VIII. PUBLIC SAFEGUARDS PAST DUE

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(originally published June 2012)[2]

Congressional critics often accuse civil servants of racing regulations to completion with little oversight. For instance, Senator Johnny Isakson (R-Ga.) once warned of "unelected bureaucrats in federal agencies who now are able to freely write rules and regulations."[3]

Ironically, Congress often sets deadlines for the agencies to complete regulations, and most of those deadlines are missed.

We reviewed 159 regulations subject to statutory deadlines that were listed in the government's fall 2011 report of pending and recently completed regulations that were due no later than June 2012. Of these, 79 percent missed their congressionally established deadlines and more than half remained incomplete as of the end of June.

As discussed elsewhere in this book, an array of obligations, including the Regulatory Flexibility Act and Executive Order 12866, hinder agencies' ability to complete rules. An additional obstacle that is prominent in the examples discussed in this chapter is the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA), which reviews draft rules created by non-independent agencies.

Under Executive Order 12866, OIRA is allotted 90 days to review submitted drafts of regulations, with one 30-day extension.[4]

But the agency often does not abide by the 120-day guideline.[5] For example, all 14 of the rules included in this study that are currently at OIRA have been under review for more than 120 days. In total, 51 percent of the rules submitted to OIRA that were included in this study exceeded 120 days of review.

But solely blaming requirements for the government's poor record in meeting deadlines would be overly simplistic. The agencies and OIRA also play a determinative role in pushing rules to fruition when they have the will to do so.

Consider the contrast between OIRA's record of reviewing rules in recent years with its current performance. Although OIRA missed its deadline on all 14 rules currently under its review, the office's previous record was better. Among rules included in this report that previously went through OIRA, more than two-thirds were processed within 120 days. Common sense suggests that OIRA slowed down its rulemaking efforts in 2012 because this is a presidential election year and regulations are a major issue.

Findings

The data set used in this analysis was limited to rules listed in the fall 2011 issue of the Unified Agenda of Federal Regulatory and Deregulatory Actions. Public Citizen assessed whether rules with statutory deadlines assigned to 12 public safety and consumer protection agencies were issued by congressionally mandated due dates.[6] (Methodology discussed in footnote.) For those rules that underwent review by OIRA, Public Citizen calculated whether OIRA's review exceeded 120 days.[7]

The data set includes 159 rules. Public Citizen's analysis found that nearly four-fifths of these rules missed their deadline, and that more than half of those rules whose due dates have passed remain incomplete. (Note: Figures are as of June 2012). Specifically:

- 79 percent of the rules included in this study were not issued by the statutory deadline;
- 51 percent of the rules included in this study remain incomplete;

- 51 percent of the rules that were sent to OIRA were reviewed more than 120 days, the maximum review time that OIRA is afforded; and
- Each of the rules included in this study that are currently at OIRA has been under review for more than 120 days.

Eight of the twelve agencies included in this study missed at least 70 percent of their statutory deadlines. The Environmental Protection Agency (EPA) missed 89 percent of its deadlines. The Commodity Futures Trading Commission (CFTC) and Securities and Exchange Commission (SEC), two agencies tasked with creating rules to implement the Dodd-Frank Wall Street Reform and Consumer Protection Act, were responsible for more than one-third of the rules included in Public Citizen's analysis. Combined, these eight agencies also missed 89 percent of their deadlines. [See Figure 1]

Public Citizen asked the Office of Management and Budget if it believes OIRA's track record of reviewing rules within its allotted 120 days is acceptable. OMB's response is published in an Appendix at the end of this chapter.

Figure 1: Agencies' Records of Completing Rules with Statutory Deadlines

Agency	No. of Rules with Statutory Deadlines	No. of Rules that Met Deadline	No. of Rules that Missed Deadline	Pct. of Rules Delayed
Consumer Product Safety Commission	1	0	1	100.0%
Commodity Futures Trading Commission	24	2	22	91.7%
Environmental Protection Agency	9	1	8	88.9%
Securities & Exchange Commission	32	4	28	87.5%
Department of Energy	21	3	18	85.7%
Department of Transportation	37	8	29	78.4%
Food and Drug Administration	8	2	6	75.0%
Department of Agriculture	11	3	8	72.7%

Agency	No. of Rules with Statutory Deadlines	No. of Rules that Met Deadline	No. of Rules that Missed Deadline	Pct. of Rules Delayed
Comptroller of the Currency	3	1	2	66.7%
Federal Communications Commission	4	3	1	25.0%
Federal Reserve System	8	6	2	25.0%
Consumer Financial Protection Bureau	1	1	0	0.0%
Totals	159	34	125	78.6%

Source: Public Citizen analysis of rules with statutory deadlines listed in 2011 issue of the Unified Agenda of Federal Regulatory and Deregulatory Actions

Case Studies

This study examines four delayed rules (or sets of rules). It looks at rules to improve food safety, a rule to prevent backover automobile accidents, a rule requiring labeling of minerals from a war-torn section of Africa, and a rule mandating a reduction in the use of fossil fuels in federal buildings.

