DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

RIN 1018–AB80

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

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The purpose of this action is to revise the current nontoxic shot approval procedures by establishing a tiered approval process. Shot or shot coating approval is considered at each tier. An environmentally benign shot or a minor modification of previously approved shot may receive nontoxic approval after the first tier contingent on existence of appropriate toxicological data and an ecological risk assessment. If not, further testing would be required.

DATES: This final rule takes effect December 31, 1997.

ADDRESSES: Director (FWS/MBMO), U.S. Fish and Wildlife Service, 634 ARLSQ, 1849 C ST., NW, Washington, D.C. 20240.

FOR FURTHER INFORMATION CONTACT: Paul Schmidt, Chief, or Carol Anderson, Wildlife Biologist, Office of Migratory Bird Management, 703/358–1714.

SUPPLEMENTARY INFORMATION: The U.S. Fish and Wildlife Service (Service) is revising the existing nontoxic shot and shot coating approval procedures (50 CFR 20.134) by establishing a three-tier approval process. Shot or shot coating approval is considered at each tier. An environmentally benign shot or a minor modification of previously approved shot may receive nontoxic approval after the first tier contingent upon the existence of appropriate toxicological data and an ecological risk assessment. The Service has modified the existing regulation because:

1. From an ecosystem management perspective, in addition to waterfowl, we need to evaluate species such as invertebrates and fish as these provide a food base for many waterfowl species;

2. Since the original regulations were in effect, advancements in the field of ecological risk assessment can be applied to this process;

3. Reduction of time, expense and burden on the Federal Government and applicants can occur without risk to wildlife; and

4. From an animal welfare standpoint, reduction in numbers of test animals used can occur without risk to wildlife.

The original procedures were put in place in 1986 and the first submission requesting approval of nontoxic shot came in October of 1993. Our experience with this shot approval process has shown that the procedures need modification to accommodate situations where existing information can minimize the need for full testing. Thus, the Service and the U.S. Geological Survey—Biological Resources Division cooperatively have developed an alternative set of procedures for evaluating nontoxic shot and shot coatings to replace the testing requirements presently in effect. As with the current procedures, the new set of approval procedures carry the requirement that the applicant carry the burden of providing that the candidate shot or shot coating is nontoxic.

The system has three tiers, with each tier enhancing the information base on the candidate material. Those candidate materials where appropriate background information, toxicological data, ecological risk assessment, and reproductive effects information are available demonstrating the candidate material to be benign may receive nontoxic approval. Those candidate materials not approved as a result of subjecting them to the standards set at Tier 1 will be subject to the standards of Tier 2, Tier 3, or both.

Tier 1 sets out comprehensive and detailed requirements that must be provided to the Service in order to consider approval. After evaluation of Tier 1 information, the Service will determine to grant or deny approval, or require testing of Tier 2, Tier 3, or both.

The scope of Tier 1 includes: (1) Physical and chemical characterization of candidate shot or shot coating; (2) information on the toxicity of the candidate material; (3) an ecological risk assessment; and (4) effects on reproduction in water birds of the candidate material.

The scope of Tier 2 includes *in vitro* erosion rate testing, short-term (30-day) acute toxicity testing on mallards, and toxicity tests with invertebrates and early-life stage vertebrates to assess potential impacts on waterfowl habitat. The inclusion of lead shot (positive) and steel shot (negative) control groups in the waterfowl feeding studies is necessary to account for the experimental variability associated with: (1) Tests performed by different laboratories; (2) a series of tests performed within a given laboratory; and/or (3) an individual test, given changing conditions which are beyond control of the experimental protocol. Further, although the positive control group is essential to every shot ingestion study series, the Service has considered the documented history of the results of lead shot ingestion by waterfowl and reduced the numbers of birds required for that aspect of the protocol.

The scope of Tier 3 includes chronic exposure under adverse environmental conditions and effects on reproduction in mallards.

Modification of the experimental procedures to address the specific composition and erosion characteristics of the candidate shot or shot coating may be made by the Service, if necessary. If the candidate shot or shot coating is not metal or metalloid, the Service, with the applicant, may develop other equivalent testing procedures to evaluate the effects of the components of the candidate shot and/or shot coating.

Statistical analyses are to 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.

