

Feature Story

FDA Proposes \$547 Million Rule to Verify Safety of Imported Foods



The Food and Drug Administration published a [proposed rule](#) that would require food importers to “perform risk-based foreign supplier verification activities... to verify that food imported into the United States is as safe as food produced and sold within the United States...The proposed [Foreign Supplier Verification Program] regulations are intended to work in tandem with other provisions of [the Food Safety Modernization Act] and the [Food, Drug, and Cosmetic] Act to ... [provide] appropriate layers of protection for U.S. consumers.” Under the regulation, importers would have to conduct on-site audits or other verification methods for most foreign suppliers, with different requirements for very small suppliers and importers, importers of dietary supplements, and suppliers in countries “whose food safety

system FDA has officially recognized as ‘comparable’...[or] equivalent to that of the United States.” Estimated cost of the rule is between \$529 million and \$547 million per year. Because the proposed rule “would not itself establish safety requirements for food manufacturing and processing, [but] would benefit the public health by helping to ensure that imported food is produced in compliance with other applicable food safety regulations,” the public health benefits are accounted for in “the preventive controls, produce safety, and other applicable food safety regulations instead of in this rule.” [Comments](#) on the proposed rule are due by November 26th.

Opinion

- The Government Has Your Data at Its Fingertips
- Stop overregulating businesses: Opposing view
- New Regulations Batter The Middle Class. Obama Changes The Subject.
- Fed up with Wall Street’s revolving door
- Bringing compounding pharmacies under federal regulation
- The Affordable Care Act’s Rate-Setting Won’t Work
- Obama’s Fed Circus
- The EPA’s Game of Secret Science
- Not Too Big to Fail
- Congress Confronts ‘Laws Gone Wild’
- How Delaware Ditched or Reformed 140 Regulations
- Old-Fashioned Regulators Miss What’s New in Finance

Marketplace of Ideas

American Action Forum

- The Week in Regulation: July 22-26, *Sam Batkins*

In the News

7/24/13

[Activists petition judge in California to force EPA to protect children from pesticide drift](#), *Washington Post*

[Schakowsky pushes delayed car rearview camera rule](#), *The Hill*

[White House claims billions in savings from eased regulations](#), *The Hill*

[Labor board nominees pass to full Senate](#), *The Hill*

[The FDA: Working Hard to Protect Industry](#), *Huffington Post*

[Regulators may weaken plan to rein in mortgage underwriting-sources](#), *Reuters*

[House panel advances bills to rein in regulations](#), *The Hill*

[‘Sue and settle’ bill sets off civil rights flap](#), *The Hill*

[Softened Mortgage Rule Said to Be Proposed Soon by U.S. Agencies](#), *Bloomberg*

7/25/13

[House passes legislation giving states more control over coal ash](#), *Washington Post*

[Wonkbook: The White House wants Summers for the Fed. But will they actually choose him?](#), *Washington Post*

[Gay spouses have same rights as straight couples, FEC rules](#), *Washington Post*

[Bill would require more lists of expected rules](#), *The Hill*

[Paul amendment would give Congress sway over expensive regs](#), *The Hill*

[Senate regulatory panel to hold inaugural hearing](#), *The Hill*



- Retrospective Review Update: Disposable Wipe Exemptions, *Dan Goldbeck*

- The House on Regulation: REINS Act 2.0, *Sam Batkins*

Center for American Progress

- Sequestration Delays The Implementation of Important Regulations, *Bryce Covert*

Center for Effective Government

- Success of EPA Climate Standards Will Depend on White House Support, *Katie Greenhaw*

- With New Leader in Place, EPA Can Recommit to Its Environmental Agenda

- Public Safeguards Given Little Weight at Conference on Natural Gas Expansion

- Updated Database Reveals Significant Chemical Risks Are Distributed Across the Country

Center for Progressive Reform

- Shelanski Said What During the House Small Business Committee?, *James Goodwin*

- Chemical Safety Board Introduces a Most Wanted List of Reforms to Protect Workers, *Matt Shudtz*

- New CPR Issue Alert on TSCA Reform: Progressive Principles for Toxic Risk Regulation, *Matt Shudtz*

- TESTIMONY: Strengthening Public Health Protections by Addressing Toxic Chemical Threats, *Thomas McGarity*