Food Safety Rules

In 2011, according to the Centers for Disease Control and Prevention (CDC), 48 million people in United States contracted foodborne illnesses. Of these, 128,000 were hospitalized and 3,000 died.[8] In November 2011, Congress passed the Food Safety Modernization Act, or FSMA, the most significant revision to U.S. food safety regulations in 70 years.[9] Although the Department of Agriculture is responsible for overseeing meat, poultry, and egg products, the Food and Drug Administration (FDA) regulates most of the U.S. food supply.[10] FSMA provides the FDA with tools to better protect the U.S. food supply, more quickly recall tainted foods, and more effectively respond to foodborne illness outbreaks.

Four important FSMA rules are stuck in the regulatory review process. [See Figure 2] They will eventually implement safety measures at food and animal feed processing facilities, create minimum requirements for the safe handling of produce, and require food importers to meet U.S. food safety standards.

Figure 2: Pending Food Safety Rules with Statutory Deadlines Required by FSMA

Rule	Deadline	Type of Rule Required by Deadline	Delay	Rule is Currently at OIRA	Date OIRA Received Rule
Preventive Controls for Food Processing Facilities	7/4/2012	Final	Yes	Yes	11/22/2011
Preventive Controls for Animal Feed Processing Facilities	9/27/2009‡	Final	Yes	Yes	12/5/2011
Foreign Supplier Verification Program	1/4/2012	Final	Yes	Yes	11/28/2011
Produce Safety Regulation	1/4/2012	Proposed	Yes	Yes	12/9/2011

Source: Public Citizen analysis of OIRA Regulatory Dashboard provided by the Office of Management and Budget (http://www.reginfo.gov)

‡The Food and Drug Amendments of 2007 set a statutory deadline for animal feed safety that had yet to be fulfilled by the end of June 2012. FSMA included a substantially similar requirement.

Because these four pending rules are considered to pose significant costs and have a significant economic impact on small entities, the FDA must complete a variety of analyses before finalizing the rules. For example, it must conduct comprehensive cost-benefit and Regulatory Flexibility Act analyses.

There is a "logistical challenge of getting this volume of rulemaking done and out the door at the same time," Michael Taylor, deputy commissioner for foods at the FDA, told *Food Safety News* in January.[11]

The FDA drafted proposed versions of the four rules within the last year and submitted them to OIRA. OIRA has had each of the proposals under review for the past six months. The delay at OIRA "baffles consumer advocates and industry groups," which in rare agreement joined forces to lobby for passage of the legislation and press for its funding,[12] *The Washington Post* reported in May. Both consumer and industry representatives are uncertain about why OIRA is delaying the release of the proposed rules.

Even after OIRA completes its review, critical steps remain before the FDA can issue final regulations: The agency must

officially release the proposed versions to the public, conduct public comment periods (typically lasting 60 days or more) and, after having considered all public comments, prepare final rules. The FDA must then send the final rules to OIRA for review before they can be issued. This section breaks out four components of the law.

Preventive Controls for Food Processing Facilities: This pending regulation would improve manufacturing, processing, packing, and distribution of food at processing facilities.[13] FSMA requires companies to develop written food safety plans that identify hazards at food processing facilities and aim to prevent food contamination.[14] Safety plans can address issues surrounding environmental pathogens, food allergens, mandatory employee training, and sanitation of food contact surfaces.[15] Before the passage of FSMA, FDA had not updated standards for good manufacturing practices since 1986.[16] The FDA is to inspect the safety plans, and confirm that they are effective and properly followed by food processors.

