§20.134 Approval of nontoxic shot types and shot coatings.

The U.S. Fish and Wildlife Service conducts a process to approve shot material determined not to impose a significant toxicity danger to migratory birds and other wildlife or their habitats. The regulations in this section set forth the approval process. Upon receipt of an application and supporting data submitted in accordance with this section, the Service will review the application materials together with all other relevant available evidence, including public comment. If the Director concludes that the spent shot material will not present a significant toxicity danger to migratory birds and other wildlife or their habitats, we will add the shot material to the list of approved nontoxic shot materials at 50 CFR 20.21(j).

(a) Information collection approval. The Office of Management and Budget approved the information collection requirements contained in this section under 44 U.S.C. 3501 et seq. and assigned OMB Control No. 1018-0067. We collect this information so that we can conduct a methodical and objective review of a shot type you submit as nontoxic for hunting waterfowl. An agency may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number. You may submit comments on this information collection to the Service Information Collection Officer, U.S. Fish and Wildlife Service, 1849 C Street NW., Washington, DC 20240.

(b) Limitations on nontoxic shot type approval. We will not approve as nontoxic any shot type or shot coating with a lead content of 1 percent or more.

(1) Before we will approve any shot type or shot coating as nontoxic, a shotshell loaded with the shot type or coated shot must be demonstrated to be identifiable as not being lead in a portable field testing device for use by enforcement officers.

(2) The testing device can be regular magnets, rare-earth magnets, or the “HOT*SHOT” field-testing device from Stream Systems of Concord, CA. We will consider other field-testing devices that may be readily available to law enforcement officers.

(c) Application submission and review. We use a 3-tier strategy for approval of nontoxic shot types and shot coatings. You must submit any application for approval under this section with supporting documentation in accordance with the following procedures and must include at least the supporting materials and information for Tier 1 in the approval system. If your application is not complete, we will return it to you with an explanation of the additional information we need to initiate review of your submission.

(d) Tier 1 application fee. The fee for consideration of a Tier 1 application is $1,630. Submit the fee, payable to the U.S. Fish and Wildlife Service, with your application.

(e) Tier 1 application. If you wish to submit a shot type or shot coating for consideration as nontoxic for waterfowl hunting, you must provide statements of use, chemical characterization, production variability, volume of use of the candidate material, and a sample of the shot or shot coating.

(1) Provide a statement of how you propose to use the candidate material in creating waterfowl hunting shotshells.

(2) Provide a description of the chemical composition of the material comprising the shot.

(i) Provide the chemical names, Chemical Abstracts Service numbers (consult the American Chemical Society), and structures of the components of the shot.

(ii) Provide a chemical characterization for organics and organometallics for the core and/or coating, including the empirical formula, melting point, molecular weight, solubility, specific gravity, partition coefficients, hydrolysis half-life, leaching rate in water and in soil, degradation half-life, vapor pressure, stability, and other relevant characteristics for each component.

(iii) Provide data on the composition, weight, and sectional density of the shot material.

(iv) Provide data on the thickness, quantity in milligrams (mg) per shot, and chemical composition of any coating on the shot.

(3) Provide documentation that the shot can be readily identified as nontoxic with a standard field shotshell testing device.

(4) Provide a statement of the hardness of the candidate shot type and the method used to determine the hardness.

(5) Provide a statement of the expected variability of shot during production.

(6) Provide an estimate of yearly volume of candidate shot type and/or coated shot expected to be produced for use in hunting migratory birds in the United States.

(7) Provide 5 pounds (approximately 2.18 kilograms (kg)) of the candidate shot type or shot with the proposed coating in size equivalent to U.S. standard size No. 4 of 0.13 inches (approximately 3.3 millimeters (mm)) in diameter.

(i) We or an independent laboratory may analyze the composition of the shot or the shot coating.

(ii) We will reject your application if the composition of the shot or shot coating differs substantially from what you describe in your application.

(f) Toxicological effects. You must provide information on the toxicological effects of the shot or any coating on it.

(1) Provide a summary of the acute and chronic toxicity data of the metals or compounds in the shot or the shot coating, ranking the toxicity of each. Use the following criteria to assess the toxicity of the shot or shot coating. These criteria are based on the estimated median lethal dose of the candidate shot type or shot coating. That is, the statistically derived single dose estimate of the candidate material that can be expected to cause death in 50 percent of the animals tested (LD50).