Competitive Enterprise Institute

- Regulating E-Cigarettes Creates the Wrong Incentives, *Richard Rush*

- Comments of the Competitive Enterprise Institute On The Office of Management and Budget's 2013 Draft Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act, *Clyde Wayne Crews*

The George Washington University Regulatory Studies Center

- OMB's Draft 2013 Report to Congress on Regulatory Costs and Benefits has Limitations, *Susan E. Dudley & Sofie E. Miller*

Government Accountability Office

- OMB and Agencies Need to More Effectively Implement Major Initiatives to Save Billions of Dollars, *David Powner*

- Impacts of and Regulatory Response to the 2007-2009 Financial Crisis, *Alicia Cackley*

Heritage Foundation

- How Daring is President Obama's New

[GOP launches fresh bid to block Interior mining rule](#), *The Hill*

[Wyden floats fracking regs framework](#), *The Hill*

[House votes to blunt EPA regs on coal ash](#), *The Hill*

[Sequestration, Furloughs Slow Down Review of Federal Regs](#), *Government Executive*

[Lawmakers Move to Protect Insurers](#), *Wall Street Journal*

[FDIC quietly changes rule that cost thousands their jobs](#), *USA Today*

[U.S. CFTC looks set to keep margin rules despite industry outcry](#), *Reuters*

[US FAA tells airlines to remove or inspect beacons in Boeing 787](#), *Reuters*

[NTSB goal: A nation of communicating vehicles](#), *Politico*

[FEC tweaks rules for married gay couples](#), *Politico*

[SEC's Money-Funds Rule Too Costly for Firms, U.S. Chamber Says](#), *Bloomberg*

[Biofuel Makers Seek to Ease Mandates to Avert Congress](#), *Bloomberg*

7/26/13

[FDA proposes rules to make imported foods safer after outbreaks in produce, cheese](#), *Washington Post*

[FDA unveils rules to make imported food meet U.S. standards](#), *Washington Post*

[Wonkbook: A dark horse for Fed chair?](#), *Washington Post*

[JPMorgan to consider the sale of part of its commodities business](#), *Washington Post*

[Aviation panel proposes streamlined plane regs](#), *The Hill*

['Slaughtered in the U.S.A.' meat labeling rule draws fresh legal attack](#), *The Hill*

[House Republicans probe legality of ObamaCare regs](#), *The Hill*

[FDA set to overhaul food safety rules for imported fruits, veggies](#), *The Hill*

[Summers Faces Hit on Potential Fed Nod Over His Wall Street Ties](#), *Wall Street Journal*

[FDA Says Importers Must Audit Food Safety](#), *New York Times*

[FDA issues new safety rules for imported food](#), *USA Today*

[FDA proposes rules for safer imported foods](#), *Washington Examiner*

[Texas Loses Bid to Stop EPA Takeover of Greenhouse Rules](#), *Bloomberg*

7/27/13

[Amusement park regulations, inspections different from state to state; no federal oversight](#), *Washington Post*

[JPMorgan Mulls Physical Commodities Exit Amid U.S. Review](#), *Bloomberg*

7/28/13

[GOP lawmaker warns Interior's fracking rule could lead to cascade of new regs](#), *The Hill*

[Landmark California regulations under federal fire](#), *Los Angeles Times*

[After Delayed Vote, EPA Gains a Tough Leader to Tackle Climate Change](#), *New York Times*

7/29/13

[Former aircraft parts plant site in Va. to be cleaned up, EPA assessing contaminants](#), *Washington Post*

[Regulators say JPMorgan gamed energy markets](#), *Washington Post*

[USDA holds off on disaster plan requirement for animal 'exhibitors'](#), *Washington Post*

[EPA official links fracking and drinking water issues in Dimock, Pa.](#), *Washington Post*

[Paul Volcker Explains How to Fix Big Banks](#), *US News*

[GAO report praises insurance regulators during financial crisis](#), *The Hill*

[State health exchange rates vary, but lower than expected](#), *USA Today*



Climate Action Plan?, *Nicolas Loris*

- Damaging Dodd-Frank is Making Things Worse, *Diane Katz*

IBM Center for the Business of Government

- Rulemaking 2.0: Understanding and Getting Better Public Participation, *Cynthia Farina & Mary Newhart*