FSMA's preventive measures at food processing plants are designed to address common causes of contamination, like those that led in 2011 to a listeria outbreak that infected 146 people and caused 32 fatalities.[17] Details later revealed that there was bacteria on the equipment that processed cantaloupes. Cantaloupes also were not washed with antimicrobial solutions or cooled before storage, as proper care would require.[18]

Preventive Controls for Animal Feed Processing Facilities: FSMA requires companies to develop written safety plans to prevent hazards in animal feed processing facilities similar to the preventive controls being implemented at sites handling food intended for human consumption.[19]

These preventive measures would reduce the instances of contaminated animal food products that can harm people who handle the feed, as well as the animals who consume it. From 2006 to 2008, nearly 80 people, including 32 children under the age of

two, were infected as a result of coming into contact with contaminated dog or cat food.[20] The rule would prevent pet food contamination similar to several outbreaks that occurred in the past two years involving Salmonella-contaminated pet food. An outbreak this year sickened at least 14 people in nine states.[21]

Foreign Supplier Verification Program: The foreign supplier verification program stems from the need to prevent future outbreaks similar to recent outbreaks from Salmonella-contaminated yellowfin tuna from India, which infected more than 160 people, or the outbreak from Salmonella-contaminated pet treats imported from China, which resulted in the FDA receiving 350 reports of pet illnesses. [22]

To address the 15 percent of the U.S. food supply that is imported, FSMA increases the FDA's tools and authorities to verify that imported food is produced in compliance with U.S. requirements.[23] The foreign supplier verification program will require foreign food processing facilities to adhere to the same standards as the preventive controls measures to be implemented domestically.[24] In addition to the foreign supplier verification program, FSMA requires the FDA to conduct inspections of 600 facilities worldwide within the first year of the program's enactment and double those inspections every year for the next five years.[25] In fiscal year 2011, the FDA inspected 438 foreign food facilities.[26] FSMA proposes to increase inspections by at least 37 percent during its first year of implementation.

Produce Safety Rule: According to the Center for Science in the Public Interest, produce is one of the 10 riskiest FDA-regulated foods.[27] Leafy greens—such as iceberg lettuce, baby leaf lettuce, and spinach—have caused 363 outbreaks that resulted in 13,568 reported cases of illness since 1990.[28] A cause of 64 percent of outbreaks is a pathogen called Norovirus, which spreads from unwashed hands handling produce.[29] In some cases, a more deadly strain of bacteria, such as E. coli can cause an outbreak. Earlier this

year, 58 people from nine states were infected with E. coli as a result of coming into contact with a brand of romaine lettuce.[30]

The produce safety rule would establish much-needed minimum standards for safe growing and harvesting of fresh fruits and vegetables. The rule is currently under review by OIRA.[31]

Rearview Mirrors Rule

In 2008, President George W. Bush signed the Cameron Gulbransen Kids Transportation Safety Act. The law includes several mandates aimed at reducing fatalities and injuries to children in auto accidents that do not occur in traffic.[32] Among its requirements, the law calls on the National Highway Traffic Safety Administration (NHTSA) to improve its standard on motor vehicles' rearview mirrors to enable drivers to detect the presence of people immediately behind a vehicle.[33] But a year past the deadline set by the Congress for NHTSA to issue the rule, it remained incomplete.

The act was named after two-year old Cameron Gulbransen, who was killed when his father accidentally backed over him in the family's driveway. The intent of the requirement for a new rearview mirror rule was to avoid such tragedies by expanding the field of view of a motor vehicle driver to minimize blind spots—areas in which drivers cannot see either by turning around or using their vehicles' mirrors—directly behind the vehicle.[34] NHTSA concluded that the rule would prevent 95 to 112 fatalities a year and 7,072 to 8,374 injuries.[35]

On average, 292 fatalities and 18,000 injuries result from backover crashes every year.[36] These types of crashes most often occur in areas off public roads, such as on driveways or in parking lots, because drivers cannot see a person standing directly behind the vehicle as they back up.[37] NHTSA, in its proposed rule, elaborated on the disproportionate risk backover crashes pose to children and older individuals. "When restricted to backover fatalities involving passenger vehicles," the proposed rule states, "children under 5 years old account for 44 percent of the fatalities, and adults 70 years of age and older account for 33 percent."[38]

The law permitted the improved safety standard to be met with additional mirrors, sensors, cameras or other technology.[39] But NHTSA concluded that camera-based systems were the only effective type of technology currently available to avoid backover crashes.[40] Adding cameras would cost $159 to $203 per vehicle, NHTSA calculated.[41] In anticipation of the rule, some automakers, such as Honda, have been designing some new models with camera-based systems as standard equipment.[42] According to *The New York Times*, 45 percent of all 2012 vehicle models include a rearview camera as a standard feature and 23 percent include it as an option.[43]

The law set a Feb. 28, 2011, deadline to finalize the rule, but Congress afforded the secretary of the Department of Transportation the authority to extend the deadline. Transportation Secretary Ray LaHood has subsequently extended the deadline twice,[44] most recently to Dec. 31, 2012.[45]

OIRA has held on to a draft of the rulemaking for more than seven months, well past its allotted 120 days.[46] There is little transparency into OIRA's decision-making process[47] and observers have put forth various reasons for the delay.

