The Risk to Food Safety Protections Posed by the Regulatory Accountability Act: Past, Present, and Future

The misleadingly named Regulatory Accountability Act (RAA) would have a devastating impact on the ability of the federal government to respond to outbreaks in our food supply that sicken consumers, as well as other threats to public health and the safety of our food.

The safeguards listed below, past, present, and future, would have been (or would be) undermined or stopped cold by the RAA: they would fail its inflexible cost/benefit test, be stalled by the White House, challenged in court, or simply never be initiated because the agency would balk at the prospect of a grueling trial-type hearing.

Past safeguards that would have been put at risk by the RAA:

Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration, May 26, 2016 (Major Rule):

- Purpose: Preventing intentional adulteration due to acts intended to cause wide-scale harm to public health, including acts of terrorism targeting the food supply. Such acts, while likely to be infrequent, could cause illness, death, and economic disruption of the food supply absent mitigation strategies proposed by the regulation.
- RAA risk: This safeguard would not have satisfied the RAA's cost/benefit requirement. The FDA attempted to put a dollar value on the benefits of preventing various intentional adulteration scenarios, but eventually concluded that these benefits were unquantifiable, presumably because terrorist attacks are difficult to predict.[1] In addition, any determinations by the agency regarding costs and benefits could have been disputed in a trial-type hearing or challenged in court, stalling the rule.

Final Rule on Sanitary Transportation of Human and Animal Food, April 6, 2016 (Major Rule):

- Purpose: Protecting foods from farm to table by keeping them safe from contamination during transportation.
- RAA risk: This safeguard would not have satisfied the RAA's cost/benefit requirement. The FDA concluded that it did not have sufficient data to fully quantify the rule's benefits.[2] In addition, any determinations by the agency regarding costs and benefits could have been disputed in a trial-type hearing or challenged in court, stalling the rule.

Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals, November 13, 2015 (Major Rule):

- Purpose: Verifying that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards.

- RAA risk: This safeguard would not have satisfied the RAA's cost/benefit requirement. The FDA lacked sufficient data to determine the extent to which particular safeguards might be responsible for reducing foodborne illnesses.[3] In addition, any determinations by the agency regarding costs and benefits could have been disputed in a trial-type hearing or challenged in court, stalling the rule.

Removal of partially hydrogenated oils (the major source of trans fat in the diet) from the food supply, June 17, 2015:

- Purpose: Removing the major source of artificial trans fats from the food supply, reducing deaths and coronary illness.
- RAA risk: The FDA's declaratory order removing partially hydrogenated oils from the food supply likely would have met the definition of a major guidance under the RAA, meaning the policy could not have been issued without White House review and approval. That would have taken the final decision out of the hands of public health officials and put it into the hands of politicians. While the vast majority of manufacturers have now successfully reformulated their products to exclude these harmful fats, a subset of industry would prefer certain exemptions from the ban.[4] This subset could have leveraged White House review to slow or stall the FDA's decision.[5]

Pending safeguards put at risk by the RAA:[1]

Proposed Action Level for Inorganic Arsenic in Infant Rice Cereal, April 2016 (Draft Guidance for Industry):

- Purpose: Proposing an action level, or limit, of 100 parts per billion (ppb) for inorganic arsenic in infant rice cereal to reduce infant exposure to inorganic arsenic.
- RAA risk: This guidance could meet the definition of a major guidance under the RAA, meaning it would be subject to the RAA's cost/benefit requirement and could be held up under White House review.[6]

Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, December 30, 2016 (Major Rule):

- Purpose: Implementing statutory requirements for nutrition labeling (including calorie counts) on menus for chain restaurants and similar retail food establishments.
- RAA risk: The rule, which the FDA plans to re-open, was broadly supported by the traditional restaurant industry, and the FDA determined that the benefits outweighed the costs.[7] Nevertheless, segments of the food service industry (e.g., convenience stores, grocery stores, and pizza delivery restaurants) opposed the final rule. If the rule is re-opened, these actors could be allowed to demand a

[1] The RAA does not apply to "pending" matters, but the term is not defined. Statutorily-required regulations, proposed regulations and guidance documents, and final regulations and guidance documents that could still be amended may or may not qualify.

formal hearing under the RAA and litigate any resulting determination, stalling or blocking the rule.

