products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

Bombardier, Inc. (Formerly Canadair): Docket No. FAA–2008–0977; Directorate Identifier 2008–NM–124–AD.

Comments Due Date

(a) We must receive comments by October 17, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Bombardier Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, certificated in any category, as specified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Airplanes having serial numbers 7003 through 7067 and 7069 through 7939 that have not had the modification of the refuel/defuel shutoff valves incorporated according to the original issue of Bombardier Service Bulletin 601R–28–053, dated July 12, 2004;

(2) Airplanes having serial numbers 7989, 7990, and 8000 through 8034.

Subject

(d) Air Transport Association (ATA) of America Code 28: Fuel.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

Bombardier Aerospace has completed a system safety review of the CL–600–2B19 aircraft fuel system against the new fuel tank safety standards, introduced in Chapter 525 of the Airworthiness Manual through Notice of Proposed Amendment (NPA) 2002–043. The identified non-compliances were assessed using Transport Canada Policy Letter No. 525–001 to determine if mandatory corrective action is required.

The assessment showed that insufficient electrical bonding between the refuel/defuel shutoff valves and the aircraft structure could occur due to the presence of a non-conductive gasket (Gask-O-Seal). In addition, it was also determined that the presence of an anodic coating on the shutoff valve electrical conduit connection fitting could affect electrical bonding. The above conditions, if not corrected, could result in arcing and potential ignition source inside the fuel tank during lightning strikes and consequent fuel tank explosion.

To correct the unsafe condition, this directive mandates the modification of the [shutoff valves in the] refuel/defuel system.

Actions and Compliance

(f) Unless already done, do the following actions.

(1) Within 5,000 flight hours after the effective date of this AD, modify the refuel/defuel system in the center wing fuel tank in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 601R–28–053, Revision C, dated March 14, 2006.

(2) Modifying the refuel/defuel system is also acceptable for compliance with the requirements of paragraph (f)(1) of this AD if done before the effective date of this AD in accordance with one of the following service bulletins: Bombardier Service Bulletin 601R–28–053, Revision A, dated April 21, 2005; or Revision B, dated September 15, 2005.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, New York Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Rocco Viselli, Aerospace Engineer, Airframe and Propulsion Branch, ANE–171, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228–7331; fax (516) 794–5531. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) Airworthy Product: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) Reporting Requirements: For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI Canadian Airworthiness Directive CF–2008–20, dated June 12, 2008; and Bombardier Service Bulletin 601R–28–053, Revision C, dated March 14, 2006; for related information.

Issued in Renton, Washington, on September 9, 2008.

Michael J. Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–21730 Filed 9–16–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 129 and 165

[Docket No. FDA–2008–N–0446]

Beverages; Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its bottled water regulations to require that source water, which is currently subject to weekly microbiological testing, be tested specifically for total coliform as is done for finished bottled water products. Further, FDA is proposing that if any coliform organisms are detected in source water or finished bottled water products, bottled water manufacturers would be required to test for the bacterium *Escherichia coli* (*E. coli*), an indicator of fecal contamination. FDA also is proposing to amend the adulteration provision of the bottled water standard to reflect the possibility

of adulteration caused by the presence of filth. Bottled water containing *E. coli* would be considered adulterated, and source water containing *E. coli* would not be considered to be of a safe, sanitary quality and would be prohibited from use in the production of bottled water. In addition, this rule would require bottlers to rectify or eliminate the source of *E. coli* contamination in source water and keep records of such actions. Existing regulatory provisions would require bottled water manufacturers to keep records of new testing required by this rule. FDA tentatively concludes that this proposed rule, if finalized, will ensure that FDA's standards for the minimum quality of bottled water, as affected by fecal contamination, will be no less protective of the public health than those set by the Environmental Protection Agency (EPA) for public drinking water.

DATES: Submit written or electronic comments on the proposed rule by November 17, 2008. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by October 17, 2008 (see the ''Paperwork Reduction Act of 1995'' section of this document). See section XI of the **SUPPLEMENTARY INFORMATION** section of this document for the proposed effective date of the final rule based on the proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2008–N–0446, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick Robin, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1639.

SUPPLEMENTARY INFORMATION:

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I. Background

FDA has established specific regulations for bottled water in Title 21 of the Code of Federal Regulations, including standard of identity regulations in part 165 (21 CFR part 165) (§ 165.110(a)) that define different types of bottled water and standard of quality regulations (§ 165.110(b)) that establish allowable levels for contaminants in bottled water. FDA also has established current good manufacturing practice (CGMP) regulations for the processing and bottling of bottled water (part 129 (21 CFR part 129)).

Unlike bottled water, which is regulated as a food by FDA, public drinking water in the United States is regulated by the EPA. The Safe Drinking Water Act (SDWA) (42 U.S.C. 300f *et seq.*), as amended in 1996, requires EPA to publish a National Primary Drinking Water Regulation (NPDWR) that specifies either a maximum contaminant level (MCL) or a treatment technique requirement for contaminants that may ''have an adverse effect on the health of persons,'' are ''known to occur or [have] a substantial likelihood [of occurring] in public water systems with a frequency and at levels of public health concern,'' and for which ''regulation * * * presents a meaningful opportunity for health risk reduction for persons served by public water systems'' (SDWA section 1412(b)(1)(A) (42 U.S.C. 300g–1(b)(1)(A))). Under section 410(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 349(b)(1)), not later than 180 days before the effective date of an NPDWR issued by EPA for a contaminant under section 1412 of the SDWA (42 U.S.C. 300g–1), FDA is required to issue a standard of quality regulation for that contaminant in bottled water, or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems (PWSs) but not in water used for bottled water. If FDA fails to take action within the prescribed time period in response to the NPDWR issued by EPA, section 410(b)(4)(A) of the act provides that EPA's NPDWR will apply to bottled water.

II. EPA's Ground Water Rule

In the **Federal Register** of November 8, 2006 (71 FR 65574), EPA published a new NPDWR, the Ground Water Rule (GWR), to provide for increased protection against fecal microbial pathogens in PWSs that use ground water sources (also referred to as ground water systems (GWSs)). In the GWR,

EPA established treatment techniques intended to identify and target GWSs that are susceptible to fecal contamination and require such GWSs to monitor and, when necessary, take corrective action to prevent or remove such contamination. Corrective action can include correcting all significant deficiencies, providing an alternative source of water, eliminating the source of contamination, or providing treatment that reliably achieves at least 4-log (99.00 percent) treatment of viruses (71 FR 65574 at 65602). The GWR also contains compliance monitoring requirements to ensure that treatment effectiveness is maintained when treatment is used as a corrective action, as well as notification requirements when GWS deficiencies occur.

EPA issued the GWR to protect public health because some GWSs may be at risk of supplying water that contains harmful microbial pathogens from fecal contamination. Ingestion of contaminated water can result in gastrointestinal illness, typically characterized by diarrhea, vomiting, nausea, and abdominal discomfort. Most gastrointestinal illnesses are mild and self-limiting, but these diseases can be more serious and potentially fatal in sensitive individuals, such as the elderly, young children, and persons with compromised immune systems. More serious illnesses such as meningitis, hepatitis, Legionnaires' disease, and myocarditis can also result from exposure to waterborne microbial contaminants (71 FR 65574 at 65576 and 65580).

The potential for illness to arise from fecal pathogen-contaminated ground water is demonstrated by data from the Centers for Disease Control and Prevention (CDC) indicating that GWSs were associated with 68 waterborne disease outbreaks and 10,926 illnesses between 1991 and 2000 (71 FR 65574 at 65576). These 68 outbreaks accounted for 51 percent of waterborne disease outbreaks in the United States from 1991 to 2000. The CDC identified source water contamination and inadequate treatment (or treatment failures) as the likely cause of the outbreaks (71 FR 65574 at 65576).

Ground water may also be contaminated with fecal indicators, such as *E. coli*, enterococci, or coliphage. Such fecal indicators typically are not harmful themselves, but their presence demonstrates that there is a pathway for pathogenic enteric viruses (e.g., echovirus, Coxsackie viruses, hepatitis A and E viruses, rotavirus, and noroviruses) and pathogenic enteric bacteria (e.g., *Salmonella*, *Shigella*, *Vibrio cholerae*, and pathogenic strains of *E. coli*) to enter ground water sources (71 FR 65574 at 65576).

In the GWR, EPA reviewed studies that showed the presence of fecal indicators or viral pathogens in dozens of public ground water wells (71 FR 65574 at 65576 and 65583). For example, analysis by EPA of a subset of 15 studies found that approximately 26 percent of the wells included in the studies sometimes have fecal contamination, as indicated by *E. coli*, and approximately 27 percent of the wells sometimes have viral contamination, as indicated by enterovirus (71 FR 65574 at 65583 through 65584).

In the GWR, EPA identified different pathways by which fecal contamination may reach ground water sources. One pathway involves travel through the subsurface to the intake zone of a ground water source, with movement being more likely through materials such as karst, gravel, or fractured bedrock. Potential sources of subsurface fecal contamination include improperly stored or managed manure, runoff from land-applied manure, leaking sewer lines, or failed septic systems (71 FR 65574 at 65581). A second pathway is for fecal contamination from the surface to enter a well along the casing or through cracks in the sanitary seal if the well is not properly constructed, protected, or maintained (71 FR 65574 at 65581).

EPA has found that existing regulatory provisions for GWSs do not adequately address the potential for fecal contamination of ground water sources. Prior to the GWR, there were no Federal regulations requiring monitoring or disinfection of ground water sources or requiring corrective action when fecal contamination or a risk of fecal contamination is found (71 FR 65574 at 65576).

Based on data from ground water-related outbreaks, the occurrence of fecal indicators in ground water sources, and the lack of regulations addressing fecal contamination of ground water sources, EPA concluded that the GWR is necessary to protect public health from potential exposure to bacterial and viral pathogens in fecally contaminated or at-risk ground water sources (71 FR 65574 at 65576).

EPA uses what that agency referred to as a ''risk-targeted'' approach in the GWR to identify public drinking-water GWSs susceptible to fecal contamination and to target those systems that must take corrective action to protect public health. EPA requirements include the following (71 FR 65574 at 65577):

A. Sanitary Surveys

Under the GWR, EPA, or States with primacy[1] for enforcing EPA's regulations, are required to perform regular comprehensive sanitary surveys[2] of up to eight components of GWSs: (1) Source; (2) treatment; (3) distribution system; (4) finished water storage; (5) pumps, pump facilities, and controls; (6) monitoring, reporting, and data verification; (7) system management and operation; and (8) operator compliance with State requirements (71 FR 65574 at 65577 and 65586 through 65587). These requirements are codified at 40 CFR 141.401. The purpose of the surveys is to identify ''significant deficiencies'' that are causing or could cause the introduction of contamination into water delivered to consumers. Examples of significant deficiencies related to water sources for GWSs include the following: (1) A well near a source of fecal contamination, such as a failing septic system or a leaking sewer line; (2) a well in a flood zone; (3) an improperly constructed well (e.g., improper surface or subsurface seal); and (4) spring boxes that are poorly constructed and/or subject to flooding. Examples of significant deficiencies related to treatment and finished water storage include inadequate treatment process monitoring and inadequate internal cleaning and maintenance of storage tanks (71 FR 65574 at 65587).

