

Regulation Digest Weekly

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Feature Story

NHTSA Proposed Rule Requires Electric Cars, Hybrids to Make Noise

The National Highway Traffic Safety Administration published a [proposed rule](#) that would require hybrid and electric vehicles to make a minimum amount of sound while driving slower than 18 miles per hour. Because of an electric motor, hybrid and electric vehicles create less noise than vehicles that are reliant upon internal combustion engines (ICE). According to Agency data, hybrid vehicle crashes are 40% more likely than ICE vehicle crashes to involve a pedestrian, especially at low speeds. Interestingly, the biggest crash differential between a hybrid and its ICE counterpart was between the Civic hybrid and the Civic ICE, despite the fact that the Civic hybrid's internal combustion engine does not shut off even at idle, and the two cars create a similar level of noise. "This new standard would require hybrid and electric passenger cars, light trucks and vans (LTVs), medium and heavy duty, trucks, and buses, low speed vehicles (LSVs), and motorcycles to produce sounds meeting the requirements of this standard. This proposed standard applies to electric vehicles (EVs) and to those hybrid vehicles (HVs) that are capable of propulsion in any forward or reverse gear without the vehicle's internal combustion engine (ICE) operating. This standard would ensure that blind, visually-impaired, and other pedestrians are able to detect and recognize nearby hybrid and electric vehicles, as required by the PSEA, by requiring that hybrid and electric vehicles emit sound that pedestrians would be able to hear in a range of ambient environments and contain acoustic signal content that pedestrians will recognize as being emitted from a vehicle."

NHTSA is proposing this rule to implement the 2010 Pedestrian Safety Enhancement Act, instructing the Agency to conduct a safety standard rulemaking to establish an "alert sound" for hybrid and electric vehicles. The Act requires that the noise made by a hybrid or electric vehicle could allow a pedestrian, especially a sight-impaired pedestrian, to identify the direction of the vehicle. NHTSA is also operating under the National Traffic and Motor Vehicle Safety Act, which requires NHTSA safety standards to "be performance-oriented, practicable, and objective and meet the need for safety. In addition, in developing and issuing a standard, NHTSA must consider whether the standard is reasonable, practicable, and appropriate for each type of motor vehicle covered by the standard." NHTSA estimates that 35 pedestrian lives would be saved as a result of this rule, at a cost of \$830,000 - \$990,000 per life. The total cost estimated for this proposal is about \$25 million, adding about \$30 in cost to the production of each sound-enhanced hybrid or electric vehicle. [Comments](#) are due on March 15th.

In the News

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[New federal mortgage rules aim to reduce risky lending, ensure that borrowers can afford loans](#), *Washington Post*



Consumer Financial Protection Bureau

- Prepared remarks of Richard Cordray at the ability-to-repay rule field hearing, *Richard Cordray*

Free State Foundation

- Chevron Deference and Independent Agencies, *Randolph May*

The Heritage Foundation

- Mortgage Regulation: Is CFPB Qualified?, *Diane Katz & David C. John*
- Businesses Agree: Regulation Is the Wrong Approach to Cybersecurity, *David Inserra*
- Remittance Rules: A Case Study of Regulatory Pitfalls, *Diane Katz*
- EPA's Jackson Leaves Legacy of Higher Costs, Less Consumer Choice, *Katie Tubb*
- How a FOIA Request Brought Down EPA Administrator Lisa Jackson, *Michael Sandoval*

The Mercatus Center

- The Economics and Regulation of Network Branded Prepaid Cards, *Todd Zywicki*
- Rethinking the Volcker Rule, *Hester Peirce & Robert Greene*
- The Pitfalls of Regulating Consumer Credit, *Todd Zywicki & Robert Sarvis*

New England Journal of Medicine

- The 510(k) Ancestry of a Metal-on-Metal Hip Implant, *Brent Ardaugh, Stephen Graves, & Rita Redberg*

Office of the Comptroller of the Currency

- Remarks by Thomas J. Curry Comptroller of the Currency Before the California Bankers Association Annual Bank Presidents Seminar, *Thomas Curry*

Penn Program on Regulation

- How Should the U.S. Regulate Housing Finance After the 2008 Crisis?, *Aimee Martin*
- The Regulatory Week in Review: January 11, 2013, *Mima Mohammed*
- Improving Crisis-driven Financial Regulation, *Margot Campbell*
- Study Suggests that Public Attitudes Hinder Efficient Regulation, *Lauren-Kelly Devine*
- Media, Polarization, and Regulatory Politics, *Jacquelynne Hamilton*

