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Regulatory Action Criteria for Filth and Other Extraneous Materials V. Strategy for Evaluating Hazardous and Nonhazardous Filth

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The U.S. Food and Drug Administration (FDA) uses regulatory action criteria for filth and extraneous materials to evaluate adulteration of food products. The criteria are organized into three categories: health hazards, indicators of insanitation, and natural or unavoidable defects. The health hazard category includes criteria for physical, chemical, and microbiological hazards associated with filth and extraneous materials. The health hazard category encompasses criteria for HACCP (Hazard Analysis and Critical Control Point) hazards and HACCP contributing factors. The indicators of insanitation category includes criteria for visibly objectionable contaminants, contamination from commensal pests, and other types of contamination that are associated with insanitary conditions in food processing and storage facilities. The natural or unavoidable category includes criteria for harmless, naturally occurring defects and contaminants. A decision tree is presented for the sequential application of regulatory action criteria for filth and extraneous materials associated with each category and with each type of filth or extraneous material in the three categories. This final report of a series in the development of a transparent science base for a revised FDA regulatory policy in the area of filth and extraneous materials in food includes a comprehensive list of the references that form the science base for the FDA regulatory policy.

INTRODUCTION

The primary, regulatory mission of the U.S. Food and Drug Administration (FDA) is to enforce the Food, Drug and Cosmetic Act (FD&C Act). The FD&C Act prohibits distribution of food that is adulterated. The term “adulterated” applies to food products that are defective, unsafe, filthy, or produced under insanitary conditions (Slocum, 1948). Adulterants such as filth and other extraneous materials are defined in section 402 of the FD&C Act (Food and Drug Administration, 1984).

Under section 402(a) (1) (21 U.S. Code, section 342(a) (1)), a food product shall be deemed to be adulterated if it bears or contains an added poisonous or deleterious substance which may render it injurious to health.

Under section 402(a) (3) (21 U.S. Code, section 342(a) (3)) a food product shall be deemed to be adulterated if it consists in whole or in part of a filthy, putrid, or decomposed substance.

Under section 402(a) (4) (21 U.S. Code, section 342(a) (4)) a food product shall be deemed to be adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.

The same definitions of adulteration are established, *verbatim*, in sections 301.2(c) (1), 301.2(c) (3), and 301.2(c) (4), respectively, of the Code of Federal Regulations, Title 9, Animals and Animal Products regulations of the U.S. Department of Agriculture, Food Safety and Inspection Service (Department of Agriculture, 1999a).

FDA, the U.S. Department of Agriculture (USDA) and the U.S. National Marine Fisheries Service (NMFS) have recently established HACCP (Hazard Analysis and Critical Control Point) regulations and programs that apply to hazardous adulterants for some of the commodities that are regulated by these agencies (Department of Agriculture, 1996, 1999b; Food and Drug Administration, 1998a,b; National Marine Fisheries Service, 1998). HACCP principles divide food-borne health hazards into three groups of adulterants: physical hazards, chemical hazards, and biological hazards. Although HACCP is not universally required for the food industry, voluntary food safety programs modeled on HACCP principles and regulations are becoming commonplace. The FDA Food Code, for example, recommends the use of HACCP principles in the retail food service industry (Public Health Service, 1999). HACCP principles are incorporated into the food safety guidelines of the European Community and the Codex Alimentarius (Codex Alimentarius Commission, 1997; Council of the European Communities, 1993; Food and Agriculture Organization, 1996).

HACCP rules and regulations require a processor to identify and control potentially hazardous adulterants that are reasonably likely to result in injury or illness to the consumers of a food (National Advisory

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Committee on Microbiological Criteria for Foods, 1992, 1994, 1997). The HACCP distinction between reasonably likely hazards and general sanitation, or good manufacturing practices, creates a need to precisely distinguish between filth conditions that are associated with a health risk and those that are clearly not health hazards. The purpose of this review is to assemble reliable information about types of contaminants that do and do not pose an immediate health hazard in order to clearly differentiate between situations where a hazard control is needed and situations where standard good manufacturing practices are adequate to prevent injury or illness from food-borne contaminants. The results of this review provide the scientific basis for FDA regulatory action criteria for evaluating the contamination of food with filth and extraneous materials in both HACCP and non-HACCP situations. This will assist HACCP planners, HACCP regulators, sanitarians, and other food safety professionals in planning, developing, implementing, and verifying effective, appropriate critical control points or other preventive measures to protect the food supply from adulteration. This is the fifth and final report of a series in the development of a transparent science base for a revised FDA regulatory policy in the area of filth and extraneous materials in food.

METHODOLOGY

A literature search for regulatory and scientific precedence was conducted using computer databases to develop a science base for evaluating hazardous and nonhazardous filth and extraneous materials in food. The archives of the FDA Microanalytical Branch and the FDA Health Hazard Evaluation Board, both in Washington, DC, were included in the search. The search covered the period from January 1966 to December 2000.

ACTION CRITERIA FOR HEALTH HAZARDS

There are three types of HACCP health hazards—physical hazards, chemical hazards, and biological hazards (Gorham, 1994a,b; Olsen, 1998b). Olsen (1998a,b,c) described regulatory action criteria for examples of filth and extraneous materials that are associated with each type of hazard. The criteria consist of objective, science-based profiles for determining if a contaminant is reasonably likely to be associated with a particular type of hazard. Table 1 summarizes the regulatory action criteria profiles for determining if a contaminant is a potential hazard and gives examples of contaminants that match each profile. The action criteria profiles specifically recognize the fact that subsequent processing or intended use of a product could eliminate or neutralize a potential hazard. Such processing or intended use in no way relieves a product from the requirements of the FD&C Act for cleanliness and freedom from filth and deleterious contaminants or impurities (Food and Drug Administration, 1984).

TABLE 1
Action Criteria Profiles for HACCP Hazard Groups of Filth and Extraneous Materials

Group	Action criteria profile	Example(s)
Physical hazards	1. Evidence of physical injury from ingestion; 2. Recognition as a hazard by medical authorities; and 3. Subsequent processing or intended use of product does not eliminate or neutralize the hazard.	Foreign objects (e.g., hard or sharp objects)
Chemical hazards	1. Proof of toxicity/allergenicity; 2. Evidence of ingestive effects; 3. Recognition as a hazard by medical authorities; and 4. Subsequent processing or intended use of product does not eliminate or neutralize the hazard.	Allergenic mites: *Aleuroglyphus ovatus* *Dermatophagoides farinae* *D. pteronyssinus* *Suidasia pontifica* *Thyreophagus entomophagus* *Tyrophagus putrescentiae* Allergenic cockroaches: *Blattella germanica* *Periplaneta americana* *P. fulliginosa*
Biological hazards: HACCP contributing factor	1. Synanthropy; 2. Endophily; 3. Communicative behavior; 4. Attraction to filth and human food; 5. Pathogens isolated from wild (natural) populations; and, 6. Subsequent processing or intended use of product does not eliminate or neutralize the hazard.	Passive vectors of pathogens (see Table 4)

Physical Hazards

The regulatory action criteria profile for physical hazards (Table 1) requires clinical evidence of physical injury from ingestion or other published recognition by scientific authorities, such as the Health Hazard Evaluation Board of the FDA Center for Food Safety and Applied Nutrition, that the contaminant is reasonably likely to be a hazard (Olsen, 1998a; Food and Drug Administration, 2000b). A group of FDA physicians and scientists, the Board is authorized by federal regulation to conduct *ad hoc* health hazard evaluations of incidents of potentially hazardous contamination that are reported to FDA (Food and Drug Administration, 1998c). In general, the Board bases its evaluations on the clinical literature and the collective knowledge and experience of Board members.

Recently, the profile for physical hazards (Table 1) served as the framework for developing a permanent FDA Compliance Policy Guide for hard or sharp foreign objects based, in part, on Board evaluations. After a review of the scientific literature and approximately 190 Board evaluations FDA determined that, because of the frequency and consistency of the literature reports and Board evaluations, it was appropriate to develop standardized guidance for this type of physical hazard (Olsen, 1998a; Food and Drug Administration, 1999a). The resulting FDA Compliance Policy Guide for regulatory action for hard or sharp foreign objects in food was formally issued in 1999 (Food and Drug Administration, 2000b). The Compliance Policy Guide and the action criteria profile have also been converted into an industry guideline for seafood HACCP planners and regulators to help them evaluate the need for, and effectiveness of, HACCP critical control points for physical hazards from a wide variety of hard or sharp foreign objects (Olsen, 1997; Price, 1997).

Action criteria profiles can also be applied to situations where there is insufficient data to support a permanent Compliance Policy Guide. An example is a foreign object in food that causes choking or a gag reflex. Choking hazards are difficult to characterize in terms of size and shape of the foreign object that may cause choking or a gag reflex in humans. The Consumer Product Safety Commission (CPSC) established a safety standard for choking hazards in toys that defines an upper limit above which an object is not considered a choking hazard to small children (Consumer Product Safety Commission, 1997). While the CPSC regulation defines when an object is too large and bulky to fit into the mouth of a small child, the regulation does not define a safe lower size limit for toy parts. A recent statistical survey of clinical reports of choking in small children suggests that an object with a maximum diameter <1/4 in. represents no hazard from choking (Rider and Wilson, 1996). The CPSC standard and related statistical studies (e.g., Altmann and Ozanne-Smith, 1997; Lifschultz and Donoghue, 1996; Mittleman, 1984; Rider and Wilson, 1996; Rimell *et al.*, 1995; Rothman and Boeckman, 1980) are primarily designed to evaluate risks of asphyxiation through aspiration, not swallowing or ingestion.

The clinical literature relating to choking from swallowing foreign objects consists of anecdotal reports (Awerbuck *et al.*, 1994; Bloom *et al.*, 1988; Fries, 1982; Cockerill *et al.*, 1983; Johns, 1980; Man *et al.*, 1986; Marlow *et al.*, 1997; Mittleman and Wetli, 1982; Nussbaum *et al.*, 1987) of which the predominant causes of choking from ingested objects are intrinsic components of a food (e.g., bones) or food boluses (Herranz-Gonzalez *et al.*, 1991; Taylor, 1987). There are no statistical studies that examine choking or gag reflexes from foreign objects in properly chewed and swallowed food. In this example, the number of cases evaluated by the Health Hazard Evaluation Board was too small (<20) to establish a consensus of a safe lower-end size criterion for choking hazards. Establishing an official Compliance Policy Guide for choking hazards from foreign objects in food is premature without a substantial database of clinical reports and Board evaluations. According to the profile listed in Table 1, however, potential choking hazards may be subject to regulatory action as a health hazard if the Board determines that a choking hazard is likely in a particular case.

In some cases, the distinction between physical and chemical hazards is unclear. For example, certain food-contaminating dermestid beetle larvae (e.g., *Dermestes* spp. and *Trogoderma* spp.) (Coleoptera: Dermestidae) bear specialized hairlike structures called hastisetae or spicasetae that are thought to cause illness. The larvae of these beetles have caused illness when swallowed in contaminated food (Jupp, 1956; Okumura, 1967; Lillie and Pratt, 1980). Some scientists report that illness results from mechanical irritation of tissues by the setae (Loir and Legangneux, 1922; Mumcuoglu and Rufli, 1980; Gorham, 1991a; Godard, 1993). Others report that external contact with dermestid larval hastisetae, spicasetae, and body fragments causes an allergenic reaction (Klaschka and Jung, 1976; Klaschka and Rudolph, 1980; Klaschka and Rudolph, 1981; Phillips and Burkholder, 1984; Rudolph *et al.*, 1980; Rustin and Munro, 1984). Okumura (1967) reports both types of illness associated with *Trogoderma* spp. The literature suggests that ingestion of one or two whole larvae can result in illness (Okumura, 1967) but there are no reports of cases of illness from ingestion of detached setae.