The Mercatus Center

- Energy Efficiency Benefits from 2013 Microwave Oven Regulation, *James Broughel*
- Regulatory Process, Regulatory Reform, and the Quality of Regulatory Impact Analysis, *Jerry Ellig*
- Comment on OMB's Draft 2013 Report to Congress on the Benefits and Costs of Federal Regulations, *Richard Williams*

Penn Program on Regulation

- Regulatory Entity-Centrism in Financial Services, *Anita K. Krug*
- Agencies May Differ from their Expert Scientific Panels, *Craig N. Oren*
- Debate Ensues Over Congressional Control of Agency Rulemaking, *Christina Reichert*

Small Business for Sensible Regulation

- NFIB CEO & President Dan Danner in USA Today: Stop Overregulating business – modernize the regulatory process

[U.S. regulators moving cautiously on mortgage reforms](#), *Reuters*
[U.S. power regulator says JP Morgan manipulated market](#), *Reuters*
[Fracking Tied to Pennsylvania Water Woes by EPA Official](#), *Bloomberg*

7/30/13

[HHS Inspector General Scrutinizes Medicare Rule For Observation Care](#), *Washington Post*

[GOP launches summer assault on regs](#), *The Hill*

[New EPA head McCarthy outlines ambitious agenda in Harvard speech](#), *Washington Post*

[EPA chief goes on offensive in first speech, saying climate controls will help economy](#), *Washington Post*

[Senate confirms labor nominees, moves toward filling diplomatic, law enforcement posts](#), *Washington Post*

[As new EPA chief, Gina McCarthy vows to act on climate change](#), *Washington Post*

[FDA backs low-nicotine cigarette research as it weighs new regulatory power](#), *Washington Post*

[CBO: Obama administration delay of health law's employer requirement will cost gov't \\$10B](#), *Washington Post*

[Study: REINS Act could save tens of billions in regulatory costs](#), *The Hill*

[Bill would create commission to review outdated regulations](#), *The Hill*

[Financial regulators pressed on banks' commodities](#), *The Hill*

[Magician safe; USDA relents on disaster regs for animal handlers](#), *The Hill*

[Banks Commodity Business Drawing Sharper U.S. Regulator Scrutiny](#), *Bloomberg*

[Fed Seeks Comment on Stress-Test Guidance for Midsize Banks](#), *Bloomberg*

[Banks Commodity Business Drawing Sharper U.S. Regulator Scrutiny](#), *Bloomberg*

7/31/13

[Obama needs a new SBA chief — luckily, small business leaders some have ideas](#), *Washington Post*

[Next Fed chief inherits expanded powers](#), *The Hill*

[Gina McCarthy: Climate change poses economic threat](#), *Politico*

Rulemaking

Commodity Futures Trading Commission

CFTC Issues Guidance Regarding Cross-Border Application of Swaps Provisions

The Commodity Futures Trading Commission issued its [interpretive guidance](#) and policy statement regarding the cross-border applications of the swaps provisions of the Community Exchange Act (CEA). This guidance is a statement of the general policy used by the CFTC regarding cross-border swap activities; it allows for flexibility in application to various situations, unlike a binding rule. This approach has been taken because the CFTC “understands the complex and dynamic nature of the global swap market and the need to take an adaptable approach to cross-border issues, particularly as it continues to work closely with foreign regulators to address potential conflicts with respect to each country's respective regulatory regime.” Some of the topics addressed by this guidance include “the treatment of swaps involving certain foreign branches of U.S. banks, the treatment of swaps involving a non-U.S. counterparty guaranteed by a U.S. person or ‘affiliate conduit,’ and the categorization of the Dodd-Frank swaps provisions as ‘Entity-Level Requirements’ or ‘Transaction-Level Requirements.’”

Federal Housing Finance Agency

FHFA Withdraws Proposed Rule Concerning Underwriting Standards for Fannie Mae, Freddie Mac

The Federal Housing and Finance Agency [withdrew](#) its previously published proposed rule, [Enterprise Underwriting Standards](#). This proposed rule concerned underwriting standards for the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac) relating to mortgage



assets affected by Property Assessed Clean Energy (“PACE”) programs. A California District Court ruling in 2011 ordered the Federal Housing and Finance Agency (FHFA) to seek comments on whether “restrictions relating to the regulated entities' dealing in mortgages on properties participating in PACE are necessary.” An appeal to the Ninth Circuit Court of Appeals by the FHFA raised an objection to the order because they “interfered with the exercise of Agency powers and authorities as provided by Congress in the Housing and Economic Recovery Act of 2008.” The Ninth Circuit ruled in favor of the FHFA, leading to the withdrawal of this rule.

