

(b) *What information must an IRB register?* Each IRB must provide the following information:

(1) The name and mailing address of the institution operating the IRB and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer of that institution who is responsible for overseeing activities performed by the IRB;

(2) The IRB's name, the names of each IRB chair person and each contact person (if one exists) for the IRB, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address;

(3) The number of active protocols (small, medium, or large) involving FDA-regulated products reviewed (both initial reviews and continuing reviews). For purposes of this regulation, an "active protocol" is any protocol for which an IRB conducted an initial or continuing review during the preceding calendar year. A "small" number of protocols is 1 to 25 protocols; "medium" is 26 to 499 protocols, and "large" is 500 protocols or more;

(4) A description of the types of FDA-regulated products (such as biological products, color additives, food additives, human drugs, or medical devices) involved in the protocols that the IRB reviews; and

(5) An indication whether the IRB is accredited and, if so, the date of the last accreditation and the name of the accrediting body or organization.

(c) *When must an IRB register?* Each IRB must submit an initial registration within 30 days before the date when the IRB intends to review clinical investigations regulated by FDA. Each IRB must renew its registration every 3 years. IRB registration becomes effective when HHS posts that information on its Web site.

(d) *Where can an IRB register?* Each IRB may register electronically through [Web site address to be added in the final rule]. If an IRB lacks the ability to register electronically, it must send its registration information, in writing, to [mailing address to be added in the final rule].

(e) *How does an IRB revise its registration information?* If an IRB's contact or chair person information changes, the IRB must revise its registration information by submitting any changes in that information within 90 days of the change. An IRB's decision to disband or to discontinue reviewing clinical investigations regulated by FDA is a change that must be reported within 30 days of the change. All other information changes may be reported

when the IRB renews its registration. The revised information must be sent either electronically or in writing in accordance with paragraph (d) of this section.

Dated: June 23, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-15131 Filed 7-2-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

RIN 1024-AD14

Delaware Water Gap National Recreation Area, Pennsylvania and New Jersey; U.S. Route 209 Commercial Vehicle Fees

AGENCY: National Park Service, Interior.

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Park Service (NPS) proposes to change the fee schedule for those commercial vehicles permitted to travel U.S. Route 209 through Delaware Water Gap National Recreation Area. This paragraph sets a fee schedule by number of axles. It also lists the exceptions to commercial fee requirements. Congress authorized collection of the fees to establish a sustainable program to manage commercial traffic. In recent years, the cost of fee collection has been significantly greater than annual revenue. The intent of the proposed rule is to increase fees to a level that will allow the program to be completely supported by commercial entities using the route.

DATES: Comments must be submitted on or before August 5, 2004.

ADDRESSES: Address all comments concerning this proposed rule to the Chief Ranger's Office, Delaware Water Gap National Recreation Area, River Road, Bushkill, PA 18324.

You may submit comments by sending electronic mail (E-mail) to: DEWA_Public_Comment@nps.gov.

FOR FURTHER INFORMATION CONTACT: Chief Ranger Philip Selleck, at 570-588-2414.

SUPPLEMENTARY INFORMATION:

Commercial Use Background

On March 14, 1983, the Commonwealth of Pennsylvania transferred ownership of approximately 21 miles of U.S. Route 209 within the boundaries of Delaware Water Gap

National Recreation Area to the National Park Service. This portion of road was a heavily traveled commercial vehicle route between Interstates 80 and 84, primarily because it is shorter and flatter and more direct than the alternate routes, and therefore was preferred by the commercial vehicle operators. Since § 5.6 of Title 36 Code of Federal Regulations (36 CFR 5.6), prohibits the use of roads within National park areas by commercial through traffic, the National Park Service announced that U.S. Route 209 would be closed to commercial vehicles on April 25, 1983. Due to negative comments from the trucking industry concerning the announced closure, the NPS Director, on April 23, 1983, announced a 180-day delay in the implementation of the closure.

