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Report to Congressional Requesters

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FOOD SAFETY

FDA's Use of Faster Tests to Assess the Safety of Imported Foods

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Resources, Community, and
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The Honorable Tom Bliley
Chairman, Committee on Commerce
House of Representatives

The Honorable Fred Upton
Chairman, Subcommittee on Oversight
and Investigations
Committee on Commerce
House of Representatives

According to federal officials, the U.S. food supply is among the safest in the world. Nevertheless, the Centers for Disease Control and Prevention reports that up to 76 million cases of foodborne illness and as many as 5,000 deaths from these illnesses occur each year. Ensuring the safety of domestically produced foods is a daunting task. But the challenge of ensuring the safety of the entire food supply is becoming even more difficult as Americans consume more foods imported from other countries—these imports have more than doubled in the last 7 years. The Department of Health and Human Services' Food and Drug Administration (FDA) has primary responsibility for ensuring the safety of most imported foods.[1] However, this agency currently inspects and tests less than 2 percent of the nearly 3 million shipments of imported foods each year. Moreover, before the agency can complete these tests, this food has sometimes been released into domestic commerce.

Concerned about the safety of imported foods, you asked us to examine FDA's use of faster technologies—known as rapid tests—to screen and identify potentially unsafe imported foods, particularly at ports of entry, before they enter the domestic food supply. In general, rapid tests can be completed in a day or two, thereby offering a faster, cheaper, and more convenient alternative—without sacrificing reliability—to conventional laboratory tests that may take several days or even longer to identify disease-causing pathogens in food. Specifically, you asked us to describe

[1] The U.S. Department of Agriculture's Food Safety and Inspection Service is responsible for ensuring the safety of imported meat, poultry, and processed egg products. FDA is responsible for all other foods, including seafood.

(1) rapid tests used to screen foods for pathogens such as bacteria, parasites, and viruses; (2) FDA's use of these tests, particularly at ports of entry; and (3) factors that may limit FDA's expanded use of rapid tests for foodborne pathogens.

Results in Brief

More than 150 rapid tests may be used to screen foods for bacterial pathogens such as *Salmonella,* according to FDA and scientific literature. Many of these tests have been borrowed from clinical settings, although their use with food requires a preparation step of 24 hours or more to cause a bacterial pathogen to reproduce to detectable levels. Rapid tests employ a wide variety of technologies. For example, some measure chemical substances unique to a bacterium, while others identify a specific genetic sequence associated with a bacterium or a toxin it produces. In general, rapid tests to identify parasites and viruses in foods do not exist because of technological limitations.

FDA uses dozens of rapid tests to screen food samples for bacterial pathogens. FDA's decision to use a rapid test is based on such factors as the agency's testing priorities and needs and the cost and reliability of available tests. Currently, FDA uses rapid tests in its laboratories but not at food inspection sites such as ports of entry. Testing occurs in laboratories primarily because of the need to enrich bacterial pathogens in foods, a process that should be done under the controlled conditions laboratories provide. In addition, although some rapid tests come in self-contained kits, others require specialized equipment and materials found only in laboratories. Furthermore, a laboratory technician, such as a microbiologist, may be needed to administer and/or interpret the results of some rapid tests. An FDA research plan for fiscal years 1999 through 2001 includes provisions for developing a number of additional rapid tests.

Several factors can limit FDA's expanded use of rapid tests for foodborne pathogens. For example, various ingredients and/or additives in certain foods may interfere with a test's reliability. In addition, with regard to fresh foods such as fruits and vegetables, harmless bacteria in the food may mask the presence of pathogenic bacteria. Furthermore, rapid tests, like conventional laboratory tests, are subject to sampling limitations. Specifically, the food samples tested may not be representative of the health risks of an entire food shipment or of all shipments from a particular exporter.

Background

More than 200 known illnesses associated with bacteria, parasites, or viruses are transmitted through food,[2] ranging from temporary maladies such as diarrhea or vomiting; to acute and chronic illnesses, such as kidney failure, gastroenteritis, meningitis, and paralysis; to death.[3] According to the U.S. Department of Agriculture's Economic Research Service, the costs for medical treatment and productivity losses associated with these illnesses and deaths range from $7 billion to $37 billion annually.

