

Feature Story

FDA Proposes \$95 Million Animal Food Safety Requirements, Seeks Threshold for “Very Small” Businesses

The Food and Drug Administration [proposed](#) regulations that will establish current good manufacturing practices in the manufacturing, processing, packing, and holding of animal food. These proposed standards will apply to domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The proposed regulations also require certain facilities to implement hazard analysis and risk-based preventative controls for animal foods. FDA’s proposed actions intend to provide greater assurance that animal food is safe and will not cause illness or injury to animals or humans. The

proposed standards attempt to establish an animal food safety system for the future making modern, science and risk-based preventive controls the norm across all sectors of the animal food system.

The costs of the proposed rule vary depending on how FDA defines a ‘very small business’. If a ‘very small business’ is defined as less than or equal to \$500,000 in annual revenue, the total annualized domestic costs will be \$95 million over 10 years. If defined as having annual revenue less than or equal to \$1,000,000 then the total annualized domestic cost will be \$89 million. Finally, if the proposed rule defined a ‘very small business’ as having an annual revenue of less than or equal to \$2,500,000 then the cost will be \$65 million. There is no estimate of the benefits available in the proposed rule. [Comments](#) are due on February 26, 2014.



Marketplace of Ideas

American Action Forum

- Examining Department of Housing and Urban Development’s Regulatory Growth, *Andy Winkler & Sam Batkins*
- Week in Regulation, *Sam Batkins*
- HHS Estimated 28 Minutes to Complete Exchange Applications, *Sam Batkins*
- Regulation Review: FDA Safety Standards for Animal Food, *Dan Goldbeck*

American Enterprise Institute

- The big problem for small business, *Kevin A. Hassett*
- Fall follies: The ACA lurches into operation, *Joseph Antos*

Bipartisan Policy Center

- A Better Path Forward on the Volcker Rule and the Lincoln Amendment, *James D. Cox, Jonathan R. Macey & Annette L. Nazareth*

Center for Effective Government

- Agency Extends Comment Period on Long-Overdue Worker Safety Rule, *Katie Greenhaw*

In Opinion

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- James Glassman: [Don't Kill Fannie and Freddie](#)
- Rep. David Moore: [Regulatory reform: A necessity for small business growth](#)

In the News

Congress & Regulatory Reform

- [Conservatives push for bill checking regulations](#), *The Hill*
- [House chairman asks OSHA to delay worker safety rule](#), *The Hill*
- [GOP: EPA move 'unprecedented'](#), *The Hill*
- [Republicans push back on SEC efforts to write additional capital rules](#), *The Hill*
- [Chamber's strategy on regs: 'When all else fails, sue 'em'](#), *The Hill*
- [Global Regulation Curbing Growth, World Bank Finds](#), *Wall Street Journal*
- [White House opposes House GOP financial regulation bills, says they would weaken rules](#), *Washington Post*



- Senate Briefing Highlights Causes of Regulatory Delays, *Katie Weatherford*
- Workers and Economy to Gain From New Workplace Safety Standards, *Justin Santopietro*
- Outdoor Air Pollution Identified As Major Cause of Lung Cancer, *Ronald White*

Center for Progressive Reform

- What is a “Small Business,” Exactly? Two Concepts from OSHA’s Silica Proposal, *Matt Shudtz*
- SBA’s Office of Advocacy wants even more time to review OSHA’s silica proposal, *Matt Shudtz*
- White House changes to food import rule weaken consumer protections, *Michael Patoka*
- OSHA’s new tools for addressing chemical hazards could bolster enforcement, *Matt Shudtz*
- Mass. v. EPA bears fruit for environmental petitioners, *Holly Doremus*

Chamber of Commerce

- Flight Plan: 1978 Airline Deregulation Offers Reform Lessons for Policymakers, *David Kinkade*

Competitive Enterprise Institute

- Racial Preferences and Red Tape Grow Under Federal Dodd-Frank Act, *Hans Bader*
- CEI’s Battered Business Bureau: The Week in Regulation, *Ryan Young*
- Contradictory Financial Regulations Cause Problems, *Iain Murray*

Federal Regulations Advisor

- Monday Morning Regulatory Review – 10/28/13, *Leland Beck*

Free State Foundation

- Testimony of Randolph J. May on “Evolution of Wired Communications Networks” before the Subcommittee on Communications and Technology Committee on Energy and Commerce U.S. House of Representatives

