

3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

RIN 1018-AB80

Migratory Bird Hunting: Amended Test Protocol for Nontoxic Shot Approval Procedures for Shot and Shot Coatings

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The principal purpose of this action is to promulgate a rulemaking that will update and amend the current nontoxic shot approval procedures by establishing a 3-tiered approval process. Shot approval will be considered at each tier with the testing becoming progressively more demanding. An environmentally benign shot could be granted approval at the first tier. This process is designed to include both candidate shot and shot coatings.

DATES: Comments on this proposal must be received by March 26, 1996.

ADDRESSES: Comments regarding this notice should be addressed to: Director (FWS/MBMO), U.S. Fish and Wildlife Service, 634 ARLSQ, 1849 C St., NW., Washington, DC 20240. Comments received on this notice will be available for public inspection during normal business hours in Room 634, Arlington Square Building, 4401 No. Fairfax Drive, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Paul Schmidt, Chief, or Keith Morehouse, Staff Specialist, Office of Migratory Bird Management, 703/358-1714.

SUPPLEMENTARY INFORMATION: The Service is proposing to revise and update the existing nontoxic shot approval procedures by establishing a 3-tiered approval process. Shot approval will be considered at each tier with the testing becoming progressively more demanding. An environmentally benign shot could be granted approval at the first tier. This approval process is designed to include both candidate shot and shot coatings. The Service and applicant have concluded much of the currently identified nontoxic testing required for bismuth-tin shot and the process was shown to be both confusing and cumbersome. The Service believes that this procedure needs to be modified because:

1. From an ecosystem management standpoint, species in addition to waterfowl species need to be considered;

2. Since the original regulations were promulgated, important advances have occurred in the field of ecological risk assessment that can be applied to this process;

3. Time, expense and burden on applicants and the Federal Government can be reduced without risk to wildlife; and

4. From an animal welfare standpoint, the numbers of test animals used can be reduced.

It should be noted, however, that while these procedures were put in place in 1986, the Service had not had any submission requesting approval of nontoxic shot until the bismuth-tin shot application of 1994. From our experience with the bismuth-tin shot approval process, it has been determined that procedures should be modified to accommodate situations where less than full testing is indicated. Thus, the Service and the National Biological Service (NBS) have cooperatively developed an alternative draft set of procedures proposed to be used for approving nontoxic shot as well as coatings that would replace the testing requirements presently contained in § 20.134. As with the current procedures, the proposed set of approval procedures carries the assumption that the applicant has the burden of proof that the candidate coating or shot is nontoxic.

The system proposed is 3-tiered and is meant to gradually increase the difficulty of the level of testing based on a test-in/test-out principle. That is, those candidate materials not approved

as a result of subjecting them to the standards set at Tier 1 would be subjected to the standards of Tier 2, and so forth, i.e., test-in. If the candidate material is approved at Tier 1 there would be no requirement to proceed to Tier 2 or 3, i.e., test-out. The criteria for requiring testing under Tier 2 standards would be met if data is incomplete or inconclusive as a result of review of materials and analyses conducted at Tier 1. Similarly, the criterion for requiring testing under Tier 3 standards would be met if material is found to have some poorly defined level of toxic effects at Tier 2.

As currently proposed by this regulation, Tier 1 would set out comprehensive and detailed requirements that must be provided to the Service in order for the Service to grant approval. Based on the Service's evaluation of whatever Tier 1 information could be gathered, the Service would make a decision to grant approval or require Tier 2 testing. That is, the scope of the new procedures outlined in Tier 1 would include: (1) Statements of use, chemical characterization, production variability and volume of use. The Service would request the specifics on the chemical compound(s) to be used and a complete analysis of potential environmental toxicity, as well as the thickness in the case of coating(s) and percentage of the coating in comparison to the total shot weight; (2) information on the toxicological effects of the material, including an ecological risk assessment on the toxicological effects of the coating and an assessment explaining why the applicant believes the coating or base material(s) does not pose toxicity problems for wildlife; and (3) information on the environmental fate and transport of the material. The Service would seek information on changes, if any, that are produced by firing the shot, the estimated half-life of the material and estimates of the environmental concentrations that are apt to be expected. Tier 1 procedures also contain a set of requirements defining the Service's responsibility in evaluating the submitted data/information.

