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ASSOCIATION OF FOOD AND DRUG OFFICIALS

Mission Statement

The Association of Food and Drug Officials (AFDO), established in 1896, successfully fosters uniformity in the adoption and enforcement of science-based food, drug, medical devices, cosmetics and product safety laws, rules, and regulations.

AFDO and its six regional affiliates provide the mechanism and the forum where regional, national and international issues are deliberated and resolved to uniformly provide the best public health and consumer protection in the most expeditious and cost-effective manner.

FROM THE EDITOR

As we enter the final months of the year we can look back with some satisfaction on how we have met our readers' needs. There has been much for professionals in food and drug regulation to adapt to and try to understand. Not the least of this has been the implementation of the Bioterrorism Act of 2002. As this important legislation is put into operation, a new dimension is added to our regulatory system for foods and drugs, forcing us to deal with the possibilities of deliberate terrorist actions to destroy our confidence in the safety of our food supply. For a people who have always been accustomed to taking food safety more or less for granted, the threat of terrorist attacks on our supply of foods and medicines is going to take some getting used to.

Terrorism is a criminal endeavor and as such it is important to recognize the need for us to develop a working relationship with law enforcement agencies that deal with crime and criminal acts of an overt nature. To that end I appeal to our readers who work with police and criminal investigative agencies to suggest journal topics and potential authors that we may enlist to submit papers dealing with such subjects. In so doing you will be making a valuable contribution to our knowledge and readiness for dealing with the threat of bioterrorism, one of today's grim realities.

Thomas W. (Bill) Brooks, Editor

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CFSAN PERSPECTIVE ON FOOD ALLERGENS

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Food allergens continue to be a priority for the Center for Food Safety and Applied Nutrition (CFSAN). Through allergen inspections, outreach to industry and consumers, and enforcement of regulations, CFSAN continues efforts to improve ingredient labeling of food allergens. In fiscal year 2002, the U.S. Food and Drug Administration (FDA) met its goal of 1500 allergen inspections in food processing plants. In addition, validation of food allergen test kits and regulatory issues regarding allergenic food ingredients continues to evolve. This article will address the FDA's recalls of foods due to undeclared allergens, current FDA activities and future challenges.

Food allergies affect an estimated 3.5% to 4% of the population in the United States.[1] A food allergy is an IgE-mediated immunologic reaction to an ingested food and may result in a variety of symptoms involving the skin, gastrointestinal tract, respiratory tract and/or vascular system. Currently there is no cure for food allergy; sensitive individuals must manage their food allergy through avoidance of foods containing the allergen and vigilant reading of food product labels. Any food protein is capable of causing an allergic reaction; however, only eight foods or food groups account for more than 90% of all IgE-mediated food allergies[2]. These eight most common foods are peanuts, soybeans, milk, egg, fish, crustacean shellfish, wheat, and tree nuts (e.g., hazelnuts, almonds, walnuts, pecans, pine nuts). Low amounts of the proteins in these foods may elicit an allergic response and reactions may vary from mild to life-threatening, depending on a person's particular sensitivity[3]. The FDA is actively involved in efforts focused on defining and preventing illnesses and deaths from food allergy.

Recalls of Foods with Undeclared Allergens

FDA, state agencies, industry, and consumers all play a part in discovering food products containing undeclared allergens. Whether through FDA or state inspections, quality checks by firms, or consumer complaints and adverse events, recalls continue to occur. Between 1999 and 2002, recall actions of foods containing undeclared allergens rose by 70% (68 recall actions in 1999 to 116 recall actions in 2002). Many reasons for this marked increase are possible, such as more awareness about allergens in the public and industry, increased number of inspections by state agencies and FDA, development of ELISA tests for allergens, or a true increase in the number of food products with undeclared allergens. FDA does not have the authority to order food recalls; food product recalls are generally done voluntarily by firms with FDA's help to develop a recall strategy

and monitor and assist in the recall effort. Firms should notify FDA when a recall is started and have product recall plans in place, including follow-up checks to ensure a successful recall.

In 2002, 30% of allergen-related recall actions were for products containing undeclared egg and 22% for undeclared milk/dairy (Figure 1). Only 9% of the recall actions were due to undeclared peanuts in products; this is a decrease from 24% of recall actions due to undeclared peanuts in 1999. However, recall actions due to undeclared tree nuts increased from 10% in 1999 to 19% in 2002. When looking at food categories associated with recall actions, candy and chocolate products accounted for the greatest percentage of recalls in 1999 (37%) and then decreased through 2002 to account for less than 10% of the recall actions (Figure 2). Bakery products accounted for a high percentage of recall actions from 1999 and 2002 with a particularly high percentage in 2001 (55% of recall actions, not shown in figure). Snack foods and ready-to-eat sandwiches showed little change in percentage of recall actions between 1999 and 2002.

It is the responsibility of the firm to notify FDA when recalls are started so that the allergen health risk can be evaluated, classified, and posted on the FDA website. Recalls are classified on a case-by-case basis so, as information and science becomes available, classification according to health risk can be up to date. A class I recall is one in which there is a reasonable probability of a serious health consequence or death, whereas a class II recall is one in which the probability of a serious health consequence is remote. In addition, a recall can be classified as class III if the product is not likely to cause an adverse health consequence. In fiscal year 1999, 54% of allergen-related recalls were classified as class I (Figure 3). In comparison, 85% of allergen-related recalls were classified as class I in fiscal year 2002.

Three principal factors may contribute to the presence of undeclared allergens in recalled products. One of these factors is a food product label with incorrect lists of ingredients. This occurred in 60% of the recall actions in 1999 and 66% of recall actions in 2002[4]. Examples of incorrect ingredient statements include not declaring sub-ingredients of an ingredient, inadvertently leaving ingredients off the ingredient statement, and incorrectly translating ingredient statements into English on foreign food products. A second factor is firm or supplier errors (18% of recall actions in 1999 and 20% in 2002). Firm employees may make errors on the processing or packaging lines that lead to the presence of undeclared allergens. Examples include incorrect packaging for a product or using rework that contains allergenic ingredients in the manufacture of non-allergen-containing products. Additionally, suppliers may inadvertently supply an incorrect ingredient or change an ingredient formulation without notifying the manufacturer to update the food label. A third factor may occur when leftover product that contains allergens comes into contact with the next non-allergen product

manufactured on the shared line and from equipment that has not been sufficiently cleaned. This type of cross-contact from equipment during manufacturing accounted for 18% of the recalls in 1999 and 12% in 2002.[4] Methods for reducing the possibility of cross-contact would be to run allergenic products on a separate line or to sequence allergenic products after non-allergen-containing products.