Some suggest political concerns are slowing the rule's finalization.[48] Others have focused on cost-benefit analysis.[49] If it saved 112 lives a year, the rule would cost $11.8 million per life saved.[50] NHTSA has generally deemed $6.1 million as the value of a "statistical life."[51]

But the cost-benefit analyses fail to take several factors into account, NHTSA noted. Among them, 44 percent of victims of backover crashes are "under 5 years of age with nearly their entire lives ahead of them," NHSTA wrote in the proposed rule, suggesting that the generic "value" of a human life should not apply in this instance.

Also, NHTSA noted, the horrific pain of a parent causing his or her child's death cannot be measured in dollars and cents. The cost-benefit calculation on lives saved also fails to place a value on avoiding 7,072 to 8,374 injuries in backover accidents.[52]

There are further unquantifiable benefits that would accrue from universal inclusion of cameras in vehicles, NHTSA noted, such as the "increased ease and convenience of driving, and especially parking," as well as the value that society places on the protection of children.[53]

Finally, the costs are probably greatly overstated. NHTSA forecasts that "the costs are likely to be substantially less when actually installed in future model years" because of technological innovation. But NHTSA was not permitted to factor this judgment into its calculations because the guidelines that govern cost-benefit analyses prohibited the agency from doing so.[54]

Evaluating the rule purely on a cost-benefit basis misses a more fundamental point: an unobtrusive technological solution exists to save more than 100 lives a year.

The rule could be implemented for less than the cost of three full tanks of gas for a minivan, hardly a major expenditure in relation to the price of a new car. But about two people a week are dying unnecessarily while OIRA mulls over formulas to determine whether saving those lives is worth the cost.

Conflict Minerals Rule

Many provisions of the Dodd–Frank Wall Street Reform and Consumer Protection Act were enacted to protect U.S. consumers. But Section 1502 is primarily directed at reducing the purchase of "conflict minerals," the sale of which is financing human rights abuses by combatants in the Democratic Republic of Congo. Section 1502 requires the Securities and Exchange Commission to issue a rule directing publicly held U.S. companies to disclose whether any of four metals—gold, tantalum, tungsten and tin—that are present in their products came from central Africa, where trade in these commodities has funded years of civil war.[55]

"It is the sense of Congress," the act states, "that the exploitation and trade of conflict minerals originating in the Democratic Republic of the Congo is helping to finance conflict characterized by extreme levels of violence…particularly sexual-

and gender-based violence and contributing to an emergency humanitarian situation therein."[56]

Section 1502 requires public companies to "exercise due diligence" in tracking the supply chain of the minerals to their origin.[57] Companies must contract with independent auditors to assess the composition of their products and disclose the findings in their annual reports to the SEC. Companies may label their products "DRC conflict free" if they qualify.[58]

The statute required the SEC to promulgate the rule by April 15, 2011.[59] The agency issued a proposed rule in December 2010. A year-and-a-half hence, the agency has yet to issue a final rule.

After the April 2011 deadline passed, the SEC said that the rule would be out by December. Then it said by June.[60] Numerous industry groups have likely contributed to the delay by heavily lobbying the SEC to scale back the proposed rule and to establish a phase-in period to delay its effective date.[61] [See Figure 3]

Figure 3: Selected Organizations That Have Lobbied the SEC on the Conflict Mineral Rule, 2011-2012

Organization
American Apparel & Footwear Association
AngloGold Ashanti North America Inc.
Best Buy Co.
Eastman Kodak Company
General Motors Company
National Electrical Manufacturers
National Retail Federation
Panasonic Corporation
Retail Industry Leaders Association
Siemens Corporation
The Procter & Gamble Company
Tyco Electronics Corporation
U.S. Chamber of Commerce
Wal-Mart Stores Inc.
Xerox Corporation

Source: Public Citizen analysis of Senate Disclosure Lobbying Database (http://www.senate.gov)

Human rights groups and faith-based groups have countered by urging the SEC to issue a strong rule.[62]

Federal Building Energy Efficiency Performance Standards Rule

In December 2007, President George W. Bush signed the Energy Independence and Security Act. Section 433 of the act requires the Department of Energy (DOE) to gradually achieve carbon-neutrality in new and renovated federal buildings' energy consumption by 2030.[63] The act directed the DOE to revise building energy efficiency performance standards by December 2008.[64] Three-and-a-half years later, the rule has yet to be completed.