States with primacy must conduct initial sanitary surveys of GWSs by December 31, 2012, or December 31, 2014, depending on the type of GWS and whether certain performance criteria are met,[3] and repeat those surveys every 3 or 5 years, depending on the type of GWS and performance history. GWSs must correct significant

[1] The term ''primacy'' refers to EPA granting a State primary enforcement responsibility for NPDWRs after determining that the State had adopted regulations that are no less stringent than EPA's. *See* 71 FR 65574 at 65579.

[2] For purposes of the EPA GWR, a ''sanitary survey, as conducted by the State, includes but is not limited to, an onsite review of the water source(s) (identifying sources of contamination by using results of source water assessments or other relevant information where available), facilities, equipment, operation, maintenance, and monitoring compliance of a public water system to evaluate the adequacy of the system, its sources and operations and the distribution of safe drinking water.'' *See* 40 CFR 141.401(b).

[3] States are required to complete the initial sanitary survey cycle for community water systems (CWSs) by December 31, 2012 (except those CWSs that meet certain performance criteria), or by December 31, 2014, in the case of all noncommunity water systems (NCWSs) and CWSs that meet certain performance criteria (71 FR 65574 at 65586).

deficiencies identified in the surveys within 120 days of State notification (or be in compliance with a State-approved corrective action plan and schedule). Systems that fail to make corrections will be in violation of treatment technique requirements. GWSs must also notify customers of uncorrected significant deficiencies and timelines for correction (71 FR 65574 at 65586 through 65587).

B. Triggered Source Water Monitoring

Triggered source water monitoring is followup monitoring for fecal indicators in source water that occurs when total coliforms are found in distribution systems. The GWR requires GWSs to conduct triggered source water monitoring within 24 hours of receiving notification that a routine monitoring sample collected under the Total Coliform Rule (TCR)[4] is total coliform-positive. Triggered source water monitoring consists of testing at least one ground water sample from each ground water source in use at the time the TCR-positive sample was collected for a fecal indicator. If a triggered sample is fecal-indicator positive, the GWS must notify the State and the public. Unless directed by the State to take immediate corrective action, the GWS then must collect five additional source water samples from the site that tested positive within 24 hours for testing for the same fecal indicator. If any of the five additional samples tests positive for the fecal indicator, the GWS must notify the State and the public and comply with treatment technique requirements (71 FR 65574 at 65577 and 65590 through 65594). The GWR requires States to designate one of three EPA-approved fecal indicators for each GWS: *E. coli*, enterococci, or coliphage. EPA also has approved seven methods for *E. coli* testing, three methods for enterococci, and two methods for coliphage, and specified a minimum 100-milliliter (mL) sample volume (71 FR 65574 at 65597).

The GWR provides exemptions from triggered source water monitoring for systems providing at least 4-log treatment of viruses or when samples are either invalidated or determined to be related to distribution system contamination. The GWR also establishes criteria for representative source water monitoring for GWSs with multiple sources and triggered source monitoring requirements for GWSs that purchase or sell finished drinking water (71 FR 65574 at 65592). The requirements for triggered source water monitoring are codified at 40 CFR 141.402 of EPA's regulations.

C. Assessment Source Water Monitoring

The GWR provides States with the option of requiring GWSs at higher risk of fecal contamination to conduct more stringent assessment source water monitoring. Although the exact monitoring scheme is left to the State, EPA recommends collecting and analyzing a minimum of 12 ground water samples representing each month the system is providing water. The fecal indicators and approved methods for assessment monitoring are the same as for triggered source water monitoring (71 FR 65574 at 65594 through 65597). (See 40 CFR 141.402(b) of EPA's regulations.)

D. Corrective Action Treatment Technique Requirements

Under the GWR, GWSs are subject to treatment technique requirements to address significant deficiencies identified during sanitary surveys or during monitoring (i.e., fecal contamination in ground water). When a GWS receives notice of a significant deficiency or a fecal indicator-positive sample, the GWS must consult with the State to develop a corrective action schedule within 30 days and complete the State-approved corrective actions within 120 days (or within the timeline approved by the State) (71 FR 65574 at 65601 through 65602).

Corrective action options allowed under the GWR include: (1) Correct significant deficiencies (e.g., repair well pads and sanitary seals), (2) use an alternate water source, (3) eliminate the source of contamination (e.g., provide or fix fencing or housing of wellhead, redirect drainage and runoff), and (4) provide treatment that reliably achieves at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) (71 FR 65574 at 65602). (See 40 CFR 141.403(a) of EPA's regulations.)

E. Compliance Monitoring for 4-Log Viral Disinfection

The GWR establishes compliance monitoring requirements for GWSs that use at least 4-log disinfection treatment of viruses as a corrective action or as an alternative to triggered source water monitoring. GWSs using chemical disinfection must maintain a State-approved residual disinfectant concentration every day the GWS provides water from the source, with exact monitoring requirements depending on system size. If disinfectant concentrations fall below levels required for 4-log viral inactivation for more than 4 hours, the systems will incur a treatment technique violation (71 FR 65574 at 65602). Likewise, systems that use membrane technologies or alternative treatment technologies (such as ultraviolet radiation) for disinfection must meet State requirements for maintaining, operating, and monitoring these technologies. Systems that fail to meet State operation or integrity requirements must correct the problem within 4 hours or be in violation of treatment technique requirements (71 FR 65574 at 65602 through 65603). (See 40 CFR 141.403(b) and 141.404 of EPA's regulations.)

F. Public Notification Requirements

The GWR requires GWSs to notify the public if monitoring samples are positive for a fecal indicator, if the GWSs fail to take required corrective actions or follow a State-approved corrective action plan and schedule, or if they fail to maintain 4-log treatment of viruses when they have elected to provide 4-log treatment in lieu of triggered source water monitoring. In addition, GWSs must notify the public if they fail to conduct source water monitoring or if they fail to conduct monitoring to demonstrate compliance with the 4-log disinfection treatment requirement (71 FR 65574 at 65607). (*See also* 40 CFR 141.402(g), 141.403(d), and 141.404(d) of EPA's regulations.) Depending on how soon they take corrective actions, GWSs may also be required to provide annual notice of uncorrected significant deficiencies or fecal-indicator positive source water samples in annual Consumer Confidence Reports or in annual public notices (71 FR 65574 at 65608). (See 40 CFR 141.403(a)(7) of EPA's regulations.)

G. Reporting and Recordkeeping Requirements

The GWR also introduces new reporting and recordkeeping requirements for GWSs. New reporting requirements for GWSs include: Reporting completion of corrective actions, reporting failure to meet disinfection compliance requirements for more than 4 hours, and submitting documentation of findings that total coliform positive samples result from distribution system conditions rather than from source water contamination (71 FR 65574 at 65610). New recordkeeping requirements for GWSs include maintaining documentation of

[4] In the Total Coliform Rule (54 FR 27544, June 29, 1989), EPA set both health goals (maximum contaminant level goals or MCLGs) and legal limits (MCLs) for the presence of total coliform in drinking water. The rule also details the type and frequency of testing that water systems must undertake. The rule applies to all PWSs.

the following items: Corrective actions, GWR-related public notices, determinations that total coliform positive samples result from distribution system conditions, disinfection compliance monitoring records, and notifications of TCR-positive samples by systems that sell water to other systems (71 FR 65574 at 65610). The GWR also establishes new reporting, recordkeeping, and primacy requirements that States must meet to assume and maintain enforcement primacy for their PWSs (71 FR 65574 at 65610). (*See* 40 CFR 141.405 of EPA's regulations.)

H. Effective Date of the GWR

The compliance date for triggered source water monitoring, compliance monitoring, and treatment technique requirements for GWSs under the GWR is December 1, 2009 (71 FR 65574 at 65577 through 65578). States with primacy for enforcing EPA's regulations have until December 31, 2012, to complete the initial sanitary survey cycle for community water systems (CWSs), except those that meet certain performance criteria, and until December 31, 2014, to complete the initial sanitary survey cycle for all noncommunity water systems (NCWSs) and CWSs that meet certain performance criteria (71 FR 65574 at 65586 through 65587).

III. FDA Standards

Under section 410(b)(1) of the act, not later than 180 days before the effective date (EPA compliance date) of an NPDWR issued by EPA for a contaminant under section 1412 of the SDWA (42 U.S.C. 300g–1), FDA is required to issue a standard of quality regulation for that contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in PWSs but not in water used for bottled water. Section 410(b)(3) of the act requires the standard of quality for a contaminant in bottled water to be no less stringent than EPA's MCL and no less protective of the public health than EPA's treatment technique requirements for the same contaminant. The effective date for any such standard of quality regulation is to be the same as the effective date of the NPDWR. If FDA fails to take any action within the prescribed time period in response to the NPDWR issued by EPA, then section 410(b)(4)(A) of the act provides that EPA's NPDWR will apply to bottled water. In addition, section 410(b)(2) of the act provides that a standard of quality regulation issued by FDA shall include monitoring requirements that the agency determines to be appropriate for bottled water.

A. Standard of Quality

Under section 401 of the act (21 U.S.C. 341), the agency may issue a regulation establishing a standard of quality for a food under its common or usual name, when in the judgment of the Secretary of Health and Human Services ''such action will promote honesty and fair dealing in the interest of consumers.'' On November 26, 1973 (38 FR 32558), FDA established a standard of quality for bottled water that now is set forth in § 165.110(b).

Manufacturers of bottled water are responsible for ensuring, through appropriate manufacturing techniques and sufficient quality control procedures, that all bottled water products introduced or delivered for introduction into interstate commerce comply with the standard of quality (§ 165.110(b)). Bottled water that is of a quality below the prescribed standard is required by § 165.110(c) to be labeled with a statement of substandard quality or it is deemed misbranded under section 403(h)(1) of the act (21 U.S.C. 343(h)(1)). FDA notes that a statement of substandard quality only prevents bottled water that exceeds an allowable level for a contaminant from being misbranded with regard to that contaminant; it does not prevent the water from being adulterated or otherwise misbranded. This is reflected in FDA's general food standards which state in relevant part that ''[n]o provision of any regulation prescribing a * * * standard of quality * * * shall be construed as in any way affecting the concurrent applicability of the general provisions of the act and the regulations thereunder relating to adulteration and misbranding'' (21 CFR 130.3(c)). In addition, for purposes of emphasis, the regulations currently provide that any bottled water containing a substance at a level that causes the food to be adulterated under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)) is subject to regulatory action, even if the bottled water bears a label statement of substandard quality (§ 165.110(d)).

