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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Adoption of Statement

AGENCY: Administrative Conference of the United States.

ACTION: Notice.

SUMMARY: The Administrative Conference of the United States adopted one formal statement at its Sixty-Third Plenary Session. The appended statement addresses “Issue Exhaustion in Preenforcement Judicial Review of Administrative Rulemaking.”

FOR FURTHER INFORMATION CONTACT: Gisselle Bourns, Administrative Conference of the United States, Suite 706 South, 1120 20th Street NW., Washington, DC 20036; Telephone 202-480-2080.

SUPPLEMENTARY INFORMATION: The Administrative Conference Act, 5 U.S.C. 591-596, established the Administrative Conference of the United States. The Conference studies the efficiency, adequacy, and fairness of the administrative procedures used by Federal agencies and makes recommendations for improvements to agencies, the President, Congress, and the Judicial Conference of the United States (5 U.S.C. 594(1)). For further information about the Conference and its activities, see www.acus.gov.

The Conference’s Sixty-Third Plenary Session was conducted, for the first time, as a virtual meeting, held via the Internet, in accordance with the Conference’s earlier Recommendation, 2011-7, The Federal Advisory Committee Act—Issues and Proposed Reforms. The plenary session was open for participation by Conference members and the public for the period of September 18 through September 25, 2015. The Assembly of the Conference adopted one formal statement. Statement #19, “Issue Exhaustion in Preenforcement Judicial Review of Administrative Rulemaking,” examines

judicial application of an issue exhaustion requirement in preenforcement review of administrative rulemaking. It invites courts to consider a series of factors when examining the doctrine of issue exhaustion in the context of preenforcement review of agency rules.

The Appendix below sets forth the full text of this statement. The Conference will transmit the statement to federal agencies, relevant committees of Congress, and the Judicial Conference of the United States, as appropriate, for their consideration. The statement is not binding, but it represents the collective views of the membership of the Administrative Conference of the United States. The research report prepared for the Conference on this subject is posted at: www.acus.gov/63rd.

Dated: October 2, 2015.

Shawne C. McGibbon,
General Counsel.

Appendix—Statement of the Administrative Conference of the United States

Administrative Conference Statement #19

Issue Exhaustion in Preenforcement Judicial Review of Administrative Rulemaking

Adopted September 25, 2015

The doctrine of issue exhaustion generally bars a litigant challenging agency action from raising issues in court that were not raised first with the agency. Although the doctrine originated in the context of agency adjudication, it has been extended to judicial review of challenges to agency rulemakings. Scholars have observed that issue exhaustion cases “conspicuously lack discussion of whether, when, why, or how [the issue] exhaustion doctrine developed in the context of adjudication should be applied to rulemaking.”¹ The Administrative Conference has studied the issue exhaustion doctrine in an effort to bring greater clarity to its application in the context of preenforcement review of agency rules. The Conference believes that this Statement may

¹ Jeffrey S. Lubbers, Fail to Comment at Your Own Risk: Does Issue Exhaustion Have a Place in Judicial Review of Rules: 11 (May 5, 2015) (Report to the Administrative Conference of the U.S.) [hereinafter Lubbers Report] (citing Peter L. Strauss, et al. Gellhorn and Byse’s Administrative Law 1246 (10th ed. 2003)); see also *Koretzoff v. Vilsach*, 707 F.3d 394, 399 (D.C. Cir. 2013) (Williams, J., concurring) (joining a decision to preclude preenforcement review of new issues but writing separately “primarily to note that in the realm of judicial review of agency rules, much of the language of our opinions on ‘waiver’ has been a good deal broader than the actual pattern of our holdings”).

be useful by setting forth a series of factors that it invites courts to consider when examining issue exhaustion in that context.²

Evolution of the Issue Exhaustion Doctrine

The requirement that parties exhaust their administrative remedies (“remedy exhaustion”) is a familiar feature of U.S. administrative law. This doctrine generally bars a party from appealing a final agency action to a court unless the party exhausts prescribed avenues for relief before the agency.³