A review of the records of the FDA Health Hazard Evaluation Board found that no injury or illness from insect hastisetae or spicasetae has been presented to the Board. FDA has taken regulatory action against products that were contaminated with hastiseta-bearing larvae of the warehouse beetle, *Trogoderma variabile* Ballion (Coleoptera: Dermestidae). Although the contaminated product caused a consumer to become ill, the FDA action was based on gross insanitation due to the extensive nature of the infestation, not on a perceived hazard to health (Olsen, 1991).

In this example, there is no precedence from the Board and the actual nature of the hazard, physical or chemical, is unclear. The profiles for physical and chemical hazards (Table 1) are similar enough to allow evaluation of dermestid setae regardless of the hazard category. This illustrates the flexibility of profiles as the basis for regulatory action.

Chemical Hazards: Toxins

Chemical hazards include toxic compounds, toxic chemical elements, and allergenic substances (Food and Drug Administration, 1998d). The regulatory action criteria profile for chemical hazards (Table 1) requires evidence of toxicity or allergenicity, clinical evidence of injury from ingesting the contaminant in food, and consensus of the members of the FDA Health Hazard Evaluation Board that the contaminant is reasonably likely to be a chemical hazard (Olsen, 1998a). Both toxicity and allergenicity are associated with pests that could be encountered as contaminants in food.

Cryptotoxic insects are insects that maintain a toxic substance or substances in their body fluids or tissue. These insects are known to cause illness in animals that consume contaminated feed (Arnett, 1985; Capinera *et al.*, 1985) and occasionally in humans (Brown, 1960). There are also anecdotal reports of human subjects ingesting cryptotoxic insects with no apparent ill effect (McCrae and Visser, 1975). Cryptotoxic insects that are associated with food crops or food processing facilities include rove beetles, *Paederus* spp. and *Oxytelus* spp. (Coleoptera: Staphylinidae), leatherwing beetles (Coleoptera: Oedemeridae), and blister beetles such as *Epicauta* spp. and the "Spanish Fly" beetle, *Lytta vesicatoria* (L.) (Coleoptera: Meloidae) (Budavari, 1996; Frank and Kanamitsu, 1987; Gorham, 1991a; Harwood and James, 1979; Hinton, 1945; McCrae and Visser, 1975; Mendez and Iglesias, 1982; Mumcuoglu and Rufli, 1980; Theodorides, 1950; Zehnder and Thewalt, 1977). The body fluids of these beetles contain vesicants that cause blistering of skin and mucosa if the beetle is handled or eaten.

Toxicogenic insects produce toxins only under special conditions, such as when threatened or disturbed (Eisner and Meinwald, 1966). An example of a toxicogenic insect associated with food crops is the bombardier beetle (*Brachinus* spp.) (Coleoptera: Carabidae), a beetle that generates a caustic chemical when disturbed (Hinton, 1945; Mumcuoglu and Rufli, 1980; Roth and Eisner, 1962; Thomson, 1971). Cockroaches (Dictyoptera), flour beetles (*Alphitobius* spp., *Tribolium* spp., and *Tenebrio* spp.) (Coleoptera: Tenebrionidae), and other food-contaminating insects generate benzoquinones and related chemicals as a defense against predation or as a reaction to stress (Irwin *et al.*, 1972; Loconti and Roth, 1953; Phillips and Burkholder, 1984; Roth and Eisner, 1962; Thomson, 1971; Tschinkel, 1975; Tseng *et al.*, 1971; Weatherston and Percy, 1978; Wirtz, 1984; Wirtz *et al.*, 1978a,b). Insect benzoquinones are a potential hazard in food because they are suspected of being carcinogenic or mutagenic (Hodges *et al.*, 1996; Ladisch, 1965; Ladisch *et al.*, 1968; Omaye *et al.*, 1979; St. Agatha Suter and Ladisch, 1963; Wirtz, 1991; Wirtz and Fruin, 1982). Tests on human subjects found no immediate adverse effects from consuming food contaminated with *Tribolium* spp. and other food-contaminating beetles that produce quinones (Mills and Pepper, 1939; Riley, 1922). Sokoloff (1974) provides a complete review of the benzoquinones associated with *Tribolium* spp.

To date, no cases of ingestive toxicity from cryptotoxic or toxicogenic insects have been presented to the FDA Health Hazard Evaluation Board for evaluation. It appears from the available evidence that these insects do not meet the regulatory action criteria for chemical hazards (Table 1). In actual regulatory practice, it is not presumed that contamination by a cryptotoxic or toxicogenic pest ensures that toxins have been generated and, therefore, contamination by these pests is not distinguished from contamination by other stored-product pests (Cotton, 1959; Gorham, 1975, 1979, 1981a).

Chemical Hazards: Allergens

While health hazards from cryptotoxic and toxicogenic pests are a remote possibility, the potential hazard from allergens produced by food-contaminating pests is an emerging health issue of a more serious nature. An allergen that is associated with filth or extraneous materials is a potential chemical hazard if the allergen is known to cause an IgE-mediated or other systemic allergic reaction through ingestion and if the allergenic contaminant fits the action criteria profile for chemical hazards shown in Table 1 (Olsen, 1998b).

Allergens from food-contaminating mites were recently shown to fit the action criteria profile for chemical hazards by clinical reports that documented allergic reactions in people who are sensitized to mite allergens when the people ate mite-infested food (Olsen, 1998b). The ingestive allergenicity of these mites was suspected for a number of years (Herranz and Herranz, 1963; Steinbrink and Böer, 1984) but clinical evidence of ingestive allergenicity of mites was not reported until 1993 (Erban *et al.*, 1993; Matsumoto *et al.*, 1996; Olsen, 1998b). FDA investigations have found these allergenic mites in a variety of food products (Gecan *et al.*, 1971; Olsen, 1981, 1982, 1983; Olsen *et al.*, 1987).

A major concern is the low levels of mite allergens that are reported to induce an allergic reaction in sensitized individuals. Researchers report a positive dose/response relationship for mite aeroallergens that provoke asthmatic episodes in terms of numbers of mites per square meter sample of bedding or floor area in homes of asthmatics (Platts-Mills *et al.*, 1978). A level exceeding 10 μg of mite allergen per gram of house dust (500 mites per gram) appears to be a general risk factor for asthmatics while a level as low as 2 μg per gram (100 mites per gram) may be sufficient to develop mite sensitization (Eggleston *et al.*, 1998; Environmental Protection Agency, 1994; Gaig *et al.*, 1999; Hill, 1998; Sarpong and Corey, 1998).

No similar dose/response research has been conducted to scientifically determine what levels of ingested mites might provoke an allergic reaction (Bauer *et al.*, 1997). None of the recent reports of illness involving allergenic mites as contaminants in food were reported directly to FDA for presentation to the Health Hazard Evaluation Board so there is no Board consensus to indicate what levels of allergenic mites might be considered hazardous in a food.

Contamination of food with filth from cockroaches is a historical concern of public health organizations. FDA regulatory laboratories find cockroach filth in a variety of foods (Eiduson *et al.*, 1958; Lawless, 1999). Filth from cockroaches recently emerged as a food safety health hazard issue involving ingestive allergens (Wirtz, 1991) even though ingestive allergenicity has been ascribed to cockroach filth for a number of years (Bernton and Brown, 1964, 1969; Frazier, 1969; Marchand, 1966; Sarpong and Corey, 1998; Swaminathan, 1970). The allergenicity of cockroaches is proven by scientific research and observation (Bernton, 1970; Bernton and Brown, 1964, 1967a,b, 1969; Bernton *et al.*, 1972; Cornwell, 1968, 1976; Frazier, 1969; Kang and Chang, 1985; Kang and Sulit, 1978; Kang *et al.*, 1988; Kawakami *et al.*, 1982; Platts-Mills and Carter, 1997; Pola *et al.*, 1988; Shulman, 1967; Swaminathan, 1970; Wirtz, 1984). Potent allergens are found in cockroach bodies, cast skins, egg cases, and feces (Bernton and Brown, 1970; Choovivathanavanich, 1974; Khan *et al.*, 1982; Richman *et al.*, 1984). Aeroallergens from cockroaches and cockroach excrement are recognized as environmental risk factors for asthmatics and other sensitized individuals (Duffy *et al.*, 1998; Environmental Protection Agency, 1994; Leung, *et al.*, 1998; Mungan *et al.*, 1998; Sam *et al.*, 1998; Sarpong and Corey, 1998; Sarpong and Karrison, 1998). In some geographic areas, cockroach allergens affect a small percentage (<5–20%) of the population (Caraballo *et al.*, 1998; Hulett and Dockhorn, 1979; Liccardi *et al.*, 1998). Researchers in other areas report a high incidence (20% or higher) of sensitization, especially in urban and low-income populations (Eggleston, 1998; Eggleston *et al.*, 1998; Galant *et al.*, 1998; Hulett and Dockhorn, 1979; Koehler *et al.*, 1987; Nsouli, 1999; Pola *et al.*, 1988; Rosenstreich *et al.*, 1997; Steigman, 1999). Cockroach allergens are classified as a potential chemical hazard because, like mite allergens, the reactions to cockroach allergens are IgE-mediated (Baldo and Panzani, 1988; Helm *et al.*, 1988, 1990; Richman *et al.*, 1984; Stankus *et al.*, 1990).

Table 1 includes examples of species of cockroaches and mites that are likely to fit the action criteria profile for chemical health hazards from allergenic pests. Victims of unexplained allergic reactions to food should be tested for sensitivity to mite or cockroach allergens, especially if the source of the reaction is unidentified and the victim belongs to a high-risk group (i.e., low-income or living in an urban environment) (Bernton and Brown, 1964; Kang and Chang, 1985; Rosenstreich *et al.*, 1997; Sarpong *et al.*, 1996).

There are other food-contaminating pests that are potentially allergenic (Baldo and Panzani, 1988; Heyworth, 1999). Wirtz (1984) reviewed the hazards from allergenic pests and found no cases of illness attributable to ingestion of food contaminated with filth from stored-product and commensal pests. A recent report, however, describes an isolated observation of an anaphylactic reaction to the ingestion of mealworms, *Tenebrio molitor* L. and *Zophobas morio* (F.) (Coleoptera: Tenebrionidae) during a controlled ingestion challenge experiment involving human subjects who were hypersensitive to mealworm allergens (Freye *et al.*, 1996). *T. molitor*, the yellow mealworm, is a common stored-product pest (Gorham, 1991b). Sensitivity to allergenic pests is reported for laboratory workers whose occupations require handling live cultures of these pests or for clusters of workers whose occupations expose them to food products that are infested with these pests (Centers for Disease Control and Prevention, 1984; Bernton and Brown, 1967a; Frazier, 1969; Galindo *et al.*, 1998; Godard, 1993; Gorham, 1975, 1979, 1981a; Harwood and James, 1979; Perlman, 1958; Platts-Mills and Carter, 1997; Wirtz, 1980, 1984). Some allergic sensitivities to food-contaminating insects are attributable to exposures that are not related to occupations. For example, a case report of asthma in a 12-year-old boy concluded that the asthma was an allergic response to carpet beetles, *Attagenus* sp. (Coleoptera: Dermestidae) in the child's home environment (Cuesta-Herranz *et al.*, 1997). Recent surveys have found antibodies to allergens from a booklouse, *Liposcelis bostrychophilus* Badonnel (Psocoptera: Liposcelidae) in city dwellers in Germany (Musken *et al.*, 1998; Rijckaert *et al.*, 1981) and antibodies to allergens from seven species of storage insects in 25–30% of test subjects admitted to a Washington, DC, clinic (Bernton and Brown, 1967).

