1**Supporting Statement A for**
Paperwork Reduction Act Submission

Approval Procedures for Nontoxic Shot and Shot Coatings, 50 CFR 20.134
OMB Control Number 1018-0067

Terms of Clearance: **None.**

1. Explain the circumstances that make the collection of information necessary.

This information collection is associated with regulations implementing the Migratory Bird Treaty Act (MBTA; 16 U.S.C. 703-712). The MBTA prohibits the unauthorized take of migratory birds and 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 (Service, we) controls the hunting of migratory game birds through regulations at 50 CFR part 20. In 1991, we banned lead shot for hunting waterfowl and coots in the United States, because of its toxicity to migratory birds and other wildlife. At that time, steel shot was the only available nontoxic alternative. In subsequent years, we have encouraged manufacturers to develop other alternatives for hunting use. The guidelines for approving a candidate material as nontoxic for waterfowl and coot hunting are at 50 CFR 20.134. The information collection requirements found there provide the basis by which the Director of the Service approves or disapproves the nontoxic status of candidate shot materials.

We are issuing a final rule to shorten the application and approval process. We have made the following substantive changes:

- Addition of a requirement that an application for approval of a nontoxic shot must document that a shotshell loaded with the shot is readily identifiable in the hand as containing nontoxic shot when tested with magnets, rare earth magnets, or the Hot Shot® test device. This requirement is intended to simplify enforcement of the waterfowl hunting regulations.

- A requirement that an application 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.

- Amendment of the language governing determination of Estimated Environmental Concentrations (EECs) in terrestrial and aquatic ecosystems to make clear the shot size and number of shot to be used in calculating the EECs. Applicants need to know this to calculate the EECs, but it is not specified in the current regulations.

- Addition of specific pH levels to be used in calculating the EEC in water. Applicants need to know this to calculate solubilities, but it is not specified in the current regulations.

- 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.

- A requirement to weigh all recovered shot and determine shot erosion. This requirement is being added at the final rule stage. Weighing the shot and determining erosion should have been in the proposed rule, because the erosion testing is not complete without this analysis.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. If the information collected will be disseminated to the public or used to support information that will be disseminated to the public, explain how the collection complies with all applicable Information Quality Guidelines.

We collect this information only when a manufacturer submits an application for approval of a nontoxic shot or shot coating. The regulations at 50 CFR 20.134 outline the application and approval process for new types of nontoxic shot and specify what information we collect and how we use it to determine the shot material's nontoxic status. When considering approval of a candidate material as nontoxic, we must ensure that it is not hazardous in the environment and that secondary exposure (ingestion of spent shot or its components) is not a hazard to migratory birds. To make that decision, we require each applicant to collect information about the

solubility and toxicity of the candidate material. Additionally, for law enforcement purposes, a noninvasive field detection device must be available to distinguish candidate shot from lead shot. This information constitutes the bulk of an application for approval of nontoxic shot.

3. **Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden (and specifically how this collection meets GPEA requirements).**

   We encourage submission of electronic files with the application materials. In the recent past, most applicants have submitted their entire applications electronically.

4. **Describe efforts to identify duplication.**

   There are no other information collections that gather the information we need to determine the nontoxic status of a candidate shot material. Applicants may use previously collected information, thus avoiding unnecessary duplication of risk assessments, toxicity tests, and background information.

5. **If the collection of information impacts small businesses or other small entities, describe the methods used to minimize burden.**

   This collection does not significantly impact small businesses. We collect the minimum information necessary for us to determine the nontoxic status of shot material. If a small entity chooses to submit an application, we work closely with the applicant to avoid duplication and reduce the hour/dollar burden as much as possible.

6. **Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.**

   We only collect this information when an entity applies for approval

of a new nontoxic shot. If the information were not collected, we could not determine if the candidate material is nontoxic; therefore, fewer nontoxic shot materials would be available to hunters. Increased use of nontoxic shot enhances protection of migratory waterfowl and their habitats. In addition, studies show that hunter compliance with nontoxic shot requirements improves when more nontoxic shot types are available.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- *** requiring respondents to report information to the agency more often than quarterly;**
- *** requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- *** requiring respondents to submit more than an original and two copies of any document;**
- *** requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**
- *** in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- *** requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- *** that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- *** requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

There are no special circumstances that require us to conduct this collection in a manner inconsistent with OMB guidelines.

8. Provide the date and page number of publication in the *Federal Register* of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments

received in response to that notice (or in response to a PRA statement) and describe actions taken by the agency in response to these comments.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported. [Please list the names, titles, addresses, and phone numbers of persons contacted.]

On March 4, 2013, we published a proposed rule (78 FR 14060) to add or change requirements for nontoxic shot applications. We solicited comments on the information collection requirements for 30 days, ending on April 3, 2013. All comments received are discussed in the preamble of the final rule. We received the following comments on the information collection requirements:

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 currently approved 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 1iters 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 regulatory text).

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 regulatory text).

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 have added 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. We added 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. 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.).

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

We do not provide payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

There is no assurance of confidentiality. The information contained in an application is subject to the Freedom of Information Act.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

We do not ask questions of a sensitive nature.

12. Provide estimates of the hour burden of the collection of information.

Over the past 15 years, we have received an average of less than one application per year. As a placeholder for these information collection requirements, we estimate that we will receive one application per year for a total of 3,200 annual burden hours. The hour burden associated with the information collection varies with each applicant and depends significantly on how much already-available information can be applied toward a candidate material. Our hour burden estimate ranges from 80 to 6,400 hours with an average of 3,200 hours per application. The changes to the applications will not change the hour burden for applicants. Applicants have used, and need to use, the additional information

we seek, but they were not required to provide it previously.

We estimate the total dollar value of the annual burden hours to be $148,544 (3,200 hours x $46.42). Based on Bureau of Labor Statistics Occupational Employment and Wages, May 2012, the mean hourly wage for environmental scientists and specialists is $33.16. We multiplied this wage by 1.4 to account for benefits ($46.42), in accordance with BLS News Release USDL-13-1835, September 11, 2013, Employer Costs for Employee Compensation—June 2013.

13. Provide an estimate of the total annual [nonhour] cost burden to respondents or recordkeepers resulting from the collection of information.

We estimate that the total annual nonhour cost burden to respondents will be $26,630. This amount includes the final $1,630 application processing fee and $25,000 for solubility testing. We estimate that $25,000 is the average annual cost to contract out with companies that perform the tests and analyses required for approval of a nontoxic shot material.

14. Provide estimates of annualized costs to the Federal Government.

We estimate the annual cost to the Federal Government to administer this information collection will be $2,822 for salary costs. To determine salary costs, we used the Office of Personnel Management Salary Table 2012-DCB and multiplied the hourly rate for a GS-13, step 10 ($55.46) by 1.5 to account for benefits ($83 (rounded)) in accordance with USDL 13-1835.

TASK	TOTAL ANNUAL HOURS	SALARY COSTS ($83/HR)
Application Review and Consultation	9	$ 747
Prepare Draft Environmental Assessment and Final Rule	20	1,660
Prepare Final Environmental Assessment and Final Rule	5	415
Total		**$2,822**

15. Explain the reasons for any program changes or adjustments.

There are no program changes or adjustments to the number of responses or the annual hour burden. There is a program change in the nonhour cost burden due to the application fee of $1,630. We estimate the nonhour cost burden will increase from $25,000 to $26,630.

16. For collections of information whose results will be published, outline plans for tabulation and publication.

We do not publish the results of this information collection.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

We will display the OMB control number and expiration date on appropriate materials.

18. Certification.

There are no exceptions to the certification statement.