The related but distinct concept of “issue exhaustion” prevents a party from raising issues in litigation that were not first raised before the agency, even if the petitioner participated in the administrative process.⁴ As with remedy exhaustion, the issue exhaustion doctrine initially arose in the context of agency adjudications.⁵

As the Supreme Court has recognized, “administrative issue-exhaustion requirements are largely creatures of statute.”⁶ In several judicial review provisions adopted during the 1930s, prior to the advent of the Administrative Procedure Act of 1946, Congress expressly required parties to raise all their objections to agency action before adjudicatory agencies. Since that time, Congress has included issue exhaustion provisions in many statutes governing review of agency orders.⁷ The typical statute contains an exception for “reasonable grounds” or “extraordinary circumstances” and permits the court to

² This Statement does not address the application of the doctrine in the context of a challenge to a rule in an agency enforcement action, where the passage of time and new entrants may complicate the inquiry. The Conference has previously identified issues that Congress should not ordinarily preclude courts from considering when rules are challenged in enforcement proceedings. See Admin. Conf. of the U.S., Recommendation 82-7, *Judicial Review of Rules in Enforcement Proceedings* (Dec. 17, 1982), <http://www.acus.gov/82-7>.

³ *Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50-51 (1958).

⁴ See *Fiber Tower Spectrum Holdings, LLC v. FCC*, No. 14-1039, slip. op. at 9 (D.C. Cir. Apr. 3, 2015), Issue exhaustion statutes may not always be jurisdictional. E.g., *EPA v. EME Homer City Generation, L.P.*, 134 S. Ct. 1584, 1602-03 (2014) (“A rule may be ‘jurisdictional,’ we have explained. Section 7607(d)(7)(B), we hold, is of that character. It does not speak to a court’s authority, but only to a party’s procedural obligations.”) (citations omitted); see also *Advocates for Highway and Auto Safety v. FMSCA*, 429 F.3d 1136, 1148 (D.C. Cir. 2005) (“as a general matter, a party’s presentation of issues during a rulemaking proceeding is not a jurisdictional matter”) (emphasis in original).

⁵ See *Lubbers Report*, *supra* note 1, at 2-3.

⁶ *Sims v. Apfel*, 530 U.S. 103, 107 (2000) (plurality opinion).

⁷ See *Lubbers Report*, *supra* note 1, at 4-6.

require an agency to take new evidence under certain conditions.⁸

Courts have also imposed issue exhaustion requirements in the adjudication context in the absence of an underlying statute or regulation requiring it. The Supreme Court early on characterized the “general rule that courts should not topple over administrative decisions unless the administrative body not only has erred but has erred against objection made at the time appropriate under its practice” as one of “simple fairness,” emphasizing that issue exhaustion promotes orderly procedure and good administration by offering the agency an opportunity to act on objections to its proceedings.⁹ But questions about the common law application of the doctrine were later raised in *Sims v. Apfel*, where the Court held that a judicial issue exhaustion requirement was inappropriate on review of the Social Security Administration’s informal, non-adversarial adjudicatory benefit determinations, reasoning that “the desirability of a court imposing a requirement of issue exhaustion depends on the degree to which the analogy to normal adversarial litigation applies in a particular administrative proceeding.”¹⁰

Although the issue exhaustion doctrine originated in the adjudication context, it has been extended to preenforcement review of agency rulemakings. Two statutes have been identified by the Conference as explicitly requiring issue exhaustion for review of agency rules—the Clean Air Act and the Securities Exchange Act of 1934.¹¹ Both statutes were amended to incorporate issue exhaustion provisions in the 1970s, when Congress enacted numerous regulatory statutes with significant rulemaking provisions.¹²

