codex alimentarius commission



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS WORLD HEALTH ORGANIZATION



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Agenda Item 8

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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

Comments submitted at Step 3 by Canada, Egypt, Japan and Chile

General Comments

Canada wishes to thank the Netherlands and the members of the Working Group for drafting the document CX/FH 09/41/8, **Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food**. We are pleased to provide the following comments for the CCFH's consideration:

General Comments

There are a number of expressions used in the document when referring to water. For example, under 3.1, Environmental Hygiene, 5th line, the expression "high quality water" is used. Also, under 5.1.1, Identification of steps critical to the safety of foods, 1st bullet, the expression "Safe growing water" is used. There is a need to clarify if different water quality is needed for different activities. If water quality other than potable water can be used, the different types of water should be defined under Section 2.3.

Reference to the Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993). This document is quite old and the sections do not follow the same format as the Code of General Principles. It may be better to add the wording from the Code on Mass Catering rather than referring to the sections to ensure proper guidance is captured.

Specific Comments

5.1.3 and 5.1.4

The statement "Not applicable yet" is used. It is not clear how this statement is to be interpreted.

5.5.1

3rd line, it states that only "Raw fruits and vegetables to be used in meals". We would expect that any food that is considered "RTE", as per the definition, that comes into contact with water should only be in contact with potable water. This sentence should be expanded to all RTE foods or deleted.

7.5

Gloves As this section does not exist under the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)), we suggest that it be numbered as 7.4.1 and keep Visitors as 7.5.

7.6

Last sentence: It is not clear what is meant by "Visitors should preferably use separate personal hygiene provisions". If there is a need to add to the guidance from the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)), then what is specific should be added.

10.3 Instructions and Supervision

We believe that the training should focus on transmission and disinfection steps and not on the knowledge of infectivity. We suggest to remove "to knowledge of infectivity".

Annex I

Annex I basically repeats everything found in the Code. We propose to remove this Annex.

Annex II

5.1.2

Third bullet point, the word "relaying" should be defined under Section 2 of the Code.

5.2.1

This paragraph should be rewritten to be outcome-based. We propose: The process used should reduce the level of viruses, if present, to a level not presenting a hazard to health. Even though cooking may not guarantee total inactivation of viruses, it would reduce their levels and reduce the risk of causing foodborne infection.

5.8 Recall Procedures

Not sure how the text addresses the issue of recall. It may be better to only refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 4 (2003)) as of 7.5.

9.1 Lot Identification

This paragraph is not clear. What is meant by "various growing waters". We propose the following: NoV and HAV show a long persistence in bivalve mollusks. Movements between areas where mollusks are grown and countries involved in the trade of mollusks are creating specific difficulties regarding traceability. Lots should be identified with information from areas where mollusks were grown and such areas should be registered.

9.3 Labelling 3rd line

3rd line: We believe that cooking will achieve some inactivation of viruses and suggest to replace "may" by "would".

10.2 Training Programmes

Similar comments to 10.2 from the Code. We do not believe that training should be done on "the biology" of these organisms but rather on how to control the organisms.

Annex III

3.2, 3^{rd} paragraph. It is well known that E. coli is not a reliable indicator of the presence of NoV or HAV. We suggest to reword the 2^{nd} sentence as follows: "The level of fecal contamination may indicate the potential for the presence of NoV and HAV." We also suggest to delete the last sentence as testing would be an unreliable way to ensure that production areas are acceptable for growing molluscs.

CHILE

Chile wishes to recognize the countries that participated in the development of the draft for their diligent work and at the same time wishes to express thanks for the opportunity to express our comments on the document. Specifically we would like to make the following observations:

- a) Support for the development of the draft, as an annex to the code of hygienic practices for food, and to request that the food and environment surveillance systems be complemented with more detail, in consideration of the difficulty in detecting the viruses. We request that [the committee] evaluate the possibility of including monitoring methodologies that consider the use of feasible, low cost, simple and specific indicators (bacterial or other types), so that use of PCR techniques will not be necessary.
- b) The draft refers to already developed hygienic practices, primarily in the Recommended International Code of Practice General Principles of Food Hygiene CAC/RCP 1-1969, rev. 4 (2003), and therefore we feel that it should become an annex to this Code, rather than a guideline in and of itself.

EGYPT

The document deals well with the GHP with a reference to CAC/RCP 1-1969, Rev.4 (2003), but the differentiation between food borne virus (virus transmitted through food) and viruses which cause sympton of gastroenteritis.

2- Definition

The definition of:

- A- food borne viruses.
- B- Zoonetic viruses

3-Scope

Food chain

What is difference between through consumption and till consumption?

