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FDA and Fresh Spinach Safety

PREPARED FOR
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EXECUTIVE SUMMARY

In September 2006, the United States suffered a major outbreak of *E. coli* O157:H7, causing hundreds of reported injuries and several deaths and resulting in a spinach recall. The outbreak ultimately was traced to packaged fresh spinach. This was not the first outbreak tied to fresh produce. There have been at least 20 outbreaks of *E. coli* O157:H7 in fresh spinach or lettuce in the past 12 years.

At the request of Rep. Henry A. Waxman and Rep. Rosa DeLauro, this report examines the Food and Drug Administration's efforts to protect the safety of packaged fresh spinach. As part of this investigation, the Committee requested and received inspection records for all FDA inspections of firms producing packaged fresh spinach from 2001 to 2007.

The FDA inspection records reveal:

- **Packaged fresh spinach facilities were inspected only once every 2.4 years, less than half of FDA's stated goals.** Frequent inspections are the cornerstone to the current safeguards for fresh produce and adequate resources are required for frequent inspections. FDA's performance goals state that 95% of high risk facilities like packaged fresh spinach facilities should be inspected at least once yearly. Over a seven-year period, FDA provided 199 inspection reports for 67 packaged fresh spinach facilities. This translates to an inspection rate of about one inspection of each facility every 2.4 years, less than half of FDA's stated goal.

- **FDA observed objectionable conditions during 47% of the packaged fresh spinach facility inspections.** Of the 199 inspections reviewed, 93 documented "objectionable conditions," the most common of which involved plant sanitation, plant construction, and worker sanitation. For example, more than 60% of the inspections with "objectionable conditions" revealed problems related to facility sanitation, such as inadequate restroom cleanliness or accumulations of litter.

- **Despite observing objectionable conditions in packaged fresh spinach facilities, FDA took no meaningful enforcement action.** FDA did not refer any of these inspections with objectionable conditions for further action by its own enforcement authorities. In one case, FDA did refer one inspection to the state for further action. FDA did not issue warning letters or pursue more aggressive steps such as seizures or injunctions.

- **FDA overlooked repeated violations.** In 38 cases, FDA observed repeated violations by packaged fresh spinach facilities but did nothing to force correction. Instead of taking enforcement action, FDA continued to request voluntary compliance after recording violations at each inspection. 14 of these repeat requests for voluntary compliance were for precisely the same violations.

- **FDA found repeated problems at multiple facilities operated by the firm implicated in the 2006 E. coli outbreak but took no enforcement actions.** The records show that in the years prior to the outbreak, FDA conducted multiple inspections of several packaged fresh spinach facilities operated by Natural Selection Food LLC and repeatedly found problematic conditions at a number of these facilities. According to the inspection records, however, FDA at no time required the firm to correct these conditions at any of its facilities, even after laboratory tests indicated the presence of microbial contamination at the exact site later implicated in the 2006 outbreak.

- **In eight cases, packaged fresh spinach facilities denied FDA inspectors access to records or other relevant material.** In eight instances, facilities prevented FDA inspectors from conducting a full review of the food safety practices. Under current law, FDA lacks the authority to compel production of firm records. On one occasion, inspectors were denied access to written records by the facility that was the site of the 2006 outbreak.

- **The scope of the FDA inspections appears too narrow to capture the sources of an E. coli outbreak.** The California Department of Health Services and the FDA performed a joint investigation into the causes of the 2006 spinach outbreak and found that the outbreak probably did not originate in the facilities that are inspected by FDA. Instead, the problem began outside the plants and most likely was due to contamination of the water outside of the plant by cattle feces, pig feces, or river water. FDA does not routinely inspect the fields except in outbreak investigations. In fact, none of the 199 Establishment Inspection Reports reviewed by Committee staff indicated that any observations of field conditions had taken place. Laboratory sampling can detect some microbial contaminations, but cannot prevent many outbreaks. The outdated statutory sanitation standard severely limits the scope of FDA's ability to adequately prevent many outbreaks.

