



Food and Agriculture
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Agenda Item 4

CX/FH 11/43/4 Add.1
November 2011

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty-third Session

Miami, Florida, United States of America

5 – 9 December 2011

Comments on the

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

(At Step 3)

Comments Submitted by:

**Argentina, Australia, Brazil, Colombia, Costa Rica, Egypt, Jamaica, Japan, Kenya, New Zealand,
Nicaragua, Peru, Senegal, Thailand, United States of America
and International Institute of Refrigeration (IIR)**

ARGENTINA

Argentina appreciates the opportunity to provide the following editorial comments for the consistency of the document.

SPECIFIC COMMENTS

In **paragraph 10, page 9**, Argentina believes the primary purpose of the document is to reduce the risk of foodborne virus transmission, and not the risk of illness. In this sense, we suggest that the wording be changed by deleting the strikethrough text:

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. [...]

In **paragraph 20, bullet point 1, page 10**, Argentina believes the text should be divided into two parts in order to enhance understanding and avoid confusion. The paragraph should be redrafted as follows:

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 area
- be located in areas adjacent to the processing area, but without direct access to it

In **paragraph 21, page 11**, we suggest that the wording be changed in order to enhance understanding of the text.

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 and single use paper towels to help prevent the recontamination of clean hands ~~and single use disposable paper towels~~. Hand washing and drying instructions should be visibly present for all users of these facilities..

In **paragraph 22, page 11**, Argentina believes the term “fregadero”, for *sink*, (in the Spanish version) is not appropriate and thus suggests that it be replaced with “lavabos o lavatorios”.

Los ~~fregaderos~~ lavabos/lavatorios para lavarse las manos y las instalaciones para secarlas deberían estar situados convenientemente en las zonas de producción y elaboración de alimentos de modo de asegurar que los manipuladores de alimentos tengan fácil acceso a ellos.

In **paragraph 23, page 11**, Argentina believes the application of HACCP in primary production is limited and that, for secondary levels, integral use of this system can be complex and can have unsuccessful results. In this sense, we suggest a change in the wording that highlights the adoption of programmes “based” on this system. Specifically:

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 -based systems provide a framework for the control of enteric viruses.

En el **paragraph 28, page 12**, Argentina suggests that the word “only” be deleted as it limits choices related to raw ingredients, when the text itself provides for the preference in connection with the proposed measure. Specifically:

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.

In **ANNEX I, page 20, section 5.2.2 on Heat Treatment**, Argentina believes that there is a typographical error that changes the whole interpretation. In this respect, we suggest the following change:

ANNEX I (page 20)

5.2.2 Specific process steps

(aplicable to the Spanish version)

- Tratamiento térmico: Los tratamientos térmicos de los moluscos bivalvos deberían validarse con respecto a su capacidad para inactivar virus. [...]. El hecho de que la cocción en el hogar o en restaurantes ~~no~~ puede no garantizar adecuadamente la protección del consumidor contra el consumo de moluscos bivalvos contaminados con virus en ciertas circunstancias o formas de consumo recalca la importancia de capturar moluscos bivalvos en zonas de cría con agua limpia.

ANNEX II, PARAGRAPH 16 (page 25)

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~~ type may allow viruses to remain present.

AUSTRALIA

Australia congratulates the electronic working group on the progression of the document and provides the following comments for consideration by the physical working group at the 4 December 2011 meeting.

General comments:

Parts of Annex I (e.g. Section 3) may require further elaboration. Relaying and/or depuration are best suited to reducing bacterial contamination and their suitability for reducing viral contamination to safe levels is uncertain since infectious doses for enteric viruses are generally very small. In particular, paragraph 7 states “...contamination levels will be adequately reduced.” However the level of reduction or consideration of what constitutes a ‘safe’ level is not clear. This is further complicated by the uncertainty of product safety associated with the lower limits of detection for molecular diagnostic tests (see specific comments below). Furthermore, paragraph 8 states “...viral testing of the bivalve molluscs or an equivalent approach to ensure safety...” To assist the reader, it may be useful to provide an example of an ‘equivalent approach to ensure food safety.’

Australia is pleased to see the inclusion of details on the sources of uncertainty associated with analytical methods for foodborne viruses (Point 9, Page 9). Prior to implementing testing approaches to assess the safety of foods for human consumption it is necessary to have detailed guidance on how to interpret

analytical results appropriately. This is particularly important in this case because the current methods of analysis do not distinguish infectious from non-infectious virus particles and the Guideline suggests that in some circumstances testing of shellfish for HAV and NoV may be useful to assist in the management of impacted production areas. Australia, however, suggests rewording the text to add clarity and readability (see specific comments below). The working group may wish to consider adding an additional paragraph to the Guideline which outlines the risk management options that may be undertaken in response to 'detected' and 'not detected' virus results (particularly for Annex I). Risk management responses related to virus test results should consider other key risk factors, such as bacterial indicator loading and environmental monitoring in addition to the viral test result.

Australia also suggests further guidance be added to the document on holding times (relaying periods) that are considered appropriate for virus contaminated bivalves which are held under different environmental conditions (e.g. varying seawater temperatures).

Specific comments:

Page 9, Introduction, point 9.

Suggest revising the text to add clarity.

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

Rationale:

The current wording of the paragraph lacks clarity. These new analytical methods have great potential but their use and interpretation should be clearly defined to ensure product safety.

Page 11, Facilities, Section 4.4

Suggest the addition of an extra clause specifically addressing the supply and maintenance of toilet and hand washing facilities on farm to meet the demands associated with seasonal labour influxes.

Possible wording could be:

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

Rationale:

The current text, "20. Hygienic and sanitary facilities should be available to ensure that an appropriate and acceptable degree of personal hygiene can be maintained" may be subject to substantial country variation and may not capture peak periods of labour.

Page 11, Time and temperature control, Section 5.2.1

Suggest amending the text as follows:

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 log₁₀ reduction in infectious units after 5 cycles of freezing and thawing and less than 1 log₁₀ 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. Cooling and freezing processes should not be considered suitable for the control of foodborne viruses as they do not reduce virus infectivity to levels considered safe.

Rationale:

Dot point Cooling and freezing: is far too wordy and for the purposes of this document, it would more appropriate to simply state that cooling and freezing processes are not suitable.

Page 12, Specific process steps, Section 5.2.2 point 26

There still remains inconsistency and a degree of confusion surrounding the use of virucidal treatments. Paragraph 26 should be the opening text in this section and precede the listing of the various processes. The text should also be modified to reflect the variability of successfully reducing virus loads.

Suggest:

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

Washing:etc

Rationale:

By simply listing the processes without initial qualification adds a degree of confusion to the efficacy of the various processes in reducing virus loads in food. Paragraph 8. of the introduction clearly states that, besides heat treatment, no effective, realistic and validated risk management options are available to eliminate viral contamination.

Pages 18 and 19, Annex 1, Section 3 point 7

When there is a likelihood or evidence of virus contamination through epidemiological information, environmental events or direct detection ~~through virological analysis of virus or viral RNA~~, closure of the area, destruction of contaminated bivalve molluscs and/or virucidal heat treatment (see section 5.2.2) before consumption ~~or long term relaying for of~~ already harvested bivalve molluscs is recommended. In such circumstances where viral contamination can be reliably eliminated by long term relaying or a combination of depuration and relaying, then these measures may be applied. The holding time and minimum temperature during long term relaying are determined by the competent authority having jurisdiction, using standardised protocols for specific virus/mollusc species pairings, 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 virus contamination levels will be adequately reduced is not present using validated testing methods. ~~Another option is a combination of depuration and relaying as determined by the competent authority.~~

Rationale:

The original text was vague and no guidance was given to what is considered safe, the level considered safe should be consistent with the introduction that states "...only a few viral/infectious particles (less than 100) are needed to cause infection that may lead to illness".

