REGULATORY REPORT CARD | March 2015

MERCATUS CENTER
George Mason University

AGENCY

Department of Health and Human Services, Food and Drug Administration

Rule title
Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record

RIN	0910–AF69
Publication Date	December 17, 2013
Comment Period Closing Date	June 16, 2014
Stage	Proposed rule

REGULATORY SCORING

	SCORE
1. Systemic Problem: How well does the analysis identify and demonstrate the existence of a market failure or other systemic problem the regulation is supposed to solve?	**3**/5
2. Alternatives: How well does the analysis assess the effectiveness of alternative approaches?	**3**/5
3. Benefits (or Other Outcomes): How well does the analysis identify the benefits or other desired outcomes and demonstrate that the regulation will achieve them?[1]	**3**/5
4. Costs: How well does the analysis assess costs?	**3**/5
5. Use of Analysis: Does the proposed rule or the RIA present evidence that the agency used the Regulatory Impact Analysis in any decisions?	**2**/5
6. Cognizance of Net Benefits: Did the agency maximize net benefits or explain why it chose another alternative?	**1**/5
Total Score	**15**/30

SUMMARY

The proposed regulation intends to establish conditions in which antiseptic products are safe and effective to use with water. It requires (within 12 months) manufacturers to reformulate and relabel soaps, discontinue products, relabel as cosmetic soap or health care antiseptic, or conduct studies to show effectiveness. The proposed regulation imposes $23.6 to $28.6 million in costs annually. Estimated benefits are the reduction of 2.2 million pounds of antiseptic ingredients annually. The FDA, however, makes its case for the proposed regulation on the basis of potential risk and not actual risks. The FDA acknowledges that health benefits of removing the antiseptic ingredients are mostly conjectural since studies are not available that demonstrate that products currently on the market pose harm to public health. Analysis by the FDA also fails to conduct any serious investigation of why the market fails to deal with the potential harm, since it would appear that suppliers would be willing to inform customers that they offer products that are safer than currently available.

The Regulatory Studies Program at the Mercatus Center at George Mason University issues Regulatory Report Cards scored by a team of economists for economically significant proposed regulations. For more information about the program, scorers, other scores, and scoring conventions, see www.mercatus.org/reportcard.

1. Systemic Problem: How well does the analysis identify and demonstrate the existence of a market failure or other systemic problem the regulation is supposed to solve?	3		
Does the analysis identify a market failure or other systemic problem?	5	1A	The FDA argues market failure arises from inadequate information on the potential health risks associated with daily use of antibacterial soaps and the effectiveness of these products relative to plain soap and water. According to the FDA, most antiseptic active ingredients have not been shown to be safe for this use, effective for this use, or both. The FDA also argues there are potential negative externalities from widespread antiseptic active ingredient use because some of the costs (e.g., costs associated with increased prevalence of bacterial resistant infections) are external to those who may benefit from their use.
Does the analysis outline a coherent and testable theory that explains why the problem is systemic rather than anecdotal?	4	1B	The FDA argues that demand for these products has continued to grow mostly because consumers are mostly uninformed regarding safety and effectiveness attributes. The FDA argues this will continue as long as there are insufficient incentives for producers to undertake studies in the absence of regulation.
Does the analysis present credible empirical support for the theory?	2	1C	The FDA states that consumer surveys have shown that consumers perceive antibacterial soaps to be superior to plain soap. But the FDA acknowledges that the National Health and Nutrition Examination Survey has only recently begun collecting biomonitoring data on triclosan to quantify aggregate exposure. The FDA also acknowledges that evidence associating adverse health effects with long-term exposure to washes containing antiseptic active ingredients is inconclusive at best. Further, the FDA's review of the available published literature and data determined that there is insufficient evidence to demonstrate a health benefit from use of antibacterial soap over plain soap and water in reducing the incidence of disease in the consumer setting.
Does the analysis adequately address the baseline? That is, what the state of the world is likely to be in the absence of federal intervention not just now but in the future?	3	1D	The FDA's baseline represents the state of the world in absence of the proposed regulatory action. The FDA argues that it is reasonable to assume no changes in OTC consumer antiseptic wash products and thus assumes future use of consumer antiseptic wash products and exposure to antiseptic active ingredients can be approximated by current levels. However, the FDA does not entertain the possibility that sellers could profit by marketing soap without antibacterial properties as a selling point, if there is indeed reason to believe that the exposure to antiseptic active ingredients is harmful.
Does the analysis adequately assess uncertainty about the existence or size of the problem?	2	1E	The FDA states that it lacks knowledge on the level of harm associated with current aggregate exposure, and this is a major reason why it does not attempt to quantify benefits from reduced harm stemming from proposed regulation.

