

**National Park Service
U.S. Department of the Interior**



***Benefit-Cost and Regulatory Flexibility Analyses:
Proposed Regulation Revisions for Electronic Nicotine Delivery Systems***

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Introduction

This report presents the benefit-cost and regulatory flexibility analyses of a proposed regulatory action to revise the regulation that defines smoking to include the use of electronic cigarettes and other electronic nicotine delivery systems (ENDS). Quantitative analyses were not conducted due to a lack of available data, and because the additional cost of conducting quantitative analyses was not considered to be reasonably related to the expected increase in the quantity and/or quality of relevant information. Nevertheless, the National Park Service (NPS) believes that these analyses provide an adequate assessment of all relevant costs and benefits associated with the regulatory action.

The results of the benefit-cost analysis indicate that net benefits will be generated the proposed regulatory action are justified by the associated benefits. Additionally, this proposed regulatory action will not have an annual economic effect of \$100 million, and will not adversely affect an economic sector, productivity, jobs, the environment, or other units of government. This proposed regulatory action will improve economic efficiency by reducing the potential health risks associated with ENDS and clarifying NPS smoking regulations so they are clearly communicated to NPS personnel and the public.

The results of the regulatory flexibility analysis indicate no adverse impacts for any sector of the economy or unit of government, including small entities. Given those findings, the proposed regulatory action will not impose a significant economic impact on a substantial number of small entities.

Benefit-Cost Analysis

Background

Since 2009, ENDS have emerged as an alternative means of nicotine delivery, one that does not require the burning of tobacco. Essentially, when a user “draws” on an ENDS, a liquid solution containing nicotine is heated and vaporized, and inhaled by the user. The user then exhales a vapor that mimics the exhalation from a lit tobacco cigarette; among other things, that vapor contains nicotine—a highly addictive drug—at a level roughly one-tenth of that found in second-hand smoke. In addition to nicotine, a recent study published in *Nicotine & Tobacco Research* found that the vapor emitted by the high-powered ENDS known as tank systems also contains formaldehyde, a known carcinogen. The Division of Pharmaceutical Analysis of the Food and Drug Administration (FDA) recently analyzed the ingredients in a sample of cartridges from two leading brands of ENDS, and found the devices emitted (1) tobacco-specific nitrosamines (a human carcinogen), and (2) diethylene glycol, a chemical used in antifreeze that is toxic to humans.

The Surgeon General’s 2014 report *The Health Consequences of Smoking—50 Years of Progress (Report)* calls for “rigorous surveillance” of ENDS in order to weigh

their risks and potential benefits (e.g., their possible efficacy in reducing use of combustible tobacco products). (Page 761.) The Report concludes that, in light of the links between tobacco product use and ill health, “all products containing tobacco and nicotine should be assumed to be both harmful and addictive.” (Page 780.) On April 24, 2014, the FDA issued a proposed rule that would formally deem ENDS to be “tobacco products” within the meaning of the Family Smoking Prevention and Tobacco Control Act (PL 111-31; 123 Stat. 1776). The proposed rule would require manufacturers to, among other things, curb sales to minors, place health warning labels on ENDS products, and disclose their ingredients. In a report released August 26, 2014, the World Health Organization called for a ban on the indoor use of ENDS, especially in those spaces where smoking is banned. (See Item #41, page 11.)

In the meantime, the General Services Administration (GSA) has advised the managers of all GSA-occupied space—which includes space rented on behalf of GSA for the benefit of the NPS—that ENDS are subject to the same restrictions imposed on smoking tobacco products. The U.S. Fish and Wildlife Service’s policy found at 242 FW 13 goes even further, and prohibits “vaping”—another name for ENDS use—in all “interior spaces of all [Fish and Wildlife] Service facilities,” whether Government owned or leased. In addition, vaping is also prohibited “in motor vehicles, heavy equipment, aircraft, and most watercraft we own, rent, lease, or control.” Similarly, on August 14, 2014, the U.S. Geological Survey (USGS) also banned the use of ENDS “in all interior space, courtyards, atriums, balconies and bus stops.” See, USGS Manual 370.792.3.

Statement of Need for the Proposed Regulatory Action

Executive Order 12866 (58 FR 51735) directs Federal agencies to demonstrate the need for the regulations they promulgate. In general, regulations should be promulgated only when a “market failure” exists that cannot be resolved effectively through other means. A market failure exists when private markets fail to allocate resources in an economically efficient manner. Other justifications for promulgating regulations include improving governmental functions, removing distributional inequities, and promoting privacy and personal freedom (OMB 2003).

The NPS has recently seen a rise in complaints from visitors concerning ENDS vapor. E-cigarette use has also caused confusion as to where smoking is allowed, resulting in compliance problems with existing smoking laws and concerns expressed by concessionaires about how to regulate ENDS use in concession facilities. Title 36 of the Code of Federal Regulations, section 2.21 (36 CFR 2.21), authorizes a superintendent to close a portion of a park area, or all or a portion of a building, structure, or facility to smoking. However, the definition of “smoking” under section 1.4 is limited to combustible sources such as a cigarette; it does not include the use of ENDS. To address concerns and to protect visitor health, the proposed rule would add a new definition to 36 CFR 1.4 that would define “Electronic nicotine delivery system” as an electronic device, such as an electronic cigarette, that a person uses to simulate smoking by inhaling vapor from the device. The proposed rule would also revise the definition of “Smoking” in 36

CFR 1.4 to include the direct inhalation of vapor from an electronic nicotine delivery system. After these changes are made, section 2.21 will apply to the smoking of tobacco and the use of ENDS thus prohibiting use of an ENDS device within the National Park System in the same places that conventional tobacco smoking is prohibited. This action will improve economic efficiency by reducing the potential health risks to park visitors and clarifying NPS smoking regulations so they are clearly communicated to NPS personnel and the public.

