

**Authority:** 15 U.S.C. 402, 409; 21 U.S.C. 321, 331, 335, 342, 343, 346a, 348, 351, 352, 355, 360b, 361, 362, 371, 372, 374; 42 U.S.C. 7671 *et seq.*

2. Section 2.125 is revised to read as follows:

**§ 2.125 Use of ozone-depleting substances in foods, drugs, devices, or cosmetics.**

(a) As used in this section, *ozone-depleting substance* (ODS) means any class I substance as defined in 40 CFR part 82, appendix A to subpart A, or class II substance as defined in 40 CFR part 82, appendix B to subpart A.

(b) Except as provided in paragraph (c) of this section, any food, drug, device, or cosmetic that is, consists in part of, or is contained in, an aerosol product or other pressurized dispenser that releases an ODS is not an essential use of the ODS under the Clean Air Act.

(c) A food, drug, device, or cosmetic that is, consists in part of, or is contained in, an aerosol product or other pressurized dispenser that releases an ODS is an essential use of the ODS under the Clean Air Act if paragraph (e) of this section specifies the use of that product as essential. For drugs, including biologics and animal drugs, and for devices, an investigational application or an approved marketing application must be in effect, as applicable.

(d) [Reserved]

(e) The use of ODS's in the following products is essential:

(1) *Metered-dose corticosteroid human drugs for oral inhalation.* Oral pressurized metered-dose inhalers containing the following active moieties:

- (i) Beclomethasone.
- (ii) Dexamethasone.
- (iii) Flunisolide.
- (iv) Fluticasone.
- (v) Triamcinolone.

(2) *Metered-dose short-acting adrenergic bronchodilator human drugs for oral inhalation.* Oral pressurized metered-dose inhalers containing the following active moieties:

- (i) Albuterol.
- (ii) Bitolterol.
- (iii) Metaproterenol.
- (iv) Pirbuterol.
- (v) Terbutaline.
- (vi) Epinephrine.
- (3) [Reserved]

(4) *Other essential uses.* (i) Metered-dose salmeterol drug products administered by oral inhalation for use in humans.

(ii) Metered-dose ergotamine tartrate drug products administered by oral inhalation for use in humans.

(iii) Anesthetic drugs for topical use on accessible mucous membranes of

humans where a cannula is used for application.

(iv) Metered-dose cromolyn sodium human drugs administered by oral inhalation.

(v) Metered-dose ipratropium bromide for oral inhalation.

(vi) Metered-dose atropine sulfate aerosol human drugs administered by oral inhalation.

(vii) Metered-dose nedocromil sodium human drugs administered by oral inhalation.

(viii) Metered-dose ipratropium bromide and albuterol sulfate, in combination, administered by oral inhalation for human use.

(ix) Sterile aerosol talc administered intrapleurally by thoracoscopy for human use.

(f) Any person may file a petition under part 10 of this chapter to amend paragraph (e) of this section to add or remove an essential use.

(1) If the petition is to add use of a noninvestigational product, the petitioner must submit compelling evidence that:

(i) Substantial technical barriers exist to formulating the product without ODS's;

(ii) The product will provide an unavailable important public health benefit; and

(iii) Use of the product does not release cumulatively significant amounts of ODS's into the atmosphere or the release is warranted in view of the unavailable important public health benefit.

(2) If the petition is to add use of an investigational product, the petitioner must submit compelling evidence that:

(i) Substantial technical barriers exist to formulating the investigational product without ODS's;

(ii) A high probability exists that the investigational product will provide an unavailable important public health benefit; and

(iii) Use of the investigational product does not release cumulatively significant amounts of ODS's into the atmosphere or the release is warranted in view of the high probability of an unavailable important public health benefit.