Other conditions of final approval include residual lead levels and noninvasive field testing devices. The Service has established a maximum environmentally acceptable level of lead in shot as trace amounts of <1 percent (August 15, 1995, 61 FR 42492). Any shot manufactured with lead levels equal to or exceeding 1 percent are toxic and therefore, illegal. Further, the Service has established approval contingent upon the availability of a noninvasive field testing device (August 15, 1996, 61 FR 42492) to determine shot material in the shell in the field.

A schematic representation of the approval process follows:

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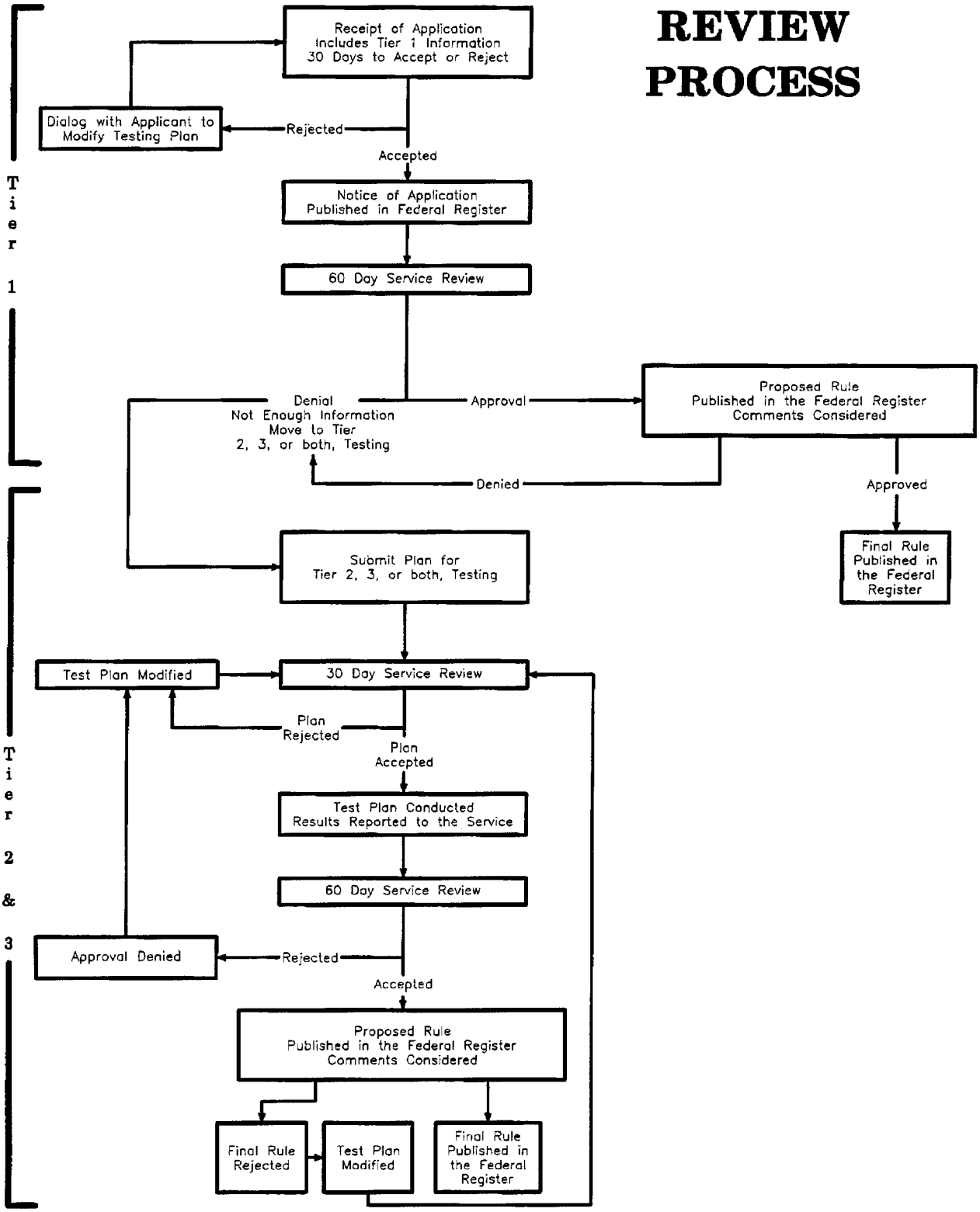

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The intent of the shot and shot coating approval procedure is to ensure that, in addition to waterfowl, other natural resources will be protected. Furthermore, materials that toxicologically are innocuous will complete the procedures at lower cost and with less paperwork for both the Service and the applicant.