If the LD50 is	the material is considered
no more than 5 mg/kg,	super toxic.
over 5 to 50 mg/kg,	extremely toxic.
over 50 to 500 mg/kg,	very toxic.
over 500 to 5,000 mg/kg,	moderately toxic.
over 5,000 to 15,000 mg/kg,	slightly toxic.
over 15,000 mg/kg,	nontoxic.

(2) Provide 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 (concentrations in water lethal to 50 percent of test populations) data, and sublethal effects, with citations.

(3) Provide 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 the toxic effect, such as mortality, impaired reproduction, substantial weight loss, disorientation, or other relevant associated clinical observations.

(4) Provide a statement with supporting rationale and citations to relevant data about whether ingestion of the shot or shot coating by invertebrates, fish, amphibians, reptiles, or mammals is cause for concern. If there is a recognized impact on invertebrates, fish, amphibians, reptiles, or mammals, we reserve the right to require additional study of the shot or shot coating.

(g) Environmental fate and transport. You must provide information on the environmental fate and transport, if any, of the shot and any coating on it.

(1) Provide a statement describing any chemical or physical alteration of the shot and shot coating upon firing.

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

(3) For each metal or other component of the shot or shot coating, determine the Estimated Environmental Concentration (EEC).

(i) Determine the EEC in a terrestrial ecosystem if 69,000 U.S. standard size No. 4 shot of 0.13 in (3.3 mm) in diameter are completely dissolved in 1 hectare (ha) (107,639 square feet (ft2)) of soil 5 centimeters (cm) (1.97 in) deep. Assess whether the EEC would exceed the clean soil standards for the Use or Disposal of Sewage Sludge at 40 CFR part 503. Explain how the estimated EEC relates to the toxicity thresholds for plants, invertebrates, and other wildlife.

(ii) Determine the EEC in an aquatic ecosystem if 69,000 U.S. standard size No. 4 shot of 0.13 in (3.3 mm) in diameter are completely dissolved in 1 ha, or 107,639 ft2, of water 1 ft (30.48 cm) deep. Express the calculated concentrations in standard units such as micrograms per liter, for water with pH of 6.5 to 9.0. Explain how the estimated EEC compares to the U.S. Environmental Protection Agency (EPA) Water Quality Criteria and toxicity thresholds in plants, invertebrates, fish, and wildlife.

(4) Conduct a risk assessment using the Quotient Method. Calculate the risk of the submitted shot material, the EEC/the Toxicological Level of Concern. For example, compare the EEC in parts per million (p/m) to an effect level such as the LD50 in p/m. Use the following criteria to assess the risk of the components of the shot or shot coating.

If the risk ratio is	then
less than 0.1,	adverse effects are not likely.
0.1 to 10.0,	adverse effects are possible.
greater than 10.0,	adverse effects are likely.

(h) In vitro evaluation. You must evaluate the candidate shot type or shot coating in a standardized test under conditions that will assess its erosion and any release of components into a liquid medium in an environment simulating the conditions of a waterfowl gizzard (see W.H. Kimball and Z.A. Munir, 1971, The corrosion of lead shot in a simulated waterfowl gizzard, Journal of Wildlife Management 35:360-365) for basic test procedures. Compare the erosion characteristics to those of lead shot and steel shot of comparable size.

(1) Test materials. You will need appropriate analysis equipment, such as for atomic absorption spectrophotometry or inductively coupled plasma mass spectrometry, a drilled aluminum block to support test tubes, a thermostatically controlled stirring hot plate, small Teflon®-coated magnets, hydrochloric acid of pH 2.0, pepsin, capped test tubes, and U.S. No. 4 lead, steel, and candidate shot type or shot with the proposed coating.

(2) Test procedures.

(i) Add hydrochloric acid and pepsin to each capped test tube at a volume and concentration that will erode a single U.S. No. 4 lead shot at the rate of 5 mg per day.

(ii) Place three test tubes, each containing lead shot, steel shot, or the candidate shot type or shot with the proposed coating 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.

(iii) Determine the erosion of shot or shot with the proposed coating daily for 14 consecutive days by weighing the shot and analyzing the digestion solution with an atomic absorption spectrophotometer.

(iv) Replicate the 14-day procedure five times.

