(n) Approval—An attainment demonstration for the 1997 8-hour ozone standard to satisfy requirements of section 182(c)(2)(A) of the Clean Air Act, and a Reasonably Available Control Measure (RACM) analysis to satisfy requirements of section 172(c)(1) of the Clean Air Act for the Greater Connecticut ozone nonattainment area, submitted by the Connecticut Department of Energy and Environmental Protection on February 1, 2008.

[FR Doc. 2013–30735 Filed 12–24–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 219

[Docket No. FRA–2001–11213, Notice No. 17]

Alcohol and Drug Testing: Determination of Minimum Random Testing Rates for 2014

AGENCY: Federal Railroad Administration (FRA), DOT.

ACTION: Notice of determination.

SUMMARY: According to data from FRA's Management Information System, the rail industry's random drug testing positive rate has remained below 1.0 percent for the last two years. FRA's Administrator has therefore determined that the minimum annual random drug testing rate for the period January 1, 2014, through December 31, 2014, will remain at 25 percent of covered railroad employees. In addition, because the industry-wide random alcohol testing violation rate has remained below 0.5 percent for the last two years, the Administrator has determined that the minimum random alcohol testing rate will remain at 10 percent of covered railroad employees for the period January 1, 2014, through December 31, 2014. Railroads remain free, as always, to conduct random testing at higher rates.

DATES: This notice of determination is effective December 26, 2013.

FOR FURTHER INFORMATION CONTACT: Jerry Powers, FRA Drug and Alcohol Program Manager, W38–105, Federal Railroad Administration, 1200 New Jersey Avenue SE., Washington, DC 20590, (telephone 202–493–6313); or Sam Noe, FRA Drug and Alcohol Program Specialist, (telephone 615–719–2951).

Issued in Washington, DC on December 20, 2013.

Karen J. Hedlund,

Deputy Administrator.

[FR Doc. 2013–30806 Filed 12–24–13; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

[Docket No. FWS–R9–MB–2011–0077; FF09M21200–134–FXMB1231099BPP0]

RIN 1018–AY59

Migratory Bird Hunting; Revision of Language for Approval of Nontoxic Shot for Use in Waterfowl Hunting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, revise our regulations regarding the approval of nontoxic shot types to make the regulations easier to understand. The language governing determination of Estimated Environmental Concentrations (EECs) in terrestrial and aquatic ecosystems is altered to make clear the shot size and number of shot to be used in calculating the EECs. We specify the pH level to be used in calculating the EEC in water. We also move the requirement for in vitro testing to Tier 1, which will allow us to better assess applications and minimize the need for Tier 2 applications. We add language for withdrawal of shot types that have been demonstrated to have detrimental environmental or biological effects, or for which no suitable field-testing device is available. We expect these changes to reduce the time required for nontoxic shot approvals. Finally, we add fees to cover our costs in evaluating these applications.

DATES: This rule is effective on January 27, 2014.

FOR FURTHER INFORMATION CONTACT: Dr. George Allen, 703–358–1825.

SUPPLEMENTARY INFORMATION:

Background

The Migratory Bird Treaty Act of 1918 (Act) (16 U.S.C. 703–712 and 16 U.S.C. 742 a–j) implements migratory bird treaties between the United States and Great Britain for Canada (1916 and 1996 as amended), Mexico (1936 and 1972 as amended), Japan (1972 and 1974 as amended), and Russia (then the Soviet Union, 1978). These treaties protect certain migratory birds from take, except as permitted under the Act. The Act authorizes the Secretary of the Interior to regulate take of migratory birds in the United States. Under this authority, the U.S. Fish and Wildlife Service (FWS or USFWS) regulates the hunting of migratory game birds through regulations in 50 CFR part 20.

Since the mid-1970s, we have sought to identify shot types that are not significant toxicity hazards to migratory birds or other wildlife. Producers of potential nontoxic shot types submit them for FWS approval under 50 CFR 20.134 as nontoxic for waterfowl hunting.

We revise the regulations to clarify them for applicants and to provide for withdrawal of approval of a shot type that is not readily detectable in the field or has environmental effects or direct toxicological effects on biota.

Comments on the Proposed Rule

We published a proposed rule on this regulations revision on March 4, 2013 (78 FR 14060). We received eight comments or sets of comments on the proposed rule. We respond to the significant comments below and explain subsequent changes we are making to the proposed regulations.

Comment. We agree . . . that there is no need to publish a ''Notice of Application'' in the **Federal Register**.