The inspection reports provided to the Committee raise serious questions about the ability of FDA to protect the safety of fresh spinach and other fresh produce. It appears that FDA is inspecting high-risk facilities infrequently, failing to take vigorous enforcement action when it does inspect and identify violations, and not even inspecting the most probable sources of many outbreaks.

Inadequate funding and resources for food safety activities at FDA may contribute to the problems identified in this report. The Science Board, an independent FDA advisory committee, submitted a report to the FDA Commissioner in December 2007 that concluded: "FDA's ability to provide its basic food system inspection, enforcement and rulemaking functions is severely eroded, as is its ability to respond to outbreaks in a timely manner and to develop and keep pace with the new regulatory science needed to prevent future problems. … [W]e can state unequivocally that the system cannot be fixed within available resources."

I. BACKGROUND

In the late summer and fall of 2006, 205 people were infected with a virulent strain of *E. coli* O157:H7 in connection with packaged fresh spinach. Reactions ranged from relatively mild to the most severe: 103 individuals were hospitalized, while three died from the infection.[1]

This was the 20th major outbreak of *E. coli* O157:H7 in fresh lettuce or spinach since 1995.[2] According to experts, there are a number of factors that are contributing to the growing incidence of fresh produce outbreaks. First, fresh-cut produce is the fastest growing segment of a fresh produce market that is growing overall, driven in part by the appeal of pre-made salads and packaged spinach among busy consumers.[3] Second, such foods often are consumed without cooking or other preparation, meaning that there is no routine "kill step" for foodborne contaminants such as *E. coli* or *salmonella*.[4] Third, food systems have grown more centralized in recent years, with food produced in a single region or even a single facility distributed to consumers throughout the country.[5] This nationwide distribution system means that once local outbreaks can now have nationwide reach, causing more illness and taking longer to detect and trace back to the source. Finally, some of the increase in fresh produce outbreaks may be due to changes in reporting.

To investigate these issues, Rep. Henry A. Waxman, Chair of the House Committee on Oversight and Government Reform, and Rep. Rosa DeLauro, Chair of the House Appropriations Subcommittee on Agriculture, requested inspection documents and data from FDA relating to its inspection of facilities producing packaged fresh spinach between January 1, 2001, and February 21, 2007.[6] In response to the Committee's request, FDA produced 199 Establishment Inspection Reports (EIRs) involving 67 facilities that produce packaged fresh spinach that were inspected during the specified six year period. These included EIRs for the facility in San Juan Bautista implicated in the spinach outbreak in Fall 2006.[7]

This report is based on an analysis of the EIRs. In preparing this report, Committee staff also consulted with food safety experts. These experts included a number of former FDA officials, such as William Hubbard, retired FDA Associate Commissioner for Policy and Planning from

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[1] California Department of Health Services and the U.S. Food and Drug Administration, *Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged* Spinach (Mar. 27, 2007).

[2] FDA, *Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce* (Nov. 4, 2005). According to this 2005 letter, 19 outbreaks of *E. coli O157:H7* in lettuce or spinach occurred from 1995 to 2005. The outbreak in 2006, therefore, was the 20th outbreak since 1995.

[3] Economic Research Service, USDA, *U.S. Fresh Produce Markets: Marketing Channels, Trade Practices, and Retail Pricing* (Sept. 22, 2003).

[4] FDA, *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables* (Mar. 2007).

[5] Economic Research Service, USDA, *U.S. Fresh Produce Markets: Marketing Channels, Trade Practices, and Retail Pricing* (Sept. 22, 2003).

[6] Letter from Chairman Henry A. Waxman and Chairwoman Rosa DeLauro to Commissioner Andrew C. Von Eschenbach (Feb. 22, 2007)(online at www.oversight.house.gov/story.asp?ID=1190).

[7] FDA, *FDA Announces Findings From Investigation of Foodborne E. coli 0157:H7 Outbreak in Spinach*, FDA News, (Sept. 29, 2006) (online at www.fda.gov/bbs/topics/NEWS/2006/NEW01474.html).

