DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions

Docket No. FDA-2013-N-1282

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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May 2015

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I. Introduction and Summary

A. Introduction

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. §§ 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule imposes new burdens on small entities, the Agency cannot certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Summary of Costs and Benefits

This final rule proposes three categories of amendments to FDA’s environmental impact regulations. The first would expand the list of Agency actions that ordinarily require the preparation of at least an environmental assessment (EA) unless a categorical exclusion exists. These actions would

include certain activities related to substantial equivalence (SE) reports and other tobacco product applications. The second category would provide new categorical exclusions for the above actions. These exclusions would exempt tobacco product manufacturers and the Agency from the need to prepare an EA and a Finding of No Significant Impact (FONSI) for such actions unless extraordinary circumstances exist. Finally, the last category would require manufacturers to submit an adequate EA with their applications, where presently EAs are prepared later in the review process through collaboration between manufacturers and FDA.

The final rule is expected to provide a net benefit (estimated benefits minus estimated costs) to society. Benefits include expanding categorical exclusions to include certain tobacco-related actions, which would reduce the costs associated with preparing and reviewing the EAs and FONSIs accompanying these actions. The final rule is not expected to impose new costs to society. Furthermore, it is also not expected to impose new significant impacts on the environment because the rule requires FDA to prepare an EA or an Environmental Impact Statement (EIS) when the Agency determines that extraordinary circumstances exist. Using a categorical exclusion requires fewer resources than preparing an EA or EIS; therefore the final rule reduces the costs to comply with the National Environmental Policy Act (NEPA). We estimate the present value associated with these one-time cost savings to approximately equal $48.3 million.

Finally, the FDA's regulation of tobacco products is fully funded by industry user fees, which are fixed by statute. This rule will not result in changes to overall FDA accounting costs or tobacco industry user fees.

II. Final Regulatory Impact Analysis

A. Background and Baseline

The National Environmental Policy Act (NEPA) requires every Agency to assess their actions' impact on the environment. For actions that normally result in insignificant environmental impacts—according to Agency experience—the agency may establish a categorical exclusion in its implementing

procedures. FDA experience indicates that certain classes of actions routinely cause negligible, if any, environmental impact. These actions include findings of substantial equivalence for provisional SE reports, rescission and temporary suspensions, and rejections of tobacco product applications.[1] Hence, the final rule proposes to include these actions in the list of existing categorical exclusions, which would exempt manufacturers and FDA from preparing an EA and FONSI for such actions, unless extraordinary circumstances indicate that these actions pose potential significant environmental impacts. In such extraordinary cases, manufacturers would need to prepare an EA.

The final rule would reduce the costs associated with preparing and reviewing EAs and FONSIs. Under the current regulatory environment, FDA generally requires an applicant to prepare an EA when requesting agency action (see §§ 25.15(a) and 25.40(b)). FDA then reviews the EA, and responds with either an EIS or FONSI as appropriate (to date, none of the actions categorically excluded in this final rule have required the preparation of an EIS). This procedure uses productive resources; capital and technology to test an application's environmental impact, and labor to review the EA and prepare the FONSI. Hence, adopting this rule would reduce the resources that regulated manufacturers and the Agency would use to comply with environmental requirements. The claim of categorical exclusion will reduce the number of EAs and FONSIs that are prepared and reviewed, resulting in potential cost savings.

B. Benefits

Adopting the final rule would reduce the costs associated with reviewing and preparing the EAs and FONSIs that are submitted with products that are subject to rescissions, rejections, temporary suspensions, and provisional substantial equivalence reports under section 910(a)(2)(B) of the FD&C Act. Prior to this rule, determining that a provisional product was substantially equivalent would require the manufacturer and the FDA to prepare an EA (see §§ 25.15(a) and 25.40(b)). FDA would then review the

[1] "Rejections" refer to those orders finding: (1) a tobacco product not substantially equivalent under section 910(a) of the FD&C Act; (2) that a new tobacco product may not be introduced or delivered into interstate commerce under section 910(c) of the FD&C Act; and (3) that a modified risk tobacco product may not be introduced or delivered into interstate commerce under section 911 of the FD&C Act.

EA, and prepare an accompanying FONSI as appropriate. However, upon implementation of the rule, FDA and manufacturers would no longer be required to prepare an EA, which would save these entities the resources used to prepare these reports. This pathway would also reduce both the number of EAs the Agency must review and the FONSIs it must prepare, thus saving the Agency the resources needed to prepare and review these reports.

Most of the final rule's cost savings are attributable to the expenses associated with preparing and reviewing EAs and FONSIs. These cost savings equal the average value of resources necessary to prepare and review these reports multiplied by the total reduction in time spent working on these reports [= (total reduction in the number of EAs and FONSIs) × (the average time, in hours, it would have taken to prepare and review these EAs and FONSIs) × (the average hourly costs associated with preparing and reviewing an EA and FONSI)].