FDA, state agencies, industry, and consumers all play a part in discovering food products containing undeclared allergens (Figure 4). In 1999, consumers identified 50% of all products recalled as containing undeclared allergens. While some consumers discover the allergen before consuming the product (possibly by direct observation of the allergen in the product), other consumers suspect the presence of an undeclared allergen after consuming the product and having an allergic reaction. In 1999, 34 allergic reactions were reported in association with the recalled products. Twenty-four consumers reported "mild allergic reactions" while 10 consumers reported more detailed reactions including itchy eyes, lips, or throat, hives, swollen eyes, swollen lips, and difficulty breathing. Through firm inspections in 1999, FDA and state health agencies discovered 31% and 10% of the recalled products, respectively, and industry discovered 6%. Since 1999, FDA has continued its outreach efforts to both industry and consumers in order to educate them about allergens and inadvertent cross-contact of other non-allergenic products with allergens. In 2002, industry increased its detection of undeclared allergens in products before these products reached the marketplace (from 6% to 25% in 2002). In contrast, discovery of undeclared allergens by consumers decreased by 46% from 1999 to 2002. During this period, FDA continued to recall products for undeclared allergens through inspections at the same level, while state health agencies saw a 41% increase.

FDA Activities

Since 2000, the FDA's CFSAN has made several accomplishments with regard to food allergy. CFSAN has made it a top priority to continue outreach activities to increase food allergy awareness among industry and consumers. Outreach efforts have provided opportunities for FDA to communicate information on policies, labeling, and current activities and gather information and concerns from industry and consumers. CFSAN is also addressing the need for better reporting of adverse events associated with food allergy and reviewing test kits that detect the presence of allergenic proteins. In addition, training was given to all FDA inspectors in the U.S. in order for FDA to ask appropriately focused questions to firms producing foods with allergenic ingredients. This training allowed FDA to ask allergen questions in an informed manner during inspections in over 1500 firms in 2002. Investigators inspected firms that produce products containing allergenic ingredients such as chocolate and candy products, processed/shelled nuts, bakery products, ice cream, and salad dressing. The inspection strategy

focused on firm practices for allergens. The information collected during the inspections is currently being evaluated.

For fiscal year 2004, allergens remain on CFSAN's A-list of program priorities. This list lays out the Center's work plan for 2004; the goal is to complete 90% of the A-list items. With regard to food allergens, the items include continuing consumer and industry outreach, completing an Association of Official Analytical Chemist (AOAC) inter-laboratory study for immunochemical peanut protein test kits following the AOAC harmonized validation protocol, issuing draft guidance to the field on the use of test kits to detect the presence of peanut protein, and publishing a proposed rule to require the declaration of carmine/cochineal extract on the ingredient statements of food, drug, and cosmetic products containing it.

Current and Future Challenges

Exposure to small amounts of allergenic protein can elicit an allergic response in individuals with IgE-mediated food allergies. A threshold dose is the lowest amount of the offending food that elicits an allergic response[3]. While several clinical studies have shown that threshold doses of common allergenic foods are possible, determination of threshold doses for allergens remains a challenge. These challenges include the lack of standardized clinical challenge protocols, difficulty in obtaining an appropriate sample of food-allergic individuals, and lack of standardized challenge materials (e.g., ground peanut vs. peanut flour).

Another challenge for a manufacturer is the voluntary placement of advisory statements ("may contain" labeling) on food packaging labels. While the advisory statements are intended to notify consumers of possible allergenic ingredients, it is unclear if the allergen is or is not present in the product. There is a wide variety of advisory statements being used by manufacturers (e.g., "may contain milk," "manufactured in a plant that also manufactures peanuts," "may contain traces of other nuts"). FDA is gathering data on the extent of use and reasons for use of advisory statements. The agency advises that use of advisory statements should not be used in lieu of good manufacturing practices.

Consumer food allergic reactions will continue to be an FDA concern in the years to come. The authors expect that there will be increased research centered on threshold levels for the eight major food allergens. Establishment of levels below which food allergic reactions would be greatly reduced will be the subject of future agency risk assessments. In addition, better restaurant disclosure of food allergens used in served meals will be included in future debates. Both a new food allergen labeling improvement rule for the food label and possibly a good manufacturing practices rule describing allergen control procedures to be used in food plants are possible future regulations. There will also be a need to measure

the effectiveness of these regulations and agency thought will move toward establishing performance measures for new food allergen programs. Finally, ELISA test kit evaluations and detection for peanut protein has been completed and this work will expand to other allergenic proteins derived from eggs, milk, and some of the tree nuts. Legislative food allergy action also is expected in some form and the different necessities Congress may require for food allergens remain unknown.