FDA has in the past most often fulfilled its obligation under section 410 of the act to respond to EPA's issuance of NPDWRs by amending the standard of quality regulations for bottled water to maintain compatibility with EPA's drinking water regulations (e.g., most recently by lowering the allowable level for arsenic (70 FR 33694, June 9, 2005)). In these rules, FDA has found that the relevant EPA standards for particular contaminants in drinking water were generally appropriate as allowable levels for contaminants in the standard of quality for bottled water when bottled water may be expected to contain the same contaminants. Further, because bottled water is increasingly used in some households as a replacement for tap water, consumption patterns considered by EPA for tap water can be used as an estimate for the maximum expected consumption of bottled water by some individuals.

B. Microbiological Quality Standard

Under the current standard of quality for bottled water, as set forth in § 165.110(b)(2), bottled water must meet one of the following standards of microbiological quality: (1) By the multiple-tube fermentation (MTF) method, not more than one of the analytical units in the sample shall have a most probable number (MPN) of 2.2 or more coliform organisms per 100 mL and no analytical unit shall have an MPN of 9.2 or more coliform organisms per 100 mL; or (2) by the membrane filter (MF) method, not more than one of the analytical units in the sample shall have 4.0 or more coliform organisms per 100 mL and the arithmetic mean of the coliform density of the sample shall not exceed one coliform organism per 100 mL.

C. Current Good Manufacturing Practices

FDA has established CGMP regulations for bottled water in part 129. The CGMPs address source approval, plant construction and design, sanitary facilities and operations, equipment, and production and process controls. Under § 129.35(a)(3)(i), source water obtained from other than a PWS is to be sampled and analyzed for microbiological contaminants at least once each week. To ensure that a plant's production complies with applicable standards, including the standard of quality for bottled water products in § 165.110(b), § 129.80(g)(1) of the CGMP regulations requires bacteriological analysis by the plant, at least once a week, of a representative sample from a batch or segment of a continuous production run for each type of bottled water produced during a day's production. In addition, the CGMPs require maintenance of testing records for 2 years (§ 129.80(g)(3) and (h)).

IV. FDA Proposal

A. Proposed Changes

Ground water is the source water for approximately 70 to 75 percent of U.S. bottled water products (Ref. 1). As a result, the potential for fecal

contamination addressed in the EPA GWR also exists for ground water sources used for bottled water. The potential also exists for bottled water products from ground water sources to be contaminated during processing and for bottled water products from other sources to be contaminated from source water or during processing. Therefore, FDA is proposing to require that source water currently subject to weekly microbiological testing be analyzed specifically for total coliform, as is currently required for finished bottled water products. Further, FDA is proposing that if any coliform organisms are detected in source water or in finished bottled water products, bottled water manufacturers would be required to test for *E. coli*, an indicator of fecal contamination. FDA tentatively concludes that the proposed requirements, as discussed in the following paragraphs, would help ensure that bottled water is subject to requirements no less protective of the public health than the treatment techniques adopted by EPA in the GWR for public drinking water.

1. Finished Bottled Water Testing

The bottled water CGMP regulations contain compliance procedures (§ 129.80(g)) that require that bottlers test a representative sample of finished bottled water at least once a week for bacteriological purposes. The bottled water standard of quality regulations establish allowable levels for total coliform in finished bottled water products (§ 165.110(b)(2)). FDA is proposing that if the total coliform test in finished bottled water products is positive (i.e., even if below the allowable levels for total coliform), bottlers would be required to test for *E. coli*. FDA is proposing to use the presence of any coliform as a trigger for *E. coli* testing, rather than the allowable levels in § 165.110(b)(2), because the presence of any amount of total coliform indicates the potential for fecal contamination. This is consistent with EPA's approach to triggered testing in the GWR. As discussed further in the legal authority section of this document, if bottled water products test positive for *E. coli*, the products would be deemed adulterated under section 402(a)(3) of the act.

2. Source Water Testing

The bottled water CGMPs (§ 129.35(a)(3)) require that bottlers conduct microbiological tests of source water obtained from other than a PWS at least once a week, but do not specify the type of testing (i.e., for what organism) or an allowable level of microbiological contamination. FDA is proposing that bottlers that obtain their water from other than a PWS test their source water at least once a week for total coliform and, if any coliform organisms are detected, that they conduct followup testing for *E. coli*. (PWSs are covered by EPA's GWR and bottlers that obtain their water from a PWS are exempt from source water testing (§ 129.35(a)(3)).) If the followup test is positive for *E. coli*, FDA would consider the source water to be not of a safe, sanitary quality, and therefore its use in bottled water would be prohibited. FDA is proposing to specify that the microbiological testing must be for total coliform to make testing requirements for source and finished bottled water uniform and to remove any uncertainty in the CGMPs about the appropriate microbiological tests for bottlers to conduct. FDA believes that most bottlers currently use total coliform testing to conduct source water tests, as is required for finished product tests in the quality standard. In addition, triggered testing requirements for fecal indicators such as *E. coli* in the EPA GWR are also based on initial total coliform results.

FDA is proposing to require followup source water testing for *E. coli* to increase public health protection by determining whether source water is contaminated and prohibiting use of such water. These requirements would help ensure that bottled water is subject to requirements no less protective of the public health than those applicable to drinking water under the GWR. As noted previously, FDA agrees with EPA's conclusions that ground water sources may be vulnerable to fecal contamination and that such fecal contamination may pose a threat to public health. Based on its concerns, EPA is requiring testing for a fecal indicator (*E. coli*, enterococci, or coliphage) in source water in response to a total coliform positive finding in the distribution system. Similarly, FDA believes that it is appropriate to require *E. coli* testing in response to a total coliform positive finding from weekly source water sampling.

FDA is proposing that source water that tests positive for *E. coli* would not be considered to be of a safe, sanitary quality for bottling, as is required for use in bottled water by § 129.35(a)(1). Therefore, bottlers could not use this water for production of bottled water until they have rectified or otherwise eliminated the source water contamination, and the source water has been retested sufficiently to be considered negative for *E. coli*. FDA is further proposing that a source would be considered negative for *E. coli* after five samples collected from the source over a 24-hour period are tested and found to be *E. coli* negative. FDA solicits comment on alternative criteria for allowing use of source water following an *E. coli* positive test.

This proposal does not include specific requirements regarding how to rectify or otherwise eliminate *E. coli* contamination of source water. Bottlers may wish to consult with States or with EPA, or review EPA guidance (*http://www.epa.gov/safewater/disinfection/gwr/compliancehelp.html*), for advice on how to eliminate sources of contamination.

FDA also did not include a requirement for a sanitary survey in this proposal. First, FDA does not have a primacy program arrangement with the States for conducting sanitary surveys of ground water sources used by bottled water manufacturers, unlike EPA, which has a primacy program with the States under the SDWA for sanitary surveys of ground water sources used by PWSs. Second, the CGMPs for bottled water already require in § 129.35(a)(1) that product water be from an approved source, defined in § 129.3(a) as ''a source of water and the water therefrom, whether it be from a spring, artesian well, drilled well, municipal water supply, or any other source, that has been inspected and the water sampled, analyzed, and found to be of a safe and sanitary quality according to applicable laws and regulations of State and local government agencies having jurisdiction.'' In addition, this proposal requires both weekly source water testing and finished bottled water testing for total coliform, with *E. coli* testing in case of a total coliform positive. In contrast, EPA's GWR, which does require a sanitary survey, does not require source water testing for ground water sources unless total coliform is detected in the distribution system. FDA tentatively concludes that the proposed requirement for weekly source water testing for total coliform (and for *E. coli*, should total coliform be detected) combined with the existing requirement in the CGMPs for source inspection and approval would help ensure that bottled water is subject to requirements no less protective of the public health than those applicable to drinking water under the GWR.

The bottled water CGMPs currently require that bottlers maintain at the plant records regarding any sampling and analysis of source water (§ 129.35(a)(3)(i)), and that such records be maintained at the plant for not less than 2 years (§ 129.80(h)). This requirement would include any records

related to testing and retesting for *E. coli*, in addition to at least weekly testing for total coliform.

FDA also is proposing in § 129.35(a)(3)(i) that bottlers maintain records of corrective measures taken to rectify or otherwise eliminate the cause of *E. coli* contamination in source water. Such records would need to be maintained at the plant for not less than 2 years under § 129.80(h). Examples of appropriate records could include receipts demonstrating that expenses were incurred to have equipment repaired or a memorandum outlining how a source of contamination was identified and removed.

3. Fecal Indicator

Under the GWR, EPA is allowing States with primacy the discretion to designate *E. coli*, enterococci, or coliphage as fecal indicators following a total coliform positive test, noting that the most appropriate indicator, in the context of a PWS, may vary from State to State or site to site (71 FR 65574 at 65597). EPA found that testing for any one of these microorganisms as a single fecal indicator provides a cost-effective means for identifying fecally contaminated wells and protecting public health (71 FR 65574 at 65597). In this proposed rule, FDA is proposing to require a single fecal indicator, *E. coli*, rather than allowing bottlers to choose from among the three fecal indicators identified in the GWR. We believe that requiring that all bottlers test for the same specific fecal indicator will allow FDA to most effectively administer and enforce its bottled water regulations. We have chosen *E. coli* as the appropriate fecal indicator because approved analytical methods for *E. coli* are commercially available, simple, reliable, and inexpensive (see 71 FR 65574 at 65597). We note that EPA believes that *E. coli* will be the fecal indicator most likely designated by States with primacy for implementation of the GWR, because *E. coli* is already used for followup testing under the TCR, and PWSs are familiar with its use and interpretation (71 FR 65574 at 65583).

B. Microbiological Quality Standard

Section 129.80(g) of the bottled water CGMPs contains compliance procedures for the standard of quality in § 165.110(b) and requires that bottlers test a representative sample of each type of bottled drinking water produced during a day's production at least once a week for bacteriological purposes. FDA is proposing that *E. coli* shall not be present in bottled water under a new microbiological quality standard in § 165.110(b)(2)(i)(B). Further, under proposed § 129.80(g)(1), if any coliform organisms are detected in a sample of bottled water, bottled water manufacturers would be required to conduct followup testing for the fecal indicator *E. coli*. If *E. coli* is detected, then the batch or daily production run of bottled water represented by the sample would be deemed adulterated under § 165.110(d) of the bottled water standard, as revised.

This followup testing would help ensure the absence of fecal contamination in finished bottled water products and help ensure that bottled water is subject to requirements no less protective of the public health than those applicable to drinking water.

