page 29 SECTION V - CONTROL OF OPERATION

Sentence 2. New Zealand notes that additional references relevant to this section have been omitted and proposes “*Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP1-1969, Rev 4 (2003), Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003) and WHO Guidelines for the safe use of wastewater, excreta and greywater. Volume 2: Wastewater use in agriculture (World Health Organization 2006 ISBN 92 4 154683 2, v. 2).*

5.1.1 Bullet point 1 and elsewhere in document – The term “water of high quality” should be consistent with wording in CAC/RCP 53 – 2003. New Zealand suggests use of the term “clean water” as defined in CAC/RCP 53 – 2003 thus “*Use of clean water of high quality during the whole production process, until the day of harvest.*”

5.1.1 Bullet point 3. New Zealand notes that the term sewage platform is restrictive and proposes “*Prevention of overflow from sewage platforms and septic tank systems after heavy rainfall that may contaminate the surface water used for production of fresh produce.*”

5.1.1 New Zealand suggests an additional bullet point “*- If the land is determined to be contaminated with pathogenic human viruses then further measures must be taken to reduce the risk to acceptable levels.*”

PERU

We propose the following changes and/or additions:

- Consequently, it is ~~conceivable~~ **evident** that considerable numbers of infectious viruses will remain when hand sanitizers are used instead of traditional hygienic hand washing with streaming water and soap followed by drying using disposable towels. (Page 8, paragraph 8).
- Regarding the objectives, these should be written as follows:
 - minimize the risk...,
 - provide advice to governments..., and
 - provide information that will be of interest to...
- **Fresh produce:** Any food in its natural state, which has not undergone any type of physical or chemical transformation.

- Instead of using the term "food worker", we suggest using the term "food handler", which is defined as any individual who is in direct or indirect contact with food in any phase or step in the food chain.
- **Primary production:** those steps involved in the growing and harvesting of fresh fruits and vegetables such as planting, irrigation, application of fertilizers, application of agricultural chemicals, etc. (Use the definition contained in the Code of Hygienic Practice for Fresh Fruits and Vegetables).
- With regard to the health status (item 3.4), we suggest emphasizing that the personnel involved in food manufacturing activities or those who have access to the manufacturing area, must not be carriers nor have symptoms of infectious/contagious diseases. This will be permanently monitored by the employer.
- In Annex II, it can be considered that disease outbreaks caused by enteric viruses after consumption of molluscs constitute an important public health hazard worldwide. The main responsible viruses are the Norovirus (Norwalk virus group), due to its high incidence throughout the world, and the Hepatitis A virus, due to the seriousness of the disease it causes. In addition, the depuration techniques for bivalve molluscs, although effective for bacterial elimination, are incapable of eliminating viral particles completely. On the other hand, in recent years, a large amount of evidence has been obtained regarding the importance of international commercial operations (including imports and exports of fresh or semi processed molluscs) in the transmission of viral gastroenteritis and Hepatitis A between remotely located geographical areas.

UNITED STATES

The United States thanks the Committee for the opportunity to review the document on

"Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food at Step 3".

General comments:

The document provides a brief description of foodborne viral pathogens as a public health problem, and guidance that operators can use to minimize the opportunity for viral contamination. Three appendices deal with specific foods (ready to eat foods, bivalve molluscs, and fresh produce). The most common viral pathogens associated with foodborne illness are norovirus (NoV) and hepatitis A virus (HAV). Other viruses could also be present in food, and the document briefly considers zoonoses such as Nipah, hepatitis E and Avian Influenza type H5N1 virus as emerging foodborne pathogens, but concludes there are insufficient data available to comment further. NoV and HAV are primarily human viruses that are spread by contact with vomitus, feces, and/or associated aerosols, which may be deposited on foods or food contact surfaces. Accordingly, the guidance focuses on hygienic procedures to prevent the spread of contaminated materials such as simple hand washing, excluding ill workers from handling foods, and enhanced vigilance when viral transmission is apparent in the community (i.e., among workers, their families, or customers). Because NoV and HAV are non-enveloped viruses (i.e., composed of nucleic acid encapsidated in a shell composed of viral protein, not a membrane derived lipid bilayer), interventions or disinfection procedures designed and validated to destroy bacteria pathogens may not be effective against foodborne viruses. For example, the guidelines indicate that alcohol-based hand sanitizers are not as effective as traditional hand washing at eliminating viral contaminants from soiled hands. The document states that *E.coli* or fecal coliforms are the preferred indicator for fecal contamination in natural or irrigation waters. However, we believe that the presence of non-enveloped viruses in natural or treated waters may not be adequately indicated by the presence of traditional bacterial indicators due to their different physical properties. Although hygienic procedures should be applied to all food production activities, Bivalve molluscs and fresh produce may be contaminated before harvesting. The United States is pleased to see that control at the growing area does mention water quality, and even recommends determining that after rainfall events; therefore, the document provides additional guidelines for ensuring the quality of waters used for growing or irrigation. Depuration is not considered to be an effective intervention for reducing NoV contamination of molluscs.