Baseline Conditions

The costs and benefits of a regulatory action are measured with respect to its baseline conditions. Baseline conditions describe the state of the world that would exist without the regulatory action. Therefore, all costs and benefits that are included in this analysis are incremental to the baseline conditions. That is, any future impacts that would occur without the proposed action, as well as any past impacts that have already occurred, are not included in this analysis.

For this proposed regulatory action, the baseline conditions are described by Policy Memorandum 15-03 that established NPS guidance on the use of e-cigarettes and other ENDS within all facilities and vehicles that are Government owned or leased, and within concessions facilities. The Policy Memorandum treats the use of ENDS as tobacco smoking and applies all sections of Director's Order #50D (Smoking Policy) to ENDS use. For most facilities occupied by the NPS, this means that ENDS may not be used in interior space, or within 25 feet of an entrance or air-intake system. Likewise, ENDS use is not permitted within any Government-owned or -leased vehicle, including heavy equipment, watercraft or aircraft. ENDS are also prohibited in shared Government quarters, but generally permissible in non-shared residential accommodation. With regard to concessions facilities, ENDS use are treated just the same as smoking under NPS Management Policies (2006), which provides that NPS concession facilities will be smoke free except for specifically designated smoking areas and rooms if allowed by State and local law.

Policy Memorandum 15-03 was issued on September 10, 2015 and has been implemented by use of the Superintendent's discretionary authority in 36 CFR 1.5 to prohibit the use of ENDS in areas where smoking is restricted by Management Policies (2006) and Director's Order #50D.

Benefits and Costs

The proposed rule would add a new definition to 36 CFR 1.4 that would define "Electronic nicotine delivery system" as an electronic device, such as an electronic cigarette, that a person uses to simulate smoking by inhaling vapor from the device. The proposed rule would also revise the definition of "Smoking" in 36 CFR 1.4 to include the direct inhalation of vapor from an electronic nicotine delivery system. Once the proposed

rule is promulgated, section 2.21 will apply to the smoking of tobacco and the use of ENDS. Thus, the use of an ENDS device within the National Park System would be prohibited in the same places that conventional tobacco smoking is prohibited.

Conditions under the proposed regulations would be the same as baseline conditions where Policy Memorandum 15-03 prohibits the use of ENDS in areas where smoking is restricted by Management Policies (2006) and Director's Order #50D. This action will not impose any additional fees, restrictions, or other management measures that would increase costs to businesses or communities. Therefore, additional costs compared to baseline are not anticipated.

However, this action is anticipated to generate positive benefits in the form of continued visitor protection from the potential health risks associated with ENDS. This action will also generate positive benefits from improved clarification of NPS smoking regulations to NPS personnel and the public. These benefits were not quantified since the additional cost of conducting quantitative analyses was not considered to be reasonably related to the expected increase in the quantity and/or quality of relevant information. Since this action will generate positive benefits and no anticipated costs, NPS concludes that positive net benefits will be generated.

Uncertainty

The benefits associated with proposed revisions to the current regulations for ENDS were not quantified. Nevertheless, positive benefits would be generated in the form of continued visitor protection from the potential health risks associated with ENDS and improved clarification of NPS smoking regulations to NPS personnel and the public. Any uncertainty involved in this analysis is associated only with the magnitude of those benefits. NPS is not aware of any other sources of uncertainty.

Conclusions

The results of this benefit-cost analysis indicate that positive net benefits will be generated by the proposed regulatory action. Given that, NPS concludes that the proposed regulatory action will generate positive benefits and no anticipated costs. Further, this proposed regulatory action is not expected to have an annual economic effect of \$100 million, or to adversely affect an economic sector, productivity, jobs, the environment, or other units of government. This proposed regulatory action will improve economic efficiency by reducing the potential health risks associated with ENDS and clarifying NPS smoking regulations to NPS personnel and the public.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act, as amended, requires agencies to analyze impacts of regulatory actions on small entities (businesses, nonprofit organizations, and governments), and to consider alternatives that minimize such impacts while achieving regulatory objectives (SBA 2012). Agencies must first conduct a threshold analysis to determine whether regulatory actions are expected to have a significant economic impact on a substantial number of small entities. If the threshold analysis indicates a significant economic impact on a substantial number of small entities, an initial regulatory flexibility analysis must be produced and made available for public review and comment along with the proposed regulatory action. A final regulatory flexibility analysis that considers public comments must then be produced and made publicly available with the final regulatory action. Agencies must publish a certification of no significant impact on a substantial number of small entities if the threshold analysis does not indicate such impacts.

This threshold analysis relies on the associated cost-benefit analysis, which concludes that this proposed regulatory action will generate positive benefits and no costs. In addition to that conclusion, this action will not impose restrictions on small businesses, governments, or non-profit organizations in the form of fees, training, record keeping, or other measures that would increase costs. Rather, this action will improve clarity of NPS smoking regulations for the public. Given those findings, this proposed regulatory action will not impose a significant economic impact on a substantial number of small entities.

References

Office of Management and Budget (OMB). Circular A-4: guidance for developing regulatory analyses. September 17, 2003.

Small Business Administration (SBA). “A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act.” May 2012.