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

(i) Tier 1 application review. Upon receipt of your completed Tier 1 application, we will promptly perform an overview. We will notify you within 30 days of receipt that our thorough review of the application will commence, and we will complete our review within 60 days of the date of publication. We will use half of the LD50/ft2 in terrestrial and aquatic systems as the level of concern in evaluating your application.

(j) Approval after Tier 1 testing. If we determine that the Tier 1 data show that the shot or shot coating does not pose a significant toxicity danger to migratory birds, other wildlife, or their habitats, we will notify you and request payment of a $20,000 final review and publication fee (payable to the U.S. Fish and Wildlife Service).

(1) After receipt of payment, we will publish a proposed rule in the Federal Register stating that we intend to approve this shot or shot coating as nontoxic and provide the public with the opportunity to comment on our decision. The proposed rule 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 1.

(2) If, after considering public comment on the proposed rule, we conclude that the shot or shot coating does not pose a significant toxicity danger to migratory birds, other wildlife, or their habitats, we will approve the shot or coating as nontoxic with publication of a final rule in the Federal Register and addition of the shot or coating to the list in §20.21(j).

(k) Additional testing. If we conclude that the Tier 1 data are inconclusive, or if we conclude that the shot or shot coating may pose a significant toxicity danger to migratory birds, other wildlife, or their habitats, we will advise you to proceed with some or all of the additional testing described for Tier 2, Tier 3, or both.

(1) We will inform you that we consider the Tier 1 test results to be inconclusive. We will request Tier 2, and possibly Tier 3, testing before we evaluate the shot any further.

(2) If you choose not to do further testing, we will deny approval of the candidate shot type or shot coating.

(l) Tier 2 application fee. The fee for consideration of a Tier 2 application is $1,530. Submit the fee, payable to the U.S. Fish and Wildlife Service, with your application.

(m) Tier 2 testing. Your Tier 2 testing procedures must be in compliance with the Good Laboratory Practice Standards (40 CFR part 160) except where they conflict with the requirements in this section or with a provision of an approved plan. We reserve the right for us or an authorized representative to inspect your laboratory facilities. We will not approve the plan and will cease further consideration of the candidate shot type if the laboratory does not meet the Good Laboratory Practice Standards.

(n) Tier 2 plan review. We will review the Tier 2 testing plan you submit within 30 days of the day on which we receive it. We may decline to approve the plan, or any part of it, if we deem it deficient in any manner with regard to timing, format, or content. We will inform you regarding what parts, if any, of the submitted testing procedures to disregard and any modifications to incorporate into the Tier 2 testing plan to gain plan approval. After we accept your plan, you may conduct Tier 2 testing.

(o) Tier 2 in vivo evaluation. Conduct a 30-day acute toxicity test in mallards using the following method unless we specify otherwise. The testing should be done in accordance with Good Laboratory Practices Standards at 40 CFR part 160.

(1) Test materials. You will need 30 male and 30 female hand-reared mallards approximately 6 to 8 months old with plumage and body conformation of wild mallards; 60 elevated outdoor pens equipped with feeders and waterers; a laboratory equipped to perform fluoroscopy, required blood and tissue assays, and necropsies; commercial duck maintenance mash; and lead, steel, and candidate shot type.

(2) Test procedures.

(i) House the mallards individually in pens and give them unrestricted access to food and water.

(ii) After 3 weeks, randomly assign them to 3 groups of 10 males and 10 females per group. Dose each duck with 8 pellets of either U.S. No. 4 lead shot (positive control), steel shot (negative control), or the candidate shot type or shot with the proposed coating.

(iii) Fluoroscope each bird at 1 week after dosing to check for shot retention.

(iv) For 30 days, observe the birds daily for signs of intoxication and mortality.

(v) Determine the body weight for each bird at the time of dosing and at days 15 and 30.

(vi) On days 15 and 30, collect blood by venipuncture and determine hematocrit, hemoglobin concentration, and other measures of blood chemistry.

(vii) Euthanize all survivors on day 30. Remove the liver and other appropriate organs from each bird and those from birds that died prior to day 30.

(viii) Analyze the organs for lead and compounds contained in the candidate shot type or shot with the proposed coating.

(ix) Perform a necropsy of all birds to determine any gross and/or microscopic pathological conditions.