In addition, it may not be appropriate to consider long term relaying a front line control measure together with closure, destruction and heat treatment. Long term relaying and depuration should only be considered in such circumstances where a competent authority has all the necessary resources to achieve virus elimination from molluscs and demonstrate product safety, i.e. epidemiological expertise, testing facilities, environmental control etc.

Page 19, Annex 1, Section 3 point 8.

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 consistent with the requirements of the competent authority should be used as part of the process of reopening the affected harvesting area to ensure product 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.

Rationale:

The suggestion that other unspecified approaches are equivalent to viral testing of bivalve molluscs is misleading.

Page 20, Sections 9.3 & 9.4 Labelling and Consumer Education, Points 20 & 21

Australia recommends the deletion of points 20 and 21.

Rationale:

Shellfish that are sold for human consumption should be uncontaminated and safe to eat. This can be assured through the application of rigorous shellfish quality assurance programmes.

BRAZIL

Brazil congratulates the drafting group led by Netherlands for the advances obtained in the document. Continuing the revision of the document, the alterations in the items described below are suggested.

SPECIFIC COMMENTS

6.1.2 CLEANING PROCEDURES AND METHODS

SURFACE DISINFECTION:

Consider deleting the text “As noted earlier”, as it is not an adopted wording in Codex documents.

40. Most other surface disinfectants lack efficacy (i.e., consistently cause less than a 3 log₁₀ 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 log₁₀ 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.

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

4.4.4 PERSONNEL HYGIENE FACILITIES AND TOILETS

Consider to transfer the paragraph 15 to a new Section 3.2.3.1 Personnel hygiene and sanitary facilities, as this paragraph is more applicable to Section 3 that applies to primary production.

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

3.2.3.1 Personel hygiene and sanitary facilities

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.

5.2.2 SPECIFIC PROCESS STEPS (PAGE 18)

Consider to delete this Section, as the proposed provisions is already covered in Introduction Section (third paragraph, fourth bullet point) of this Proposed Draft Guidelines (Main document), which says most foodborne viruses are more resistant than bacteria to commonly used control measures. Additionally, in

Section 5.2.2 Specific process procedures of the Main document states that 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.

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.~~

7.5 VISITORS (PAGE 19)

Consider to delete this Section, as the proposed hygiene provisions is already covered by Section 7.5 of the Proposed Draft (Main Document) and fourth bullet point in Section 3.2.3 Personnel health, hygiene and sanitary facilities of the Code of Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003).

7.5 VISITORS

~~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.~~

COLOMBIA

Colombia is pleased to submit the following comments on the “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, circulated by the Secretariat of the Codex Alimentarius Commission.

We herein refer to the document as it appears in Appendix I of CX/FH 11/43/4, based on the Spanish version.

INTRODUCTION– Paragraph 2

The wording should be consistent with the version in English.

“(...) Los virus transmitidos por los alimentos más importantes son aquellos que infectan por vía del tubo digestivo y son excretados en las heces y/o en el vómito (...)”

Proposal: (...) Los virus **más importantes que se transmiten** ~~idos~~ por los alimentos, ~~más importantes~~ son aquellos que infectan por vía del ~~tubo digestivo~~ **tracto gastrointestinal** y son excretados en las heces y/o en el vómito (...).

II. 3.2. HYGIENIC PRODUCTION OF FOOD SOURCES – Paragraph 15

The text originally proposed in the translated version into Spanish is not understandable or coherent.

“(...) Asimismo, durante la recolección de alimentos, debería utilizarse agua limpia, como para lavar. (...)”

Proposal: (...) Asimismo, durante la recolección **y lavado** de alimentos, debería utilizarse agua limpia, ~~como para lavar~~. (...).

III. 4.4.4.1. Changing facilities and toilets – Paragraph 4

Good practices should be complied with, regardless of whether the facilities are culturally appropriate.

“(...) be culturally appropriate (...)”

Proposal: (...) be ~~culturally~~ appropriate (...).

IV. 4.4.4.2. Hand washing facilities – Paragraph 29

When drying hands, different implements are used for the operation, such as single use towels, hot-air hand-drying systems, etc. In addition, the wording in the Spanish version should be improved to the provisions of the paragraph understandable.

“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.”

Proposal: ~~Hand washing sinks facilities~~ and drying ~~facilities~~ **implements** should be suitably located in food preparation or production areas ~~to ensure~~ so that food handlers have ready access to them.

V. 5.6. MANAGEMENT AND SUPERVISION – Paragraph 30

The wording should be consistent with the English version.

“(...) la exclusión de la presencia en los edificios de los manipuladores de alimentos o de cualesquier personas que tengan síntomas de gastroenteritis o de hepatitis aguda (...)”

Proposal: (...) la exclusión de la presencia en ~~los edificios~~ **las instalaciones** de los manipuladores de alimentos o de cualesquier personas, **incluidos los niños**, que ~~tengan presenten~~ **presenten** síntomas de gastroenteritis o de hepatitis aguda (...).

VI. 7.5. VISITORS – Paragraph 55

The wording should be consistent with the English version.

“Deberá evitarse la presencia de personas no autorizadas durante la manipulación de los alimentos o en las instalaciones donde se cultiven, cosechen, almacenen o preparen alimentos.”

Proposal: Deberá evitarse la presencia de personas no autorizadas, **como los niños**, durante la manipulación de los alimentos o en las instalaciones donde se cultiven, cosechen, almacenen o preparen alimentos.

VII. 10.1. AWARENESS AND RESPONSIBILITIES – Paragraph 61

The wording should be consistent with the English version.

“Es la responsabilidad del personal al supervisor o al empleador cuando esté enfermo con diarrea o vómito (...)”

Proposal: Es la responsabilidad del personal **informar** al supervisor o al empleador cuando esté enfermo con diarrea o vómito (...).

COSTA RICA

Costa Rica would like to thank the Codex Committee on Food Hygiene for the opportunity to comment on the document prepared by the Electronic Work Group led by The Netherlands, which developed a revised version of the Proposed Draft Guidelines, based on the written comments submitted at Step 3 and on the recommendations made and the discussions held at the 42nd session of the CCFH.

Comments on the document

1) In paragraph 11. Costa Rica proposes the following change in order to improve understanding and application.

These guidelines are applicable to all foods; **however, the focus is on ready-to-eat food** ~~(with a focus on ready-to-eat food)~~ throughout the food chain, from primary production through consumption, for the ~~control~~ **protection of food against contamination with** human enteric viruses, in particular NoV and HAV, ~~in~~ **foods. Their application** ~~They should complement~~ **is complemented with** controls in place for any other pathogens.

2) SECTION 3 - PRIMARY PRODUCTION/HARVESTING AREA

Costa Rica proposes the following change in the text in order to improve understanding.

OBJECTIVES: ~~To describe~~ **To visualize** 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 **contaminated with human or animal faeces** or by food handlers.

3.) In paragraph 13, Costa Rica requests the following change in order to extend the scope of the guidelines and to enhance understanding.