On July 30, 1983, Congress enacted Public Law 98-63, closing U.S. Route 209 to commercial vehicle use, with certain exceptions, and directed the National Park Service to establish a commercial operation fee for certain commercial vehicles excepted from the closure. In order to implement the statute, Delaware Water Gap National Recreation Area began operation of two commercial vehicle check stations, one each near the North and South entrances to the recreation area on U.S. Route 209. The check stations were operated 24 hours a day.

Public Law 98-63, as amended by Public Law 98-151 and Public Law 99-88, closed U.S. Route 209 to all commercial vehicles except:

(1) Those vehicles operated by businesses based within the recreation area;

(2) Those vehicles operated by businesses which as of July 30, 1983, operated a commercial vehicular facility in Monroe, Pike, or Northampton Counties, PA, and the vehicle operation originates or terminates at such facility;

(3) Those vehicles operated in order to provide services to businesses and persons located in or contiguous to the boundaries of the recreation area, that area determined to be composed of Lehman, Delaware, Milford, Dingman, Stroud, Westfall, Smithfield, Middle Smithfield and Upper Mount Bethel townships in Pennsylvania;

(4) Up to 125 northbound, and 125 southbound, commercial vehicles serving businesses and persons in Orange, Ulster, Rockland and Sullivan Counties, New York.

The exceptions to the closure of U.S. Route 209 were to remain in effect unless further action was taken by Congress.

Under the Omnibus Parks and Public Lands Management Act of 1996, Public

Law 100-333, enacted on November 12, 1996, U.S. Route 209 will be closed to commercial vehicle traffic on September 30, 2005. Commercial vehicles connected with the operation of the recreation area, or serving "businesses within or in the vicinity of the recreation area" will be permitted to use the highway. The Act directs the Secretary of the Interior to define the term "businesses within or in the vicinity of the recreation area".

Commercial Vehicle Fee Background

Public Law 98-63, as amended by Public Law 99-88, directed the Secretary of the Interior to establish a fee for the use of U.S. Route 209 by

commercial vehicles. The law directed the National Park Service to set aside all fees in a special account, the funds to be available for the management, operation, construction, and maintenance of U.S. Route 209 within the boundary of the recreation area. The fee schedule was not to exceed \$7 per trip. Those commercial vehicles serving businesses within, or contiguous to the boundaries of, the recreation area were exempted from the fee.

In accordance with Public Law 98-63, the National Park Service published in the **Federal Register** (48 FR 46779, October 14, 1983), a fee schedule based on the number of axles of lightweight and heavy commercial vehicles. The

fees ranged from \$0.50 for two axle cars, vans or pickups, to \$5.00 for a five or more axle vehicle. The full 1983 fee schedule can be found in Table 1.

On August 23, 1985, the National Park Service revised the fee schedule, publishing a final rule in the **Federal Register** (50 FR 34128), revising the fee schedule. The rule was based on the revised estimates of costs for management, operation, construction and maintenance of U.S. Route 209. The raised fees ranged from \$1.00 for two axle cars, vans or pickups, to \$7.00 for a five or more axle vehicle. The full 1985 fee schedule can be found in Table 1.

TABLE 1.—1983 AND 1985 FEE SCHEDULES

	1983	1985
Two axle car, van or pickup	\$0.50	\$1.00
Two axle—four wheel vehicle with trailer	1.00	2.00
Two axle—six wheel vehicle	2.00	3.00
Three axle vehicle	3.00	4.00
Four axle vehicle	4.00	5.00
Five or more axle vehicle	5.00	7.00

Public Law 98-63 Authority

Authority to collect fees for those commercial vehicles permitted to use U.S. Route 209 terminated on July 30, 1993. The NPS stopped collecting fees on that date, but was required to continue to enforce the statutory closure and exceptions to the commercial use of the highway. The commercial vehicle check stations were operated as before July 30, 1993, but no fees were collected.

On November 12, 1996, Congress enacted Public Law 100-333, which reinstated the National Park Service's authority to collect commercial vehicle fees on U.S. Route 209. Public Law 100-

333 specified that fees could not exceed \$25 per trip. The NPS resumed the collection of fees, using the 1985 fee schedule, on November 26, 1996.