Generally, these guidelines should be useful to regulated establishments making RTE products. The document is consistent with the United States thinking as it relates to shellfish. It makes a strong point that control for shellfish is most appropriately addressed at the harvest area level, citing water quality and pollution source survey as key elements of control. The HACCP concept is adaptable to any potential foodborne hazard, and the guidance could be used by establishments desiring to consider NoV or HAV as

hazards reasonably likely to occur, especially those developing sanitation protocols to address these hazards. The document does not provide very much information on interventions, other than sanitation, that could reduce viral contamination in foods. While we agree that the primary focus should be on personal hygiene and proper sanitation, interventions such as high pressure processing, irradiation, and thermal processing, have been validated for NoV and other foodborne viruses. The availability of alternative, non-destructive interventions would appear to be crucial for molluscs and fresh produce industries. It would also be helpful to have a discussion of antiviral activity associated with detergents and sanitizers (e.g., hypochlorite, quaternary ammonium, or iodine based compounds) commonly used in the food industry.

In addition, while the United States can appreciate the thinking behind establishing 3 annexes (RTE, mollusks and produce), we question whether all are needed. Specifically, we suggest deleting the annex on RTE foods, as there is nothing in it that was not covered in the base document. There may be some specific requirements for the other annexes, especially for the one on bivalve mollusks that justify a separate annex.

Specific comments (drafting suggestions underlined):

1) Pg. 6. Introduction

Insert “soil”: Viruses transmitted by the faecal-oral route have been shown to be hardy and to persist in the environment for weeks to months in soil, water, marine sediments or bivalve molluscs or on various inanimate surfaces.

2) Pg. 6. Paragraph 6: Regarding the statement “Even though high numbers of viral particles are shed in the stools of asymptomatic or infected persons (e.g. *exceeding 10^7 particles per gram of stool*)”, NoV is now estimated as high as 1 trillion viral particles per gram of stool.

3) Pg. 7. Insert “a”: 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*

4) Regarding the statement; “Estimates of the burden of disease due to NoV range from 11-3067 cases per 100 000 persons per year.” What data is this range based on? Does this range include worldwide numbers?

In the U.S. there are ~23 million cases of NV infection that occur annually; i.e., ~7600/100,000. Norovirus is responsible for more than 50% of all foodborne gastroenteritis outbreaks and 35% of all sporadic gastroenteritis outbreaks, as well as a major cause of gastrointestinal illness in hospitals and nursing homes in the United States

5) Pg. 7. Norovirus. The United States suggests the inclusion of the fact that 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 in an enclosed environment.

6) Pg. 7. Paragraph 4: Regarding the statement: “HAV and rotavirus were the major food-borne viruses that cause severe disease and significant mortality”, even though NoV is typically less virulent, it has also has caused significant mortality in the elderly and immune compromised because of the high number of NoV illness cases. It has been estimated to be equivalent to Salmonella foodborne illness deaths worldwide. The United States suggests revising the statement to reflect this.

7) Pg 7. NoV: Symptoms of NoV infection might be better described as sudden onset vomiting and/or diarrhea, as either or both symptoms may be present without any specific order to the syndrome.

8) Pg 7. NoV: Regarding the statement: “A NoV infected person sheds a large amount of infectious virus particles while having symptoms, but also before the onset of symptoms and may continue to shed up to 3 weeks after resolution of symptoms even in immuno-competent persons”, recent evidence suggests that median duration of shedding is 4 weeks, and in some cases may continue up to 8 weeks in otherwise healthy individuals. The United States suggests changing the statement to reflect this information.

9) Pg 7. HAV: Regarding shedding of viral particles, data show that HAV viral numbers shed in the faces in numbers in a range from 10^6 – 10^8 particles per gram of faces. The United States suggests changing the statement to reflect this information.

10) Pg. 8. Bullet 1. Food handlers can also contaminate food when transferring viruses from contaminated surfaces to hands during preparation of ready-to-eat food or when transferring viruses from contaminated food items to other ready-to-eat food items. The United States suggests changing the statement to reflect this information.