In summary, the purpose of this rule is to revise the current shot approval procedures and to include shot coatings.

Public Comment and Responses

The January 26, 1996, proposed rule published in the **Federal Register** (61 FR 2470) invited comments from interested parties. The closing date for receipt of all comments was May 10, 1996. During this 115-day comment period, the Service received five comment letters. A brief summary of those comments and the Service's response follows:

The National Institute of Environmental Health Sciences limited their comments to the toxicity testing (clinical observation, tissue analysis, and histopathology) of bismuth only, and as such, are not incorporated into the overall testing protocol.

The Missouri Department of Conservation asked if coatings of copper, nickel, and zinc on steel shot, which already are approved, will have ''grandfathered'' approval. Yes, they will. In December of 1986, based on a review and evaluation of information in an environmental assessment, the Director issued a Finding Of No Significant Impact and chose to approve the use of copper or nickel coating on steel shot. In May of 1993, based on information from the National Biological Survey (now the Biological Resources Division of the U.S.G.S.), the Service, and manufacturers, the Service issued an approval for zinc chloride and/or zinc chromed coating. These coatings will retain the Service's approval. However, the Service may reconsider both approvals at some future date if it is determined that the coatings may be creating toxicological problems for migratory birds.

The Wisconsin Department of Natural Resources requested deletion of ''the requirement for assessing toxicity after complete absorption [because] we suspect that most substances that would pass all of the other tests would fail this test.'' This is a worst-case scenario assumed in the risk assessment, and not an actual toxicity test that the applicant must complete. To ensure that waterfowl will be protected, this analysis must be completed.

The National Wildlife Federation expressed concern that the Service's proposal to ''scale back the testing procedures'' will increase the potential for environmental harm. The Service's decision to revise the present testing protocol is based on scientific advancements in risk assessment, toxicity testing, and modeling. In actuality, the new test protocol is far more demanding and scientifically rigorous than the current three phase nontoxic shot approval process because it approaches the issue from an ecosystem management perspective incorporating recent advancements in science. The new test protocol will increase protection of the environment by incorporating an ecosystem approach and multi-species testing rather than just a single species test with mallards. The NWF also commented that ''the USFWS argues that from an animal welfare standpoint, the numbers of test animals used can be reduced. In fact, it can be said that granting approval for a shot compound which has not been throughly tested makes the whole of the wild waterfowl population test animals.'' Under the current testing procedures, the entire ecosystem is the test subject because it ignores every environmental and biological component other than waterfowl. The Service is striving for a balanced ecosystem approach to testing without being overly burdensome. Instead of using large numbers of one species, the Service is incorporating the test with several different species. The NWF also stated that, ''there are numerous cases (e.g., the pesticide DDT) in which the harmful effects of a product became apparent only after loss of reproductive viability of wildlife became chronic, by which time the environmentally harmful substance was widely dispersed throughout the ecosystem.'' Reproductive test data is an integral part of the new test protocol. We recognize the importance of reproductive testing, and its importance in determining the safety of a product. A reproductive assessment with no adverse or inconclusive results is required for final approval of a candidate material as nontoxic. ''We [NWF] remain firmly opposed to granting full or final approval without completion of all three phases of testing. At a minimum, conditional approval should be granted only after the currently mandated phase one testing is complete.'' Granting of final approval will occur only when an applicant sufficiently has satisfied Tier 1 and shown the candidate material to be nontoxic. If Tier 1 testing results are inconclusive, completion of Tier 2, Tier 3, or both will be required showing the candidate material to be nontoxic. This does not mean that completion of each tier by each applicant is always necessary. For example, if toxicity or reproductive data on the candidate material and mallards already exists, it may be incorporated into the Tier 1 package and may be sufficient to determine that the shot and/or shot coating should be approved.

Safety Shot General Partner, Inc. reiterates their original concerns from their August 27, 1991, letter on the proposed protocol. Safety Shot states that ''the proposed rule appears to address our concerns about timing issues and unreasonable testing.''

NEPA Consideration

In compliance with 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 prepared an Environmental Assessment (EA) in November, 1996. This EA is available to the public at the Office of Migratory Bird Management, U.S. Fish and Wildlife Service, ms 634-ARLSQ, 1849 C Street NW., Washington D.C. 20240. Based on review and evaluation of the information in the EA, the Service determined the action to amend 50 CFR 20.134 would not be a major Federal action that significantly would affect the quality of the human environment.

