

(see *Comments*). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION:

I. Background

Title VIII of FDASIA (Pub. L. 112-144), entitled "Generating Antibiotic Incentives Now (GAIN)," amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add new section 505E (21 U.S.C. 355E), among other things. This new section of the FD&C Act is designed to encourage development of treatments for serious or life-threatening infections caused by bacteria or fungi. For an application for a drug that is designated a "qualified infectious disease product" under section 505E(d) of the FD&C Act, section 505E(a) provides an extension of 5 years of market exclusivity to the exclusivity periods provided by sections 505(c)(3)(E)(ii) through (c)(3)(E)(iv) (21 U.S.C. 355(c)(3)(E)(ii) through (c)(3)(E)(iv)), 505(j)(5)(F)(ii) through (j)(5)(F)(iv) (21 U.S.C. 355(j)(5)(F)(ii) through (j)(5)(F)(iv)), 505A (21 U.S.C. 355a), and 527 (21 U.S.C. 360cc) of the FD&C Act. However, as section 505E(c) of the FD&C Act states, not all applications for a "qualified infectious disease product" are eligible for the additional market exclusivity. In addition, an application for a drug designated as a "qualified infectious disease product" is eligible for priority review and fast track status (sections 524A and 506(a)(1) of the FD&C Act (21 U.S.C. 356(a)(1))), respectively.

The term "qualifying infectious disease product" refers to an antibacterial or antifungal human drug that is intended to treat serious or life-threatening infections (section 505E(g) of the FD&C Act). It includes treatments for diseases caused by antibiotic- or antifungal-resistant pathogens (including new or emerging pathogens), or "qualifying pathogens" listed by the Secretary of the Department of Health and Human Services (and, by delegation, FDA) under section 505E(f) (section 505E(g) of the FD&C Act).

According to the statute, "the term 'qualifying pathogen' means a pathogen identified and listed by the Secretary * * * that has the potential to pose a serious threat to public health, such as[:] (A) resistant [G]ram positive pathogens, including methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant *Staphylococcus aureus*, and vancomycin-resistant [*E*]nterococcus;

(B) multi-drug resistant [G]ram[-]negative bacteria, including *Acinetobacter*, *Klebsiella*, *Pseudomonas*, and *E. coli* species; (C) multi-drug resistant tuberculosis; and (D) *Clostridium difficile*" (section 505E(f)(1) of the FD&C Act). FDA is required under the law to consider four factors in establishing and maintaining the list of qualifying pathogens:

- The impact on the public health due to drug-resistant organisms in humans;
- The rate of growth of drug-resistant organisms in humans;
- The increase in resistance rates in humans; and
- The morbidity and mortality in humans.

(section 505E(f)(2)(B)(i) of the FD&C Act). Furthermore, in determining which pathogens should be listed, consultation with infectious disease and antibiotic resistance experts, including those in the medical and clinical research communities, along with the Centers for Disease Control and Prevention (CDC), is required (section 505E(f)(2)(B)(ii) of the FD&C Act).

II. Purpose and Scope of the Hearing

We are holding this hearing to fulfill the statutory consultation requirement and to obtain public comment on the following issues related to establishing the list of qualifying pathogens described in section 505E(f) of the FD&C Act:

1. FDASIA requires FDA to "consider" the following factors in establishing and maintaining the list of qualifying pathogens:

- The impact on the public health due to drug-resistant organisms in humans;
- The rate of growth of drug-resistant organisms in humans;
- The increase in resistance rates in humans; and
- The morbidity and mortality in humans.

How should these factors be applied to a pathogen to determine whether it should be included in the list?

2. Aside from the considerations noted in question 1 (i.e., those required by section 505E(f)(2)(B)(i) of the FD&C Act), are there any other factors FDA should consider when establishing and maintaining the list of qualifying pathogens? If so, how should these factors be applied to a pathogen to determine whether it should be included in the list?

3. Which specific pathogens do you believe should be listed as qualifying pathogens? Provide justification for your recommendations, including how you

applied the considerations described in section 505E(f)(2)(B)(i) of the FD&C Act, and any other factors that you considered, in recommending the pathogen for inclusion on the list of qualifying pathogens.