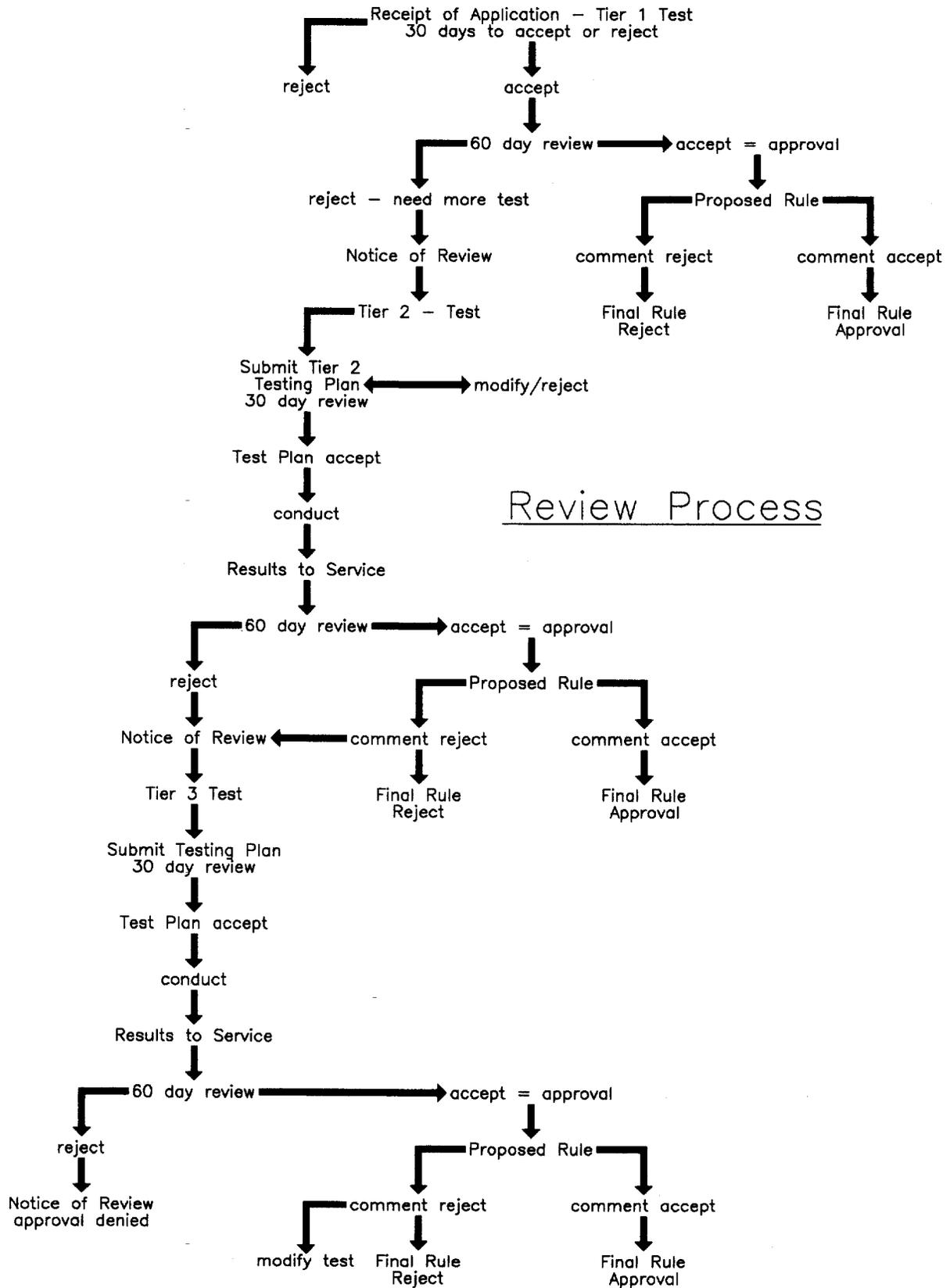
Previously codified candidate shot testing procedures would be divided between Tiers 2 and 3, with the *in vitro* erosion rate testing and the short-term (30-day) acute toxicity testing part of Tier 2, and the chronic exposure under adverse conditions and the chronic exposure reproduction testing part of Tier 3. Tier 2 will also include a test protocol that would assess the potential for the candidate shot to affect aquatic organisms, such as fish and/or

invertebrates, although it may not require *in vivo* testing, *per se*.

Applicants would be required to provide the Service with all the required information at the time of application or processing would be delayed. The information provided by the applicant will allow the Service, or others, to conduct an independent analysis and to make an informed decision on approval.

A schematic representation of the approval process is provided here to aid the reader:

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Although this new set of proposed approval procedures appears to be more lengthy, the Service feels that it is more flexible and simplifies the approval process. It is intended that these proposed changes will allow materials that are somewhat innocuous, with regard to known toxicity, to be processed more quickly, at lower cost and with less paperwork for both the applicant and the Service while ensuring that natural resources are protected.

In 50 CFR 20.134, the Service provides a procedure for approval of nontoxic shot which has been in effect since 1986; however, it was not clear that this procedure also pertained to the shot coating which is applied to prevent corrosion and potential fusion of the shot. Shot coatings were not given consideration since they are typically quite thinly applied and constitute a small percent of the pellet by weight. Nonetheless, the Service is concerned that the coating, although present in small amounts, may in and of itself be toxic and pose a hazard to migratory birds or other wildlife. Therefore, the Service is proposing by this regulation to codify its informal policy on approval of the types of shot coatings with which a waterfowler may hunt and to establish a process for that approval.