Endangered Species Act Considerations

Section 7 of the Endangered Species Act (ESA) of 1972, as amended (16 U.S.C. 1531 *et seq.*), 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 * * *'' The Service completed a Section 7 consultation under the ESA for this rule. The conclusion of that consultation is that the long-term effect of the rule would be beneficial, and that the rule itself is not likely to adversely affect listed species. However, as the nature of substances to be reviewed is not known at this time, each application will be reviewed for potential effects to listed species. The result of the Service's consultation under Section 7 of the ESA is available to the public through the Office of Migratory Bird Management, U.S. Fish and Wildlife Service, ms 634 ARLSQ, 1849 C Street NW., Washington D.C. 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 or governmental jurisdictions. Since this is a revision to existing procedures designed to reduce cost and time requirements in determining the toxicity of a candidate material, 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. The information collection requirements contained within this part have been approved by the Office of Management and Budget (OMB) under 44 U.S.C. 3507 and assigned Clearance Number 1018–0067 which expires on 06/30/2000. The information must be provided in order to obtain the benefit of being approved as nontoxic shot. This information is being collected to evaluate an applicant's candidate material.

The likely respondents to this collection of information will be companies producing and/or marketing shot and/or shot coatings who wish to obtain approval of the candidate shot as nontoxic for use in hunting waterfowl and coots. In order to make this decision, the Service requires that applicants submit information collected about the toxicity of their candidate material to migratory birds and the environment. This data provides the bulk of the application. The information from scientific literature, risk assessment analysis, and toxicity studies, will be gathered and packaged by the applicant. The Service expects to receive one request each year. The annual burden of reporting and record keeping is estimated to be about 3,200 hours.

The principal economic effect of this rule will be to allow sport hunting retailers sales of more nontoxic shot types. This will provide some additional sales, however these sales are within a niche market and not likely to dislocate any other products. It is thought that these sales may slightly reduce some of the lead shot sales. The overall effect to hunting expenditures in general will be minor. This rule will accommodate situations where existing information can minimize the need for full testing thereby reducing the time, expense, and burden on the Federal Government and applicant without risk to wildlife. Therefore, this rulemaking was not subject to review by the Office of Management and Budget under Executive Order 12866.

The potential applicants are likely to be small entities, therefore, the economic effects as described in Executive Order 12866 are the same or similar to the economic impacts of annual hunting on small business entities. The economic impacts of annual hunting on small business entities were analyzed in detail and a Small Entity Flexibility Analysis (Analysis), under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), was issued by the Service in 1995 (copies available upon request from Office of Migratory Bird Management). The Analysis documented the significant beneficial economic effect on a substantial number of small entities. The primary source of information about hunter expenditures for migratory game bird hunting is the National Hunting and Fishing Survey, which is conducted at 5-year intervals. The Analysis utilized the 1991 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns from which it was estimated that migratory bird hunters would spend between $10 and $59 million at small businesses in 1995. The approval of other nontoxic alternative shot to steel will have a minor positive impact on small businesses by allowing them to sell an additional nontoxic shot to the hunting public. However, the overall effect to hunting expenditures in general would be minor.

Unfunded Mandates Reform

The Service has determined and certifies pursuant to the Unfunded Mandates Act, 2 U.S.C. 1502 *et seq.*, that this rulemaking will not impose a cost of $100 million or more in any given year on local or State government or private entities.

Civil Justice Reform—Executive Order 12988

The Service, in promulgating this rule, has determined that these regulations meet the applicable standards provided in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Authorship

The primary authors of this rule are Cynthia M. Perry and Keith A. Morehouse, U.S. Fish and Wildlife Service, and Barnett Rattner, Biological Research Division of the U.S. Geological Survey.

List of Subjects in 50 CFR Part 20

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

Accordingly, the Service amends part 20, Subchapter B, Chapter I of Title 50 of the Code of Federal Regulations as follows:

PART 20—[AMENDED]

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

Authority: 16 U.S.C. 703–712; and 16 U.S.C. 742 a–j.