(g) FDA will use notice-and-comment rulemaking to remove the essential-use listing of a product in paragraph (e) of this section if the product meets any one of the following criteria:

(1) The product using an ODS is no longer being marketed; or

(2) After January 1, 2005, the product is not available without an ODS and FDA determines that the product no longer meets the criteria in paragraph (f) of this section after consultation with a

relevant advisory committee(s) and after an open public meeting; or

(3) For individual active moieties marketed as ODS products and represented by one new drug application (NDA) and one strength:

(i) At least one non-ODS product with the same active moiety is marketed with the same route of administration, for the same indication, and with approximately the same level of convenience of use as the ODS product containing that active moiety;

(ii) Supplies and production capacity for the non-ODS product(s) exist or will exist at levels sufficient to meet patient need;

(iii) At least 1 year of U.S. postmarketing use data is available for the non-ODS product(s); and

(iv) Patients who medically required the ODS product are adequately served by the non-ODS product(s) containing that active moiety and other available products; or

(4) For individual active moieties marketed as ODS products and represented by two or more NDA's or marketed in multiple distinct strengths:

(i) At least two non-ODS products that contain the same active moiety are being marketed with the same route of delivery, for the same indication, and with approximately the same level of convenience of use as the ODS products; and

(ii) The requirements of paragraphs (g)(3)(ii), (g)(3)(iii), and (g)(3)(iv) of this section are met.

Dated: August 19, 1999.

**Jane E. Henney,**

*Commissioner of Food and Drugs.*

**Donna E. Shalala,**

*Secretary of Health and Human Services.*

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## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### 23 CFR Chapter I

[FHWA Docket No. FHWA-99-4970]

RIN 2125-AE54

#### Federal Lands Highway Program; Transportation Planning Procedures and Management Systems Pertaining to the Fish and Wildlife Service and the Refuge Roads Program

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Advance notice of proposed rulemaking (ANPRM); request for comments.

**SUMMARY:** The FHWA seeks public comment concerning the development of transportation planning procedures affecting Federal land management agencies and management systems pertaining to pavement, bridge, safety and congestion for roads funded under the Federal lands highway program (FLHP). This ANPRM requests comments on the advisability of the FHWA, in consultation with the Fish and Wildlife Service (FWS), to develop a rule to meet the transportation planning and management systems requirements of the Transportation Equity Act for the 21st Century (TEA-21) pertaining to the FWS and the refuge roads program. This ANPRM also requests comments on a number of specific issues concerning transportation planning procedures and management systems pertaining to the FWS and the refuge roads program. Section 1115(d) of the TEA-21 requires the Secretary of Transportation, in consultation with appropriate Federal land management agencies, to develop transportation planning procedures that are consistent with the metropolitan and statewide transportation planning processes required under 23 U.S.C. 134 and 135. The TEA-21 also requires the Secretary of Transportation and the Secretary of each appropriate Federal land management agency to develop, to the extent appropriate, safety, bridge, pavement, and congestion management systems for roads funded under the FLHP. The roads funded under the FLHP include park roads and parkways, forest highways, refuge roads, and Indian reservation roads. The FHWA was delegated the authority by the Secretary to serve as the lead agency within the DOT to implement the FLHP.

**DATES:** Comments must be received on or before November 1, 1999.

**ADDRESSES:** Your signed, written comments must refer to the docket number appearing at the top of this document and you must submit the comments to the Docket Clerk, U.S. DOT Dockets, Room PL-401, 400 Seventh Street, SW., Washington, DC 20590-0001. All comments received will be available for examination at the above address between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped envelope or postcard.

**FOR FURTHER INFORMATION CONTACT:** Mr. Paul Schneider, Federal Lands Highway Office, HFPD-2, (202) 366-6799; or Ms. Grace Reidy, Office of the Chief Counsel, HCC-32, (202) 366-6226, Federal Highway Administration, 400

Seventh Street, SW., Washington, D.C. 20590-0001. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

**Electronic Access**

Internet users can access all comments received by the U.S. DOT Dockets, Room PL-401, by using the universal resource locator (URL): <http://dms.dot.gov>. It is available 24 hours each day, 365 days each year. Please follow the instructions online for more information and help.