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs (the Commissioner) is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner and the Center for Drug Evaluation and Research.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (see 21 CFR part 10, subpart C). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

Dated: November 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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ADVISORY COUNCIL ON HISTORIC PRESERVATION

Program Comment Issued for Streamlining Section 106 Review for Actions Affecting Post-1945 Concrete and Steel Bridges

AGENCY: Advisory Council on Historic Preservation.

ACTION: Program Comment issued for streamlining Section 106 review for undertakings affecting post-1945 concrete and steel bridges.

SUMMARY: The Advisory Council on Historic Preservation (ACHP) issued a

Program Comment at the request of the U.S. Department of Transportation Federal Highway Administration to relieve it and other federal agencies from the requirement under Section 106 of the National Historic Preservation Act to consider the effects of undertakings on common bridges and culverts constructed of concrete or steel after 1945. The federal agencies using the Program Comment must still complete Section 106 review for the undertaking, including the identification of historic properties and consideration of effects of the undertaking on historic properties other than the common bridge itself.

DATES: The Program Comment was issued by the ACHP on November 2, 2012.

ADDRESSES: Address all questions concerning the Program Comment to Carol Legard, Office of Federal Agency Programs, Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue NW., Suite 803, Washington, DC 20004. Fax (202) 606-8522. You may submit electronic questions to: clegard@achp.gov.

FOR FURTHER INFORMATION CONTACT: Carol Legard, (202) 606-8522, clegard@achp.gov.

SUPPLEMENTARY INFORMATION: Section 106 of the National Historic Preservation Act (Section 106) requires federal agencies to consider the effects of their undertakings on historic properties and to provide the Advisory Council on Historic Preservation (ACHP) a reasonable opportunity to comment with regard to such undertakings. The ACHP has issued the regulations that set forth the process through which Federal agencies comply with these duties. Those regulations are codified under 36 CFR part 800 (Section 106 regulations).

Under Section 800.14(e) of those regulations, agencies can request the ACHP to issue a "Program Comment" on a particular category of undertakings in lieu of conducting reviews of each individual undertaking under such category, as set forth in 36 CFR 800.3 through 800.7. An agency can meet its Section 106 responsibilities with regard to the effects of particular aspects of those undertakings by taking into account an applicable Program Comment that has been issued by the ACHP and following the steps set forth in that comment.

I. Background

The ACHP has issued a Program Comment to relieve all federal agencies from the Section 106 requirement to consider the effects of undertakings on

common bridges and culverts constructed of concrete or steel after 1945. The ACHP membership voted in favor of issuing the Program Comment via an unassembled vote that concluded on November 2, 2012.

According to the requirements for obtaining a Program Comment, the Federal Highway Administration (FHWA) formally requested the ACHP to comment on the effects of a category of undertakings in lieu of conducting individual reviews for effects to certain types of bridges commonly constructed in the United States since 1945. Bridges of the types covered in the Program Comment were constructed in vast numbers from plans that quickly became standardized around the middle of the 20th century. These bridges are generally undistinguished from an engineering or architectural perspective, are considered to have little value for preservation in place, and are rarely viable candidates for relocation. However, because they may meet or approach the age criteria for evaluation as historic properties, considerable time and resources are currently expended to address effects to them on a case-by-case basis under the Section 106 process. The Program Comment applies to effects of undertakings on certain common concrete and steel bridges lacking distinction, not previously listed in or determined eligible for listing in the National Register of Historic Places, and not located within or adjacent to historic districts. The Program Comment proposed by FHWA was received by the ACHP on August 6, 2012.

To develop the Program Comment, FHWA met with individuals from the ACHP staff, the National Conference of State Historic Preservation Officers, the American Association of State Highway and Transportation Officials, and the National Trust for Historic Preservation. With the assistance of these individuals, FHWA prepared an initial draft of the proposed Program Comment which was then shared with key stakeholders and additional organizations and individuals with expertise in historic bridges and in the Section 106 review process. This outreach effort resulted in a number of revisions intended to address concerns raised about the applicability of the Program Comment, the ability of states to identify examples of common bridges that should be excluded from the Program Comment, and the types and range of bridges that would be exempted from Section 106 review. FHWA worked with the ACHP in developing the new draft, which was discussed at the ACHP Federal Agency Program Committee meeting on August 8, 2012.