[Obama's new team takes shape: Solis departing, attorney general, HHS, VA secretaries to stay](#), *Washington Post*

[Hilda Solis resigns as labor secretary; some others in Cabinet to stay on](#), *Washington Post*

[Quiet electric cars must be noisier to alert people, NHTSA proposal says](#), *Washington Post*

[SEC charges 2 KPMG auditors with failing to get accurate data on loans by failed TierOne Bank](#), *Washington Post*

[Why the CFPB's new mortgage rule matters](#), *Washington Post*

[U.S. judges look favorably on Obama gun reporting rule](#), *Reuters*

[Pain Pill Makers Get Guidance on Thwarting Drug Addicts](#), *Bloomberg*

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[FCC report blames phone companies for loss of 911 service after derecho storm](#), *Washington Post*

[FDA to require lower recommended dosages for sleep drugs](#), *Washington Post*

[FDA orders lower doses of Ambien and other sleeping pills to prevent morning drowsiness](#), *Washington Post*

[SEC Suits, Sukuk 'Lessons', Volcker Loopholes: Compliance](#), *Bloomberg*

[Lender Review of Borrowers Tightened Under Mortgage Rules](#), *Bloomberg*

[Lew-for-Geithner Switch Ends Era of Tight Fed-Treasury Ties](#), *Bloomberg*

[Berkshire's Peltier Says Mortgage Rule Clears Loan Path](#), *Bloomberg*

[Neil Barofsky on Bank Capitalization, Regulation](#), *Bloomberg TV*

[Banks Need Activists More Than New Rules, Mayo Says](#), *Bloomberg*

[Buffett Says Banks Free of Excess Pose No U.S. Threat](#), *Bloomberg*

[Regulatory 'Loophole' Allowing Unsafe Devices to be Marketed, Say Researchers](#), *Regulatory Focus*

[FCC: Verizon 'has much more to do' to improve 911 reliability](#), *Washington Post*

[New mortgage rules give small banks a chance](#), *Washington Post*

[New mortgage rules: A checklist for consumers](#), *Washington Post*

[U.S. watchdog to hear banks' gripes on new rules Jan. 24](#), *Reuters*

[SEC Sues Volt Information for Allegedly Misstated Revenue](#), *Bloomberg*

1/11/13

[Regulation on Research Misconduct Withdrawn by FDA](#), *Regulatory Focus*

[Regulators critical of Verizon's response to powerful wind storm; question level of fixes](#), *Washington Post*

[Why Boeing's dream plane is under review: questions and answers about the problems of the 787](#), *Washington Post*

[After fire, fuel leak, FAA to conduct review of Boeing's 787 – but officials say plane is safe](#), *Washington Post*

[Federal judge vacates plan designating Alaska polar bear habitat, says it went too far](#), *Washington Post*

[Regulators shut down small lender in Washington state, representing first bank failure of 2013](#), *Washington Post*

[Basel's ratings reliance complicates task for US regulators](#), *Reuters*

[Boeing 787 Power System Said Focus of Special FAA Review](#), *Bloomberg*

[Court Reverses Rule Protecting Polar Bear Habitat](#), *Wall Street Journal*

[Regulator Turns to Peregrine Executives for Fixes, Details on Fraud](#), *Wall Street Journal*

[FDA Leaning Toward Requiring Generic Opioids to Contain Abuse-Deterrent Qualities, Hamburg Says](#), *Regulatory Focus*

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[Energy regulations prompt law firm merger](#), *Washington Post*

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[Report: New regulations cost \\$216B and 87 million hours of paperwork. What do](#)



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[they reap?](#), *Washington Post*

[Will SEC's new rules on marketing be a boon for start-ups or a risk for investors?](#), *Washington Post*

[Government orders JPMorgan to fix oversight tied to \\$6 billion trading loss, money laundering](#), *Washington Post*

[Regulators hit JPMorgan with two enforcement actions](#), *Washington Post*

[St. Jude Receives FDA Warning Letter on Heart Devices](#), *Wall Street Journal*

[FDA Proposes 'New Pathway' to Approve Drugs for Unmet Needs](#), *Regulatory Focus*

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[CBOE to drop traders from board following SEC probe](#), *Reuters*

[Appraisal Standards for Higher-Risk Mortgages Approved by FDIC](#), *Bloomberg*

[SEC-Nasdaq, Morgan Stanley Restitution: Compliance](#), *Bloomberg*

[Banks say they are bogged down by new consumer agency's inexperienced examiners, slow process](#), *Washington Post*