FDA and manufacturers jointly prepare EAs. For manufacturers, the primary cost to prepare an EA is the value of labor preparing these reports. FDA experience indicates that these reports are usually prepared by workers with expertise in the following areas:

- Environmental science, to assess the submission's environmental impact;
- Law, to provide legal advice; and
- Natural science management, to review the submission.

We measure manufacturer costs using the wages corresponding to these occupational categories. To measure wages, we use the 2013 occupational wages from the Bureau of Labor Statistics (BLS). BLS does not report these particular occupational category wages for tobacco manufacturers. Hence, we proxy these values using the occupational category wages for general manufacturing. To estimate these workers' average hourly wage, we calculated the weighted average of manufacturing industry-specific wages for environmental scientists ($48.22), lawyers ($78.60), and natural science managers ($65.91) (Ref. R1). Next, we assigned these occupations weights equaling 50 percent, 25 percent, and 25 percent, respectively, to approximate the proportion of hours spent by each type of worker in the preparation of an

EA.[2] Given this procedure, the resulting composite money wage equals $60.24 (=(0.50 × $48.22) + (0.25 × $78.60) + (0.25 × $65.91)). We doubled this amount to $120.48 to account for benefits and overhead.

FDA scientists review EAs, and also work jointly with applicants to prepare EAs. The primary cost to prepare and review these reports is the economic value of FDA reviewers' time. The standard method to estimate a reviewer's economic value of time is to use the average hourly wage for full-time FDA employees. FDA budget data indicate that the average hourly budgetary outlay for full-time FDA employees, including benefits and overhead, is approximately $120.

Total time savings equals the reduction in EAs multiplied by the average time to prepare and review these reports. CTP estimates the time it takes to complete the average EA using the standards published by the Council for Environmental Quality (CEQ). To provide assurance that an action would have no significant impact, CEQ recommends preparers to invest roughly 120 hours to conduct the assessments necessary to thoroughly evaluate an action's impact (Ref. R2). Among these 120 hours, CTP estimates that their tobacco experts invest roughly 112 hours (72 hours to prepare the EA and another 40 hours to review it) while manufacturers invest 8 hours (8 hours to consult the FDA on certain subject matter). FDA notes that the above values represent averages, and that some applicants contribute more or less effort, and thus time, to prepare EAs.[3]

Estimating the time saved working on EAs requires data on the total reduction in tobacco-related actions qualifying for categorical exclusion under 910(a)(2)(B), which include provisional SE reports, rescissions, rejections, and temporary suspensions.

FDA's Center for Tobacco Products (CTP) indicates that reviews are still pending for 3,245 provisional substantial equivalent reports which will now be covered by a categorical exclusion. Provisional SE reports are only those reports submitted between February 15, 2007 (the date defining new products), and March 22, 2011 (the cutoff date defining a transitional period during which new products

[2] FDA's Office of Planning worked with FDA's Center for Tobacco Products to determine these weights.
[3] The current practice is that the FDA tends to prepare the EA, while manufacturers tend to only be consulted on preparing the EA. As a result, FDA tends to invest more time preparing EAs, on average.

could be marketed so long as an SE report was submitted by the end of the period and FDA had not issued a finding of not substantially equivalent). The report also indicates that few, if any, reviews are still pending for tobacco-related actions related to rescissions, rejections, or temporary suspensions.

The final rule's cost savings are also attributed to the expenses associated with preparing FONSIs. The annual expense to prepare FONSIs equals the average value of resources necessary to process a FONSI multiplied by the annual reduction in time spent working on FONSIs [= (annual reduction in the number of FONSIs) × (the average time, in hours, it takes to prepare a FONSI) × (the average hourly costs associated with preparing and reviewing a FONSI)]. Because this procedure is similar to preparing an EA, we estimate this procedure's average hourly cost using the FDA hourly wage associated with processing an EA, which is $120.

The total time spent working on FONSIs equals the total reports prepared multiplied by their average preparation time. FDA expects to prepare one FONSI per EA. Hence, we estimate that FDA would prepare 3,245 FONSIs. CTP data also indicate that it takes roughly 4 hours to prepare a FONSI.

To summarize, categorical exclusions will cover 3,245 provisional substantial equivalence reports received by March 22, 2011 under section 910(a)(2)(B) . The available data indicate that manufacturers spend 8 hours preparing EAs for these reports at a cost of $120.48 per hour, while the FDA spends 116 hours preparing and reviewing EAs and FONSIs for these reports and their accompanying materials at a cost of $120 per hour. Assuming FDA can work through these reports in one year, we estimate the present value associated with the rule's one-time cost savings to approximately equal $48.3 million (=(3,245 EAs × 8 manufacturer hours per EA × $120.48 per hour + 3,245 EAs × 116 FDA hours to prepare and review an EA and FONSI × $120 per hour).