Upon submitting its formal request to the ACHP, FHWA took additional steps to inform the public and stakeholders about the proposed Program Comment, including an email distribution, posting on the agency web site, and a notice published in the **Federal Register** on September 5, 2012 (**Federal Register** Volume 77, Number 172, pages 54652-54655). In response, the Federal Highway Administration received comments from 14 individuals and organizations.

In accordance with our regulations at 36 CFR 800.14(e), the ACHP is responsible for obtaining the views of State Historic Preservation Officers (SHPOs) and Tribal Historic Preservation Officers before reaching a decision on issuing a Program Comment. Although the Program Comment was drafted so that it does not apply to tribal lands, the ACHP transmitted the proposed Program Comment to Indian tribes and Tribal Historic Preservation Officers to ensure that their views were considered in its decision on whether to issue the program comment. The ACHP requested comments on the Program Comment, as submitted by FHWA, on September 7, 2012.

As a result of both FHWA's **Federal Register** notice and the ACHP's solicitation of views from SHPOs and Tribal Historic Preservation Officers, comments were received from six SHPOs, one Indian tribe, one Native Hawaiian Organization, and 12 other individuals and organizations.

The proposed Program Comment received strong support from the American Public Works Association (APWA), National Association of County Engineers (NACE), American Road and Transportation Builders Association (ARTBA), the Commissioner of Highways for the Commonwealth of Virginia, the New York State County Highway Superintendents Association (NYSCHSA), and the County of Los Angeles Department of Public Works. Comments from these organizations stressed that the Program Comment is a logical, common sense approach that will save taxpayers money and allow needed infrastructure improvements to be completed more efficiently. The President of the NYSCHSA stated that by excluding these common bridges from Section 106 review, taxpayers could save up to \$78 million over a 10-year period.

Four respondents to the **Federal Register** notice objected to the premise that post-1945 concrete and steel highway bridges are generally undistinguished, having little value for

preservation in place. One also took exception to statements in the introduction and background sections of the Program Comment that, in her view, indicated a lack of understanding of the significance and rehabilitation potential for post-1945 common bridges. These four reviewers, and four SHPOs, further disagreed with FHWA that examples of common bridge types of exceptional significance can be readily identified without a statewide inventory by knowledgeable professional cultural resource specialists. The reviewers, two of which are historic bridge experts working as consultants, argued that streamlining Section 106 review for bridges, even those built after 1945, is best accomplished by completing a statewide historic bridge inventory and individual determinations of historic significance based on a statewide historic context and generally accepted scholarship.

Two commenters expressed confusion about how the identification of exceptional bridges can be completed by December 31, 2012, particularly where the main source of data is the National Bridge Inventory (NBI). Distrust for the accuracy of information in the NBI and the fact that a number of states lack recent historic bridge inventories were the reasons these parties were concerned about the ability of the FHWA Division in each state to identify especially important examples of the common bridge types within the tight timeframe provided in the review draft.

In response to these concerns, the Program Comment was revised to extend the timeframe for completing the list of exceptional bridges to March 31, 2013. It also encourages, but does not require, FHWA Divisions to complete the list by that date. If additional time is needed to complete the list, it will be granted. Also, FHWA Divisions may add to the list of exceptional bridges, as more information becomes available regarding the historic bridges in a state. The Program Comment also now clarifies that to complete the list of exceptional bridges, a statewide survey or context does not need to be developed where none exists. The list need not be exhaustive; the intent behind the list is to be able to exclude readily recognizable exceptional bridges from the Program Comment. Although the commenters are correct that this may not be sufficient in some states to identify all exceptionally significant bridges, we believe that the Program Comment establishes a good balance between protecting the most significant historic bridges of these common types and eliminating repetitive and redundant documentation and reviews

that can be costly to the government and have limited value to the broader public.

