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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

RIN 1018–AU04; 1018–AU 09; 1018–AU13; 1018–AU28

Migratory Bird Hunting; Approval of Tungsten-Iron-Copper-Nickel, Iron-Tungsten-Nickel Alloy, and Tungsten-Bronze (Additional Formulation), and Tungsten-Tin-Iron Shot Types as Nontoxic for Hunting Waterfowl and Coots; Availability of Environmental Assessments

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; notice of availability.

SUMMARY: The U.S. Fish and Wildlife Service (we, us, or USFWS) proposes to approve four shot types or alloys for hunting waterfowl and coots and to change the listing of approved nontoxic shot types in 50 CFR 20.21(j) to reflect the cumulative approvals of nontoxic shot types and alloys.

These four shot types or alloys were submitted to us separately, and we published advance notices of proposed rulemakings for these shot types under RINs 1018–AU04, 1018–AU09, 1018– AU13, and 1018–AU28, respectively. We now combine all these actions under RIN 1018–AU04.

In addition, we propose to approve alloys of several metals because we have approved the metals individually at or near 100% in nontoxic shot.

DATES: Send comments on this proposal by September 23, 2005.

ADDRESSES: You may submit comments, identified by RIN 1018–AU04, by any of the following methods:

• Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

• Agency Web Site: *http:// migratorybirds.fws.gov.* Follow the links to submit a comment.

• E-mail address for comments: George_T_Allen@fws.gov. Include "RIN 1018–AU04" in the subject line of the message. Please submit electronic comments as text files; do not use file compression or any special formatting.

• Fax: 703–358–2217.

• Mail: Chief, Division of Migratory Bird Management, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Mail Stop MBSP–4107, Arlington, Virginia 22203–1610. • Hand Delivery: Division of Migratory Bird Management, U.S. Fish and Wildlife Service, 4501 North Fairfax Drive, Room 4091, Arlington, Virginia 22203–1610.

For specific instructions on submitting or inspecting public comments, inspecting the complete file for this rule, or requesting a copy of the draft environmental assessment, see Public Comments in **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Dr. George T. Allen, Division of Migratory Bird Management, 703–358–1714. SUPPLEMENTARY INFORMATION:

Background

The Migratory Bird Treaty Act of 1918 (Act) (16 U.S.C. 703-711) and the Fish and Wildlife Improvement Act of 1978 (16 U.S.C. 712) implement migratory bird treaties between the United States and Great Britain for Canada (1916, amended), Mexico (1936, amended), Japan (1972, amended), and Russia (then the Soviet Union, 1978). These treaties protect certain migratory birds from take, except as permitted under the Acts. The Acts authorize 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 controls the hunting of migratory game birds through regulations in 50 CFR part 20.

Deposition of toxic shot and release of toxic shot components in waterfowl hunting locations are potentially harmful to many organisms. Research has shown that ingested spent lead shot causes significant mortality in migratory birds. Since the mid-1970s, we have sought to identify shot types that do not pose significant toxicity hazards to migratory birds or other wildlife. We addressed the issue of lead poisoning in waterfowl in an Environmental Impact Statement in 1976, and again in a 1986 supplemental EIS. The 1986 document provided the scientific justification for a ban on the use of lead shot and the subsequent approval of steel shot for hunting waterfowl and coots that began that year, with a complete ban of lead for waterfowl and coot hunting in 1991. We have continued to consider other potential candidates for approval as nontoxic shot. We are obligated to review applications for approval of alternative shot types as nontoxic for hunting waterfowl and coots.