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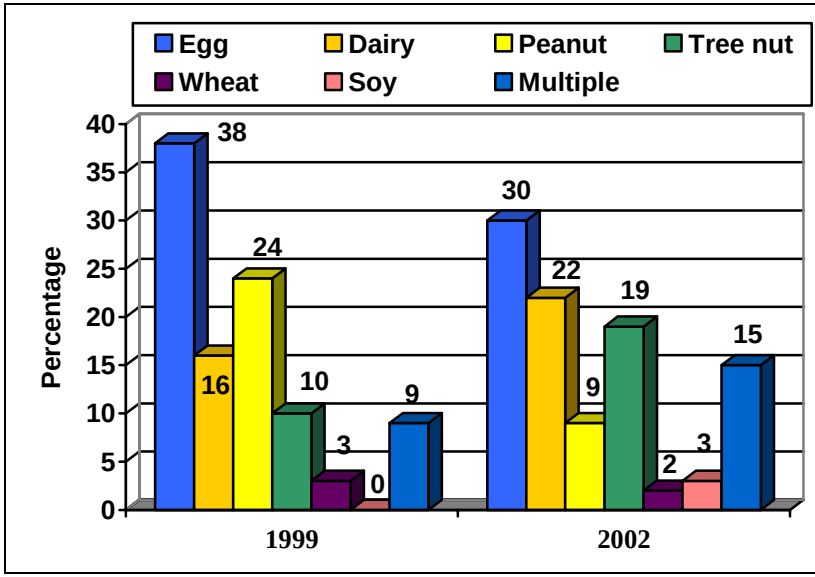

Figure1: Recalls of products due to undeclared allergens, by allergen, 1999- 2002

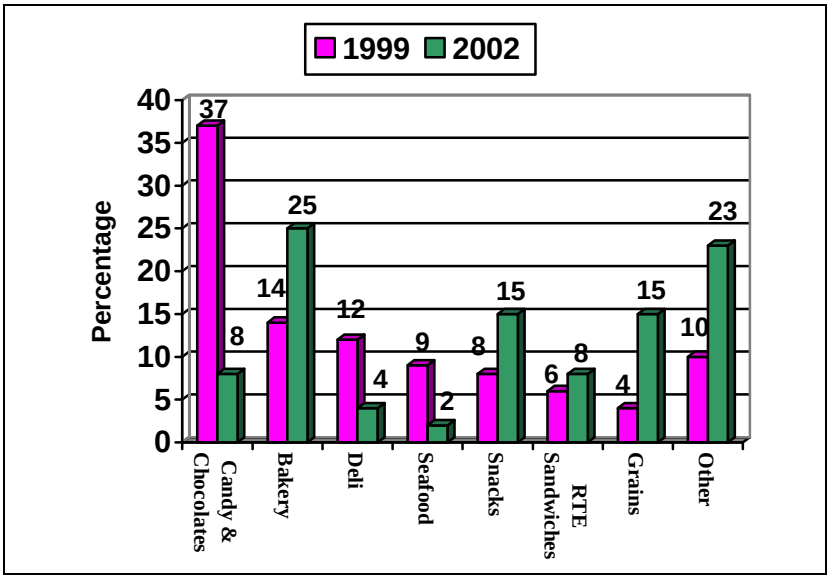

Figure2: Recalls of products due to undeclared allergens, by food category, 1999- 2002

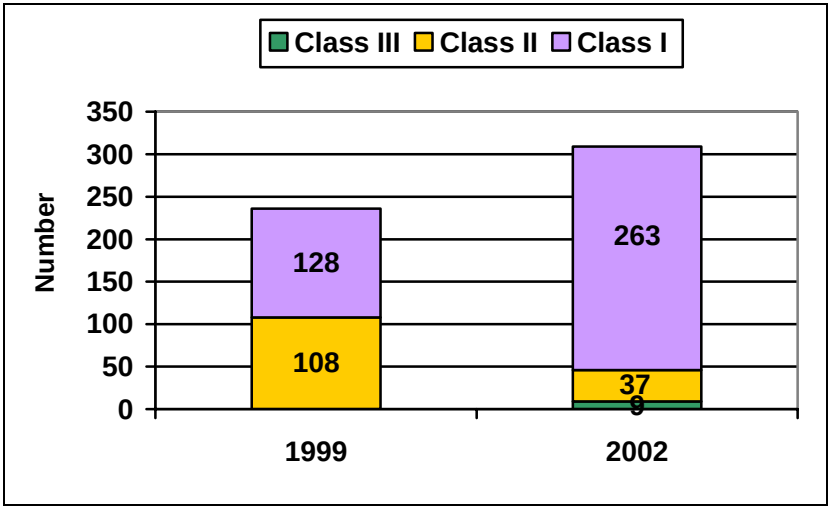

Figure3: Recalls of products due to undeclared allergens, by class, 1999- 2002

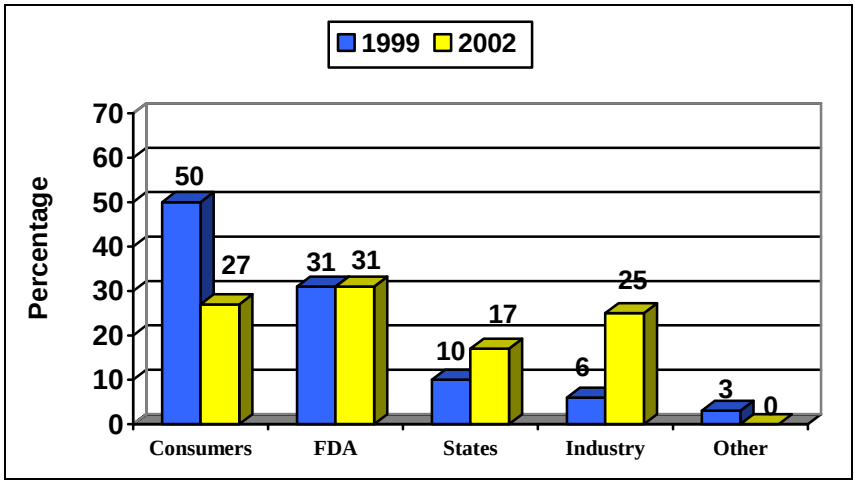

Figure 4: Parties responsible for first identifying undeclared allergens, 1999 and 2002 recall actions

AN INTRODUCTION TO FOODNET

What is FoodNet?

CDC's Emerging Infections Program
Foodborne Diseases Active Surveillance Network (FoodNet)

FoodNet is the principal foodborne disease component of CDC's Emerging Infections Program (EIP). FoodNet is a collaborative project of the CDC, ten EIP sites (California, Colorado, Connecticut, Georgia, New York, Maryland, Minnesota, Oregon, Tennessee and New Mexico), the U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA). The project consists of active surveillance for foodborne diseases and related epidemiologic studies designed to help public health officials better understand the epidemiology of foodborne diseases in the United States.