JAPAN

Japan 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 for consideration at the forthcoming 41st Session of the Codex Committee on Food Hygiene.

General Comments

Japan is of the opinion that this document should provide guidance on control measures that effectively minimize contamination of viruses in foods, because the viruses causing food poisoning can trigger outbreaks with minute amount of contaminated materials; for example, 1 mg of patient's stool may contain as many as 10,000~100,000 virus particles and as few as 10~100 particles can cause symptomatic infections.

As the report of the FAO/WHO scientific meeting indicates there are clear differences in morphology, infectivity, persistence and epidemiology between viruses and common foodborne bacteria, and control of viral hazards often requires measures different from those typically employed to combat bacterial hazards. Thus Japan supports creating food hygiene guidelines which should be effective for viruses.

Japan suggests that, in principle, this document should not repeat the same texts that have been already available in the "*Recommended International Code of Practice - General Principles of Food Hygiene-CAC/RCP 1-1969*". CCFH should develop a concise document focusing on specific requirements for the control of viruses. In this respect, Japan proposes that the relevant replicated texts should be replaced with the reference to the "*Recommended International Code of Practice (CAC/RCP 1-1969*)" throughout the document. With regard to the issue on ready-to-eat (RTE) foods, Japan proposes to delete the whole text of

ANNEX I because a number of replications appear and suggests that the text on RTE food in the main document should be improved by reflecting all the context of ANNEX I, where necessary and appropriate.

Specific Comments

Proposed amendments are presented in underlined bold font and proposed deletions are struck out as follows:

INTRODUCTION

3rd paragraph

Japan proposes to insert "formally known as Norwalk-like virus," immediately after "norovirus (NoV)" in the first sentence and consequently proposes to delete the definitions for norovirus (NoV) and hepatitis A virus (HAV).

4th paragraph, 6th bullet point

<u>Combination of traditional hygienic hand-washing practices and proper use of relevant chemical disinfectants is Hand disinfectants may not be as effective for virus inactivation on hand.as compared to traditional hygienic hand washing practices. It should be noted that Moreover the majority of chemical disinfectants used do not effectively inactivate non-enveloped viruses, as was shown e.g. for HAV. Proper use of hand disinfectants may reduce virus load on hand up to 2 logs.
</u>

Rationale: A number of enteroviruses are inactivated by chlorine, chlorine dioxide, peracetic acid and ozone (harakeh and Bulter, 1984). These chlorine based substances are needed for surface disinfection. It is known that hand disinfactants may be effective for 2 log reduction of viruses.

12th paragraph , 4th and 5th sentences

While several surface disinfectants (e.g. chlorine, chlorine dioxide, peracetic acid) are effective to inactivate enteric viruses. As is the case for hand disinfection, most surface <u>disinfectants</u> lack efficacy (i.e. cause less than a 1000 fold reduction in infectivity) against enteric viruses at manufacturers recommended concentrations. <u>Therefore combination of traditional hand washing with physical removal of virus and a proper hand disinfection is important to inactivate viruses.</u> In fact, it is well recognized that the majority of chemical disinfectants used in both institutional and domestic environments do not effectively inactivate HAV.

Rationale: A number of enteroviruses were inactivated by chlorine, chlorine dioxide, peracetic acid and ozone (Harakeh and Bulter, 1984). In Japan, chlorine is used for surface disinfection. Free chlorine at 0.4 mg/l inactivates HPA in 0.05M phosphate buffer by 3 log10 in 0.5 min and 4 logs in 2.5 min. (Grabow et al (1983)).

13th paragraph

Japan proposes the following deletion in the second sentence describing the ongoing activity in CEN/TAG4 because it is not appropriate to refer to ongoing work. When the document is completed, the information may become obsolete.

The URL for Health Canada should also be deleted. The Commission, at its 32nd Session, agreed that links to website should be included in Codex documents when it is absolutely necessary and only when the link is expected to be stable (para.104 of ALINORM 09/32/REP). Japan proposes the deletion of the weblink .CCFH may wish to elaborate a short texts explaining validation of detection methods for food-borne viruses in bivalve mollusks, by excerpting some texts available on the website.

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

SECTION II- SCOPE, USE AND DEFINITION

2.1 SCOPE

2.1.1 Food Chain

Japan proposes to insert "focus on ready-to-eat food," after the term "consumption" in the first sentence in order to highlight the importance of minimizing cross contamination in RTE foods which may lead to potential risks associated with contamination of NoV and/or HAV.