Although allergenic pests of food products fit the profile for chemical hazards (Table 1), there is no dose/response database for allergenic pests in food products. A dose/response database is a prerequisite for any future regulation of allergenic pests in food. In the interim, contamination by pests such as mites and cockroaches remains subject to the filth sanctions of sections 402(a) (3) and 402(a) (4) of the FD&C Act and, for allergenic species, subject to review by FDA as a possible hazard.

The literature also reports IgE-mediated allergic reactions from the ingestion of carmine dye in food (Baldwin *et al.*, 1997; Beaudouin *et al.*, 1995; Galindo *et al.*, 1998; Kagi *et al.*, 1994). Carmine dye, derived from the cochineal insect, *Dactylopius coccus* Costa (Homoptera: Dactylopidae), is intentionally used in food and therefore not normally subject to the regulatory actions for filth and extraneous materials that are discussed in this review (Olsen and Olsen, 1996). The use of carmine in food is regulated by FDA food additive regulations (Food and Drug Administration, 1998i).

Biological Hazards: Contributing Factors

To be classified as a food-borne biological hazard, a contaminant must be the causative agent of a disease and must be actively or passively transmitted by food (Archer and Young, 1988). From a regulatory standpoint, the most common food-borne biological hazards are bacterial, or microbial, pathogens. In the case of microbial pathogens, the contaminated food must also be a "potentially hazardous food" in order for the pathogen to be considered hazardous. Normally, a potentially hazardous food (PHF) is one that is capable of supporting rapid and progressive growth of infectious or toxicogenic microorganisms (Guzewich, 1984). Other food-borne biological hazards include intestinal parasites that are transmitted to human hosts via food and flies that cause intestinal myiasis, a condition whereby living fly larvae infect a victim's gastrointestinal tract (Godard, 1993). Food-borne intestinal myiasis is rare (Banks, 1912; James, 1947; Olsen, 1998c; Scott, 1964; Zumpt, 1965). The scientific literature concerning the flies that cause intestinal myiasis in humans is reviewed by Godard (1993), Harwood and James (1979), Hall and Wall (1995), James (1947), Olsen (1998c), and Zumpt (1965).

Although flies are rarely the direct cause of disease, some fly species are potential contributing factors to the spread of the pathogens that cause food-borne disease (Cox *et al.*, 1912; Godard, 1993; Greenberg, 1971, 1973; Harwood and James, 1979; Kettle, 1982; Mariluis, 1999; Mortimer and Wallace, 1994; National Advisory Committee on Microbiological Criteria for Foods, 1999; Olsen, 1996b; Olsen *et al.*, 1993; Ostrolenk and Welch, 1942; Ryser and Marth, 1999; Torrey, 1912; Tortorino *et al.*, 1992; West, 1951). Olsen (1998c) reviewed the role of flies as carriers of food-borne pathogens and discussed the regulatory action criteria profile for determining if a particular species of fly is reasonably likely to act as a contributing factor to biological hazards from food-borne pathogens. Briefly, the profile consists of five attributes which, *in combination*, differentiate between a species that is likely to be a contributing factor to the adulteration of a food product with food-borne pathogens and a species that is unlikely to be a contributing factor. The five attributes are synanthropy, endophily, communicative behavior, attraction to filth and to human food, and harborage of pathogens in natural (wild) populations (Hedges, 1998a; Olsen, 1998c, 1999). Medical entomology authorities recognize the five attributes as defining whether a species of fly is reasonably likely to transmit food-borne pathogens to human food (Fischer, 1999; Greenberg, 1973; Mihalyi, 1967a,b). The species of flies that match the profile for contributing factors are historically associated with the transmission of pathogenic *Escherichia coli*, *Campylobacter*, *Listeria*, *Salmonella*, *Shigella*, and *Vibrio cholerae* (Barua and Greenough, 1992; Greenberg, 1971, 1973; Olsen, 1998c; Oye, 1964; Wachsmuth *et al.*, 1994).

House flies, *Musca domestica* (L.) (Diptera: Muscidae), have been shown in laboratory studies to be capable of mechanically transmitting *Cryptosporidium parvum* (Graczyk *et al.*, 1999a, 1999b), *Helicobacter pylori* (Grübel and Cave, 1998; Grübel *et al.*, 1998; Li and Stutzenberger, 2000), and disease-causing rotaviruses (Tan *et al.*, 1997). Laboratory studies have also discovered that a disease-carrying fly that occurs in Europe, *Sarcophaga carneria* (L.) (Diptera: Sarcophagidae), may act as vector of prion diseases such as scrapie (Post *et al.*, 1999) and that the pomace fly, *Drosophila melanogaster* (Meigen) (Diptera: Drosophilidae), is capable of infecting apples with disease-causing *E. coli* O157:H7 (Janisiewicz *et al.*, 1999). While the laboratory studies may appear alarming, they do not demonstrate that these vector–pathogen pairs exist in nature. Findings from laboratory studies demonstrating a capability to transmit a pathogen are not, of themselves, sufficient evidence to conclude that a fly is a natural vector of a particular pathogen (Everhart, 2000; Greenberg, 1971; Olsen, 1998c; Osato *et al.*, 1998; Vaira and Holton, 1998). Additional field studies, such as those which established the connections between flies and *Campylobacter*, *Listeria*, *Salmonella*, *Shigella*, and *V. cholerae*, must be conducted in order to conclude that flies also are also vectors of emerging pathogens.

For example, a recent study demonstrated that house flies are a natural reservoir of *Salmonella enteritidis* at egg farms which produced table eggs that were implicated in outbreaks of *S. enteritidis* (Olsen and Hammack, 2000). Other studies found that wild, or natural, populations of disease-carrying flies may harbor *E. coli* O157:H7. A recent series of field studies showed that wild flies were intimately associated with outbreaks of illness from *E. coli* O157:H7 in Japan. Wild populations of house flies associated with the outbreaks were shown to persistently harbor pathogenic *E. coli* O157:H7 (Iwasa *et al.*, 1998). *E. coli* O157:H7 not only persists in house flies but proliferates in the mouth parts and intestinal tract of the flies. House flies are able to retain and shed *E. coli* O157:H7 for at least 3 days after feeding on medium that contains the pathogen (Kobayashi *et al.*, 1999; Sasaki *et al.*, 2000). A recent epidemiological study found that house flies were the only identifiable source of the *E. coli* O157:H7 that caused multiple illnesses in a school in Japan (Moriya *et al.*, 1999). Although earlier studies found that wild house flies harbor pathogenic strains of *Salmonella* (Greenberg *et al.*, 1963) and *E. coli* (Echeverria *et al.*, 1983; Sanada *et al.*, 1998) the connection between wild flies and these emerging pathogens was not firmly established until the recent epidemiological data was published.

The attributes listed in Table 1 as regulatory action criteria profile for contributing factors are suitable for evaluating whether other pests are reasonably likely to contribute to contamination of food products with pathogens. For example, four common species of cockroaches exhibit the attributes of the profile. The species that match the profile for contributing factors are the American cockroach, *Periplaneta americana* (L.); the brownbanded cockroach, *Supella longipalpa* (Fabricius); the German cockroach, *Blattella germanica* (L.); and the Oriental cockroach, *Blatta orientalis* (L.). These species are synanthropic and endophilic, and they exhibit communicative behavior (Brenner, 1991; Brenner *et al.*, 1987; Cornwell, 1968; Guthrie and Tindall, 1968; Mielke, 1995). They are attracted to excrement, garbage, and human food. Wild populations are known to harbor a variety of food-borne pathogens (Alcamo and Frishman, 1980; Cornwell, 1968; Burgess and Cowan, 1993; Singh *et al.*, 1980). The same four cockroach species are reliably associated with the transmission of food-borne pathogens (Ash and Greenberg, 1980; Beatson, 1976; Beck and Coffee, 1943; Bennett, 1993; Burgess *et al.*, 1973b; Cervantes, 1967; Cornwell, 1968; Cornwell and Mendes, 1981; Garcia and Bruckner, 1998; Cornwell, 1976; Godard, 1993; Herms and Nelson, 1913; Klowden and Greenberg, 1977a; Kreig *et al.*, 1959; Macfie, 1922; Mackerras and Mackerras, 1949; Mackerras and Pope, 1948; Mitscherlich and Marth, 1984; Morischita and Tsuchimochi, 1926; Morell, 1911; Olson and Rueger, 1950; Panhotra *et al.*, 1981; Roth and Willis, 1957; Shrewsbury and Barson, 1948; Stek *et al.*, 1979; Tarshis, 1962; Tejera, 1926; Wedberg *et al.*, 1949).

The cockroach species listed in Table 2 meet all the attributes of the profile criteria including the harborage of pathogens in wild populations. It has long been known that these cockroach species harbor pathogens in their bodies, especially in the colon, for 14–16 days and continue to excrete pathogens in their feces during that time (Bignell, 1977; Klowden and Greenberg, 1976; Olson, 1949; Stek, 1982). Postmortem survival of *Salmonella* in cockroach carcasses may last 60 days (Klowden and Greenberg, 1977b). Extermination of the German cockroach was shown to have a positive correlation to the reduction of morbidity and mortality during an outbreak of salmonellosis in a hospital in Belgium (Graffar and Mertens, 1950) and during an outbreak of hepatitis in Los Angeles (Tarshis, 1962). Table 2 lists major literature references reporting the observation of the regulatory action criteria attributes for each of the four species of cockroaches. Table 3 lists the food-borne pathogens that are associated with wild populations of each of the four species. The information found in Tables 2 and 3 establishes *P. americana*, *S. longipalpa*, *B. germanica*, and *B. orientalis* as potential HACCP contributing factors to the spread of food-borne pathogens.