Earlier, the Service responded to a request from industry and approved the use of both copper and nickel coatings for steel shot used in waterfowl hunting. This request specified that coating thickness would be, nominally, 2 ten-thousandths of an inch thick (0.0002") and 1 percent or less of the total weight of the shot. These two coatings had been the only ones approved for waterfowling since May, 1986. More recently, the Service received a request to approve zinc as a coating and learned, in the process of acquiring more information, that one ammunition manufacturer was already marketing a zinc coated steel shot and another had been planning to market a zinc coated steel shot for, what was then, an upcoming season (1993-94). Apparently, despite past efforts to publicize the information, there was no recognition of the Service's role in this aspect of nontoxic shot regulation in some quarters and a definite recognition of that role in others. Thus, the Service perceives there is a need to incorporate into this regulation standards which allow only approved coatings on pellets utilized in waterfowl hunting.

In summary, the principal purpose of this action is to promulgate a rulemaking that will update and amend the current nontoxic shot approval procedures to include both candidate

nontoxic shot and nontoxic shot coatings.

NEPA Consideration

Pursuant to the requirements of section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4332(C)), and the Council on Environmental Quality's regulation for implementing NEPA (40 CFR 1500-1508), the Service will comply with NEPA prior to adopting a final rule.

Endangered Species Act Considerations

Section 7 of the Endangered Species Act (ESA), as amended (16 U.S.C. 1531-1543; 87 Stat. 884), provides that, "The Secretary shall review other programs administered by him and utilize such programs in furtherance of the purposes of this Act" (and) shall "insure that any action authorized, funded or carried out * * * is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of (critical) habitat * * *"

Consequently, the Service will initiate Section 7 consultation under the ESA for this proposed rulemaking to amend the nontoxic shot and shot coating approval process. When completed, the results of the Service's consultation under Section 7 of the ESA may be inspected at, and will be available from, the Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, Washington, DC 20240.

Regulatory Flexibility Act, Executive Order 12866, and the Paperwork Reduction Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 et seq.) requires the preparation of flexibility analyses for rules that will have a significant effect on a substantial number of small entities, which includes small businesses, organizations and/or governmental jurisdictions. However, since this is an amendment to existing procedures and is designed to reduce the cost and time that is required to determine the toxicity of a candidate shot, this rule will have no significant effect on small entities. No dislocation or other local effects, with regard to hunters and others, are apt to be evidenced. This rule was not subject to Office of Management and Budget (OMB) review under Executive Order 12866. This rule does not contain any additional information collection efforts requiring approval by the OMB under Public Law 104-13. This rule is being promulgated under existing Office of Management and Budget information

collection requirements clearance number 1018-0067.

Authorship

The primary authors of this proposed rule are Drs. Keith A. Morehouse, U.S. Fish and Wildlife Service, and Barnett Rattner, Patuxent Environmental Science Center, National Biological Service, Laurel, Maryland.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

Accordingly, Part 20, Subchapter B, Chapter I of Title 50 of the Code of Federal Regulations is proposed to be amended as follows:

PART 20—[AMENDED]

1. The authority citation for Part 20 continues to read as follows:

Authority: Migratory Bird Treaty Act (July 3, 1918), as amended (16 U.S.C. 703-711); the Fish and Wildlife Improvement Act of 1978 (November 8, 1978), as amended (16 U.S.C. 712); and the Fish and Wildlife Act of 1956 (August 8, 1956), as amended (16 U.S.C. 742 a-d and e-j).

2. Section 20.134 is amended by revising paragraph (b) as set forth below and removing paragraph (c):

§ 20.134 Nontoxic shot.

* * * * *

(b) Application and review. *Tiered Strategy for Approval of Nontoxic Shot and Anti-corrosion Thin-Coating for Nontoxic Shot.*

(1) All applications for approval under these sections will be submitted with supporting documentation to the Director in accordance with the following procedures, and will include at a minimum the supporting materials and information covered by Tier 1 in the tiered approval system as follows:

(2) *Tier 1.* (i) (A) Applicant provides statements of use, chemical characterization, production variability, volume of use of material requested to be approved and shot sample as listed in paragraphs (b)(2)(i)(A) (1) through (5) of this section. The candidate shot and/or coating may be chemically analyzed by the Service or an independent laboratory and the results will be compared to the applicant's descriptions of shot composition and composition variability. If the application is incomplete or if the composition of the candidate material, upon analysis, varies from that described by the applicant it will be rejected.

(1) Statement of proposed use, i.e., purpose and types.

(2) Description of the chemical composition of the intact material.

(i) Chemical names, Chemical Abstracts Service numbers, and structures.

(ii) Chemical characterization for organics and organometallics for coating and core (e.g., empirical formula, melting point, molecular weight, solubility, specific gravity, partition coefficients, hydrolysis half-life, leaching rate (in water and soil) degradation half-life, vapor pressure, stability and other relevant characteristics).