U.S. public health officials believe that the risk of foodborne illness has generally been increasing over the last 20 years. These increases are linked, in part, to changes in Americans' eating habits, including their consumption of more fresh fruits and vegetables and increased dining out. They are also linked to Americans' consumption of more foods from other countries. With the number of imported food shipments increasing dramatically in recent years, these foods have introduced new risks or have increased the incidence of illnesses. For example, in 1996 and 1997, outbreaks of foodborne illness linked with the *Cyclospora* parasite in raspberries from Guatemala affected nearly 2,500 people in the United States, causing gastrointestinal distress and other painful symptoms. Also in 1997, a Hepatitis A virus outbreak affecting more than 250 children and teachers in Michigan schools was found to have been caused by contaminated strawberries imported from Mexico.

In carrying out its food safety responsibilities under the Federal Food, Drug, and Cosmetic Act, as amended,[4] FDA relies primarily on selecting and testing samples taken at food inspection sites, such as ports of entry, warehouses, and businesses. In selecting samples for examination, FDA relies heavily on its inspectors' judgment. To help inspectors make informed judgments, FDA provides a number of tools, including sampling guidance contained in its annual work plans and food compliance programs, and databases containing historical or other pertinent information on exporters. In conducting these examinations, inspectors rely, in part, on their own senses of sight, smell, and touch to assess the

[2] These include bacterial pathogens such as *Campylobacter jejuni*, *Escherichia coli* (*E. coli*) O157:H7, *Listeria monocytogenes*, and *Salmonella*; parasites such as *Cryptosporidium parvum* and *Toxoplasma gondii*; and viruses such as Hepatitis A and Norwalk-like.

[3] Individuals may also experience long-term health effects from pesticide or drug residues that may occur in food.

[4] 21 U.S.C. 301 et seq.

condition of food shipments, including possible spoilage or the presence of filth, such as rodent hair or urine. However, to determine possible pathogenic contamination, inspectors must send samples from a shipment to an FDA laboratory for testing. Traditionally, this testing has taken several days to a week or more to complete. In the interim, the food shipment may have been released into the domestic food supply.

As the number of imported food shipments has increased, FDA's inspection coverage has fallen from an estimated 8 percent of these shipments in fiscal year 1992 to an estimated 1.7 percent in fiscal year 1997.[5] This fact, along with growing public concerns about foodborne illnesses, have led to an increasing interest among the Congress, government regulators, food processors, and consumer groups to develop and use faster tests to screen and identify potentially unsafe foods before they enter domestic commerce.

Many Rapid Tests Are Used to Screen Foods for Pathogens

According to FDA and scientific literature, more than 150 rapid tests may be used to screen foods for bacterial pathogens, but similar tests for identifying parasites and viruses in food do not exist because of technological limitations. Determining the overall universe of rapid tests that are useful for identifying bacterial pathogens is difficult because new or improved tests are constantly being introduced by private companies and laboratories, universities, and government agencies. The term "rapid test" is also somewhat subjective, used loosely to describe many diagnostic tests that may take from 1 or 2 hours to a half a day or more to complete. In addition, even modifications to conventional laboratory tests that may eliminate or reduce the time taken for one or more steps are sometimes referred to as rapid tests.