Comment. ''. . . I speak principally for the handloading hunter when I explain how simple it should be to identify his shotshells as non-lead in nature. The shot he might be using will be of two types usually; either steel or tungsten/alloy balls. Steel is easy to detect by simple magnet identification. Tungsten alloys usually deflect at least slightly when they are exposed to a rare earth magnet. A simple exam of the pellets involves using a needle nose pliers to open up the shell and squeeze the shot, and makes obvious to the agent how much softer the lead ball is compared to a tungsten/alloy ball. The shell is able to be reclosed usually on the spot and no big harm or inconv[en]ience has been done to either hunter or agents.

Now, it is important to understand that these Tungsten alloys are not purposely made to be non magnetic. When we make them, if we use high enough concentrations of iron to make them more magnetic in nature, they spuriously loose [sic] density and become harder, both of which is unacceptable to the user . . . So why do we want to create entrepreneurial as well as manufacturing hurdles when it is usually accepted hunters are doing the right thing and using non-toxic shells. Simple common sense should

prevail, tungsten alloys DO NOT look like lead, and are dissimilar as well when manipulated by pliers. I would suggest we concentrate our efforts in other areas where we might be able to solve important issues.''

Response. We agree that shells used in waterfowl hunting are *often* loaded with either steel or tungsten-alloy pellets. However, there may be other suitable shot types in the future, for which a test device or devices may be needed. In addition, testing as the commenter suggests will require rendering any tested shell unusable for hunting, at least until it is recrimped. A law enforcement officer may not wish to take the time in the field to open and test shells, or to have to replace any that he or she opens.

Comment. ''No field test shall be approved if it requires human intervention and/or interpretation. In other words the results of a field test cannot be influenced by the administer[er]. As an example, a field test using rare-earth magnets HELD by a human from a string and OBSERVING the effects of the magnets when a shotgun shell was introduced to the magnet field requires human intervention and interpretation. Such field tests should not be approved.''

Comment. ''A valid field test must not be influenced by external conditions such as wind, snow, rain.''

Comment. All field tests must be non-invasive. Meaning no officer can cut open a shell to conduct a field test. However a game officer can cut open a shell to investigate further if given probable cause.

Response. We agree, and attempt to approve easily-applied field tests.

Comment. ''ANY shot that has a negative impact on the environment and/or wildlife shall be denied and revoked if approved.''

Response. These considerations are the reasons for, and the provisions of, this regulation.

Comment. ''ANY shot that has a negative impact on a game officer's ability to use existing practices or equipment in their ability to identify Lead shall be denied and revoked if approved.''

Response. We disagree with this suggestion. We need to be prepared to accept new technologies and new ways of ensuring compliance with the prohibition on lead shot in waterfowl hunting.

Comment. ''While it is a good idea to specify pH for water testing, one should apply the pH and other parameters specified by EPA for this purpose. pH should accordingly be 6.5–9.0 to represent normal range of typical freshwater bodies suitable for waterfowl habitat. It is my professional opinion that testing at pH of 4.0 will automatically cause most presently approved shot types to exceed SMAV's [sic, Species Mean Acute Values] for many sensitive organisms. This would include most, if not all, types of coated/plated steel shot types!''

Comment. ''We understand the intent behind specifying the pH levels to be used in calculating the EEC I water in item #5 [adding specific pH levels to be used in calculating the EEC in water], but we believe the new regulations for testing in vitro shot should use the extensive database of freshwater parameters specified by the US EPA, as they are continuously monitored and updated tor many different conditions and for use in a variety of applications (fish and wildlife, agriculture, municipal water supply, waste disposal, etc.). We understand that the currently approved and accepted requirements are those published in a series of documents, ''Aquatic Life Ambient Freshwater Quality Criteria— ''for a wide spectrum of specific water parameters''— and which also reference other EPA documents.

A specific example of problems that can occur when the EPA standards are arbitrarily replaced by other criteria concerns the range of pH that should be addressed when performing corrosion testing in aqueous environments. EPA recommends that a pH range of 6.5–9.0 should be investigated as representative of normal levels encountered in natural waters of importance. The newly proposed USFWS range of 4.0–9.0 appears to represent extreme values that EPA has not included as reasonably ''normal''.

Imposition of a pH value as low as 4.0 would have a catastrophic impact on most, it not all, types of currentlyapproved nontoxic shot. It is our professional opinion, as a company heavily involved in material science, that perhaps only bare, uncoated steel shot would survive this type of scrutiny, as all of the metallic shot coatings currently approved for corrosion protection of steel (Zn, Cu, Ni, Cr) would be rapidly solubilized.