The rule, designed to be a national model for carbon-neutral construction, will phase out the use of energy generated from fossil fuels—coal, oil, natural gas, kerosene, and liquefied petroleum—in new federal buildings by 2030. The gradual elimination of fossil fuels was set to begin with a 55 percent reduction by 2010, a 65 percent reduction by 2015, an 80 percent reduction by 2020, a 90 percent reduction by 2025, and a complete elimination of fossil fuel use by 2030.[65] The rule also would apply to any building set to undergo renovations costing more than $2.5 million.[66]

The federal government spends more than $7 billion annually to operate 502,000 buildings.[67] In fiscal year 2007, the latest year for which data is available, federal buildings accounted for 2.2 percent of all U.S. building energy consumption.[68]

For the past 10 months, the rule has been under review by OIRA, which signed off on a proposed draft in 2010.[69]

On April 12, 2012, eight months into OIRA's second review of the rule, representatives of OIRA, the DOE and the White House Council on Environmental Quality met with representatives from the American Gas Association (AGA) and the Federal Performance Contracting Coalition in a closed-door meeting.[70] During the meeting, the AGA said that it would be calling on Congress to eliminate or substantially change the rule.[71] Since 2010, the AGA has spent $1.9 million on lobbying and has given about $700,000 in campaign contributions to congressional members and candidates.[72]

An amendment was inserted in the fiscal year 2013 Energy and Water Appropriations Bill (which the House Appropriations

Committee approved in April 2012) to prohibit funding of the rule.[73] The author of the amendment, Representative Rodney Alexander (R-La.) said that implementing the rule would be harmful to the gas industry.[74] The rule now languishes at OIRA and faces an uncertain funding future.

Conclusion

As this report outlines, agencies often miss statutory deadlines for issuance of rules needed to implement new laws.

Members of both houses of Congress have proposed bills that threaten to further hamper the already cumbersome and lengthy rulemaking process. These bills, such as the Regulatory Accountability Act (H.R. 3010, S. 1606) and the Regulatory Freeze for Jobs Act (H.R. 4078), would further politicize rulemakings and exacerbate the delay of critical rules.

The rulemaking process is already bottled up due to requirements that agencies conduct dense analyses and reviews. Even when Congress sets a deadline to prioritize a rulemaking, agencies are missing nearly four-fifths of those deadlines. Congress should be looking for ways to make the rulemaking process more efficient, not proposing hurdles to slow it down.

Appendix

OMB's Response to Public Citizen's Query on Whether It Deems OIRA's Track Record on Meeting Its 120 Day Review Deadline Acceptable

The mission of the White House Office of Information and Regulatory Affairs includes managing the important process of interagency review of regulatory action—drawing on expertise across the administration to help ensure that rules comply with the law and, to the extent permitted by law, maximize benefits while minimizing costs. As part of this process, OIRA maintains an open door policy for receiving public input while rules are under review. There is also an extensive public comment period that accompanies proposed regulations, which provides an extensive opportunity for participation from all members of the public. The Administration works as expeditiously as possible on draft rules.

At the same time, it is critical that we take the time to get it right—particularly for complex rules that are important to public safety. When a review is extended, it is because we are committed to getting it right.

On [pending] food safety [rules]: The Administration is working as expeditiously as possible to implement legislation we fought so hard for. When it comes to rules with this degree of importance and complexity, it is critical that we get it right.

Our regulatory record reflects the Administration's commitment to protecting the health, welfare, and safety of the American people at the same time that we promote economic growth, job creation, competitiveness, and innovation. That record includes billions of dollars in regulatory benefits, including not only extraordinary economic savings for businesses and consumers, but also deaths prevented and illnesses and accidents avoided.

The net benefits of regulations issued through the third fiscal year of the Obama Administration have exceeded $91 billion. This amount, including not only monetary savings but also lives saved and injuries prevented, is over 25 times the net benefits through the third fiscal year of the Bush Administration.

–Moira Mack, spokeswoman,
Office of Management and Budget (June 2012)