One Federally Recognized Indian tribe and one Native Hawaiian Organization commented on the Program Comment. Both expressed concern that the Program Comment may be seen as a broad waiver of Section 106 review for projects affecting historic bridges, leading to the destruction of other types of sites as a result of construction. To address this concern, the Introduction (Section I) and Section III (Applicability) were revised to explicitly and clearly state that while the Program Comment relieves Federal agencies from the Section 106 requirement to consider the effects of undertakings on the bridge types identified in Section V, it is not a waiver from Section 106 requirements for the consideration of other historic properties that may be affected by a bridge rehabilitation or replacement project. It further clarifies that the Program Comment is not a waiver from applicable Federal requirements to consult with Indian tribes or Native Hawaiian organizations (NHOs) regarding undertakings that may affect historic properties to which a tribe or NHO ascribe traditional cultural and religious significance.

Three commenters proposed changes to the common bridge types covered by the Program Comment (Section V). One proposed that pre-stressed concrete should be included as a discrete bridge type and that all pre-stressed concrete bridges built prior to 1966 be excluded from the Program Comment. The ACHP declined to make this change as it would be inconsistent with the other bridge types in Section V, which are based on structure type (design) and material, and not just the material with which it is constructed. Other recommendations were incorporated into the final Program Comment including: Removing reinforced concrete rigid frames, metal rigid frames, and curved metal girders from the list of common types (they are, in fact, not as common as the other types); and adding culverts and reinforced concrete boxes among the common bridge types covered by the Program Comment.

Two commenters offered recommendations for improving the programmatic mitigation in Section VI. One recommended including specifics regarding the manner in which the FHWA will encourage the update of inventories. The other offered additional suggestions for mitigation. One additional mitigation measure was incorporated into the Program Comment

based on these recommendations. Section VI now requires FHWA to complete and make available to the public a brief illustrated history of post-1945 highway bridge engineering and design to document for the general public the innovations and contributions of the bridges to transportation in the post-World War II era. FHWA is required to complete this illustrated history and documentation using Historic American Engineering Record (HAER) standards of at least one example of each common bridge type before December 31, 2013. A third programmatic mitigation measure was left unchanged: A commitment for FHWA to encourage State transportation agencies that have not recently done so to update inventories of historic bridges in their states. The ACHP agrees with commenters that updating and maintaining statewide historic bridge inventories and management plans for historic bridges is the best way to plan for the protection and preservation of the State's most significant bridges. However, requiring State transportation agencies to complete these inventories would place an unfair burden on states without the resources to do these studies, and we do not agree that such inventories are necessary to identify exceptional examples in a state, provided the state DOT and Federal Highway Administration consults with the SHPO and others in developing the list of exceptional bridges, as required.

The ACHP received comments on the FHWA proposed Program Comment from six SHPOs: Delaware, Hawaii, Nevada, New Hampshire, Puerto Rico, and Wisconsin. Wisconsin and Nevada SHPOs support the Program Comment and offered minor suggestions for improving Section IV (Considerations) which were incorporated into the final document.

Four SHPO representatives expressed objections or strong reservations to the approach because of concerns that important post-1945 concrete and steel bridges would remain unidentified and unprotected in the absence of a comprehensive statewide historic bridge survey. As with some of the commenters on the **Federal Register** notice (summarized above), these SHPO reviewers equated the elimination of individual review requirements for common bridge types with a lack of historic significance. The ACHP has revised the Program Comment to clarify that the intent is to streamline Section 106 review by replacing individual documentation and treatment of the common bridge types in Section V with the programmatic mitigation in Section VI. The purpose of the considerations in

Section IV of the Program Comment is not to identify and protect all significant bridges, but to provide the Federal Highway Administration in each State an opportunity to identify and exclude from the Program Comment: (1) Bridges that have already been listed or determined eligible for listing in the National Register, and (2) common post-1945 concrete and steel bridges that are known to have exceptional significance. Although a statewide inventory to identify exceptional bridges is not a requirement for agencies wishing to apply the Program Comment to undertakings affecting post-1945 bridges in a state, FHWA will encourage states to update inventories of historic bridges to better ensure that bridges meeting the considerations in Section IV are identified and considered early in the Section 106 review process.

The National Conference of State Historic Preservation Officers (NCSHPO) worked closely with FHWA to develop the Program Comment, and has expressed strong support for it.