(iii) Composition and weight of shot material.

(iv) Thickness, quantity (e.g., mg/shot), and chemical composition of coating per shot.

(3) Statement of the expected variability of shot coating or shot during production.

(4) Estimate of yearly volume of coated shot or shot used for hunting migratory birds in the U.S.

(5) 25 pounds of the candidate shot and/or shot with coating, as applicable, in size equivalent to United States standard size No. 4 (0.17 inches in diameter).

(B) Applicant provides information on the toxicological effects of the shot coating and/or shot as follows:

(1) A brief synopsis of the acute and chronic mammalian toxicity data of the shot coating and/or shot material ranking its toxicity (e.g., LD50 < 5 mg/kg = super-toxic, 5–50 mg/kg = extremely toxic, 50–500 mg/kg = very toxic, 500–5,000 mg/kg = moderately toxic, 5,000–15,000 mg/kg = slightly toxic, > 15,000 mg/kg = practically nontoxic).

(2) A summary of known toxicological data of the chemicals comprising the shot and/or shot coating material with respect to birds, particularly waterfowl (include LD50 or LC50 data, and sublethal effects).

(3) A narrative description of the toxic effect of complete erosion and absorption of the shot and/or coating material in a 24-hour period. (Define the nature of toxic effect—e.g., mortality, impaired reproduction, substantial weight loss, disorientation and other relevant associated observations.)

(4) A statement that there is or is not any basis for concern for shot or coated shot material ingestion by fish or mammals. If there is some recognized impact on mammals or fish, the Service may require additional study.

(5) Summarize the toxicity data of the shot and/or shot coating material to aquatic and terrestrial invertebrates, amphibians and reptiles.

(C) Applicant provides information on the environmental fate and transport, if

any, of the shot and/or shot coating material as follows:

(1) A statement that the shot coatings and/or shot is or is not chemically or physically altered upon firing. If so, the statement must describe any alterations.

(2) An estimate of the environmental half-life of the shot and/or shot coating and a description of the chemical form of the breakdown products of the shot coating and/or shot.

(3) Information on the Estimated Environmental Concentration (EEC) assuming 69,000 shot per hectare (Bellrose 1959) for:

(i) A terrestrial ecosystem, assuming complete erosion of material in 5 cm of soil. What would be the EEC and does the EEC exceed existing clean soil standards? (Environmental Protection Agency [EPA] standards for the Use of Disposal of Sewage Sludge; 40 CFR Part 503). What is the estimated EEC and how does that relate to the toxicity threshold for plants, invertebrates, fish and wildlife?

(ii) An aquatic ecosystem, assuming complete erosion of the shot coating and/or shot in 1 cubic foot of water. What is the estimated EEC, and how does it compare to the EPA Water Quality Criteria and toxicity thresholds in plants, invertebrates, fish and wildlife.

(D) Fish and Wildlife Service evaluation of an application.

(1) The Service will conduct a risk assessment using 1 LD50/square foot as the level of concern based on granular pesticides.

(2) In cooperation with the applicant, the Service will conduct a risk assessment using the Quotient Method (Barntouse *et al.* 1982): Risk = EEC/Toxicological Level of Concern Compare EEC in ppm to an effect level (e.g., LD50 in ppm). If $Q < 0.1$ = No Adverse Effects; If $0.1 \leq Q \leq 10.0$ = Possible Adverse Effects; If $Q > 10.0$ = Probable Adverse Effects.

(ii) Upon receipt of the Tier 1 application, the Director will review it to determine if the submission is complete. If complete, the applicant will be notified within 30 days of receipt that a thorough review of the application will commence. A *Notice of Review* will be published in the Federal Register announcing the initiation of review of a Tier 1 application. Review of a Tier 1 application will be concluded within 60 days of the date published in the *Notice of Review*.

(iii) If after review of the Tier 1 test data materials the Service determines that the information does not conclusively establish that the shot and coating material do not impose a significant danger to migratory birds

and other wildlife and their habitats or that significant data are incomplete, the applicant will be advised to proceed with the additional testing described in Tier 2. The public will be informed by a *Notice of Review* that Tier 1 test results are inconclusive and Tier 2 testing has been recommended.

(iv) If review of the Tier 1 test data results in a preliminary determination that the candidate materials do not impose a significant danger to migratory birds and other wildlife and their habitats, the Director will publish in the Federal Register a proposed rule stating the Service's intention to approve this shot and/or coating. The rulemaking will include a description of the chemical composition of the candidate shot and/or coating and a synopsis of findings under the standards required for Tier 1. If, at the end of the comment period, the Service finds no technical or scientific basis upon which to deny approval, the candidate material will be approved by the publication of a final rule in the Federal Register. If as a result of the comment period, the Service determines that the information does not conclusively establish that the shot and/or coating material do not impose a significant danger to migratory birds and other wildlife and their habitats, Tier 2 testing will be recommended and a *Notice of Review* will be published in the Federal Register. If the applicant chooses not to proceed, the determination denying approval will be published in the Federal Register.