The requirement for bottled water to meet the allowable level for total coliform in the standard of quality unless the label bears a statement of substandard quality under § 165.110(c) for bottled water would remain. The labeling provision would be relevant if bottled water exceeds the total coliform standard but tests negative for *E. coli*. In contrast, because any *E. coli* in bottled water causes the water to be adulterated, the substandard labeling provision is not relevant for *E. coli*.

FDA is also proposing to revise the adulteration provision in § 165.110(d) to clarify the potential application of section 402(a)(3) of the act to bottled water, in addition to section 402(a)(1) of the act. Current § 165.110(d) provides that bottled water containing a substance injurious to health under section 402(a)(1) of the act is deemed to be adulterated, regardless of whether the bottle bears a label statement of substandard quality prescribed by § 165.110(c). Section 402(a)(3) of the act provides another basis for adulteration if the food item ''consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.'' Section 402(a)(3) would apply, for example, in situations where bottled water is found to be contaminated with *E. coli*. Section 165.110(d) would be revised by adding the phrase ''consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food under section 402(a)(3)'' between the words ''402(a)(1)'' and ''the act.'' To clarify the applicability of § 165.110(d) in cases involving *E. coli*, § 165.110(d) also would be revised by adding the statement: ''If *E. coli* is present in bottled water, then the bottled water will be deemed adulterated under section 402(a)(3) of the act.'' FDA notes that although the regulations as proposed would specifically identify section 402(a)(1) and (a)(3) as applicable to bottled water, other adulteration provisions in section 402 of the act, such as section 402(a)(4) (insanitary conditions) apply as well.

C. CGMP Regulations for Bottled Water

FDA is proposing in § 129.35(a)(3)(i) that bottled water manufacturers that obtain their source water from other than a PWS test their source water at least weekly for total coliform and that they conduct followup testing for *E. coli* when source water is total coliform positive. Further, if source water is found to contain *E. coli*, then the water would not be considered water of a safe, sanitary quality as required by § 129.35(a)(1). To make these changes, FDA would revise the CGMP regulations by replacing the phrase ''microbiological contaminants'' with the phrase ''total coliform'' in the second sentence of § 129.35(a)(3)(i), and by adding the following two sentences to the section: ''If any coliform organisms are detected, followup testing must be conducted to determine whether any of the coliform organisms are *Escherichia coli* * * * Source water found to contain *E. coli* is not considered water of a safe, sanitary quality as required for use in bottled water by paragraph (a)(1) of this section.''

FDA is also proposing that a bottler could not use source water found to contain *E. coli* for production of bottled water until the bottler has rectified or otherwise eliminated the source water contamination, and the source water has been sufficiently retested such that it can be considered negative for *E. coli*. To make these changes, FDA would revise the CGMP regulations by adding the following sentences to § 129.35(a)(3)(i): ''The bottler must take appropriate measures to rectify or otherwise eliminate the cause of *E. coli* contamination in a manner sufficient to prevent its reoccurrence. Source water previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected from the source water supply over a 24-hour period are tested and found to be *E. coli* negative.''

In addition, FDA is also proposing to require that bottlers maintain records of corrective measures taken to rectify or eliminate *E. coli* contamination. To make this change, FDA is revising § 129.35(a)(3)(i) to include ''records describing corrective measures taken in response to a finding of *E. coli*'' among the records required to be maintained on file at bottled water plants. Finally, FDA would revise § 129.35(a)(4)(iv) to include a reference to the potential application of section 402(a)(3) of the act as a basis for adulteration, in

addition to section 402(a)(1), for the reasons discussed previously.

D. Analytical Methods for E. coli Testing

In the GWR, EPA listed numerous analytical methods that it had approved for use by PWSs for monitoring source water for *E. coli*, enterococci, and coliphage. However, FDA is not proposing to adopt new analytical methods or to change the allowable levels or testing requirements for total coliform in the current microbiological standard of quality for bottled water. The MTF and MF methods cited in § 165.110(b)(2) would still be appropriate for total coliform testing. The MTF and MF methods are not presence/absence methods, but allow enumeration of total coliform levels, unlike some of the methods approved by EPA in the GWR. The MTF and MF methods also can be used for followup *E. coli* testing, if needed. Therefore, FDA is proposing to cite the existing MTF and MF methods for both total coliform and *E. coli* testing in the new § 165.110(b)(2)(ii). FDA notes that bottlers can use different methods approved by the government agency or agencies having jurisdiction, if they desire. However, FDA will use the MTF and MF methods when it tests products and bottlers that want to use different methods must ensure that their methods give comparable results.

E. Monitoring and Recordkeeping Provisions of CGMP Regulations for Bottled Water

Under proposed § 129.35(a)(3)(i) in the CGMP regulations, all source waters other than from a PWS would have to be analyzed by bottled water plants for total coliform at least once each week. Bottlers would also be required to test for *E. coli*, if any coliform organisms are detected in the source water. If *E. coli* is detected in the source water, bottlers would also be required to rectify or otherwise eliminate the source water contamination and subsequently retest for *E. coli*. In addition, under proposed § 129.80(g)(1) in the CGMP regulations, bottlers would have to test finished products for total coliform at least once a week, and for *E. coli*, if any coliform organisms are detected in the finished bottled water.

Section 129.80(h) of the CGMP regulations currently provides that all records required under part 129 shall be maintained at the plant for not less than 2 years and shall be available for official review at reasonable times. The required records include records of analytical results for microbiological tests of both source and finished bottled water. Section 129.80(h) would apply to the new testing requirements for total coliform and *E. coli* for source water and finished bottled water, as well as new recordkeeping relating to measures taken to rectify or otherwise eliminate source water contamination, as discussed previously.

V. Legal Authority

FDA is proposing changes to both the bottled water standard (§ 165.110) and the bottled water CGMP regulations (part 129). The proposed microbiological quality standard for *E. coli* in finished water is authorized under sections 401 and 410 of the act. Section 401 of the act explicitly provides for the issuance of standards of quality. Further, section 410(b)(1) of the act requires that not later than 180 days before the effective date of an NPDWR issued by EPA for a contaminant under section 1412 of the SDWA (42 U.S.C. 300g–1), FDA is required to issue a standard of quality regulation for that contaminant in bottled water, or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in PWSs but not in water used for bottled water.

Section 410(b)(3) of the act requires the standard of quality for a contaminant in bottled water to be no less stringent than EPA's MCL and no less protective of the public health than EPA's treatment technique requirements for the same contaminant. In addition, section 410(b)(2) of the act provides that a standard of quality regulation issued by FDA shall include monitoring requirements that the agency determines to be appropriate for bottled water.

On November 8, 2006, EPA published an NPDWR to provide for increased protection against fecal microbiological pathogens in PWSs that use ground water sources. FDA tentatively concludes that this proposed rule, if finalized, will ensure that FDA's standards for the minimum quality of bottled water, as affected by fecal contamination, will be no less protective of the public health than those set by the EPA for public drinking water.

FDA is proposing to revise § 165.110(d), *Adulteration*, of the bottled water standard to provide that bottled water containing *E. coli* is deemed to be adulterated under section 402(a)(3) of the act. Under section 402(a)(3), a food is deemed adulterated if ''it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.'' As EPA recognized in its GWR, water that contains *E. coli* is fecally contaminated. Such water consists in part of a ''filthy'' or ''putrid'' substance under section 402(a)(3) of the act. Therefore, if bottled water products test positive for *E. coli*, the products would be adulterated under section 402(a)(3) of the act.

In addition to the change to the bottled water standard, FDA is proposing to amend the bottled water CGMP regulations. FDA is proposing to amend the current requirement in § 129.35(a)(3)(i) of the CGMP regulations to test source water obtained from other than a PWS for microbiological contaminants to specifically identify total coliform as the contaminant subject to mandatory testing. Such testing for total coliform is currently required for finished bottled water by § 129.80(g). The presence of any coliform indicates that the water may contain *E. coli*, an indicator of fecal contamination. Therefore, if either source water or finished water tests positive for total coliform, FDA is proposing to require that the water be tested for *E. coli* (under proposed § 129.35(a)(3)(i) for source water and under proposed § 129.80(g)(1) for finished bottled water) to determine whether it is fecally contaminated. Source water that is fecally contaminated would not be considered water of a safe, sanitary quality under the CGMPs, and therefore its use in bottled water would be prohibited. Finished bottled water that is fecally contaminated would be deemed adulterated under section 402(a)(3), as reflected in proposed § 165.110(d) of the bottled water standard.

After testing indicates that source water is fecally contaminated, FDA is proposing to require that bottlers could not use this water for production of bottled water until they have rectified or otherwise eliminated the source water contamination, and the source water has been retested sufficiently to be considered negative for *E. coli*. FDA is further proposing that a source would be considered negative for *E. coli* after five samples collected from the source over a 24-hour period are tested and found to be *E. coli* negative. Failure to remedy the cause of the contamination would create the possibility of future contamination from the same cause.

FDA's legal authority for these proposed requirements is based on the act's adulteration provisions in section 402(a)(3) and (a)(4), and under section 701(a) of the act (21 U.S.C. 371(a)). As described previously, water containing *E. coli* consists in part of a ''filthy'' or ''putrid'' substance under section 402(a)(3) and is therefore adulterated under section 402(a)(3). Under section 402(a)(4) of the act, a food is adulterated ''if it has been 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.'' Failure to ensure the water is prepared, packed, and held under conditions in which water does not become fecally contaminated constitutes an insanitary condition and thus renders the water adulterated under section 402(a)(4) of the act. Under section 701(a) of the act, FDA is authorized to issue regulations for the efficient enforcement of the act. A regulation that requires measures to prevent bottled water from consisting in part of filth and from being prepared, packed, and held under insanitary conditions allows for the efficient enforcement of the act.

FDA's proposal includes a requirement that bottlers maintain records of measures taken to address a positive *E. coli* finding in source water. Records of corrective measures are needed for FDA to determine compliance with the rule's requirement that bottlers take appropriate measures to rectify or otherwise eliminate the cause of *E. coli* contamination in source water. Records would provide assurance to both the bottler and FDA that the risk of water becoming fecally contaminated is being minimized. Failure to take and document these measures would result in a bottler producing water under insanitary conditions whereby the water may become contaminated with filth under section 402(a)(4) of the act.