Proposal To Increase Fees

Congress specified that the fees collected from commercial vehicles excepted from the closure of U.S. Route 209 be made available, "without further appropriation, for the management, operation, construction, and maintenance of highway 209 within the boundaries of the recreation area". Congress intended the income from the commercial vehicle fee program to equal or exceed the cost of operating the program, and to fund the program

without further appropriation or use of other operating funds.

Initially, fee collection revenues from U.S. Route 209 provided enough revenue to operate the commercial use program, purchase equipment related to the operation of U.S. Route 209, and do some maintenance. The amount of revenue generated has decreased over time as several large commercial vehicle facilities closed their local terminals, and stopped traveling on U.S. Route 209. Fluctuations in the local economy have also had an effect. A comparison of revenue generated through the fee operation from fiscal years 1984 to 2002 is illustrated in Figure 1.

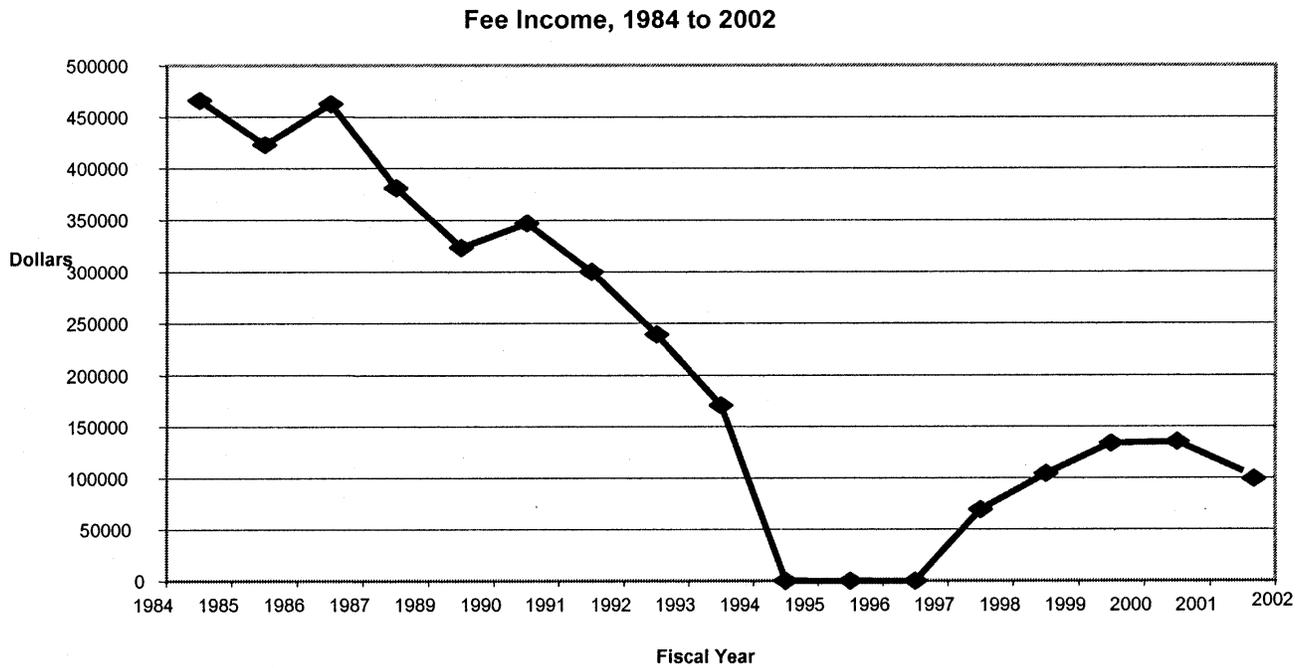


Fig. 1. Fee collection revenue, FY 1984 to FY 2001. (No fees collected, 7/30/93 to 11/26/96.)

Large 5-axle tractor-trailers have been the most important permitted commercial vehicles to use U.S. Route 209, both in total number of commercial vehicles, and in fees generated. Trucks

paying the maximum fee of \$7.00 for a five-axle vehicle account for approximately 75 percent of the total number of fee-paying vehicles, and nearly 90 percent of the total revenue

received. A comparison of the percent of total fee vehicles, by number of vehicles and revenue collected, for each class of vehicle may be found in Figure 2.