1991-2005; Michael Taylor, former Deputy Commissioner for Policy at the FDA from 1991-1994 and Food Safety and Inspection Service Administrator from 1994-1996; and Leroy Gomez, retired Regional Food and Drug Director, Southwest Region.

II. FDA INSPECTION AND ENFORCEMENT PROCEDURES

Under the Federal Food, Drug and Cosmetic Act, any food that 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" is deemed adulterated and its sale is prohibited.[8] To implement the Act's prohibition on the sale of adulterated or otherwise contaminated food, FDA has issued Good Manufacturing Practices (GMPs) for foods, including packaged fresh produce.[9] These GMPs, created in 1986, impose basic safety standards, including requirements for worker sanitation, plant construction, and plant cleanliness.[10] Though not specific to fresh produce, the GMPs provide the basis for FDA's authority with regard to fresh packaged spinach facility inspections.

Inspections are the mechanism for enforcement for food GMPs. According to FDA, with respect to food, "inspections and surveillance are the primary means of assuring the safety of marketed products. Consumers rely on the FDA to prevent dangerous and unreliable products from entering commerce."[11]

At the close of every inspection, FDA inspectors issue an EIR which details the production history and management of the firm, inspection findings, samples taken, and inspection conclusions. This EIR is submitted to a regional FDA district office after the inspection.[12]

In addition to the EIR, which is issued for all inspections, an inspector who observes "objectionable conditions" also must prepare a Form 483 to record such observations. Under FDA procedures, the Form 483 serves as the written notice to firms of any "objectionable conditions" that are found.[13]

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[8] 21 U.S.C. § 342; 21 U.S.C. § 331.

[9] 21 C.F.R. 110 (2006).

[10] *Id.*

[11] Office of Management, FDA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2007* (online at http://www.fda.gov/oc/oms/ofm/budget/2007/HTML/1Foods.htm).

[12] Office of Regulatory Affairs, FDA, *ORA Field Management Directive No. 86: Establishment Inspection Report Conclusions and Decisions* (June 2007) (online at www.fda.gov/ora/Inspect_ref/fmd/ fmd86.htm).

[13] *Id.* The Form 483 is used to notify a firm's management of significant objectionable conditions "when in the Investigator's 'judgment' conditions or practices observed indicate that any food ... [has] been adulterated or [is] being prepared, packed, or held under conditions whereby [it] may become adulterated or rendered injurious to health."

As defined by FDA regulations, objectionable conditions are those that "indicate that the food [has] been adulterated or [is] being prepared, packed, or held under conditions whereby [it] may become adulterated or rendered injurious to health."[14]

Based on the EIR and the Form 483, FDA assigns an Inspection Conclusion for each inspection, designating the type of follow-up action indicated according to the following categories:

- No Action Indicated (NAI): No objectionable conditions or practices were found during the inspection or the objectionable conditions found do not justify further regulatory action.

- Voluntary Action Indicated (VAI): Objectionable conditions were found but the district office is not prepared to take or recommend any administrative or regulatory action. Any corrective action is left to the establishment to take voluntarily.

- Official Action Indicated (OAI): Regulatory or administrative sanctions will be recommended, including voluntary recalls where the district has decided conditions warrant either regulatory or administrative action. Such enforcement action may include a citation, a warning letter, or seizure. Additional enforcement action may also include fines for pesticide tolerance violations or criminal cases.

- Referred to State (RTS): Normally, only EIRs in which objectionable conditions were observed for which FDA either cannot or chooses not to take regulatory or administrative action are referred to states. The district office is obligated to maintain contact with the state to learn if action is taken.[15]

III. FRESH PRODUCE INSPECTIONS AND ENFORCEMENT FINDINGS

A. Objectionable Conditions

The EIRs provided to the Committee varied in format and language. While "objectionable conditions" was the most common classifying term, additional negative observations were also noted as "discussion with management," "deficiencies," or "concerns." In 199 of the EIRs

[14] Office of Regulatory Affairs, FDA, *Investigations Operations Manual*, Ch. 5 § 2.3.2 (Feb. 2007) (online at www.fda.gov/ora/inspect_ref/iom/ChapterText/5_2.html#5.2.3.2).