The George Washington University Regulatory Studies Center

- Measuring Regulatory Activity: Pre- and Post- Shutdown, *Sofie E. Miller*
- BOOK DISCUSSION: The Politics of Regulatory Reform, November 8, 2013, 10:00 – 11:30

Government Accountability Office

- NEW TOBACCO PRODUCTS: FDA Needs to Set Time Frames for Its Review Process, *Marcia Crosse*

[Senate approves Obama pick Richard Griffin for a top job at National Labor Relations Board](#), *Washington Post*

Financial Markets & Housing

[SEC proposes ‘crowdfunding’ rules for start-up businesses](#), *Washington Post*
[JPMorgan to pay Fannie Mae, Freddie Mac \\$5.1 billion over mortgage securities](#), *Washington Post*

[SEC introduces, unanimously approves crowdfunding proposals](#), *Washington Post*

[Regulators vow to work with industry on mortgage rules](#), *The Hill*

[Bipartisan think tank offers Volcker alternative](#), *The Hill*

[Financial regulator: Dodd-Frank rules ‘largely completed’](#), *The Hill*

[Consumer bureau outlines examination process, unveils online regulation tool](#), *The Hill*

[CFPB tweaks mortgage-lending rules](#), *The Hill*

[Mortgage industry prepped for regulatory overhaul, Cordray says](#), *The Hill*

[Credit unions say new rules will hurt lending](#), *The Hill*

[Regulators Weigh Reductions in Size of U.S.-Guaranteed Mortgages](#), *Bloomberg*

[CFTC to Furlough Workers After Collecting \\$1.7 Billion](#), *Bloomberg*

[Volcker Hedging Exemption Said Disputed by Gensler, Stein](#), *Bloomberg*

[Fed to Propose Banks Hold Funds for Credit Drought](#), *Bloomberg*

[FDIC Regulation Squeezing CLO Creation in U.S., Barclays Says](#), *Bloomberg*

[Fed Loan Warning May Hurt Riskiest Borrowers, Trade Group Says](#), *Bloomberg*

[SEC Plans Push to Cut Credit Rating References, Gallagher Says](#), *Bloomberg*

[Fed Liquidity Proposal Seen Trading Safety for Costlier Credit](#), *Bloomberg*

[Cordray Doesn’t Expect Wave of Litigation Over CFPB’s QM Rule](#), *Bloomberg*

[High-Frequency Trading Targeted in EU Deal, Lawmaker Says](#), *Bloomberg*

[Banks Said to Seize ‘Footnote 513’ to Keep Swaps Private](#), *Bloomberg*

[Hair-Raising Critique Aimed at Options Clearing by SEC](#), *Bloomberg*

[Fed to Propose Banks Hold Funds for Credit Drought](#), *Bloomberg*

[Fed’s Tarullo Says Liquidity Rule to Promote Stability](#), *Bloomberg*

[New crowdfunding rules: The good and bad news for entrepreneurs and investors](#), *Washington Post*

Energy & Environment

[Understanding the Social Cost of Carbon](#), *The Billings Gazette*

[W.Va. chicken farmer wins lawsuit against EPA over stormwater runoff, permit requirement](#), *Washington Post*

[Greenhouse gas emissions from power plants declined from 2011 to 2012, EPA says](#), *Washington Post*

[AAA: New fuel regulations could increase gas prices at pump](#), *The Hill*

[Businesses flock to White House ahead of biofuel rule](#), *The Hill*

[Dems tell White House to speed up fracking guidance](#), *The Hill*

Health & Safety

[Obama administration spells out those health care site problems – and its efforts to fix them](#), *Washington Post*

[Head of US Consumer Product Safety Commission says she’s leaving post to join law firm in SC](#), *Washington Post*

[FDA proposes new rules to make pet food, animal feed safer](#), *Washington Post*

[FDA backs tighter controls on painkiller hydrocodone in wake of addiction epidemic](#), *Washington Post*

[Republicans ready to question Sebelius about troubled rollout of Obama’s](#)



The Mercatus Center

- Public Interest Comment - DOE Energy Conservation Program: Energy Conservation Standards for Metal Halide Lamp Fixtures, *James Broughel*
- PUBLIC INTEREST COMMENT: Regulatory Capital: Enhanced Supplementary Leverage Ratio Standards for Certain Bank Holding Companies, *Arnold Kling*
- Energy Efficiency as Foreign Aid?, *James Broughel*
- It's Time to Change the Incentives of Regulators, *Patrick McLaughlin*