[Auto Safety Advances Sell at Prices Beyond Reach of Many](#), *Bloomberg*

[FCC Conducting Review of Hearing Aid-Focused Regulations](#), *Regulatory Focus*

[Dozens of Medical Device Standards Adopted, Re-Affirmed by FDA](#), *Regulatory Focus*

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[AP Exclusive: EPA reversed course on tainted Texas water wells after gas company protested](#), *Washington Post*

['Odd Couple' in U.S. House to Tackle Mortgage Finance](#), *Bloomberg*

[U.S. FTC finds POM Wonderful health claims deceptive](#), *Chicago Tribune*

[SEC may release 'muni adviser' definition by mid-year](#), *Reuters*

['No End in Sight' to Volcker Rule Process, SEC Commissioner Says](#), *Bloomberg*

Rulemaking

Environmental Protection Agency

EPA Publishes Final Rule Reducing Allowable Annual PM_{2.5} Ambient Air Concentrations by 20 Percent

The Environmental Protection Agency published a [final rule](#) on Tuesday updating the National Ambient Air Quality Standards (NAAQS) for particular matter (PM) and reducing the allowable annual amount of fine particulate matter (PM_{2.5}) content in the air by 20 percent, while leaving standards for PM₁₀ the same. "With regard to the primary standards for fine particles, the EPA is revising the annual PM 2.5 standard by lowering the level from 15.0 to 12.0 µg/m so as to provide increased protection against health effects associated with long- and short-term exposures. The EPA is retaining the level (35 µg/m) and the form (98th percentile) of the 24-hour PM 2.5 standard to continue to provide supplemental protection against health effects associated with short-term exposures. This action provides increased protection for children, older adults, persons with pre-existing heart and lung disease, and other at-risk populations against an array of PM 2.5-related adverse health effects that include premature mortality, increased hospital admissions and emergency department visits, and development of chronic respiratory disease. The EPA also is eliminating spatial averaging provisions as part of the form of the annual standard to avoid potential disproportionate impacts on at-risk populations." EPA estimates that the benefits of this rule range from between \$3.6 billion – \$9.1 billion over the next seven years (or \$514 million – \$1.3 billion annually), with costs ranging from \$53 million – \$350 million annually.

Food and Drug Administration

FDA Proposes Growing, Harvesting, and Packaging Requirements to Prevent Food Contamination

The Food and Drug Administration published a [proposed rule](#) establishing minimum standards for growing, harvesting, and packaging of fruits and vegetables in order to minimize the risk of death or illness from the consumption of contaminated produce. Among other things, the rule would require standards for worker health and hygiene, water intended for agricultural uses, domesticated animals on produce plots, equipment, tools, buildings, and the documentation of the treatment of beans and seeds for sprouting. FDA estimates that these requirements will incur \$630 million in costs annually for covered producers, both domestically and abroad. Additionally, FDA



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estimates that the benefits resulting from reducing illness and death associated with contaminated food will be \$1.04 billion, representing 65 percent of all U.S. illnesses and deaths caused by the consumption of contaminated foods. In clarifying the scope of the rule, FDA specifies that the requirements “would not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity.” The rule, if finalized, will be effective 60 days after publication; however, small businesses are granted an additional three years for compliance. [Comments](#) are due on May 16th.

FDA Proposes Amendments to Existing Good Practices for Manufacturing Human Food

The Food and Drug Administration published a [proposed rule](#) revising its existing rule governing good manufacturing practices for manufacturing, packing, and holding food for human consumption. The good manufacturing practices, last updated in 1986, are being changed to implement hazard analysis and risk-based preventive controls for international and domestic producers. “These preventive controls would include requirements for covered facilities to maintain a food safety plan, perform a hazard analysis, and institute preventive controls for the mitigation of those hazards. Facilities would also be required to monitor their controls, verify that they were effective, take any appropriate corrective actions, and maintain records documenting these actions.” FDA estimates that these requirements will cost between \$319 million – \$475 million annually for covered entities. However, the Agency was unable to estimate any benefits, and instead relies on a breakeven percentage point at which the benefits of the rule will justify the costs. By this measure, the rule must prevent between 16 and 24 percent of domestic food product illnesses annually. [Comments](#) are due on May 16th.