Nutrition Standards for School Lunches, January 26, 2012 (Major Rule):

- Purpose: Enhancing the diet and health of school children and helping mitigate the childhood obesity trend.
- RAA risk: The rule, which the USDA plans to re-open, would not have met the RAA's cost/benefit requirement because the USDA's Food and Nutrition Service couldn't calculate the benefits of reduced childhood obesity, improved confidence of parents and families in the nutritional quality of school meals, or the contribution of school meals to the overall nutrition of the school environment.[8] In addition, any determinations by the agency regarding costs and benefits could have been disputed in a trial-type hearing, stalling the rule.

Food Labeling: Revision of the Nutrition and Supplement Facts Labels, May 27, 2016 (Major Rule):

- Purpose: Updating the nutrition information offered on food packaging to be consistent with current data on the associations between nutrients and chronic diseases, health-related conditions, and/or maintaining a healthy dietary pattern that reflects current public health conditions in the United States, and corresponds to new information on consumer understanding and consumption patterns.
- RAA Impact: This rule is finalized, but the current administration has proposed delaying implementation, and the rule may be re-opened. The FDA's analysis shows benefits ranging from $200 million to $5 billion, and costs ranging from $200 million to $800 million. But these overlapping estimates rely on data and analysis that could easily be disputed by opponents of the new—at least enough to allow opponents to demand a trial-type hearing, stalling the rule.[9]

FDA Draft Guidance for Industry: Voluntary Sodium Reduction Goals, June 2016:

- Purpose: Helping Americans achieve the Dietary Guidelines-recommended sodium levels by encouraging food manufacturers, restaurants, and food service operations to reduce sodium in foods.
- RAA Impact: The final guidance may qualify as a major guidance, requiring cost benefits analysis and White House review. Approximately 75 percent of total sodium intake comes from processed and commercially prepared (e.g. restaurant) foods, and the food industry has pushed back on efforts to reduce these levels. White House review opens up new opportunities for industry to fight or undermine even sensible public health efforts like this one.

Rule on Labeling for foods with genetically modified ingredients (GMOs):

- Purpose: Congress passed a law in 2016[10] directing the USDA to require food packages to disclose whether the foods contain genetically modified ingredients.
- RAA Impact: The GMO law was pushed for by industry in order to preempt state law labeling requirements, to the dismay of certain consumer groups. (CSPI's

own position on biotechnology can be read here.) The final law contains three different options for labeling: a text label, a symbol, or an electronic code readable by smartphone. If the RAA passes, any regulatory implementation will likely be held up in further dispute.

Future safeguards put at risk by the RAA:

Response to Multidrug-Resistant Pathogens:

- Moving forward, the RAA could affect the USDA's and FDA's ability to respond to emerging threats involving food-borne illness, including the threat of multidrug-resistant pathogens in the food supply.

  For example, CSPI is currently seeking a USDA ban on four strains of antibiotic-resistant *Salmonella* that have been linked to at least 2,358 illnesses, 424 hospitalizations, and 8 deaths (read our petition here). A similar ban was instituted for a certain strain of *Escherichia coli* after an outbreak that involved Jack in the Box hamburgers in the 1990s caused more than 600 illnesses and the deaths of four young children (3 toddlers age two and under and one child age 6). Applying the RAA's cost/benefit requirement to the *Salmonella* petition would require the agency to weigh future deaths and illnesses, including those of small children, against potential costs to industry. Any disputed facts could be challenged in a trial-type hearing and later in court.

Eliminating Lead from baby food and juice:

- Recent reports indicate that lead may be present in more than 80 percent of some types of baby food and juice marketed for infants and children.[11] The FDA has established only a few limits on lead levels in foods and has not developed a threshold for baby food. Its threshold for lead in fruit juice is 50 parts per billion (ppb), which is 10 times higher than its threshold for lead in bottled water.

  Any attempt by the FDA to set additional limits on lead levels in baby food and juice could run afoul of RAA requirements, particularly if it required industry to spend money in order to change current practices.

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Endnotes

[1] U.S. Government Accountability Office. Department of Health and Human Services, Food and Drug Administration: Mitigation Strategies To Protect Food Against Intentional Adulteration. RIN: 0910-AG63. Jun 10, 2016. www.gao.gov/assets/680/677968.pdf.

[2] U.S. Government Accountability Office. Department of Health and Human Services, Food and Drug Administration: Sanitary Transportation of Human and Animal Food. RIN: 0910-AG98. Apr 22, 2016. www.gao.gov/assets/680/676890.pdf.

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[11] Aubrey A, Lead detected in baby food samples. Pediatricians say there is no safe level. *NPR*. June 15, 2017. www.npr.org/sections/thesalt/2017/06/15/533103892/lead-detected-in-baby-food-samples-pediatricians-say-theres-no-safe-level.