2. Amend § 20.134 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 Shot Coating. (1) All applications for approval under this section must be submitted with supporting documentation to the Director in accordance with the following procedures and must 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 candidate material and shot sample as listed in paragraphs (b)(2)(i)(A)(*1*) through (*5*), (b)(2)(i)(B)(*1*) through (*5*), and (b)(2)(i)(C)(*1*) through (*3*) of this section. The candidate shot or shot coating may be chemically analyzed by the Service or an independent laboratory to compare the results with the applicant's descriptions of shot composition and composition variability. Rejection of the application will occur if it is incomplete or if the composition of the candidate material, upon analysis, varies significantly from that described by the applicant.

(*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 (if available), 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 shot coating.

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

(*4*) Estimate of yearly volume of candidate shot and/or coated shot expected for use in hunting migratory birds in the U.S.

(*5*) Five pounds of the candidate shot and/or coated shot, as applicable, in size equivalent to United States standard size No. 4 (0.13 inches in diameter).

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

(*1*) A summary of the acute and chronic mammalian toxicity data of the shot or shot coating 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 = slightly toxic, >15,000 mg/kg = practically nontoxic) with citations.

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

(*3*) A narrative description, with citations to relevant data, predicting the toxic effect in waterfowl of complete erosion and absorption of one shot or coated shot in a 24-hour period. Define the nature of toxic effect (e.g., mortality, impaired reproduction, substantial weight loss, disorientation and other relevant associated clinical observations).

(*4*) A statement, with supporting rationale and citations to relevant data, that there is or is not any reasonable basis for concern for shot or coated shot ingestion by fish, amphibians, reptiles or mammals. If there is some recognized impact on fish, amphibians, reptiles, or mammals, the Service may require additional study.

(*5*) Summarize the toxicity data of chemicals comprising the shot or shot coating to aquatic and terrestrial invertebrates, fish, amphibians, reptiles, and mammals.

(C) Applicant provides information on the environmental fate and transport, if any, of the shot or shot coating as follows:

(*1*) A statement of the alteration of the shot or shot coating, chemically or physically, upon firing. The statement must describe any alterations.

(*2*) An estimate of the environmental half-life of the organic or organometallic component of the shot or shot coating, and a description of the chemical form of the breakdown products.

(*3*) Information on the Estimated Environmental Concentration (EEC) assuming 69,000 shot per hectare (Bellrose 1959; Pain 1990) for:

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

(*ii*) An aquatic ecosystem, assuming complete dissolution of the shot or shot coating 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) Service evaluation of an application.

(*1*) In reviewing the submission, the Service will use an exceedence of 1 LD50/square foot as the level of concern (U.S.E.P.A. 1992) as a criteria in the risk assessment.

(*2*) In cooperation with the applicant, the Service will conduct a risk assessment using the Quotient Method (Environmental Protection Agency 1986): 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.

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

(E) If, after review of the Tier 1 data, the Service does not conclude that the shot or shot coating does not impose a significant danger to migratory birds, other wildlife, and their habitats, the applicant is advised to proceed with the additional testing described for Tier 2, Tier 3, or both. A *Notice of Review* will inform the public that Tier 1 test results are inconclusive, and Tier 2, Tier 3, or both testing are required before further consideration.

(F) If review of the Tier 1 data results in a preliminary determination that the candidate material does not impose a significant danger to migratory birds, 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 or shot coating based on the toxicological report and toxicity studies. The rulemaking will include a description of the chemical composition of the candidate shot or shot 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 alter its conclusion, the candidate material will be approved by the publication of a final rule in the **Federal Register**. If, after receiving public comment, the Service determines that all available information does not establish that the shot and/or shot coating does not impose a significant danger to migratory birds, other wildlife, and their habitats, Tier 2, Tier 3, or both testing will be required and a *Notice of Review* will appear in the **Federal Register**. If only one of these two Tier tests are required, the Service will explain in the notice why the other is not required. If the applicant chooses not to proceed, the determination denying approval will appear in the **Federal Register**.

(ii) *Reserved*.

(3) *Tier 2*.

(i) If Tier 2 testing is required, the applicant must submit a plan that addresses paragraph (b)(3)(ii) requirements. The Director will review the Tier 2 testing plan submitted by the applicant 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 to disregard and any modifications to incorporate into the Tier 2 testing plan in order to gain plan approval. All testing procedures will be in compliance with the Good Laboratory Practices Standards (40 CFR part 160) except where they conflict with the regulations in this section or with a provision of an approved plan. The Director, or authorized representative, may elect to inspect the applicant's laboratory facilities and may decline to approve the plan and further consideration of the candidate shot if the facility does not meet the Good Laboratory Practices Standards. After the plan is accepted, Tier 2 testing will commence. Required analyses and reports, in accordance with the regulations in this section, must be sent to the Director. 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.