We have received applications for approval of four shot types as nontoxic for hunting waterfowl and coots. Those shot types are:

1. Tungsten-Iron-Copper-Nickel (TICN) shot, of 40–76 percent tungsten, 10–37 percent iron, 9–16 percent copper, and 5–7 percent nickel (70 FR 3180, January 21, 2005);

2. Iron-Tungsten-Nickel (ITN) alloys composed of 20–70 percent tungsten, 10–40 percent nickel, and 10–70 percent iron (70 FR 22625, May 2, 2005);

3. Tungsten-Bronze (TB) shot made of 60 percent tungsten, 35.1 percent copper, 3.9 percent tin, and 1 percent iron (70 FR 22624, May 2, 2005, Note: This formulation differs from the Tungsten-Bronze nontoxic shot formulation approved in 2004.); and

4. Tungsten-Tin-Iron (TTI) shot composed of 58 percent tungsten, 38 percent tin, and 4 percent iron.

The metals in these shot types have already been approved in other nontoxic shot types. In considering approval of these shot types, we were particularly concerned about the solubility and bioavailability of the nickel and copper in them. In addition, because tungsten, tin, and iron have already been approved at very high proportions of other nontoxic shot types with no known negative effects of the metals, we will propose approval of all alloys of these four metals.

The data provided to us indicate that the shot types are nontoxic when ingested by waterfowl and should not pose a significant danger to migratory birds, other wildlife, or their habitats. We conclude that they raise no particular concerns about deposition in the environment or about ingestion by waterfowl or predators.

The process for submission and evaluation of new shot types for approval as nontoxic is given at 50 CFR 20.134. The list of shot types approved as nontoxic for use in hunting migratory birds is provided in the table at 50 CFR 20.21(j). With this proposed rule, we also propose to revise the listing of approved nontoxic shot types in § 20.21(j) to include the cumulative approvals of the shot types considered in this proposed rule with the other nontoxic shot types already in the table.

Many hunters believe that some nontoxic shot types do not compare favorably to lead and that they may damage some shotgun barrels, and a small percentage of hunters have not complied with nontoxic shot regulations. Allowing use of additional nontoxic shot types may encourage greater hunter compliance and participation with nontoxic shot requirements and discourage the use of lead shot. The use of nontoxic shot for waterfowl hunting has increased in recent years (Anderson et al. 2000), but we believe that compliance will continue to increase with the availability and approval of other

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nontoxic shot types. Increased use of nontoxic shot will enhance protection of migratory waterfowl and their habitats. More important, however, is that the Fish and Wildlife Service is obligated to consider all complete nontoxic shot submissions.

We also propose to add a column to the table of approved shot types that lists the field testing device suitable for each shot type. The information in this column is strictly informational, not regulatory. Because these regulations are used by both waterfowl hunters and law enforcement officers, we believe that information on suitable testing devices is a useful addition to the table.

Affected Environment

Waterfowl Populations

The taxonomic family Anatidae, principally subfamily Anatinae (ducks) and their habitats, comprise the affected environment. Waterfowl habitats and populations in North America in 2004 were described by the U.S. Fish and Wildlife Service (Garrettson et al. 2004). In the Breeding Population and Habitat Survey traditional survey area (strata 1-18, 20–50, and 75–77), the total-duck population estimate was $32.2 \pm 0.6 (\pm 1)$ standard error) million birds, 11 percent below the 2003 estimate of 36.2 ± 0.7 million birds, and 3 percent below the 1955-2003 long-term average. Mallards (Anas platyrhynchos) were estimated at 7.4 ± 0.3 million, similar to last year's estimate of 7.9 ± 0.3 million birds and to the long-term average. Blue-winged teal (A. discors) numbered 4.1 ± 0.2 million, 26 percent below last year's estimate of 5.5 ± 0.3 million and 10 percent below the long-term average. Among other duck species, only northern shovelers (A. clypeata, $2.8 \pm$ 0.2 million) and American wigeon (A. americana, 2.0 ± 0.1 million) were both

22 percent below their 2003 estimates. As in 2003, gadwall (*A. strepera*, 2.6 \pm 0.2 million, +56 percent), green-winged teal (*A. crecca*, 2.5 \pm 0.1 million, +33 percent), and northern shovelers (+32 percent) were above their long-term averages. Northern pintails (*A. acuta*, 2.2 \pm 0.2 million, \cdot 48 percent), scaup (*Aythya affinis* and *A. marila*, 3.8 \pm 0.2 million, \cdot 27 percent), and American wigeon (\cdot 25 percent) were well below their long-term averages in 2004.