VI. Environmental Impact Analysis

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Executive Order 12866 and Regulatory Flexibility Act

A. Preliminary Economic Impact Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency tentatively concludes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the costs per entity of this rule are small, the agency tentatively concludes that the proposed rule will not have a significant economic impact on a substantial number of small entities. FDA requests comment on the impact of this rule on small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

1. Need for Regulation

EPA published the GWR, in part, because data indicated that GWSs are susceptible to fecal contamination. Prior to the GWR, there were no Federal regulations requiring monitoring or disinfection of ground water sources or requiring corrective action when fecal contamination or a risk of fecal contamination is found. The GWR puts in place a regulatory process, including treatment techniques, to identify and target GWSs that are susceptible to fecal contamination, and to require higher risk GWSs to monitor and, when necessary, take corrective action. Under section 410 of the act, FDA is required to respond to the GWR published by EPA by issuing its own standard of quality regulation for bottled water that is no less protective of the public health than the treatment techniques adopted by EPA in the GWR, unless it makes a finding that such additional regulations are not necessary to protect the public health. As noted previously, if FDA fails to take action within the prescribed time period in response to the GWR, then under section 410(b)(4)(A) of the act, EPA's GWR will apply to bottled water. Further, section 410(b)(2) of the act requires that a standard of quality regulation issued by FDA shall include monitoring requirements that the agency determines to be appropriate for bottled water.

EPA determined that there is the potential for ground water to be contaminated with pathogenic bacteria or viruses, or both, and that the presence of fecal indicators can demonstrate a pathway for pathogenic enteric bacteria and viruses to enter GWSs. Ground water sources supply water for 70 to 75 percent of all U.S. bottled water products (Ref. 1). Based on EPA's findings in the GWR, FDA tentatively concludes that the potential for fecal contamination that exists for PWS ground water sources regulated by EPA's GWR also exists for bottled water using ground water sources. The potential also exists for bottled water products from ground water sources to be contaminated during processing and for bottled water products from other sources to be contaminated from source water or during processing.

Dun's Market Identifiers database lists 378 U.S. establishments under North American Industry Classification System (NAICS) code 312112 Bottled Water Manufacturing (69 FR 70082 at 70084, December 2, 2004). These 378 establishments correspond to 318 firms. Because a firm may own more than one establishment and each establishment may be a source, a bottling plant or both, this analysis will assume that each establishment corresponds to one source. Foreign bottled water establishments that produce and export their bottled water products for consumption in the United States will have to meet the same FDA requirements as domestic establishments. FDA is aware of at least 35 major brands of bottled water that are imported into the United States. When sales of a particular brand constitute a significant portion of the market share for this industry, then the brand is considered a major brand. If each imported brand corresponds to one foreign establishment, then an additional 35 foreign establishments will also be affected, giving a total of 413 establishments covered by this rule (Ref. 2). Because FDA assumes that each establishment is equivalent to a single water source, we estimate that 413 bottlers, both domestic and foreign, will be covered by our proposed regulation. FDA asks for comments on these estimates.

2. Regulatory Options

FDA evaluates three regulatory options in this analysis:

Option 1. Take no action. If FDA fails to issue a standard of quality regulation or make a finding that such a regulation is not necessary to protect the public

health, then EPA's GWR will apply to bottled water.

Option 2. Issue the regulations in this proposed rule, as outlined in Option 3, but remove the existing exemption for weekly microbiological testing of source water from PWSs.

Option 3. Issue the regulations in this proposed rule. FDA is proposing to require that source water currently subject to weekly microbiological testing be analyzed specifically for total coliform and if any coliform organisms are detected in source water or in finished bottled water products, then bottled water manufacturers would be required to test for *E. coli*. Source water containing *E. coli* would not be considered to be of a safe, sanitary quality and would be prohibited from use in the production of bottled water until the bottler has taken appropriate measures (as evidenced by records) to rectify or otherwise eliminate the cause of the contamination. Source water previously found to contain *E. coli* would be considered negative for *E. coli* after five samples collected from the source water supply over a 24-hour period are tested and found to be *E. coli* negative. Finished bottled water products containing *E. coli* will be deemed adulterated.

Costs and Benefits of Options

Option 1. Take no action. If FDA does not issue a regulation by the statutory deadline, EPA's GWR for drinking water would become applicable to bottled water. EPA's GWR is designed for PWSs, which differ in significant ways from bottled water plants. Some of its provisions, such as those that address public water distribution systems, cannot be applied literally to bottled water plants, which do not have such distribution systems. Accordingly, FDA believes that Option 1 is not efficient and therefore less desirable than the proposed option.

Option 2. Change the testing requirements for source water and finished bottled water products to include total coliform testing of source water for all bottlers (i.e., remove the existing exemption for weekly microbiological testing of source water from PWSs) and require followup testing for *E. coli* when total coliform positives occur.

Bottlers that obtain their water from PWSs are not required to conduct microbiological testing of their source water under the CGMPs (21 CFR 129.35(a)(3)(i)). FDA considered removing this exemption. This would have the advantage of requiring all bottlers to conduct the same tests (i.e., to test their source water for total coliform) and to conduct followup testing for *E. coli* when total coliform positives occur. However, removing the exemption for weekly microbiological testing of source water would be inefficient because PWSs are already covered by EPA drinking water regulations, including the GWR.

Option 3. FDA's proposed action. Each requirement of FDA's proposed action will be evaluated separately in the following order:

1. Require that source water currently subject to weekly microbiological testing be analyzed specifically for total coliform;

2. Require followup testing for *E. coli* when total coliform positives occur in source water or finished bottled water products; and

3. Require bottlers, in the event the source water tests positive for *E. coli*, to rectify or otherwise eliminate the cause of contamination (as evidenced by records), and then retest the source water sufficiently until it is considered negative for *E. coli*. Finished bottled water products that test positive for *E. coli* will be deemed adulterated.

Option 3 Explained

1. Require that source water currently subject to weekly microbiological testing be analyzed specifically for total coliform.

The bottled water CGMPs at § 129.35(a)(3)(i) require that bottlers that obtain source water from other than a PWS conduct microbiological tests at least once a week. The CGMPs do not specify what organism to test for or the allowable level of bacterial contamination. FDA is now proposing to specify that bottlers that obtain their water from other than a PWS must test their source water at least once a week for total coliform. FDA expects that most bottlers currently use total coliform testing to conduct these microbiological tests. For example, the Model Code of the International Bottled Water Association (IBWA), a trade association representing a large segment of the bottled water industry, requires total coliform testing of source water (Ref. 3). Furthermore, the 35 foreign producers mentioned in this analysis are members of IBWA. Because microbiological testing is already a requirement of the existing CGMPs and total coliform testing is a widely used test for microbiological quality of water, and also because producers are already required to test for total coliform in finished products, FDA expects that the number of establishments affected by this requirement will be negligible and no additional costs are estimated for this provision.

2. Require followup testing for *E. coli* when total coliform positives occur in source water or finished bottled water products.

As noted previously, FDA proposes to require that bottlers that obtain their water from other than a PWS test their source water at least weekly for total coliform. Finished water products are already required to be tested for total coliform under the existing CGMPs. FDA is now proposing that if any coliform organisms are detected in source water or in finished water products, then the bottler must conduct followup testing for *E. coli*. The presence of any coliform indicates that the water may contain *E. coli*, an indicator of fecal contamination. Further, FDA agrees with EPA's conclusions that ground water sources may be vulnerable to fecal contamination and that such fecal contamination may pose a threat to health. Because ground water is the source water for approximately 75 percent of U.S. bottled water products, the potential for fecal contamination also exists for ground water sources used for bottled water. The potential also exists for finished bottled water products, whether from ground water sources or from other sources such as PWSs, to be contaminated during processing. FDA has determined that it is appropriate to require *E. coli* testing in response to a total coliform positive finding from weekly source and finished bottled water sampling. In this proposal, FDA estimates the costs of *E. coli* testing resulting from a total coliform positive. The estimated costs are based on the probability that the source water or a finished product will test positive for total coliform during any given year.

3. Require bottlers, in the event the source water tests positive for *E. coli*, to rectify or otherwise eliminate the cause of contamination (as evidenced by records), and then retest the source water sufficiently until it is considered negative for *E. coli*. Finished bottled water products that test positive for *E. coli* will be deemed adulterated.

If source water tests positive for *E. coli*, this cost model assumes that bottlers will respond by taking action to rectify or eliminate the source water contamination, by keeping records of those actions, and by retesting the source water sufficiently until it is considered negative for *E. coli*. The source water would be considered negative for *E. coli* after five samples collected from the source over a 24-hour period are tested and found to be *E. coli* negative.

Finished bottled water products that test positive for *E. coli* will be deemed

adulterated under section 402(a)(3) of the act and revised § 165.110(d) of the regulations. Costs to rectify or otherwise eliminate the cause of contamination in finished bottled water products are not estimated in this analysis.

Per Sample Testing Costs for E. coli

For purposes of this analysis, FDA assumes that 75 percent of domestic bottled water establishments obtain their water directly from sources other than a PWS ((66 FR 35439 at 35440, July 5, 2001) and (Ref. 1)) and that the other 25 percent obtain their water from PWSs. FDA is assuming that all 35 foreign producers that export bottled water to the United States obtain their water from other than a PWS and are currently testing their sources for total coliform. As mentioned previously, FDA assumes that for all domestic and foreign producers, one establishment corresponds to one source. Thus, an estimated 284 (75 percent) of 378 domestic establishments and all 35 foreign bottled water establishments (284 + 35 = 319) whose products are consumed in the United States obtain their water from other than a PWS and are already conducting total coliform testing of their source water. And approximately 25 percent of the estimated total of 378 domestic bottled water establishments (approximately 95) obtains their water from a PWS.

Table 1 of this document covers *E. coli* testing costs per sample. The estimates of the laboratory fees and testing costs are derived from the GWR (Ref. 4). EPA estimated the national average testing costs per sample for *E. coli* based on 25 to 100 tests conducted annually. The estimated costs per sample can vary depending if the test is conducted in-house or at a commercial laboratory.

TABLE 1—*E. coli* TESTING COSTS PER SAMPLE

Laboratory Type	Hourly Labor Cost	Labor Hours for Sample Collection	Cost of Sample Collection	Labor Hours for Sample Analysis	Analysis Materials	Per Sample Analysis Cost	Total Costs per Sample
In-house	$ 21.44	.5	$ 10.72	.5	$ 8.95	$ 19.67	$ 30.39
Commercial	$ 21.44	.5	$ 10.72	0	$ 74.80	$ 74.80	$ 85.52

For in-house laboratories, the laboratory materials cost per sample is estimated to be $8.95 and the labor cost to be $21.44 for one labor hour per sample (one half hour for collecting and handling the sample and another half hour for conducting the analysis). For an independent commercial laboratory analysis, the test cost per sample would include a shipping and commercial analysis fee of $74.80 and a labor cost of one half hour to collect the sample and arrange for delivery to the laboratory.

FDA is not aware of how many potentially affected establishments will either use in-house testing facilities or outsource testing to commercial laboratories. For the purpose of this analysis, FDA assumes that all large bottlers will use in-house testing facilities and that either 50 percent (low cost assumption) or 100 percent (high cost assumption) of small bottled water establishments will outsource their testing. According to the Small Business Administration's definition of small business for this industry, about 82 percent of bottled water establishments are defined as small (69 FR 70082 at 70088, December 2, 2004). This may overestimate the number of bottlers that will outsource testing and thus may overestimate the cost of the rule. FDA requests comment on this assumption.