Foodborne diseases include infections caused by bacteria such as *Salmonella*, *Shigella*, *Campylobacter*, *Escherichia coli O157*, *Listeria monocytogenes*, *Yersinia enterocolitica*, and *Vibrio* and parasites such as *Cryptosporidium* and *Cyclospora*. In 1995, FoodNet surveillance began in five locations: California, Connecticut, Georgia, Minnesota and Oregon. Each year the surveillance area, or catchment, has expanded, with the inclusion of additional counties or additional sites (New York and Maryland in 1998, Tennessee in 2000, Colorado in 2001 and New Mexico in 2004). The total population of the 2003 bacterial catchment is 37.6 million persons, or 13.8% of the United States population.

FoodNet provides a network for responding to new and emerging foodborne diseases of national importance, monitoring the burden of foodborne diseases, and identifying the sources of specific foodborne diseases.

FoodNet goals

- Determine more precisely the burden of foodborne diseases in the United States
- Monitor foodborne disease trends in the United States
- Determine the proportion of foodborne diseases attributable to specific foods and settings in the Unites States

Why is FoodNet important to public health?

Foodborne diseases are common; an estimated 76 million cases occur each year in the United States. Although most of these infections cause mild illness, severe infections and serious complications do occur. The public health challenges of foodborne diseases are changing rapidly; in recent years, new and emerging foodborne pathogens have been described and changes in food production have led to new food safety concerns. Foodborne diseases have been associated with many different foods, including some previously thought to be safe, such as eggs and fruit juice, both of which have transmitted *Salmonella* during recent outbreaks. Public health officials in the nine EIP sites are monitoring foodborne diseases, conducting epidemiologic and laboratory studies of these diseases, and responding to new challenges from these diseases. Information gained through this network will lead to new interventions and prevention strategies for addressing the public health problem of foodborne diseases.

How is FoodNet different from other foodborne disease surveillance systems?

Current "passive" surveillance systems rely upon reporting of foodborne diseases by clinical laboratories to state health departments, which in turn report to CDC. Although foodborne diseases are extremely common, only a fraction of these illnesses are routinely reported to CDC via these surveillance systems. This is because a complex chain of events must occur before such a case is reported, and a break at any link along the chain will result in a case not being reported. FoodNet is an "active" surveillance system, meaning public health officials frequently contact laboratory directors to find new cases of foodborne diseases and report these cases electronically to CDC. In addition, FoodNet is designed to monitor each of the events that occurs along the foodborne diseases pyramid and thereby allow more accurate and precise estimates and interpretation of the burden of foodborne diseases over time. Because most foodborne infections cause diarrheal illness, FoodNet focuses these efforts on persons who have a diarrheal illness.

FoodNet has 5 components:

1. **Active, laboratory based surveillance**
2. **Survey of clinical laboratories**
3. **Survey of physicians**
4. **Survey of the population**
5. **Epidemiologic studies**

Component 1. Active laboratory based surveillance

The core of FoodNet is laboratory based active surveillance at over 450 clinical laboratories that test stool samples in the ten FoodNet sites. In active surveillance, the laboratories in the catchment areas are contacted regularly by collaborating FoodNet investigators to collect information on all of the laboratory confirmed cases of diarrheal illness. Information is being collected on every laboratory diagnosed case of bacterial pathogens including *Salmonella*, *Shigella*, *Campylobacter*, *Escherichia coli* O157, *Listeria monocytogenes*, *Yersinia enterocolitica*, and *Vibrio* and parasitic organisms including *Cryptosporidium* and *Cyclo-spora* infection among residents of the catchment areas of the FoodNet sites; this information is transmitted electronically to CDC. In addition to collecting laboratory diagnosed cases of foodborne pathogens, investigators at FoodNet sites began active surveillance for hemolytic uremic syndrome (HUS) (a serious complication of *E. coli* O157 infection), Guillain-Barré syndrome (a serious com-plication of *Campylobacter* infection) and toxoplasmosis. The result is a comprehensive and timely database of foodborne illness in a well-defined population.

Component 2. Survey of clinical laboratories

In October 1995, collaborating FoodNet investigators conducted a baseline survey of all clinical laboratories in the five original catchment areas to determine which pathogens are included in routine bacterial stool cultures, which tests must be specifically requested by the physician, and what specific techniques are used to isolate the pathogens. In 1997, a baseline survey was conducted in the two new sites, and a follow-up survey was done in the five original sites to assess any recent changes in laboratory practices. Practices in clinical laboratories have been found to vary; some laboratories look for a wider variety of bacteria than others. The methods used to collect and examine specimens are being investigated because these can influence whether the laboratory finds disease-causing bacteria.

Component 3. Survey of physicians

To obtain information on physician stool culturing practices, collaborating FoodNet investigators mailed a survey questionnaire to 5,000 physicians during 1996 in five sites and 750 physicians in 1997 in the two new sites. Because laboratories test stool specimens from a patient only upon the request of a physician or other health care provider, it is important to measure how often and under what circumstances physicians order these tests. As changes occur in the way health care is provided in the United States, stool culturing practices may also change over time. The practices of physicians who send stool samples to laboratories within the catchment areas have been monitored by three laboratory surveys.

Component 4. Survey of the population

Collaborating FoodNet investigators contact randomly selected residents of a catchment area and ask if the person has had a recent diarrheal illness, whether he or she sought treatment for the illness, and whether he or she had consumed certain foods known to have caused outbreaks of foodborne illness. During 1996, 750 residents of the catchment areas were interviewed by telephone each month (9,000/year). Because many people who become ill with diarrhea do not see a physician, little is known about the number of cases of diarrhea in the general population and how often persons with diarrhea seek medical care. The population survey is an essential part of active surveillance for foodborne illness because it allows for an estimate of the population who seek medical care when affected by diarrheal illness.