11) Pg. 8. Transmission routes: include contaminated utensils, e.g., chopping equipment, such as a dicer; cutting knives, serving utensils, in both the ready-to-eat food and fresh produce bullets.

12) Pg 8. Regarding bivalve mollusks, the United States suggests noting that NoV do not simply contaminate surfaces as with other food commodities, but actually bind to the gut of bivalve molluscs and can thereby bio-accumulate.

13) Pg. 8. Insert "soil": The *persistence* of viruses in soil, water, on inanimate surfaces or in foods is well documented.

14) Pg. 8. Insert "soil (used for primary cultivation),"; *for fresh produce:* through contaminated soil (used for primary cultivation), water (used for irrigation, or fertilizer application, or wash water)

15) Pg. 8. Middle of page on "no realistic post-harvest risk management options", suggest adding the word "primarily" to "Such prevention will have to occur at the pre-harvest level..." so that it reads "Such prevention will have to occur primarily at the pre-harvest level..." (since we still need to prevent contamination during handling by food workers).

16) Pg. 8. The same paragraph ends with "If viruses contaminate foods at the end of the food chain, acid resistance and ...are more important." More important than what?

17) Pg. 8. Next to the last paragraph on Health Canada methods, change "~~it's~~" to "its"

18) Pg. 9. Objectives

The United States suggests re-writing the first sentence; something appears to have been left out.

19) Pg. 9. 2.1.1 Food chain

Change the first sentence to read "These guidelines are applicable to all foods throughout the food chain..." to enhance readability

20) Pg. 9. 2.2 Use

The references to the annexes should be changed so they use the actual titles that appear in the annexes.

21) Pg. 10. *NoV* – *should read:* norovirus, formerly known as Norwalk-like virus.

22) 3.1 Environmental hygiene

Should it include reference to the fresh fruit and vegetable document as well as the General Principles of Food Hygiene (GPFH)?

23) Pg. 10. Same paragraph as above. In the last lines after the e.g., it should be "to high quality water" rather than "with" ("restrict...to", not "restrict...with")

24) Pg 10. Same line. *Need to define* "high quality water"

25) Pg. 10. 3.4. Last line on page. Insert "to production area": A person with symptoms of acute hepatitis should seek medical advice. In case of gastroenteritis, allow returning of persons to production area only after a period 10)

26) Pg. 10. Same section. 3.4 Cleaning. Line 3 change "excluded to be present in..." to "excluded from..."

27) Pg. 11, line 1 and Page 13, 3rd paragraph and Page 16, 7.2. Regarding return of sick workers to work, the United States suggests changing 48 hours to 72 hours.

28) Pg. 11. Section 4: Change to: RATIONALE: Inability to properly clean and disinfect may result in persistence of the virus leading to potential contamination of food.

29) Pg. 11. Pg 11 Line 4. As noted earlier, recent evidence suggests shedding on average for 4 weeks.

30) Pg. 12. 5.1.1 Identification of steps critical to the safety of food

The U.S. is unclear about the purpose of this section, and the bullets do not seem to fit the header. We request that the working group provide clarification as to the intent of this section..

31) Pg 12. Given the potential for food handler contamination even when that food handler is not actually infected (e.g., care giver for infected child at home), any deviation from strict hygienic practice may represent a risk for viral contamination. As such, suggest revising this sentence.

32) Pg. 12. 5.1.2 Implement effective control procedures at those steps

Again, the purpose of the section is unclear. Perhaps 5.1.1 is meant to be situations in which viral contamination occurs and 5.1.2 the control measures. In this case, since section 5.1 is control measures, these bullets in 5.1.2 are all that need to be listed. The first bullet here is not needed - water is addressed in 5.5. The second and third bullets deals with personnel hygiene, which is in section 7. A better approach might be to refer to the appropriate sections of the document and not repeat text. In the 4th bullet with respect to "vomit particles or aerosols containing vomit particles" is the second part needed? (this could be changed to "...vomit particles, including through aerosols..."). The next 4 bullets on page 13 should be addressed in section 7. The last bullet is repeated in 5.3; to avoid redundancy this bullet should refer to the appropriate section.

33) Pg. 13 bullet 2; insert "and/or serve as a fomite carrying infectious virus on their person"; I.e., acknowledge the fact that when a family/house member of one of the staff members has symptoms of gastroenteritis or hepatitis, the staff member may also be (asymptotically) infected, and/or serve as a fomite carrying infectious virus on their person.