[15] Office of Regulatory Affairs, FDA, *Field Management Directive No. 86: Establishment Inspection Report Conclusion* (June 2007) (online at www.fda.gov/ora/Inspect_ref/fmd/fmd86.htm); FDA. *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables, Draft Final Guidance* (Mar. 2007). Raw agricultural commodities are not subject to Current Good Manufacturing Practice requirements, but packaged fresh produce is considered processed food and therefore falls under Current Good Manufacturing Practice requirements under 21 C.F.R. § 110.

reviewed by Committee staff, 93 (47%) contained "objectionable conditions." Including the additional ways in which unsatisfactory conditions were noted, 116 (58%) EIRs contained negative observations. These records demonstrate potentially unsafe conditions at more than half of the spinach facilities inspected by FDA from 2001 to 2007.

The most common problem observed related to basic plant cleanliness: more than 60% of the inspections reporting "objectionable conditions" revealed problems related to facility sanitation, such as inadequate restroom cleanliness or accumulations of litter. The next most common problem identified was plant construction, cited in more than half of the violations. Observations in this area included findings that condensation had accumulated inside the plant, threatening to contaminate the food with water-borne microorganisms, and that plant design allowed for rodent infiltration, which might introduce filth or otherwise contaminate the food. The third major concern was worker sanitation, including issues such as uncovered hair, jewelry, or clothing, and poor hygiene practices. Worker sanitation concerns were raised in more than one tenth of the violations.

B. No Official Enforcement Action

FDA inspectors observed problems at many of the facilities inspected, but "objectionable conditions" were not referred for official action in any of the inspections reviewed. As shown in figure 1, FDA classified 117 of the EIRs as "no action indicated." 81 of the EIRs were classified as "voluntary action indicated" and one EIR was referred to a state for further action.[16] FDA did not classify a single case as OAI.[17]

Figure 1: FDA Inspections and Classification	
No Action Indicated	117
Voluntary Action Indicated	81
Official Action Indicated*	0
Referred to State	1
Total Number of Inspections	199

In an inspection conducted in September 2005, FDA found serious objectionable conditions at a Fresh Express facility. Inspectors observed spinach leaf pieces, carrot pieces, and salad residue on facility equipment, as well as an unidentifiable "scrapable" brown residue on at least four chutes and at least two product conveyor lines.[18] In addition, the broccoli conveyor, lined with broccoli flowerets, had a four inch tear through it. Finally, rust and condensation were seen on the beams over the scales and the salad line, and the ceiling panels were loose and cracked.[19]

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[16] FDA referred one case to the state of New Jersey, issued a warning letter to the firm after this referral. New Jersey District Office, FDA, *Establishment Inspection Report:* Seabrook Bros & Sons (May 19-22, 2006).

[17] The narrative of one EIR mentions a warning letter, but in documents provided to the Committee, the inspection was classified by FDA as VAI. In communications with the Committee, FDA indicated that the state in which this firm was located separately issued a warning letter to the firm. Detroit District Office, FDA. *Establishment Inspection Report:* All American Produce, Inc. (Jul. 23, 2002).

[18] San Francisco District Office, FDA, *Establishment Inspection Report*: Fresh Express Fresh Foods (Sept. 13-15, 2005).

[19] *Id.*

Based on these observations, FDA issued a Form 483 and classified the inspection as Voluntary Action Indicated. [20] Under a VAI classification, FDA may issue an untitled letter, request a regulatory meeting, or request a written response from the firm.[21] FDA took no such actions with regard to Fresh Express.

In fact, according to the records provided to the Committee, FDA took no such actions with respect to any packaged fresh spinach facility issued a VAI classification.

C. Repeat Observations and Classifications

As noted above, 81 of the 199 EIRs reviewed were classified by FDA as Voluntary Action Indicated, or VAI. Approximately 47% of these classifications (38) were repeat VAI classifications for a facility that had been designated as VAI in the previous inspection. 14 of these VAI classifications were due to the same objectionable observation made in the prior inspection. In the other 24 EIRs, the classification was based upon different objectionable observations.