Component 5. Epidemiologic studies

In 1996, FoodNet began epidemiologic studies of *E. coli* O157 and *Salmonella* serogroups B and D infections. More than 60% of *Salmonella* infections in the United States are caused by serogroups B and D *Salmonella*. In 1998, FoodNet began a case-control study of *Campylobacter*. *Campylobacter* is consistently the most frequently isolated pathogen in FoodNet sites. These large epidemiologic studies will provide more precise information about which food items or other exposures might be risk factors for infections with these organisms. To allow the most precise classification of the isolates from the patients in these studies, *Salmonella*, *E. coli* O157, and *Campylobacter* isolates from these patients are sent from FoodNet sites to CDC for further study, including antibiotic resistance testing, phage typing, and molecular subtyping.

2003 FoodNet priorities

Following are the top 5 priorities established at the 2003 FoodNet vision meeting:

1. Outbreaks
2. Interventions
3. Attribution
4. *E. coli*/HUS/STEC surveillance
5. Norovirus

What is CDC's Emerging Infections Program?

In the early 1990s, the National Academy of Science's Institute of Medicine published a report that emphasized the ongoing threat of emerging infectious diseases, and the Centers for Disease Control and Prevention (CDC) developed a strategy to respond to this threat. A central feature of this strategy was the establishment of the Emerging Infections Program (EIP) in ten sites across the United States. The goals of the EIP network are to improve national surveillance for new and emerging infectious diseases, conduct applied epidemiologic and laboratory research, develop prevention and control measures, and strengthen the national public health infrastructure.

Copied from the Centers for Disease Control website with permission: www.cdc.gov.

INFANT FORMULA (IF) AND NUTRIENT REQUIREMENTS

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Infant formulas are liquids or reconstituted powders fed to infants and young children. They serve as substitutes for human milk. Infant formulas have a special role to play in the diets of infants because for infants they are often the only source of nutrients. For this reason, the composition of commercial formulas is carefully controlled and FDA requires that these products meet very strict standards.

Infant formulas are fed during a sensitive period of development and may therefore have short- and long-term consequences for infant health. The issue of the context or matrix in which nutrients are provided in milk remains a challenge to IF manufacturers as they try to match human-milk composition and breast-feeding performance. Human milk is very complex, and scientists are still trying to unravel and understand what makes it such a good source of nutrition for rapidly growing and developing infants.

In 1971, FDA published regulations relating to the manufacturing and marketing of infant formula. The minimum concentrations of vitamins and minerals stipulated by the FDA were largely those recommended by the Committee on Nutrition. The Committee on Nutrition revised and extended its recommendations in 1976. An amendment to the Food, Drug and Cosmetic Act, referred to as the Infant Formula Act of 1980, gave FDA authority to establish quality-control procedures for infant formula manufacturing, to establish recall procedures, to establish and subsequently revise, if necessary, nutrient levels, and to regulate labeling. A task force of the American Academy of Pediatrics submitted revised recommendations on nutrient content of infant formulas to the FDA in 1983.

The final rule, published by the FDA in 1985, specifies minimum concentration of 29 nutrients (units per 100 kcal) and maximum concentrations of 9 of these nutrients (Table 1). As more information becomes available about infants' nutrient needs, FDA's nutrient specifications for infant formulas may be modified to incorporate that information. In addition, quality-control procedures require manufacturers to analyze each batch of formula before marketing to assure that nutrient concentrations meet specifications, to test representative samples for stability over the period of shelf-life of the product, to code containers to identify the batch, and to make all associated records available to FDA investigators. In January 1986 labeling rules for infant formulas became effective. These required that nutrient information be displayed in a standard tabular format and that

directions for preparation and use be included. In 1987, the FDA published rules concerning recall of batches of infant formulas found to be in violation of the stipulations of the Infant Formula Act. These rules require the manufacturer to act immediately to recall any violative infant formula, extending to and including the retail level.

Before the 1971 publication of the FDA rule that specified minimum vitamin and mineral concentrations for infant formulas, a number of cases of nutritional deficiency disorders involving vitamin A, vitamin K, thiamin, folic acid/vitamin C, pyridoxine, and iodine were reported. Each nutrient is important to the development, growth and health of the infant. Table 2 describes function, deficiency and toxicity of these nutrients.

FDA also has a surveillance program where inspections are conducted every year at establishments manufacturing infant formulas to ascertain the firm's compliance with all the requirements of Section 412 of the Act. During these inspections samples are collected and sent to the Southeast Regional Laboratory for nutrient and microbiological analyses.

Table 1. Infant Formula Nutrients Requirements

INFANT FORMULA NUTRIENTS REQUIREMENTS		
Nutrient	Minimum level [a]	Maximum level [a]
Protein (gm)	1.8	4.5
Fat: gm percent cal	 3.3 30	 6.0 54
Linoleic acid: percent cal mg	 2.7 300	
Vitamins: A (IU) D (IU) E (IU) K (µg) B1 (thiamine) (µg) B2 (riboflavin)(µg) B6 (pyridoxine) B12 (µg) Niacin (µg)[b] Folic acid (µg) Pantothenic acid (µg) Biotin (µg)[c]	 250 40 0.7 4 40 60 35 0.15 250 4. 300 1.5	750 100

C (ascorbic acid) (mg)	8	
Choline (mg)[c]	7	
Inositol (mg)[c]	4	
Minerals:		
Calcium (mg)	60	
Phosphorus (mg)	30	
Magnesium (mg)	6	
Iron (mg)	0.15	3.0
Zinc (mg)	0.5	
Manganese (µg)	5	
Copper (µg)	60.0	
Iodine (µg)	5	75
Sodium (mg)	20	60
Potassium (mg)	80	200
Chloride (mg)	55	150

[a] Nutrient specifications as per 21CFR107.100; minimum and maximum levels specified for each 100 kilocalories of the infant formula in the form prepared for consumption as directed in the container.

[b] The generic term “niacin” includes niacin (nicotinic acid) and niacinamide (nicotinamide).

[c] Required only for non-milk-based infant formulas.