Table 2 of this document shows the breakdown of bottlers by the low-cost and high-cost testing models, based on laboratory choice and an 82 percent small business rate. For the 319 bottlers using other than a PWS source, either 188 bottlers (59 percent) will use in-house testing facilities and 131 bottlers (41 percent) will use commercial laboratories or 57 bottlers (18 percent) will use in-house testing facilities and 262 bottlers (82 percent) will use commercial laboratories. For the 95 bottlers using PWS sources, either 56 bottlers (59 percent) will use in-house testing facilities and 39 bottlers (41 percent) will use commercial laboratories or 17 bottlers (18 percent) will use in-house testing facilities and 78 bottlers (82 percent) will use commercial laboratories.

TABLE 2—HIGH COST AND LOW COST ASSUMPTIONS ABOUT THE NUMBER OF BOTTLED WATER ESTABLISHMENTS USING EITHER IN-HOUSE OR COMMERCIAL LABORATORIES

	Number of Bottlers Using Other Than a PWS Source		Number of Bottlers Using a PWS Source	
	Low Cost	High Cost	Low Cost	High Cost
In-house laboratory	188 (59%)	57 (18%)	56 (59%)	17 (18%)
Commercial laboratory	131 (41%)	262 (82%)	39 (41%)	78 (82%)
Total	319	319	95	95

Total Coliform Frequency Estimates

To estimate the number of samples that are likely to test positive for total coliform each year, FDA assumes that the frequency of total coliform positive samples is proportional to EPA's total coliform positive frequency estimates (Ref. 5). FDA requests comments on this assumption.

EPA's total coliform positive frequency estimates are dependent on the probability of a total coliform positive, which is dependent on the annual number of samples tested, which varies by system size. FDA requirements would include at least weekly testing for total coliform in source water and finished products, or at least 52 source samples and 52 finished product samples per year. For example, bottlers whose source is other than a PWS would have to test their source water at least once a week and also their finished

product at least once a week. Bottlers whose source is a PWS are only required to test their finished product. (For this model, FDA assumes that each bottler is testing one type of finished product.) EPA found that the frequency rate for total coliform positives in ground water PWSs testing between 31 and 82 samples for total coliform each year ranged between 0.22 and 3 samples per year per system (Ref. 5). FDA assumes that the same frequency rates are applicable to bottled water plants testing 52 samples a year, thus the expected annual frequency rate of total coliform positive samples per bottled water source is, at most, three per year. FDA further assumes that the annual frequency of a total coliform positive for finished product testing is also, at most, three per bottler. For example, bottlers that are conducting total coliform tests for both their source and finished product can expect to find three total coliform positives from their source and three total coliform positives in their finished product or a total of six total coliform positive samples per year. This means that they will need to conduct six tests for *E. coli* in 1 year. Bottlers whose sources are PWSs and are only required to conduct total coliform tests of their finished products can expect three positive samples per year. Combining this information, table 3 of this document shows *E. coli* testing costs for source water and finished bottled water products.

TABLE 3—COSTS OF TESTING SOURCE WATER AND FINISHED BOTTLED WATER PRODUCTS FOR *E. coli*

		A	B	C	(A X B X 6) + (A X C X 3)
		Cost per sample	Number of Bottlers Testing Both Source and Finished Product (Six Tests/ Year)	Number of Bottlers Testing Only Finished Product (Three Tests/ Year)	Total Annual Costs of *E. coli* Testing
Low cost assumption	In-house laboratory	$30	188	56	$39,000
	Commercial laboratory	$86	131	39	$77,000
Total low cost assumption					$116,000
High cost assumption	In-house laboratory	$30	57	17	$12,000
	Commercial laboratory	$86	262	78	$154,000
Total high cost assumption					$166,000

[1] Estimates are not exact due to rounding.

Source water that tests positive for *E. coli* would not be considered to be of a safe and sanitary quality for bottling, as required in § 129.35(a)(1), and finished products that test positive for *E. coli* would be considered adulterated under section 402(a)(3) of the act and revised § 165.110(d) of the regulations.

A bottler could not use source water found to contain *E. coli* for production of bottled water until the bottler has rectified or otherwise eliminated the source water contamination, and the source water has been sufficiently retested such that it can be considered negative for *E. coli*. Source water previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected from the source water supply over a 24-hour period are tested and found to be *E. coli* negative.

This cost model assumes that bottlers will take action to rectify or eliminate source water contamination based on the first positive *E. coli* sample. Thus, the estimated number of bottlers that will find an *E. coli* positive sample per year will be equal to the estimated number of bottlers that will take action to rectify contamination each year. To estimate the number of establishments that are likely to take action to rectify contamination, FDA relied on EPA's estimate of the percentage of PWSs that use ground water sources with identified deficiencies (Ref. 6). EPA's estimate in turn was based on survey data from the Association of State Drinking Water Administrators (ASDWA 1997). FDA lacks better or more recent data. Establishments that have significant deficiencies or that detect fecal contamination are required to take corrective actions under the GWR. The survey responses indicated that 17 percent of systems had wells that were not constructed according to State regulations. FDA uses this percentage as an estimate of the number of systems that will have an *E. coli* positive result in source or product water over a 25-year period. EPA's cost model assumes deficiencies occur equally beginning in year 4 through 25 (22 years) of the analysis, which translates into 0.77 percent of all GWSs taking a corrective action each year over a 22-year period. Thus, of the 319 bottling establishments that use sources other than PWSs, about 53 (17 percent) are likely to take corrective action as a result of an *E. coli* finding in a 22-year period. This translates to 2.5 bottlers every year. For its analysis, FDA also assumes that each of these 2.5 bottlers will incur an *E. coli* positive finding only once in a given year. Table 4 of this document summarizes these estimates.

TABLE 4—NUMBER OF BOTTLERS THAT INCUR AN *E. coli* POSITIVE IN SOURCE WATER AND MUST RECTIFY CONTAMINATION

Number of bottlers that use sources other than a PWS	319

TABLE 4—NUMBER OF BOTTLERS THAT INCUR AN *E. coli* POSITIVE IN SOURCE WATER AND MUST RECTIFY CONTAMINATION—Continued

Fraction of bottlers with potential source water contamination (17 percent/22 years)	0.0077
Number of bottlers that must rectify contamination each year over a 22-year period	2.5

As stated earlier, source water would be considered negative for *E. coli* after five samples collected from the source over a 24-hour period are tested and found to be negative. Therefore the number of bottlers that will test five more source samples after taking some type of action to rectify contamination is also 2.5. Assuming the retesting is conducted in-house or in a commercial laboratory, total annual costs of retesting five samples for *E. coli* is estimated to be either $380 or $1,069 per year. Table 5 of this document summarizes these estimates.

TABLE 5—TOTAL ANNUAL COSTS OF RETESTING FIVE MORE SAMPLES FOR *E. coli* AFTER A POSITIVE FINDING[1]

	A	B	A X B X 5
	Cost per Sample	Number of Bottlers Re-testing Source Water	Total Annual Costs of Re-testing Five Samples for *E. coli*
In-house laboratory	$30	2.5	$380
Commercial laboratory	$86	2.5	$1,069

[1] Estimates are not exact due to rounding.

Costs to Rectify Source Water Contamination

As noted previously, FDA requires bottlers to rectify or otherwise eliminate the source water contamination. FDA drew on EPA's Economic Impact Analysis of the GWR to provide estimates for costs of rectifying or eliminating contamination. EPA estimated costs using a high and low cost distribution. The low cost scenario assumes a greater percentage (60 percent) of systems with significant deficiencies will have less expensive (low-cost) deficiencies to correct. The high cost scenario assumes a greater percentage of systems will have more expensive (high-cost) deficiencies to correct. EPA provides examples of a low-cost deficiency (replacing a sanitary well seal) and a high-cost deficiency (rehabilitating an existing well). Unit costs for these repairs are based on the Technology and Cost Documents for the Final GWR (Ref. 6) and appear here in table 6 of this document. EPA expects that the costs of these significant deficiencies represent the range of costs that establishments would be expected to incur although there are many other corrective actions that could be taken. For example, drilling a new well or purchasing water from a different supplier could be done but in most cases would probably be more expensive than the options listed earlier.

Based on EPA's assumptions, FDA estimates one-time costs to bottlers of rectifying contamination range from approximately $17,000 to $22,000 each year.

TABLE 6—ESTIMATED ANNUAL COSTS OF RECTIFYING CONTAMINATED SOURCES[1]

Action	Unit cost	Distribution of actions	Number of bottlers that will rectify a contaminated source each year	Total annual costs of rectifying contaminated sources
Replace a sanitary well seal	$3,627	.60	2.5	$5,441
Rehabilitate an existing well	$11,986	.40	2.5	$11,986
Total costs assuming a low-cost distribution (rounding up)				$17,427
Replace a sanitary well seal	$3,627	.40	2.5	$3,627
Rehabilitate an existing well	$11,986	.60	2.5	$17,979
Total costs assuming a high-cost distribution (rounding up)				$21,606

[1] Estimates are not exact due to rounding.

Based on discussions with experts, EPA suggests that still other corrective actions such as fencing off or limiting access to protective wells could actually cost less than the two options listed previously from their model (Ref. 6).

In addition to the costs of a sanitary well or the costs of rehabilitating an existing well, other potential costs could include product loss, temporarily shutting down the operation, or changing to an alternate source. FDA

has not quantified these costs and requests comments.

Recordkeeping Costs

Under this proposed rule, those bottlers that would be required to test their source water and finished bottled water products at least weekly for total coliform (and for *E. coli* if any coliform organisms are detected) would be required to maintain a record of the microbiological test results for at least 2 years under proposed § 129.35(a)(3)(i), as well as current § 129.80(g) and (h) of the CGMP regulations. The current CGMP regulations already reflect the time and associated recordkeeping costs for those bottlers that are required to conduct microbiological testing of their source water, as well as total coliform testing of their finished bottled water products. FDA tentatively concludes that any additional costs in recordkeeping based on the new proposed testing requirements for source water and finished bottled water products would be negligible.

Summary of Costs

Total costs for the proposed action, including the estimated annual costs for *E. coli* testing and for rectifying source water contamination, are shown in tables 7 through 11 of this document. Annual testing costs are estimated as either low or high costs depending on the number of bottlers that use either in-house testing laboratories or outsource testing to commercial laboratories. Costs of rectifying source water contamination are estimated using the low and high cost distribution from EPA's Economic Impact Analysis of the GWR.