One notable example of repeat observations involved the Yuma, Arizona, facility of Natural Selection Foods LLC. The Yuma facility was inspected five times between March 6, 2002, and February 6, 2006, by the Los Angeles FDA district office, receiving a VAI classification and a Form 483 at each inspection. Several repeat observations were reported over this four-year period, including indications that the facility failed to take effective measures to prevent extraneous materials from entering the food; failed to clean and maintain processing equipment; failed to ensure that condensation did not contaminate the product; and failed to review and verify plant records pertaining to sanitation.[22] Despite these repeated violations, FDA never initiated any enforcement action against Natural Selection Foods. In 2006, the San Juan Bautista facility of Natural Selection Foods was identified as the source of the 2006 *E. coli* O157:H7 outbreak in packaged fresh spinach.[23]

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[20] *Id.*

[21] Office of Regulatory Affairs, FDA, *ORA Field Management Directive No. 86: Establishment Inspection Report Conclusions and Decisions* (June 2007) (online at www.fda.gov/ora/Inspect_ref/ fmd/fmd86.htm).

[22] Los Angeles District Office, FDA, *Establishment Inspection Report*: Natural Selection Foods LLC (Mar. 6-7, 2002); Los Angeles District Office, FDA, *Establishment Inspection Report*: Natural Selection Foods LLC (Jan. 8-9, 2003); Los Angeles District Office, FDA, *Establishment Inspection Report*: Natural Selection Foods LLC (Feb. 27, 2004); Los Angeles District Office, FDA, *Establishment Inspection Report*: Natural Selection Foods LLC (Dec. 8-9, 2004); Los Angeles District Office, FDA, *Establishment Inspection Report*: Natural Selection Foods LLC (Feb. 6-8, 2006).

[23] FDA, *FDA Announces Findings From Investigation of Foodborne E. coli 0157:H7 Outbreak in Spinach*, FDA News (Sept. 29, 2006) (online at www.fda.gov/bbs/topics/NEWS/2006/NEW01474.html).

D. Laboratory Sampling

Laboratory sampling could reveal serious health threats such as microbial contamination by *E. coli* O157:H7. The staff analysis found that FDA tested product samples in only 41 of 199 inspections, just one-fifth of the total inspections. Even when presented with information indicating the presence of possible contamination, FDA neglected to collect product samples. Moreover, inspections rarely referenced sampling results from earlier inspections of the same facility. In only three of the 41 cases involving sampling were the results mentioned in the following inspection.

These findings are illustrated by the July 2001 inspection of the Natural Selection Foods facility in San Juan Bautista implicated in the 2006 spinach outbreak. The facility told FDA during the inspection that "a swab taken in a drain in the raw storage product room came back positive for *Listeria*" but that additional swab results were negative for these bacteria after a thorough cleaning. The FDA inspector did not collect samples at that inspection or at the next inspection in April 2002. FDA took samples only at a third inspection, in August 2002, over a year after learning of a potential contamination. These samples were positive, this time for a more dangerous type of *Listeria* that can cause meningitis and death in people with deficiencies in their immune system or stillbirths in pregnant women.[24] There is no evidence that after the positive sample in August 2002 — in four inspections from 2003 to 2005 — FDA again took samples at this facility. Nor did FDA mention these prior, multiple instances of microbial contamination in any of these four subsequent inspections.

E. Records Refusals During Inspections

In eight of the 199 EIRs reviewed, FDA inspectors reported that the facility being inspected refused to grant access to records. The most common items refused were facility records (e.g., food sampling and maintenance records) and consumer complaint files. Under current law FDA lacks the authority to compel access to such records.

One of the facilities that refused to grant access to records was the Natural Selection Foods facility in San Juan Bautista, California, the facility implicated in the 2006 spinach outbreak.[25] FDA inspectors at this site requested written procedures on recalls during two separate inspections, one in 2001 and one in 2002. The facility refused to provide access to these records during both inspections.[26]

A refusal also occurred during FDA's inspection of Fresh Express Fresh Foods in Salinas, California, in September 2005. In that inspection, the facility refused to allow inspectors to

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[24] FDA. *Bad Bug Book- Listeria monocytogenes* (online at www.cfsan.gov/~mow/chap6.html).