Many rapid tests used to screen foods for bacterial pathogens have been borrowed from clinical settings, where they are used to screen blood, tissue, stool, or urine samples for pathogens. However, before it is possible to use a rapid test to identify a specific pathogen in food, the food sample

[5] FDA's inspection coverage also dropped because of a decrease in the resources devoted to inspecting imported foods during this period. Specifically, these resources declined by 22 percent, from 328 staff years for inspectors in fiscal year 1992 to 257 staff years for inspectors in fiscal year 1997.

must be selectively enriched to cause the pathogen to reproduce to detectable levels while suppressing the growth of other bacteria in the sample. This enrichment, which may take up to 24 hours or longer, results in a concentrated culture of the pathogen that is needed for testing. FDA officials noted that rapid tests are not available to screen foods for parasites and viruses in part because these pathogens do not reproduce or replicate outside of a living host organism. Hence, it is not possible to enrich them in a culture medium.[6]

Rapid tests employ a wide variety of diagnostic tools. For example, some measure the interaction of antigens and antibodies unique to a bacterium,[7] while others identify a specific genetic sequence associated with a bacterium or a toxin it produces. In addition, some measure metabolites[8] specific to a bacterium and others measure changes in the electrical conductivity of a pathogen culture. In general, these tests can be used to identify a variety of bacterial pathogens in foods, including certain strains of *Escherichia coli* (*E. coli*), *Listeria*, and *Salmonella*.[9] However, individual tests are usually pathogen-specific, and the food items on which they can be used may also be limited.

FDA's Use of Rapid Tests for Foodborne Pathogens

FDA uses dozens of rapid tests to screen food samples for bacterial pathogens. Some of these tests have been developed by FDA, while others are commercially available from private companies or from universities. FDA selects rapid tests on the basis of factors such as its testing priorities and needs and the cost and reliability of available tests. At present, FDA uses rapid tests for bacterial pathogens in its laboratories but not at food inspection sites, such as ports of entry, primarily because of the need to

[6] Culture medium refers to a nutrient-rich substance conducive to a living cell's survival and reproduction. For example, agar, a gelatinous substance derived from red alga, is commonly used as a culture medium.

[7] An antigen is an enzyme, or complex protein, capable of stimulating an immune response. An antibody is an immunoglobulin, or serum protein, produced by a living organism in response to specific antigens to counteract their effects.

[8] A metabolite is a product of metabolism. The latter term refers to the chemical changes in a living cell that provide energy for the cell's vital activities and allow the cell to assimilate new material.

[9] The principal pathogenic bacteria causing foodborne illnesses include certain strains of *E. coli*, *Listeria*, and *Salmonella*.

enrich a pathogen to detectable levels under controlled conditions. FDA's food safety research plan for fiscal years 1999 through 2001 includes provisions for developing a number of additional rapid tests.

FDA Uses Dozens of Rapid Tests for Foodborne Pathogens

FDA uses dozens of rapid tests for foodborne pathogens in its laboratories. Although the agency does not maintain a specific list of these rapid tests, our review of the agency's *Bacteriological Analytical Manual* and related documents showed that FDA uses more than 70 rapid tests for detecting a variety of bacterial pathogens in foods, including certain strains of *E. coli*, *Listeria*, and *Salmonella*. FDA's use of these tests is for screening purposes, with negative results (that is, a finding that the pathogen is not present in the sample) considered definitive and positive results considered presumptive and thus subject to confirmatory testing using conventional test methods. However, the actual frequency with which FDA uses any of these rapid tests is uncertain because the agency does not track the test methods used in its database of processed samples.

FDA officials cited a number of advantages to using rapid tests as screening tools. For example, a rapid test allows for a relatively quick decision (even allowing for enrichment time) to be made on whether a food sample is contaminated with a pathogen. This is especially important for highly perishable foods, such as fresh fruits and vegetables, that are moved quickly into commerce. Relatedly, because a negative result is considered definitive, there is no need to proceed with conventional tests that are both time-consuming and laborious. This means that laboratory resources, including equipment, materials, and staff, are available to meet other testing exigencies. According to FDA officials, historically, over 90 percent of the food samples tested by FDA are negative. Therefore, rapid tests have great potential to improve the efficiency of laboratory operations. In turn, greater efficiency could allow FDA's laboratories to process even more food samples.