Penn Program on Regulation

- The Politics of Regulatory Reform, *Stuart Shapiro & Debra Borie-Holtz*

Small Business for Sensible Regulations

- Industry Week: Increasing Number of Regulations Challenge Manufacturers
- Fruit and Vegetable Growers Worry about Food Safety Regulations

[health care law](#), *Washington Post*

[OSHA pumps brakes on worker safety rule](#), *The Hill*

[FDA extends landmark food safety overhaul to animals](#), *The Hill*

[FDA moves to tighten rules on painkiller](#), *The Hill*

[OSHA chief warns rules are 'dangerously out of date'](#), *The Hill*

[Progressive group issues pre-emptive strike on silica rule's cost](#), *The Hill*

[Chemical safety groups push for action ahead of agency recommendations](#), *The Hill*

[Safety commission to publish cradle safety rules](#), *The Hill*

[SBA office asks OSHA for more comment time on safety rule](#), *The Hill*

[CPSC Head to Join Nelson Mullins: Business of Law](#), *Bloomberg*

[Awaiting FDA, states pursue their own e-cigarette rules](#), *Washington Post*

Business

[United Airlines fined \\$1.1M for stranding passengers on planes during stormy day in Chicago](#), *Washington Post*

[Disputed appointee headed to labor board](#), *The Hill*

[Increasing Number of Regulations Challenge Manufacturers](#), *Industry Week*

Technology

[Passenger Devices Rule Delayed by Shutdown Due Soon: FAA](#), *Bloomberg*

Rulemaking

Department of Health and Human Services

HHS Finalizes Rule Establishing Financial Integrity Standards for Risk Adjustment, Reinsurance Programs

The Department of Health and Human Services issued a [final rule](#) implementing the provisions of the Affordable Care Act. Starting October 1, 2013, qualified individuals and qualified employees may purchase private health insurance coverage through competitive marketplaces called Affordable Insurance Exchanges, or "Exchanges" (also called Health Insurance Marketplaces). This final rule sets forth oversight and financial integrity standards with respect to Exchanges, Qualified Health Plan (QHP) issuers in Federally-facilitated Exchanges (FFE's), and States with regard to the operation of risk adjustment and reinsurance programs. "It also establishes additional standards for special enrollment periods, survey vendors that may conduct enrollee satisfaction surveys on behalf of QHP issuers, and issuer participation in an FFE, and makes certain amendments to definitions and standards related to the market reform rules. These standards, which include financial integrity provisions and protections against fraud and abuse, are consistent with Title I of the Affordable Care Act. This final rule also amends and adopts as final interim provisions set forth in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the Federal Register on March 11, 2013, related to risk corridors and cost-sharing reduction reconciliation." The rule will be effective as of December 30, 2013.

Department of Energy

DOE Proposes \$3 Billion Energy Efficiency Standard for Residential Furnace Fans

The Department of Energy published a [proposed rule](#) setting new energy conservation standards for residential furnace fans in order to comply with the [Energy Policy and Conservation Act of 1975 \(EPCA\)](#), as amended, that establishes the Energy Conservation Program for Consumer Products Other Than Automobiles, a program covering most major household appliances. EPCA requires DOE to determine whether such standards would be technologically feasible and economically justified, and would save a significant amount of energy. DOE's analysis shows the proposed standards would save a significant amount of energy over a 30-year period, amounting to 4.58 quads, in which the energy savings are equal to 0.3 percent of total projected residential energy use in 2030. The benefits of the proposed rule are estimated to be \$23.2 billion annually with a 7 percent discount rate; and the costs are estimated to be \$3.1 billion with a 7 percent discount rate. DOE will hold a public meeting on Tuesday, December 3, 2013, from 9 a.m. to 4 p.m., in Washington, DC to receive [comment](#) on these proposed standards and associated analyses and results.



DOE Seeks Information on Ceiling Fan Usage for Upcoming Energy Efficiency Rule

The Department of Energy is [seeking](#) information from the public on ceiling fan usage to inform its current rulemaking to set energy efficiency standards for ceiling fans. “Specifically, DOE seeks information and data on how use of a ceiling fan affects the way that consumers set the thermostat of their central air conditioner or the frequency of use of a room air conditioner... DOE seeks information and data on how use of a ceiling fan affects the operating duration, operating time (e.g., time of day or year), and energy consumption of an air conditioner.” [Comments](#) are due on November 21st.