13. Potential sources of viral contamination of the environment should be identified in the sites selected and their immediate surroundings prior to production activities initiation. All necessary preventive or corrective measures should be taken to reduce the possibility of viral contamination to a minimum, since virus removal

might not be feasible during subsequent steps. Particular attention should be paid to faecal contamination sources of human or domestic or wild animal origin, as well as to water, slope and proximity to other production activities which could result in run-off or flooding with virus-contaminated waters. Primary food production should not be carried on in areas where potential virus contamination sources have not been controlled ~~the presence of viruses may lead to the viral contamination of food.~~

4) 3.2 HYGIENIC PRODUCTION OF FOOD SOURCES.

Costa Rica proposes to replace the word “de” with “**para**” (in the Spanish version) in order to improve understanding, as follows: “PRODUCCIÓN HIGIÉNICA DE MATERIAS PRIMAS ~~DE~~ PARA LOS ALIMENTOS”.

5) In paragraph 14, Costa Rica proposes the following change in the text in order to make it clearer and to improve understanding.

~~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.~~

Care must be taken to protect food sources from faecal contamination, human vomit or aerosol. To achieve this, the personnel working in the production area must comply with applicable health and hygiene requirements.

6) In section 4 - Establishment: design and facilities

Objectives: Costa Rica proposes to add the term "washed", since cleaning does not always include washing.

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

Additionally, in the rationale, Costa Rica proposes to change the text as follows in order to enhance understanding.

Rationale. ~~Inappropriate inability to properly clean and disinfect~~ **cleaning, washing** and **disinfection** may can result in persistence of the virus ~~leading to potential contamination of in~~ food.

7) In paragraph 20, Costa Rica proposes the following change in the text in order to improve understanding.

Hygienic and sanitary facilities **in good hygiene and maintenance conditions** should be available to **help maintain good** ~~ensure that an appropriate and acceptable degree of personal hygiene can be maintained.~~ These should:

- be **strategically** located in proximity to the production or processing areas,
- **access doors should** not open directly to food handling areas,
- be in sufficient numbers to accommodate personnel,
- ~~be culturally appropriate~~ **be functional and appropriate based on user custom,**
- ~~be of appropriate design~~ **designed** to **allow** ensure hygienic removal of wastes **to be removed hygienically and safely,**
- have adequate means for ~~hygienically~~ washing and drying hands,
- be maintained ~~under sanitary conditions~~ **clean, disinfected** and **in** good repair,
- be **frequently** ~~appropriately~~ cleaned and disinfected (see 6.2 cleaning programmes) and
- ~~preferably be separate for guests and personnel of the establishment.~~

Costa Rica proposes to remove this entire bullet point, since the recommendation proposed in the document is that no guests should be allowed, especially children, in production premises or areas.

8) In paragraph 21, Costa Rica proposes the following change:

Hand washing facilities ~~sinks~~ should be supplied with ~~hand cleanser (soap)~~ **dispenser with disinfectant liquid 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 recontamination of clean hands and single-use disposable paper towels. Hand washing and drying instructions should be visibly present for all users of these facilities.

9) In paragraph 22, Costa Rica proposes the following change in the text in order to improve understanding:

Hand washing sinks and ~~drying facilities~~ **hand driers** should be suitably located in food preparation or production areas to **facilitate** ~~ensure~~ food handlers' ~~have ready access to them.~~

10) In paragraph 29, Costa Rica proposes to delete this paragraph or to move it to the introduction of the document, since it does not provide any recommendation or requirement for the effective packing of raw materials.

~~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.~~

11) In paragraph 30, Costa Rica proposes the following change in the text in order to enhance understanding:

30. All Managers and supervisors should understand the importance of **applying** good hygiene practices and personnel health and hygiene, ~~such as the following:~~ **in aspects such as:**

- ~~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 **until their full recovery in order to allow for their proper treatment until they have fully recovered** ~~or those recovering from these infections~~ (see section 7.2) and
- ~~how to~~ clean and disinfect surfaces when contaminated.

12) In section 5.8, Costa Rica proposes the following change in the section heading, since the paragraph it introduces is not a procedure for recalling foods.

~~RECALL PROCEDURES~~ **RECALLING FOODS.**

13) In paragraph 43, Costa Rica proposes the inclusion of the terms in bold and underlined; otherwise, it could be interpreted that food handlers would be deprived of their labor rights.

Diarrhea 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 **until they have been clinically treated and cured**, to reduce the likelihood of transmission of any infectious agents via food (section 3.4).

14) In paragraph 45, Costa Rica proposes to change the words in bold in order to improve text understanding (in the Spanish version).

Los manipuladores de alimentos que tengan síntomas clínicos de gastroenteritis o síntomas de hepatitis aguda deben excluirse de las actividades de manipulación de alimentos, de las superficies que entren en contacto con los alimentos y del equipo utilizado para alimentos y no deberían estar presentes en la zona en que los alimentos están expuestos, ~~de manera de~~ **para** reducir la probabilidad de la transmisión de los virus entéricos humanos, el NoV y el VHA. Los trabajadores deberían salir de la zona de manipulación de alimentos, de ser posible, antes de la aparición del vómito o de la primera diarrea y, en todo caso, inmediatamente después de estos acontecimientos. Toda persona que tenga síntomas de hepatitis aguda ~~debería~~ **debe** consultar a un médico

15) In paragraph 47, Costa Rica proposes to remove highlighted terms, since it considers that the values assigned are not an average value obtained from a data set.

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.

16) In paragraph 48. Costa Rica believes that there must be specific recommendations, either in this paragraph or elsewhere in the document, regarding the handling, washing and treatment of the work uniforms or clothing of food handlers who have been infected, or suspected to have been infected, by NoV or HAV in order to reduce the likelihood of contamination, since some companies wash the uniforms within their facilities, whilst others allow them to be washed at home.

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.

17) In paragraph 51, Costa Rica proposes a change that applies only to the Spanish version, i.e. to replace the term "fregadero".

Antes de manipular alimentos, el personal debería lavarse y secarse las manos La manera más eficaz de prevenir la propagación de los virus es el lavado meticuloso de las manos. Las manos deberían enjabonarse y luego lavarse con agua corriente limpia² Debería fomentarse el uso de toallas de mano desechables y de grifos no manuales siempre que sea posible. El lavado de manos debería realizarse en ~~fregaderos~~ lavamanos destinados a tal fin y no en ~~fregaderos~~ en lavamanos, los que se lava la vajilla o se preparan los alimentos.

EGYPT

Egypt agrees on the "Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food (REP 11/FH para. 86 and Appendix IV). The Proposed Guidelines are well scientifically designed, and deal with one of the important hazards in foods, Fish and Fishery Products, Fresh Fruits and Vegetables, and contamination from wastewater, excreta, grey water and their use in agriculture.