(ii) Evaluation of the candidate shot or shot coating will first be in a standardized test under *in vitro* conditions (see paragraph (b)(3)(ii)(A)) that will assess its erosion and any release of components into a liquid medium in an environment simulating *in vivo* conditions of a waterfowl gizzard. Erosion characteristics are to be compared with those of lead shot and steel shot of comparable size. Following the erosion rate testing, the applicant must conduct a 30-day acute toxicity test in mallards, and a test to determine the candidate shot and/or shot coating effects on selected invertebrates and fish and include the results in the report for the Director.

(A) *In Vitro* Erosion Rate Test. Conduct a standardized *in vitro* test to determine erosion rate of the candidate shot or shot coating using the guidelines in Kimball and Munir (1971), unless otherwise provided by the Service.

(*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; and Lead, steel and candidate shot/coated shot.

(*2*) Typical test procedures. Add hydrochloric acid and pepsin to each capped test tube at a volume and concentration that will erode a single ı4 lead shot at a rate of 5 mg/day. Place three test tubes, each containing either lead shot, steel shot or candidate shot and/or coated shot, in an aluminum block on the stirring hot plate. Add a Teflon® coated magnet to each test tube and set the hot plate at 42 degrees centigrade and 500 revolutions per minute. Determine the erosion of shot or coated shot daily for 14 consecutive days by weighing the shot and analyzing the digestion solution with an atomic absorption spectrophotometer. Replicate the 14-day procedure five times.

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

(B) 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 guidelines described as follows or as otherwise provided by the Service:

(*1*) Typical test materials: 30 male and 30 female hand-reared mallards approximately 6 to 8 months old (mallards must have plumage and body conformation that resemble wild mallards); 60 elevated outdoor pens equipped with feeders and waterers; Laboratory equipped to perform fluoroscopy, required blood and tissue assays, and necropsies; Commercial duck maintenance mash; and Lead, steel and candidate shot.

(*2*) Typical test procedures. House mallards individually in pens and give *ad libitum* access to food and water. After 3 weeks, randomly assign to 3 groups (10 males and 10 females/group), dose with eight pellets of either No. 4 lead shot (positive control), steel shot (negative control), or the candidate shot or coated shot. Fluoroscope birds at 1 week after dosage to check for shot retention. Observe birds daily for signs of intoxication and mortality over a 30-day period. Determine body weight at the time of dosing, and at days 15 and 30 of the test. On days 15 and 30, collect blood by venipuncture, determine hematocrit, hemoglobin concentration and other specified blood chemistries. Sacrifice all survivors on day 30. Remove the liver and other appropriate organs from the sacrificed birds and from birds that died prior to sacrifice on day 30 for histopathological analysis. Analyze the organs for lead and compounds contained in the candidate shot or coated shot. Necropsy all birds to determine any pathological conditions.

(*3*) Typical test analyses. Analyze mortality among the specified groups with appropriate chi-square statistical procedures. Analyze physiological data and tissue contaminant data by analysis of variance or other appropriate statistical procedures to include the factors of shot type and sex. Compare sacrificed birds and birds that died prior to sacrifice whenever sample sizes are adequate for meaningful comparison.

(C) Daphnid and Fish Early-Life Toxicity Tests. Determine the toxicity of the compounds that comprise the shot or shot coating (at conditions maximizing solubility without adversely affecting controls) to selected invertebrates and fish. These methods are 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* (conducted in accordance with 40 CFR 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 Daphnid exposure to a chemical in static and flow-through systems, with the agencies assessing the hazard the compound(s) may present to an aquatic environment.

(*2*) The second test is the *Daphnid Chronic Toxicity Test* (conducted in accordance with 40 CFR 797.1330). This gathers data on the chronic toxicity of chemical substances in which Daphnids (*Daphnia* spp.) 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 the compound(s) may present to an aquatic environment.