Finally, the FDA's regulation of tobacco products is fully funded by industry user fees, which are fixed by statute. This rule will not result in changes to overall FDA accounting costs or tobacco industry user fees.

C. Manufacturer Costs

The proposed rule imposes no new social costs or changes to overall tobacco industry user fees. However, once finalized, it would require manufacturers to submit an adequate EA with their application (FDA now collaborates with manufacturers to prepare EAs during the review process). The rule proposes that submitting an inadequate environmental assessment is sufficient grounds for the FDA to refuse to approve or file certain applications, unless these applications are associated with actions that are categorically excluded. Permitting FDA to refuse applications providing inadequate environmental assessments effectively shifts the costs associated with preparing EAs to industry. These applications include non-provisional substantial equivalence petitions, modified risk tobacco product applications (MRTP), and premarket tobacco product applications (PMTA).

The above proposal would transfer the current costs associated with the preparation of EAs from FDA to manufacturers. To estimate the total shift in burden from FDA to manufacturers, we multiply the Agency's average burden to prepare EAs by the average annual number of non-provisional substantial equivalence petitions, MRTPs, and PMTAs [=(increase in average hours manufacturers are expected to spend to prepare the portion of EA that the Agency currently prepares) x (average hourly wage of manufacturer employees that would prepare the EA) x (annual number of applications)].

Between March 22nd, 2011 and April 1st, 2014, CTP records indicated that they received 857 non-provisional substantial equivalence reports, and only a few MRTPs and PMTAs. Assuming this trend were to remain stable over time, we estimate that CTP would be expected to receive roughly 286 applications, per year, requiring an EA (=857 reports / 3 years). However, we note that the proposed deeming rule, if finalized, could increase the annual number of applications requiring an EA. If the proposed deeming rule is finalized, the costs of including EAs for those added applications will be discussed in the RIA for that rule.

The time to prepare an environmental assessment varies by application. For non-provisional substantial equivalence reports, FDA requires 72 hours, while for MRTPs and PMTAs, FDA requires 205 hours. However, because CTP receives few MRTPs and PMTAs, we estimate the time to prepare EAs

using the average time it takes FDA to prepare the EAs associated with non-provisional substantial equivalence reports (=72 hours). Assuming manufacturers require as much time as FDA to prepare these reports, we estimate that the above proposal would increase the average time manufacturers require to prepare an environmental assessment by 72 hours.

We estimated above that the average weighted hourly wage cost associated with those that would prepare EAs (lawyers, environmental scientists, natural science managers) is approximately equal to $120.48. Given this value, we estimate the expected annual shift in burden from FDA to manufacturers to approximately equal $2.5 million (= 286 EAs per year * 72 hour increase per EA * $120.48 per hour).

Finally, the FDA's regulation of tobacco products is fully funded by industry user fees, which are fixed by statute. This rule will not result in changes to overall FDA accounting costs or tobacco industry user fees.

D. Summary of Costs and Benefits; Conclusion

FDA expects that, if finalized, the final rule would impose no new costs on society. However, it is expected to shift the FDA's costs of preparing EAs (for non-provisional SE petitions, MRTPs, and PMTAs) from FDA to manufacturers. We estimate the annual shift in burden to approximately equal $2.5 million.

We also expect that the rule could provide one-time cost savings by expanding categorical exclusions to include rescissions, rejections, temporary suspensions, and provisional substantial equivalence reports under section 910(a)(2)(B) of the FD&C Act. Expanding exclusions to include these actions would reduce the costs associated with preparing and reviewing the EAs and FONSIs accompanying these actions, resulting in modest cost savings. We estimate these one-time cost savings to approximately equal to $48.3 million.

Finally, the FDA's regulation of tobacco products is fully funded by industry user fees, which are fixed by statute. This rule will not result in changes to overall FDA accounting costs or tobacco industry user fees.

III. Final Regulatory Flexibility Analysis

FDA has examined the economic implications of the final rule as required by the Regulatory Flexibility Act. If a final rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. This final rule would impose new burdens on small entities. Hence, this analysis, together with other relevant sections of this document, serves as the final regulatory flexibility analysis, as required under the Regulatory Flexibility Act.

To assess the rule's economic impact on small entities, we compare each establishment's revenues with its rule-related costs [=(establishment's expected rule-induced costs) / (establishment's annual revenues in 2013)]. This analysis requires revenue and cost data, and a measure to assess whether the establishment is "small". The most common method to measure an establishment's size is to use its number of workers. The Small Business Administration (SBA) defines entities classified in NAICS category 312230 (Tobacco Manufacturing) to be small if they employ fewer than 1,000 workers (Ref. R3).