- 1- Egypt deliberates and shows that this type of contamination is well known, and now supersedes other types because of the European outbreaks crisis from the EHEC group of *E. coli*, or mainly, the *E.coli* O104:H4 strain that lately emerged.
 - In recent years, viruses have been also increasingly recognized as important causes of foodborne diseases. Viruses are strictly host-dependent for their replication and have their own typical host range and cell preference (tropism). Viruses can be transmitted in different ways, e.g., via the respiratory or faecal-oral routes. Some human viruses can be transmitted directly from person-to person, but also indirectly via virus-contaminated water, air, soil, surfaces or food. 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.
 - The human enteric viruses *most frequently involved in foodborne outbreaks* are norovirus (NoV) and hepatitis A virus (HAV), but other viruses such as rotavirus, hepatitis E virus (HEV), astrovirus, Aichi virus, sapovirus, enterovirus, coronavirus, parvovirus and adenovirus can also be transmitted by food,
- 2- *Proposed Draft Guidelines* includes important recommendations such as:
 - Food handlers with clinical symptoms of gastroenteritis (diarrhoea and/or vomiting) or with symptoms of acute hepatitis (fever, headache, fatigue combined with dark urine and light stools, or jaundice), should be excluded from food handling and should not be present in the food handling area, so as to reduce the likelihood of transmission of the human enteric viruses, NoV and HAV. Worker(s) should leave the foodhandling area, if possible, before the onset of vomiting or the first diarrhea event and in any case directly after these events .
 - The effects of heat treatment on virus infectivity in foods are highly dependent on virus (sub)-type and food matrix. Commonly used cooking procedures are considered adequate treatments to destroy viral infectivity in most 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, but NoV and HAV are unlikely to be completely inactivated at those treatments. Complete inactivation also depends upon initial levels of any viral contaminant.
 - *The Proposed Draft Guidelines* referred to effective control measures and training Programmes, such as:
 - Annex I: Control of Hepatitis A Virus (HAV) and Norovirus (NoV) in Bivalve Molluscs
 - Annex II: Control of Hepatitis A Virus (Hav) and Norovirus (Nov) in Fresh Produce.

- The Guidelines recommended that:

- 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. sewage treatment, temperature;
- Personal hygiene (see Section 7, Main document); REP 11/FH Appendix IV 91
- Control measures to prevent faecally contaminated water being used in primary production;
- Control measures to prevent fresh produce becoming contaminated by contagious food handlers.

3- *The Proposed Draft Guidelines based on many important international resources, mainly:*

- *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. Refer to Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*
- *Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003)*
- *WHO Guidelines for the safe use of wastewater, excreta ad grey water. Volume 2: Wastewater use in agriculture (World Health Organization 2006 ISBN 92 4 154683 2,v.2).*
- *Roles of governments, industry and consumers Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP1-1969).*
- *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969) and other applicable codes such as Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003)*
- *Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).*
- *Codex Recommended International Code of Practice – General Principles of Food Hygiene- (CAC/RCP 1-1969).*
- *Code of Hygienic Practice for fresh Fruits and Vegetables (CAC/RCP 53–2003).*
- *WHO Guidelines for the safe use of wastewater, excreta ad grey water. Volume 2: Wastewater use in agriculture (World Health Organization 2006 ISBN 92 4 154683 2,v.2).*
- *Definitions of the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007)*
- *The Standard for Live and Raw bivalve Molluscs (CODEX STAN 292-2008).*
- *Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003), Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003), and Annex on Fresh Leafy Vegetables.*
- *WHO Guidelines for the safe use of wastewater, excreta ad grey water. Volume 2: Wastewater use in agriculture (World Health Organization 2006 ISBN 92 4 154683 2,v.2).*

JAMAICA

General comments

Jamaica is of the belief that while the proposed guideline will be very useful for the intended users, the draft would be easier to follow if there were distinct separations of requirements for production in the field versus production in an establishment.

Specific comments**INTRODUCTION*****Page 7, Bullet 6***

- ~~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.~~

Rationale:

This bullet point does not provide any additional information for the intended users of this Guideline. Jamaica suggests that this bullet point be deleted.

Page 7, Bullet 7

- Zoonotic foodborne transmission of viruses is not ~~as common~~ **as commonly reported/ documented/diagnosed** as is the case for many bacterial pathogens, such as *Salmonella* and *Campylobacter*, however, it does occur, e.g., for HEV.

Rationale:

The insert provides a technical clarification on the use of the words 'as common'. When conducting an investigation one may not have been searching for viruses and as such, they [viruses] are not commonly noted/reported as a etiological agent of a food borne disease (FBD).

Page 8, Para.4

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.

Comment:

There is sufficient scientific evidence to support the Horseshoe bat as the source of the SARS virus.

Section 3 - PRIMARY PRODUCTION/HARVESTING AREA**3.3 HANDLING, STORAGE AND TRANSPORT**

Para 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.

Rationale:

This statement is not very useful because it does not provide any guidance. Could there be some concrete examples of how to minimize the risks of virus contamination using one or two known methods of handling, storage and transport?

Section 4 - ESTABLISHMENT: DESIGN AND FACILITIES**4.4 FACILITIES*****4.4.4.1 Changing facilities and toilets***

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

- **ensure that the waste facility should be designed so that there is no seepage into underground water or enter the agricultural field.**

Rationale:

This new bullet point is important for agricultural areas with high underground water tables and also for the production of vegetables.

SECTION 5 - CONTROL OF OPERATION

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

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.~~
- Food Ingredients and products should be washed in potable water. Water can be treated with UV, Ozone, chlorine, etc. The food ingredients or products must be whole.

Rationale:

Suggested rewording for clarity.

Para 26. Often these processes by themselves will be inadequate to protect the consumer, but when the processes are combined, the ~~additive~~ cumulative effect of the processes may enhance the level of inactivation of viruses present.

Rationale:

Grammatical

5.6 MANAGEMENT AND SUPERVISION

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

- **Exclusion from premises animals including pets**

Rationale:

Insert of an additional bullet point notes that the matter of animals is also an important risk factor for the transmission of viruses.

6.1 MAINTENANCE AND CLEANING

Surface disinfection

Para 37. The solution is corrosive, and needs to be thoroughly removed afterwards **by washing with potable water.**

Rationale:

Insert is a suggestion for the method of removing disinfecting solution.

Para 40. New compounds and/or methods can be considered if they show virucidal activity of $> 3 \log_{10}$ for non-enveloped viruses in standardized carrier tests **and is approved for use on food contact surfaces.**

Rationale:

It is critical to note that not all chemicals that meet the virucidal criteria in Para 40. are safe for use on food contact surfaces.

7.2 ILLNESS AND INJURIES

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.

Comment: Should the infected person be allowed to return to work during the period when they are still shedding the virus?

7.3 PERSONAL CLEANLINESS

Para 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~~ **handling** food.

Rationale:

The word ‘handling’ is encompassing and therefore covers other steps in food processing.

JAPAN

Japan wishes to thank the Netherlands and the members of the working group for re-drafting the document. We are pleased to offer the following comments:

General Comments

1. The introduction part is useful. However, it should be condensed to the essence by making reference to the FAO/WHO Expert meeting report for the detail. Japan suggests the following amendments;

1 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.

3. Some noteworthy characteristics aspects of foodborne viruses and the associated infections/illnesses that determine management strategies to be different from management strategies for bacterial pathogens are listed in section 1.4 of the FAO/WHO Expert meeting on “Viruses in Food”¹. In addition, the following aspects are important to be recognized:

~~• 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 10⁶ 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.~~

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 Norovirus 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 (106-1010 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 immunocompetent 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 (person elder than 40 years old 40 year+), 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 (106-108 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.

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 semiquantitative.

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.

Specific comments

2.3 DEFINITIONS

Japan would like to propose the insertion of “Clean Water” definition.

Clean water - water that does not compromise food safety in the circumstances of its use.(applied only in the main document and the Annex II)

Rationale: To make sure that clean water definition used in the main document and Annex II is different from the definition of clean water in the Annex I.