Table 2. Nutrients: Function, Deficiency & Toxicity

Nutrient	Function	Effects of Deficiency	Effects of Excessive Consumption/ Toxicity
Protein	Serves as the major structural component of all cells in the body, and functions as enzymes, in membranes, as transport carriers, and as some hormones. During digestion and absorption dietary proteins are broken down to amino acids, which become the building blocks of these structural and functional compounds	Growth, immune response, repair, and production of enzymes and hormones are all impaired in severe protein deficiency.	
Fat	Energy source, when found in foods, is a source of *n*-6 and *n*-3 polyunsaturated fatty acids. Its presence in the diet increases absorption of fat soluble vitamins and precursors such as vitamin A and pro-vitamin A carotenoids; important for brain and central nervous system development.	Growth impairment.	
Linoleic acid	Essential component of structural membrane lipids, involved with cell signaling, and precursor of eicosanoids; required for growth and normal skin function.	Growth cessation, dermatosis, significant changes in metabolism, affecting the lipid (fat) content of blood, platelet function, inflammatory responses, and certain immune responses.	
Vitamin A	Required for normal vision, gene expression, reproduction, embryonic development and immune function.	Changes in the tissue of the eye that ultimately result in irreversible blindness. Skin lesions, appetite loss, lack of growth, increased susceptibility to infections.	Headaches, peeling of skin, vomiting, liver damage, brain swelling, and bone abnormalities.
Vitamin D	Maintain serum calcium and phosphorus concentrations; resorption, mineralization, and collagen maturation of bone.	Skeletal diseases: - Rickets (impaired mineralization of the growing bones, bone pain, muscular tenderness, hypocalcemic tetany) in infants and children. - Osteomalacia (muscular weakness, bone tenderness) in adults.	High levels of calcium in blood and kidney, heart damage, anorexia.

Nutrient	Function	Effects of Deficiency	Effects of Excessive Consumption/ Toxicity
Vitamin E	Intracellular antioxidant, scavenger of free radicals in biologic membranes.	Haemolytic anemia, neurologic damage, creatinuria, ceroid deposition in muscle.	Interferes with enzymes, increased infection.
Vitamin K	Coenzyme during the synthesis of many proteins involved in blood clotting and bone metabolism	Impaired blood coagulation, hemorrhage.	Kernicterus - disorder due to jaundice in a newborn baby.
Thiamine (B_1)	Coenzyme in the metabolism of carbohydrates and branched-chain amino acids. Central and peripheral nerve cell function, myocardial function.	Beriberi, infantile and adult. Infantile beriberi which can be quickly fatal is characterized by vomiting, convulsions, abdominal distention, and anorexia.	
Riboflavin (B_2)	Coenzyme in numerous redox reactions. Many aspects of energy and protein metabolism, integrity of mucous membranes.	Dermatitis, nervous disorders, angular stomatitis, corneal vascularization, impairment of vision.	
Vitamin B6	Coenzyme in the metabolism of amino acids, glycogen and sphingoid bases. Necessary part of hemoglobin synthesis.	Retarded growth, convulsions in infancy, anemia, neuropathy, skin lesions.	Peripheral neuropathy.
Vitamin B12	Coenzyme in nucleic acid metabolism; prevents megaloblastic anemia, related to folate coenzymes; methionine and acetate synthesis.	Pernicious anemia, megaloblastic anemia.	
Niacin	Coenzyme or co-substrate in many biological reduction and oxidation reactions, thus required for energy metabolism.	Pellagra, disease characterized by skin lesions, gastrointestinal disturbances and nervousness.	
Folic acid	Coenzyme in the metabolism of nucleic and amino acids; prevents megaloblastic anemia. Syntheses of purines and pyridines.	Anemia, megaloblastic anemia.	
Pantothenic acid	Coenzyme in fatty acid metabolism. Performs an important role in the oxidation of fats and carbohydrates and certain amino acids.	Inducement of the deficiency in humans produced many symptoms including headache, fatigue, insomnia, intestinal disturbances and paresthesia.	

Nutrient	Function	Effects of Deficiency	Effects of Excessive Consumption/ Toxicity
Biotin	Coenzyme in synthesis of fat, glycogen, and amino acids.	Characterized by anorexia, nausea, vomiting, inflammation of the tongue, mental depression, hair loss, dermatitis.	
Vitamin C	Cofactor for reactions requiring reduced copper or iron metalloenzyme and as a protective antioxidant. Essential to osteoid tissue, collagen formation, vascular function, and wound healing.	Scurvy – disease characterized by spongy gums, loosening of the teeth, and bleeding into the skin and mucous membranes. Slow healing of wounds.	Gastrointestinal disturbances, kidney stones, excess iron absorption.
Choline	Essential to liver function and the metabolism of fat. Precursor for acetylcholine, phospholipids and betaine.	Combined deficiency of choline (included in the b vitamin complex) and all other methyl group donors causes liver cirrhosis.	Fishy body odor, sweating, salivation, hypotension, hepatotoxicity.
Inositol	Required for proper formation of cell membranes. Affects nerve transmission and helps in transporting fats within the body.	May result in high blood cholesterol, constipation, eczema, hair loss.	
Calcium	Essential for a variety of bodily functions, such as, blood clotting, muscle contraction, nerve transmission, proper heart function and bone and tooth formation.	Hypocalcemia - muscle cramps, abdominal cramps, spasms, and hyperactive deep tendon reflexes. Rickets - usually children Osteomalacia - usually adult	Kidney stones, hypercalcemia, milk alkali syndrome, and renal failure.
Phosphorus	Maintenance of pH, storage and transfer of energy and nucleotide synthesis. Bone and tooth formation.	Irritability, weakness, blood cell disorders, GI tract and renal dysfunction.	Metastatic calcification, skeletal porosity, interference with calcium absorption.