The revision year of the "*Recommended International Code of Practice- General Principles of Food Hygiene*" should be deleted as it is not necessary the revision number may change frequently, leaving only "CAC/RCP 1-1969". The same modification should be made throughout the document.

These guidelines are intended for all kind of foods and are applicable throughout the food chain, from primary production through consumption, <u>focus on ready-to-eat food</u>, and are necessary to control viruses in foods in conjunction with Good Hygienic Practices (GHPs) ...

2.3 DEFINITIONS

The following definition for "clean water" should be added. Then the term high water quality "should be replaced with "clean water" in this section as well as in Section 3.1 of the main document, sub-section 5.1.2 of Annex II, sub-sections 5.1.1 and 5.1.2 of Annex III.

<u>Clean water- water from any source where harmful microbiological contamination, harmful substances</u> and/or toxic plankton are not present in such quantities as may affect the health of consumer.

Japan proposes the following deletions and changes:

HAV hepatitis A virus

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

Rationale: Refer to the comment on paragraph 3 of INTRODUCTION above.

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

Rationale: It is not necessary.

Fresh produce - including fresh leafy vegetable. products

Rationale: To be consistent with the relevant term in the title of the Proposed Draft Annex on Fresh Leafy Vegetables (in CX/FH 09/41/5)

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

Rationale: The definition has already been included in the Recommended International Code of Practice - General Principles of Food Hygiene CAC/RCP 1-1969

Ready-to-eat food (RTE-food) - any food that is normally eaten in its raw state or any food handled, processed, mixed, cooked, or otherwise prepared into a form, which is normally eaten without further virucidal steps, e.g. by processing.

Rational: To remove redundancy.

Japan proposes the deletion of the definition for *shellfish*. The following definition for Shellfish available in the *Code of Practice for Fish and Fish Products* (CAC/RCP 52-2003) should apply in this document:

Shellfish means those species of aquatic molluscs and crustaceans that are commonly used for food.

SECTION III- PRIMARY PRODUCTION/HARVESTING AREA

3.1 ENVIRONMENTAL HYGIENE

2nd sentence

Japan proposes to delete "or soil" as "the use of soil" makes no sense.

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

2nd paragraph, 4th sentence

Japan proposes the following changes:

In case of gastroenteritis, allow returning of persons only after confirmation that <u>the test result of virus</u> <u>in fecal samples shows "undetectable" a period without symptoms of diarrhoea and vomiting (e.g.</u> <u>period of 48 hours which is an accepted practice</u>) or in case of hepatitis, allow returning of persons after disappearance of jaundice and medical examination and medical advice.

Japan wonders if scientific evidence is available to prove that "period of 48 hours" is an accepted practice to prevent virus contamination in foods through food handlers. Shedding of viruses (e.g. NoV, HAV) may continue post-symptomatically. The NoV continues to be present in the stool for as long as 2 to 3 weeks after recovery). Sick workers should be allowed to return to the food handling work only after conformation that the virus concerned is not detected from their fecal samples. If this practice is not feasible, those workers should work only in non-direct food contact area (e.g. distribution of packed product) after their return to work.

Japan suggests that the same amendments should be made in the 7th dash point of Section 5.1.2 and the 5th sentence of Section 7.2.

5th sentence

Japan proposes the following deletion.

Japan is of the opinion that, in principle, sick workers should be allowed to return to the food handling work (either direct or indirect handling) only after confirmation that the virus is not detected from their fecal samples. If the sick worker returns after a certain predetermined period (e.g. period of 48 hours) without symptoms of diarrhea and/or vomiting, but is not yet examined for a fecal test of virus's presence, he or she may still in the period of viruses shedding. Therefore, in principle, such worker should not be involved in food handling work. If this practice is not feasible, it may be allowed that the worker should be involved in non-direct food handling work (e.g. packing and/or distribution of packed products) till a fecal test results in virus negative.

As shedding of viruses, such as NoV or HAV, may continue post-symptomatically (e.g. the NoV continues to be present in the stool for as long as 2 to 3 weeks after recovery), these persons should comply with strict hand hygiene instructions (i.e. thorough hand washing with soap and running water² and preferably drying hands with disposable (paper) towels.) and preferably use a separate bathroom.

Japan suggests that the same deletion should be made in the 6th sentence of 7.2 ILLNESS AND INJURIES.

A footnote should be added to refer to the WHO guideline on hand hygine in health care as follows:

(footnote) ² WHO Guideline on hand hygiene in health care. WHO/EIP/SPO/QPS/05.2.

http://whqlibdoc.who.int/hq/2005/WHO_EIP_SPO_QPS_05.2.pdf

Rationale: To be consistent with other hand washing descriptions in the same document such as in Section 7.3.