(3) *Tier 2*, (i) Upon determination that Tier 1 information is inconclusive, the applicant will be notified by the Director to submit a Tier 2 testing plan for conducting further testing as outlined in paragraphs (b)(3)(ii), (A), (B) and (C) of this section. The Tier 2 testing plan submitted by the applicant will be reviewed by the Director within 30 days of receipt. The Director may decline to approve the plan, or any part of it, if deficient in any manner with regard to timing, format or content. The Director shall apprise the applicant regarding what parts, if any, of the submitted testing procedures need not be conducted and any modifications that must be incorporated into the Tier 2 testing plan. The Director, or authorized representative, may elect to inspect laboratory facilities to be used. If the plan is accepted, Tier 2 testing will then be conducted, analyzed and reported by the applicant to the Director.

(ii) The candidate shot and/or coating will first be run through a standardized test under *in vitro* conditions (see below) that will assess its erosion in an

environment simulating *in vivo* conditions of a waterfowl gizzard, and any release of components into a liquid medium. Erosion characteristics will be compared to those of lead shot and steel shot of comparable size. Following the erosion rate testing, the candidate shot and/or coating will be subjected to a 30-day acute toxicity test and a test to determine its effects on selected fish and invertebrates.

(A) Conduct a standardized *in vitro* test to determine erosion rate of the candidate shot and/or coating using the general guidelines as follows:

Standardized Test for Erosion Rate.

(Ref.: Kimball, W.H., and Z.A. Munir. 1971. The corrosion of lead shot in a simulated waterfowl gizzard. J. Wildl. Manage. 35(2):360-365.)

(1) *Typical Test Materials.*

Atomic absorption spectrophotometer.
Drilled aluminum block to support test tubes.
Thermostatically controlled stirring hot plate.
Small teflon-coated magnets.
Hydrochloric acid (pH 2.0) and pepsin.
Capped test tubes.
Lead, steel and candidate shot (if appropriate).

(2) *Typical Test Procedures.*

Hydrochloric acid and pepsin are added to each capped test tube at a volume and concentration that will erode a single #4 lead shot at a rate of 5 mg/day. Three test tubes, each containing either lead shot, steel shot or candidate shot and/or coating, are placed in the aluminum block on the stirring hot plate. A teflon coated magnet is added to each test tube and the hot plate is set at 42 degrees centigrade and 500 revolutions per minute. Erosion of shot and/or coating will be determined on a daily basis for 14 consecutive days by weighing the shot and analyzing the digestion solution with an atomic absorption spectrophotometer. The 14-day procedure will be replicated five times.

(3) *Typical Test Analyses.* Erosion rates of the three types of shot will be compared by appropriate analysis of variance and regression procedures. The statistical analysis will determine whether the rate of erosion of the candidate shot and/or coating is significantly greater or less than that of lead and steel. This determination is important to any subsequent toxicity testing.

(ii) *Acute Toxicity Test—Tier 2 (Short-term, 30-day acute toxicity test using a commercially available duck food.)* Over a 30-day period, conduct a short-term acute toxicity test that complies with the general guidelines described as follows:

(1) *Typical Test Materials.*

48 male and 48 female hand-reared mallards approximately 6 to 8 months old.

Mallards must have plumage and body conformation that resemble wild mallards. 96 outdoor pens equipped with food containers and water. Laboratory equipped to perform fluoroscopy, required blood and tissue assays. Commercial duck food. Lead, steel and candidate shot.

(2) *Typical Test Procedures.* Mallards will be housed individually in pens and given *ad libitum* access to food and water. After 3 weeks, they will be randomly assigned to 6 groups (8 males and 8 females/group), dosed with 8 pellets of No. 4 lead, steel, or the candidate shot and/or coatings. Birds will be fluoroscoped 1 week after dosage to check for shot retention. Birds will be observed daily for signs of intoxication and mortality over a 30-day period. Body weight will be determined at the time of dosing, and at day 15 and 30 of the test. On days 15 and 30 blood will be collected by venipuncture for determination of hematocrit, hemoglobin concentration and other specified blood chemistries. All survivors will be sacrificed on day 30. The liver and other appropriate organs will be removed from the sacrificed birds and from other birds dying prior to sacrifice on day 30 for histopathological analysis. The organs will be analyzed for lead and compounds contained in the candidate shot and/or shot coatings. All birds will be necropsied to determine any pathological conditions.