Nutrient	Function	Effects of Deficiency	Effects of Excessive Consumption/ Toxicity
Magnesium	Cofactor for enzyme systems. Bone and tooth formation, nerve conduction, muscle contraction, enzyme activation.	Hypomagnesemia: weakness, muscle cramps, tremor, nystagmus, hypertension, tachycardia, ventricular arrhythmias, confusion, disorientation.	Abnormally low blood pressure, respiratory failure, cardiac disturbances.
Iron	Component of hemoglobin and numerous enzymes; plays a role in the transport of oxygen by the blood, prevents microcytic hypochromic anemia.	Iron deficiency anemia: fatigability, tachycardia, palpitations, smooth tongue, brittle nails, inflammation and cracking of the lips.	Gastrointestinal distress, hemochromatosis, cirrhosis, diabetes mellitus, skin pigmentation.
Zinc	Component of multiple enzymes and proteins; involved in the regulation of gene expression.	Growth retardation, decreased activity of urea-cycle enzymes, inflammation of the prostate.	Reduced copper status.
Manganese	Involved in the formation of bone, as well as in enzymes involved in amino acid, cholesterol, and carbohydrate metabolism.	Skin problems, change in hair color.	Elevated blood concentration and neurotoxicity.
Copper	Component of enzymes in iron metabolism. It is essential in nutrition, being a component of various proteins.	Anemia, bone changes, Menke's kinky hair syndrome.	Gastrointestinal distress, liver damage.
Iodine	Component of the thyroid hormones; prevents goiter and cretinism.	Goiter - enlargement of the thyroid gland. Cretinism - congenital hypothyroidism (deafness, short statue, and/or impaired thinking).	Elevated thyroid stimulating hormone (TSH) concentration.
Sodium	Maintains fluid volume outside of cells and thus normal cell function. Acid-base balance, osmotic pressure, blood pH, muscle contractility, nerve transmission.	Diarrhea, dehydration, vomiting, kidney disease.	Hypertension; increased risk of cardiovascular disease and stroke.
Potassium	Maintains fluid volume inside/outside of cells and thus normal cell function; acts to blunt the rise of blood pressure in response to excess sodium intake, and decrease markers of bone turnover and recurrence of kidney stones.	Muscle fatigue and cramps, constipation, intestinal obstruction. If severe, flaccid paralysis, diminished or weakened reflexes.	Paralysis, cardiac disturbances.

Nutrient	Function	Effects of Deficiency	Effects of Excessive Consumption/ Toxicity
Chloride	With sodium, maintains fluid volume outside of cells and thus normal cell function.	Alkalosis (abnormally high alkalinity of the blood and body fluids), dehydration. Infants – vomiting, diarrhea, renal disease, diuretics.	In concert with sodium, results in hypertension.

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The author thanks Ana Maria Osorio, MD, MPH, FDA Pacific Regional Officer for her input on the elements deficiencies in humans.

CLEAN HANDS WEEK:
A VERY GOOD IDEA ON SEVERAL LEVELS

By Roy E. Costa, R.S., M.S.
Co Chairman-Membership and By Laws Subcommittee

Clean Hands Coalition

When it comes to a simple solution for disease prevention, clean hands wins…well, hands down. With that said, it is still very clear that this message is not reaching the people who need to hear it most. If we are to judge the effectiveness of hand hygiene by the rates of hospital-acquired infection, or by the incidence of foodborne illness, we must conclude that many people are not getting the message and not practicing effective hand hygiene.

The Clean Hands Coalition (CHC) was formed in early 2003 through the efforts of the Centers for Disease Control and Prevention, the USDA, FDA, Cooperative Extension agents, medical professionals, educators, consultants, professional associations, and industry to address the need for a centralized national hand cleanliness campaign. This unified alliance of public and private partners has been developing several initiatives, and is continuing to organize itself around the central theme "Clean Hands Save Lives". To learn more about the philosophy, goals and organization of the CHC please go to www.cleanhandscoalition.org.

Poor hand hygiene continues to cost thousands of lives every year. Hardest hit are the young, the old and special segments of the immune-compromised such as pregnant women and those on a variety of life-supporting medicines. The Clean Hands Coalition will build awareness as to the scope of the problem and light a path to the behavior-changing solutions. The CHC is committed to improving health and saving lives with better hand hygiene.

Its first national initiative is "Clean Hands Week," which will take place September 19 through 26. Do we need another "week," you may ask? If Clean Hands Week were the end of the effort, I would say no. However, because it provides a platform to bring the many hand hygiene education initiatives around the country into focus, "Clean Hands Week" serves a very useful function.

Look at Clean Hands Week as a time to showcase your hand hygiene programs. And look to the CHC as a central point of reference for the media and other interested parties. List your programs, materials such as booklets, handouts, etc., or if you have a hand hygiene–related website, link your website to the CHC website, and then direct media parties or interested persons to visit. Once at the site they can be educated about the CHC and about the many educational programs around the nation. To create your link at the CHC website, please contact info@cleanhandscoalition.org.

To facilitate dialog between Clean Hands Week participants across the nation, the media, and other stakeholders, The Washington State Cooperative Extension, a charter member of the CHC, has developed an informational packet. The packet contains templates for a Clean Hands Week proclamation, a press release, fact sheets and resources.

Please go to www.cleanhandscoalition.org to download the packet. You can reproduce copies and get them out to your colleagues to further spread the news about Clean Hands Week and the goals of the Clean Hands Coalition.

Once you receive a packet we will send you a follow-up questionnaire and ask you to provide us with information, such as:

1. How many copies of the packet did you make?
2. How did you get the funds to make the copies and distribute the packets?
3. Who did you distribute them to?
4. Were the copies you sent out further copied and distributed?
5. Who were the media contacts (newspaper, TV, radio) you sent a media release to?
6. Did you send the Proclamation to a legislator?

To help us at the CHC, if you download a packet, please be prepared to let us know how it was used. Please also be willing to ask the persons you distributed the packets to about how they used them.

Clean Hands Week represents a major opportunity on several levels. It's an initiative to bring together hand hygiene programs across the nation and to introduce the Clean Hands Coalition, it provides a means for the CHC and other groups to disseminate information at a particular point in time, and it also provides a means for understanding the best methods for distribution and further dissemination of hand hygiene information. But most important, the purpose of Clean Hands Week is to educate one and all that "Clean Hands Save Lives".

