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Agenda Item 13

**CX/FH 00/13
August 2000**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD HYGIENE**

Thirty-third Session

WASHINGTON, D.C. USA, 23-28 OCTOBER 2000

**DISCUSSION PAPER ON PROPOSED DRAFT GUIDELINES FOR
EVALUATING OBJECTIONABLE MATTER IN FOOD**

(Prepared by the United States of America)

BACKGROUND

The science relating to objectionable matter and filth in food has developed in recent years to the point that it would seem appropriate for the Codex Committee on Food Hygiene to develop a set of guidelines for evaluating objectionable matter. At the thirty-second session of the Codex Committee on Food Hygiene, the Delegation of the United States noted the development of the science in this area, the existence of only general guidance on this subject in the *Recommended International Code of Practice – General Principles of Food Hygiene* and recommended the development of such guidelines. The Committee agreed to initiate work on *Guidelines for the Evaluation of Objectionable Matter* and requested the Delegation of the United States to prepare a draft discussion paper and outline of the Guidelines, with the assistance of Mexico and the Netherlands, for consideration at the next meeting of the Committee. It was proposed that the *Guidelines* be developed as an Annex to the *Recommended International Code of Practice: General Principles of Food Hygiene*.¹

The proposed guidelines shall focus exclusively on issues of food safety and wholesomeness of foods. This includes issues relating to sanitation, good hygienic practices and the prevention of foodborne illness or injury. The guidelines shall not involve the aesthetics of food or other food quality issues that are more appropriately addressed elsewhere.

¹ CAC/RCP 1-1969, Rev. 3-1997

PURPOSE AND NEED FOR THE GUIDELINES

No detailed guidance is presented in the *General Principles of Food Hygiene* concerning the evaluation of the presence of hazardous foreign matter and/or other objectionable matter in foods. The purpose of the proposed work is to provide an objective, uniform framework of guidelines for evaluating objectionable foreign matter in food and for evaluating any reasonably likely risks associated with foreign matter and disease-carrying pests. Such guidelines are especially important for the development of modern food safety programs that rely on risk management and/or HACCP principles to ensure the safety and wholesomeness of the food supply.

Microbial Risk Management Applications. Disease-carrying pests are known to be vectors of foodborne pathogens. Scientific studies have proven that certain disease-carrying pests are potential sources of microbiological hazards as a result of contact of the pests with food. Currently, there are no guidelines for deciding if a potential vector should, or should not, be considered for inclusion in risk profiles and other risk management activities. In order to make such decisions, the risk managers need objective criteria for evaluating the potential microbial risks associated with a particular vector. Furthermore, it is important to develop guidance that eliminates doubt as to which pests pose a reasonably likely risk of transmission of a pathogen and which do not. This is necessary to prevent the inclusion of a pest in a risk management activity where that pest does not belong.

HACCP Applications. HACCP planners and regulators need guidelines for evaluating the potential physical, chemical and microbiological hazards associated with various types of objectionable matter in food. There are no international guidelines for evaluating non-microbial hazards such as physical hazards from foreign objects in food or allergen hazards from pests such as dust mites or cockroaches in food. In addition, HACCP planners need guidance for evaluating whether or not an objectionable condition or practice is a likely contributing factor to contamination from pathogens so that appropriate control measures, corrective actions and verifications can be designed into prerequisite.

General Food Hygiene Applications. Good Manufacturing Practices (GMPs) mandate the exclusion of objectionable matter from food and the control of pests in and around food processing or storage facilities. The *General Principles of Food Hygiene* requires a balanced approach to food hygiene that includes food safety issues. The guidance provided in the *General Principles of Food Hygiene* for preventing objectionable matter in food and for controlling pest activity needs to be amplified for the following reasons:

- To clarify the relationship between health hazards and objectionable matter associated with poor hygiene.
- To serve as a source document for HACCP planners in developing basic Sanitation Standard Operating Procedures.
- To achieve harmonization in evaluating the significance of objectionable matter in food and insanitary conditions in food processing and storage facilities.
- To guide pest control systems operators in determining appropriate responses to pest infestations and pest activity.
- To improve the transparency of the scientific basis for good food hygiene.

