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

Prepared by the United States of America with the assistance of Australia,
Canada, France, and the International Dairy Federation

Background

1. The *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 3 (1997)) (GPFH) calls for the control and prevention of all likely hazards. In many cases the GPFH elaborates on how to evaluate common types of hazards through specific recommendations that take into account such things as good primary production practices, facility construction and processing controls. In the case of objectionable matter, however, the GPFH does not provide guidance on how to determine if a type of objectionable matter could present a hazard either directly (e.g., glass fragments) or indirectly (e.g., flies carrying foodborne hazards, mites causing allergies). Additionally, the HACCP Annex of the GPFH calls for identifying hazards without elaborating on how to distinguish between hazardous and non-hazardous types of objectionable matter or between disease-carrying pests and other pests.
2. To strengthen the GPFH in the area of objectionable matter, practical, science-based guidelines are needed to differentiate between the types of objectionable matter and related unhygienic conditions that are potentially hazardous and those that are not. The science relating to these hazards has developed to the point that it is now possible to develop a set of guidelines for determining if there is a reasonably likely hazard associated with a given type of objectionable matter (see Annex II).
3. Guidelines on objectionable matter can be helpful for a number of practical reasons.
 - It is difficult to tell if objectionable matter is a hazard or not. This is illustrated by the example of physical hazards from foreign objects, such as pieces of metal or glass, in food. The factors that must be evaluated may include size, sharpness, special risk groups (e.g., infants, elderly), intended use of the product, likely sources of contamination, and feasibility of detection and control. Hazard evaluation must also consider natural components, such as

bones in whole fish, which may resemble a hazardous foreign object. The level of complexity requires supplemental guidance.

- It is difficult to evaluate hazards associated with pests of food. Certain species of flies, cockroaches and rodents are contributing factors to the spread of food-borne illness because they are natural vectors of pathogens such as *Shigella*, *Salmonella* Enteritidis, *Escherichia coli* O157:H7, *Campylobacter jejuni* and the parasite *Cryptosporidium parvum*. Only a small number of pest species carry these pathogens and transmit them to humans or human food; further, these same species do not transmit disease all the time but only under certain circumstances. Telling the difference between a disease vector and a pest that is not a vector is difficult but very important. There is additional difficulty in identifying the conditions under which vectors transmit pathogen hazards to consumers. Supplemental guidance is needed to identify and evaluate the conditions under which pests are reasonably likely to represent a contributing factor to a microbial hazard.
- Allergenic mites are a discrete food safety issue. Recent studies in Asia, Europe and North America report life-threatening allergic reactions due to the consumption of food contaminated with allergenic mites (see Annex 2 - Summary of the Science Basis). Preventing hazards from mite allergens is more difficult than preventing hazards from allergenic food ingredients because the etiologies of the two types of allergens are different. Mite allergens are a result of environmental contamination while inadvertent ingredient allergens are the result of unintentionally adding an ingredient to a food during production. Separate guidance is required because the controls for preventing injury from ingredient allergens are not effective in preventing environmental contamination by food-infesting allergenic mites.

4. The purposes of the proposed guidelines are several. The proposed guidelines will:

- Assist in explaining how to implement the provisions of the GPFH with respect to hazards from objectionable matter and pest exclusion.
- Serve as a supplemental compendium of guidelines for evaluating hazards related to objectionable material for use in developing HACCP and prerequisite sanitation programs.
- Assist pest control operators in forming accurate evaluations of the health significance of pest activity and thus helping to reduce indiscriminate or unnecessary use of pesticides.

5. Additionally, the proposed guidelines will:

- Establish uniform international criteria for evaluating hazards associated with objectionable matter where no criteria currently exists.
- Provide a scientific basis for the food hygiene provisions of the *Codex Alimentarius* that relate to objectionable matter.

6. The terms objectionable matter, foreign matter, foreign object and extraneous matter are often used interchangeably. The GPFH defines contaminant as “any biological or chemical agent, foreign matter, or other substances not intentionally added to a food which may compromise food safety or suitability. For purpose of this document, objectionable matter is included in this definition as “foreign matter not intentionally added to a food that may compromise its safety”.

Foreign matter, foreign objects and extraneous matter, in the context of this document, are broader terms which include objectionable matter but which also include matter that poses no hazard to health such as aesthetic defects.