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**Background**

Section 1115(d) of TEA-21 (Pub. L. 105-178, 112 Stat. 107, 156 (1998)) amended 23 U.S.C. 204. Section 204 now requires the development of transportation planning procedures affecting Federal land management agencies and management systems pertaining to roads funded under the FLHP. Section 1115(d)(1) of TEA-21 requires the Secretary of Transportation, in consultation with the Secretary of each appropriate Federal land management agency, to develop transportation planning procedures that are consistent with the metropolitan and statewide transportation planning processes required under 23 U.S.C. 134 and 135. Section 1115(d)(1) of TEA-21 also requires the Secretary of Transportation and the Secretary of each appropriate Federal land management agency, to the extent appropriate, to develop by rule safety, bridge, pavement and congestion management systems for roads funded under the FLHP. The roads funded under the FLHP include park roads and parkways, forest highways, refuge roads and Indian reservation roads. The FHWA has the lead for the Department of Transportation in these efforts.

The FHWA is contemplating developing four rules to meet the requirements of TEA-21. Under this approach, separate rules would be developed pertaining to the National Park Service and the park roads and parkways program; the FWS and the refuge roads program; the Bureau of Indian Affairs and the Indian reservations roads program; and the Forest Service and the forest highway

program. The FHWA would consider developing a "separate rule" pertaining to each agency and program area because the ownership, jurisdictional, and maintenance responsibilities for the roads in each program area are significantly different; therefore, we anticipate that each rule would be moderately different. The variances between the rules would allow for the significant differences in the ownership, jurisdictional, and maintenance responsibilities that the agencies exercise over the subject roadways to be addressed in the rules. To ensure uniformity between the four separate rules, however, the FHWA would coordinate the development of each rule, ensuring that similar text and format is contained in each of the rules. This ANPRM requests comments on the proposal for the FHWA, in consultation with the FWS, to develop a "separate rule" to meet the transportation planning and management systems requirements of TEA-21 pertaining to the FWS and the refuge roads program. Additionally, this ANPRM requests comments on the alternative of developing "one rule" that would apply to all four agencies and programs. Finally, this ANPRM also requests comments on a number of other specific issues concerning transportation planning procedures and management systems pertaining to the FWS and the refuge roads program. The specific issues are listed, as follows:

- What types of institutions or coordination efforts are needed to coordinate an FWS unit's transportation planning with State, local and tribal governments?
- How should an FWS unit's transportation planning and development be coordinated with the metropolitan and statewide planning processes?
- How should the transportation planning process address the need to minimize transportation's adverse impacts on fish and wildlife areas owned and maintained by the FWS and on surrounding areas?
- How should the transportation planning procedures address the accommodation of various modes of transportation in FWS units?
- How should the management systems requirements be addressed?

Refuge roads are public roads that provide access to or within a unit of the National Wildlife Refuge System and for which the title and maintenance responsibilities are vested in the United States. A vast majority of the refuge roads are owned and maintained by the FWS. Changes to the refuge transportation system may affect the

surrounding transportation system; and changes to the surrounding transportation system may significantly affect the refuge transportation system. Therefore, transportation planning procedures would be developed to provide guidance for systematizing transportation planning within the refuges and to coordinate their transportation planning efforts with other agencies and organizations. Management systems would be developed that support the transportation planning efforts.

To ensure that the full range of issues related to this anticipated rulemaking process are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments and questions concerning this proposed action should be directed to the FHWA at the address provided above. Likewise, in separate advance notices of proposed rulemaking published elsewhere in today's **Federal Register**, FHWA Docket No. FHWA-99-4967, *Federal Lands Highway Program; Transportation Planning Procedures and Management Systems Pertaining to the National Park Service and the Park Roads and Parkways Program*, FHWA Docket No. FHWA-99-4968, *Federal Lands Highway Program; Transportation Planning Procedures and Management Systems Pertaining to the Bureau of Indian Affairs and the Indian Reservation Roads Program*, FHWA Docket No. FHWA-99-4969, *Federal Lands Highway Program; Transportation Planning Procedures and Management Systems Pertaining to the Forest Service and the Forest Highways Program*, the FHWA is seeking public comment on the propriety of developing transportation planning procedures affecting other Federal land management agencies and management systems pertaining to other roads funded under the FLHP.