SUMMARY OF THE SCIENCE BASIS

Physical Hazards. Evaluations by medical experts of physical hazards in food were recently summarized in the scientific literature (1). As a result, it is now possible to characterize the potential hazards from hard or sharp foreign objects in terms of the sizes of objects that cause injury when eaten in a contaminated food. The data available for evaluating these and other physical hazards consist of compilations of reports of injuries from foreign objects in food; government and industry standards for foreign matter in food; and statistical analyses of the prevalence and population distribution of injuries from accidentally ingesting objects of different sizes and shapes.

Allergens. Recent studies in Asia, Europe and North America report life-threatening systemic allergic reactions due to the consumption of food contaminated with allergenic mites (2). The evidence indicates that ingestion of a relatively small number of mites in a food may induce anaphylaxis or other systemic allergic reactions in sensitized individuals (3). Mite allergens are not denatured by normal cooking or by freezing. The allergenic mites involved in these incidents are all food-contaminating species that thrive under insanitary conditions (4). Other food-contaminating pests, such as cockroaches, are emerging as significant causes of allergy illnesses (5). Although there is no dose/response database for ingesting allergenic mites, the literature contains ample dose/response data for contact and inhalant exposure to the same mite species that cause ingestive allergy illness (6,7,8). There are also governmental guidelines that specify limits on numbers of mites in certain foods.

Disease-Carrying Pests. The major vectors of foodborne pathogens are flies, cockroaches, birds and rodents (9). Scientific studies report that these pests are natural reservoirs and mechanical vectors of foodborne pathogens (10, 11,12). Of particular concern are recent findings that implicate flies as potential contributing factors to outbreaks of human illness from *E. coli* O157:H7 in beef or fruit products (13, 14, 15) and *Salmonella* Enteritidis in eggs (16). Most recently, scientists discovered flies to be biological vectors that are capable of amplifying pathogens such as enterohemorrhagic *E. coli* O157:H7 (17). Databases relating to the disease-carrying capabilities of these pests take five forms.

- Epidemiological case control studies that assign risk factors relating to failures to exclude pests from food.
- Vector control studies that report statistically significant positive correlations between the suppression of pest populations and the reduction of disease.
- Behavioral studies that document pest behaviors conducive to the transmission of pathogens to food.
- Ecological studies that report the prevalence of specific pathogens in wild populations of a pest species.
- Laboratory studies of the abilities of a pest species to transmit pathogens.

Additional databases include integrated pest management (IPM) studies that recommend threshold levels for various disease-carrying pests; government guidelines for control of disease-carrying pests, including World Health Organization guidelines;² industry guidelines for evaluating objectionable matter from disease-carrying pests in food; and published questionnaire surveys that reveal tolerance attitudes of the average consumer toward these pests.

² WHO/VBC/86.937

OTHER CONSIDERATIONS

Pest Management Systems. Section 6.3 of the *General Principles of Food Hygiene* recognizes the need to minimize the use of pesticides. In general, uniform guidance that relates to pest control issues should reduce the unnecessary use of pesticides in and around food processing facilities by reducing the likelihood of over-reaction to pest activity that is not associated with poor hygiene or the spread of foodborne disease and by facilitating IPM programs that incorporate alternative methods of pest control.

There are five sequential elements in the decision-making process for a pest management system: 1) detection; 2) identification; 3) economic/health significance; 4) control method selection; 5) evaluation (verification). The proposed guidelines will provide a framework for determining health significance, enabling the process to proceed to selection of the most appropriate control methods.

Emphasis on Prevention. The primary focus of the proposed guidelines will be to prevent hazards and objectionable matter from entering the food chain. The key to prevention is to make effective use of existing preventive systems and programs such as HACCP systems, pest control systems, Good Manufacturing Practices (GMPs) and sanitation programs. The proposed guidelines will be designed to interface with these other systems and programs.

Trace Evidence. With respect to objectionable matter, trace evidence of poor food hygiene consists of small (< 2 mm) to microscopic traces of extraneous material and trace amounts of chemical evidence of pest activity. In some cases, trace evidence may indicate a relationship to a hazardous contaminant. Examples include objectionable matter such as glass fragments (physical injury) and allergenic mites (allergens). Trace evidence may indicate exposure to disease-carrying pests or lapses in GMPs. Examples include rodent urine or excreta and body fragments from disease-carrying flies, cockroaches or other commensal pests. Other types of trace evidence, such as natural defects or traces of agricultural pests, may simply indicate an aesthetic problem.