[25] California Department of Health Services and the U.S. Food and Drug Administration, *Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged* Spinach (Mar. 27, 2007).

[26] San Francisco District Office. FDA, *Establishment Inspection Report*: Natural Selection dba Earthbround Farms (Jul. 25-26, 2001); San Francisco District Office, FDA, *Establishment Inspection Report*: Natural Selection dba Earthbound Farms (Aug. 8-30, 2002).

review records pertaining to environmental sampling, final product testing, pest control, water sampling, and consumer complaints.[27]

F. Scope of FDA Inspections

In March 2007, the California Department of Health Services and FDA issued a report of a comprehensive investigation into the causes of the 2006 outbreak of *E. coli* O157:H7 in spinach. The investigators determined that the most likely source of introduction was in the field, an area FDA does not routinely inspect. The investigation found no obvious sources for introduction at the processing facility, but did find multiple factors in the facility that could have contributed to the spread of the pathogen, such as invalidated methods for testing wash water and incomplete records.

The causative *E. coli* DNA fingerprint was found in feces from nearby grazing cattle, feces from wild boars that had apparently gained access to the fields, and river water. The most likely route for this *E. coli* to contaminate the spinach was probably the contamination of water outside of the plant, either contamination of irrigation water or contamination of the water used to process the spinach, or both.

None of the 199 inspection reports reviewed by Committee staff contained any observations from practices in the fields. Instead, the FDA inspectors primarily examined the general sanitation and construction of the facilities themselves. The statutory sanitation standard that authorizes these inspections dates back to 1938 and does not provide clear authority to inspect the fields. Nor does this standard provide clear authority to require facilities to test product and water as they enter the plant for processing.

Laboratory sampling can detect some microbial contaminations, but as noted above, this testing is not currently adequate. Even a robust system of sampling would miss many bacterial contaminations since some diseases can be spread with just a few microbes. The outdated statutory sanitation standard for inspections severely limits the scope of FDA's ability to adequately prevent many outbreaks.

IV. CONCLUSION

The Committee staff review of inspection documents reveals that packaged fresh spinach facilities were inspected infrequently. Objectionable findings were common, but FDA took virtually no meaningful enforcement action, even after repeated violations. In some cases, FDA inspectors were not even granted access to records or other key materials at the facility. In

[27] San Francisco District Office, FDA, *Establishment Inspection Report*: Fresh Express Fresh Foods (Sept. 13-15, 2005).

addition, the system of FDA's inspections appear to be poorly targeted since the most likely source of the outbreak of *E. coli* in spinach appears to have originated in the fields, an area that FDA does not routinely inspect.

The problems identified in this report may in part derive from inadequate funding and resources for food safety activities at FDA. The Science Board, an independent FDA advisory committee, submitted a report to the FDA Commissioner in December 2007 that addressed FDA's capacity to protect the food supply. The Science Board concluded: "we can state unequivocally that the system cannot be fixed within available resources."[28] According to the report:

> FDA's ability to provide its basic food system inspection, enforcement and rulemaking functions is severely eroded, as is its ability to respond to outbreaks in a timely manner and to develop and keep pace with the new regulatory science needed to prevent future problems arising from both novel (prion disease, genetically modified organism) and traditional (resistant microbes, chemical contamination) sources. There is an appallingly low inspection rate: the FDA cannot sufficiently monitor either the tremendous volume of products manufactured domestically or the exponential growth of imported products. During the past 35 years, the decrease in FDA funding for inspection of our food supply has forced FDA to impose a 78 percent reduction in food inspections, at a time the food industry has been rapidly expanding and food importation has exponentially increased. FDA estimates that, at most, it inspects food manufacturers once every 10 years, and cosmetic manufacturers even less frequently. The Agency conducts no inspections of retail food establishments or of food-producing farms.[29]

[28] FDA Science Board. Supra note 28 at 53.

[29] FDA Science Board. FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology, 21(Nov. 2007).