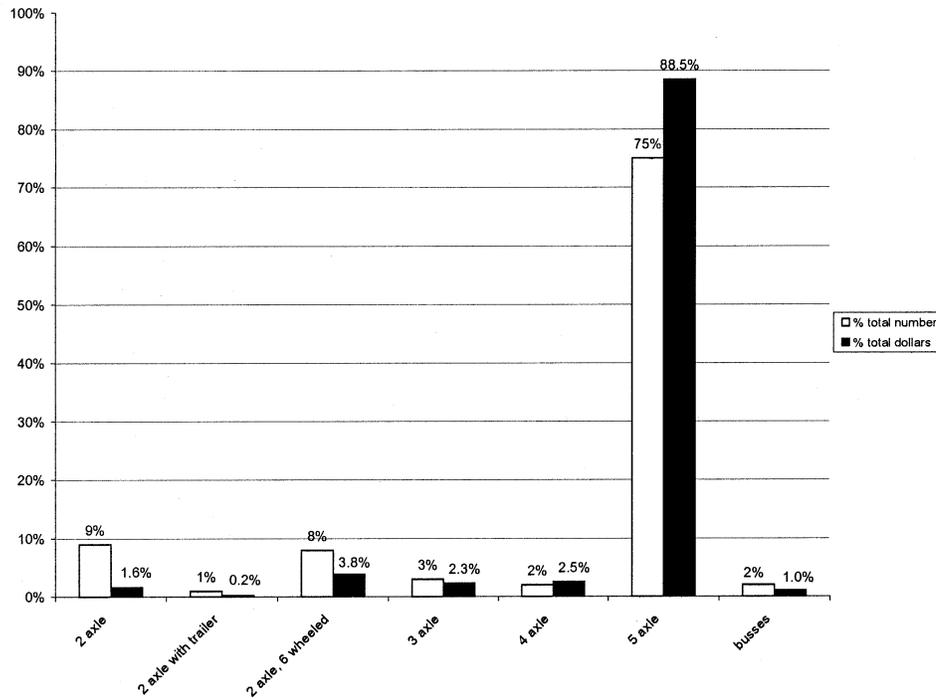


Fig. 2. Percent of total fee vehicles by class of vehicle, FY 2000, number and dollars collected.

In recent years the cost of operating the commercial operation program has largely exceeded the income generated by fees. The trends of fee revenue

remaining relatively steady and increasing expenses is expected to continue. The operating deficit is made up with funds appropriated for normal

park operations (ONPS funds). A year by year comparison of income and expenditures may be found in Figure 3.

