during preenforcement review of an agency rule. The list should be understood as a checklist of potentially relevant factors, not a fixed doctrinal formula, and as inapplicable where a statute directs otherwise. Specifically, the list includes consideration of whether:

- The issue was raised by a participant in the rulemaking other than the litigant.[23]
- The issue was addressed by the agency on its own initiative in the rulemaking.[24]
- The agency failed to address an issue that was so fundamental to the rulemaking proceeding or to the rule's basis and purpose that the agency had an affirmative responsibility to address it.[25]
- The issue involves an objection that the rule violates the U.S. Constitution.[26]
- It would have been futile to raise the issue during the rulemaking proceeding because the agency clearly indicated that it would not entertain comments on or objections regarding that issue.[27]
- The issue could not reasonably be expected to have been raised during the rulemaking proceeding because of the procedures used by the agency.[28]
- The basis for the objection did not exist at a time when rulemaking participants could raise it in a timely comment.[29]

If an issue exhaustion question arises in litigation, litigants should be given an opportunity to demonstrate that some participant adequately raised the issue during the rulemaking or that circumstances exist to justify not requiring issue exhaustion. And if a court declines to apply issue exhaustion principles to preclude review of new issues, the agency should be given an opportunity to respond to new objections on the merits.[30] Where application of the issue exhaustion doctrine forecloses judicial review, the Administrative Procedure Act, 5 U.S.C. 553(e), can provide a procedural mechanism for the public to raise new issues that were not presented to the agency during a rulemaking proceeding: The right to petition agencies for amendment or repeal of rules.

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[23] *See Portland Gen. Elec. Co.* v. *Bonneville Power Admin.,* 501 F.3d 1009, 1024 (9th Cir. 2007) (''In general, we will not invoke the waiver rule in our review of a notice-and-comment proceeding if an agency has had an opportunity to consider the issue. This is true even if the issue was considered sua sponte by the agency or was raised by someone other than the petitioning party.'').

[24] *Id.*

[25] *See NRDC* v. *EPA,* 755 F.3d 1010, 1023 (D.C. Cir. 2014) (''EPA retains a duty to examine key assumptions as part of its affirmative burden of promulgating and explaining a nonarbitrary, non-capricious rule . . .'') (internal quotation marks omitted). This factor may include issues arising under the applicable substantive statute or the APA.

[26] *Cf., Noel Canning* v. *NLRB,* 705 F.3d 490, 497 (D.C. Cir. 2013), *aff'd NLRB* v. *Noel Canning,* 134 S. Ct. 2550 (2014) (invoking ''extraordinary circumstances'' exception in statutory provision requiring issue exhaustion to address constitutional issue not raised with the NLRB because the issue went to the very power of the agency to act and implicated fundamental separation of powers concerns). It is worth emphasizing that regardless of whether the issue exhaustion doctrine would apply, participants in a rulemaking should raise constitutional issues during the rulemaking proceeding to give the agency an opportunity to adjust its rule to eliminate the constitutional objection or at least to explain in the administrative record why its rule does not raise constitutional concerns.

[27] *See Comite De Apoyo A Los Trabajadores Agricolas* v. *Solis,* No. 09–240, 2010 WL 3431761, at *18 (E.D. Pa. Aug. 31, 2010); *cf. WATCH* v. *FCC,* 712 F.2d 677, 682 (D.C. Cir. 1983) (remarking that ''[a] reviewing court . . . may in some cases consider arguments that it would have been futile to raise before the agency,'' but cautioning that ''[f]utility should not lightly be presumed'').

[28] *See Alaska Survival* v. *Surface Transp. Bd.,* 705 F.3d 1073 (9th Cir. 2013) (declining to apply issue exhaustion because the agency's procedures were informal and ''never provided direct notice of or requested public comment'' on challenged issue).

[29] *Cf. CSX Transp., Inc.,* v. *Surface Transp. Bd.,* 584 F.3d 1076, 1079–81 (D.C. Cir. 2009) (declining to apply issue exhaustion to a litigant's argument that the final rule was not a logical outgrowth of the noticed rule).

[30] Courts have a variety of options for soliciting the agency's views that should vary depending on the circumstances. These options include permitting the agency to brief the issue or supplement the administrative record, or ordering a remand for the limited purpose of soliciting the agency's views.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2015–0062]

Availability of an Environmental Assessment and Finding of No Significant Impact for Field Use of Vaccines Against Avian Influenza H5 Virus Strains

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: We are advising the public that an environmental assessment has been prepared by the Animal and Plant Health Inspection Service relative to the use of one or more veterinary biological products as a treatment for and as an aid in the reduction of highly pathogenic avian influenza (HPAI) incidence caused by strains such as Eurasian H5 viruses of clade 2.3.4.4 lineage. Any biological products would become part of the measures to reduce the incidence of HPAI in the nation's commercial poultry flocks. Based on the environmental assessment, we have concluded that the use of vaccines as described in the environmental assessment will not have a significant impact on the human environment. We are making this environmental assessment and finding of no significant impact available to the public for review and comment.

DATES: We will consider all comments that we receive on or before November 6, 2015.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0062.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2015–0062, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0062* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Donna Malloy, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 851–3426, fax (301) 734–4314.

SUPPLEMENTARY INFORMATION: Under the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) is authorized to promulgate regulations designed to ensure that veterinary biological products are pure, safe, potent, and efficacious. Veterinary biological products include viruses, serums, toxins, and analogous products of natural or synthetic origin, such as vaccines, antitoxins, or the immunizing components of microorganisms intended for the diagnosis, treatment, or prevention of diseases in domestic animals.

