

Guidance for FDA Staff and Industry

Compliance Policy Guides Manual

Sec. 555.600

Filth from Insects, Rodents, and Other Pests in Foods

Submit written comments regarding this final guidance document to the Division of Compliance Policy (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Additional copies of this document may be obtained by sending a request to the above address, or from the Internet at:
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**U.S. Department of Health and Human Services
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Compliance Policy Guide

Compliance Policy Guidance for FDA Staff

CHAPTER - 5 SUB CHAPTER - 555

Sec. 555.600 - Filth *from Insects, Rodents, and Other Pests* in Foods (CPG 7120.18)

This guidance document represents the Agency's current thinking on filth from insects, rodents, and other pests based on recent advances in science. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

INTRODUCTION

This compliance policy document updates the Compliance Policy Guides Manual (2000 edition). It is a revised Compliance Policy Guide and will be included in the next printing of the Compliance Policy Guides Manual. It is intended for FDA personnel and may also be used by the industry. It is available to the public. This guidance document represents the Agency's current thinking on filth from insects, rodents, and other pests based on recent advances in science. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulation, or both.

BACKGROUND

Recent scientific advances have increased the precision of the scientific criteria used to interpret the regulatory significance of adulteration involving insects, rodents, and other pests in foods. The revisions of this guideline are based on those advances in science.

*TERMS AND DEFINITIONS:

Attraction - drawn by a sensory stimulus such as odor, color, etc. Observations indicating the presence of pests exhibiting attraction include, but are not limited to:

1. Inspectional observations such as live flies observed on exposed product in cutting room (attracted to human food) or rodent tracks observed in dust in a trash disposal area (attracted to filth).

Or

2. Analytical observations such as a filth exhibit identified as one insect entrance hole, 1/4 inch in diameter, penetrating to inside of a product container (attracted to human food) or static material found to contain one egg case of the oriental cockroach (attracted to filth).

Communicative behavior - oscillating between filth (e.g., garbage, mammalian excreta or other sources of pathogens) and human food. Observations indicating the presence of pests exhibiting communicative behavior include, but are not limited to:

1. Inspectional observations such as a rodent runway exhibiting smear marks and numerous rodent excreta pellets observed between a garbage can and a raw materials storage bin.

Or

2. Analytical observations such as finding filth from the American cockroach in a filth exhibit of food product and finding cockroach excreta in a filth exhibit collected from the toilet facility.

Endophily - observed willingness to enter buildings. Observations indicating the presence of pests exhibiting endophily include, but are not limited to:

1. Inspectional observations such as live cockroaches observed on the north wall approximately 10 feet from the northeast corner inside building A of the production plant.

Or

2. Analytical observations such as striated hair identified as belonging to the Asian musk shrew, *Suncus murinus*, an endophilic species.

Exophily - observed reluctance to enter buildings. Observations indicating the presence of pests exhibiting exophily include, but are not limited to:

1. Inspectional observations such as live sparrows observed on the roof over the open loading dock door on the south side of a building but no sparrows observed entering the building.

Or

2. Analytical observations such as a filth exhibit identified as the corn earworm, an exophilic insect.

Synanthropy - association with humans or their dwellings. Observations indicating the presence of pests exhibiting synanthropy include, but are not limited to:

1. Inspectional observations such as live flies observed in the vicinity of the main production facility, both inside and outside the facility.

Or

2. Analytical observations such as a filth exhibit identified as one adult house fly, *Musca domestica* L., a synanthropic species.

POLICY:

Regulatory action criteria are organized into three categories: vectors (pests that carry pathogens from one host, source or place to another), indicators of insanitary conditions, and incidental pests. Each category has a unique forensic profile to interpret the regulatory significance of adulteration from potentially food-contaminating pests.

The following forensic profiles should be used to interpret the regulatory significance of adulteration from food-contaminating pests.

Forensic Category I. Vectors

This category includes vectors of foodborne pathogens regardless of whether a microbiological hazard is detected. A pest should meet all of the attributes in the following profile in order to be placed in Category I:

1. Synanthropy
2. Endophily
3. Attraction to filth and to human food
4. Communicative behavior
5. Past or present evidence that foodborne pathogens are associated with natural populations of the pest.

Examples include, but are not limited to: house fly, oriental cockroach, pharaoh ant, house mouse.

Forensic Category II. Pests that are Indicators of Insanitation.

This category includes pests whose presence in food or in the vicinity of food processing or storage areas is an indication of insanitary conditions. A pest should meet all of the attributes of any one of the following profiles (A., B., or C.) in order to be placed in Category II.

A. Opportunistic Pests

1. Synanthropy
2. Endophily

3. Attraction to stored food
4. Communicative behavior

Examples include, but are not limited to: common silverfish, Argentine ant, lesser bandicoot rat.

B. Adventive Pests

1. Synanthropy
2. Endophily
3. A lack of attraction to stored food
4. A lack of communicative behavior

Examples include, but are not limited to: cluster fly, cellar spider, pigeon, little brown bat.

C. Obligatory Pests (storage insects and other stored-product pests)

1. Synanthropy
2. Endophily
3. Attraction to stored food
4. A lack of communicative behavior

Examples include, but are not limited to: granary weevil, confused flour beetle, cigarette beetle, Indianmeal moth, cheese skipper, booklouse.

D. Parasites and Predators

1. Synanthropy
2. Endophily
3. Attraction to a host or prey that fits a profile from Category I or Category II

Examples include, but are not limited to: lesser ensign wasp, warehouse pirate bug, window pane fly, house pseudoscorpion.

Forensic Category III. Incidental Pests

This category includes agricultural pests, nuisance pests and other incidental pests that do not meet the attributes of one of the profiles described in Category I and Category II.*

Specific numerical defect action levels for *incidental pests* or insect fragments in foods (refer to Food Defect Action Levels, 1998, Industry Activities Staff, HFS-565, FDA, *5100 Paint Branch Parkway, College Park, Maryland 20740*) do not include *category I pests or category II pests, unless there are specific references to category I or category II pests* in the Regulatory Action Guidance section of the Compliance Policy Guide.

For guidance regarding insect contamination resulting from insanitary storage conditions, refer to

*(a) Sec. 555.500 (for CPG 7120.24) All Food Sanitation (Including Bacteriological) Inspections - Classification of Establishments

and

(b)* Sec. 580.100 (for CPG 7103.01) Food Storage and Warehousing - Adulteration - Filth (Domestic and Import).

For lists of additional examples of pests in the various categories, refer to Fundamentals of Microanalytical Entomology: A Practical Guide to Detecting and Identifying Filth in Foods. A.R. Olsen, T.H. Sidebottom and S.A. Knight, editors. CRC Press. 1996.

*

Flow Chart for Regulatory Action Criteria Categories		
Does the pest meet all the attributes of the profile in Forensic Category I?	YES	Vector
NO		
Does the pest meet all the attributes of the profile in Forensic Category II?	YES	Indicator of Insanitation
NO		
Incidental Pest (Forensic Category III)		

*

Material between asterisks is new or revised.

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