The principles in the proposed guidelines also apply to the evaluation of trace evidence in food. A detailed guideline for the interpretation of trace evidence in food is beyond the scope of the proposed work because, in most cases, the interpretation of small or microscopic bits of evidence must take into account additional requirements or conditions that are associated with a specific food item or food group. Should the proposed guidelines be adopted as an annex to the *General Principles of Food Hygiene* the guidelines will become available as a base document for any commodity Codes that require additional material for the evaluation of trace evidence relating to objectionable matter in foods subject to that particular commodity Code.

DESIGN AND ELEMENTS OF THE GUIDELINES

The design of the proposed guidelines is based on scientific principles whose validity is recognized by the international community of public health and forensic scientists (10, 18, 19, 20, 21, 22, 23). The guidelines are designed to be flexible. The principles of the guidelines apply to hazards; to objectionable matter in food; and to objectionable and/or potentially hazardous conditions and practices in food processing and storage facilities. This flexibility is necessary in order to interface with HACCP systems and other food safety systems. An outline of the proposed guidelines is appended to this discussion paper (Appendix).

The key elements of the guidelines are found in sections 4 and 5 of the outline. Section 4 will consist of generally recognized scientific criteria for categorizing common types of objectionable matter according to food safety significance. Examples of these criteria are given in Figure 1 of the Appendix. The categories in section 4 can also be applied to objectionable conditions, such as exposed glass light bulbs (potential physical hazard) or rodent infestations (potential contributing

factor to microbiological hazards). Section 5 will contain guidelines for evaluating acceptable and unacceptable limits for specific types of objectionable matter or objectionable conditions. For example, a section 5 guideline for glass might include the minimum size of glass fragments known to cause injury from ingestion. In some cases, such as glass fragments, the guidelines may prove universal. In other cases, such as rodent infestations, the guidelines may require stratification in response to, for example, differences between conditions in primary production areas versus manufacturing areas.

The guidelines are designed to facilitate the use of a decision tree for evaluating food safety situations that involve objectionable matter in food and related objectionable conditions in food processing and storage facilities. The decision tree will be included in the Guidelines (see Figure 2 in the Appendix). The decision tree uses the guidelines as a framework to sequentially address the issues of:

- evaluating health hazards and contributing factors to health hazards.
- evaluating objectionable matter and objectionable food handling or storage practices
- determining when a situation is aesthetic in nature and therefore not subject to the guidelines.

RECOMMENDATION

The Committee is invited to recommend the initiation of new work on Proposed Draft Guidelines for Evaluating Objectionable Material In Food.

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OUTLINE

PROPOSED DRAFT ANNEX OF GUIDELINES FOR EVALUATING OBJECTIONABLE MATTER

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4. General Food Safety Categories
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 - 6.3.2 HACCP Contributing Factors
 - 6.3.3 Sanitation Standard Operating Procedures
 - 6.3.4 Documentation and Records
7. Decision Tree for the Evaluation Procedure

FIGURE 1. Example of the Evaluation Process

4. General Food Safety Categories

4.1 Category 1a: Direct Hazards from Foreign Matter and Pests

4.1.1 Criteria for Physical Hazards

In order for a contaminant to be categorized as a physical hazard, the contaminant must meet all of the following criteria:

- There must be scientific evidence of physical injury from ingestion of the type and size of contaminant
- There must be a general consensus among medical authorities that the type and size of contaminant is a potential hazard in food
- Subsequent processing or intended use of the product does not eliminate or neutralize the hazard
- The contaminant is not a natural component of the product that a consumer would normally expect to find in the product (*e.g.*, fish bones in whole fish)

5. Evaluation Guidelines

5.1 Category 1a: Hazardous Foreign Matter

5.1.1 Sharp Foreign Objects

- Corrective action is indicated upon finding one (or more) sharp foreign object that meets the criteria of section 4.1.1 and that is equal to or exceeding 7 millimeters in length
- In cases where the product is intended for use by special risk groups (*e.g.*, infants, elderly, *etc.*), corrective action is indicated upon finding one (or more) sharp foreign object that meets the criteria of section 4.1.1 and that is equal to or exceeding 2 millimeters in length

Figure 2: Decision Tree Flow Diagram