Finally, Federal agencies may only use the Program Comment in states where the relevant FHWA Division has completed and filed a list of exceptional common bridges with the FHWA Federal Preservation Officer (FPO) in accordance with Section IV. While the ACHP does not intend to limit the usefulness of the Program Comment to federal agencies wishing to use it, we note that the effectiveness of the Program Comment hinges on the FHWA Divisions in each state taking the step to identify bridges that should be exempted from the Program Comment. We encourage Federal agencies other than FHWA wishing to use the Program Comment to contact the relevant FHWA Division office or the State Historic Preservation Office to find out the status of its efforts to complete the list required in Section IV. The FHWA FPO has agreed to post on FHWA's Web site (<http://www.environment.fhwa.dot.gov/histpres/index.asp>) information about the lists once they are submitted. Other agencies may check with the FHWA FPO or check the Web site to determine if a list of exceptional bridges has been completed by a state Division of FHWA. FHWA is committed to working with states and FHWA Divisions to ensure that the requirements of the Program Comment are communicated through the publication of guidance, FHWA's Web site, and coordination by Headquarters and the FPO.

II. Final Text of the Program Comment

The following is the text of the proposed Program Comment:

Program Comment for Common Post-1945 Concrete and Steel Bridges

I. Introduction

Every year, the Federal Highway Administration (FHWA) funds the rehabilitation and replacement of hundreds of bridges under the Federal-aid program administered across the U.S. by State departments of transportation (DOT) and the Federal Lands Highway program. Other Federal agencies are also involved with projects affecting bridges through Federal assistance, approvals, or permits. Many of the bridges affected by these programs are of common types constructed by State transportation agencies after 1945, using reinforced concrete or steel beams and designs that quickly became standardized. These common bridge types are generally undistinguished, and although some of them may be eligible for inclusion in the National Register of Historic Places, when repair or replacement is needed, they are rarely viable candidates for either preservation in place or relocation. Yet, every federally funded or permitted undertaking affecting such a bridge requires review and consultation pursuant to Section 106 of the National Historic Preservation Act (Section 106), 16 U.S.C. 470f to assess whether the bridge is eligible for inclusion in the National Register and, if so, to resolve adverse effects to it. The regulations implementing Section 106, codified at 36 CFR part 800, describe the procedures Federal agencies must follow to meet this obligation.

Alternate compliance methods, provided by the Section 106 regulations, allow agencies to meet these Section 106 obligations but tailor the process to their mission and needs. Section 800.14(e) of the regulations provides that any agency may request a "Program Comment" from the ACHP in lieu of case-by-case review. The benefit of a Program Comment is that it allows a federal agency to comply with Section 106 in a single action for a class of undertakings rather than addressing each undertaking as a separate action. At FHWA's request, the ACHP has issued the following Program Comment in accordance with 36 CFR § 800.14(e) in order to waive, with limited exceptions, case-by-case Section 106 consideration of effects on common post-1945 bridges. This Program Comment is available for use by all federal agencies and State officials delegated the responsibility to comply with Section 106 for the particular undertakings by statute or a program alternative under 36 CFR § 800.14 (federal agencies). It relieves federal agencies from the need, under Section 106, to individually consider the effects of undertakings on the bridges described in Section V of this Program Comment, with the exceptions noted in Section IV.

It is important to note that this Program Comment is not a waiver from Section 106 review for undertakings that may affect common bridges or other historic properties as described in Section V. Neither is it a waiver from applicable federal requirements to consult with Indian tribes or Native Hawaiian organizations (NHO) regarding undertakings that may affect historic

properties to which a tribe or NHO ascribes traditional cultural and religious significance. Federal agency officials must still complete Section 106 review and consider effects of the undertaking on historic properties other than the common bridge itself. Such effects to other historic properties may be direct or indirect, and must be considered by the federal agency official whether or not the Program Comment is applicable to the subject bridge.

II. Background

In October 2005, the National Cooperative Highway Research Program published "A Context for Common Historic Bridge Types." That context revealed that a great many of the bridge structures built after 1935, and especially since 1946, are strictly utilitarian and lacking in distinctive engineering or architectural qualities. Increasing standardization associated with highway design as a result of growing federal funding and the evolving standards of the American Association of State Highway and Transportation Officials (AASHTO) both contributed to the uniformity of design in bridges of certain types.