Department of Transportation

NHTSA Announces Draft Environmental Assessment for Hybrid Noise Rule

The National Highway Traffic Safety Administration published a [notice](#) announcing the availability of a [Draft Environmental Assessment](#) evaluating potential environmental impacts of the Agency’s proposed rule, *Minimum Sound Requirements for Hybrid and Electric Vehicles*. The rule would require manufacturers of hybrid and electric vehicles to meet certain noise requirements for vehicles traveling at slower than 18 miles per hour in order to alert nearby pedestrians to the vehicle. [Comments](#) on the environmental assessment are due on March 15th.

FAA Proposes Rule Prohibiting Flightcrew from Using Cell Phones, Laptops on Flight Deck

The Federal Aviation Administration published a [proposed rule](#) that would prohibit flightcrew members from using cell phones or laptops on the flight deck during the operation of aircraft, except in cases of emergency or to perform tasks directly related to the operation of the aircraft. “This rule is intended to ensure that certain non-essential activities do not contribute to the challenge of task management on the flight deck and do not contribute to a loss of situational awareness due to attention to non-essential activities, as the previously discussed incidents highlight. Situational awareness is an attention based phenomenon that reflects the flightcrew's knowledge of where the aircraft is in regard to location, air traffic control, weather, regulations, aircraft status, and other factors.” [Comments](#) are due on March 17th.

Department of the Interior

FWS Proposed Rule Would Designate Gunnison Sage-Grouse as an Endangered Species

The Fish and Wildlife Service published a [proposed rule](#) that would designate the Gunnison Sage-Grouse as an endangered species under the Endangered Species Act (ESA). In response to a judicially-approved settlement agreement, the FWS is required to make a determination regarding the endangered status of the sage-grouse before September 30th, 2013. “Based on the best available scientific and commercial data, we have determined that the principal threat to Gunnison sage-grouse is habitat loss, degradation, and fragmentation due to residential, exurban, and commercial development and associated infrastructure such as roads and power lines. The human population is increasing throughout much of the range of Gunnison sage-grouse, and data indicate this trend will continue. With this growth, we expect an increase in human development, further contributing to loss and fragmentation of Gunnison sage-grouse habitats. Other threats to the species include improper grazing management; predation (often facilitated by human development or disturbance); genetic risks in the declining, smaller populations; and inadequate local, State, and Federal regulatory mechanisms (e.g., laws, regulations, zoning) to conserve the species.” [Comments](#) are due on March 12th.



FWS Proposal Designates 1.7 Million Acres in Utah as Critical Habitat for Gunnison Sage-Grouse

The Fish and Wildlife Service published a [proposed rule](#) designating revised critical habitat for the Gunnison Sage-Grouse under the Endangered Species Act (ESA). This rule would designate 1,704,227 acres (approximately 2,663 square miles) as critical habitat for the sage-grouse in order to conserve the sage-grouse's habitat. In a separate rulemaking, FWS is proposing to designate the sage-grouse as an endangered species. Designation of an area as critical habitat ensures that “those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical and biological features within an area, we focus on the principal biological or physical constituent elements (primary constituent elements such as roost sites, nesting grounds, seasonal wetlands, water quality, tide, soil type) that are essential to the conservation of the species. Primary constituent elements are those specific elements of the physical or biological features that provide for a species' life-history processes and are essential to the conservation of the species.” The areas designated as critical habitat are located in Utah. [Comments](#) are due on March 12th.

Agencies

Environmental Protection Agency

EPA Releases Draft Documents on Review of National Ambient Air Quality Standards for Lead

The Environmental Protection Agency published a [notice](#) announcing the availability of a [draft document](#) prepared for the review of the National Ambient Air Quality Standards (NAAQS) for lead (Pb) titled *Policy Assessment for the Review of the Lead National Ambient Air Quality Standards, External Review Draft* for public review. “Presently, EPA is reviewing the air quality criteria and NAAQS for Pb. The EPA's overall plan and schedule for this review is presented in the Integrated Review Plan for the Lead National Ambient Air Quality Standards. The draft PA document announced today, when final, will serve to “bridge the gap” between the scientific information and the judgments required of the Administrator in determining whether to retain or revise the existing NAAQS for Pb, and, if revision is considered, what revisions may be appropriate. The draft PA builds upon information presented in the third draft Integrated Science Assessment for Lead and health and ecological risk assessments developed in the last review.” [Comments](#) are due on February 4th.

