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codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 8 **CX/FICS 08/17/8**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION

AND CERTIFICATION SYSTEMS

Seventeenth Session

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DISCUSSION PAPER ON THE DEVELOPMENT OF GUIDANCE ON THE PREVENTION OF INTENTIONAL CONTAMINATION OF FOOD

(prepared by the United States of America)

BACKGROUND

1. Protecting the global food supply is a common goal for food control authorities to protect public health and to prevent economic losses. Food protection encompasses both minimizing the inadvertent (unintentional) contamination of food and preventing intentional contamination. Historically, food regulatory agencies and the area of food standards (including Codex texts) have largely dealt with unintentional contamination, while controls for intentional contamination have not been formally addressed. Doing so would enhance existing Codex texts and make them more useful to national governments and other stakeholders.

2. At the 16th (2007) Session of CCFICS, the United States raised the subject of intentional contamination of food as a possible area of work for CCFICS. The Delegation of the United States of America explained that intentional food contamination was related to, but distinct from, traditional food safety and had a greater potential to result in market disruption and human death. Over the past years many food control authorities, industries and international organizations, such as WHO, have been engaged in the development of guidance to minimize the risk due to intentional contamination of food, e.g. intentional tampering, unsafe economic adulteration. It has been noted that although some Codex texts provided elements of guidance that could be applied when assessing intentional contamination, currently there are no Codex texts providing substantial comprehensive guidance.

3. The Delegation stated that it would be helpful for Codex to consider developing such guidance, particularly with respect to systems assessing the vulnerability to, and controlling, intentional contamination. Therefore, they proposed to develop a discussion paper that would address: i) the nature of intentional contamination of food; ii) the nature and extent of guidance that has been developed by governments, industry and international organizations; iii) an analysis of existing Codex texts, especially those related to intentional contamination, to identify gaps; and iv) an assessment of specific work that CCFICS might develop in this area, including an analysis of why CCFICS would be the appropriate venue for such work.

4. Several delegations recognized that intentional contamination was an important subject for discussion and that countries should assess their vulnerability to it and their capacity to control it. Concern was expressed as to whether CCFICS was the appropriate venue to develop such guidance since the control of intentional contamination fell within multiple jurisdictions. In view of the general support for continuing the discussion on this subject, the Committee agreed to the proposal of the Delegation of the United States of America to develop the discussion paper, as described above, for consideration at its next session.

NATURE OF INTENTIONAL CONTAMINATION OF FOOD

5. Intentional contamination of food is rarely reported; however, recent events have focused attention on the increasing possibility of this type of problem.

6. Intentional contamination has occurred for basically two different purposes. The first of these is intentional contamination for the purpose economic gain and usually involves a specific decision, often at a management level, to substitute or add ingredients to a product in order increase the financial return. While the intent of contamination for economic gain is generally not intended to include illness, examples exist that demonstrate such intentional contamination can inadvertently do so by using an ingredient in sufficient levels to result in human or animal illnesses and deaths. An example of an intentional contamination for economic gain involved the purposeful substitution of vegetable protein products contaminated with melamine and melamine analogs for wheat gluten and rice protein concentrate. This 2007 incident resulted in the sickness and deaths of cats and dogs, the recall of hundreds of brands of pet food products and concern regarding the possible associated human health risk.

7. The second purpose of intentional contamination of food can encompass adding microbiological, chemical and physical hazards to food at levels sufficient with the intention of causing human or animal illnesses and deaths, as well as economic loss. Examples of intentional contamination of food that resulted in harm to life as well as economic loss include:

- The deaths in 2002 of 40 school-aged children and adults with 200 more hospitalized after consuming breakfast food purposefully contaminated with rat poison by a competitor of the fast-food restaurant.
- The threat in 1989 of intentional cyanide poisoning to grapes from Chile which created significant economic loss.
- The 1984 threats to a candy maker that product would be poisoned unless the company paid cash.

8. Food safety assessments have provided predictability to unintentional contamination, identifying what can naturally occur and which protective measures will reduce the hazard. However, intentional contamination can occur at points that are not predictable (e.g. employees using agents not naturally occurring in food production such as arsenic, rodenticides and other chemicals) as well as adding ingredients for economic gain without knowing the harmful effects to human and animal life. A food protection system should include measures to prevent the unpredictable intentional contamination in addition to the predictable unintentional contamination.