The doctrine has also been extended to the rulemaking context through common law. Despite *Sims’* focus in the adjudication context on the extent to which the underlying administrative proceeding resembled adversarial litigation for purposes of determining whether the doctrine applied, appellate courts have increasingly applied the doctrine in the absence of a statute requiring it when reviewing preenforcement challenges to agency rules enacted via notice-and-comment proceedings.¹³ And at least

two appellate courts have applied the doctrine to review of administrative rulemaking after specifically considering *Sims*,¹⁴ although *Sims* was recently cited by the Ninth Circuit as militating against issue exhaustion in an informal rulemaking issued without notice-and-comment procedures.¹⁵

Relying on their equitable authority, courts have also fashioned exceptions to the issue exhaustion doctrine.¹⁶ The Conference commissioned a consultant’s report to identify and articulate the scope of these exceptions in federal appellate case law, as well as to examine the general arguments for or against the doctrine in the rulemaking context.¹⁷ Without endorsing every conclusion expressed therein, the Conference believes that the report of its consultant can provide guidance to courts considering the application of the doctrine as it pertains to preenforcement review of administrative rulemaking.

Factors for Courts To Consider in Applying the Issue Exhaustion Doctrine

The Administrative Conference believes that stakeholders, agencies, and courts benefit when issues are raised during rulemaking proceedings with sufficient specificity to give the agency notice and a fair opportunity to address them prior to judicial review.¹⁸ Many of the justifications for applying the doctrine in judicial review of agency adjudicatory decisions apply squarely to review of rulemakings. The doctrine promotes active public participation, creates orderly processes for resolution of important

(“[g]enerally speaking, then, the price for a ticket to facial review is to raise objections in the rulemaking”); *City of Portland, Or. v. EPA*, 507 F.3d 706, 710 (D.C. Cir. 2007); *Military Toxics Project v. EPA*, 146 F.3d 948, 956–57 (D.C. Cir. 1998); see also Lubbers Report, *supra* note 1, at 27–30 (describing application of the doctrine as well as varied precedent in appellate courts other than the U.S. Court of Appeals for the D.C. Circuit). No cases were identified that applied the issue exhaustion doctrine in the context of new issues raised during enforcement challenges to rules.

¹⁴ *Advocates for Highway and Auto Safety v. FMSCA*, 429 F.3d 1136, 1148–49 (D.C. Cir. 2005); *Universal Health Servs., Inc. v. Thompson*, 363 F.3d 1013, 1020 (9th Cir. 2004).

¹⁵ See *Alaska Survival v. Surface Transp. Bd.*, 705 F.3d 1073, 1080 (9th Cir. 2013) (describing a Surface Transportation Board (STB) exemption proceeding as a rulemaking but applying the *Sims* rationale to it because the STB’s procedures were informal and public comments were not sought).

¹⁶ E.g., *Washington Ass’n for Television and Children (“WATCH”) v. FCC*, 712 F.2d 677, 681–82 (D.C. Cir. 1983) (“[Our] cases assume that § 405 contains implied exceptions without explaining why. We understand these cases, however, as implicitly interpreting § 405 to codify the judicially-created doctrine of exhaustion of administrative remedies, which permits courts some discretion to waive exhaustion.”) (footnotes omitted).

¹⁷ See generally Lubbers Report, *supra* note 1.

¹⁸ *Nat’l Ass’n of Mfrs. v. U.S. Dep’t of the Interior*, 134 F.3d 1095, 1111 (D.C. Cir. 1998); see also *Ctr. for Sustainable Econ. v. Jewell*, 779 F.3d 588, 602 (D.C. Cir. 2015) (holding on review of an agency adjudicatory decision that “the question in determining whether an issue was preserved, however, is not simply whether it was raised in some fashion, but whether it was raised with sufficient precision, clarity, and emphasis to give the agency a fair opportunity to address it”).

legal and policy issues raised in agency proceedings, ensures fully informed decisionmaking by administrative agencies, provides a robust record for judicial review, and lends certainty and finality to agency decisionmaking. Issue exhaustion also avoids the potential for significant disruption to extensive work by the agency, which can result if an issue is raised only during judicial review, after the rule has been developed. Application of the doctrine spares courts from hearing objections that could have been cured at the administrative level and reduces the need for agencies to create post-hoc rationalizations.¹⁹