#### **Rulemaking Analyses and Notices**

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination using the docket number appearing at the top of this document in the docket room at the above address. The FHWA will file comments received after the comment closing date in the docket and will consider late comments to the extent practicable. In addition to late comments, the FHWA will also continue to file, in the docket, relevant information becoming available after the comment closing date, and interested persons should continue to examine the docket for new material.

#### **Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures**

The FHWA has determined preliminarily that the contemplated rule would be a significant regulatory action within the meaning of Executive Order 12866 and the regulatory policies and procedures of the Department of Transportation because of the substantial public interest anticipated in the transportation facilities on Fish and Wildlife system units. There is also substantial interest by Federal, State, regional, local and tribal governments, and private groups due to the necessary coordination with these organizations when transportation planning is being performed for transportation facilities within and approaching the Fish and Wildlife system units.

It is anticipated that the economic impact of any action taken in this rulemaking process will be minimal. Any changes are not anticipated to adversely affect, in a material way, any sector of the economy. In addition, any changes are not likely to interfere with any action taken or planned by another agency or to materially alter the budgetary impact of any entitlement, grants, user fees, or loan programs.

Based upon the information received in response to this action, the FHWA intends to carefully consider the costs and benefits associated with this rulemaking. Accordingly, comments, information, and data are solicited on the economic impact of the changes described in this document or any alternative proposal submitted.

#### **Regulatory Flexibility Act**

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601-612), and based upon the information received in response to this ANPRM, the FHWA will evaluate the effects of any action proposed on small entities. This ANPRM will only generate comments and discussions on transportation planning procedures and management systems pertaining to pavement, bridge, safety, and congestion for FLHP-funded roads in accordance with existing laws, regulations, and guidance. If the final rule contemplated in this ANPRM is promulgated, States may be affected by the rule due to the possibility of expending additional resources during the transportation planning process, although it is anticipated that any additional expenditures would be minor. Because the States are not included in the definition of "small entity" set forth in 5 U.S.C. 601, we do not anticipate that any transportation planning procedures or management

systems requirements would have substantial economic impact on small entities within the meaning of the Regulatory Flexibility Act. We encourage commenters to evaluate any options addressed here with regard to the potential for impact, however, and to formulate their comments accordingly.

#### **Unfunded Mandates Reform Act of 1995**

This ANPRM would not impose a Federal mandate resulting in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year (2 U.S.C. 1532). Further, in compliance with the Unfunded Mandates Reform Act of 1995, the FHWA will evaluate any regulatory action that might be proposed in subsequent stages of the proceeding to assess the effects on State, local, and tribal governments and the private sector.

#### **Executive Order 12612 (Federalism Assessment)**

Any action that might be proposed in subsequent stages of this proceeding will be analyzed in accordance with the principles and criteria contained in Executive Order 12612. Given the nature of the issues involved in this proceeding, the FHWA anticipates that any action contemplated will not have sufficient federalism implications to warrant the preparation of a federalism assessment. Nor does the FHWA anticipate that any action taken would preempt any State law or State regulation or affect the States' ability to discharge traditional State governmental functions. We encourage commenters to consider these issues, however, as well as matters concerning any costs or burdens that might be imposed on the States as a result of actions considered here.

#### **Executive Order 12372 (Intergovernmental Review)**

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program. Accordingly, the FHWA solicits comment on this issue.

#### **Paperwork Reduction Act**

Any action that might be contemplated in subsequent phases of this proceeding is not likely to involve a collection of information requirement for the purposes of the Paperwork

Reduction Act of 1995, 44 U.S.C. 3501—3520, or information collection requirements not already approved for transportation planning and management systems. The FHWA, however, will evaluate any actions that might be considered in accordance with the terms of the Paperwork Reduction Act.