(3) *Typical Test Analyses.* Mortality among the specified groups will be analyzed with appropriate chi-square statistical procedures. Physiological data and tissue contaminant data will be analyzed by analysis of variance or other appropriate statistical procedures to include the factors of shot type and sex. Comparison between sacrificed birds and birds dying before sacrifice will be made whenever sample sizes are adequate for meaningful comparison. Procedures should be in compliance with the Good Laboratory Practices Standards (40 CFR Part 160). The applicant will ensure that copies of all the raw data and statistical analyses accompany the laboratory reports and final comprehensive report of this test when they are sent to the Director.

(C) *Daphnid and Fish Early-Life Toxicity Tests.* Determine the toxicity of the shot or shot coating (whole shot and eroded coating) to selected fish and invertebrates subject to the environmental effects test regulations developed under the authority of the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*), as follows:

(1) The first test, the *Daphnid Acute Toxicity Test* (40 CFR Section

797.1300), is a guideline for use in developing data on the acute toxicity of chemical substances. This guideline prescribes an acute toxicity test in which daphnids are exposed to a chemical in a static and flow-through system with the resulting data used by the agencies to assess the hazard that the chemical may present to an aquatic environment.

(2) The second test is the *Daphnid Chronic Toxicity Test* (40 CFR Section 797.1330) and is used to develop data on the chronic toxicity of chemical substances in which daphnia are exposed to a chemical in a renewal or flow-through system. The data from this test are again used to assess the hazard that chemical may present to an aquatic environment.

(3) A third test, *Fish Early Life Stage Toxicity Test* (40 CFR Section 797.1600), is required and is a test to assess the adverse effects of chemical substances to fish in the early stages of their growth and development. Data from this test are also used to determine the hazard a chemical may present to an aquatic environment.

(iii) After the Tier 2 testing is concluded, the applicant will report the results to the Director. Submitted materials will include test results (data analysis reports, lab data) and a written final report. If after review of the Tier 2 test data the Service determines that the information does not conclusively establish that the shot and/or coating material do not impose a significant danger to migratory birds and other wildlife and their habitats or that significant data are missing and/or incomplete, the applicant will be advised to proceed with the additional testing described in Tier 3. The public will be informed by a *Notice of Review* that Tier 2 test results are inconclusive and Tier 3 testing has been recommended.

(iv) If review of the Tier 2 test data results in a preliminary determination that the candidate shot and/or coating materials do not impose a significant danger to migratory birds and other wildlife and their habitats, the Director will publish in the Federal Register a proposed rule stating the Service's intention to approve this shot and/or coating. The rulemaking will include a description of chemical composition of the candidate shot and/or coating and a synopsis of findings under the standards required at Tier 2. If at the end of the comment period, the Service finds no technical or scientific basis upon which to deny approval, the candidate shot and/or coating material will be

approved by publication of a final rule in the Federal Register. If, as a result of the comment period, the Service determines that the information does not conclusively establish that the shot and coating material do not impose a significant damage to migratory birds and other wildlife habitats, Tier 3 testing will be recommended and a *Notice of Review* will be published in the Federal Register. If the applicant chooses not to proceed, the determination denying approval will be published in the Federal Register denying approval of the candidate shot.

(4) *Tier 3.*

(i) Upon determination that the Tier 2 information is inconclusive, the applicant will be notified by the Director to submit a Tier 3 testing plan for conducting further testing as outlined in paragraphs (b)(4)(i) (A) and (B) of this section. The Tier 3 testing plan submitted by the applicant will be reviewed by the Director within 30 days of receipt. The Director may decline to approve the plan, or any part of it, if deficient in any manner with regard to timing, format or content. The Director shall apprise the applicant regarding what parts, if any, of the submitted testing procedure need not be conducted and any modifications that may be necessary to incorporate into the Tier 3 plan. The Director, or authorized representative, may elect to inspect laboratory facilities to be used. If the plan is accepted, Tier 3 testing will then be conducted, analyzed and reported by the applicant to the Director.

(A) *Chronic Toxicity Test—Tier 3 (Long-term, 8–9 week toxicity test under depressed temperature conditions using a nutritionally-deficient diet.)* Conduct a chronic exposure test under adverse conditions that complies with the general guidelines described as follows:

(1) *Typical Test Materials.*

36 male and 36 female hand-reared mallards approximately 6 to 8 months old. The mallards must have plumage and body conformation that resembles wild mallards. 72 elevated outdoor pens equipped with food containers and waterers.

Laboratory equipped to perform fluoroscopy, required blood and tissue assays, and necropsies.

Whole kernel corn.

Lead, steel, and candidate shot with or without coating, or coating, as applicable.

(2) *Typical Test Procedures.* (i) This test will be conducted at a location where the mean monthly low temperature during December through March is between 20 and 40 degrees Fahrenheit (–6.6 and 4.4 degrees centigrade, respectively). Mallards will be individually assigned to elevated outdoor pens during the first week of

December and acclimated to an *ad libitum* diet of whole kernel corn for 2 weeks. Birds will be randomly assigned to 5 groups (lead group of 4 males and 4 females, 4 other groups of 8 males and 8 females/group). The lead group will be dosed with 1 size No. 4 pellet of lead. One group (8 males and 8 females) will be dosed with 8 size No. 4 pellets of steel and the 3 other groups (8 males and 8 females/group) will be dosed with 1, 4 and 8 size No. 4 pellets of candidate shot and/or coating, respectively.