Some of the rapid tests FDA uses were developed by its own staff to meet specific testing priorities or needs. In using commercially available rapid tests, FDA considers cost and reliability factors in addition to its testing priorities and needs. The cost of most of these commercial tests—specifically, the cost of the test kits—varies from less than $100 to several thousand dollars. This cost does not include the costs of specialized equipment and/or materials that may also be required but that are not included in a kit. On the other hand, many kits contain multiple tests for a target pathogen; thus, the cost per test may be as low $3 to $10.

FDA's use of a commercial rapid test also depends on the test's reliability. Specifically, FDA first uses the test on a trial basis in its laboratories to assess its performance characteristics, including accuracy, repeatability, and sensitivity. However, FDA must also determine the test's suitability for the agency's regulatory enforcement needs, which it does through its Center for Food Safety and Applied Nutrition and its Office of Regulatory Affairs.

FDA also uses rapid tests that have been validated and adopted as official methods by AOAC INTERNATIONAL,[10] the principal scientific organization that validates test methods for use in determining whether a food product is in compliance with government regulations. The organization does this by arranging studies in which proposed test methods are independently assessed in separate laboratories under identical conditions. AOAC INTERNATIONAL's *Official Methods*[sm] are recognized worldwide as authoritative; as such, they are written into government regulations and relied on in legal proceedings. However, FDA's use of rapid tests adopted by AOAC INTERNATIONAL is not automatic. The agency's Microbiology Rapid Methods Working Group[11] must first determine that a test adopted by the organization has merit for FDA's regulatory enforcement purposes. FDA's Center for Food Safety and Applied Nutrition and the agency's Office of Regulatory Affairs must concur with the working group's recommendations.[12]

FDA Does Not Use Rapid Tests for Foodborne Pathogens at Food Inspection Sites

FDA officials said they do not use rapid tests for bacterial pathogens at food inspection sites, such as ports of entry, because of the need for enrichment, controlled conditions, and specialized equipment, materials, and/or expertise. Others agreed that these factors inhibit on-site testing:

[10] This organization was formerly known as the Association of Official Analytical Chemists.

[11] FDA's Microbiology Rapid Methods Working Group convened in Jan. 1996 to explore the use of rapid test methods for the agency's food compliance programs. The group, made up of both headquarters and field staff, first chose to identify rapid tests adopted by AOAC INTERNATIONAL that would be useful for screening foods for the presence of *Listeria* and *Salmonella*; these tests were identified in guidance documents issued in 1998. The working group plans to consider other rapid tests adopted by AOAC INTERNATIONAL on the basis of FDA's priorities and needs.

[12] As of Oct. 1999, AOAC INTERNATIONAL had validated nearly 40 rapid test methods for foodborne pathogens that are commercially available in test kits. Of these, FDA has adopted 11 tests, either for *Listeria* or *Salmonella*, for its use.

officials at the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service, the agency responsible for ensuring the safety of imported meats, poultry, and processed egg products; AOAC INTERNATIONAL; the National Food Processors Association; and various rapid test kit manufacturers.

Most rapid tests for bacterial pathogens first require an enrichment step to increase the numbers of a target pathogen in a food sample to detectable levels, which is labor-intensive and time-consuming and usually requires specialized equipment and materials. It also requires controlled conditions, such as those found in laboratories, to ensure a concentrated culture of the pathogen and to prevent the accidental release of the microorganism.[13] Furthermore, after enrichment has been done and the rapid test has been performed, waste materials resulting from these procedures must be disposed of as potential biohazards. Again, laboratories provide a controlled environment for incinerating or otherwise disposing of these materials.

Finally, although many rapid tests come in self-contained kits, others require additional equipment and materials found only in laboratories. Similarly, although some rapid test kits can be used by a nonscientist with limited training, others require the knowledge and experience of a microbiologist or chemist to run the test and/or interpret its results.

FDA Plans to Develop New Rapid Tests to Detect Foodborne Pathogens

FDA's food safety research plan for fiscal years 1999 through 2001 includes provisions for developing additional rapid tests to detect foodborne pathogens.[14] This plan was developed in response to two 1997 presidential initiatives on food safety: the National Food Safety Initiative and the Produce and Imported Foods Safety Initiative. One of the key components of these initiatives is focusing food safety research on, among other things,

[13] Testing and storage of pathogens in a laboratory is usually done in a room or other area with a separate ventilation system that creates negative air pressure to prevent the accidental release of the pathogen via the air.