6th sentence

Japan proposes the following insertion to define what "all staff members" are:

When one of the staff members calls in with symptoms of gastroenteritis or hepatitis, other staff members may also be (asymptomatically) infected and all staff members food handlers who have direct or indirect contact with the infected staff should comply with strict hand hygiene.

SECTION IV- ESTABLISHMENT: DESIGN AND FACILITIES

4.4 FACILITIES

4.4.4.1 Changing facilities and toilets

1st paragraph, 3rd sentence

Japan proposes the following change, for clarity:

These should be located in close proximity to the production area, in sufficient number to accommodate personnel, be of appropriate design to ensure hygienic removal of wastes, have adequate means of hygienically washing and drying hands, be maintained under sanitary conditions and good repair, following cleaning and disinfection programme(see 6.2 cleaning programmes) and be included in disinfection programmes (for the latter see 6.2).

SECTION V- CONTROL OF FOOD HAZARDS IN RELATION TO VIRAL CONTAMINATION

5.1 CONTROL OF FOOD HAZARDS

5.1.1 Identification of steps critical to the safety of food

2^{nd} dash point

Japan proposes to delete the second sentence as it is fully covered in the fifth and sixth dash points in 5.1.2.

5.1.2 Implement effective control procedures at those steps

To shorten the text, Japan proposes to insert the following text just below the subsection title and delete the first, third and sixth dash points as they are replication of the texts in *the Recommended International Code* of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

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

9th dash point

For consistency with the texts in Section 6.2, the term "cleaning" should be inserted to read the texts as follows:

Having cleaning and disinfection programmes, disinfectant agent....

SECTION VI ESTABLISHMENT: MAINTENANCE AND SANITATION

6.1 MAINTENANCE AND CLEANING

6.1.2 Cleaning procedures and methods-

3rd paragraph

Japan proposes to amend the first sentence to read as follows:

• Many disinfection agents recommended for use in food establishments are not effective against the non-enveloped viruses, such as NoV or HAV. One of the effective methods is e.g. the use of sodium hypochlorite (1000 <u>µl/l in clean condition and 5000 µl/l in the unclean condition</u>) for at least 5 min. Freshly constituted hypochlorite solutions (e.g. using tablets) are preferable.

Rationale: Sodium hypochlorite at 1000 μ l/l is adequate to disinfect viruses in a clean condition but is ineffective against the viruses in an unclean condition. In order to indicate this fact, Japan proposes to add some texts.

6.2 CLEANING PROGRAMMES

The last sentence should be deleted to avoid replication with Section 6.1.2.

SECTION VII- ESTABLISHMENT: PERSONAL HYGIENE

7.1 HEALTH STATUS

The context of 2^{nd} paragraph has already been described elsewhere in this document. So Japan proposes to delete the whole text.

7.2 ILLNESS AND INJURIES

2nd sentence- "acute" should be inserted before in order to clarify the term "hepatitis".

Food handlers with clinical symptoms of gastroenteritis (diarrhoea and/or vomiting) or with symptoms of <u>acute</u> hepatitis (fever, headache, fatigue combined with dark urine and light stools, or jaundice.), should be excluded from food handling and should also be excluded from being present in the food

handling area to reduce the likelihood of transmission of enteric viruses, such as NoV and HAV, that may be the underlying cause of the symptoms of gastroenteritis or hepatitis, respectively.

7.3 PERSONAL CLEANLINESS

2nd paragraph

Japan proposes to delete the second sentence. The context has already been covered in the *Recommended International Code of Practice code of practice- General Principles of Food Hygiene CAC/RCP 1-1969.*

ANNEX I

HYGIENIC PRACTICE BY FOOD HANDLERS FOR CONTROL OF HEPATITIS A

VIRUS (HAV) AND NOROVIRUS (NOV) IN READY TO EAT FOODS

Japan proposes to delete the entire text of ANNEX1. Most of the current text just repeats what is written on RTE food in the main document. It is very crucial to follow more stringent preventive control measures with a view to avoiding virus contamination in RTE foods. There is no process existed to eliminate viruses before RTE food consumption. Rather than elaborating the Annex, it is preferable to improve the text of the main document on RTE food in order to draw special attention to the importance of following the stringent measures.