(x) Weigh all recovered shot and determine shot erosion.

(3) Test analyses.

(i) Analyze mortality among the specified groups with appropriate statistical procedures, such as chi-square, with $\alpha = 0.05$, and $\beta = 0.8$.

(ii) 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, with $\alpha = 0.05$ and $\beta = 0.8$.

(iii) Compare euthanized birds and birds that died prior to day 30 whenever sample sizes are adequate for meaningful comparison.

(p) Daphnia 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 Daphnia (Daphnia species) Acute Toxicity Test, must be conducted in accordance with 40 CFR 797.1300. It provides data on the acute toxicity of chemical substances. The guideline prescribes an acute toxicity test in which Daphnia are exposed to a chemical in static and flow-through systems for assessing the hazard the compound(s) may present to an aquatic environment.

(2) The second test, the Daphnia Chronic Toxicity Test, must be conducted in accordance with 40 CFR 797.1330. It provides 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 also are used to assess the hazard that the compound(s) may present to an aquatic environment.

(3) The third test, the Fish Early-Life-Stage Toxicity Test, must be conducted in accordance with 40 CFR 797.1600. It assesses the adverse effects of chemical substances to fish in the early stages of their growth and development. Data from this test also are used to determine hazards of the compound(s) in an aquatic environment.

(q) Evaluation of Tier 2 testing. If, after Tier 2 testing, you wish to continue the application process, send the Tier 2 testing results and analyses to us. You must ensure that copies of all the raw data and statistical analyses accompany the laboratory reports and final comprehensive report of this test. We will review the data within 60 days of the day on which we receive your Tier 2 application materials.

(r) Approval after Tier 2 testing. If we determine that the Tier 2 test data show that the shot or shot coating does not pose a significant toxicity danger to migratory birds, other wildlife, or their habitats, we will notify you and request payment of a $20,000 final review and publication fee (payable to the U.S. Fish and Wildlife Service).

(1) After receipt of payment, we will publish a proposed rule in the Federal Register stating that we intend to approve this shot or shot coating and provide the public with the opportunity to comment. The proposed rule 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 2.

(2) If, at the end of the comment period, we conclude that the shot or shot coating does not pose a significant toxicity danger to migratory birds, other wildlife, or their habitats, we will approve the shot or coating as nontoxic with publication of a final rule in the Federal Register and subsequent addition of the shot or coating to the list in §20.21(j).

(s) Additional testing. If we conclude that the Tier 2 data are inconclusive, or if we conclude that the shot or shot coating may pose a significant toxicity danger to migratory birds, other wildlife, or their habitats, or if public comment on the proposed rule indicates that we should require further testing, we will advise you to proceed with the additional testing described for Tier 3. We will require Tier 3 testing before we evaluate the shot any further. If you choose not to do Tier 3 testing, we will deny approval of the candidate shot type or shot coating.

(t) Tier 3 application fee. The fee for consideration of a Tier 3 application is $1,530. Submit the fee, payable to the U.S. Fish and Wildlife Service, with your application.

(u) Tier 3 testing. We will review your Tier 3 testing plan within 30 days of the day on which we receive it. All testing procedures in the plan should be in compliance with the Good Laboratory Practice Standards (40 CFR part 160), except where they conflict with the requirements in this section or with a provision of an approved plan. We, or our authorized representative, may elect to inspect your laboratory facilities and may decline to approve the plan and further consideration of the candidate shot type and/or shot coating if the facility is not in compliance with the Good Laboratory Practice Standards.

(1) We will not approve the plan, or any part of it, if we deem it deficient in any manner with regard to timing, format, or content. We will tell you what parts, if any, of the submitted testing procedure to disregard, and any modifications to incorporate into the Tier 3 plan needed for us to approve it.

(2) After acceptance of the plan, you may conduct the Tier 3 testing. You must ensure that copies of the raw data and the statistical analyses accompany the laboratory reports and final comprehensive report on this test.

(i) Chronic toxicity test. This is a 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 following general guidelines unless we tell you otherwise.

(A) Test materials. You will need 36 male and 36 female hand-reared mallards approximately 6 to 8 months old with plumage and body conformation of wild mallards; 72 elevated outdoor pens equipped with feeders and waterers; a laboratory equipped to perform fluoroscopy, required blood and tissue assays, and necropsies; whole kernel corn; and lead, steel, and candidate shot type or shot with the proposed coating.