Habitats

Waterfowl hunting occurs in habitats used by many taxa of migratory birds, as well as by aquatic invertebrates, amphibians and some mammals. Fish also may be found in many hunting locations. In 2004, total May ponds in Prairie Canada, and the north-central United States combined were estimated at 3.9 ± 0.2 million, which was 24 percent lower than the figure for 2003 and 19 percent below the long-term average. Pond numbers in both Canada $(2.5 \pm 0.1 \text{ million})$ and the U. S. $(1.4 \pm$ 0.1 million) were below 2003 estimates (\cdot 29 percent in Canada, and \cdot 16 percent in the United States), and pond numbers in Canada were 25 percent below the long-term average for the region.

Fall Flight Forecasts

The projected mallard fall flight index was 9.4 ± 0.1 million birds, similar to the 2003 estimate of 10.3 ± 0.1 million. The 2004 total duck population estimate for the eastern survey area (strata 51–56 and 62–69) was 3.9 ± 0.3 million birds. This estimate was similar to the 2003 estimate of 3.6 ± 0.3 million birds, and to the 1996–2003 average. Individual species estimates for this area were similar to 2003 estimates and to 1996– 2003 averages, with the exception of American wigeon (0.1 ± 0.1 million) and goldeneyes (*Bucephala clangula* and *B. islandica*, 0.4 ± 0.1 million), which were 61 percent and 42 percent below their 1996–2003 averages, respectively, and ring-necked ducks (*Aythya collaris*, 0.7 \pm 0.2 million), which increased by 67 percent relative to the 2003 estimate of their numbers.

Characterization of the Four Shot Types

TICN Alloys

Spherical Precision, Inc. of Tustin, CA, submitted Tungsten-Iron-Copper-Nickel (TICN) shot for approval. The advance notice of proposed rulemaking for this group of alloys was published in the Federal Register on January 21, 2005, under RIN 1018-AU04 (70 FR 3180). This is an array of layered alloys or metals of 40-76 percent tungsten, 10-37 percent iron, 9–16 percent copper, and 5-7 percent nickel. TICN shot has a density ranging from 10.0 to 14.0 grams per cubic centimeter (g/cm³), is noncorrosive, and is magnetic. Spherical Precision estimates that the volume of TICN shot for use in hunting migratory birds in the United States will be approximately 50,000 pounds (lb) (22,700 kilograms (kg)) during the first year of sale, and perhaps 100,000 lb (45,400 kg) per year thereafter.

ITN Alloys

ENVIRON-Metal of Sweet Home, OR, submitted Iron-Tungsten-Nickel (ITN) alloys, which are cast alloys containing 10–70 percent iron, 20–70 percent tungsten, and 10–40 percent nickel. The advance notice of proposed rulemaking for this group of alloys published in the **Federal Register** on May 2, 2005, under RIN 1018–AU09 (70 FR 22625). The proposed shot types have densities ranging from about 8.5 to about 13.5 g/ cm³. The compositions of the alloys are shown in table 1.

TABLE 1.—COMPOSITION OF ITN SHOT ALLOYS

	Density Chat weight		Iron		Tungsten		Nickel	
Alloy	Density (g/cm ³) ¹	Shot weight (mg) ²	Percent	Weight (mg)	Percent	Weight (mg)	Percent	Weight (mg)
1	8.8	165.89	70	116.12	20	33.18	10	16.59
2	9.0	169.65	40	67.86	20	67.86	40	33.93
3	9.8	184.73	44	81.28	33	60.96	23	42.49
4	11.3	213.00	10	21.30	50	106.50	40	85.20
5	13.3	250.71	20	50.14	70	175.49	10	25.07
6	13.55	255.42	10	25.54	70	178.79	20	51.08

Note.—Weights are based on one number 4 shot.