34) Pg. 13. 5.5.1 and 5.5.2 should refer to the GPFH. Reference to the WHO guidelines for drinking water quality is not needed as the GPFH defines potable water in 4.4.1 as meeting WHO guidelines for drinking water quality. The same applies in 5.5.3.

35) Pg. 14. 5.5.4 repeats text in GPFH 4.4.1 on non-potable water and only reference to that section is needed.

36) Pg. 15. Paragraph 2.

Advice should be provided on appropriate disposal of materials used to clean up feces and vomit.

Rubber gloves should not be used, unless procedures are in place to properly sanitize the gloves after each use. Clean-up of vomit should only be done by employees that have been trained in cleaning-up infectious material. Proper personal protective equipment for personnel cleaning vomit should include face masks, disposable gloves, and aprons.

37) Pg. 15. Paragraph 3. On what data is the 1000ppm for at least 5 min. based? Many recent studies have found 5000 ppm sodium hypochlorite for 5 min. is needed to eliminate NoV. Data finding 1000 ppm sodium hypochlorite effective is based on the effect on feline calicivirus (FCV), which has been found to be a poor surrogate for chemical disinfection of NoV. However, 1000 ppm of freshly constituted Sodium Dichloroisocyanurate (NaDCC) has been found to have a 5 log reduction against FCV with a 1-minute contact time, and with a reduction this large, this indicates that it may also be effective against NoV.

38) Pg. 15. Same paragraph. Second sentence, should begin "One effective method is the use of..." for clarity

39) Pg. 15. 6.4 add "food contact" before "surfaces" at the end.

40) Pg. 15. Section VII Objectives

Reword for clarity "To prevent food handlers from contaminating food due to..."

41) Pg. 16. 7.1, middle of second paragraph reword for clarity: "Persons reporting the above symptoms should therefore be excluded from handling food or being present..." The last sentence should be deleted as it is not needed.

42) Pg. 16. 7.2 - much of the beginning of the paragraph is a repeat from 7. and should thus be deleted in one place or the other. The second part of the paragraph is a repeat from the bottom of page 10 and the top of page 11 in the primary production area. It is more appropriate here, and perhaps the earlier section should refer to this section. The working group should reassess the advice at the end of the paragraph - how likely is it that if one staff member has symptoms of gastroenteritis or hepatitis other staff members may be asymptotically infected? It would be better to recommend that if one staff member has symptoms, the establishment should evaluate the potential for other staff members to be infected, particularly in the case of

HAV. Moreover, the advice here is to comply with strict hand hygiene. Is there “regular” hand hygiene and then “strict” hand hygiene that apply in different scenarios?

43) Pg. 17. Section 7.5. Gloves. Suggest revising second to last sentence of paragraph as shown:

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

44) Pg. 17. IX.

The United States suggests this be rewritten, as it suggests labeling with a virus warning.

45) Pg. 18. 10.1. Suggest adding phrase and changing last sentence as follows:

It is the responsibility of the managers to educate and train their employees, to monitor employees to ensure they practice what they learned, to keep control on the level of awareness of the training content, and have both cleaning and disinfection programs operational.

46) Pg. 18. 10.2. Suggest including new last sentence as shown below:

..., and in addition if a household member is ill, probably the staff member may be (asymptotically) infected too. Staff employees should also be taught to stay away from work and not have direct contact with any ready-to-eat food if they have symptoms.

47) Pg. 18. 10.3. The United States suggests deleting the word "Extent" in line 2 of the paragraph; we do not think it is necessary.

48) Pg. 19. Annex I - not needed

49) Pg. 19. Annex 1. Introduction. “Since vomiting is a symptom of NoV infection in 70-80% of the cases,” *What data is this percentage based on?*

SECTION III - PRIMARY PRODUCTION/HARVESTING AREA

50) Pg. 20. Need to include environmental contamination during primary culture via soil or water

51) Pg. 22. 6.1.2. Suggest to include disinfection of equipment and utensils, e.g., dicers, knives, etc.

ANNEX 2: BIVALVE MOLLUSKS

52) Pg. 23. Annex II. Title. Delete the words "Annex to"

53) Pg. 23. 2.1. Scope

Rewrite first sentence: "These guidelines are applicable to bivalve mollusks and focus on control measures prevent contamination with HAV and NoV."

3rd paragraph - the two sentences are in conflict. If the codes mentioned "should be suitable" then why are additional measures needed? Suggest saying "are applicable to control viruses in foods" in the first sentence instead of "~~should be suitable to control viruses in foods.~~"

54) Pg. 23. Introduction. It is stated that viruses have been observed to persist in shellfish for 8 to 10 weeks. Three weeks is the time the US has proposed. Is this difference attributable to shellfish that have been removed from the water (8 to 10 weeks) versus shellfish that remain in the water (3 weeks) where natural cleansing can take place?