Information about America's bridges, including their age and condition, is readily available in FHWA's National Bridge Inventory (NBI). The NBI is a collection of information (database) covering just under 600,000 of the nation's bridges located on public roads, including Interstate Highways, U.S. highways, State and county roads, as well as publicly accessible bridges on federal lands. It presents a State by State summary analysis of the number, location, and general condition of highway bridges within each State. This database contains technical and engineering information about hundreds of thousands of bridges in the United States, including year built, bridge type, condition and many other fields. Some 45,000 bridges in the NBI are rated as structurally deficient, meaning that portions of the bridge may be in poor condition. Approximately 61,680 are identified as functionally obsolete, meaning that the design of the bridge does not meet current guidelines for its use, such as lack of safety shoulders or the inability to handle certain traffic volume, speed, size, or weight. Bridges in these categories are frequent candidates for replacement. This Program Comment is intended to eliminate the administrative burden of considering the effects of replacement on these bridges on a case-by-case basis and make delivery of these critical projects more efficient in recognition of the very limited preservation value of the vast majority of common post-1945 bridges.

III. Applicability

This Program Comment relieves federal agencies from the Section 106 requirement to consider the effects of undertakings on the bridge types identified in Section V of this Program Comment, except for those subject to the considerations noted in Section IV of this Program Comment.

Undertakings include those that involve applications from State transportation agencies or local governments for federal permits, approvals, or assistance that will result in alteration, replacement, or

demolition of one or more of the common bridges or culverts listed in Section V below (common bridges). All federal agencies may take advantage of the streamlining provided by this Program Comment. Federal agencies may use data from the NBI or existing State surveys to support the determination that a particular bridge is a common bridge under this Program Comment. However, if data from the NBI is used, that information must be verified in the field by a qualified engineer or cultural resource professional to ensure that the date and type have been correctly recorded and that the bridge does not meet any of the other considerations under Section IV.

The Program Comment applies to common bridges regardless of ownership, except for those located on tribal lands.¹ As noted above, even if the undertaking involves a common bridge not subject to considerations under Section IV, federal agency officials must still complete Section 106 review for the undertaking, including the identification of historic properties and consideration of effects of the undertaking on historic properties other than the common bridge itself. Such effects to other historic properties may be direct or indirect, and must be considered by the federal agency official whether or not the Program Comment is applicable to the subject bridge. For example, bridge replacement projects may have the following types of effects to non-common bridge historic properties that would need to be considered:

- disturbance to archeological sites as a result of construction-related ground disturbing activities;
- change in physical features that contribute to historic significance of a historic property, including alterations that a new bridge may have on the historic setting and feeling of an adjacent historic district;
- change in traffic patterns that may affect the setting, feeling, and association of a historic district; or
- effects to other historic properties based on the need for temporary construction, detours, or rights-of-way.

A federal agency is not required to use this Program Comment. Federal agencies that choose not to use this Program Comment must comply with Section 106 through the process in the Section 106 regulations at 36 CFR §§ 800.3 through 800.7, or 36 CFR § 800.8(c), or another existing program alternative under 36 CFR § 800.14. Any federal agency that chooses to use this Program Comment for an undertaking should notify consulting parties that it will use it with regard to the effects of the undertaking on the bridge types identified in Section V of this Program Comment.

IV. Considerations

Prior to utilizing this Program Comment for an undertaking that may affect a common bridge, a federal agency, based on the work of a qualified cultural resource specialist,

¹ Indian tribes wishing to use the streamlining measures in this Program Comment for common bridges on lands under their jurisdiction are encouraged to enter into program alternatives pursuant to 36 CFR 800.14.

must complete a review to determine if any of the considerations listed below apply to the bridge at issue. If the federal agency determines that the common bridge in question meets any of these considerations, the agency may not utilize this Program Comment with regard to that common bridge.

(A) The bridge is listed in or has previously been determined eligible for the National Register of Historic Places or is located adjacent to or within a National Register listed or eligible historic district, including linear historic districts such as a parkway, historic road, or canal;

(B) The bridge in question is or includes spans of the following types: Arch bridges, truss bridges, bridges with movable spans, suspension bridges, cable-stayed bridges, or covered bridges; or

(C) The bridge was identified in a list created through the process detailed below as having exceptional significance for association with an event or individual, or being a very early or particularly important example of its type in a State or the nation, having distinctive engineering or architectural features that depart from standard designs, such as an aesthetic railing or balustrade, includes spans of exceptional length or complexity, or displaying other elements that were engineered to respond to a unique environmental context.