(ii) Birds will be weighed and fluoroscoped weekly. All recovered shot will be weighed to measure erosion. Blood parameters given in the 30-day acute toxicity test will again be determined in this procedure. Body weight and blood parameter measurements will be made on samples drawn at 24 hours after dosage and at the end of days 30 and 60. At the end of 60 days, all survivors will be sacrificed. The liver and other appropriate organs will be removed from the sacrificed birds and birds dying prior to sacrifice on day 60 for histopathological analysis. The organs will be analyzed for lead and other metals contained in the steel and candidate shot and/or coating. All birds dying prior to sacrifice will be necropsied to determine pathological conditions associated with death.

(3) *Typical Test Analyses.* Mortality among the specified groups will be analyzed with appropriate chi-square statistical procedures. Any effects on the previously mentioned physiological parameters caused by the candidate shot and/or coating must be significantly less than those caused by lead shot and must not be significantly greater than those caused by steel shot. Physiological data and tissue contaminant data will be analyzed by analysis of variance or appropriate statistical procedures to include the factors of shot type, dose and sex. Comparisons between sacrificed birds and birds dying before sacrifice will be made whenever sample sizes are adequate for a meaningful comparison. Procedures should be in compliance with the Good Laboratory Practices Standards (40 CFR Part 160). The applicant will ensure that copies of all the raw data and statistical analyses accompany the lab analyses and final comprehensive reports of this test when they are sent to the Director.

(B) *Chronic Dosage Study—Tier 3 (Moderately long-term study that includes reproductive assessment.)* Conduct chronic exposure reproduction trial with the general guidelines described as follows:

(1) *Typical Test Materials.*

60 male and 60 female hand-reared first year mallards. These mallards must have plumage and body conformation that resemble wild mallards.

Pens suitable for quarantine and acclimation and for reasonably holding 5–10 ducks each.

60 elevated, pens equipped with feeders, waterers and nest boxes.

Laboratory equipped to perform fluoroscopy and required blood assays.

Corn and commercial duck breeder mash. Steel and candidate shot and/or coating, as applicable.

(2) *Typical Test Procedures.* (i)

Mallards will be randomly assigned to 2 groups (30 males and 30 females/group) in December and held in same-sex groups until mid-January (dates apply to outdoor test facility only and will reflect where in the U.S. tests are conducted). After a 3-week acclimation period, birds will be provided an *ad libitum* diet of corn for 60 days and are then paired (one pair/pen) and switched to commercial mash. Dosing of the 2 groups with 8 pellets of No. 4 steel (group 1) and candidate shot and/or coating (group 2) will occur after the acclimation period (day 0) and redosed after 30, 60, and 90 days.

(ii) Birds will be fluoroscoped 1 week after dosage to check shot retention. Males and females will be weighed the day of initial dosing (day 0), at each subsequent dosing, and at death. Blood parameters identified in the 30–Day Acute Toxicity Test will again be measured in this test using samples drawn at time of weighing. The date of first egg will be noted as will the mean number of days per egg laid. Laying will be concluded after 21 normal, uncracked eggs are laid or after 150 days, at which time the adults will be sacrificed. The liver and other appropriate organs will be removed from the sacrificed birds and from other birds dying prior to sacrifice for histopathological analysis. The organs and the 11th egg will be analyzed for compounds contained in the candidate shot or shot coatings. All birds will be necropsied to determine any pathological conditions. Nests will be checked daily to collect eggs. Any eggs laid before pairing will be discarded. Eggs will be artificially incubated and the percent shell-less, percent eggs cracked, percent fertility (as determined by candling), and percent hatch of fertile eggs will be calculated for each female. Ducklings will be provided with starter mash after hatching. All ducklings will be sacrificed when reaching 14 days of age. Survival to day 14 and weight of the ducklings at hatching and sacrifice will be measured. Blood parameters identified in the 30–Day Acute Toxicity Test will be

measured using samples drawn when sacrificed.

(3) *Typical Test Analyses.*

Any mortality, reproductive inhibition or effects on the previously mentioned physiological parameters by the candidate shot and/or coating must not be significantly greater than those caused by steel shot. Percentage data will be subjected to an arcsine, square root transformation prior to statistical analyses. Physiological and reproductive data will be analyzed by one-tailed *t*-tests ($\alpha=0.05$), or other appropriate statistical procedures. Procedures should be in compliance with the Good Laboratory Practice Standards (40 CFR Part 160). The applicant will ensure that copies of all raw data and statistical analyses accompany the lab analyses and comprehensive reports of this test when they are sent to the Director.