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

SECTION II - SCOPE, USE AND DEFINITION

2.1 SCOPE

1st paragraph

Japan proposes the following amendments:

 These guidelines are intended for bivalve molluscs and will focus on control measures that can be used, where appropriate, to minimize and/or prevent the contamination of HAV and NoV. These guidelines are based on the results of the FAO/WHO risk assessment the FAO/ WHO <u>expert</u>-Expert meeting Meeting, held on 21–24 May 2007(in Bilthoven, The Netherlands) other available risk assessments and <u>other</u> epidemiological evaluations. They highlight key control measures that affect key factors that influence the frequency and extent of contamination of bivalve molluscs with HAV and NoV and thus the risk of hepatitis and gastroenteritis.

Rationale: For accuracy, the correct name of the meeting should appear.

As far as Japan recognizes, there is no published "Virus –food" risk assessment conducted by international organizations such as FAO and WHO. Otherwise, specific references should be added here.

SECTION III - PRIMARY PRODUCTION

2nd sentence from the bottom

Japan proposes the following deletion:

Otherwise, Japan would like to seek for scientific evidence that proves this minimum requirement of "two months".

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

The last sentence

Japan proposes the following amendments to explain in detail what the sanitary surveys requirements are:

Other conditions including the sanitary surveys requirements should also have been satisfied as a condition of reopening the area. They should include the identification of sources of

pollution/contamination (e.g. sewage plants, industrial waste sources, sewage overflows, sewage discharges or disposal of sewage/faecal matter from ships, storm drains). They may also include: rural land with domestic animals, forest or marsh areas dominated by wild animals and/or birds, the effects of rainfall, river and tidal flows, farming activities, and geographical proximity from the source to the harvesting areas.

SECTION V- CONTROL OF OPERATION

5.1 CONTROL OF FOOD HAZARDS IN RELATION TO VIRAL CONTAMINATION

5.1.2 Implement effective control procedures at those steps

2nd dash point

Japan proposes to add a text for more clarity.

-Sewage treatments should be improved to obtain maximal reduction of viral loads of the effluents. After heavy rainfall, growing and harvesting waters may be contaminated with virus, harvesting of oysters should be postponed until no virus is detected from the water.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Specific process steps

1st sentence

Japan proposes to replace "should" with "may". Primarily effectiveness of commercial heat treatment processes (cooking temperature) should be proven by industries, not by the competent authorities. But in some case the competent authorities may approve such processes.

The country's competent authority <u>shouldmay</u> approve commercial heat treatment processes, (e.g. the UK heat cook parameters of raising the internal temperature of bivalve molluscs meats to 90 °C for 1.5 4 min).

3rd sentence

Japan proposes the following amendments:

Also the inability of home or restaurant cooking to provide adequate guarantees of consumer protection against viral contamination for bivalve shellfish emphasis the reliance on harvesting from growing areas if control measures required in Section 5.1 can be implemented to ensure safe water virus safe water growing areas.

The text "the reliance on harvesting from virus safe water growing areas" is not clear enough to be understood. What does it mean?

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

INTRODUCTION

3rd paragraph, 3rd sentence

Japan proposes to replace "NoV" with "Norovirus" as NoV is introduced later in this annex.

SECTION II- SCOPE, USE AND DEFINITION

2.1 SCOPE

1st paragraph, 2nd sentence

Japan proposes the following amendment as the scope of this annex covers fresh produce including leafy products:

The same amendment should also be made to the first paragraph of Section III (the first, the second, the third sentences) and the first sentence of Section 3.2.1.

Specifically, this Annex is applicable to fresh fruits and vegetables fresh produce grown in the field (with or without cover) or in protected facilities (hydroponic systems, greenhouses).

Japan proposes the following deletion, as the same term defined in the main document should also be applied in this annex.

Fresh produce including leafy greens.

SECTION III- PRIMARY PRODUCTION

2nd paragraph

Japan proposes the following amendments to further clarity the meaning of the paragraph:

In addition, <u>fF</u>resh produce may be contaminated by food pickers directly through vomiting in the field <u>if viruses are present</u>. On the other hand, retail <u>fF</u>ood handlers <u>in retail shops</u> and/<u>or</u> food preparers <u>at</u> <u>in the home</u>, <u>if they spread viruses</u>, can contaminate highly handled "prepared" foods with viruses immediately prior to consumption.

SECTION V- CONTROL OF OPERATION

5.8 RECALL PROCEDURES

To avoid the repetition of description in the *Recommended International Code of Practice - General Principles of Food Hygiene -CAC/RCP 1-1969,* Japan proposes the following deletion:

Based on the determined level of risk associated with the presence of NoV and HAV in a given fresh produce, corrective actions may be taken and/or a decision may be taken to recall the contaminated product from the market. The need for public warnings should be considered.