FDA estimates that 95 establishments that use PWSs are likely to find a total coliform positive three times a year in their finished product and thus will incur testing costs for *E. coli* three times a year as shown in table 7 of this document. Of the 95 bottlers that use PWS sources in table 7, either 56 bottlers (59 percent) will use in-house testing facilities at $30 per sample and 39 bottlers (41 percent) will use commercial laboratories at $86 per sample totaling approximately $15,000 under the low-cost assumption, or about 17 bottlers (18 percent) will use in-house testing facilities at $30 per sample and 78 bottlers (82 percent) will use commercial laboratories at $86 per sample costing about $21,000 under the high-cost assumption.

TABLE 7—ESTIMATED TOTAL ANNUAL AND DISCOUNTED *E. coli* TESTING COSTS TO BOTTLERS THAT USE PWSS[1]

Total *E. coli* Testing Costs	Annual Costs	Discounted Costs (20 years at 7 percent)
Number of bottlers with PWS source = 95		
Total cost of finished product testing (low-cost assumption)	$15,000	$160,000
Total cost of finished product testing (high-cost assumption)	$21,000	$230,000

[1] Estimates are not exact due to rounding.

FDA estimates that 319 establishments that use sources other than PWSs are likely to find a total coliform positive about six times a year (three times in their source and three times in their finished product) and therefore, will incur testing costs for *E. coli* six times a year as shown in table 8 of this document. Of the 319 bottlers that obtain their water from other than a PWS, 188 bottlers (59 percent) will use in-house testing facilities at $30 per sample and 131 bottlers (41 percent) will use commercial laboratories at $86 per sample totaling approximately $101,000 under the low-cost assumption, and about 57 bottlers (18 percent) will use in-house testing facilities at $30 per sample and 262 bottlers (82 percent) will use commercial laboratories at $86 per sample costing about $145,000 under the high-cost assumption.

TABLE 8—ESTIMATED TOTAL ANNUAL AND DISCOUNTED *E. coli* TESTING COSTS TO BOTTLERS THAT USE SOURCES OTHER THAN PWSS[1]

E. coli Testing Costs	Annual Costs	Discounted Costs (20 years at 7 percent)
Number of bottlers = 319		
Total costs of source and finished product testing (low-cost assumption)	$101,000	$1 million
Total costs of source and finished product testing (high-cost assumption)	$145,000	$1.5 million

[1] Estimates are not exact due to rounding.

Of the 319 establishments that obtain their water from other than a PWS, it is likely that 2.5 establishments will test positive for *E. coli* annually over 22 years and may need to take corrective action and conduct retesting. Estimated costs to rectify the source water contamination using low and high cost assumptions appear in table 9 of this document.

TABLE 9—ESTIMATED TOTAL ANNUAL AND DISCOUNTED COSTS TO RECTIFY CONTAMINATION[1]

Costs to Rectify Contamination	Annual Costs	Discounted Costs (20 years at 7 percent)
Number of bottlers = 2.5		
Total costs to rectify contamination (low cost)	$17,000	$185,000
Total costs to rectify contamination (high cost)	$22,000	$230,000

[1] Estimates are not exact due to rounding.

Retesting costs are shown in table 10 of this document and illustrate costs for bottlers that will use either in-house or commercial laboratories.

TABLE 10—ESTIMATED TOTAL ANNUAL AND DISCOUNTED RETESTING COSTS FOR *E. coli*

Retesting Costs	Annual Costs	Discounted Costs (20 years at 7 percent)
Number of bottlers	2.5	2.5
Total costs of five additional tests if using in-house laboratory	$380	$4,000
Total costs of five additional tests if using commercial laboratory	$1,069	$11,000

Table 11 of this document shows the estimated total annual costs of the proposed rule (Option 3) by adding tables 7, 8, 9, and 10 of this document to be $134,000 (low cost) and $189,000 (high cost). The estimated total discounted or present value costs (using 7 percent interest rate over 20-year period) are $1.4 million (low) and $1.9 million (high).

TABLE 11—ESTIMATED TOTAL ANNUAL AND DISCOUNTED COSTS OF PROPOSED RULE

	Total Annual Costs of Proposed Rule	Total Discounted Costs of Proposed Rule (20 years at 7 percent)
Low cost	$134,000	$1.4 million
High cost	$189,000	$1.9 million

Benefits

FDA is not aware of any outbreaks or enforcement actions associated with fecal pathogens in bottled water in the last 10 years. Therefore, we are not able to quantify any public health benefits of this option.

However, while FDA is not aware of any recent outbreaks associated with fecal pathogens in bottled water, this does not mean that such outbreaks could never occur. Under the current FDA regulations, the potential exists for fecal pathogens in ground water to be undetected and be distributed to consumers in bottled water and cause illness. Testing for the fecal indicator *E. coli*, if total coliform is present, and prohibiting *E. coli*-contaminated water from being used as source water or product water, would reduce this potential.

By issuing this regulation, FDA will ensure that FDA's standards for the microbial quality of bottled water will be no less protective of the public health than those set by EPA for public drinking water.

B. Small Entity Analysis

FDA examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. This rule may have a significant economic impact on a substantial number of small entities. The Small Business Administration's definition of a small business for NAICS code 312112 Bottled Water Manufacturing, is an entity with 500 or fewer employees. Under this definition, 82 percent of the bottled water firms (260 of 318) in the Dun's Market Identifiers database are identified as small firms (69 FR 70082 at 70088, December 2, 2004). Assuming that 82 percent of total annual costs shown in table 11 of this document will be incurred by small firms, and that 92 percent of the small firms are domestic, then total annual domestic costs of $100,000 to $140,000 will be incurred by the 260 small firms. However, because it is possible that a firm may not find a total coliform positive in any year during a 20-year period, subsequent testing for *E. coli* or taking action to rectify contamination would not be needed and thus, average estimated annual costs per firm can be as low as $380. Average estimated annual costs per firm can be as high as $540 because it is also possible for a firm to incur costs to rectify contamination in any given year over a

20-year period as a result of finding total coliform and *E. coli* positives. This rule will affect a substantial number of small bottled water manufacturers. Although the number of small bottlers affected is large, the average annual costs per business are small. The annual average cost per small bottler (weighted by requirement costs) is summarized in table 12 of this document.

TABLE 12—WEIGHTED AVERAGE ANNUAL COSTS PER SMALL ENTITY[1]

Annual Costs per Requirement	Weighted Average Annual Costs per Entity	
	Low Cost	High Cost
Number of small firms = 260		
E. coli testing of source water and finished products	$285	$407
E. coli testing finished product only	$50	$70
E. coli retesting	$1	$3
Costs to rectify contamination	$50	$60
Average costs per bottler	$380	$540

[1] Estimates are not exact due to rounding.

To investigate the potential significance of these impacts, FDA entered these costs into a model created under contract by Eastern Research Group, Inc. (ERG) (Ref. 7). The model is designed to estimate the percentage of small firms that would go out of business because of compliance costs if those costs accrued to all small firms in a given industry. According to this model, an annual cost of $380 to $540 would generate a near zero percent probability that a small firm with less than 20 employees that faced those costs would go out of business. Because the costs per entity of this rule are small, the agency tentatively concludes that the proposed rule will not have a significant economic impact on a substantial number of small entities. FDA requests comment on the impact of this rule on small entities.

VIII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the following paragraphs with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Recordkeeping Due to New Testing Requirements for Bottled Water.

Description: The FDA is proposing to amend its bottled water regulations by requiring testing for the fecal indicator *E. coli* if any coliform organisms are detected in a weekly sample of finished bottled water products. FDA also is proposing to amend the adulteration provision of the bottled water standard to indicate that finished product that tests positive for *E. coli* will be deemed adulterated under section 402(a)(3) of the act. In addition, FDA is proposing to amend the CGMP regulations for bottled water by requiring that source water from other than a PWS be tested at least weekly for total coliform. If any coliform organisms are detected in the source water, the bottled water manufacturer would be required to test the source water for *E. coli*. Source water found to contain *E. coli* would not be considered water of a safe, sanitary quality and would be unsuitable for bottled water production until the bottler has taken appropriate measures (as evidenced by records) to rectify or otherwise eliminate the cause of the contamination. Source water previously found to contain *E. coli* would be considered negative for *E. coli* after five samples collected from the source water supply over a 24-hour period are tested and found to be *E. coli* negative.

Description of Respondents: This rule would require both domestic and foreign bottled water manufacturers that sell bottled water in the United States to maintain records of *E. coli* testing in addition to existing recordkeeping requirements.

Burden: FDA estimates the burden for this information collection in table 13 of this document as follows:

TABLE 13—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Total Hours
§ 129.35(a)(3)(i), § 129.80(h)	319 (bottlers subject to source water and finished product testing)	6	1,914	0.08	153

TABLE 13—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Total Hours
§ 129.80(g), § 129.80(h)	95 (bottlers testing finished product only)	3	285	0.08	23
§ 129.35(a)(3)(i), § 129.80(h)	2.5 (bottlers retesting source water)	5	12	0.08	1
§ 129.35(a)(3)(i), § 129.80(h)	2.5 (bottlers rectifying source water contamination)	3	7.5	.25	2
Total annual burden					179

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The current CGMP regulations already reflect the time and associated recordkeeping costs for those bottlers that are required to conduct microbiological testing of their source water, as well as total coliform testing of their finished bottled water products. FDA tentatively concludes that any additional burden and costs in recordkeeping based on the new proposed testing requirements for source and finished bottled water would be negligible. FDA estimates that the labor burden of keeping records of each test is about 5 minutes per test. FDA is also requiring followup testing of source water and finished bottled water products for *E. coli* when total coliform positives occur. FDA expects that 319 bottlers that use sources other than PWSs may find a total coliform positive sample about three times per year in source testing and about three times in finished product testing, for a total of 153 hours recordkeeping. In addition to the 319 bottlers, about 95 bottlers that use PWSs may find a total coliform positive sample about three times per year in finished product testing, for a total of 23 hours of recordkeeping. Upon finding a total coliform sample, bottlers will then have to conduct a followup test for *E. coli*.

FDA expects that recordkeeping for the followup test for *E. coli* will also take about 5 minutes per test. As shown in table 13 of this document, FDA expects that 2.5 bottlers per year will have to carry out the additional *E. coli* testing, with a burden of 1 hour. These bottlers will also have to keep records about rectifying the source contamination, for a burden of 2 hours. For all expected total coliform testing, *E. coli* testing, and source rectification, FDA estimates a total burden of 179 hours.