MEASURES FOR PREVENTING INTENTIONAL CONTAMINATION

<u>Intentional contamination to effect public health or cause economic loss</u>

9. Some control measures that are currently used for food safety to protect against unintentional contamination will also protect against the effects of intentional contamination. Examples include measures used to kill microbial pathogens such as Salmonella and Listeria monocytogenes or to detect physical hazards such as metal fragments and glass. However, the agents that might be used in an intentional contamination may be heat stable and are not regularly looked for in traditional food safety testing, thus, requiring a different protective measure.

10. Intentional contamination for the purpose of effecting public health or causing economic loss can occur any place in the food chain to include production and transporting of raw ingredients, plant processing, and transportation of final product going to commerce. It can occur through the efforts of an employee or outside individual.

11. Vulnerability assessments conducted by government food authorities and industry members have identified potential areas of greatest vulnerability in food chain where, if contamination occurred, the impact would be significant. The assessments have identified suggested mitigation such as physical outside and inside security, limited access to critical areas, raw ingredient storage areas security, control of chemicals, and employee background checks.

Intentional contamination for economic gain

12. Generally, intentional contamination for economic gain would be expected to be limited to a processing step inside of the plant rather than another place in the food chain. Because the contamination is probably known and endorsed by management, a food defense plan developed and monitored by senior management may not be an effective measure for prevention. However, mitigation may include developing awareness among plant managers about the possible unintentional affects of adding certain ingredients and training the work force to question and report unusual ingredients or practices to authorities.

EXTENT OF DEVELOPED GUIDANCE

13. Some governments have developed guidance to help prevent the intentional contamination of food that would effect public health or cause economic loss, both for use by the competent authorities themselves as well as for use by the affected industry including food producers and processors, food importers, and food distributors and retailers. In the United States, for example, the U.S. Food and Drug Administration and United States Department of Agriculture's Food Safety and Inspection Service have developed guidance for the industries they regulate including meat and poultry processors, dairy farms and milk processors, and other food producers, processors, and transporters. Industry-specific guidance has also been developed to allow self-assessment and the development of plans to prevent the intentional contamination of food. These agencies have also worked closely with industry to assess vulnerable points in food systems and to develop mitigation strategies to protect the food supply.

14. International organizations have been engaged in developing guidance relating to protecting food from intentional contamination. For example the World Health Organization (WHO) has published a monograph that supports strengthening of programs that underlie food production, processing, and preparation to respond to food terrorism. It also describes the role of WHO, with its public health mandate, in responding to food safety emergencies of significance to international public health.

15. The Asia Pacific Economic Cooperation (APEC) Economy members have adopted protecting the food supply from intentional contamination as an issue of importance and it has been the lead counterterrorism initiative within the APEC. As part of this initiative, APEC members developed and agreed upon a set of nine voluntary principles that provide the scientific basis for protecting food supply from terrorism and provide a framework for continued cooperation on this initiative. In September of 2007, APEC became the first international forum to issue guidance when the leaders of the 21 member economies agreed to these region-wide principles to prevent the intentional contamination of food.

16. The European Commission on 11 July 2007 adopted a Green Paper on bio-preparedness. The aim of the paper is to stimulate a debate and launch a process of consultation at the European level on how to reduce biological risks, and to enhance preparedness and response capabilities. This paper addressed issues regarding the potential for an intentional contamination of the food supply.

17. Additionally, in 2004 and 2005, G8 leaders committed to defending against bioterrorism, by strengthening national and international biosurveillance capabilities; increasing protection of the global food supply; and improving bioterrorism investigation, response and mitigation capabilities. In 2005 the G8 Bioterrorism Experts Group (BTEX) agreed on a work plan for the development of a food defense tabletop exercise. This exercise serves to initiate a dialogue between G8 member nations on response mechanisms and investigation methods regarding an intentional bioterrorist attack upon the G8 food supply. This exercise also provides the opportunity for G8 nations to outline joint prevention and mitigation strategies, lines of communication and notification, and possible joint recovery plans. The simulated attack is based around a food product that is widely exported to and/or imported from all G8 nations.