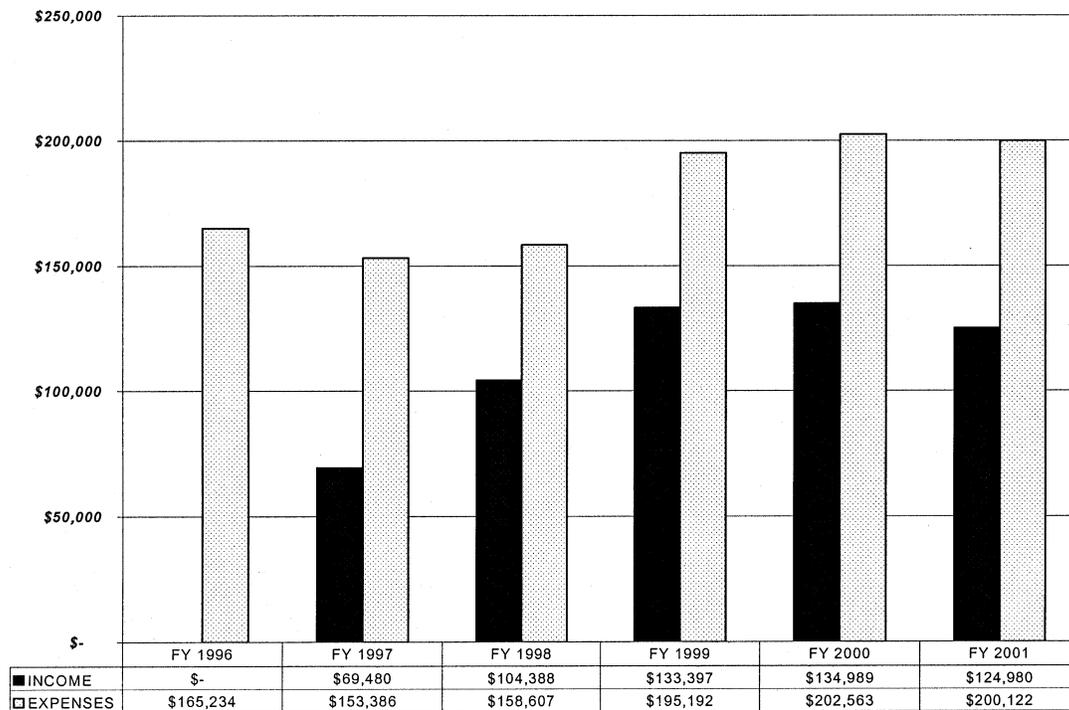


Fig. 3. Income vs. expenses, fiscal years 1996 through 2001.

Justification for the Fee Schedule

When the current commercial vehicle policy on U.S. Route 209 was begun in 1983, closing the highway and charging a fee for permitted uses were very controversial issues. Under the circumstances, promulgating special regulations implementing the closure and fees was an appropriate action. The revenue generated was much greater than the cost of operating the fee program at that time, and there was a carry-over balance that was available for other uses related to the operation and maintenance of U.S. Route 209. As documented above, in recent years the cost of managing commercial operations has been more than the revenue collected. The collection of fees for commercial vehicle use of U.S. Route 209 is authorized by federal statute, and Congress's intent is that the commercial vehicle fees collected fund the commercial traffic management program. The National Park Service thus intends for the revenue collected to approximately equal or exceed the cost of collection, and to fund the commercial traffic management program with the collected revenue. There is no plan to set fees at a level that would provide funds for maintenance of the highway or any other use. The proposed fee schedule is provided in Table 2.

TABLE 2.—PROPOSED NEW FEE SCHEDULE

Vehicle description	Fee
2 axle cars, vans, trucks	\$3
2 axle vehicles with trailer	5
2 axle, 6 wheeled vehicles	8
3 axle vehicles	10
4 axle vehicles	13
5 axle vehicles	18

Effect of a Fee Increase on the Trucking Industry

Prior to the partial closure of U.S. Route 209 to commercial vehicles in 1983, more than 2,000 tractor-trailers per day traveled through the recreation area. That number has been reduced to fewer than 200 per day in 2001, including fee-paying and fee-exempt trucks. The 5-axle, fee-paying tractor-trailers using U.S. Route 209 use the highway because it is the most convenient route between their points of origin and destination. A majority of these trucks are making trips between points within one hundred miles north or south of the recreation area. Generally, these trucks are either based in Monroe or Northampton Counties, PA, or are serving businesses in the four-county New York area. Relatively few trucks originating more than a hundred miles from Delaware Water

Gap National Recreation Area use the highway, even if they would be permitted to use the highway based on their destination. The trucks using U.S. Route 209 do so because it is the most convenient, and economically feasible, alternative.

There are two potential alternate routes available to the majority of trucks currently using U.S. Route 209. The first is to bypass the highway through the recreation area by traveling between Interstates 80 and 84 via Route 402. This route is not usable to the majority of trucks because there is a weight limit of 20,000 lbs.; an average weight for a loaded tractor-trailer is 80,000 lbs. The second alternative is to use Interstate 380 between Routes 80 and 84. This route adds approximately 46 miles to each one-way trip. Using a 2003 estimate of \$1.45 per mile for shipping freight via tractor trailers, travel via Interstate 380 adds an additional \$66. Other alternatives, such as using Route 94 or Interstate 287, are unlikely to be chosen because of traffic congestion, additional miles, and tolls. Therefore, NPS expects the large 5-axle, fee-paying traffic to remain relatively constant.