TABLE 2

Health Hazard Contributing Factor Attributes of the American, Brownbanded, German, and Oriental Cockroaches

Attributes	References
Synanthropy and endophily	Dow, 1955; Fotedar *et al.*, 1991; Koehler *et al.*, 1987; Kopanic *et al.*, 1994; Owens and Bennett, 1982; Panhotra *et al.*, 1981; Rivault *et al.*, 1993; Schal and Hamilton, 1990; Zungoli and Robinson, 1984
Communicative behavior	Cornwell, 1968; Eads *et al.*, 1954; Ebeling, 1991
Attraction to human food and to excrement	Bell and Adiyodi, 1981; Cloarec *et al.*, 1992; El-Khohy and Gohar, 1945; Fotedar *et al.*, 1991; Le Guyader *et al.*, 1989; Schal and Hamilton, 1990; Wirtz, 1991
Wild populations harbor food-borne pathogens	Briscoe *et al.*, 1961 Gazivoda and Fish, 1985; Ishiyama,1967; Janda and Abbott, 1998; Jung and Shaffer, 1952; Okafor, 1981; Olson, 1949; Shrewsbury and Barson, 1948; Singh *et al.*, 1980; Steinhaus, 1941; Stek, 1982; Tauber and Griffith, 1942; Wegner *et al.*, 1978

The Pharaoh ant, *Monomorium pharaonis* (L.), and the thief ant, *Solenopsis molesta* (Say) (Hymenoptera: Formicidae), also exhibit the attributes listed in Table 1 and are therefore potential contributing factors to biological hazards from food-borne pathogens. Both species are synanthropic and endophilic and exhibit communicative behavior in their foraging activities (Hedges, 1998b; Hogue, 1993; Hölldobler and Wilson, 1990; Metcalf *et al.*, 1962; Smith, 1965). They are attracted to pathogen reservoirs such as excrement and to food (Avaritt and Richter, 1996; Hedges, 1998a,b; Metcalf *et al.*,1962). Wild populations are known to harbor food-borne pathogens (Avaritt and Richter, 1996; Barber, 1914; Beatson, 1972, 1973; Edwards, 1981; Eichler, 1964; Gorham, 1991a; Harwood and James, 1979; Hedges, 1998a,b; Hölldobler and Wilson, 1990; Mitscherlich and Marth, 1984; Singh *et al.*, 1980).

Rodent pest species that meet the action criteria profile for contributing factors to the spread of food-borne pathogens include the Norway rat, *Rattus norvegicus*; the roof rat, *R. rattus*; the Polynesian rat, *R. exulans*; and the house mouse, *Mus musculus* (Acha and Szyfres, 1987; Brooks and Rowe, 1987; Healing, 1991; Howard and Marsh, 1981; Ludwig and Bryce,

TABLE 3
Food-Borne Pathogens Found in Wild Populations of Cockroaches

Pathogen	Cockroach Species	References
Escherichia coli	American cockroach *Periplaneta americana* (L.)	Bitter and Williams, 1949; Greenberg and Sanati, 1970; Okafor, 1981
	Brownbanded cockroach *Supella longipalpa* (F.)	Le Guyader *et al.*, 1989; Rivault *et al.*, 1993
	German cockroach *Blattella germanica* (L.)	Alcamo and Frishman, 1980; Fotedar *et al.*, 1991; Frishman and Alcamo,1977; Rivault *et al.*, 1993; Steinhaus, 1941
	Oriental cockroach *Blatta orientalis* L.	Burgess *et al.* 1973a; Cornwell and Mendes, 1981; Rivault *et al.*, 1993
Salmonella spp.	American cockroach *Periplaneta americana* (L.)	Agbodaze and Owusu, 1989. Bitters and Williams, 1949; Kopanic *et al.*, 1994; Mackerras and Mackerras, 1948; Okafor, 1981; Reuger and Olson, 1969
	German cockroach *Blattella germanica* (L.)	Bitters and Williams, 1949; Graffar and Mertens, 1950; Janssen and Wedberg, 1952; Mackerras and Mackerras, 1948; Wegner *et al.*, 1978
	Oriental cockroach *Blatta orientalis* L.	Frishman and Alcamo, 1977
Shigella spp.	American cockroach *Periplaneta americana* (L.)	Agbodaze and Owusu, 1989; Okafor, 1981
	German cockroach *Blattella germanica* L.	Brenner *et al.*, 1987
	Oriental cockroach *Blatta orientalis* L.	Cornwell,1968
Staphylococcus spp.	American cockroach *Periplaneta americana* (L.)	Frishman and Alcamo, 1977; Okafor, 1981; Rueger and Olson, 1969
	Brownbanded cockroach *Supella longipalpa* (F.)	Le Guyader *et al.*, 1989; Mitscherlich and Marth, 1984
	German cockroach *Blattella germanica* (L.)	Frishman and Alcamo, 1977; Mitscherlich and Marth, 1984
	Oriental cockroach *Blatta orientalis* L.	Frishman and Alcamo, 1977

1996; Marsh and Howard, 1981). These commensal pests are synanthropic and endophilic and exhibit communicative behavior (Browne, 1960; Bjornson *et al.*, 1969; Nowalk, 1991). They are attracted to excrement, to other pathogen reservoirs, and to human food (Ingles, 1947; Nowalk, 1991; Patton, 1931). Wild populations harbor food-borne pathogens, especially disease-causing strains of *E. coli*, *Salmonella*, and *Listeria* (Blackwell, 1981; Fenlon, 1999; Inoue *et al.*, 1992; Ryser and Marth, 1999; Scott, 1959a; Scott and Borom, 1965; Singh *et al.*, 1980; Staff and Grover, 1936; Welch *et al.*, 1941). *S. enteritidis* is transmitted from infected rats to other rats (Welch *et al.*, 1941) and from infected mice to other mice (Bartram *et al.*, 1940; Shimi *et al.*, 1979). Mice and rats have been implicated in the transmission of *Salmonella* to poultry (Davies and Wray, 1995; Henzler and Opitz, 1992; National Academy of Sciences, 1969) and to sheep (Hunter *et al.*, 1976). Rats and mice were also implicated as contributing factors in nine outbreaks of food-borne salmonellosis in humans (Beckers *et al.*, 1982; Eisenberg, 1981; Salthe and Krumweide, 1924; Spray, 1926; Staff and Grover, 1936; Tucker *et al.*, 1946). Norway rats in cattle feed lots were recently discovered to harbor *E. coli* O157:H7 (Cízek *et al.*, 1999). Under laboratory conditions, *S. enteritidis* and *E. coli* may persist in rodent fecal pellets for extended periods ranging up to 160 days (Badi *et al.*, 1992; Kirchner *et al.*, 1982; Ostrolenk *et al.*, 1947; Welch *et al.*, 1941); however, researchers who examined spices that were contaminated with rodent and bird feces found that the fecal contaminants from the various spices rarely contained *Salmonella* or *E. coli*. The researchers attributed their results to microbial "die off" as a result of the debilitating effects of natural drying of the feces (Satchell *et al.*, 1989).

Weil's disease (leptospirosis) can be transmitted by the urine of a wide range of animals including mice, rats, dogs, cattle, swine, and racoons (Gorham, 1981a; Heath *et al.*, 1965). The disease is normally transmitted by the pathogen, a spirochete, entering the body orally, through mucous membranes, or through abrasions of the skin as a result of contact with contaminated water. The disease is not normally associated with contaminated food; however, there is one report of an outbreak of Weil's disease associated with the consumption of undercooked rat meat (Agrawal and Srivastava, 1986). Other animals, especially wild birds and lizards, may come under suspicion as potential contributing factors to the spread of food-borne disease because they are known to harbor pathogens. Bird populations may serve as reservoirs for food-borne pathogens and are associated with the transmission of pathogens to livestock (Bennett *et al.*, 1988; Berg and Anderson, 1972; Butterfield *et al.*, 1983; Edel *et al.*, 1976; Fenlon, 1985; Makino *et al.*, 2000; Scott, 1959b, 1961; Tizard *et al.*, 1979; Tiedemann, 1977). Lizards, turtles, and other reptiles may harbor *Salmonella* spp. but human salmonellosis associated with reptiles is attributed to direct exposure to pets, not to contamination of food by these animals (Burnham *et al.*, 1998; de Hamel and McInnes, 1971; Dessi *et al.*, 1992; Fujita *et al.*, 1981; Iveson *et al.*, 1969; Kourany *et al.*, 1970; Kourany and Telford, 1981; Levy *et al.*, 1999; Mackey, 1955; Makin *et al.*, 1996; Manolis *et al.*, 1991; Paton, 1996; Plummer *et al.*, 1992; Roggendorf and Müller, 1976; Trust and Bartlett, 1979; Williams and Hedson, 1965; Woodward *et al.*, 1997). Handling pet turtles has been singled out as a significant contributing factor to salmonellosis in children (Atlman *et al.*, 1972; D'Aoust *et al.*, 1990; Hardy, 1988; Lamm *et al.*, 1972; Williams, 1980). The sale or

TABLE 4
Examples of Pests That Exhibit the Attributes of a Contributing Factor of the Spread of Food-Borne Pathogens

Common Name	Scientific Name
German cockroach	*Blattella germanica* (L.) (Dicityoptera: Blattellidae)
Brownbanded cockroach	*Supella longipalpa* (Fabriculus) (Dictyoptera: Blattellidae)
Oriental cockroach	*Blatta orientalis* L. (Dictyoptera: Blattidae)
American cockroach	*Periplaneta americana* (L.) (Dictyoptera: Blattidae)
Pharaoh ant	*Monomorium pharaonis* (L.) (Hymenoptera: Formicidae)
Thief ant	*Solenopsis molesta* (Say) (Hymenoptera: Formicidae)
House fly	*Musca domestica* L. (Diptera: Muscidae)
Stable fly	*Stomoxys calcitrans* (L.) (Diptera: Muscidae)
Little house fly	*Fannia canicularis* (L.) (Diptera: Muscidae)
Latrine fly	*Fannia scalaris* (Fabricius) (Diptera: Muscidae)
Cosmopolitan blue bottle fly	*Calliphora vicina* Robineau-Desvoidy (Diptera: Calliphoridae)
Holarctic blue bottle fly	*Calliphora vomitoria* (L.) (Diptera: Calliphoridae)
Oriental latrine fly	*Chrysomya megacephala* (Fabricius) (Diptera: Calliphoridae)
Secondary screwworm	*Cochliomyia macellaria* (Fabricius) (Diptera: Calliphoridae)
Blue bottle fly	*Cynomyopsis cadaverina* Robineau-Desvoidy (Diptera: Calliphoridae)
Green bottle fly	*Phaenicia sericata* (Meigen) (Diptera: Calliphoridae)
Black blow fly	*Phormia regina* (Meigen) (Diptera: Calliphoridae)
Redtailed flesh fly	*Sarcophaga haemorrhoidalis* (Fallén) (Diptera: Sarcophagidae)
House mouse	*Mus musculus* (Mammalia: Muridae)
Polynesian rat	*Rattus exulans* (Mammalia: Muridae)
Norway rat	*Rattus norvegicus* (Mammalia: Muridae)
Roof rat	*Rattus rattus* (Mammalia: Muridae)

distribution of small (<4 in.) pet turtles is banned (Food and Drug Administration, 1998j, 2000a). Although products made from reptiles may be contaminated with pathogens (Babu *et al.*, 1990), the literature contains no reports that link reptiles with the transmission of pathogens to processed human food under normal circumstances (Minette, 1984). Typically, transmission of pathogens such as *Salmonella* by domestic pets of any kind is attributed to the handling of the animals (Altman *et al.*, 1972; Centers for Disease Control and Prevention, 1995; Borland, 1975; Chiodoni and Sundberg, 1981; Galton, 1969; Harvey and Greenwood, 1985; Kaufmann *et al.*, 1972; Lamm *et al.*, 1972; Wall et al., 1996; Williams, 1980).