Indeed, unprotected steel is already known to have its own set of problems, including rusting and forming agglomerated ''slugs'' within shotshells, resulting in dangerous barrel obstruction. It is our opinion that this level of acidity would cause most metals to exceed allowable EEC's for 69,000 shot in 3.048×10^6 liters of freshwater, and that the most important ''indicator species'' of aquatic organisms (e.g., *Daphnia, Gammarus,* et al.) would not thrive in water of such low pH, especially if such acidic values were intermittent or seasonal in nature, thereby impeding genetic adaptation of the organisms. In other words, at a pH of 4.0, there would be little aquatic life to preserve, and metal dissolution would not be a significant additional problem.''

Response. We agree with these comments. Calculating for a pH range of 6.5 to 9.0 will provide a useful assessment of the potential concentration (see paragraph (g)(3)(ii) of the rule portion of this document).

Comment. ''Inventing an entirely new (and arbitrary) method of measuring and comparing shot hardness values is not a valid materials testing approach. Simply require the applicant to certify that the shot is softer than gun barrel steels, as determined by standard (e.g., ASTM testing) methods.''

Comment. ''In item #3, specifying that applicants must submit a relative hardness value referenced to that of lead as ''1.0'' is not very meaningful. The many different material hardness measurement methods (e.g., ''Rockwell'' of at least six different scales, ''Vickers,'' ''Mohs,'' ''Brinell,'' ''Shore,'' ''Durometer,'' et al.) are designed for specific ranges of values and types of materials. Perhaps a more meaningful requirement would be to simply state whether the submitted shot type is harder or softer than standard steel shot. This is meaningful because shotgun manufacturers currently differentiate between guns rated for steel and those that are not, taking into account important factors other than hardness, notably gun barrel bursting strength/pressure ratings.

Response. We have changed this requirement to state that the submitter must inform us of the method used to determine the hardness of the shot and the hardness value (see paragraph (e)(4) of the rule portion of this document).

Comment. ''With respect to solubility (and/or ''artificial gizzard'') testing, allow applicants to either perform the indicated testing or submit published (''in vitro'' and/or ''in vivo'') data acceptable to USFWS. (There is no reason to ''reinvent'' data for common materials which have already been thoroughly evaluated in prior art.)''

Response. Though we understand the intent of this comment, it would be arbitrary to accept test results from similar shot types or shot coatings, because different production methods or slightly different alloys could mean different solubility test results.

Comment. ''We agree with item #6 [*moving the former Tier 2 solubility testing to Tier 1*], but we believe the

qualifying condition should be added that original solubility data must be submitted with the application ''unless sufficient published data from scientific sources acceptable to USFWS can be cited.''

Response. We will continue to require original solubility testing with each application for a new shot type or coating.

Comment. ''Moving the in vitro evaluation of erosion rate from Tier II into Tier I is reasonable. It would be helpful if the citation of this method (Kimball, W.H. and Z.A. Munir. 1971. The corrosion of lead shot in a simulated waterfowl gizzard. Journal of Wildlife Management 35(2):360–365) was provided in the document. It should also be stated that this testing should be in compliance with Good Laboratory Practices Standards.''

Response. We added the citation for the benefit of applicants, and we agree that applicants should follow the standards in 40 CFR 160. We added this requirement in paragraph (h).

Comment. ''Require applicants to demonstrate effectiveness and availability of shot detection methods to USFWS's satisfaction, rather than calling out one particular type and source of a specific instrument.''

Comment. ''We think the regulation in item #2 [*Specifying that an application for approval of a nontoxic alloy must document that a shotshell loaded with shot of the alloy can be readily identified as containing nontoxic shot with a standard field shotshell testing device*] for detection in the field should say only that a method for confirming that a shotshell contains nontoxic shot must be demonstrated by the applicant. It seems inappropriate for the government to make reference to one specific commercial product from one small source (e.g., ''HOT SHOT'' device from Stream Systems) when metal detection technologies (especially electronic types) are continually being advanced. We believe USFWS would be better served by simply stating that availability of a field method acceptable to USFWS must be demonstrated. This approach would encourage innovation and competition that may actually benefit law enforcement efforts. It would also provide some flexibility to USFWS and manufacturers in the event that a particular detection method becomes unavailable or unaffordable to law enforcement agencies.''