ANALYSIS OF EXISTING CODEX TEXTS

18. Existing Codex texts currently provide many elements of guidance that may be applied in assessing the intentional contamination of food and food vulnerabilities. Texts developed by CCFICS include provisions relating to certain aspects of food control systems, certificates and emergency response. Texts developed by other Codex subsidiary bodies (e.g., Codex Committee on Food Hygiene) provide information on certain control measures (e.g., measures relating to control of microbial pathogens, prevention of chemical/microbiological/physical contamination, food recalls), primarily as they apply to unintentional contamination but with application that may be appropriate in some instances to intentional contamination.

However, no current Codex text speaks directly to the intentional contamination of food nor provides substantial or comprehensive guidance on the subject including aspects noted in paragraph 20.

ASSESSMENT OF SPECIFIC WORK FOR CCFICS

19. It is suggested that the development of Codex principles and guidance relating to the intentional contamination of food could be helpful additional information for use by governments and the food industry. Principles relating to the intentional contamination of food could cover such aspects as:

- Intentional contamination of food being distinct from but related to the unintentional contamination of food;
- Intentional contamination of food being a shared responsibility between both government and industry;
- The need for effective and timely communication among stakeholders;
- The importance of prevention, preparedness, response and recovery; and
- The importance of mitigation to be consistent with the risk profile and vulnerability.

20. General guidance serves to increase awareness and would include information pertaining to such areas as: ingredient sourcing; management and supervision of food establishment operations including those related to processing, warehousing, shipping and distribution; recall strategies; laboratory operations; facility security; security of water and utilities; IT security; and, evaluating the effectiveness of measures to prevent the unintentional contamination of food. Guidance also includes approaches to vulnerability assessment.

21. Work undertaken to develop principles and guidance related to the prevention of intentional contamination of food would take into account information developed on the subject by countries, by WHO, by APEC and by other organizations as appropriate.

CCFICS MOST APPROPRIATE VENUE FOR WORK ON INTENTIONAL CONTAMINATION OF FOOD

22. The United States notes that guidance relating to preventing the intentional contamination of food is largely systems-based guidance. While specific control measures may be employed to control hazards that arise from the intentional contamination of food, and these measure can be the same or similar to those used to control microbiological, chemical hazards and physical hazards and thus are in the domain of other Codex general subject committees such as the Codex Committee on Food Hygiene and the Codex Committee on Contaminants in Foods, the nature of the guidance proposed in this Discussion Paper is that related to the overarching system, generally irrespective of the nature of the specific microbial or chemical hazard. Thus the expertise needed to do this work is that related generally to food control systems, the very expertise that is maintained by CCFICS.

RECOMMENDATIONS

23. The United States encourages CCFICS to give favourable consideration to the development of principles and guidance relating to the prevention of unintentional contamination of food. Such guidance will augment existing information on food import and export control systems relating to inadvertent/ unintentional contamination of food, substantially strengthening extent of food safety protection capabilities offered by these systems.

24. The Committee is invited to consider the recommendations for work to develop principles and guidance relating to the prevention of intentional contamination of food as outlined in the Project Document in Attachment 1 for approval as new work by the 32nd Session of the Codex Alimentarius Commission in 2009.

ATTACHMENT 1

Project Document

Proposal for New Work – Codex Committee on Food Import and Export Inspection and Certification systems

PROPOSAL TO DEVELOP PRINCIPLES AND GUIDELINES ON THE PREVENTION OF INTENTIONAL CONTAMINATION OF FOOD

1. The purposes and scope of the standard

The purpose of the standard is to provide guidance to governments and other interested parties on the prevention of the intentional contamination of food both with respect to: a) intentional contamination arising from an attempt to achieve economic gain in which harm is caused; and, b) intentional contamination in which the original intent is to cause harm

2. Relevance and timeliness

While rarely reported, recent events have focused on the increasing possibility of the intentional contamination of food that can result in serious adverse public health consequences and/or significant economic loss. For example, a 2007 incident involving the contamination of pet food with melamine and melamine analogues for economic adulteration purposes resulted in the sickness and death of cats and dogs, and associated concerns regarding possible human health risk from the consumption of potentially contaminated vegetable protein products. While existing Codex texts focus on the prevention and control of unintentional contamination of food, there is no Codex guidance that specifically addresses the intentional contamination of food. Considering the potential for, and actual occurrence of, such problems, the development of the proposed guidance is both relevant and timely.