Public health authorities that recognize rodents, flies, and cockroaches as contributing factors to the spread of food-borne pathogens include FDA (Angelotti, 1973; National Advisory Committee on Microbiological Criteria for Foods, 1999), USDA (National Academy of Sciences, 1969), the U.S. Environmental Protection Agency (National Academy of Sciences, 1980), the U.S. Public Health Service (Scott, 1959a,b; Scott and Borom, 1965), and the United Nations World Health Organization (Bailey, 1977; Berenson, 1995; Dunsmore, 1986; Rozendaal, 1997; Salvato, 1976; World Health Organization, 1993). Table 4 summarizes examples of common pest species that exhibit all the attributes of a contributing factor to the spread of food-borne disease (cf. Table 1). In addition to the species discussed above, Table 4 includes the fly species that have been identified as potential contributing factors (Olsen, 1988c). In a HACCP environment where one or more critical control points have been established for preventing microbial hazards, each of the pests listed in Table 4 is classifiable as a potential contributing factor (Mortimer and Wallace, 1994), specifically, a category C13 HACCP contributing factor (storage in a contaminated environment) as defined by Bryan *et al.* (1997).

Application of the Regulatory Action Criteria Profiles for Health Hazards

The FD&C Act specifically differentiates actual hazards to health from insanitary conditions involving contributing factors to a health hazard. Physical and chemical health hazards from filth and extraneous materials are regulated according to the definition of adulteration found in section 402(a) (1) which defines a product as adulterated if it bears or contains an added poisonous or deleterious substance which may render the product injurious to health (Food and Drug Administration, 1984). The regulatory prerequisites for categorizing a contaminant as a physical or chemical health hazard are those listed in the regulatory action criteria profile found in Table 1.

Contributing factors to biological health hazards are regulated by the health hazard provision of section 402(a) (4) of the FD&C Act which deems a product as adulterated if it is prepared, packed, or held under insanitary conditions whereby the product may have been rendered injurious to health (Food and Drug

Administration, 1984). Regulatory action involving 402(a) (4) adulteration normally requires a showing of probable routes of contamination; however, a finding of contaminants in correlated samples of product is not required (Food and Drug Administration, 2000c,d).

For physical hazards, chemical hazards, and contributing factors, it is important to consider the intended use of the product, subsequent processing, HACCP critical control points, HACCP sanitation standard operating procedures, and other factors that would neutralize or remove the actual hazard (Mortimer and Wallace, 1994).

ACTION CRITERIA FOR INDICATORS OF INSANITATION

The FD&C Act goes beyond regulating contaminants that cause injury or disease. Sections 402(a) (3) and 402(a) (4) of the Act require that foods be protected from contamination with filth and be produced in sanitary facilities. Filth includes "contaminants such as rat, mouse or other animal hairs and excreta, whole insects, insect parts and excreta, parasitic worms, pollution from the excrement of humans and animals, as well as other extraneous materials which, because of their repulsiveness, would not knowingly be eaten or used" (Food and Drug Administration, 1986).

FDA regulatory policy relating to food sanitation is found in the FDA Current Good Manufacturing Practices (GMP) regulations (Food and Drug Administration, 1998d). Additional food sanitation recommendations regarding filth and extraneous materials are published in the FDA Food Code (Food and Drug Administration, 1999b). The following are descriptions of the FDA regulatory action criteria profiles for the most common groups of indicators of insanitation that are regulated under sections 402(a) (3) and 402(a) (4) of the FD&C Act.

Visibly Objectionable Contaminants

Visible contaminants are normally objectionable to consumers (Eisenberg, 1974; Hyman *et al.*, 1993; Olsen, 1996a). Research shows that consumers readily detect contaminants that are 5 to 10 mm, or larger, in size (Biles and Ziobro, 2000). Federal regulations and policy require of food handlers and processors the prevention of gross contamination of food with large, visibly objectionable adulterants (Food and Drug Administration, 1998a,d; Rodeheaver, 1996). Good Manufacturing Practices (GMP) regulations require processors to clean raw agricultural commodities prior to sale or prior to use as an ingredient in a processed food. In addition, GMP regulations require processors to take steps to prevent gross contamination during the processing and storage of a food product (Food and Drug Administration, 1998a,d).

Insects, especially flies and insect larvae, are defined as objectionable filth by section 110.3(j) of the Current GMP regulations (Food and Drug Administration, 1998a). Public tolerance of visible insect filth is generally low (Byrne *et al.*, 1984; Thoms, 1985). A survey of public attitudes toward cockroaches, for example, found that a majority of the people who were surveyed (>70%) would "do something to control cockroaches" after one or two indoor sightings of the insects. The same survey found that most consumers routinely discard food that is defiled by cockroaches (Zungoli and Robinson, 1984). Smaller insects (<10 mm) such as the storage insects discussed in the next section are objectionable if they are visible in a product. For general regulatory purposes, a visible contaminant in one immediate container of a product is considered an indication of insanitation that requires immediate regulatory action (Food and Drug Administration, 2000e; Harris *et al.*, 1952). An immediate container is defined as the "receptacle or other covering in which any product is directly contained or wholly or partially enclosed" (Department of Agriculture, 1999a). The immediate container is the packaging component that is in immediate contact with the product, e.g., the innermost component whether it be a carton, a liner inside a carton.

A 4-year survey of FDA regulatory actions involving insects found that, annually, from 54 to 62% of the regulatory actions were based on visible insects in a food (Bauer, 1984). A recent survey of FDA consumer complaints that were referred to the authors over a 20-month period (June 1994–February 1996) found that whole insects in food are the third-ranking source of consumer complaints involving contaminants that were detected by the consumer, either visually or by odor (Table 5). According to the survey, other sources of complaints involving easily detected contaminants were off-odor or taste (potential chemical hazard), hard or sharp objects (potential physical hazard), mold, and rodent excreta pellets (Table 5).

Excrement of any kind is considered an objectionable indicator of insanitation (Eisenberg, 1981; Thrasher,

TABLE 5
Consumer Complaints Reported to FDA (June 1994–February 1996)

Cause of complaint	Number of complaints	Percentage of total	Reported injuries
Off odor/taste	26	32.50	22
Hard/sharp object	15	18.75	11
Whole insect	13	16.25	6
Mold	8	10.00	3
Container integrity	6	7.50	4
Rodent filth	4	5.00	1
Choking hazard	1	1.25	1
Other	7	8.75	3

1981). FDA guidance outlines regulatory action levels for indicators of insanitation such as visible droppings, urine stains, and other forms of visibly evident defilement by commensal rodents and birds (Food and Drug Administration, 2000e).

Filth Associated with Food-Contaminating Commensal Pests

Commensalism is a form of symbiotic relationship between a commensal species and a host species in which the commensal species benefits and the host species derives no benefit or harm (Schuh, 1989). In relation to humans, a commensal species is one that shares our dwellings or settlements and derives some benefit from doing so (Schuh, 1989; Hölldobler and Wilson, 1990). Gorham (1991a) defines three basic groups of food-contaminating commensal pests that are indicators of insanitation. He characterizes the three groups as opportunistic, inadvertent, and obligatory contaminators of food. Although these three groups contain potential vectors of food-borne pathogens, the groupings are based on the pests' relationship to human food, not on their capabilities as vectors of food-borne pathogens (Gorham, 1991a). A fourth group that is not mentioned by Gorham consists of the parasitic and predatory insects and mites associated with members of the other three basic groups.

Opportunistic pests are synanthropic and endophilic, exhibit communicative behavior, and are attracted to human food but the association with food-borne pathogens that is characteristic of the species listed in Table 4 is either absent or neutralized. Opportunistic pests can survive without human food but they will utilize stored food whenever they have the opportunity. This group includes cockroaches, flies, ants, rats, and mice (Gorham, 1991a).

There is an area of overlap among the pests that are contributing factors to the spread of pathogens and those that are opportunistic. Specifically, items 1 through 4 of the profile for contributing factors (Table 1) are also attributes of opportunistic pests. In cases where the potential hazards from pathogens are effectively controlled by cooking or other processing controls, the pests that could be potential contributing factors, i.e., those listed in Table 4, no longer meet item 6 of the profile for contributing factors to a biological hazard. In the absence of a reasonably likely pathogen hazard (Table 1, Contributing Factor profile item 6), these pests are otherwise categorized as opportunistic pests because they still exhibit the four attributes held in common by disease-carrying pests that are contributing factors and by opportunistic pests.

Gorham's "inadvertent" pests are more widely known as "adventive" pests (Smith, 1988). Adventive pests include birds, bats, lizards, spiders, nuisance flies, and other hemisynanthropic pests that use food storage or processing facilities as an extension of their environment (Gorham, 1991a; Olsen *et al.*, 1996; Scott, 1959b, 1963; Smith, 1988). Hemisynanthropes tend toward synanthropy but they do not require association with humans in order to flourish (Greenberg, 1971). Their presence near food storage or preparation areas is adventive in the sense that adventive pests use these areas or facilities as convenient places to rest, roost, or nest and may, in the process, contaminate food products (Gorham, 1991a). Adventive pests do not normally exhibit communicative behavior and are not particularly attracted to human food.

The obligatory group consists of the group of insects and mites known as stored-product pests. For regulatory purposes, FDA categorizes these pests as "storage insects" or "stored-product insects" (Food and Drug Administration, 2000c,d). Storage insects exhibit a form of commensalism known as inquilinism, or the sharing of another species' home or nest for the specific purpose of stealing the host's food (Schuh, 1989; Hölldobler and Wilson, 1990). These inquilines are synanthropic and endophilic. Storage insects are attracted to human food. They do not normally exhibit communicative behavior. Instead, storage insects are obligatory inhabitants of stored-product ecological niches, living and breeding (producing offspring) in a product for many generations of the pest species' life cycle (Dunkel, 1992; Linsley, 1944; Metcalf *et al.*, 1962; Olsen, 1996a). Obligatory pests are dependent on stored foods and derive all their food, water, and shelter from the foods they infest. Adulteration involving obligatory pests is associated with insanitary conditions that are conducive to the spread of disease even though the pests pose no immediate hazard to health.

The diversity of stored-product and commensal pests is estimated to be as large as 600 species or more (Sinha and Watters, 1985). Comprehensive reference lists of the species of pests that attack stored food products have been compiled by Sinha and Watters (1985), Gorham (1991b), and Olsen *et al.* (1996). Examples of storage pests include flour beetles, *Tribolium* spp. (Coleoptera: Tenebrionidae); flour moths, *Ephestia* spp. (Lepidoptera: Pyralidae); cheese skippers, *Piophila* spp. (Diptera: Piophilidae); booklice, *Liposcelis* spp. (Psocoptera: Liposcelidae); and grain mites (Astigmata: Acaridae) (Hughes, 1976; Metcalf *et al.*, 1962; Mockford, 1993; Olsen *et al.*, 1996).

The parasites and predators group consists of ectoparasites, parasitoids (parasitic wasps), and predators of food-contaminating pests. Parasites and predators are as synanthropic and endophilic as their host or prey. They are attracted to food-contaminating pests, not the human food itself. The presence of parasites or predators is an indicator of insanitation that suggests a relatively long-standing infestation by one of the storage or commensal pests that is their natural host or prey (Kvenberg, 1981).