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 **that apply these guidelines** ~~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.

Rationale: It is unclear of the meaning of "adequate food safety management system". We think that it is more appropriate to refer to these guidelines.

7.2 ILLNESS AND INJURIES

45. Food handlers with clinical symptoms of gastroenteritis or with symptoms of acute hepatitis, **and asymptomatic food handlers who have been confirmed to be infected with NoV or HPA virus by laboratory testing** 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.

Rationale: Since asymptomatic food handlers who have been confirmed to be infected with NoV or HPA virus by laboratory testing may be sources of virus contamination, they also should be excluded from food handling etc.

46. Persons who have had gastroenteritis should only be allowed to return to work after a period without symptoms of diarrhoea and vomiting. Returning period and/or condition should be determined by competent authorities, taking training/education requirement and feasibility of the stringent hand practices into account. ~~(e.g., period of 48 hours).~~ Persons, who have had hepatitis, should only be allowed to return to work after disappearance of jaundice.

Rationale: Japan would like to propose the deletion of the "48 hours" example, since shedding of viruses, such as NoV or HAV, may continue for several weeks after symptoms have subsided and there is no scientific evidence to justify the "48 hour" example. Therefore, we think it is more appropriate that competent authorities determine relevant period/condition of return by taking training requirement and feasibility of stringent hand washing practices into account.

ANNEX I Bivalve mollusks

Japan would like to propose the insertion of Section title "2.3 Definition" and new definition of "Clean Water".

2.3 DEFINITION

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

Rationale: To make sure the "Clean water" definition used in the Annex I is the one included in the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

KENYA

Agenda 4: PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF VIRUSES IN FOOD - CX/FH 11/43/4 (AT STEP 4)

GENERAL OBSERVATIONS:

- Structure and revisions were appropriate
- content and objectives were acceptable Introduction is considered to be long but it is necessary since it is a new field and as such more information is required to provide guidance to users.

JUSTIFICATION:

The observations are in line with recommendations of the 42nd session of CCFH

Section III. PRIMARY PRODUCTION/Harvesting Area

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

RATIONALE: Food may become contaminated at the primary production area by fiscally contaminated water or soil or by infected food handlers.

SPECIFIC COMMENTS

Kenya would like to comment on the rationale added above by adding the words '*by harvesting containers and utensils*'.

Justification: This is in line with the ensuing text

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

Third para. last sentence to read 'also during harvesting of foods clean **safe** water should be used.

Justification: The word '**safe**' is added to take care of the microbiological aspect.

4.4.4.2. Hand Washing Facilities

Much discussion on hand washing facilities, non- hand operable taps and their availability, practicality and other options was discussed in detail. Kenya concluded that the statement is acceptable and should be maintained.

Justification: Text is non-prescriptive and allows technological innovation.

5.2.2. Specific Process Procedures

Bullet 6. Gamma (γ) Irradiation

We recommend the use of the term '*ionizing*' irradiation to replace Gamma (γ) Irradiation.

Justification: This is in line with Recommended Code of Practice for Irradiation Processing of Foods (CAC/RCP 19-1979)

7.5 VISITORS

Even though there is reservation on the statement on the exclusion of children from handling, processing and harvesting areas, Kenya concluded that the provision which excludes children *during food handling or on premises where food is grown, harvested, stored or prepared* should stand because of the higher risk that children carry in the spread of the viruses in endemic areas.

Justification: The statement makes provision to allow, to the extent possible, the presence of children in these areas and does not entirely prohibit the presence of children.

9. PRODUCT INFORMATION & CONSUMER AWARENESS

Kenya considered the need to make provision for awareness of consumers in respect of their role in the prevention and control of viral infections.

We propose to add the word '**responsibility**' to the heading to read '**PRODUCT INFORMATION, CONSUMER AWARENESS AND RESPONSIBILITY**'

Justification: This is in line with section Sect.9.4 of RCP: 1969 General Principles of Food Hygiene (GPFH).The word '**responsibility**' is added to point out the role of consumers when making choices about consumption of these products.

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

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

3. PRIMARY PRODUCTION

Par.7

- Kenya discussed whether there was a need to state **relaying and depuration** times and concluded that Competent Authorities should determine depuration and relaying times depending on the degree of contamination.

Comment: Kenya considered the non definition of the terms **relaying and depuration** as appropriate.

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

- Justification** : Conditions in geographical areas vary and levels of contamination should be determined by Competent Authorities in order to state the relay and depuration times

These terms are defined in the Code of Practice of Fish and Fishery Products CAC /RCP, 52-2003

9.4. CONSUMER EDUCATION

Kenya noted that the phrase “**treated bivalve mollusks**” is appropriate.

Justification: It is non prescriptive and an improvement on the original text in CX/FH10/42/5.

PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF VIRUSES IN FOOD**AGENDA IV - ANNEX II****CONTROL OF HEPATITIS A VIRUS (HAV) AND NOROVIRUS (No. V) IN FRESH PRODUCE****GENERAL COMMENT**

The document was found to be good and devoid of contentious issues.

NEW ZEALAND

New Zealand would like to thank Netherlands and members of the electronic working group for preparing the Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food.

New Zealand would like to offer the following specific comments on the draft text within the **main document**:

Section	Proposed change	Rationale
5.2 paragraph 27	When new viricidal technologies or treatment combinations are being developed, they should be validated with the appropriate hazard/food combination prior to their implementation in the food production chain.	New Zealand suggests that when the technologies are validated it must be against the specific hazard and food that they are intended to target
7.1 paragraph 43	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)(section 7.2)	The text refers to section 3.4 but this section has been deleted. Should this be section 7.2 instead?

New Zealand would like to offer the following specific comments on the draft text within **Annex I: Control of Hepatitis A Virus (HAV) and Norovirus (NoV) in Bivalve Molluscs**:

Section	Proposed change	Rationale
3.1 Environmental Hygiene paragraph 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,	New Zealand suggests deletion of the last sentence as relaying is dealt with in paragraph 13. Also, the sentence talks about contamination of the relaying area when conditions for relaying are more completely described in the CODEX

Section	Proposed change	Rationale
	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.	Code of Practice for Fish and Fishery Products.
3.1- Environmental Hygiene, paragraph 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. <u>Another option is long term relaying or a combination of depuration and relaying as determined by the competent authority.</u> Alternatively long term relaying or depuration is recommended and should be validated with respect to viral inactivation or removal.	New Zealand recommends that, in light of the statement in Section 3-Primary Production, paragraph 6 that states "but depuration, as usually performed, is inadequate in the elimination of viruses" the last sentence be amended as written, providing consistency throughout Section 3.
Section 3.2- Hygienic production of Food Sources, paragraph 17:	In addition to the use of clean water during primary production, other control measures for enteric viruses, such as NoV and HAV, include <u>long term relaying or a combination of depuration and relaying as determined by the competent authority.</u> bivalve molluscs depuration and relaying, which should be validated with respect to viral inactivation or removal.	New Zealand recommends that the paragraph be amended after the comma to provide consistency throughout Section 3.
Section 9.4- Consumer Education, paragraph 21:	Each country has specific consumption habits; therefore communication programmes pertaining to viruses are most effective when established by <u>individual national</u> governments. Consumers should be made aware of the risk of becoming infected with NoV or HAV after consuming raw or treated bivalve molluscs.	New Zealand suggests deletion of the last sentence because the specificity of communication can be determined by national governments.