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

(iii) After the Tier 2 testing, the applicant will report the results to the Director. If, after review of the Tier 2 data, the Service determines that the information does not establish that the shot or shot coating does not impose a significant danger to migratory birds, other wildlife, and their habitats, the applicant is advised to proceed with the additional testing in Tier 3. A *Notice of Review* advises the public that, in conjunction with Tier 1 data, Tier 2 test results are inconclusive and Tier 3 testing is required for continued consideration.

(iv) If review of the Tier 2 test data results in a preliminary determination that the candidate shot or shot coating does not impose a significant danger to migratory birds, 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 and why Tier 3 testing is unnecessary. The rulemaking will include a description of chemical composition of the shot or shot 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 or shot coating approval is published as a final rule in the **Federal Register**. If, as a result of the comment period, the Service determines that the information does not establish that the shot and/or shot coating does not impose a significant danger to migratory birds, other wildlife, and their habitats, Tier 3 testing will be required and a *Notice of Review* published in the

Federal Register. If the applicant chooses not to proceed, the determination denying approval of the candidate shot or shot coating will appear in the **Federal Register**.

(4) *Tier 3.*

(i) If the Director determines that the Tier 1 or Tier 2 information is inconclusive, the Director will notify the applicant to submit a Tier 3 testing plan for conducting further testing as outlined in paragraphs (b)(4)(i) (A) and (B) of this section. Review, by the Director, of the Tier 3 testing plan submitted by the applicant will occur 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 to disregard and any modifications to incorporate into the Tier 3 plan in order to gain plan approval. All testing procedures should be in compliance with the Good Laboratory Practices Standards (40 CFR part 160), except where they conflict with the regulations in this section or with a provision of an approved plan. The Director, or authorized representative, may elect to inspect the applicant's laboratory facilities and may decline to approve the plan and further consideration of the candidate shot and/or shot coating if the facility is not in compliance with the Good Laboratory Practices Standards. After acceptance of the plan, Tier 3 testing will commence. Required analyses and reports must be sent to the Director. 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.

(A) Chronic Toxicity Test—Tier 3 (Long-term 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 unless otherwise provided by the Service:

(*1*) Typical test materials: 36 male and 36 female hand-reared mallards approximately 6 to 8 months old (Mallards must have plumage and body conformation that resembles wild mallards); 72 elevated outdoor pens equipped with feeders and waterers; Laboratory equipped to perform fluoroscopy, required blood and tissue assays, and necropsies; Whole kernel corn; and Lead, steel, and candidate shot or coated shot.

(*2*) Typical test procedures.

(*i*) Conduct this test 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). Assign individual mallards to elevated outdoor pens during the first week of December and acclimate to an *ad libitum* diet of whole kernel corn for 2 weeks. Randomly assign birds to 5 groups (lead group of 4 males and 4 females, 4 other groups of 8 males and 8 females/group). Dose the lead group (positive control) with one size No. 4 pellet of lead shot. Dose one group (8 males and 8 females) with eight size No. 4 pellets of steel shot (negative control) and dose the 3 other groups (8 males and 8 females/group) with one, four and eight size No. 4 pellets of candidate shot or coated shot.

(*ii*) Weigh and fluoroscope birds weekly. Weigh all recovered shot to measure erosion. Determine blood parameters given in the 30-day acute toxicity test. Provide body weight and blood parameter measurements on samples drawn at 24 hours after dosage and at the end of days 30 and 60. At the end of 60 days, sacrifice all survivors. Remove the liver and other appropriate organs from sacrificed birds and birds dying prior to sacrifice on day 60 for histopathological analysis. Analyze organs for lead and other metals potentially contained in the candidate shot or shot coating. Necropsy all birds that died prior to sacrifice to determine pathological conditions associated with death.

(*3*) Typical test analyses. Analyze mortality among the specified groups with appropriate chi-square statistical procedures. Any effects on the previously mentioned physiological parameters caused by the shot or shot coating must be significantly less than those caused by lead shot and must not be significantly greater than those caused by steel shot. Analyze physiological data and tissue contaminant data by analysis of variance or appropriate statistical procedures to include the factors of shot type, dose and sex. Compare sacrificed birds and birds that died prior to sacrifice whenever sample sizes are adequate for a meaningful comparison.

(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 unless otherwise provided by the Service:

(*1*) Typical test materials: 44 male and 44 female hand-reared first year mallards (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; 44 elevated, pens equipped with feeders, waterers and nest boxes; Laboratory equipped to perform fluoroscopy, required blood and tissue assays, and necropsies; Whole kernel corn, and commercial duck maintenance and breeder mash; and Lead, steel and candidate shot or coated shot.