TABLE 6
Parasitic (Parasitoid) and Predatory Insects Approved for the Biological Control of Insect Pests in Stored Raw Whole Grains

Group	Family	Genus
Parasitic wasps (order Hymenoptera)	Trichogrammatidae	*Trichogramma*
	Braconidae	*Bracon*
	Ichneumonidae	*Venturia*
		Mesostenus
	Pteromalidae	*Anisopteromalus*
		Choetospila
		Lariophagus
		Dibrachys
		Habrocytus
		Pteromalus
	Bethylidae	*Cephalonomia*
		Holepyris
		Laelius
Predatory true bugs (order Hemiptera)	Anthocoridae	*Xylocoris*
		Lyctocoris
		Dufouriellus

The parasitic wasps found in stored foods are normally host specific rather than habitat specific (Gordh and Hartman, 1991). As a result of their host specificity, parasitic wasps have been promoted as a means of biological control for storage pests (Avaritt and Richter, 1996). The use of parasitic wasps to control pests is regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (Environmental Protection Agency, 1991). Under FIFRA authority, the U.S. Environmental Protection Agency (EPA) approved the use of certain parasitic wasps, as well as certain predatory insects, for controlling insect pests in stored raw whole grains (Environmental Protection Agency, 1992). According to EPA regulations, the permitted parasites and predators are exempted from the requirement of a tolerance level for residues; however, whole insects, fragments, parts, and other residues of these parasites and predators remain subject to regulation as filth under section 402(a) (3) of the Food, Drug and Cosmetic Act (Environmental Protection Agency, 1999). EPA, USDA, and FDA expect that when an approved parasite or predator is introduced into stored grain as a biological control agent, the insects will be removed by cleaning prior to milling or other subsequent processing (Environmental Protection Agency, 1991). Table 6 lists insects that are approved by EPA for use as biological control agents in stored raw whole grains.

Another group of pests that infest human food are the pests that attack crops in the field. These pests are differentiated from commensal pests by two important factors found in the regulatory action criteria profiles for these pest groups. Unlike commensal and storage pests which are endophilic and attack stored products, field pests are exophilic (preferring outdoor habitats) and they mainly attack living crops in the agricultural fields (Eisenberg, 1981). The field pest group includes a variety of insect and mite pests of agricultural crops. They are mainly responsible for aesthetic defects in fresh produce. FDA recognizes several categories of common field pests including aphids (Homoptera: Aphididae and related families); scale insects (Homoptera: Coccidae and related families); thrips (Thysanoptera); true bugs (Hemiptera: Miridae); noctuid moths (Lepidoptera: Noctuidae); fruit flies (Diptera: Tephritidae); and leaf miners (Diptera: Anthomyiidae) (Food and Drug Administration, 1998g). Filth from field insects is fully discussed in the FDA Macroanalytical Procedures Manual (Olsen *et al.*, 1998). The action criteria for filth from field insects are discussed in detail in the section on natural or unavoidable contaminants.

Table 7 summarizes the action criteria profiles for differentiating among the four groups of commensal

TABLE 7
Action Criteria Profiles for Pests as Indicators of Insanitation

Group	Action Criteria Profile	Examples
Opportunistic commensal pests	1. Synanthropy;	Roof rats[a]
	2. Endophily;	House mice[a]
	3. Attracted to stroed food;	Cockraches[a]
	4. Communicative behavior; and	Fifth files[a]
	5. Rarely found living in stored food.	Sllverfish
Adventive commensal pests	1. Synanthropy;	Birds[a]
	2. Endophily (roosting or nesting);	Bats
	3. Rarely attracted to stored food;	Lizards[a]
	4. Lacking communicative behavior; and	Nulsance files
	5. Rarely found living in stored food.	Spiders
Obligatory commensal pests (storage insects)	1. Synanthropy;	Flour beetles
	2. Endophily;	Flour moths
	3. Attracted to stored food;	Booklice[b]
	4. Lacking communicative behavior; and	Cheese skippers[c]
	5. Live and breed in stored food.	Grain mites[b]
Parasites and predators	1. Synanthropy;	Parasitic wasps
	2. Endophily;	Predatory true bugs
	3. Not attracted to stored food; and	
	4. Attached to a specific host or prey.	

[a]May also pose a potential health hazard as a carrier of food-borne pathogens.
[b]May also pose a potential health hazard if an allergenic species is involved.
[c]May also pose a potential health hazard as a cause of myiasis.

pests. Pests that exhibit all of the action criteria profile attributes for any one of the groups listed in Table 7 are indicators of insanitation as defined by Gorham (1991a).

The impact of FDA's regulatory action criteria for filth from commensal pests is revealed in a survey of 547 randomly selected reports of analytical findings from food samples that were submitted to the authors by FDA district offices nationwide between June 1995 and March 1999. A sample distribution was tabulated for samples that contained contaminants that fit one or another of the profiles, from Table 7, for indicators of insanitation. Survey samples generally consisted of six subsamples randomly collected from goods offered for import in the form of lots, although a small number of samples had as few as 3 subsamples or as many as 12. The contaminants that were found during the survey included whole insects that fit the obligatory pest profile, large body parts of insects that fit the same profile, and whole hairs of mammals that fit the opportunistic pest profile. Whole insects are intact, dead insects whose three major body regions (head, thorax, abdomen) remained articulated or attached to each other. Large body parts are defined as one disarticulated body region or two attached body regions (i.e., an insect with either the head or the abdomen missing). Whole hairs are the entire hair from root to tip. The survey did not gather data on levels of aesthetic defects such as those governed by Defect Action Levels for natural or unavoidable contaminants. No hazardous contaminants were reported from the 547 samples.

Table 8 lists the distributions of samples that were above and below the levels of contamination that are the FDA minimal levels of regulatory concern for dead insects, insect body parts, or whole hairs in food (Food and Drug Administration, 2000e). The data shows that 34 of the 547 samples (6.2%) exceeded the level of concern for filth from commensal pests that fit the profiles listed in Table 7. The majority of samples (93.8%) were below the regulatory threshold for filth from these commensal pests.

TABLE 8
Distribution of Contaminants That Are Indicators of Insanitation in Food Samples (Total 547 Samples)

Contaminant	Regulatory threshold	No. (%) of samples at or above the threshold
Whole insects	One or more in each of three or more subsamples	17(3.1%)
Large body parts of insects	Three or more in each of three or more subsamples	15(2.7%)
Whole hairs	One or more in each of three or more subsamples	2(0.4%)

Application of the Regulatory Action Criteria Profiles for Indicators of Insanitation

Contamination by indicators of insanitation is regulated through the insanitation provisions of sections 402(a) (3) and 402(a) (4) of the FD&C Act and through the regulations for Current Good Manufacturing Practices (Food and Drug Administration, 1998d). As discussed previously, some of the pests that meet the criteria for indicators of insanitation (Table 7) may also be included among the pests that meet the criteria for potential health hazards (Table 4). This is because all of the pests in Table 7 thrive under the insanitary conditions that promote disease and are therefore indicators of insanitation. In HACCP environments, pests that are potential HACCP contributing factors (Table 4) are treated as potential health hazards only in circumstances where it is reasonably likely that the pest could cross-contaminate a food with pathogens. In the absence of a reasonable likelihood of cross-contamination or other microbial health hazard, the vector capacity of disease-carrying pests is effectively neutralized, making them general indicators of insanitation along with the other pests discussed in this section. Contamination by indicators of insanitation is normally controlled under a sanitation program, such as a firm's Sanitation Standard Operating Procedure (SSOP) (Food and Drug Administration, 1998a) or GMP pest control program (Bernard *et al.*, 1999; Food and Drug Administration, 1998d). According to current FDA and USDA HACCP regulations, sanitation programs are prerequisites for HACCP plans and exclusion of pests is a mandatory component of these prerequisite sanitation programs (Department of Agriculture, 1999b; Food and Drug Administration, 1998a).

Insanitation involving pest activity in or near food-handling or storage facilities is regulated under the provision of section 402(a) (4) of the FD&C Act that defines a product as adulterated if it is prepared, packed, or held under insanitary conditions whereby the product may have become contaminated with filth. Processing equipment and food-contact surfaces that are defiled by storage insects or commensal pests are also regulated through section 402(a) (4) (Food and Drug Administration, 1984). A general regulatory guideline for this type of insanitation is found in FDA's Compliance Policy Guide 580.100 for food storage and warehousing (Food and Drug Administration, 2000e).

ACTION CRITERIA FOR NATURAL OR UNAVOIDABLE CONTAMINANTS

Natural or unavoidable contaminants are contaminants or defects that pose no hazard to health and that are natural or unavoidable, to a degree, in rural environments where food crops are grown and harvested (Food and Drug Administration, 1984, 1998g). Federal regulations empower FDA to establish limits, or regulatory defect action levels, for filth and extraneous materials that meet the criteria for a harmless, natural, or unavoidable defect (Food and Drug Administration, 1998f).

Natural or Unavoidable Defects Involving Filth and Extraneous Materials in Food

The necessity for establishing defect levels was recognized soon after passage of the 1906 Federal Food and Drugs Act. One of the earliest defect levels was established in 1919 for mold in tomato pulp. These action levels were at various times known as "Confidential Administrative Tolerances," "Field Legal Action Guides," or "Administrative Guidelines." These internal action guides were considered confidential and were available only to certain agency personnel (Welch, 1944).

Over the years, the Food and Drug Administration received requests from consumers, industry, the news media, and others to make public the levels of natural or unavoidable defects in food for human use which are used in considering recommendations for regulatory actions. In March 1972 the Food and Drug Administration decided that the public was entitled to this information and subsequently published a notice of proposed rule making on natural or unavoidable defects in food for human use that present no health hazard, now known as "Food Defect Action Levels."

The FD&C Act and Defect Action Levels

Under section 402(a) (3) of the FD&C Act, a food is technically illegal if it contains any insect or rodent filth, mold, rot, or other similar substances. Even with modern technology, few foods are completely free of natural or unavoidable defects. Foreign material cannot be wholly processed out of foods, and levels of many contaminants introduced into foods through the environment can be reduced only by reducing their occurrence in the environment. The FD&C Act, nonetheless, was designed to protect the consuming public from violations to its aesthetic sensibilities as well as from poisonous, filthy, decomposed, and putrid foods and foods prepared under insanitary conditions (Kurtz and Harris, 1962). The food industry must continually strive to minimize natural and unavoidable defects in foods.

Federal regulations recognize that even when produced under current good manufacturing practices, some foods contain natural or unavoidable defects at low levels that are not hazardous to health. Currently, the regulations allow FDA to establish maximum levels for such defects in foods produced under current good manufacturing practices and to use these levels, called defect action levels (DALs), as a basis for regulatory actions (Food and Drug Administration, 1998f). New defect action levels are established for products whenever it is necessary and feasible. Existing action levels are subject to change upon the development of new technologies or the availability of new information (Bandler *et al.*, 1984). Table 9 lists examples of the types of defects and products that are subject to defect action levels. Federal regulations require FDA to periodically publish a complete listing of current DALs (Food and Drug Administration, 1998f). FDA periodically publishes a plain-language summary of DALs for filth and extraneous materials (Food and Drug Administration, 1998g).