ENVIRON-Metal estimated that the yearly volume of ITN shot types with densities between those of steel (7.86 g/ cm³) and lead (11.3 g/cm³) expected for use in hunting migratory birds in the

United States is approximately 200,000 lb (113,500 kg) during the first year of sale. In the second year and beyond, sales upwards of 500,000 lb (227,000 kg) per year are anticipated. ITN shot types with densities greater than that of lead may ultimately attain sales levels of 1,000,000 lb (454,000 kg) per year.

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TB Shot

The Olin Corporation of East Alton, IL, submitted Tungsten-Bronze (TB) shot for approval. The advance notice of proposed rulemaking for this shot type was published in the Federal Register on May 2, 2005, under RIN 1018-AU13 (70 FR 22624). This is a sintered composite with an average composition of 60 percent tungsten, 35.1 percent copper, 3.9 percent tin, and 1 percent iron. The copper and tin make up 39 percent of the shot as a 90:10 ratio, respectively, in the form of a bronze alloy. The shot has a density of 12.0 g/ cm³, compared to 11.1–11.3 g/cm³ for lead, and 7.9 g/cm³ for steel. Olin estimated that the yearly volume of the TB shot in hunting migratory birds in North America will be approximately 300,000 lb (136,200 kg).

TTI Shot

Tungsten-Tin-Iron (TTI) shot, submitted by Nice Shot, Inc., of Albion, PA, is a cast alloy composed of 58 percent tungsten, 38 percent tin, and 4 percent iron. This shot type has a density of 11.0 g/cm³. Nice Shot, Inc. estimated that approximately 5,000 lb (2,270 kg) of TTI shot are expected to be sold for use in hunting migratory birds in the United States during the first year of sale. TTI shot contains less than 1 percent lead, and will not be coated.

Each of the four shot types has a residual lead level of less than 1 percent. To inhibit corrosion, TICN shot may be coated with tin, and ITN shot may be surface-coated with thin petroleum-based films. Neither TB nor TTI shot will be coated.

Environmental Fate of the Metals in the Four Shot Types

All of the metals in these shot types have been approved in other nontoxic shot types, and the submitters asserted that the four shot types pose no adverse toxicological risks to waterfowl or other forms of terrestrial or aquatic life. Our particular concern in considering approval of these shot types is the solubility and bioavailability of the nickel and copper in them.

The metals in the four shot types are insoluble under hot and cold (Weast 1986). Neither manufacturing the shot nor firing shotshells containing the shot will alter the metals or change how they dissolve in the environment. The shot types are not chemically or physically altered by firing from a shotgun. Iron is naturally widespread. It comprises approximately 2 percent of the composition of soils and sediments in the United States. The iron in the shot types is not soluble.

Elemental tungsten and iron are virtually insoluble in water, and therefore do not weather and degrade in the environment. Tungsten is stable in acids and does not easily form compounds with other substances. Preferential uptake by plants in acidic soil suggests uptake of tungsten when it has formed compounds with other substances rather than when it is in its elemental form (Kabata-Pendias and Pendias 1984).

Elemental copper can be oxidized by organic and mineral acids that contain an oxidizing agent. Elemental copper is not oxidized in water (Aaseth and Norseth 1986).

Nickel is common in fresh waters, though usually at concentrations of less than 1 part per billion (p/b) in locations unaffected by human activities. Pure nickel is not soluble in water, and resists corrosion at temperatures between ·20 °C and 30 °C (Chau and Kulikovsky-Cordeiro 1995). Free nickel may be part of chemical reactions, such as sorption, precipitation, and complexation. "Under anaerobic conditions, typical of deep groundwater, precipitation of nickel sulfide keeps nickel concentrations low" (Eisler 1998). Reactions of nickel with anions are unlikely. Complexation with organic agents is poorly understood (U.S. Environmental Protection Agency [EPA] 1986). Water hardness is the dominant factor governing nickel effects on biota (Stokes 1988).

Tin is only very slightly soluble at pH values from 4 to 11, as found in natural settings. Tin occurs naturally in soils at 2 to 200 mg/g (parts per thousand or ppt) with areas of enrichment at concentrations up to 1,000 mg/g (WHO 1980). In general, however, soil concentrations in the United States are between 1 and 5 parts per million (p/m) (Kabata-Pendias and Pendias 1984).