DESIGN AND ELEMENTS OF THE GUIDELINES

7. The design of the proposed guidelines is based on scientific principles whose validity is recognized by the international community of public health scientists (see Annex 2). The guidelines are designed to be flexible in that they may be applied to objectionable matter in food as well as to potentially hazardous conditions, such as exposed glass light bulbs (potential physical hazard) or rodent infestations (potential contributing factor to microbiological hazards). This flexibility is necessary in order to interface with HACCP systems and other food safety systems.

8. The key elements of the guidelines are:

- Section 1: Introductory material including background and rationale.
- Section 2: Statement of the scope of the guidelines, with limitations that exclude quantitative acceptance levels and aesthetic defects.
- Section 3: Definitions of terms not defined in other basic texts.
- Section 4: Procedural guidelines for distinguishing between hazardous and non-hazardous types of objectionable matter or conditions and for determining when a situation is aesthetic in nature and therefore not subject to the guidelines.
- Section 5: Technical guidelines for evaluating whether a specific type of objectionable matter or objectionable condition does or does not represent a reasonably likely hazard.
- Section 6: Advisory guidance for HACCP hazard analysis; examples of hazardous objectionable matter; examples of types of injury caused and illustrative decision trees.

9. It is proposed that *Guidelines for Evaluating Objectionable Material in Food* be developed as an annex to the *Recommended International Code of Practice: General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 3 (1997)). An outline of the proposed guidelines and associated examples is given in Annex 1.

RECOMMENDATION

10. The Committee is invited to consider recommending to the Codex Alimentarius Commission the establishment of new work for the development of Proposed *Draft Guidelines for Evaluating Objectionable Material in Food* as an Annex to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 3 (1997)).

Annex 1**OUTLINE****PROPOSED DRAFT GUIDELINES FOR EVALUATING OBJECTIONABLE MATTER IN FOOD**

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1. Introduction
2. Scope
3. Definitions of Terms
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 - 4.1 Category 1: Physical Hazards from foreign objects
 - 4.2 Category 2: Allergen Hazards from Food-Infesting Pests
 - 4.3 Category 3: Vectors of Microbiological Hazards
 - 4.4 Non-hazardous Extraneous Matter
5. Technical Guidance for Evaluating Hazards
 - 5.1 Evaluation of Physical Hazards from Foreign Objects (Category 1)
 - 5.2 Evaluation of Allergen Hazards from Food-Infesting Pests (Category 2)
 - 5.3 Evaluation of Vectors of Microbial Hazards (Category 3)
 - 5.3.1 Disease-Carrying Pests
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 - 6.1 Control of Operation
 - 6.1.1 Physical Hazards (Category 1)
 - 6.1.2 Allergen Hazards (Category 2)
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 - 6.2 Decision Trees
 - 6.2.1 Evaluating Hazards Associated with Objectionable Matter in Food
 - 6.2.2 Evaluating Vectors as Contributing Factors to Microbial Hazards

ILLUSTRATIVE EXAMPLES OF SECTION CONTENT

Example 1:

4. Procedural Guidance for Categorizing Objectionable Matter as Hazardous or Non-hazardous

4.1 Category 1: Physical Hazards from Foreign Objects

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 contaminants of that type and size.
- Subsequent processing or intended use of the product does not eliminate or neutralize the hazard
- The object is not a normal constituent that a consumer would expect to find in the product (*e.g.*, fish bones in whole fish).

4.2 Category 2: Allergen Hazards from Food-Infesting Pests

In order for pest contamination to be categorized as an allergen hazard, the pest contaminant must meet all of the following criteria:

- There must be scientific evidence of IgE-mediated allergic injury from ingestion of the contaminant in contaminated food.
- Subsequent processing or intended use of the product does not eliminate or neutralize the allergen hazard
- The contaminant is not a recognized food ingredient or approved food additive that is properly declared on a product's label (*e.g.*, carmine food coloring derived from cochineal insects)

Example 2:

5. Evaluation Guidelines

5.1 Evaluation of Physical Hazards (Category 1)

5.1.1 Trauma Hazard from Sharp Foreign Objects

- Corrective action is indicated upon finding sharp foreign objects that meet the criteria of section 4.1 and that are of sufficient length to represent a potential physical hazard. Special consideration may need to be given to special risk groups (*e.g.*, infants, the elderly) for such characteristics as size and shape of foreign objects.