### National Environmental Policy Act

The agency also will analyze any action that might be proposed for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4347) to assess whether there would be any affect on the quality of the environment.

### Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

### List of Subjects in 23 CFR Chapter I

Bridge and congestion management systems, Bridges, Defense access roads, Forest highways, Highways and roads, Metropolitan transportation planning, Pavement, Safety, Statewide transportation planning, and Traffic monitoring systems.

(Authority: 23 U.S.C. 134, 135, 204, and 315; sec. 1115, Pub. L. 105–178, 112 Stat. 107 (1998); 49 CFR 1.48.)

Issued on: August 25, 1999.

**Gloria J. Jeff,**

*Federal Highway Deputy Administrator.*

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## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### 23 CFR Chapter I

[FHWA Docket No. FHWA–99–4969]

RIN 2125–AE55

### Federal Lands Highway Program; Transportation Planning Procedures and Management Systems Pertaining to the Forest Service and the Forest Highway Program

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Advance notice of proposed rulemaking (ANPRM); request for comments.

**SUMMARY:** The FHWA seeks public comment concerning the development of transportation planning procedures affecting Federal land management agencies and management systems pertaining to pavement, bridge, safety, and congestion for roads funded under the Federal lands highway program (FLHP). This ANPRM requests comments on the advisability of the FHWA, in consultation with the Forest Service (FS), to develop a rule to meet the transportation planning and management systems requirements of the Transportation Equity Act for the 21st Century (TEA–21) pertaining to the FS and the forest highway program. This ANPRM also requests comments on a number of specific issues concerning transportation planning procedures and management systems pertaining to the FS and the forest highway program. Section 1115(d) of the TEA–21 requires the Secretary of Transportation, in consultation with appropriate Federal land management agencies, to develop transportation planning procedures that are consistent with the metropolitan and statewide transportation planning processes required under 23 U.S.C. 134 and 135. The TEA–21 also requires the Secretary of Transportation and the Secretary of each appropriate Federal land management agency to develop, to the extent appropriate, safety, bridge, pavement, and congestion management systems for roads funded under the FLHP. The roads funded under the FLHP include park roads and parkways, forest highways, refuge roads, and Indian reservation roads. The FHWA was delegated the authority by the Secretary to serve as the lead agency within the DOT to implement the FLHP. **DATES:** Comments must be received on or before November 1, 1999.

**ADDRESSES:** Your signed, written comments must refer to the docket number appearing at the top of this document and you must submit the comments to the Docket Clerk, U.S. DOT Dockets, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590–0001. All comments received will be available for examination at the above address between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped envelope or postcard.

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#### Background

Section 1115(d) of TEA–21 (Pub. L. 105–178, 112 Stat 107, 156 (1998)) amended 23 U.S.C. 204. Section 204 now requires the development of uniform transportation planning procedures affecting Federal land management agencies and management systems pertaining to roads funded under the FLHP. Section 1115(d)(1) of TEA–21 requires the Secretary of Transportation, in consultation with the Secretary of each appropriate Federal land management agency, to develop transportation planning procedures that are consistent with the metropolitan and statewide transportation planning processes required under 23 U.S.C. 134 and 135. Section 1115(d)(1) of TEA–21 also requires the Secretary of Transportation and the Secretary of each appropriate Federal land management agency, to the extent appropriate, to develop safety, bridge, pavement and congestion management systems for roads funded under the FLHP. The roads funded under the FLHP include park roads and parkways, forest highways, refuge roads and Indian reservation roads. The FHWA has the lead for the Department of Transportation in these efforts.

The FHWA is contemplating developing four rules to meet the requirements of TEA–21. Under this approach, separate rules would be developed pertaining to the National Park Service and the park roads and parkways program; the FWS and the refuge roads program; the Bureau of Indian Affairs and the Indian reservations roads program; and the Forest Service and the forest highway