NICARAGUA

No viruses have been detected in food at the national level. We have identified needs in water and food. The national laboratory has a PCR for diagnosis of norovirus, which is now being tested by Elisa. There is a hepatitis monograph as well.

Position

Nicaragua appreciates the Netherlands' leadership in the Electronic Working Group and the excellent document proposed. Our position on the proposed draft guidelines is the following:

Nicaragua supports the process of developing these documents and would like to request that it be kept at Step 5/8, this way, they will be a tool for the prevention of waterborne and foodborne virus outbreaks. The country has installed capacity (equipment) to detect viruses in food; however, the laboratory's staff needs technical assistance to buy reagents and to receive training.

PERU

General Comments:

The introduction of the proposal includes a good risk profile, which allows for adequate assessment of the problem. However, it is acknowledged that the data considered come from developed countries.

The guidelines are relevant inasmuch as these virus diseases are a current public health issue and a barrier to the export of non-processed foods. The design of the proposed guidelines is correctly aimed at preventing primary level and processed food contamination.

However, monitoring systems have not been developed in the text, and there is no reference to the types of method to be used, or the frequency with which tests will be done, which take into account virus survival in the contaminated environment.

Specific Comments:

1. In Section 5.2.1 on Heat Treatment, short or fast pasteurization temperatures are mentioned:” *short time (HTST; 71.7 °C for 15 to 20 seconds)*...”. In this sense, we suggest a temperature of 72°C and the range, as is usually found in the literature and various Codex standards.
2. The document does not include information on the application of the methodology to be used or guidelines for the detection of viruses in food, considering that the only references mentioning viruses appear in certain Codex documents relating to microbiological criteria applicable to foodstuffs, which outline only the following:
 - “It is established that the conventional faecal indicators are unreliable for determining the presence or absence of NoV, and to determine the periods of shellfish purification” and (**References missing**)
 - “When analytical methods are sufficiently developed to be established criteria for pathogenic viruses in live bivalve molluscs.” (**References missing**)

Therefore, due to this regulatory void, there is a need to develop an analytical methodology that allows testing for the most common viruses in food for use in health control laboratories.

SENEGAL

GENERAL COMMENTS

- The introduction is very long.
- Objectives and content are acceptable

Review the part about health condition in the Code

SPECIFIC COMMENTS

- **Section 6 -1** : Maintenance and Sanitation : replace with **sanitary maintenance** _
- **Section 6-2** : replace cleaning programs with **sanitary program**
- **Section 7-3** : Personal hygiene : replace non-hand operable taps with **automatic control taps**

Rationale

- Sanitary maintenance includes cleaning and disinfection
- Hygiene includes cleaning and disinfection

- From the moment that the term actionnement is used, automatism no longer exist

(applies to French version only)

THAILAND

Thailand acknowledges the effort of the electronic working group led by the Netherlands in preparing and revising this document. Generally, Thailand supports the guidelines that have been developed for control of viruses in food. However, we have comments on particular parts of the guidelines as follows.

Specific Comments

SECTION 5 Control of Operation

5.2.1 Time and temperature control

Second bullet point: Heat treatment

...Cooking procedures ~~commonly used in food preparation~~, where an internal temperature of the food reaches at least 90 °C for 90 seconds, are considered adequate treatments to destroy viral infectivity in most foods. ~~However, 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. 113°C for 55 minutes) is considered an adequate treatment to destroy viral infectivity in foods.

Rationale:

Removing the third sentence helps emphasizing the procedure that is effective for most foods. Also, removing of the example in the forth sentence is due to variation of time and temperature according to various sizes of can and types of food to be considered in commercial canning

SECTION 6 Establishment: Maintenance and sanitation

6.1.2 Cleaning procedures and methods (paragraph 37)

...Freshly constituted hypochlorite solutions ~~(e.g., using tablets)~~ are preferable. The solution is corrosive, and needs to be thoroughly removed afterwards.

Rationale:

Chlorine is available in various forms e.g. liquid, powder or tablet. Also, tablet form is not commonly available in some countries.

SECTION 7 Establishment: Personal hygiene

7.3 Personal cleanliness (paragraph 51)

...Hands should be lathered with soap and then washed with clean running water². The use of disposable hand towels and non-hand operable taps should be encouraged wherever possible. Hands should be washed in sinks dedicated to such a purpose and not washed in dishwashing sinks or food preparation sinks, to the extent possible.

Rationale:

The use of “to the extent possible” gives more flexibility to smaller manufacturers.

Annex II Control of Hepatitis A Virus (HAV) and Novovirus (NoV) in fresh produce

3.2.1 Water for primary production (paragraph 12)

...The assessment of the microbial quality of the sources of water used on the farm for the presence of NoV and HAV should include an assessment of possible human faecal contamination sources of the water (sanitary survey) and, if deemed necessary, testing for faecal contamination indicator. 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, where possible.

Rationale:

- For clarification, testing for faecal contamination indicator e.g. E.coli/faecal coliforms should be specified.

- 'Where possible' is added to provide more flexibility and practicality to small holder farmers.

3.2.1 Water for primary production (paragraph 13)

Testing for E.coli/faecal coliforms/~~total coliforms~~ is useful to determine the level of faecal contamination of the water...

Rationale:

Some coliforms are normal flora in the environment. Total coliforms may not be a good indicator for faecal contamination.

UNITED STATES OF AMERICA

The following is the United States response to the request for country comments on the CCFH text, *Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food*, CX/FH 11/43/4.

GENERAL COMMENTS

The Delegation from the Netherlands and its Working Group partners are to be congratulated on the significant revisions of the *Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food*. This version is a great improvement and more comprehensive than the last version. The United States offers the comments below to provide additional clarity.

SPECIFIC COMMENTS

In the comments below, text to be removed is indicated by strike outs and text to be added is underlined.

INTRODUCTION

Paragraph 3. Include a new bullet after the third bullet that would state the following:

- Non-enveloped viruses, such as NoV and HAV, are covered in a protein-based structure called a capsid. Enveloped viruses, such as influenza, have a capsid and are further coated in a biological membrane derived from the host cell. Both the capsid and envelope structures influence environmental persistence and resistance to cleaning and disinfection and interventions. However, the non-enveloped viruses tend to be more resistant to inactivation from solvents (e.g., chloroform) and desiccation.

Rationale: This is important information as it relates to susceptibility to cleaning and disinfection and interventions used on food surfaces.

Paragraph 4: Line 8. Change the term "are likely to" to "may" as shown below:

"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~~ may play a role."

Rationale: Improves clarity.

Paragraph 5: Line 7. Edit the sentence to insert a phrase after the term "infections" to state:

"Clear wintertime peaks in incidence have been observed when looking at reported outbreaks, but other than in the case of bivalve molluscs these are particularly associated with infections spread through person-to-person contact or contaminated environmental surfaces (e.g., outbreaks in healthcare facilities) rather than foodborne infections."

Rationale: This helps to demonstrate a more appropriate distinction of outbreaks based on the mode of transmission.

Paragraph 5: Line 8. A comma is needed after the term "symptoms," and a semicolon is needed after the term "hours;...".

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 h.

Rationale: Editorial correction.

Paragraph 6: Line 13. Replace the term "illness" with the term "symptomatic phase":

“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~~ symptomatic phase.”

Rationale: Editorial change for clarity as it is not clear when the “illness” begins.