APHIS issues licenses to qualified establishments that produce veterinary biological products and issues permits to importers of such products. APHIS also enforces requirements concerning production, packaging, labeling, and shipping of these products and sets standards for the testing of these products. Regulations concerning veterinary biological products are contained in 9 CFR parts 101 to 124.

Veterinary biological products meeting the requirements of the regulations may be considered for addition to the U.S. National Veterinary Stockpile (NVS). The NVS is the nation's repository of vaccines and other

critical veterinary supplies and equipment. It exists to augment State and local resources in responding to high-consequence livestock diseases that could potentially devastate U.S. agriculture, seriously affect the economy, and threaten public health. NVS vaccines would be used in APHIS programs or under department control or supervision. The addition of vaccines to the stockpile would not preclude private development and use of other poultry vaccines meeting the requirements of the Virus-Serum-Toxin Act.

The arrival in December 2014 of Eurasian H5 strains of highly pathogenic avian influenza (HPAI) and their subsequent dissemination in North America caused a catastrophic outbreak in both domestic poultry and avian wildlife. It is thought that wild, migratory waterfowl carried an H5 virus into North America, which generated reassortants (genetic variants resulting from crosses among AI strains) that spilled over into the domestic poultry population. The H5 viruses are likely to persist within the endemic wild, migratory waterfowl population, which is the primary reservoir of the virus. This viral reservoir will continue to pose a significant threat to U.S. poultry and avian collections.

Two poultry production sectors, commercial meat turkeys and laying chickens, were heavily impacted by these H5 viruses, resulting in the loss or destruction of over 48 million birds between December 2014 and June 2015. Response by regulatory agencies combined with migration of wild waterfowl and the natural disinfectant action of the summer heat temporarily halted new disease outbreaks. The return of potentially infected migratory waterfowl in autumn, however, may precipitate a new round of outbreaks on an expanded national scale.

Therefore, we are advising the public that we have prepared an environmental assessment (EA) entitled ''For Field Use of Avian Influenza Vaccines Against Avian Influenza H5 Virus Strains (August 2015)'' to analyze the potential use of one or more veterinary biological products as a treatment for and as an aid in the reduction of HPAI incidence caused by H5 strain viruses. We are publishing this notice to inform the public that we will accept written comments regarding the EA from interested or affected persons for a period of 30 days from the date of this notice. Based on an individual vaccine's risk analysis and the findings in this EA, APHIS would authorize deployment (including shipment, field testing, addition to the NVS, and use in commercial poultry production) of safe, well-characterized biological products upon making a finding of no significant impact (FONSI).

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. If APHIS receives substantive comments that were not previously considered, the Agency would consider issuing a supplement to the EA and FONSI. Because timeliness is essential, it is imperative that APHIS authorize shipment and field use of safe, well-characterized vaccines as soon as possible, and possibly prior to the close of the comment period of this notice.

Possible Field Use Locations: Where Federal and State authorities agree on use.

The EA has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Authority: 21 U.S.C. 151–159.

Done in Washington, DC, this 1st day of October 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–25445 Filed 10–6–15; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Farm Service Agency

Information Collection; Direct Loan Making

AGENCY: Farm Service Agency, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on a revision and an extension of a currently approved information collection that supports 7 CFR part 764. The Direct Loan Making regulations specify the application process and requirements for direct loan assistance. FSA is adding additional information collection to the existing collection to reflect the addition of the Direct Farm Ownership Microloan (DFOML). The collected information is used in eligibility and feasibility determinations on farm loan applications.

DATES: We will consider comments that we receive by December 7, 2015.

ADDRESSES: We invite you to submit comments on this notice. In your comments, include date, volume, and page number of this issue of the **Federal Register**. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal: Go to www.regulations.gov*. Follow the online instructions for submitting comments.
- *Mail:* Russ Clanton, Branch Chief, Direct Loan Making and Funds Management, USDA/FSA/FLP, STOP 0523, 1400 Independence Avenue SW., Washington, DC 20250–0503.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Copies of the information collection may be requested by contacting Russ Clanton at the above address.

FOR FURTHER INFORMATION CONTACT: Russ Clanton, (202) 690–0214.

SUPPLEMENTARY INFORMATION:

Title: Farm Loan Programs, Direct Loan Making.

OMB Number: 0560–0237.

Expiration Date: 02/29/2016.

Type of Request: Revision and Extension.

Abstract: FSA's Farm Loan Programs provide loans to family farmers to purchase real estate and equipment, and to finance agricultural production. Direct Loan Making regulations at 7 CFR part 764 provide the requirements and process for determining an applicant's eligibility for a direct loan.

Several changes are being made in the estimates for the burden hours and the number of respondents in anticipation of the new DFOML, which will be implemented through rulemaking. FSA anticipates an increase in the use of the forms. Also, the burden hours have changed due to the removal of the existing collection, which was previously included in error. The specific changes are explained below.

There will be no new or revised forms for DFOMLs. With the planned addition of the DFOML and the new applicants expected to apply for these real estate microloans, FSA anticipates the total burden hours for Direct Loan Making increasing by 1,725 hours. The anticipated 3,530 burden hours for DFOML takes into account the number of regular FO applications normally received for loan requests of $50,000 or less, which have a reduced application process and paperwork burden. The hours for the Land Contract Guarantee