Before the Program Comment may be used for undertakings in a State, the relevant FHWA Division must first develop a list of bridges in that State that are of the types considered common bridges, but that also meet the considerations in IV.C above, and therefore fall outside the scope of this Program Comment. Each FHWA Division wishing to apply the provisions of this Program Comment must organize a meeting of the relevant SHPO, DOT, and other interested parties in order to develop the list of bridges that meet the criteria considerations in IV.C. The list should be finalized and submitted to the Federal Preservation Officer of FHWA by March 31, 2013. FHWA Divisions are not required to develop a statewide survey or context studies to support the development of such lists where none exist. The list is not intended to be exhaustive, but will be informed by input received at the meeting. The intent behind the list is to be able to exclude readily recognizable exceptional bridges from the Program Comment. Where States already have a current (within the last 5 years) Programmatic Agreement, inventory, or management plan for historic bridges that identifies common bridges meeting any of the listed considerations, the data included in those Programmatic Agreements, inventories, or management plans may suffice to create the list. States lacking up to date historic bridge inventories may subsequently identify additional bridges to include on the list of exceptional bridges excluded from the Program Comment based on information obtained in a field verification required in Section III of this Program Comment.

V. Description of Common Bridges Within the Scope of This Program Comment

Based on the historic bridge context, the NBI, information developed in statewide

bridge inventories across the United States, and consultation with the National Conference of SHPOs and other stakeholders, the following common bridge types are considered well-documented standardized designs that lack individual distinction.² It is understood that some of the bridges that fall into the specified types may be eligible for the National Register under local or State significance. Nevertheless, provided none of the considerations specified in Section IV above apply, the following are the common bridge types that fall within the scope of this Program Comment:

- (A) Reinforced concrete slab bridges
 - (i) Reinforced concrete cast-in-place slabs
 - (ii) Reinforced concrete pre-cast slabs
 - (iii) Pre-stressed concrete slabs
- (B) Reinforced concrete beam and girder bridges
 - (i) Reinforced concrete Tee Beams
 - (ii) Reinforced concrete channel beams
 - (iii) Pre-stressed concrete I-Beams and Bulb Tees
 - (iv) Pre-stressed concrete box beams
- (C) Steel Multi-Beam or Multi-Girder bridges
 - (i) Steel-rolled multi-beams
 - (ii) Steel fabricated (built up) girders
- (D) Culverts and reinforced concrete boxes
 - (i) Reinforced concrete boxes
 - (ii) Concrete box culverts
 - (iii) Concrete pipe culverts
 - (iv) Steel pipe culverts

VI. Programmatic Mitigation

The programmatic mitigation measures in this section resolve adverse effects that could result from the potential replacement of common bridges and provide appropriate documentation of those common bridges covered by this program comment. By completing the requirements of Section IV, federal agencies will ensure that this Program Comment is appropriately applied to individual undertakings affecting common bridges. The measures included in this Section, when completed by FHWA, will provide a long-term record of these common bridge types and information about the historic and technological significance of this period of innovation in transportation.

(A) If a suitable example from at least one State is not already included in the Historic American Engineering Record (HAER) collection, one set of HAER documentation, including at least narrative history and photographs, for each bridge type in Section V shall be prepared and submitted by FHWA for acceptance by HAER before December 31, 2013. The FHWA will coordinate with HAER to determine which, if any, of these types are not yet represented in the HAER collection and will work with the FHWA Division offices and State DOTs to identify a candidate for each type not already represented.

(B) FHWA will complete a brief illustrated history of post-1945 highway bridge engineering and design to document for the general public the innovations and

² Descriptions and examples of these common bridge types can be found in *A Context for Common Historic Bridge Types*, NCHRP Project 25–25, task 15, October 2005 (http://onlinepubs.trb.org/onlinepubs/archive/NotesDocs/25-25%2815%29_FR.pdf).

contributions to transportation in the Post World War II era. The illustrated history will be published as a brochure and/or posted on the Internet, and shall be completed and available to the public prior to December 31, 2013.

(C) The FHWA will encourage State transportation agencies that have not done so within the last 5 years to update inventories of historic bridges in their States to better ensure that bridges meeting the considerations in Section IV above are identified and considered early in the Section 106 review process.