To support Clean Hands Week, do the following:

1. Contact the Clean Hands Coalition.
2. Link your hand hygiene info. to the CHC website.
3. Provide your link to CHC for us to link back to you.
4. Promote the CHC website as a central repository of hand hygiene education programs.
5. Download a Clean Hands Week Information Packet.

6. Make copies of the Press Release, putting your organization in the blank space, and send it to your media contacts. Ask your media contact to, in some way, promote Clean Hands Week to their market.
7. Send the proclamation to your legislators.
8. Be prepared to let us know how the materials you downloaded were used and the results.

Roy Costa can be reached at Environ Health Associates at 1.866.734.5187 or rcosta1@cfl.rr.com.

AFDO MISSION STATEMENT

The Association of Food and Drug Officials (AFDO), established in 1896, successfully fosters uniformity in the adoption and enforcement of science-based food, drug, medical devices, cosmetics and product safety laws, rules, and regulations.

AFDO and its six regional affiliates provide the mechanism and the forum where regional, national and international issues are deliberated and resolved to uniformly provide the best public health and consumer protection in the most expeditious and cost-effective manner.

AFDO Accomplishes Its Mission by:

- Promoting education, communication and cooperation among government, industry and consumers.
- Fostering understanding and cooperation between industry, regulators and consumers.
- Promoting the adoption and uniform enforcement of laws and regulations at all levels of government.
- Providing guidance and training programs for regulatory officials and the regulated industry, to promote nationally and internationally uniform inspections, analyses, interpretations and investigations.
- Identifying and resolving inconsistencies in consumer and public health protection laws, regulations, standards and policies.
- Providing a permanent working committee structure to research current issues, obtain input from interested parties and produce recommendations for action.
- Developing model laws, regulations and guidance documents and seeking their adoption throughout the United States.

Conducting an Annual Educational Conference, where for over a century, AFDO has provided the opportunity for individuals from government, industry, and the public to participate in, listen to, and learn valuable information and develop initiatives concerning food, drug, medical device, cosmetic and product safety issues.

AFDO Regional Affiliate Associations

AFDOSS — Association of Food and Drug Officials of the Southern States

ANNUAL: September 12-15, 2004, Gatlinburg, TN

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CASA — Central Atlantic States Association

ANNUAL: May 17-20, 2005, Hamburg, NY

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MCA — Mid-Continental Association of Food and Drug Officials

ANNUAL: June 4-8, 2005, Kansas City, MO

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NCAFDO — North Central Association of Food and Drug Officials

ANNUAL: October 18-20, 2004, Minneapolis, MN

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NEFDOA — Northeast Food and Drug Officials Association

ANNUAL: May 10-13, 2005, Hampton Beach, NH

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NEFDOA Secretary Gene Blake	City of Concord Health Svcs. 37 Green St. Concord, NH 03301 E-Mail: eblake@ci.concord.nh.us	Phone:(603) 230-3639 Fax:(603) 225-8586

WAFDO — Western Association of Food and Drug Officials

ANNUAL: September 12-15, 2004, San Diego, CA

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CATEGORIES OF MEMBERSHIP
The Association of Food and Drug Officials

New Membership Dues Structure:

- **Individual membership** is designed for singular memberships. All individual members may choose to receive the quarterly journal on-line or by mail.
- **Group memberships** are designed for those agencies/organizations that would like reduced rates to enroll several members. One quarterly journal is provided for each group by mail; other group members may access the journal on-line.*
- **Contributing memberships** are designed for those agencies/organizations that would like to support the ongoing activities of the Association of Food and Drug Officials through an "increased" level of contribution. Contributing members receive the quarterly newsletter and may choose to receive the quarterly journal via mail or on-line.*

Organization, group and contributing memberships must be received together and processed as a group.

JOURNAL OF THE ASSOCIATION OF FOOD AND DRUG OFFICIALS

Inquiries: For editorial matters, contact the Editor: Thomas (Bill) Brooks, PO Box 11280 Columbia, SC 29211-1280; Phone (803) 737-9700; Fax (803) 737-9703. For all other matters contact AFDO's office: 2550 Kingston Road, Suite 311, York, PA 17402; Phone (717) 757-2888; Fax (717) 755-8089; email afdo@afdo.org.

Subscription Rates For Non-Members: United States and Canada: $80; other countries: $90 (includes airmail); single issues: $20.

Responsibility: The opinions and statements presented in the contents of this Journal are those of the contributors, and the Association assumes no responsibility.

Manuscripts: The Journal solicits papers related to its objectives and reserves the right to determine if a submitted work is publishable. Letters, viewpoints, formal papers and other notes of interest will be considered for publication.

Reprints and References: Reprints of articles may be obtained at standard rates. Most materials published in the Journal do not have references.

ASSOCIATION OF FOOD AND DRUG OFFICIALS MEMBERSHIP APPLICATION

MEMBERSHIP INFORMATION:

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Title_____

Organization_____

Address_____

City _____ State_____ Zip_____

Telephone_____ Fax_____

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1. Individual Membership:

Individual Members	On-line Journal	Journal
Alumni/Students	☐ $50	☐ $65
Regulatory	☐ $50	☐ $85
Consumers/Educational	☐ $50	☐ $85
Small Business/Consultants	☐ $225	☐ $275
Associate Industry	☐ $325	☐ $375

2. Group Membership: ***Group membership applications must be submitted together.***

# of Group Members	Government	Non-Government
5-10	☐ $46 each	☐ $300 each ☐
11-20	☐ $44 each	☐ $285 each ☐
21-50	☐ $42 each	☐ $270 each ☐
Greater than 50	☐ $40 each	☐ $255 each ☐

3. Contributing Membership: ***Contributing membership applications must be submitted together.***

Contributing Member Classifications	Government # of Memberships	Non-Government # of Memberships
Platinum	5 for $750 ($150 ea.)	5 for $2,500 ($500 ea.)
Gold	3 for $500 ($166 ea.)	3 for $1,750 ($583 ea.)
Silver	2 for $350 ($175 ea.)	2 for $1,250 ($625 ea.)

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