3. The main aspects to be covered

The work will include both the development of principles and general guidance relating to the prevention of the intentional contamination of food both with respect to: a) intentional contamination arising from an attempt to achieve economic gain in which harm is caused; and, b) intentional contamination in which the original intent is to cause harm. Principles could cover such aspects as: the distinction of intentional contamination of food from unintentional contamination; the importance of prevention, preparedness, response and recovery; the importance of mitigation being consistent with the risk profile of the hazard and vulnerability; and the need for effective and timely communication among stakeholders. General guidance, which as appropriate will be specific for the different types of intentional contamination, would provide information pertaining to such areas as: ingredient sourcing; management and supervision of food establishment operations including processing, warehousing, shipping and distribution; recall strategies; laboratory operations, facility and IT security; and vulnerability assessments.

4. An assessment against the *Criteria for the Establishment of Work Priorities*

General Criterion

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

Development of principles and guidelines for the prevention of the intentional contamination of food contribute to consumer protection from the point of view of health and food safety in that the guidance will help prevent the occurrence of intentionally added public health hazards to food. The guidance will be developed to provide flexibility for its application by countries with differing levels of development of food safety control systems.

Criteria Applicable to general subjects

(a) Diversification of national legislation and apparent resultant or potential impediments to international trade.

Several countries have developed or are developing guidance in the area of the prevention of intentional contamination of food. Development of Codex guidance in this area should assist in obtaining international harmonization of nationally developed guidance in this area.

(b) Scope of work and establishment of priorities between the various sections of the work.

The work will apply to all food and food ingredients and will encompasses the development of both principles and general guidance as noted under "main aspects" above. The various sections of the work will be developed simultaneously.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).

The work will take into consideration guidance relating to the prevention of intentional contamination of food developed by countries and regional entities, including the United States and the European Community. Also considered will be work carried out by international organizations including WHO and APEC.

5. Relevance to the Codex strategic objectives

This work is consistent with the following strategic goals.

Goal 1: Promoting Sound Regulatory Frameworks

Food Safety Regulatory Frameworks should take into account the public health impact arising from both the unintentional and intentional contamination of food. Codex food safety guidance does not specifically address the unintentional contamination of food; hence the development of Codex guidance and its availability for use by governments will assist in promoting sound regulatory frameworks.

Goal 2: Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis

As with guidance development for the prevention of unintentional contamination of food, guidance relating to the prevention of the intentional contamination of food must rely, in several areas, on the underlying science relating to the control of microbial, chemical and physical hazards. To this extent, the guidance developed through the project will contribute to the widest and consistent application of scientific principles. Additionally, control programs relating to the prevention of the intentional contamination of food are components of effective risk assessment, risk management and risk communication programs and thus contribute to the promoting the widest and consistent use of risk analysis.

6. Information on the relation between the proposal and other existing Codex documents

Existing Codex texts currently provide many elements of guidance that may be applied in assessing and controlling the intentional contamination of food and food vulnerabilities. Texts developed by CCFICS include provisions relating to certain aspects of food control systems, certificates and emergency response. Texts developed by other Codex subsidiary bodies (e.g., Codex Committee on Food Hygiene) provide information on certain control measures (e.g., measures relating to control of microbial pathogens, prevention of chemical/microbiological/physical contamination, food recalls), primarily as the apply to unintentional contamination but with application that may be appropriate in some instances to intentional contamination. However, no current Codex text speaks directly to the intentional contamination of food nor provides substantial or comprehensive guidance on the subject including those noted above in the "main aspects to be covered".

7. Identification of any requirement for and availability of expert scientific advice

None anticipated being required.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

None anticipated being required.

9. The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years

The following timeline is proposed for completion of the work, assuming the interval of CCFICS meetings does not change.

- Consideration of this Discussion Paper by the 17th CCFICS, 2009.

- If recommended for new work, approval by the Codex Alimentarius Commission at the Commission's 32nd Session in 2009.
- Development of an initial draft Paper for consideration at Step 3 by CCFICS in 2009.
- Adoption of the standard at Step 5 by the CAC in 2011.
- Adoption of the standard at Step 8 by the CAC in 2012 or 2013.