5.1.2 Choking Hazard from Foreign Objects

- Corrective action is indicated upon finding foreign objects that meet the criteria of section 4.1 and that are of sufficient

dimensions (length and width) to represent a potential choking hazard.

- [additional criteria may be inserted here.]

5.1.3 Dental Hazard from Hard Foreign Objects

- Criteria may be inserted here.

5.2 Evaluation of Allergen Hazards from Food-Infesting Pests (Category 2)

5.2.1 Allergenic Mites

- Corrective action is indicated upon finding a live infestation, in finished product or raw materials, of a pest that meets the criteria of section 4.2.
- If valid dose/response data is available for ingestive allergenicity of a particular mite allergen, corrective action is indicated if the levels of contamination in a food exceed the thresholds indicated by the dose/response data.
- In the absence of suitable ingestive dose/response data for a particular mite allergen, a general safety level may be recommended based on other scientific studies that are appropriately related, e.g., no more than 75 allergenic mites per 100 grams of product is indicated, based on scientific studies conducted on airborne allergens from allergenic mites.

Example 3:

6. HACCP Hazards and Control Guide for Objectionable Matter

6.1 Control of Operation

6.1.1 Physical Hazards (Category 1)

Foreign objects can cause injury to the consumer. Likely sources include raw materials, processing machinery with parts that can break loose, worn equipment, poor facility maintenance and personal items that employees may bring into the processing facility. Preventive measures can include in-line detectors, inspection of incoming raw materials, good manufacturing practices [other examples may be inserted].

6.1.1.1 Examples of Physical Hazards from nonmetallic objects.

Nonmetallic Object	Potential Hazard	Possible Source(s)
Bone (sliver/chip)	Trauma	Processing (e.g., hard/sharp bone pieces separated from flesh)
Wood splinter	Trauma	Raw materials (e.g., crate) Processing (e.g., table, tool handle)

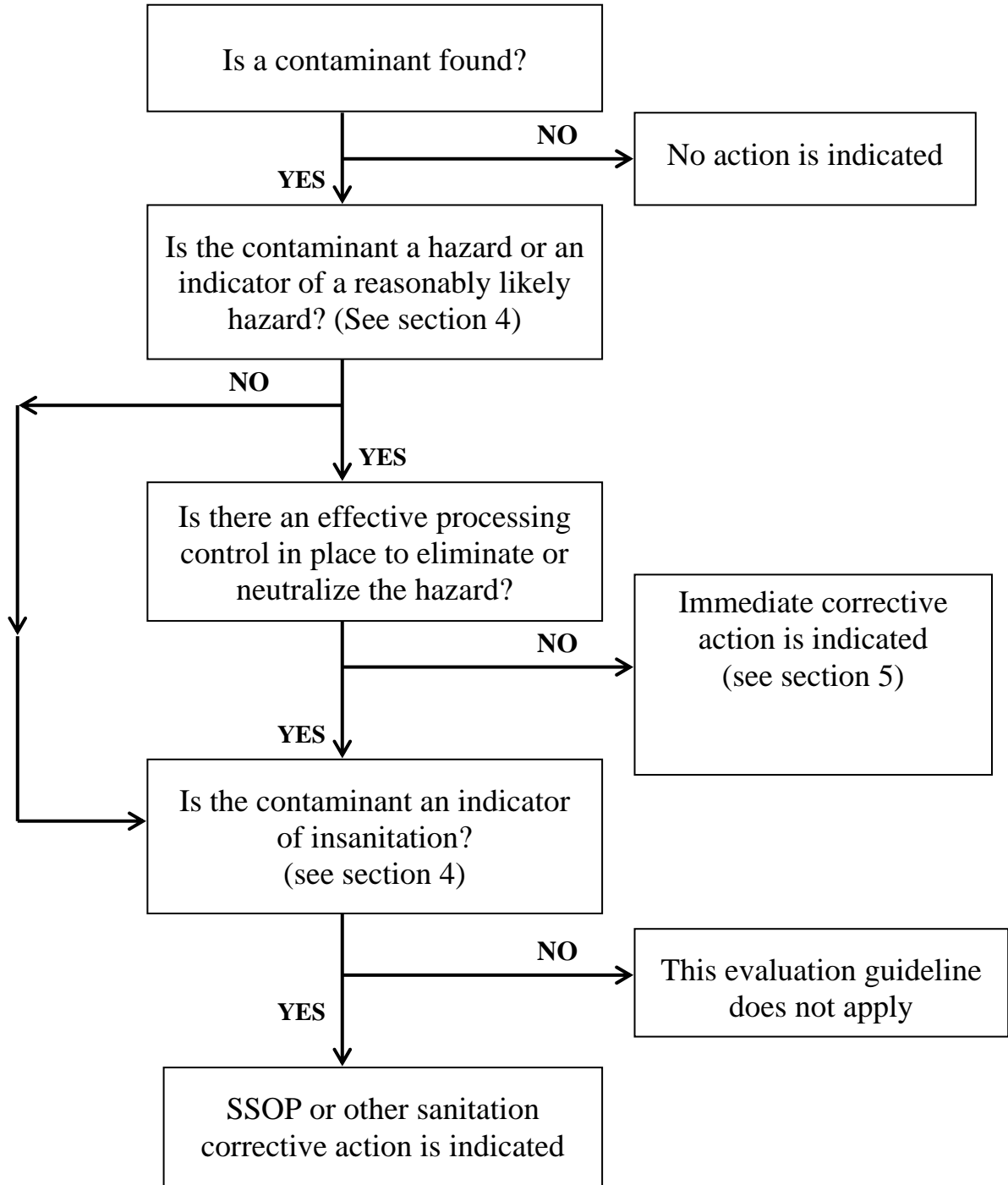
Glass	Trauma	Processing (e.g., glass container) Facility (e.g. unshielded light fixture)
Hard plastic	Trauma	Processing (e.g., tote bin, plastic tools) Personal effects (e.g., false fingernail)
Soft Plastic	Choking	Processing (e.g. packaging)
Insulation	Trauma	Facility (e.g., asbestos fiber)
Burr	Trauma/ Dental	Raw materials
Thorn	Trauma/ Dental	Raw materials
Button	Dental	Personal effects
Stone	Dental	Raw materials