(B) Test procedures. (1) 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).

(2) Assign individual mallards to elevated outdoor pens during the first week of December and give them an unrestricted diet of whole kernel corn for 2 weeks.

(3) Randomly assign birds to five groups—a lead group of 4 males and 4 females, and 4 other groups of 8 males and 8 females per group.

(4) Dose each bird in the lead group (the positive control) with one U.S. No. 4 pellet of lead shot. Dose each bird in one group of 8 males and 8 females with 8 U.S. No. 4 pellets of steel shot (the negative control). Dose each bird in 1 remaining group of 8 males and 8 females with one U.S. No. 4 pellet of the candidate shot type or shot with the proposed coating, each bird in 1 of the remaining 2 groups of 8 males and 8 females with 4 U.S. No. 4 pellets of the candidate shot type or shot with the proposed coating, and each bird in the final group of 8 males and 8 females with 8 U.S. No. 4 pellets of the candidate shot type or shot with the proposed coating.

(5) Weigh and fluoroscope the birds weekly.

(6) Weigh all recovered shot and determine shot erosion.

(7) 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 dosing, and at the end of days 30 and 60.

(8) Remove the liver and other appropriate organs from all birds that die prior to day 60.

(9) At the end of 60 days, euthanize all survivors. Remove the liver and other appropriate organs from the euthanized birds. Analyze the organs for lead and other metals in the candidate shot type or shot coating.

(10) Necropsy all birds that died prior to day 60 to determine any gross and/or microscopic pathological conditions associated with their deaths.

(C) Test analyses. (1) 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, with $\alpha = 0.05$, and $\beta = 0.8$.

(2) 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 with $\alpha = 0.05$, and $\beta = 0.8$.

(3) Compare euthanized birds and birds that died prior to being euthanized whenever sample sizes are adequate for a meaningful comparison.

(ii) Chronic dosing study. This moderately long-term study includes an assessment of reproduction. Conduct a chronic exposure reproduction trial within the following general guidelines unless we tell you otherwise.

(A) Test materials. You will need 44 male and 44 female hand-reared first-year mallards with plumage and body conformation of wild mallards; pens suitable for quarantine and acclimation and for reasonably holding 5 to 10 ducks each; 44 elevated pens equipped with feeders, waterers, and nest boxes; a laboratory equipped to perform fluoroscopy, required blood and tissue assays, and necropsies; whole kernel corn, and commercial duck maintenance and breeder mash; and U.S. No. 4 lead, steel, and candidate shot type or shot with the proposed coating.

(B) Test procedures. (1) In December, randomly assign the mallards to 3 groups—a positive control group of 4 males and 4 females that will be tested with lead; a negative control group of 20 males and 20 females that will be tested with steel; and a final group with 20 males and 20 females that will be tested with the candidate shot type or shot with the proposed coating. Hold the ducks in same-sex groups until mid-January. If the test is not conducted in the northern United States or comparable latitudes, the test must be completed in low-temperature units.

(2) After a 3-week acclimation period in which the ducks are fed with commercial maintenance mash, provide them an unrestricted diet of corn for 60 days and then pair them, put one pair in each pen, and provide them with commercial breeder mash.

(3) After the acclimation period, dose each bird in the lead group with 1 pellet of U.S. No. 4 lead shot, each bird in one of the groups of 20 males and 20 females with 8 pellets of U.S. No. 4 steel shot, and each bird in the remaining group of 20 males and 20 females with 8 pellets of U.S. No. 4 candidate shot type or shot with the proposed coating.

(4) Redose each bird with the appropriate shot after 30, 60, and 90 days. Few, if any, of the lead-dosed birds should survive and reproduce.

(5) Fluoroscope each bird 1 week after dosing it to check for shot retention.

(6) Weigh each bird the day of initial dosing (day 0), at each subsequent dosing, and at death.

(7) Collect a blood sample from each bird on the days on which it is dosed and immediately prior to euthanizing it.

(8) Check nests daily and collect any eggs laid. Note the date of first egg laid and the mean number of days per egg laid. Conclude monitoring of laying after 21 normal, uncracked eggs are laid or after 150 days.

(9) Collect eggs and discard any eggs laid before pairing.