[14] This plan is the "Three-Year Plan for Research in Support of the National Food Safety Initiative and Produce and Imported Foods Safety Initiative," 1999-2001 Update, Aug. 1999.

improving detection methods for foodborne pathogens.[15] Moreover, FDA's research plan states that an essential component of a comprehensive strategy to enhance food safety is the development of an arsenal of rapid and sensitive tests for detecting microbial pathogens and their toxic metabolites.

The August 1999 update to the FDA plan notes seven research projects containing one or more components related to the development of rapid tests. For example, the purpose of one project is to develop rapid detection and quantification methods for pathogens and their toxins, with special emphasis on certain imported and domestic perishable foods that occasionally contain low levels of contamination. The components of this particular project include the development of new or refined rapid tests to identify bacterial or viral pathogens in selected foods, including fruit and fruit juices, sprouts, and infant formula.

Several Factors Can Limit FDA's Expanded Use of Rapid Tests for Foodborne Pathogens

Several factors can limit FDA's use of additional rapid tests for foodborne pathogens. In general, these factors relate to a test's sensitivity and reliability. For example, the presence of various ingredients and additives in foods, as well as indigenous bacteria in fresh fruits and vegetables, may interfere with a test's reliability. The use of rapid tests, as well as conventional tests, is also subject to sampling limitations; thus, the samples tested may not be representative of the health risks of an entire food shipment or all shipments from a particular exporter.

Test Sensitivity and Reliability

In general, when testing for pathogenic contamination, FDA requires that a test be capable of detecting specific pathogens at levels of 1 microbe per 25 grams of food. This criterion reflects the agency's regulatory policy of "zero tolerance" for life-threatening microorganisms in ready-to-eat foods. However, most rapid tests lack this level of sensitivity. Accordingly, before these tests can be used, a food sample must be enriched to cause the target organism to grow to detectable levels. This step, especially when it takes 48 hours or longer, can significantly reduce the time advantage of some rapid tests.

[15] Other research priorities of the initiatives include understanding resistance to traditional preservation technologies; understanding antibiotic drug resistance; pathogen avoidance, reduction, and elimination; and the impact of food handling, distribution, and storage on food safety.

The ability of a rapid test to detect a pathogen may also depend on the complexity of the food being tested. Foods are composed of an infinite array of ingredients—such as water, carbohydrates, proteins, fats, oils, and additives—many of which can interfere with the identification of specific pathogens in food. For example, FDA has rejected the use of some rapid tests because of the high frequency of false positive or negative results that may occur with certain foods or ingredients.

In addition, the presence of other microorganisms in a food sample complicates testing. For example, some foods, especially raw products, may contain indigenous bacteria. Although these bacteria generally pose no health risk, their physical presence may mask that of pathogenic bacteria, which usually occur in low numbers in foods. Such masking becomes especially critical in foods examined for bacterial pathogens that cause illness even when present in very small numbers, such as certain strains of *E. coli* and *Shigella*.

Finally, most rapid tests are designed to detect a single pathogen, which makes them useful for screening foods for a particular pathogen. However, FDA must sometimes screen food samples for a variety of pathogens simultaneously. Although simultaneous analyses can be done fairly easily with conventional test methods, analysis of a single sample with multiple rapid tests could be complex and costly.

Sampling Limitations

The testing of food samples, whether by a rapid or conventional test, is subject to the adequacy and availability of effective sampling techniques. However, current sampling techniques are a limiting factor because pathogens in foods are usually present in very low numbers, occur only sporadically, and are not uniformly distributed within a food item or shipment. Therefore, in order to achieve a high level of assurance that a food shipment is free of pathogens, a large percentage of the shipment must be subjected to testing. This would be both cumbersome and very expensive. According to FDA, overcoming sampling limitations is currently a research priority for the agency's Center for Food Safety and Applied Nutrition.