Paragraph 8: Line 3. After the term “characteristics of the food,” we recommend adding a sentence:

“Long-term relay of bivalve molluscs to clean environmental waters can be effective for eliminating the risk of illness from viruses, but often this is impractical due to added costs or lack of clean areas in reasonable proximity to contaminated harvest sites.”

Rationale: This helps to further describe the challenges of risk management options.

2.3 DEFINITIONS

Consider revising the end of the definition for “Ready-to-eat food” as follows:

“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 to achieve food safety ~~which could remove viruses or eliminate their infectivity.~~”

Rationale: The definition of “ready-to-eat food” should not be defined solely on the basis of removing viruses. Food safety does not relate to a particular type of hazard.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

Paragraph 14, end of the first line. We recommend deleting the phrase: “since products exposed to vomit or faecal matter in primary production areas could become contaminated and pose a risk to human health.” The sentence would then state:

“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.~~”

Rationale: This entire code is about risks to human health. The last part of the sentence is not necessary.

Paragraph 14. The last sentence of the paragraph should be deleted:

~~Hygiene and health requirements should be followed to ensure that personnel who come directly into contact with food during production are not likely to do not contaminate the product.~~

Rationale: This information is covered under Section 7 – Personal Hygiene.

Paragraph 15, second sentence. Are there guidance documents that should be recommended that are applicable to viral contamination of water?

Rationale: Such information might be useful to countries where viral contamination of water is a problem.

Paragraph 16. Add the following to the end of the paragraph:

“Growers should seek appropriate guidance on the use and treatment of biosolids, manures and waste by-products.”

Rationale: The statement provides additional guidance that should be considered.

3.3 HANDLING, STORAGE AND TRANSPORT

Paragraph 19: Edit the sentence to state:

“Harvesting equipment, utensils and containers should be in a clean condition and should not be damaged.”

Rationale: There is a difference between harvesting equipment and utensils and it is important to recommend that all should be in clean condition and not damaged.

SECTION IV ESTABLISHMENT DESIGN AND FACILITIES

4.4.4.1 Changing facilities and toilets

Paragraph 20: Delete the forth bullet:

- Be culturally appropriate

Rationale: It is unclear how this relates to food safety. Countries should always do what is culturally appropriate without having to say so in guidance specific to virus control.

Paragraph 20: Delete the last bullet:

- ~~preferably be separate for guests and personnel of the establishment~~

Rationale: It is unclear as to how this helps control viruses.

5.1 CONTROL OF FOOD HAZARDS IN RELATION TO VIRAL CONTAMINATION

Paragraph 23. Consider revising this paragraph to state:

“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~~ hygiene control systems, which could be referred to as Good Hygienic Practices (GHPs), sanitation standard operating procedures (SSOPs), or other names. These prerequisite programs, together with HACCP validated interventions designed to prevent, eliminate or reduce enteric viruses to acceptable levels, e.g., as part of a HACCP program, provide a framework for the control of enteric viruses.”

Rationale: Improves clarity and identifies other hygiene control systems and validated interventions that might be considered.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

Section 5.2 Key Aspects of Hygiene Control Systems

Organize this section into two parts: 5.2.1 General Control Programs and 5.2.2 Process-Specific Control Systems. as follows:

5.2.1 General Control Programs

[Followed by paragraphs 24 and 25]

5.2.2 Process-Specific Control Systems

5.2.2.1 Time and temperature control [followed by the bullets in that section]

5.2.2.2 Specific process procedures [followed by the bullets in that section]

Rationale: To improve clarity and organization

Paragraph 24. Revise the last sentence as follows:

“Any food handled by an ill person should be considered a risk and ~~should be discarded~~ consideration should be given to discarding the food.”

Rationale: The original sentence is not consistent with the recommendation in paragraph 36, Section 6.1.2, which recommends undertaking an evaluation as to whether the food handled by an ill person should be discarded and, where food has been handled by someone with NoV, discarding the food. The change makes paragraph 24 consistent with information provided in paragraph 36.

Section 5.2.1 Time and Temperature Control. Delete the term “initial” so the sentence states:

“...For NoV freezing tends to preserve infectivity, however, there may be ~~an initial~~ loss in virus titer with each freeze-thaw cycle.”

Rationale: The term “initial” is contradictory with the end of the sentence which states “**each** freeze-thaw cycle” [Emphasis added].

Section 5.2.2 Specific Process Procedures. In the first bullet delete the term “wash” before the term “water.”

“The washing of food ingredients or products in ~~wash~~-water, either treated...”

Rationale: Editorial change.

Last bullet under 5.2.2. A suggested revision to this section is as follows:

Gamma Irradiation: Ionizing radiation (gamma, X-ray, or electron beam). Ionizing radiation may reduce virus infectivity. The use of ionizing radiation to target viruses should be validated under operating conditions to establish the dose required to achieve desired reductions. The use of ionizing radiation should be in accordance with The Codex General Standard for Irradiated Foods (CODEX STAN 106-1983, REV.1-

2003) and the Recommended International Code of Practice for Radiation Processing of Food (CAC/RCP 19-1979, Rev. 2-2003). The effectiveness of ionizing radiation to effectively reduce infectious viral particles is dependent upon a number of factors, including dosage (energy), food matrix (consistency, density) and virus type. ~~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.~~

Rationale: It is more correct to label this bullet “Ionizing radiation,” as in addition to gamma radiation, x-rays and electron beams may be used. Further, with sufficient dose the numbers of infective viruses may be greatly reduced, although this dose may be too high for practical use. Reference should be made to relevant Codex standards (*CAC/RCP 19-1979, Rev. 2-2003*, and *CODEX STAN 106-1983, REV.1-2003*).

5.3 INCOMING MATERIAL REQUIREMENTS

Paragraph 28. Insert into the second sentence reference to “process-specific interventions, if appropriate” as follows:

“...this includes the use of process-specific interventions, if appropriate; clean or potable water; adequately trained personnel; high personnel hygiene standard; availability of adequate hygiene facilities; and a good health supervision system.

Rationale: To further elaborate on the elements of an “adequate food safety management system.”

5.4 PACKAGING

Paragraph 29. Modify as shown below:

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

Rationale: Editorial changes to improve clarity.

6.1 MAINTENANCE AND CLEANING

Under Section 6.1.2 Cleaning Procedures and Methods, paragraph 37. Edit the end of the paragraph as follows:

“The solution is corrosive, and needs to be thoroughly ~~removed~~ rinsed from food contact surfaces afterwards. An alternate disinfectant is chlorine dioxide. Chlorine dioxide solutions at concentrations of 200 ppm are effective viricides. Adequate precautions should be taken...”

Rationale: Collectively, paragraphs 37-39 imply that chlorine (hypochlorite solutions), vaporous hydrogen peroxide, and UV irradiation (with limits) are the only effective surface disinfection agents, which is not correct. Chlorine dioxide, for example, is a very effective surface disinfectant, and may be more effective than chlorine. Other changes are editorial.

6.2 CLEANING PROGRAMS

Paragraph 41. Revise the sentence as follows:

“Cleaning and disinfection programs should include disinfectant agents and specific cleaning (including manual and automatic dishwashing) and disinfection procedures that are ~~able~~ demonstrated to inactivate enteric viruses...”

Rationale: It may be misunderstood that automatic dishwashing is an unacceptable cleaning procedure. The revision eliminates confusion about acceptable cleaning procedures and improves clarity.

7.1 HEALTH STATUS

Paragraph 43. Delete the parenthetical text.