(10) Euthanize the adults after they complete laying or after 150 days.

(11) Remove the liver and other appropriate organs from each euthanized bird and from each bird that dies prior to being euthanized.

(12) Analyze the organs and the eleventh egg for compounds contained in the shot or shot coating.

(13) Necropsy all the birds to determine any gross and/or microscopic pathological conditions that affected them.

(14) Artificially incubate the normal eggs and calculate the percent shell thickness for each (compared to typical shell thickness), the percent of eggs cracked, the percent fertility (as determined by candling), and the percentage of fertile eggs hatched for each female.

(15) Provide ducklings that hatch with starter mash. Euthanize all ducklings at 14 days of age.

(16) Determine survival to day 14 and weight of the ducklings at hatching and at being euthanized.

(17) Measure duckling blood for hemoglobin concentration and other blood chemistries using blood samples drawn when the ducklings are euthanized.

(C) Test analyses. Any mortality, reproductive inhibition, or effects on physiological parameters due to the shot or shot coating must not be significantly greater than those caused by steel shot. If necessary, transform percentage data with an arcsine, square root, or other suitable transformation prior to statistical analyses. Analyze the physiological and reproductive data with one-tailed t-tests or other appropriate statistical procedures with $\alpha = 0.05$, and $\beta = 0.8$.

(v) Evaluation of Tier 3 testing. Report the results of your Tier 3 testing to us. We will review the data within 60 days of the day on which we receive your Tier 3 application materials. You must ensure that copies of the raw data and the statistical analyses accompany the laboratory reports and final comprehensive report on this test.

(w) Approval after Tier 3 testing. If we determine that the Tier 3 test data show that the shot or shot coating does not pose a significant toxicity danger to migratory birds, other wildlife, or their habitats, we will notify you and request payment of a $20,000 final review and publication fee (payable to the U.S. Fish and Wildlife Service).

(1) After receipt of payment, we will publish a proposed rule in the Federal Register stating that we intend to approve this shot or shot coating and provide the public with the opportunity to comment. The proposed rule 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.

(2) If, at the end of the comment period, we conclude that the shot or shot coating does not pose a significant toxicity danger to migratory birds, other wildlife, or their habitats, we will approve the shot or coating as nontoxic with publication of a final rule in the Federal Register and subsequent addition of the shot or coating to the list in §20.21(j).

(x) Additional testing after Tier 3. If we conclude that the Tier 3 data are inconclusive, or if we conclude that the shot or shot coating may pose a significant toxicity danger to migratory birds, other wildlife, or their habitats, we may ask you to repeat tests we deem inconclusive. If you choose not to repeat the tests, we will deny approval of the candidate shot type or shot coating.

(y) Denial after Tier 3 testing. If we conclude that the shot or shot coating may pose a significant toxicity danger to migratory birds, other wildlife, or their habitats, we will notify you that we deny approval of the candidate shot type or shot coating.

(z) Withdrawal of the approval of a shot type or shot coating. If we find that an approved shot type or shot coating is not readily detectable in the field or has environmental effects or direct toxicological effects on biota, we may withdraw our approval of the shot type or shot coating. This includes any previously approved shot type or shot coating.

(1) We may consult the Service Law Enforcement Laboratory to determine whether any particular shot type or shot coating is readily detectable in the field by law enforcement officers. If the shot type is not readily detectable in the field, we will give the shotshell producer 180 days to remedy the situation by improving either the shot or the detection method.

(2) We may consider new evidence, consistent with the provisions of the Migratory Bird Treaty Act and the Information Quality Act (Pub. L. 106-554, 2001; Office of Management and Budget Guidance, 67 FR 8452-8460, February 22, 2002) that shows that an approved shot type or shot coating has significant environmental effects or direct toxicological effects that were not known when we approved the shot type or shot coating.

(3) After the 180-day period for a shot type that cannot be tested in the field (see paragraph (z)(1) of this section), or at any time after we learn of significant environmental effects or direct toxicological effects, we will publish a notice in the Federal Register informing manufacturers and the public of our pending withdrawal of the approval of the shot type or shot coating. We will revise the table of approved shot types at §20.21(j) to reflect the withdrawal of the approval, to be effective on January 1st, after allowing manufacturers 1 full calendar year to prepare for the change.

[78 FR 78280, Dec. 26, 2013]