2. Alternatives: How well does the analysis assess alternative approaches?	**3**		
Does the analysis enumerate other alternatives to address the problem?	4	2A	The alternatives are identical rules where the compliance dates are 6 months and 18 months instead of proposed 12 months.
Is the range of alternatives considered narrow (e.g., some exemptions to a regulation) or broad (e.g., performance-based regulation vs. command and control, market mechanisms, nonbinding guidance, information disclosure, addressing any government failures that caused the original problem)?	1	2B	Narrow. The FDA offers two otherwise identical rules to the one proposed: one with a 6-month and another with an 18-month compliance period. The main impact of changing the compliance period is on the total costs of relabeling.
Does the analysis evaluate how alternative approaches would affect the amount of benefits or other outcome achieved?	3	2C	The FDA measures effectiveness of alternatives in terms of the total reduction in exposure to antiseptic active ingredients linked to consumer antiseptic washes. That is, there is no dollar amount, only the reduction in pounds of the chemicals used, which is not necessarily a very good measure of improved public health.
Does the analysis identify and quantify incremental costs of all alternatives considered?	5	2D	The FDA estimates the cost per pound of reduced exposure to antiseptic active ingredients under the proposed rule and the two regulatory alternatives.
Does the analysis identify the alternative that maximizes net benefits?	**0**	2E	No; it cannot identify net benefits, as it does not monetize benefits.
Does the analysis identify the cost-effectiveness of each alternative considered?	4	2F	The FDA identifies which alternative has the lowest cost per pound of antiseptic active ingredient reduced.
3. Benefits (or other Outcomes): How well does the analysis identify the benefits or other desired outcomes and demonstrate that the regulation will achieve them?	3		
Does the analysis clearly identify ultimate outcomes that affect citizens' quality of life?	4	3A	Citizens are believed to benefit from reduced use of antibacterial soaps since such soaps have not been shown to reduce the incidence of infection or disease and there are unresolved safety considerations regarding long-term daily use.
Does the analysis identify how these outcomes are to be measured?	2	3B	Primary estimated benefits come from reduced exposure to antiseptic active ingredients by 2.2 million pounds per year. However, no dollar value is placed on this, as benefits are inconclusive.
Does the analysis provide a coherent and testable theory showing how the regulation will produce the desired outcomes?	4	3C	The proposed rule would require all consumer hand and body washes containing any antiseptic active ingredient to provide a clinically meaningful benefit over plain soap and water. The rule would also require those products to demonstrate safety under revised standards. The FDA, however, does not monetize benefits associated with estimated harm reduction since it merely estimates the proposed rule will reduce exposure to antiseptic active ingredients by 2.2 million pounds per year. That is, there is a significant disconnect between reduction to exposure and ultimate increase in public health.

Does the analysis present credible empirical support for the theory?	2	3D	The FDA acknowledges it lacks certainty over whether there is a relationship between exposure and adverse health outcomes. The FDA also admits it is difficult to quantify the value of a health risk reduction because they do not have data on the adverse health effects caused by the widespread use of consumer antiseptic active ingredients.
Does the analysis adequately assess uncertainty about the outcomes?	1	3E	The FDA admits it cannot estimate the potential reductions in adverse health outcomes, but argues any change away from the widespread use of antiseptic active ingredients should reduce any risk associated with exposure to those ingredients, resulting in positive public health benefits. FDA provides low, medium, and high estimates of reduced exposures.
Does the analysis identify all parties who would receive benefits and assess the incidence of benefits?	2	3F	All consumers are assumed to benefit, but there is no breakdown by age, income, health status, etc.
4. Costs: How well does the analysis assess costs of the regulation?	3		
Does the analysis identify all expenditures likely to arise as a result of the regulation?	5	4A	The FDA estimates costs of manufacturers, distributors, relabelers, and repackers of consumer antiseptic hand and body wash products. The FDA identifies costs of reformulation, relabeling, and testing for GRAS/E.
Does the analysis identify how the regulation would likely affect the prices of goods and services?	0	4B	Not discussed.
Does the analysis examine costs that stem from changes in human behavior as consumers and producers respond to the regulation?	3	4C	100 percent compliance is expected. The FDA argues that it would be plausible for firms to react in a number of ways, which could include reformulating the affected products as nonantimicrobial soap by removing the antiseptic active ingredient, relabeling without reformulation, conducting the testing required under this proposed rule, or obtaining an approved new drug application to continue marketing for consumer antiseptic wash use, which would require conducting the same testing required under this proposed rule. The FDA does not consider how proposed regulation would affect prices and thus ignores possible reductions in consumer surplus.
If costs are uncertain, does the analysis present a range of estimates and/or perform a sensitivity analysis?	3	4D	Low, medium, and high estimates are made. No sensitivity analysis.
Does the analysis identify all parties who would bear costs and assess the incidence of costs?	3	4E	Manufacturers are expected to incur most product reformulation and relabeling costs, with the impact to relabelers, repackers, and distributors being considerably less. The FDA believes that exempting small businesses would not be desirable because the Small Business Administration classifies 99.2 percent of the consumer antiseptic wash industry as small businesses.

5. Use of Analysis: Does the proposed rule or the RIA present evidence that the agency used the analysis in any decisions?	2	5	Little to no evidence that the FDA used the analysis to determine the proposed rule. The FDA simply estimated costs of the proposed rule along with associated reductions in exposure to antiseptic active ingredients. There is no attempt to monetize benefits to public health that might come from such reductions in exposure. The extent to which this exercise increases public health is unclear. The FDA does not appear to have any interest in determining what an optimal rule might look like.
6. Net Benefits: Did the agency maximize net benefits or explain why it chose another alternative?	1	6	The FDA does not maximize net benefits because it does not monetize benefits. The FDA identifies which alternative has the lowest cost per pound of antiseptic active ingredient reduced, but the proposed regulation does not exhibit the lowest cost among the alternatives. No reason is given for why it does not choose the lowest cost alternative.