NPS has identified the six most common companies using U.S. Route 209 on a fee basis. These six companies paid approximately 45 percent of all the

5-axle fees paid in fiscal year 2001. NPS received approximately \$46,277 from these companies in calendar year 2001, out of a total of \$103,838 paid by all 5-axle vehicles in fiscal year 2001. This compares a calendar year to a fiscal

year, so therefore these are estimates, but they should be approximately correct because the traffic from these six companies is relatively constant. These companies will be the most affected by a fee increase. Increasing the fees by

155% will proportionally increase the cost of using U.S. Route 209 to these companies. Table 3 summarizes the total number of paid trips by these companies and the revenue received from them in calendar year 2001.

TABLE 3.—TOTAL 5-AXLE FEE TRIPS AND REVENUE RECEIVED CALENDAR YEAR 2001

	Dicks Concrete Co.	East Penn Trucking Co.	Rollin Johnson Inc.	Moyer Packing Co. (MOPAC)	Roadway Express Inc.	F.T. Silfies, Inc.
Total number of 5 axle fees trips	1,941	274	1,607	678	859	1,252
Total fees paid (\$)	13,587	1,918	11,249	4,746	6,013	8,764

Effect of Proposed Fee Increase on NPS

NPS anticipates fee revenue will increase by about 155% the when the proposed rule becomes final and the fee schedule is increased. Revenue from commercial vehicles decreased over the years of the program, but NPS does not have enough years of data since the resumption of fee collection in 1996 to predict future collections. A small percentage of commercial vehicles may elect to use an alternate route, rather than using U.S. Route 209. However, the larger 5-axle trucks are still expected to

use the highway, as \$18 per trip will still be less expensive than driving the additional miles on alternate routes. If those assumptions are correct, the revenue collected will be affected mostly by economic conditions.

The NPS estimates the fee revenue will be \$270,300 in the first fiscal year following implementation of the revised fee schedule. NPS believes the fee increase will be implemented on or shortly before the beginning of fiscal year 2005 on October 1, 2004. NPS anticipates spending an average

additional 3.3% per year to operate the commercial vehicle fee program, based on increases in personnel costs. Figure 4 illustrates expected revenue collected, expenses, and carryover until the end of fiscal year 2005. This projection is based on the current hours of operation which targets about 90% of the commercial traffic. If the fee collection operation were extended beyond the end of fiscal year 2005, and revenue remained constant, the operation would be operating at a deficit during fiscal year 2007.

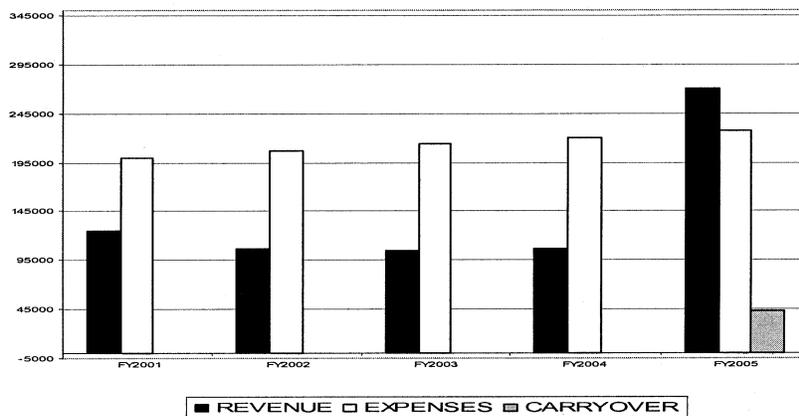


Figure 4. Revenue, expenses and carryover, FY01-05.

Compliance With Other Laws

Regulatory Planning and Review (Executive Order 12866)

This document is not significant rule and has not been reviewed by the Office of Management and Budget under Executive Order 12866.

(1) This rule will not have an effect of \$100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

The NPS has prepared an Initial Cost-Benefit analysis to support this statement. That analysis can be viewed at www.nps.gov/dewa.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. Actions taken under this rule will not interfere with other agencies or local government plans, policies, or controls. This is an agency-specific rule.