VII. Definitions

If not specifically addressed below, terms used within this Program Comment shall be defined consistent with the definitions provided in 36 CFR Part 800.

“*Common Bridge*” is, for purposes of this Program Comment, a common post-1945 bridge or culvert of a type identified in Section V.

“*Program Comment*” is an alternative to Section 106 review that allows a Federal agency to request the ACHP to comment on a category of undertakings in lieu of conducting individual reviews under Sections 800.4 through 800.6 of the regulations (36 CFR Part 800).

“*Qualified cultural resource specialist*” means an individual meeting the Secretary of the Interior’s professional qualifications for historian or architectural historian by virtue of education and experience to carry out historic preservation work.

Authority: 36 CFR 800.14(e).

Dated: November 8, 2012.

John M. Fowler,
Executive Director.

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DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2012–0046]

Protected Critical Infrastructure Information (PCII) Office Self-Assessment Questionnaire

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 60-day notice and request for comments; New Information Collection Request: 1670—NEW.

SUMMARY: The Department of Homeland Security (DHS), National Protection and Programs Directorate (NPPD), Office of Infrastructure Protection (IP), Infrastructure Information Collection Division (IICD), Protected Critical Infrastructure Information (PCII) Program will submit the following Information Collection Request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork

Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until January 15, 2013. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and questions about this Information Collection Request should be forwarded to DHS/NPPD/IP/IICD, 245 Murray Lane, SW., Mail Stop 0602, Arlington, VA 20598–0602. Emailed requests should go to Joseph Maltby, joseph.maltby@dhs.gov. Written comments should reach the contact person listed no later than January 15, 2013. Comments must be identified by “DHS–2012–0046” and may be submitted by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>.
- Email: Include the docket number in the subject line of the message.

Instructions: All submissions received must include the words “Department of Homeland Security” and the docket number for this action. Comments received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided.

SUPPLEMENTARY INFORMATION: Congress created the PCII Program under the Critical Infrastructure Information Act of 2002 for DHS to encourage voluntary information sharing by owners and operators of critical infrastructure and protected systems. IICD administers the PCII Program. The PCII Program is implemented by 6 CFR part 29, Procedures for Handling Critical Infrastructure Information; Final Rule (the Regulation), issued in 2006. PCII refers to critical infrastructure information not customarily in the public domain and related to the security of critical infrastructure or protected systems, which is voluntarily submitted to DHS for homeland security purposes and validated under the authority of the PCII Program Manager. The PCII Program provides a statutory exemption from release of information under the Freedom of Information Act and state and local sunshine laws, and prohibits the use of the information in civil litigation.

The PCII Program is responsible for ensuring compliance with the regulation’s uniform procedures for the handling, use, dissemination, and safeguarding of PCII. In this capacity, the PCII Program oversees a community of stakeholders, including submitters of critical infrastructure information, authorized users of PCII and accredited Federal, state and local entities with

homeland security duties. The PCII Program is required by its authorizing regulation to assist the PCII Officers in overseeing their own accredited PCII programs at the state and local level. See 6 CFR 29.4(d). This questionnaire is designed to gather information from PCII Officers that will be used by the NPPD/IP PCII Program to assess state and local programs, their compliance with PCII rules and requirements, and the specific needs of their accredited programs. These assessments are designed to help the DHS PCII Program and Officers to ensure that PCII is being properly protected and to limit the potential for mishandling and improper disclosures. OMB is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Analysis

Agency: Department of Homeland Security, National Protection and Programs Directorate, Office of Infrastructure Protection, Infrastructure Information Collection Division, Protected Critical Infrastructure Information Program.

Title: Protected Critical Infrastructure Information (PCII) Office Self-Assessment Questionnaire.

OMB Number: 1670–NEW.

Frequency: Annually.

Affected Public: PCII Officers.

Number of Respondents: 80 (estimate).

Estimated Time per Respondent: 1 hour.

Total Burden Hours: 80 annual burden hours.

Total Burden Cost (capital/startup): \$0.

Total Recordkeeping Burden: \$0 (This assessment will reside on existing PCII information storage systems).

Total Burden Cost (operating/maintaining): \$8,316.