Food and Drug Administration

FDA Proposes Framework for Third-Party Certification for Foreign Food Safety Standards

The Food and Drug Administration also published a [proposed rule](#) establishing a framework for third-party foreign food safety auditors and certification bodies. The rule “contains procedures for recognition and accreditation, as well as requirements relating to monitoring and oversight of participating accreditation bodies and auditors/certification bodies.” If finalized, the rule “will help FDA ensure the competence and independence of third-party auditors/certification bodies who conduct foreign food safety audits” to satisfy FSVP requirements. “It also will help ensure the reliability of food and facility certifications issued by third-party auditors/certification bodies that FDA will use in making certain decisions relating to imported food.” Estimated annual costs are between \$72.6 million and \$74.4 million. Though the FDA was “unable to estimate quantitatively the benefits of the proposed rule” the Agency posits that this rule will benefit the public health by helping to ensure that imported food complies with applicable food safety requirements. [Comments](#) on the proposed rule are due November 26th.

FDA Issues Direct Final Rule Offering Alternatives to Mandatory Tiny Turtle Destruction

The Food and Drug Administration issued a [direct final rule](#) and an accompanying [proposed rule](#) amending previous regulations regarding the prohibition on the sale of viable turtle eggs and live turtles with a carapace length of less than 4 inches. This rule was previously put into place to stop the spread of salmonellosis associated with turtles. If turtle eggs or live turtles with a carapace of less than 4 inches are held for sale, they were previously subject to destruction in a humane manner by FDA. This amendment removes these provisions for destructions as alternative means of preventing salmonellosis. Some of these alternatives, as cited by the FDA, include “raising the turtles until the turtles achieve a carapace length of 4 inches or greater; donating the viable turtle eggs or live turtles to an entity that meets one of the bona fide scientific, educational, or exhibitional exemptions, as provided in the regulations; or exporting the turtles in compliance with all applicable laws.” However, this direct final rule does not lift the ban on selling turtle eggs or live turtles with a carapace of less than four inches. [Comments](#) are due on October 8th.

Department of Agriculture

APHIS Stays Enforcement of Rule Requiring Disaster Plans for Animals Used for Exhibition

The Animal and Plant Health Inspection Service [issued](#) a stay of its December 2012 [final rule](#) on itinerary submission by any person who is subject to the Animal Welfare Act. These itineraries must meet certain requirements for contingency planning and training of personnel for people who intend to exhibit any animal at any location other than the person's approved site when travel will extend overnight. The Animal and Plant Health Inspection Service plans to consider the impact of the requirements on regulated entities, “taking into account a reexamination of any unique circumstances and costs that may vary by the type and size of businesses.” This review is in response to newly voiced concerns on how the regulation would impact small animal exhibitors, such as magicians who employ use of a rabbit for their magic act.

CCC Finalizes Rule Dictating Allowable Use of Sugar Program Sugar by Bioenergy Producers

The Commodity Credit Corporation (CCC) published a [final rule](#) that amends the restrictions on how CCC can dispose of its sugar inventory from the Sugar Program. This disposal comes primarily through the establishment of the Feedstock Flexibility Program in the same rule. FFP is intended to help keep the Sugar Program operating at no cost to the Federal Government “to the maximum extent practicable” by requiring CCC to purchase domestically produced sugar that would otherwise be forfeited. The sugar must then be sold to bioenergy producers, “permanently removing such sugar from the market for human consumption.” FFP is expected to cost CCC “\$54.5 million more than using the least-cost surplus management option,” in FY 2013, with a total cost of \$92.3 million. “Despite this cost, FFP has at least one benefit that is not available with other sugar supply reduction methods. Specifically, FFP will allow the generation of Renewable Identification Numbers (RINs), which will help gasoline



and diesel blenders meet their Renewable Fuels Standard (RFS) mandates in 2014.” In order to avoid forfeiture of the 2012 Sugar Crop, the final rule is effective immediately.