Agency Comments

We provided FDA and USDA's Food Safety and Inspection Service with a draft of this report for review and comment. The agencies generally agreed with the information contained in the report and provided minor technical suggestions, which we incorporated into the report as appropriate.

Scope and Methodology

To describe the rapid tests used to screen and identify pathogens in food, we interviewed and obtained documentation from officials in FDA's Center for Food Safety and Applied Nutrition, including the Center's Senior Science Advisor and officials in its Division of Microbiological Studies. We also interviewed and obtained documentation from officials in USDA's Agricultural Research Service and Food Safety and Inspection Service; AOAC INTERNATIONAL; the National Food Processors Association; and a variety of private companies and universities that develop and/or market rapid test kits. In addition, we obtained and reviewed scientific journal articles on the use and development of rapid tests to detect foodborne pathogens.

To describe FDA's use of rapid tests, we interviewed and obtained documentation from FDA officials who work in the agency's Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, and Office of Regulatory Affairs. We also interviewed and obtained documentation from officials in FDA's Pacific Region, including the agency's Pacific Regional Laboratory Northwest and its San Francisco District Laboratory. In addition, we accompanied food safety inspectors assigned to the Pacific Region during their inspections of imported food containers and seafood in San Francisco and Seattle. Finally, we reviewed FDA's *Bacteriological Analytical Manual* and related guidance issued by the agency's Microbiology Rapid Methods Working Group, as well as the Center for Food Safety and Applied Nutrition's multi-year research plan.

To describe factors that may limit FDA's expanded use of rapid tests, we interviewed officials at FDA, USDA, AOAC INTERNATIONAL, the National Food Processors Association, private companies, and universities. We also obtained and reviewed documentation from these officials.

We conducted our review from August 1999 through January 2000 in accordance with generally accepted government auditing standards.

As agreed, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies of this report to Representative John Dingell, Ranking Minority Member, House Committee on Commerce; Representative Ron Klink, Ranking Minority Member, Subcommittee on Oversight and Investigations, House Committee on Commerce; other congressional committees with jurisdiction over food safety issues; the

Honorable Dan Glickman, Secretary of Agriculture; the Honorable Donna E. Shalala, Secretary of Health and Human Services; the Honorable Catherine E. Woteki, Ph.D., Under Secretary for Food Safety, USDA; the Honorable Thomas J. Billy, Administrator, Food Safety and Inspection Service, USDA; the Honorable Jane E. Henney, M.D., Commissioner, Food and Drug Administration; the Honorable Jacob J. Lew, Director of the Office of Management and Budget; and other interested parties. We will also make copies available to others on request.

If you or your staff have any questions about this report, please contact me or Jim Jones, Assistant Director, at (202) 512-5138. Key contributors to this report were Patrick Dunphy and Richard Shargots.

Lawrence J. Dyckman
Director, Food and
Agriculture Issues

Related GAO Products

Food Safety: Agencies Should Further Test Plans for Responding to Deliberate Contamination (GAO/RCED-00-3, Oct. 27, 1999).

Food Safety: Weak and Inconsistently Applied Controls Allow Unsafe Imported Food to Enter U.S. Commerce (GAO/T-RCED-98-271, Sept. 10, 1998).

Food Safety: Opportunities to Redirect Federal Resources and Funds Can Enhance Effectiveness (GAO/RCED-98-224, Aug. 6, 1998).

Food Safety: Federal Efforts to Ensure Imported Food Safety Are Inconsistent and Unreliable (GAO/T-RCED-98-191, May 14, 1998).

Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable (GAO/RCED-98-103, Apr. 30, 1998).

Food Safety: Fundamental Changes Needed to Improve Food Safety (GAO/RCED-97-249R, Sept. 9, 1997).

Food Safety: Reducing the Threat of Foodborne Illnesses (GAO/T-RCED-96-185, May 23, 1996).

Food Safety: Information on Foodborne Illnesses (GAO/RCED-96-96, May 8, 1996).

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