Food and Drug Administration

FDA Announces Availability of Draft Risk Assessment for New FDA Food Safety Rules

The Food and Drug Administration [announced](#) the availability of a draft qualitative risk assessment for activities conducted on farms and the risks they may pose to food safety. “The purpose of the draft RA is to provide a science-based risk analysis of those activity/food combinations that would be considered low risk. FDA conducted this draft RA to satisfy requirements of the FDA Food Safety 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. Elsewhere in this issue of the Federal Register, FDA is using the results of the draft RA to propose to exempt food facilities that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities identified in the draft RA as low-risk activity/food combinations from the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for hazard analysis and risk-based preventive controls.” [Comments](#) are due on February 15th.

FDA Permits Chicken of the Sea to Deviate from Identity Standards by Selling Flavored Tuna

The Food and Drug Administration published a [notice](#) announcing its intent to allow Chicken of the Sea International to sell canned tuna that does not conform with the FDA's identity standards for canned tuna in order to gauge market response and consumer demand. “The permit covers limited interstate marketing tests of products identified as “no drain canned tuna” products. These test products deviate from the U.S. standard of identity for canned tuna... in that the test products are prepared by: (1) Adding such a small amount of liquid that the products will not contain a packing medium in accordance with the standard; (2) adding seasoning and flavoring ingredients (i.e., lemon juice concentrate, lime oil, and chili paste) that are not permitted under the current standard; and (3) deviating from the fill requirements of the standard without including on the product label a general statement of substandard fill. The test products meet all the requirements of the standard with the exception of these three deviations. The purpose of this temporary permit is to market test the product throughout the United States. The permit will allow the applicant to measure customer acceptance of the new product and assess the new product's commercial feasibility.”



FDA Announces Public Hearing on New Approval Pathways to Expedite Approval of Certain Drugs

The Food and Drug Administration published a [notice](#) announcing a public hearing on February 4th and 5th to obtain public input on “a potential new pathway to expedite the development of drugs, including biological products, for serious or life-threatening conditions that would address an unmet medical need. The drug's safety and effectiveness would be studied in a smaller subpopulation of patients with more serious manifestations of a condition. Such a pathway could involve smaller and more rapid clinical trials than would occur if the drug were studied in a broader group of patients with a wide range of clinical manifestations. The labeling of drugs approved using this pathway would make clear that the drug is narrowly indicated for use in limited, well-defined subpopulations in which the drug's benefits have been shown to outweigh its risks. The purpose of the public hearing is to obtain information and comments from the public on the need for and feasibility of this pathway and its potential advantages and disadvantages.” [Comments](#) are due on February 28th.

Securities and Exchange Commission

SEC Announces January 18th Public Meeting of the Dodd-Frank Investor Advisor Committee

The Securities and Exchange Commission published a [notice](#) announcing a public meeting of the Dodd-Frank Investor Advisor Committee on Friday, January 18th from 10:00am – 4:00pm. “The agenda for the meeting includes: Introductory remarks from Chairman Walter and Commissioners; introductory remarks from Committee officers; discussion of administrative matters; and reports from the four Investor Advisory Committee subcommittees (the Investor as Owner subcommittee, the Investor as Purchaser subcommittee, the Investor Education subcommittee, and the Market Structure subcommittee).”

SEC Announces February 1st Public Meeting of SEC Advisory Committee on Small and Emerging Companies

The Securities and Exchange Commission published a [notice](#) announcing a public meeting of the SEC’s Advisory Committee on Small and Emerging Companies on Friday, February 1st at 9:30am. “The public is invited to submit written statements to the Committee. The agenda for the meeting includes consideration of recommendations and other matters relating to rules and regulations affecting small and emerging companies under the federal securities laws.”

Export-Import Bank

Ex-Im Bank Receives Application for \$100+ Million to Fund Boeing Exports to South Korea

The Export-Import Bank published a [notice](#) announcing the receipt of an application for a long-term loan or financial guarantee in excess of \$100 million to fund the export of commercial Boeing aircraft to South Korea. If successful, these aircraft would be used for long-haul passenger and cargo air service between South Korea and other countries. [Comments](#) are due on February 8th.

Ex-Im Bank Receives Application for \$100+ Million to Fund Boeing Exports to Chile

The Export-Import Bank published a [notice](#) announcing the receipt of an application for a long-term loan or financial guarantee in excess of \$100 million to fund the export of commercial Boeing aircraft to Chile. These exports would be used for long-haul passenger and cargo air service from Chile and Brazil to other countries. [Comments](#) are due on February 8th.