A. Description and Number of Affected Small Entities

The proposed rule would impact entities that manufacture tobacco products. Aggregate permitting data obtained from the Alcohol and Tobacco Tax and Trade Bureau (TTB) shows that 41 entities manufacture cigarettes, 21 entities manufacture roll-your-own (RYO) tobacco, 12 manufacture chew tobacco, and 17 manufacture snuff. TTB also indicates that some manufacturers produce multiple products (e.g., some cigarette manufacturers also produce RYO and chew tobacco).

As TTB permit applications are considered confidential tax data, we are not able to identify specific manufacturers using the TTB data. We therefore conducted a comprehensive internet search and searched the tobacco directories reported by various state tobacco agencies. These search results indicated that there are 48 domestic manufacturers of currently regulated tobacco products in the United States.

Among these 48 tobacco manufacturers, 38 produce cigarettes, 22 roll-your-own tobacco, and 17 produce chew, snuff, or both.

TTB results indicate that there might be more than 48 domestic tobacco manufacturers. However, given that our manufacturer numbers approximately equal those reported by the TTB, we expect that our sample is relatively representative of domestic tobacco manufacturers.

Table 1 presents the number of tobacco manufacturers that employ the following number of workers: 1 to 4, 5 to 9, 10 to 19, 20 to 99, 100 to 499, 500 to 999, and 1,000 or more. To estimate employee numbers, we used the Dun and Bradstreet database (Dunn & Bradstreet, Inc.). This database contains commercial information on over 225 million companies, which includes data on company sales, number of employees, and its parent company (for subsidiaries). The results indicate that 41 of the 48 tobacco manufacturers are small businesses (employ under 1,000 workers) which translates to 85 percent of all tobacco manufacturers (=41/48).

Table 1. Estimated Number of Establishments by Employee Size Categories

Tobacco Manufacturers		
Size by Number of Employees	Number of Establishments	Average Annual Revenues ($000s)
1 - 4	7	388
5 - 9	1	770
10 - 19	4	2,150
20 - 99	12	5,822
100 - 499	12	30,083
500 - 999	5	91,700
1,000 or more	7	377,140,957
Total	48	61,407,434

B. Costs for Small Entities

To estimate the rule's potential impact on small tobacco manufacturers, we compare manufacturer revenues to the expected increase in costs associated with preparing EAs. We estimate manufacturer revenues using the Dun and Bradstreet database (Dunn & Bradstreet, Inc.).

We estimated above that the average increase in manufacturer costs associated with preparing an EA is expected to approximately equal $8,675 (=72 hour increase per EA * $120.48 per hour). Assuming tobacco manufacturers are expected to prepare 286 EAs per year, we estimate the average increase in costs to prepare EAs to approximately equal $51,581 per manufacturer (= $8,675 increase in cost to prepare an EA x $\frac{\text{286 EAs per year}}{\text{48 tobacco manufacturers}}$).

Table 2 presents the rule's potential impact on small tobacco manufacturers by size category. The results suggest that shifting the burden could impose substantial costs on tobacco manufacturers. The annual cost associated with this shift in burden ranges between 0.06 percent and 13.29 percent of average annual revenues for tobacco manufacturers

Table 2. Potential Impact on Tobacco Product Manufactures (by Size)

Tobacco Manufacturers			
Size by Number of Employees	Number of Establishments	Average Revenues ($1,000)	Annual Distributional Cost as % Average Revenues
1 - 4	7	388	13.29%
5 - 9	1	770	6.70%
10 - 19	4	2,150	2.40%
20 - 99	12	5,822	0.89%
100 - 499	12	30,083	0.17%
500 - 999	5	91,700	0.06%

The above analysis overstates the distributional costs associated with the smallest establishments. The available data does not indicate the number of EAs prepared at either the manufacturer or size category level. Hence, to estimate this value, we took a simple average, which approximately equaled 6 EAs per manufacturer ($\frac{\text{286 EAs per year}}{\text{48 tobacco manufacturers}}$). However, we note this average appears to be skewed by a few companies submitting a large number of SE reports. More than half of all businesses submitted fewer than 6 SE reports over the entire time period. Therefore, using the above simple average estimate is expected to overestimate the proposed rule's impact on small tobacco manufacturers.

IV. References

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2. Council For Environmental Quality "The NEPA Task Force: Report To The Council For Environmental Quality" accessed July 2014, https://ceq.doe.gov/ntf/report/finalreport.pdf

3. U.S. Small Business Administration, "Table of Size Standards." accessed October 2014, http://www.sba.gov/content/table-small-business-size-standards.