“...of any infectious agents via food (~~section 3.4~~).”

Rationale: There is no section 3.4 in the main document.

7.2 ILLNESS AND INJURIES

Paragraph 46. Revise the first sentence as follows:

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

Rationale: Editorial correction. The text in the parentheses at the end of the first sentence should follow the word “period” as it is an example of a period of time.

ANNEX 1 BIVALVE MOLLUSCS

Introduction

Paragraph 1, 4th sentence. Revise as follows:

“Furthermore, studies indicate that there may even be a risk of infection if contaminated bivalve molluscs are consumed after ~~heat treatment~~ being heat treated for less than 90 degrees C for 90 seconds or an equivalent treatment.”

Rationale: Editorial change to add clarification. In the Main Document (Section 5.2, paragraph 25) and in this annex (section 5.2.2) there is a discussion that application of heat treatment of 90 degrees C for 90 seconds is adequate treatment to destroy viral activity in most foods. It is unclear if the reference to “after heat treatment” in paragraph 1 of this annex refers to the heat treatment of 90 degrees C for 90 seconds or some lesser treatment. In section 5.2.2 of the annex, it is mentioned that consumers are not likely to achieve the 90 degrees C for 90 seconds.

3 PRIMARY PRODUCTION

Paragraph 6, first sentence. Revise as follows:

“It is important to ensure the seawater quality of growing areas (Section 3.1) ~~by improving sewage treatment efficiency for virus removal/inactivation and avoid discharging of inadequately treated sewage in the surroundings of the~~ to minimize or prevent viral contamination of bivalve molluscs growing areas....”

Rationale: The first sentence is redundant with information that is in Section 3.1 and more appropriately belongs in Section 3.1 (see comment below on Section 3.1).

Paragraphs 6 and 7. The distinction between “long-term relaying” and “deuration” is not clear and the guidance provided is not very helpful. The primary issue here is that for neither option is a time period specified. That would seem to be the most crucial piece of information. We propose rearranging some of the sentences and modifying the text as shown below:

[Paragraph 6 – divided into two paragraphs]

“...To control the hazards, identification and monitoring of growing areas is very important for bivalve mollusc 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.” [END OF PARAGRAPH]

[NEW PARAGRAPH]

If using short-term or long-term relaying as a means to reduce microbial contaminants, the effectiveness of the treatment is dependent upon the water quality and conditions of the location to which the bivalve molluscs are relayed. The time used for relaying bivalve molluscs should be verified as appropriate by the competent authority having jurisdiction. 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 mollusc species involved and local geographic or hydrographic conditions to ensure that contamination levels will be adequately reduced. A short-term deuration process commonly reduces low levels of bacterial contamination, and thus contributes to the safety of bivalve molluscs, but deuration, as usually performed, is inadequate for the elimination of viruses.

[Paragraph 7 – one sentence was moved to the new paragraph above]

“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 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, if verified by the competent authority, is a combination of deuration and relaying ~~as determined by the competent authority.~~”

When taken together, the first three paragraphs, without editorial marks, would appear as follows:

[Paragraph 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.

[New Paragraph 6 bis]. If using short-term or long-term relaying as a means to reduce microbial contaminants, the effectiveness of the treatment is dependent upon the water quality and conditions that the bivalve molluscs are relayed to. The time used for relaying bivalve molluscs should be verified as appropriate by the competent authority having jurisdiction. The holding time and minimum temperature during long term relaying should be based on the degree of contamination before relaying, the temperature of the water, the bivalve molluscs species involved and local geographic or hydrographic conditions to ensure that contamination levels will be adequately reduced. 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 for the elimination of viruses.

[Paragraph 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. Another option, if verified by the competent authority, is a combination of depuration and relaying.”

Rationale: To provide clarification to the distinction between relaying and depuration. Some editorial revisions to group the discussion about relaying time together and to remove redundancy.

Paragraph 6, last sentence, last line. Clarify what is meant by the phrase “as usually performed” in the statement “...but depuration, as usually performed, is inadequate in the elimination of viruses.”

Rationale: Clarification is needed to understand the phrase “as usually performed.”

3.1 ENVIRONMENTAL HYGIENE

Paragraph 11, 4th sentence. Delete the term “per year” in the following sentence:

“Treatment plants should be designed in such a way as to minimize storm overflows ~~per year~~ that may affect the fishery.”

Rationale: Editorial correction.

Paragraph 16. Revise as shown below:

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~~ During such periods, the monitoring of areas should be reinforced.

Rationale: Editorial change to improve readability.

Paragraph 16. The paragraph recommends encouraging the monitoring of risk areas during periods when there are risks of contamination. Clarify for what the harvest area should be monitored. Is it to monitor that there is no harvesting taking place, or is it to monitor for contamination levels in risk areas so additional validated process steps, such as long-term relaying/depuration can be applied?

Rationale: Clarification is needed to understand the guidance.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

Subsection 5.2.2, second bullet - High Hydrostatic Pressure (HHP). The following insert is recommended:

“High Hydrostatic Pressure (HHP); HHP may reduce virus titers in bivalve mollusks with relatively small effects on the character of the meat. A pressure of 600 MPa applied at 6° C for five minutes completely

inactivated NoV in oysters. The HPP conditions for inactivation depend upon pressure as well as time, temperature and the salinity of the water. The use of HHP alone or in combination with..."

Rationale: For the heat treatment paragraph there is a very specific example given. A similar example for this section is appropriate (defining the magnitude of the pressure). The example comes from Leon et al., 2011 (*Applied Env. Microbiol.* Vol 77 pages 5476-5482).

ANNEX 2 – FRESH PRODUCE

3.1 ENVIRONMENTAL HYGIENE

Paragraph 11.

Is there an acceptable performance standard for elimination of viruses in sewage? Consider clarifying what is meant by "adequate (maximal) reduction". As an alternative, consider replacing the sentence with the following statement:

"Sewage treatments should reduce viral loads in treated sewage so it is no longer a potential source of viruses. ~~ensure adequate (maximal) reduction of viral loads in treated sewage,~~ as The the following could be potential sources of contamination:.

Rationale: Improves clarity.

INTERNATIONAL INSTITUTE OF REFRIGERATION (IIR)

The International Institute of Refrigeration (IIR) wishes to submit the following comments on the PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF VIRUSES IN FOOD (At Step 3):

The text of the first paragraph "cooling and freezing" of the subsection 5.2.1 "Time and temperature control" could lead one to think that refrigeration is detrimental (whereas it is a good way of controlling or stopping the growth of microbes and other pathogenic agents), and worse, that repeated freezing and thawing cycles could have a positive effect. Given that freezing and thawing cycles are very detrimental to food preservation, such practices should be avoided. The IIR therefore proposes to replace the text of this paragraph with the following:

5.2.1 Time and temperature control

- Cooling and freezing: The maintenance of the cold chain minimizes the growth of bacteria, and it is therefore important for both food quality and safety. However, the infectivity of viruses is influenced very little or not at all by low temperatures. Viruses are known to survive longer on fresh produce kept cold, and some can survive longer than the shelf life of the product. Certain viruses (noroviruses, for instance) remain infective during and following freezing. Cooling and freezing cannot be used to control virus infectivity, although their role remains highly relevant to maintain food safety.
- 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 log₁₀ reduction in infectious units after 5 cycles of freezing and thawing and less than 1 log₁₀ 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.~~