The information collection provisions of this proposed rule have been submitted to OMB for review. Interested persons are requested to fax comments regarding information collection by October 17, 2008, to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

IX. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed revisions to the standard of quality for bottled water relating to microbiological quality (21 CFR 165.110(b)(2)), if finalized as proposed, would have a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision, or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 403A(a)(1) of the act (21 U.S.C. 343–1(a)(1)) provides that ''no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—(1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g) * * *.'' FDA has interpreted this provision to apply to standards of quality (21 CFR 100.1(c)(4)). Although the proposed revisions relating specifically to the standard of quality for bottled water, if finalized as proposed, will have preemptive effect in that it would preclude States from issuing requirements for microbiological testing in bottled water that are not identical to the microbiological testing requirements as set forth in this proposed rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act.

Section 4(c) of the Executive order further requires that ''any regulatory preemption of State law shall be restricted to the minimum level necessary'' to achieve the regulatory objective. Under section 410 of the act, not later than 180 days before the effective date of an NPDWR issued by EPA for a contaminant under section 1412 of the SDWA (42 U.S.C. 300g–1), FDA is required to issue a standard of quality regulation for that contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in PWSs but not in water used for bottled water. Further, section 410(b)(3) of the act requires a standard of quality for a contaminant in bottled water to be no less stringent than EPA's MCL and no less protective of the public health than EPA's treatment techniques required for the same contaminant. On November 8, 2006, EPA issued an NPDWR containing a risk-targeted approach, including treatment techniques, identifying and targeting GWSs susceptible to fecal contamination (71 FR 65574). FDA has determined that establishing new microbiological testing requirements and standards for source water and bottled water products is appropriate as a response to EPA's action, and is issuing this proposed regulation consistent with section 410 of the act.

Further, section 4(e) of the Executive order provides that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' Given the statutory framework of section 410 of the act for bottled water, EPA's issuance of the GWR provided notice of

possible FDA action to revise the microbiological quality standard for bottled water. FDA did not receive any correspondence from State and local officials regarding possible changes to the microbiological quality standard for bottled water subsequent to EPA's issuance of the GWR. In addition, we are providing an opportunity for State and local officials to comment on proposed changes to the CGMPs and quality standard in the context of this rulemaking. For the reasons set forth previously in this document, the agency believes that it has complied with all of the applicable requirements under the Executive order.

In conclusion, FDA has determined that the preemptive effects of this rule, if finalized, will be consistent with Executive Order 13132.

X. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

XI. Effective Date of the Related Final Rule

The agency intends to make any final rule based on this proposal effective December 1, 2009. The agency will publish a final rule in the **Federal Register** no later than 180 days before the effective date. The agency is providing 180 days before the effective date to permit affected firms adequate time to take appropriate steps to bring their product into compliance with the standard imposed by the new rule.

XII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. International Bottled Water Association, 2007. Personal communication. August 30, 2007.

2. Skipton, S.O., D. Hay, and J.A. Albrecht, ''Drinking Water: Bottled or Tap?'' University of Nebraska of Nebraska-Lincoln, Institute of Agriculture and Natural Resources, G1448, January 2002. Accessed online at *http://www.ianrpubs.unl.edu/epublic/live/g1448/build/g1448.pdf*.

3. International Bottled Water Association, 2005, IBWA Model Code, Version March 2005. Accessed online at *http://www.bottledwater.org/public/pdf/IBWA05ModelCode_Mar2.pdf*.

4. Economic Analysis for the Final Groundwater Rule, Office of Water (4606–M) EPA 85–R–06–014, October 2006, Section 6.2.2 Laboratory Fees. Accessed online at *http://www.epa.gov/safewater/disinfection/gwr/pdfs/support_gwr_economicanalysis.pdf*.

5. Economic Analysis for the Final Groundwater Rule, Office of Water (4606–M) EPA 85–R–06–014, October 2006, Section 4.2.7 Triggered Monitoring Baseline, pp. 4–21 through 4–22. Accessed online at *http://www.epa.gov/safewater/disinfection/gwr/pdfs/support_gwr_economicanalysis.pdf*.

6. Economic Analysis for the Final Groundwater Rule, Office of Water (4606–M) EPA 85–R–06–014, October 2006, Section 6.4.4 Sanitary Survey Corrective Actions, p. 6–33. Accessed online at *http://www.epa.gov/safewater/disinfection/gwr/pdfs/support_gwr_economicanalysis.pdf*.

7. ERG (Eastern Research Group, Inc.), ''Model for Estimating the Impacts of Regulatory Costs on the Survival of Small Businesses and its Application to Four FDA-Regulated Industries,'' Contract No. 223–01–2461, June 7, 2002.

List of Subjects

21 CFR Part 129

Beverages, Bottled water, Food packaging, Reporting and recordkeeping requirements.

21 CFR Part 165

Beverages, Bottled water, Food grades and standards, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 129 and 165 be amended as follows:

PART 129—PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

1. The authority citation for 21 CFR part 129 continues to read as follows:

Authority: 21 U.S.C. 342, 348, 371, 374; 42 U.S.C. 264.

2. Section 129.35 is amended by revising paragraphs (a)(3)(i) and (a)(4)(iv) to read as follows:

§ 129.35 Sanitary facilities.

* * * * *

(a) * * *

(3) * * *

(i) Samples of source water are to be taken and analyzed by the plant as often as necessary, but at a minimum frequency of once each year for chemical contaminants and once every 4 years for radiological contaminants. Additionally, source water obtained from other than a public water system is to be sampled and analyzed for total coliform at least once each week. If any coliform organisms are detected, followup testing must be conducted to determine whether any of the coliform organisms are *Escherichia coli*. This sampling is in addition to any performed by government agencies having jurisdiction. Source water found to contain *E. coli* is not considered water of a safe, sanitary quality as required for use in bottled water by paragraph (a)(1) of this section. The bottler must take appropriate measures to rectify or otherwise eliminate the cause of *E. coli* contamination in a manner sufficient to prevent its reoccurrence. Source water previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected from the source water supply over a 24-hour period are tested and found to be *E. coli* negative. Records of approval of the source water by government agencies having jurisdiction, records of sampling and analyses for which the plant is responsible, and records describing corrective measures taken in response to a finding of *E. coli* are to be maintained on file at the plant.

* * * * *

(4) * * *

(iv) The finished bottled water must comply with bottled water quality standards (§ 165.110(b) of this chapter) and section 402(a)(1) and (a)(3) of the Federal Food, Drug, and Cosmetic Act dealing with adulterated foods.

* * * * *

3. Section 129.80 is amended by revising paragraph (g)(1) to read as follows:

§ 129.80 Processes and controls.

* * * * *

(g) * * *

(1) For bacteriological purposes, take and analyze at least once a week for total coliform a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's

production. The representative sample shall consist of primary containers of product or unit packages of product. If any coliform organisms are detected, followup testing must be conducted to determine whether any of the coliform organisms are *E. coli*.

* * * * *

PART 165—BEVERAGES

4. The authority citation for 21 CFR part 165 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 343–1, 348, 349, 371, 379e.

5. Section 165.110 is amended by revising paragraphs (b)(2), (c)(1), and (d) to read as follows:

§ 165.110 Bottled water.

* * * * *

(b) * * *

(2) *Microbiological quality.*

(i) Bottled water shall, when a sample consisting of analytical units of equal volume is examined by the methods described in paragraph (b)(2)(ii) of this section, meet the following standards of microbiological quality:

(A) *Total coliform.*

(*1*) *Multiple-tube fermentation (MTF) method.* Not more than one of the analytical units in the sample shall have a most probable number (MPN) of 2.2 or more coliform organisms per 100 milliliters and no analytical unit shall have an MPN of 9.2 or more coliform organisms per 100 milliliters; or

(*2*) *Membrane filter (MF) method.* Not more than one of the analytical units in the sample shall have 4.0 or more coliform organisms per 100 milliliters and the arithmetic mean of the coliform density of the sample shall not exceed one coliform organism per 100 milliliters.

(B) *E. coli.* No *E. coli* shall be detected. If *E. coli* is present, then the bottled water will be deemed adulterated under paragraph (d) of this section.

(ii) Analyses conducted to determine compliance with paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section and § 129.35(a)(3)(i) of this chapter shall be made in accordance with the multiple-tube fermentation (MTF) or the membrane filter (MF) method described in the applicable sections of ''Standard Methods for the Examination of Water and Wastewater,'' 20th Ed. (1998), American Public Health Association. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the American Public Health Association, 800 I St. NW., Washington, DC 20001. You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

* * * * *

(c) * * *

(1) ''Contains Excessive Bacteria'' if the bottled water fails to meet the requirements of paragraph (b)(2)(i)(A) of this section.

* * * * *

(d) *Adulteration.* Bottled water containing a substance at a level considered injurious to health under section 402(a)(1) of the act, or that consists in whole or in part of any filthy, putrid, or decomposed substance, or that is otherwise unfit for food under section 402(a)(3) of the act is deemed to be adulterated, regardless of whether or not the water bears a label statement of substandard quality prescribed by paragraph (c) of this section. If *E. coli* is present in bottled water, then the bottled water will be deemed adulterated under section 402(a)(3) of the act.

Dated: September 10, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–21619 Filed 9–16–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

RIN 1545–BB67

[REG–157711–02]

Unified Rule for Loss on Subsidiary Stock

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Partial withdrawal of notice of proposed rulemaking.

SUMMARY: This document withdraws proposed regulations relating to the application of section 362(e)(2) to intercompany transactions and to certain modifications to the investment adjustment rules.

FOR FURTHER INFORMATION CONTACT: Marcie P. Barese, (202) 622–7790 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

On January 23, 2007, the IRS and Treasury Department published a notice of proposed rulemaking in the **Federal Register** (72 FR 2964) under § 1.1502–36 (Unified Loss Rule). The proposed regulations provided rules under § 1.1502–13(e)(4) that would suspend the application of section 362(e)(2) in the case of intercompany transactions. The proposed regulations also provided rules under § 1.1502–32(c)(1)(ii) relating to the treatment of items attributable to property transferred in an intercompany section 362(e)(2) transaction.

After consideration of the comments received responding to the notice of proposed rulemaking, the IRS and Treasury Department have concluded that the proposed rules would not be promulgated and, instead, that final regulations would make section 362(e)(2) generally inapplicable to intercompany transactions. Accordingly, §§ 1.1502–13(e)(4) and 1.1502–32(c)(1)(ii) of the proposed regulations are hereby withdrawn.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Partial Withdrawal of Proposed Regulations

Accordingly, under the authority of 26 U.S.C. 7805, proposed §§ 1.1502–13(e)(4) and 1.1502–32(c)(1)(ii) published in the **Federal Register** on January 23, 2007 are withdrawn.

Linda E. Stiff,

Deputy Commissioner for Services and Enforcement.

[FR Doc. E8–21005 Filed 9–9–08; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 250

[Docket ID: MMS–2008–OMM–0023]

RIN 1010–AD50

Technical Changes to Production Measurement and Training Requirements

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the production measurement regulations to establish meter proving,