(*2*) Typical test procedures. (*i*) Randomly assign mallards to 3 groups (Lead group = 4 males and 4 females; steel group = 20 males and 20 females; candidate shot/coated shot group = 20 males and 20 females) in December and hold 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). Tests conducted in the southern U.S. will need to be completed in low temperature units. After a 3-week acclimation period with ducks receiving commercial maintenance mash, provide birds with an *ad libitum* diet of corn for 60 days and then pair birds (one pair/pen) and provide commercial breeder mash. Dosing of the 3 groups with one pellet of No. 4 lead shot (positive control); eight pellets of No. 4 steel shot (negative control); and eight pellets of No. 4 candidate shot or coated shot will occur after the acclimation period (day 0) and redosed after 30, 60, and 90 days. Few, if any, of the lead-dosed birds (positive control) should survive and reproduce.

(*ii*) Fluoroscope birds 1 week after dosage to check for shot retention. Weigh males and females the day of initial dosing (day 0), at each subsequent dosing, and at death. Measure blood parameters identified in the 30-Day Acute Toxicity Test in this test using samples drawn at time of weighing. Note the date of first egg and the mean number of days per egg laid. Conclude laying after 21 normal, uncracked eggs are laid or after 150 days. Sacrifice adults after completion of laying period. Remove the liver and other appropriate organs from sacrificed birds and from other birds that died prior to sacrifice for histopathological analysis. Analyze organs and the 11th egg for compounds contained in the shot or shot coating. Necropsy all birds to determine any pathological conditions. Check nests daily to collect eggs. Discard any eggs laid before pairing. Artificially incubate eggs and calculate the percent shell thickness, percent eggs cracked, percent fertility (as determined by candling), and percent hatch of fertile eggs for each female. Provide ducklings with starter mash after hatching. Sacrifice all ducklings at 14 days of age. Measure survival to day 14 and weight of the

ducklings at hatching and sacrifice. Measure blood parameters identified in the 30-Day Acute Toxicity Test using samples drawn at sacrificing.

(*3*) Typical test analyses.

(*i*) Any mortality, reproductive inhibition or effects on the physiological parameters in paragraph (b)(4) by the shot or shot coating must not be significantly greater than those caused by steel shot. Percentage data is subject to an arcsine, square root transformation prior to statistical analyses. Physiological and reproductive data is analyzed by one-tailed *t*-tests (α=0.05), or other appropriate statistical procedures by the applicant.

(*ii*) After conclusion of Tier 3 testing, the applicant must report the results to the Director. If after review of the Tier 3 data (completion 60 days after receipt of material) the Service determines that all of the information gathered and submitted in accordance with Tiers 1, 2, and 3, as applicable, does not establish that the shot or shot coating does not impose a significant danger to migratory birds, other wildlife, and their habitats, the applicant will have the option of repeating the tests that the Director deems are inconclusive. If the applicant chooses not to repeat the tests, approval of the candidate shot or shot coating is denied. A *Notice of Review* will inform the public that Tier 3 results are inconclusive, the applicant's decision not to repeat Tier 3 testing, and the Service's subsequent denial of the shot or shot coating.

(*iii*) If review of either the initial or repeated Tier 3 test data results in a preliminary determination that the shot or shot coating does not impose a significant danger to migratory birds, 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 or shot coating and providing the public with the opportunity to comment. The rulemaking will include a description of the chemical composition of the shot or shot coating and a synopsis of findings under the standards required by Tier 3. If at the end of the comment period, the Service concludes that the shot or shot coating does not impose a significant danger to migratory birds, other wildlife, or their habitats, the shot or shot coating will be approved as nontoxic with publication of a final rule in the **Federal Register**.

(5) *Residual lead levels.* The Service's maximum environmentally acceptable level of lead in shot is trace amounts or <1 percent. Any shot manufactured with lead levels equal to or exceeding 1 percent are considered toxic and, therefore, illegal.

(6) *Field Detection Device.* Before approval of any shot for use in migratory game bird hunting, a noninvasive field testing device must be available for enforcement officers to determine the shot material in a given shell in the field.

Dated: November 3, 1997.

Donald J. Barry,

Acting Assistant Secretary for Fish and Wildlife and Parks.

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