(3) This rule does not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights

or obligations of their recipients. This rule will have no effects on entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients. No grants or other forms of monetary supplements are involved.

(4) This rule does not raise novel policy issues.

Regulatory Flexibility Act

The Department of the Interior certifies that this document will not have a significant economic effect on a substantial number of small entities

under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This certification is based on a Regulatory Flexibility threshold analysis performed by NPS economists in October 2003. That document can be viewed at www.nps.gov/dewa.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

- Does not have an annual effect on the economy of \$100 million or more.
- Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.
- Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than \$100 million per year. The rule does not have a significant or unique effect on State, local or tribal governments or the private sector.

This rule is an agency-specific rule and imposes no other requirements on other agencies, governments, or the private sector.

Takings (Executive Order 12630)

In accordance with Executive Order 12630, the rule does not have significant taking implications. A taking implication assessment is not required. No takings of personal property will occur as a result of this rule.

Federalism (Executive Order 13132)

In accordance with Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

This proposed rule only affects use of NPS-administered lands and waters. It has no outside effects on other areas.

Civil Justice Reform (Executive Order 12988)

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act

This regulation does not require an information collection from 10 or more

parties and a submission under the Paperwork Reduction Act is not required. An OMB form 83-I is not required.

National Environmental Policy Act

A Final Environmental Impact Statement for the management of U.S. Route 209 was issued in September 1983. The Department has determined that further compliance under this Act is not required for any of these proposed actions.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, "Government to Government Relations with Native American Tribal Governments" (59 FR 22951) and 512 DM 2:

We have evaluated potential effects on federally recognized Indian tribes and have determined that there are no potential effects.

Clarity of Rule

Executive Order 12866 requires each agency to write regulations that are easy to understand. We invite your comments on how to make this rule easier to understand, including answers to questions such as the following: (1) Are the requirements in the rule clearly stated? (2) Does the rule contain technical language or jargon that interferes with its clarity? (3) Does the format of the rule (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity? (4) Would the rule be easier to read if it were divided into more (but shorter) sections? (A "section" appears in bold type and is preceded by the symbol "\$" and a numbered heading; for example § 7.71 Delaware Water Gap National Recreation Area.) (5) Is the description of the rule in the SUPPLEMENTARY INFORMATION section of the preamble helpful in understanding the proposed rule? What else could we do to make the rule easier to understand?

Send a copy of any comments that concern how we could make this rule easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street, NW., Washington, DC 20240.

Drafting Information

The principle contributors to this proposed rulemaking are Joel Schwartz, Fee Collection Program Manager, and Brian McDonnell, Park Ranger, and Philip A. Selleck, Chief Ranger, Delaware Water Gap NRA.

List of Subjects in 36 CFR Part 7

District of Columbia, National parks, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the National Park Service proposes to amend 36 CFR Part 7 as follows:

PART 7—SPECIAL REGULATIONS, AREAS OF THE NATIONAL PARK SYSTEM

1. The authority citation for Part 7 continues to read as follows:

Authority: 16 U.S.C. 1, 3, 9a, 460(q), 462(k); Sec. 7.96 also issued under DC Code 8-137 (1981) and DC Code 40-721 (1981).

2. Section 7.71 is amended by revising paragraphs (e)(1)(i) through (vi) to read as follows:

§ 7.71 Delaware Water Gap National Recreation Area.

* * * * *
(e) * * *
(1) * * *

- Two-axle car, van or truck—\$3
- Two-axle vehicle with trailer—\$5
- Two-axle 6-wheeled vehicle—\$8
- Three-axle vehicle—\$10
- Four-axle vehicle—\$13
- Five or more-axle vehicle—\$18

* * * * *

Dated: June 14, 2004.

Paul Hoffman,

Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 04-14114 Filed 7-2-04; 8:45 am]

BILLING CODE 4312-JG-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL-7781-8]

Connecticut: Proposed Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and notice of informational meeting.

SUMMARY: The State of Connecticut has applied to EPA for Final authorization of changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The revisions consist of State regulations which update the State's program to meet federal requirements through January 1, 2001. The revisions cover the EPA RCRA Clusters Non-