Response. The footnote at the end of the approved shot types table in 50 CFR 20.21(j)(1) states ''The information in the ''Field Testing Device'' column is strictly informational, not regulatory.'' The listing is not an endorsement of any particular field testing device, such as the ''Hot Shot'' tool. We provide the information about field test methods for the use of law enforcement officers. If we become aware of any additional suitable field test devices, or if another type device is required for a newly approved shot type, we will add it or them to the ''Field Testing Device'' column.

Comment. ''We strongly disagree with item #7 [*adding a provision for withdrawal of an approved shot type*] as a matter of resource stewardship. If the shot is nontoxic, changes in detectability in the field should not lead to its withdrawal from the market. Instead, USFWS can require applicants to demonstrate detectability again. If detectability becomes a problem in the field, USFWS can give the manufacturer a complete description of the technical problem and a reasonable period, perhaps 180 days, to remedy the situation by improving either the shot or the detection method.

These new, nontoxic alloys are not generally materials with years of metallurgical practice behind them, and withdrawing approvals on the basis of occasional field reports of detection difficulty seems arbitrary and capricious, especially when manufacturers could potentially fix the problems and continue to offer the products to consumers.

After all the years, solubility testing, animal gavage, process development, and quality assurance efforts that a small company undertakes to qualify one of these products, allowing USFWS to withdraw approval without some kind of reasonable due process seems unfair.

It also seems to invite competitive manipulation, where competitors could allege detection difficulties to slow the adoption of a better nontoxic alternative. This area clearly requires more thought before USFWS changes policy.''

Response. Competitors cannot allege detection difficulties; we rely on tribal, State, and Federal law enforcement officers to advise us about field testing problems. We revised the relevant language at paragraph (z)(1) to give shotshell producers opportunities to resolve field detection problems.

Comment. ''I firmly believe that the USFW and tax payers should not absorb the costs associated with the approval process of non-toxic shot. Adopting fees for the approval process would insure those individuals applying for the approval are serious and not wasting the USFW time and tax payer's money.''

Response. We proposed to add the fees to recoup costs to the government.

Comment. ''We strongly disagree with the proposal to increase fees. The ''service'' USFWS renders does not ''provide special benefits to an identifiable recipient beyond those that accrue to the general public.'' The easiest shotshell to make is a lead shotshell. The public, that is the nation as a whole, benefits when manufacturers advance nontoxic shot technology because it helps conserve the migratory waterfowl resource. Once a new shot type is approved, any manufacturer with the technology can use the approval. Those without the technology can buy approved shot from the producer.

Our company pioneered high-density tungsten-nickel-iron shot in 2001, and by 2006 all major ammunition companies had competing products. The public benefited from choice and falling prices for nontoxic shot. The manufacturers certainly earned no special benefits that did not also accrue to the general public.

Small innovators who manage to surmount the toxicology, solubility, and process technology challenges of introducing new nontoxic products for the public should not see this effort squashed by a looming $20,000 fee at the end of the line. This proposal will slow innovation in the field, and deprive the public of improvements that lower the cost of and encourage compliance with nontoxic regulations.

We could agree with the higher review fees, which we do not think will impede innovation. But the **Federal Register** fee is prohibitively high for a small company, and small companies have been behind most of the innovation in nontoxic shot products.''

Response. Office of Management and Budget Circular A–25 establishes Federal policy regarding fees assessed for Government services. We proposed to add fees to cover costs that we would continue to have to absorb in reviewing nontoxic shot or shot coating submissions and changing the regulations to approve them. The **Federal Register** fee will be a burden for companies that submit nontoxic shot or shot coatings, but it has been a burden for the Division of Migratory Bird Management. This provision of the proposed rule is unchanged.

Comment. Recovery of staff costs for the review of a submission is a great notion . . . However, I believe the proposed staff hours for review may underestimate the actual cost and value. I would propose 40 hours for each of the Tiers.

Response. In the proposed rule, we estimated fewer hours for reviews conducted by our colleagues at the U.S.

Geological Survey (USGS) than the commenter suggests. After considering this comment and further reviewing the work required of USGS, which involves conducting and checking calculations, determining if the literature review is thorough and accurate, and drafting a response with comments to provide for our use in carrying out the rulemaking process, we change the estimated review time for the USGS toxicologist for each tier from 5 to 15 hours. The estimated cost for the Tier 1 USGS review, therefore, rises from $415 in the proposed rule to $1,245. Subsequently, we revise the Tier 1 review fee from $800 to $1,630. We revise the Tier 2 fee and Tier 3 fees to $1,530 each (see paragraphs (d), (l), and (t) in the rule portion of this document.).