55) Pg. 24. Section III

The US disagrees with long term relay or heat treatment are recommended when viruses are directly detected in shellfish or by epidemiological implication or a contamination event, but does agree with long-term (2 month) relay recommendation.

56) Pg. 24. 3.1. The United States acknowledges the recognition of safety needs here, but suggests that CODEX also recommend that the authority go back and reclassify the area, or find and fix the contamination problem; i.e. we suggest rewording as follows:, "Efforts should be made to restrict growing and harvesting of bivalve molluscs to areas of high water quality, and areas found to contain shellfish harboring viruses

should be reclassified or closed to harvest until the source(s) of contamination has been remediated and shellfish are found to no longer harbor viruses.

57) Pg. 24. Section III. Last line in first paragraph. Revise to say "Other conditions, including meeting the sanitary survey criteria should..."

58) Pg. 24. 5.1.2. Although the US is in favor of water quality testing in most instances, the option given here for testing water by RT-PCR (for the viruses) prior to re-opening is not a practical option. Pathogens are usually too infrequent in contaminated shellfish waters to detect reliably, and too much water would need to be concentrated for this purpose. The US recommends rather testing the shellfish and also confirming water quality by fecal coliform or *E. coli* tests on water samples from the area. The United States suggests adding the following statement to that section: "Additionally, since shellfish are frequently eaten raw, without cooking, it is vital that they all be harvested only from the cleanest waters. Shellfish safety programs achieve the necessary safety and quality by classifying shellfish harvest areas and controlling the harvest activities, which includes enforcement of closures and prohibiting harvest for any purpose from heavily contaminated areas. In this manner, consumers are spared exposures to the pathogens and filth introduced by fecal contamination."

59) Pg. 24. The United States suggests deleting 5.1.1 - as noted above, the purpose is unclear and it is not needed.

60) Pg. 25. 5.2.1 It is not necessary that competent authorities approve commercial heat treatments; the sentence should be reworded "Heat treatments should be validated with respect to viral inactivation, e.g.," Change "~~emphasis~~" to "emphasizes" in the last line of the paragraph.

61) Pg. 25. 5.8 Is this needed? Shouldn't the recall section in the GPFH suffice?

62) Pg. 25. 9.3. There is a recommendation that product be labeled with end-point treatment information. If shellfish are harvested from approved waters which is advised in the Guidelines, then viruses should not be present (unless an illegal discharge occurs, for example overboard discharge). That being the case, labeling is not necessary. Furthermore, the usual methods of cooking do not provide sufficient heat and time to inactivate viruses, therefore, including end-point treatment labeling is of no value since the time and temperatures that would be necessary to destroy the viruses (inactivation of HAV in foods requires internal meat temperatures of 190°F - about 90°C) for 5 minutes would render the shellfish inedible as is stated in the guidance under Section 5.2.1 on page 25. The US recommends that end-point treatment labeling be removed from the Guidelines.

63) Pg. 27. Annex III. Suggest inserting "or through contaminated sewage seeping into the soil" to the second paragraph.

Direct contact with human sewage can be a cause of pre-harvest contamination of fresh produce items through the use of sewage-contaminated waters in irrigation, washing, as fertilizer or for fertilizer/pesticide application, or through contaminated sewage seeping into the soil.

64) Pg. 27. Section II. Scope. Paragraph 2: Change NOV to NoV.

65) Pg. 28. Section III. Primary Production. Paragraph 2.

Suggest inserting: "or through contaminated sewage seeping into the soil" to the second paragraph.

Sewage-contaminated surface waters can be a cause of pre-harvest contamination of fresh produce items through the use of sewage-contaminated waters in irrigation, washing, as fertilizer or for fertilizer/pesticide application, or through contaminated sewage seeping into the soil.

66) Pg. 29.

The control of NoV and HAV in fresh produce should be focusing on prevention of contamination of fresh produce with human faecal contamination, as no effective post-harvest treatments are available at the present time. *U.S. comment: Studies have shown UV irradiation to be effective against other caliciviruses*

67) Pg. 29. 5.1.1.

The United States suggests inserting "Monitoring of sewage tanks and pipes to ensure there is no seepage of sewage into soil"

-Prevention of overflow from sewage platforms after heavy rainfall that may contaminate the surface....

- Monitoring of sewage tanks and pipes to ensure there is no seepage of sewage into soil