On the other hand, the Conference also recognizes some practical and doctrinal concerns with uncritically applying issue exhaustion principles developed in the context of formal adversarial agency adjudications to the context of preenforcement rulemaking review.²⁰ Overbroad application of the doctrine to rulemaking proceedings could serve as a barrier to judicial review for persons or firms who reasonably did not engage in continuous monitoring of the agency in question.²¹ Issue exhaustion requirements may also contribute to the burdens of participating in a rulemaking proceeding, by exerting pressure on commenters to raise at the administrative level every issue that they might conceivably invoke on judicial review.²² Also, an overbroad exhaustion requirement may result in unnecessary uncertainty and inefficiencies by leaving unaddressed fundamental legal questions—such as a rule’s constitutionality or validity under a substantive federal statute. These and other concerns have led some observers to question the value of the doctrine as applied to rulemaking, or at least to call for limitations on its scope.

The Conference has compiled a list of factors—some of which may be dispositive in particular cases—that it invites courts to consider when deciding whether to preclude a litigant from raising issues for the first time

¹⁹ The argument for judicial application of the doctrine may be especially strong where the challenged issue concerns the factual basis of a rule, the agency’s evaluation of alternatives, or the agency’s failure to exercise its discretion in a particular manner. Judicial evaluation of the reasonableness of an agency’s action in such cases under an arbitrary and capricious standard of review may depend heavily on the administrative record and on the agency’s analysis of those issues. See generally *Gage v. Atomic Energy Comm’n*, 479 F.2d 1214, 1217–19 (D.C. Cir. 1973).

²⁰ See William Funk, *Exhaustion of Administrative Remedies—New Dimensions Since Darby*, 18 Pace Envtl. L. Rev. 1, 17 (2000) (“[u]nfortunately, some courts have ignored the specific statutory origin for [issue exhaustion] and have applied a similar exhaustion requirement in cases totally unrelated to that statute, while citing cases involving application of that statute”).

²¹ The impact of such barriers can fall most heavily on persons or entities whose interests are not in close alignment with the interests that have been advanced most forcefully by other participants in a given proceeding. See *Koretov v. Vilsack*, 707 F.3d 394, 401 (D.C. Cir. 2013) (Williams, J., concurring).

²² See Wendy E. Wagner, *Administrative Law, Filter Failure, and Information Capture*, 59 Duke L.J. 1321, 1363–64 (2010); Lubbers Report, *supra* note 1, at 38–40.

⁸ E.g., 15 U.S.C. § 77i(a); 29 U.S.C. § 160(e); 42 U.S.C. § 1320a-8(d)(1).

⁹ *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952) (reviewing an adjudicative order issued by the Interstate Commerce Commission after an adversarial hearing); see also *Advocates for Highway and Auto Safety v. FMSCA*, 429 F.3d 1136, 1149 (D.C. Cir. 2005) (applying the same rationale to rulemaking).

¹⁰ *Sims v. Apfel*, 530 U.S. 103, 108–12 (2000) (plurality opinion).

¹¹ 42 U.S.C. 7607(d)(7)(B); 15 U.S.C. 78y(c)(1). However, provisions governing some agencies’ “orders” have been held to apply to judicial review of rules. See *Citizens Awareness Network v. U.S.*, 391 F.3d 338, 345–47 (1st Cir. 2004); see also *Inv. Co. Inst. v. Bd. of Govs.*, 551 F.2d 1270, 1276–77 (D.C. Cir. 1977); *American Public Gas Ass’n v. Fed. Power Comm’n*, 546 F.2d 983, 986–88 (D.C. Cir. 1976).

¹² Lubbers Report, *supra* note 1, at 4, 11, 13.

¹³ E.g., *Koretov v. Vilsack*, 707 F.3d 394, 401 (D.C. Cir. 2013) (Williams, J., concurring).

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

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 Agrícolas 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).

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.

[FR Doc. 2015–25570 Filed 10–6–15; 8:45 am]

BILLING CODE 6110–1–P

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.

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.

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