6.1.1.2 Examples of Physical Hazards from Metallic Objects (to be developed).

Example 4:

6.2 Decision Trees

6.2.1 Evaluating Hazards Associated with Objectionable Matter in Food



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 demographics of injuries from accidentally ingesting objects of different sizes and shapes.

Allergens. Recent studies in Asia, Europe and North America report life-threatening allergic reactions due to the consumption of food contaminated with allergenic mites (2). The ingestion of small numbers of mites in a food may induce IgE-mediated systemic allergic reactions, including anaphylaxis, 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 illness (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).

Disease-Carrying Pests. Flies, cockroaches, birds and rodents are natural reservoirs and mechanical vectors of foodborne pathogens (9,10,11,12). Recent findings implicate flies as potential vectors for *E. coli* O157:H7 in beef or fruit products (13, 14, 15) and *Salmonella* Enteritidis in eggs (16). Scientific reports also implicate flies as reservoirs and vectors of enterohemorrhagic *E. coli* O157:H7 (EHEC-O157). These include epidemiological studies of the role of flies as vectors and reservoirs of EHEC-O157 in Obihiro City and Saga Prefecture, Japan, both sites of recent outbreaks of EHEC-O157. In the latter case, flies were found to harbor and proliferate EHEC-O157 (17,18). The DNA pattern and vero-toxin were identical in the EHEC-O157 isolated from both patients and flies. Exclusion of flies from exposed food and utensils halted the Saga outbreak even though the excluded flies continued to test positive for EHEC-O157. Databases relating to the disease-carrying capabilities of these pests include:

Epidemiological case control studies of risk factors for 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.

Studies of the pest behaviors that are conducive to the transmission of pathogens to food.

Ecological studies that report the prevalence of pathogens in wild populations of a pest species.

Laboratory studies of the abilities of a pest species to transmit pathogens.

Additional databases may include: studies on evaluating the danger from disease-carrying pests (19); government criteria for evaluating disease-carrying pests (20); World Health Organization manuals (21) and guidelines;¹ and published questionnaire surveys that reveal tolerance attitudes of the average consumer toward these pests (22).

¹ WHO/VBC/86.937

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