Comment. ''As a non-hunter who picks up litter, I note a lot of plastic shot gun shells are discarded during hunting. Any chance of looking at whether those plastics are laden with BPAs and other toxins that can leach as well? Might there ever be a safe (for the hunter) and truly biodegradable shell? Were there paper casings before plastic?''

Response. Paper shotgun shells were in use long before plastic shells, but the bases of the shells are still metal. The idea of a biodegradable shell is laudable, but it might create problems for hunters because the shells may get wet and dirty before they are used. We agree that fired shotgun shells should not be discarded in the field. However, this regulation is limited to the approval of the shot types and shot coatings used in waterfowl and coot hunting.

Other Changes From the Proposed Rule

We added invertebrates to the listing of potentially affected biota in paragraph (f)(4). Assessment of impacts of a shot type or coating on invertebrates is required in paragraph (g). We intended to be consistent between paragraphs (f) and (g), but we inadvertently left ''invertebrates'' out of paragraph (f)(4).

We added a requirement in paragraph (o)(2)(x) to weigh all recovered shot and determine shot erosion. Weighing the shot and determining erosion should have been in the proposed rule because, without this analysis, the erosion testing is not complete.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. Executive Order 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small businesses, small organizations, and small government jurisdictions. However, no regulatory flexibility analysis is required if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Thus, for a regulatory flexibility analysis to be required, impacts must exceed a threshold for ''significant impact'' and a threshold for a ''substantial number of small entities.'' See 5 U.S.C. 605(b). SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule would not have a significant economic impact on a substantial number of small entities.

The rule requires additional information in the initial application and increases the application fee. As a result, companies applying for nontoxic shot approval will incur additional costs. These companies include ammunition companies. The U.S. Small Business Administration defines a ''small business'' as one with employment that meets or is below the established size standard, which is 1,000 employees for ''Small Arms Ammunition Manufacturing'' businesses (NAICS 332992). In 2010, the U.S. Census Bureau shows that about 93 percent of the 112 Small Arms Ammunition Manufacturing establishments qualify as small businesses (fewer than 1,000 employees). We receive an average of only about one application per year, and in some years we receive none. Less than one percent of affected small businesses would be impacted.

The rule has minimal impacts on the application process for nontoxic shot. Applicants already submit the additional application information that the regulations will require. Therefore, the information in an application would change minimally.

The rule includes application fees because revised OMB circular A–25 directs Executive Branch agencies to establish ''user charges . . . sufficient to recover the full cost to the Federal Government.'' A large portion of the application costs consist of **Federal Register** publication fees ($17,500, as reflected in table 1 in the proposed rule). Because we are required to publish each approved nontoxic shot application in the **Federal Register**, we will recoup these fees from each company that applies for a nontoxic shot approval.

We have examined this rule's potential effects on small entities, and have determined that it will not have a significant economic impact on a substantial number of small entities because less than one percent of small businesses would be impacted. We certify that this rule will not have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). An initial/final Regulatory Flexibility Analysis is not required. Accordingly, a Small Entity Compliance Guide is not required.

Small Business Regulatory Enforcement Fairness Act

This is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act.

a. This rule does not have an annual effect on the economy of $100 million or more. It will not change the costs for submission of shot types for approval as nontoxic.

b. This rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

c. This rule will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based

enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.), we have determined the following:

a. This rule will not ''significantly or uniquely'' affect small governments. A Small Government Agency Plan is not required. Regulation of nontoxic shot for migratory bird hunting does not affect small government activities.

b. This rule will not produce a Federal mandate of $100 million or greater in any year, so it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act. The regulation revision will not affect State regulations.

Takings

This rule does not affect private property, and has no takings implications. In accordance with Executive Order 12630, a takings implication assessment is not required.

Federalism

This rule does not have sufficient Federalism effects to warrant preparation of a Federalism assessment under Executive Order 13132. It will not interfere with the States' abilities to manage themselves or their funds. No significant economic impacts should result because of these changes to the regulation of nontoxic shot approval.

Civil Justice Reform

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act

This rule contains a collection of information that we submitted to the Office of Management and Budget (OMB) for review and approval under Sec. 3507(d) of the Paperwork Reduction Act (PRA). OMB has approved the information collection requirements associated with the approval of nontoxic shot for use in waterfowl hunting and assigned OMB Control Number 1018–0067, which expires ____. 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.