Consumer Product Safety Commission

CPSC Finalizes Rule Tightening Voluntary Standards for Bassinet and Cradle Safety

The Consumer Product Safety Commission published a [final rule](#) tightening the existing voluntary standards for bassinet and cradle safety and making these standards mandatory for all bassinet and cradle manufacturers. CPSC is proposing this rule in response to data indicating that there are 84 cradle and bassinet incidents annually, both fatal and nonfatal, 52 of which are caused by product design flaws. Overall, 5% of the reported fatalities associated with cradles and bassinets are caused by product design flaws, while the remaining product fatalities are primarily (87%) caused by infant positioning and consumer-added bedding materials. The final rule enhances the voluntary standard for use of labels warning consumers about the potential suffocation dangers of added bedding: “The Commission supports the strengthening of the suffocation warning label as included in the latest revision of the ASTM voluntary standard and *does not believe that there are additional requirements that can be put in place in the standard to address unsafe sleep environments and unsafe sleep practices*. The Commission will continue information and education efforts, such as the Safe Sleep campaign, to address suffocation and other serious sleep hazards.”

However, the Commission goes on to mandate more stringent standards for cradles and bassinets than prescribed in the 2012 ASTM voluntary standards to address the 5% of fatalities caused by product design flaws: “These proposed changes include a revision to an existing test method (the bassinet stability test method), two additional new requirements and associated test methods (for mattress flatness and removable bassinet bed attachments), and a revised scope and associated definitions or references to support these additions.”

Food and Drug Administration

FDA Requests Comment on Qualitative Risk Assessment for Low-Risk Animal Foods

The Food and Drug Administration is [requesting comment](#) on a qualitative risk assessment that provides a science-based risk analysis of those activity/animal food combinations that would be considered low risk. The document is entitled “Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm”. FDA’s draft risk assessment was conducted to satisfy the statutory requirements of the [Food Safety and Modernization Act \(FSMA\)](#) to conduct a science-based risk analysis and to consider the results of that analysis in rulemaking that is required by FSMA. [Comments](#) are due on February 26, 2014.

Environmental Protection Agency

EPA Extends Comment Period for Proposed Switch to Electronic Reporting for Paper-Based NPDES Reports

The Environmental Protection Agency is [extending](#) the public comment deadline for its July 31, 2013 [proposed rule](#), *NPDES Electronic Reporting Rule*, which 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 now due December 12th.



Agencies

Office of the Comptroller of the Currency

OCC Seeks Comment on Paperwork Requirements for Stress Test Reporting Rules

The Office of the Comptroller of the Currency published a [notice](#) announcing that OCC is seeking public comment on paperwork requirements of the Office's proposed regulation for national banks and Federal savings associations, *Company-Run Annual Stress Test Reporting Template and Documentation for Covered Institutions with Total Consolidated Assets of \$10 Billion to \$50 Billion under the Dodd-Frank Wall Street Reform and Consumer Protection Act*. "The OCC intends to use the data collected through this [proposed rule] to assess the reasonableness of the stress test results of covered institutions and to provide forward-looking information to the OCC regarding a covered institution's capital adequacy. The OCC also may use the results of the stress tests to determine whether additional analytical techniques and exercises could be appropriate to identify, measure, and monitor risks at the covered institution. The stress test results are expected to support ongoing improvement in a covered institution's stress testing practices with respect to its internal assessments of capital adequacy and overall capital planning.

"The Dodd-Frank Act stress testing (DFAST) requirements apply to all covered institutions, but the OCC recognizes that many covered institutions with consolidated total assets of \$50 billion or more have been subject to existing stress testing requirements under the Board's Comprehensive Capital Analysis and Review (CCAR). The OCC also recognizes that these institutions' stress tests will be applied to more complex portfolios and therefore warrant a broader set of reports to adequately capture the results of the company-run stress tests. These reports necessarily will require more detail than would be appropriate for smaller, less complex institutions. Therefore, the OCC has decided to specify separate reporting templates for covered institutions with total consolidated assets between \$10 and \$50 billion and for covered institutions with total consolidated assets of \$50 billion or more." [Comments](#) are due on November 21st.

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