(ii) After the Tier 3 testing is concluded, the applicant will report the results to the Director. Submitted materials will include test results (data analysis reports, lab data) and a written final report. If after review of the Tier 3 test data (to be completed 60 days after receipt of material) the Service determines that the information does not conclusively establish that the shot and/or coating material do not impose a significant danger to migratory birds and other wildlife and their habitats, or that significant data are incomplete, the applicant will be given the option of repeating the tests in Tier 3 that were deemed inconclusive. If the applicant chooses not to repeat the tests, approval of the candidate shot and/or coating will be denied. The public will be informed by a *Notice of Review* that Tier 3 test results are inconclusive and of the applicant's decision not to repeat Tier 3 testing. The publication will state that approval of candidate shot and/or coating is denied.

(iii) If review of either the initial or repeated Tier 3 test data results in a preliminary determination that the candidate materials do not impose a significant danger to migratory birds and other wildlife and their habitats, the Director will publish in the Federal Register a proposed rule stating the Service's intention to approve this shot and/or coating. The rulemaking will include a description of chemical composition of the candidate shot and/or coating and a synopsis of findings under the standards required by Tier 3. If at the end of the comment period, the Service finds no technical or scientific basis upon which to deny approval, the candidate shot and/or coating material will be approved by publication of a final rule in the Federal Register. If, as

a result of the comment period the Service determines that the information does not conclusively establish that the shot and/or coating material do not impose a significant danger to migratory birds and other wildlife and their habitats, the applicant will be given an opportunity to answer the concerns expressed by the comments with additional testing. The decision to conduct additional testing will be published as a *Notice of Review*. If the applicant chooses not to proceed, the final determination denying approval will be published in the Federal Register.

(iv)(A) The Tier 2 toxicity tests involving invertebrates and early-life stage vertebrates are intended to assess potential impacts on waterfowl habitat. The three toxicity tests with waterfowl described in Tiers 2 and 3 represent an evaluation of the three major categories of toxic effects: short-term periodic exposure; chronic exposure under adverse environmental conditions; and chronic exposure impact on reproduction. In the appropriate situations, the test animals will be exposed to the candidate material: both acutely and chronically; both stressed and non-stressed by diet and temperature; and with comparisons made to lead and steel shot regarding mortality and sublethal effects. The inclusion of lead shot and steel shot control groups in the waterfowl feeding studies is considered necessary for dealing with the experimental variability associated with tests being performed by different laboratories under a variety of conditions beyond control of the experimental protocol. Toxicity tests described in this rule are designed for testing the effects of metal or metalloid shot. The details of the experimental procedures can be modified, if necessary, to address the specific composition and erosion characteristics of the candidate shot. If the candidate shot is not metal or metalloid, other testing procedures will have to be developed and approved to evaluate the effects of the components of the candidate shot and/or coating materials.

(B) Statistical analyses will be performed on all data from each test. For the purpose of this section (20.134) the terms *significant* and *significantly* refer to a ($P \leq 0.05$) finding of significance.

Dated: October 25, 1995.
George T. Frampton, Jr.,
Assistant Secretary for Fish and Wildlife and Parks.
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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 646

[I.D. 011696E]

Snapper-Grouper Fishery of the South Atlantic; Public Scoping Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Public scoping meetings.

SUMMARY: The South Atlantic Fishery Management Council (Council) is holding two public scoping meetings to solicit comments on the sale of fish (all species) caught under the recreational bag limits established by the Council's fishery management plans (FMPs) and on the issue of recreational catch and the commercial bycatch of wreckfish under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic (Snapper-Grouper FMP).

DATES: The public scoping meetings are scheduled to begin at 6:30 p.m. on Monday, February 12, 1996, in St. Augustine, FL, and will end when all business is completed.

ADDRESSES: The public scoping meetings will be held in conjunction with the South Atlantic Fishery Management Council public meetings to be held February 12-14, 1996, at the Ponce de Leon, 4000 US Highway 1 North, St. Augustine, FL 32095; telephone: (800) 228-2821.

Requests for copies of public scoping documents should be sent to the Council at the following address: South Atlantic Fishery Management Council, One Southpark Circle, Suite 306, Charleston, SC 29407-4699.

FOR FURTHER INFORMATION CONTACT: Robert K. Mahood, Council Executive Director; telephone: (803) 571-4366; fax: (803) 769-4520.

SUPPLEMENTARY INFORMATION: At the first scoping meeting, comments will be solicited on the sale of fish caught under the recreational bag limits for all species as established by the Council's FMPs. The Council has considered this issue on numerous occasions over the past several years, and both commercial and recreational fishermen have expressed concern about this matter. Currently, all of the Council's FMPs allow for the sale of fish taken in a legal bag limit. The issue regarding the sale of fish caught under bag limits involves several considerations, including: (1) The definitions of recreational and