TABLE 9

Examples of Defects and Affected Foods That Are Regulated by a Defect Action Level for Filth or Extraneous Materials

Type of defect	Example	Affected food
Animal filth	Insect fragments	Flour
	Whole or equivalent insects	Spices (beetles)
	Insect damage	Nuts (insect boring)
	Insect eggs	Catsup (*Drosophila* eggs)
	Animal hairs	Cocoa powder (rodent hairs)
	Excreta	Wheat (rodent excreta pellets)
	Mites	Mushrooms
Decomposition	Microscopic mold	Catsup (Howard mold count)
	Visible mold	Greens (mildew)
	Rot	Plums (spots)
	Dry rot	Beets
Foreign matter	Shell	Chocolate products
	Stems	Clove
	Sand/grit	Peanut butter
	Pits	Olives
	Field corn	Popcorn
	Miscellaneous trash	Black pepper (pickings and siftings)

New DALs are established or existing DALs are updated based on statistically valid nationwide surveys that are designed to be representative of the retail market for both domestic and foreign produced commodities. Results of these surveys have been published for a variety of products. Table 10 lists the published results of the major surveys that have been completed since 1972. In order to develop a realistic data base of contaminant profiles, the study must consider relevant factors such as geographical origin of the product and environmental and seasonal influences which may affect contamination of the commodity. Table 11 lists the regulatory action criteria profile for establishing a defect action level for contamination involving filth and extraneous materials (Bandler *et al.*, 1984). Defect action levels established or updated after 1972 are based on the upper 99% confidence limit of the 95th percentile of the frequency distribution for each defect included in the survey data. In other words, the defect action limit is approximately the 97–98% point on the frequency distribution for each defect element. Interpreted literally, the defect action level is selected from the survey data

TABLE 10
Defect Action Level Surveys and Related FDA Surveys Published Since 1972

Product	Defect(s)	Survey references
Chocolate	Insect fragments, rodent hairs	Gecan *et al.*, 1978
Coffee beans	Insect damage, mammallan excreta, mold	Gecan *et al.*, 1988a
Cranberry sauce	Howard mold count	Gecan *et al.*, 1979
Fruit nectar, infant purees	Howard mold count	Bandler *et al.*, 1982
Macaroni, noodles	Insect fragments, rodent hairs	Gecan and Atkinson, 1983b
Seafood, canned	Flies, insect fragments, rodent hairs	Gecan *et al.*, 1988b
Shrimp, dried	Mites, rodent hairs	Olsen, 1982
Shrimp, fresh/frozen	Whole insects, Insect fragments, rodent hairs, cockroach excreta	Gecan *et al.*, 1994
Spices	Insect fragments, rodent hairs	Gecan *et al.*, 1983a,b
Tree nuts	Insect damage, mold, rancidity, decomposition, shriveled, blank and dirt	Gecan *et al.*, 1987
Vegetable	Whole insects greens	Gecan and Bandler, 1990
Wheat	Insect damage, rodent excreta	Gecan *et al.*, 1980
Wheat flour	Insect fragments, rodent hairs	Gecan and Atkinson, 1983a

as a level of cleanliness that has been achieved by 97–98% of the producers of the product that was surveyed.

DAL surveys and DAL regulatory actions depend on reliable and uniform analytical methodologies for end-product testing for defects. The design and application of these methods are described in several technical manuals (Gorham, 1977, 1981b; Olsen *et al.*, 1996). Federal regulations require FDA to publish these and other analytical methods in official compendia (Food and Drug Administration, 1998h). The analytical methods for DAL analyses are compiled in official compendia such as Boese and Cichowicz (1995) and Olsen *et al.* (1998).

Application of the Regulatory Action Criteria Profiles for Natural or Unavoidable Contaminants

Levels of natural or unavoidable contaminants that exceed a DAL are regulated as filth according to section 402(a) (3) of the FD&C Act (Food and Drug Administration, 1998g). Compliance with DALs, however, does not exempt food from the requirement of section 402(a) (4) that food be prepared, packed, or held under sanitary conditions or food manufacturers, distributors, and holders from the requirement to observe current good manufacturing practices. Furthermore, mixing food containing defects above the current DAL

TABLE 11
Action Criteria Profile for Defect Action Levels Involving Filth and Extraneous Materials

Element	Requirement	Examples
Product	Define the target product in terms of product identity and manufacturing process	Shrimp (product identity): fresh, forzen, dried, canned, etc. (manufacturing process)
Defect	Identify defect element(s)	Insect fragments, rodent hairs
Analytical method	1. Evaluate the application of an existing method or	AOAC International method, AACC method, MPM method
	2. Develop a new method	Collaborative study to develop, validate new method
Sampling plan	1. New DAL	1500 lots
	2. Update existing DAL	500 lots
Sampling strategy	1. Sample size	Specified in analytical method
	2. Collection sites	Retail outlets in randomly selected metropolitan areas
	3. Representative sampling	Ratio of domestic to import reflects volume market shares
	4. Seasonal variation	Multiyear study to consider influence of seasonal environmental variables on defects
Sample collection	1. Disinterested third party	Contractor, FDA investigator
	2. Shipping	Preserve original state of product (fresh, frozen, *etc.*)
Sample analysis	Use a qualified/accredited analyst and laboratory	FDA regional laboratories, state laboratories
Data analysis	1. Data presentation	Frequency distribution tables covering each defect
	2. Derive DAL from frequency distribution data	Select defect action levels at the upper 99th confidence limit of the 95th percentile.

with another food in an attempt to produce an average defect level that does not exceed the DAL is not permitted and would render the final food adulterated regardless of the defect level of the final food (Food and Drug Administration, 1984, 1998f,g).

Mold in food is often regulated as an natural or unavoidable defect. Machinery mold, *Geotrichum candidum*, is a notable exception. Contamination with machinery mold is recognized as a true indication of insanitation because machinery mold is found on unclean food processing equipment (Cichowicz and Eisenberg, 1974; Emrick, 1977). Widely distributed in nature (Carmichael, 1957), *G. candidum* assumes a distinctive, feathery morphology when growing on machinery which differentiates it from aesthetic types of food-contaminating molds (Cichowicz, 1981).

Defect action levels for filth and extraneous materials are established for contaminants that pose no hazard to health. Any contaminants which might be harmful to consumers are subject to the regulatory actions described above, whether or not the product exceeds a particular DAL (Food and Drug Administration, 1984). Similarly, products that are contaminated with filth from indicators of insanitation are subject to the regulatory actions described above for that category of contaminants, regardless of whether the product does or does not exceed a particular DAL.

RELATING TRACE EVIDENCE TO REGULATORY ACTION CRITERIA

There are three recognized categories of forensic entomology: urban forensic entomology, medicolegal forensic entomology, and stored-product forensic entomology (Lord and Stevenson, 1986). The latter category, stored-product forensic entomology, deals with contamination or infestation of foods or other commercial products by insects or other pests and with trace evidence of contamination attributable to these pests (Catts and Goff, 1992). FDA investigators and entomologists apply stored-product forensic entomology to the investigation of contamination of food products with filth and extraneous materials (Olsen, 1996a).

Contaminant Profiles and FDA Investigations

As a regulatory agency, FDA may conduct investigations by gathering and developing forensic evidence to prove violations of the laws that the agency enforces (Zimmerman and Brickey, 1996). During the course of an investigation for violations involving filth and extraneous materials, the FDA investigator normally records observations and collects bits of physical evidence, called “filth exhibits,” to corroborate the investigator’s observations (Kurtz and Harris, 1962). FDA investigators are required to generally identify insects and other pests. Investigators must also trace routes of contamination and observe all means by which the contamination could have been incorporated into a food product. The action criteria profiles for insects and other pests as HACCP contributing factors (Table 1) or indicators of insanitation (Table 7) serve as forensic profiles that can be used by an investigator in two ways. First, the profiles can be used to recognize these pests by observing the behavior that pests exhibit during an investigation and comparing the observed behavior to the attributes in Table 7. Second, the profiles can be used to evaluate contaminants by identifying the pest species and then consulting the scientific literature to determine whether that species meets the criteria of a profile from Table 7.

From a stored-product forensic entomology standpoint, the action criteria profiles described in Table 7 for indicators of insanitation are analogous to the profiles used by medicolegal forensic entomologists for insects and other arthropods that are observed at homicide crime scenes. The medicolegal profile groups include (1) necrophagous species, (2) omnivorous species, (3) adventive species, and (4) parasites and predators (Smith, 1988). These medicolegal profile groups are analogous, respectively, to the (1) obligatory pests, (2) opportunistic pests, (3) adventive pests, and (4) parasites and predators listed in Table 7.

Development of Trace Evidence

One of the regulatory challenges involving filth and extraneous materials is the development of trace evidence from the types of contaminants that are discussed above and in previous articles in this series. Forensic trace evidence is used to (1) help solve crimes; (2) associate people, places, and things involved in the crime; (3) deduce the occupation(s) of the principal(s) involved in the crime; and (4) reconstruct the crime scene and/or the event itself. Forensic scientists divide trace evidence into two morphological forms, fibrous and particulate. Fibrous forms of trace evidence include textile fibers, hairs, and feathers. Particulate forms include insect parts, glass, wood, and other extraneous materials (Petraco and De Forest, 1993).

Trace evidence of filth and extraneous materials in food falls in the domain of forensic stored-product entomology even though some of the contaminants do not originate from insects or other pests. The development of trace evidence of fibers and particles in food is a specialized field known as microanalytical entomology (Kurtz and Harris, 1962; Olsen, 1996a).

The identification of small to microscopic insect fragments and hairs is central to the application of microanalytical entomology to the regulation of food sanitation. Insect fragments are actually particles of insect cuticle that have become incorporated into a contaminated food. Microscopic characteristics can be used to differentiate fragments of insect cuticle from fragments of plant

TABLE 12
Action Criteria Profile of Recognition Characteristics for Nondescript Insect Fragments

Recognition level	Character	Insect cuticle fragment
Conclusive	Distinctive shape	Readily recognizable shape of a whole or portion of a specific appendage or body part of an insect
	Articulation	Readily recognizable joint or other typical insect articulation structure
	Seta	Hairlike structure arising from a pit; lacking internal septation or cellular structures
	Setal pit	Circular pit; opening surrounded by a ring
	Sculpture	Surface sculpture pattern of a type known to occur in a specific insect
	Sutures	Sections of cuticle interlocked or hinged at a thin suture
Helpful, but not conclusive	Rigidity	Flexible yet tough
	Dimensionality	Thin, plate-like
	Luster	Surface sheen
	Internal structure	Lacks true cellularity

material and other small particles found in food (Gecan and Brickey, 1964; Harris, 1950; Vazquez, 1977; Olsen, 1996c). Table 12 summarizes the FDA action criteria profile for trace evidence consisting of nondescript, microscopic insect fragments in food (Gecan and Brickey, 1964; Vazquez, 1977). Nondescript insect fragments, as well as fragments from agricultural, or "field," pests are categorized as natural or unavoidable filth for regulatory purposes.

Experienced forensic entomologists can sometimes identify fragments of storage insects and other indicators of insanitation to precise taxonomic levels such as genus or species level. The scientific literature concerned with identifying insect fragments was reviewed by Olsen (1996c). Other particulate forms of extraneous materials, such as glass (Eisenberg and Schulze, 1981) and mold (Cichowicz, 1981), can sometimes be identified to very precise levels. Several photographic compendia are dedicated to the identification of particulate trace evidence (Gentry and Harris, 1991; Kurtz and Harris, 1962; McCrone *et al.*, 1968).