Department of Transportation

FHWA Proposes National Tunnel Inspection Standards

The Federal Highway Administration (FHWA) published a [proposed rule](#) establishing National Tunnel Inspection Standards (NTIS) and to “establish requirements for tunnel owners, including the establishment of a program for the inspection of highway tunnels, maintenance of a tunnel inventory, reporting of the inspection findings to FHWA, and correction of any critical findings identified during these inspections.” The purpose of the rule is to ensure that all structural, mechanical, electrical, hydraulic and ventilation systems of tunnel structures are inspected and tested on a regular basis. The NTIS would enhance the safety of highway tunnels, and would make tunnel inspections consistent nationwide. Currently, FHWA does not have sufficient information to estimate total costs and total benefits of this rulemaking. The Agency has preliminary estimates regarding just the inspection portion of the rulemaking and believes them to be between \$219,485 (low) and \$2,506,102 (high). The FHWA seeks information regarding the full costs and benefits of this rulemaking. [Comments](#) are due September 30th.

PHMSA Amends Hazardous Materials Regulations Applicable to Air Bags, Seat Belt Components

The Pipeline and Hazardous Materials Safety Administration (PHMSA) [published](#) a final rule amending the Hazardous Materials Regulations applicable to air bag inflators, air bag modules, and seat-belt pretensioners. The rulemaking finalizes revisions to five regulatory initiatives that are intended to reduce the regulatory burden on the automotive industry and facilitate commerce, while continuing to maintain an equivalent level of safety. The costs and benefits of the rulemaking are dependent on the level of preexisting compliance with two special permits (DOT-SP 12332 and DOT-SP 13996) and overall effectiveness of the amended regulations. The Agency believes that the rulemaking will reduce the burden in how airbag inflators, air bag modules, and seat-belt pretensioners are authorized for shipment by eliminating the necessity to submit approval applications to PHMSA, and thus provide significant savings. According to PHMSA, the costs associated with the rule are “negligible due to minor revisions to the recordkeeping requirements.” PHMSA estimates that the first-year net benefits to be \$1.14 million. According market analysis presented in the regulatory impact assessment, it is assumed that these benefits will grow at an annual average rate of 5 percent. Thus, the 10-year benefits at 7% and 3% discount rates are estimated to be \$10-12 million. [Comments](#) are now being accepted.

Environmental Protection Agency

EPA Finalizes Rule Modifying Hazardous Waste Management of Solvent-Contaminated Wipes

The Environmental Protection Agency published a [final rule](#) modifying the hazardous waste management of solvent-contaminated wipes. This rule revises the definition of solid waste to conditionally exclude solvent-contaminated reusable wipes and revises the definition of hazardous waste to conditionally exclude solvent-contaminated disposable wipes. This exclusion only covers the solvent-contaminated wipes and not free liquid spent solvent. According to EPA, the main purpose of this rule is “to provide a consistent regulatory framework that is appropriate to the level of risk posed by solvent-contaminated wipes in a way that maintains protection of human health and the environment, while reducing overall compliance costs for industry.” The estimated net benefits for this rule are between \$21.7 million and \$27.8 on an annual basis, with \$18 million in regulatory cost savings to industries affected.

EPA Proposes Switch to Electronic Reporting for Paper-Based NPDES Reports

The Environmental Protection Agency published a [proposed](#) rule that would require electronic reporting for current paper-based National Pollutant Discharge Elimination System (NPDES) reports. According to the EPA, the benefits of this rulemaking include allowing “NPDES-authorized programs in states, tribes, and territories to shift resources from data management activities to those more targeted to solving water quality and noncompliance issues.” EPA claims that this will lead to increased compliance, improved water quality, and a level playing field for the regulated community. In efforts to promote transparency and accountability, EPA intends that this rule will provide a more complete set of data to the public, providing communities with easily accessible information of facility and government performance. The EPA estimates that savings for the ten-year period are \$290.2 million while cumulative costs are \$69.9 million. [Comments](#) are due October 28th.

Did you find this information helpful? Consider [giving a gift](#) to the George Washington University Regulatory Studies Center so we can continue to provide you with cutting edge information regarding federal regulations.