The regulations at 50 CFR 20.134 contain the following new information collection requirements:

• Application must document that a shotshell loaded with shot of the alloy can be readily identified as containing nontoxic shot with a standard field shotshell testing device. Wildlife law enforcement officers should be able to use simple, readily available testing devices for nontoxic shotshells.

• For shot types, the application must include a statement of the hardness of the candidate alloy and the method used to determine the hardness. This information will help the public decide about the type of firearm in which the shot type can be used safely.

• Required shot size and number of shot to be used in calculating the Estimated Environmental Concentrations (EECs) in terrestrial and aquatic ecosystems.

• A provision for testing loaded shotshells containing an approved shot type and revoking approval of that shot type if it is not identifiable in loaded shotshells held in the hand in the field. Slight manufacturing changes can alter the chemical and magnetic properties of an approved shot so that it cannot be detected in the field. This has created enforcement problems for law enforcement officers.

• Requirement to weigh all recovered shot and determine shot erosion.

• Specific pH level to be used in calculating the EEC in water.

We expect that the above requirements will add very little to the application preparation time or cost; therefore, we have not increased the completion time for an application. In addition to the above requirements, we move the former Tier 2 solubility testing to Tier 1. This change will allow us to better assess applications and minimize the need for Tier 2 applications.

We are adding fees for different stages of an application sufficient to offset the estimated costs associated with processing the application. We have increased our estimate of the nonhour burden cost by including the $1,630 application fee for Tier 1 applications.

Title: Approval Procedures for Nontoxic Shot and Shot Coatings, 50 CFR 20.134.

OMB Control Number: 1018–0067.

Service Form Number: None.

Description of Respondents: Businesses that produce and/or market approved nontoxic shot types or nontoxic shot coatings.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Estimated Number of Respondents: 1.

Estimated Number of Annual Responses: 1.

Estimated Completion Time per Response: 3,200 hours.

Estimated Total Annual Burden Hours: 3,200.

Estimated Total Nonhour Burden Cost: $26,630 ($1,630 for application processing fees, plus $25,000 for solubility testing).

You may send comments on any aspect of these information collection requirements to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Mail Stop 2042–PDM, Arlington, VA 22203 (mail) or *hope_grey@fws.gov* (email).

National Environmental Policy Act

We have analyzed this rule in accordance with the criteria of the National Environmental Policy Act and 516 DM. This rule does not constitute a major Federal action significantly affecting the quality of the human environment, and does not require the preparation of an environmental impact statement or an environmental assessment. The changes are largely to reorganize the regulations and put them into easier-to-understand language. Because the revision of 50 CFR 20.134 is administrative, it will have no environmental effects. It is categorically excluded from further NEPA requirements (43 CFR 46.210(i)).

Environmental Consequences of the Action

The changes are primarily in the reorganizing and rewriting of the regulations. The environmental impacts of this action are minimal.

Socio-economic. This rule will have no socio-economic impacts.

Wildlife populations. This regulations change does not significantly alter the approval of nontoxic shot in the United States. This rule will not affect wildlife populations.

Endangered and threatened species. The regulations change will not affect threatened or endangered species.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, and 512 DM 2, we have determined that there are no potential effects on federally recognized Indian tribes. This rule will not interfere with Tribes' abilities to manage themselves or their funds or to regulate migratory bird hunting on tribal lands.

Energy Supply, Distribution or Use

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. This rule will not affect energy

supplies, distribution, or use, so it does not require a Statement of Energy Effects.

Compliance With Endangered Species Act Requirements

Section 7 of the Endangered Species Act (ESA) of 1973, as amended (16 U.S.C. 1531 *et seq.*), requires that ''The Secretary [of the Interior] shall review other programs administered by him and utilize such programs in furtherance of the purposes of this chapter'' (16 U.S.C. 1536(a)(1)). It further states that the Secretary must ''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'' (16 U.S.C. 1536(a)(2)). The proposed regulations change would not affect listed species.

List of Subjects in 50 CFR Part 20

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

For the reasons discussed in the preamble, we hereby amend part 20, subchapter B, chapter I of title 50 of the Code of Federal Regulations as set forth below.

PART 20—[AMENDED]

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

Authority: 16 U.S.C. 703–712.

■ 2. Revise § 20.134, including the section heading, to read as follows:

§ 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 (ft^2)) 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 ft^2, 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/ft^2 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.

Dated: December 19, 2013.

Rachel Jacobson,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

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