Fibrous forms of trace evidence in food consist of animal hairs, human hairs, feather fragments, and textile fibers. As is the case with particulate forms, these forms of trace evidence can often be identified to precise levels (Bresee, 1987; Bisbing, 1982; Gaudette, 1988; Ludwig and Bryce, 1996; Petraco and De Forest, 1993; Vazquez, 1961). Ludwig and Bryce (1996) and Vazquez (1961) provide identification keys for the identification of hairs and feather fragments. In order to accurately identify specimens of particulate and fibrous trace evidence, the forensic entomologist requires an archive of reference specimens of examples of trace evidence elements that have been scientifically authenticated (Frei-Sulzer, 1965; Semey, 1996). Suspect particles and fibers that are collected as evidence or are isolated from food products are identified by comparison with the validated reference specimens from the forensic entomologist's reference collections.

Application of the Regulatory Action Profiles to Trace Evidence

In general, trace evidence shares the same regulatory categorization (health hazard, indicator of insanitation, natural unavoidable defect) as the originating source. Straightforward cases involving trace evidence normally follow a regulatory action procedure similar to that applied to other contaminants of similar origin. If, for example, a product contaminant were subject to action under a provision of section 402(a) (3) then forensic evidence that originated from the same contaminant would normally be subject to regulatory action under the same provision of section 402(a) (3).

Trace evidence may prove useful in establishing responsibility for insanitary or potentially hazardous contaminants. This is accomplished by matching trace evidence with evidentiary exhibits that are collected to document violations of section 402(a) (4). By demonstrating the etiology of contamination, the trace evidence establishes associations between persons and contaminated goods that are admissible in court as evidence of responsibility for a violation of the FD&C Act. In the event that trace evidence shows contamination of a food product from the same source as the basis for a related 402(a) (4) violation, a 402(a) (3) violation may also be charged, regardless of the amount of contaminant found in the product.

DISCUSSION

Filth and extraneous materials that are found in food products can be grouped into three regulatory action categories using the action criteria profiles discussed in this review. The profiles for category 1 (health hazards) and category 2 (indicators of insanitation) are contaminant specific. Each profile describes a type of contaminant. The regulatory action criteria for category 3 (natural or unavoidable filth) contaminants are product specific. Each category represents a different application of sections 402(a) (1), 402(a) (3), or 402(a) (4) of the FD&C Act.

Category 1 includes contaminants that are associated with a potential hazard to health. Regulatory action criteria for adulterants in this category are profiled in Table 1. Category 1 health hazards, i.e., those that match all the numbered elements of any one of the three profiles from Table 1, are the area of highest concern to consumers, food processors, and food regulators. Filth or other extraneous materials that match a profile from Table 1 are categorized as adulterants within the meaning of the health hazard provisions of sections 402(a) (1) or 402(a) (4) of the FD&C Act. Enforcement of these health hazard provisions may include seizure of adulterated goods, prosecution of the firm or individual alleged to be responsible for the violation, injunction to restrain a firm or individual from traffic in adulterated goods, or recall of the adulterated goods (Brickey, 1981a).

Category 2 contaminants, i.e., those that match all of the numbered attributes of any one of the profiles from Table 7, are an area of serious concern to consumers, food processors, and food regulators. Filth or other extraneous materials that match a profile from Table 7 are categorized as adulterants within the meaning of the filth and insanitation provisions of sections 402(a) (3) or 402(a) (4) of the FD&C Act. Enforcement of these insanitation provisions may include seizure of adulterated goods, prosecution of the firm or individual alleged to be responsible for the violation, injunction to restrain a firm or individual from traffic in adulterated goods, or, rarely, recall of the adulterated goods (Brickey, 1981a).

Category 3 includes adulterants that are aesthetic in nature. The regulatory action criteria for adulterants in this category are often established in written guidelines such as the FDA Compliance Policy Guides, some of which are also known as defect action levels (Food and Drug Administration, 1998g). Category 3 adulterants are an area of concern over the quality of the food that enters the marketplace. Natural or unavoidable types of filth and extraneous materials are categorized as adulterants within the meaning of section 402(a) (3) of the

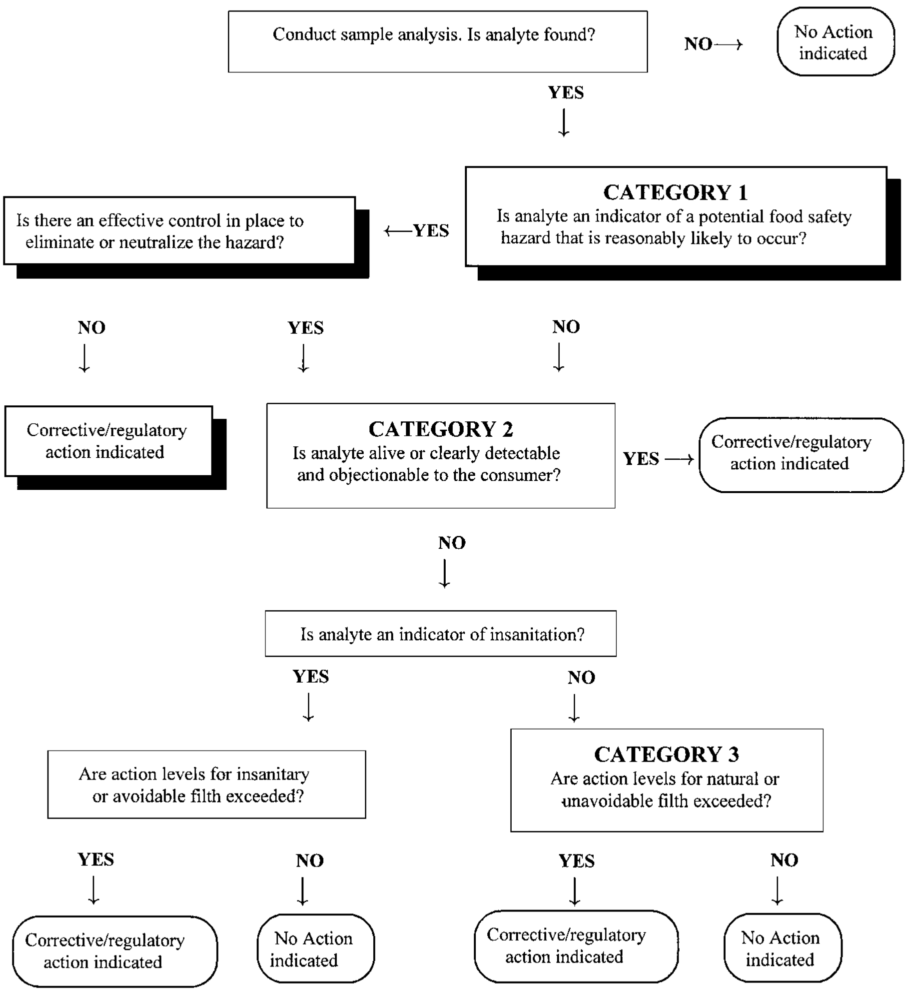

FIG. 1. Procedure for applying regulatory action criteria profiles for filth and extraneous materials.

FD&C Act. Enforcement normally involves seizure of adulterated goods.

For purposes of enforcing the FD&C Act, the regulatory action criteria profiles are applied sequentially, in the order of the ranking of the three regulatory action categories. Health hazards receive first consideration. An adulterant that does not match any of the health hazard profiles (Table 1) is compared to the profiles for indicators of insanitation (Table 7). Adulterants that do not match any of the profiles for health hazards or indicators of insanitation are evaluated for their regulatory significance as natural or unavoidable adulterants. Figure 1 is a regulatory decision tree that illustrates the application of the regulatory action criteria profiles in each category to the evaluation of the results of laboratory analyses of food products for adulteration with filth and other extraneous materials. The regulatory decision-making process depicted in Fig. 1 reflects the FDA regulatory strategy for filth and extraneous materials in food as endorsed by the FDA Food Advisory Committee (Food and Drug Administration, 1999c). The committee is an advisory body of scientists, consumer representatives, and industry experts that reports to the Commissioner of the Food and Drug Administration on issues relating to the regulation of food products.

It is important to recognize that sections 402(a) (1), 402(a) (3), and 402(a) (4) are independent clauses of the FD&C Act so that proof of adulteration as defined in any one of these sections is not dependent on proof of a corollary violation under another section in order to warrant regulatory action (Brickey, 1981b; Gorham, 1996). For example, a violation of section 402(a) (4) (insanitary conditions) is sustainable in court even in the absence of a finding of contaminants in the product produced under the insanitary conditions. Under established legal precedence, FDA is not required to demonstrate product contamination in order to regulate “insanitary conditions whereby it [a product] may have become contaminated with filth” (Gorham, 1981b). Furthermore, FDA may take enforcement action based on poor manufacturing practices without regard to defect action levels or other established regulatory action criteria (Food and Drug Administration, 1998g). The government is not required to demonstrate an immediate hazard to health in order to regulate filth in foods because filth in the food-processing environment is an indication of the type of insanitation that is prohibited by sections 402(a) (3) and 402(a) (4) of the FD&C Act (Gorham, 1996).

CONCLUSION

This review concludes the assemblage of a transparent (public and predictable) science base for FDA regulatory policy in the area of filth and extraneous materials in food. The regulatory action criteria profiles and regulatory action categories discussed in this review provide a uniform, science-based strategy for investigating, evaluating, and regulating adulteration involving health hazards, indicators of insanitation, and natural or unavoidable adulterants associated with filth and extraneous materials in food. The 478 entries of the reference section represent the transparent science base upon which FDA regulatory policy rests. Although this review reports a science base for evaluating filth and other extraneous materials, the review does not preclude FDA from taking appropriate regulatory and enforcement actions based on other, equally valid, criteria.

Future research needs in the area of filth and extraneous materials include the development of uniform, hazard-specific analytical and forensic methods for the detection, identification, and control of hazardous types of filth and extraneous materials in food products. These methods must be designed to reliably detect a particular type of hazardous adulterant in any of the potentially hazardous foods that represent a reasonably likely risk of injury from the adulterant. For example, hazard-specific methodology for detecting parasites in fish is published in FDA Technical Bulletin No. 5 (Olsen *et al.*, 1998) and a number of hazard-specific methods for detecting and controlling hazards from foreign objects are published in FDA and HACCP manuals (Food and Drug Administration, 1998k; Olsen, 1997; Price, 1997). There is an urgent need for hazard-specific methods for detecting allergenic mites, allergens of food-contaminating pests, and filth from pests that are HACCP contributing factors.

From the forensic and epidemiological standpoints, there is a need to develop rapid field techniques for detecting and identifying pests that are potential contributing factors to the spread of food-borne disease. Epidemiological field investigations of outbreaks of food-borne illnesses should identify these potential contributing factors (De Roever, 1999). The need is also evident for products manufactured in a HACCP environment because HACCP programs often encourage in-plant controls that rely on the rapid implementation of corrective actions based on field observations alone.

The authors further recognize a need to report incidents of injury or illness involving choking hazards, reactions to food adulterated with mites, cockroaches, or dermestid beetles to FDA for evaluation.

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