Possible Environmental Concentrations for Metals in the Four Shot Types in Terrestrial Systems

Calculation of the estimated environmental concentration (EEC) of a candidate shot in a terrestrial ecosystem is based on 69,000 shot per hectare (50 CFR 20.134). These calculations assume that the shot dissolves promptly and completely after deposition.

TICN Alloys

The maximum EEC for TICN shot for tungsten in soil is 21.3 p/m. This is below the EEC for several other tungsten-based shot types that we have previously approved. We are not aware of any problems associated with those shot types. The U.S. EPA does not have a biosolids application limit for tungsten.

For TICN shot, if the shot are completely dissolved in dry, porous soil, the maximum EEC for iron is 7.40 p/m. Iron is naturally widespread, comprising approximately 2 percent of the composition of soils and sediments in the United States. The EEC for iron from TICN shot is much lower than that level.

For copper in TICN shot, the maximum EEC in soils is 3.36 p/m. In comparison, the ceiling concentration limit for biosolids application for copper is 4,300 p/m (EPA 2000).

The maximum EEC for nickel in TICN shot in soils is 1.62 p/m. This concentration is a small fraction of the EPA biosolids application limit of 420 p/m (EPA 2000).

If TICN shot is coated with tin, the EEC for tin in dry soils is 1.31 p/m. There is no EPA biosolids application limit for tin, but it occurs naturally in soils at 2 to 200 p/m, with areas of enrichment at concentrations up to 1,000 p/m (WHO 1980). In general, soil concentrations in the United States are between 1 and 5 p/m; the suggested maximum concentration in surface soil tolerated by plants is 50 p/m dry weight (Kabata-Pendias and Pendias 1984).

ITN Alloys

The terrestrial EECs for the iron and tungsten from any ITN alloy (table 2) are below those from approved shot types, and we do not believe they are a problem in soils. Though data on iron concentrations in biosolids are unavailable, natural soil background concentrations range from 5,000 to 50,000 p/m. This is equivalent to 32,500 to 325,000 kg per hectare (kg/h). We do not believe that the worst-case additional 8.01 kg of iron per hectare (about 0.025 percent of natural background concentrations) would have any effect on plants or animals, especially since the iron in the shot is not in a soluble form.

TABLE 2.—EXPECTED TERRESTRIAL ENVIRONMENTAL CONCENTRATIONS OF THE METALS	IN ITN ALLOYS
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Alloy	Shot weight (kg)	Deposition (kg)			Terrestrial EEC (p/m)			
(% I/T/N)		Iron	Tungsten	Nickel	Iron	Tungsten	Nickel	
1 (70/20/10)	11.446	8.01	2.29	1.15	12.33	3.52	1.76	
2 (40/20/40)	11.706	4.68	2.34	4.68	7.20	3.60	7.20	
3 (44/33/23)	12.746	5.61	4.21	2.93	8.63	6.47	4.51	
4 (10/50/40)	14.700	1.47	7.35	5.88	2.26	11.31	9.05	
5 (20/70/10)	17.299	3.46	12.11	1.73	5.32	18.63	2.66	
6 (10/70/20)	17.624	1.76	12.34	3.52	2.71	18.98	5.42	

Data from biosolid studies indicate that tungsten generally is present at 40 to 180 p/m, about four times the worst EEC for tungsten from ITN shot. Therefore, it is unlikely that tungsten from the shot would exceed concentrations obtained from biosolid applications.

The estimated soil concentration (p/m soil) of nickel for ITN alloy 4 (the highest in nickel) is a very small fraction of the 420 p/m maximum concentration allowed for terrestrial application of biosolids and is two orders of magnitude less than the maximum cumulative loading rate for nickel of 420 kg/h per year (*http:// www.epa.gov/cgi-bin/claritgw*). We do not believe that nickel from ITN shot would pose an environmental problem in soils.

TB Shot

Based on the maximum concentration of each metal in any formulation of TB shot, the increased concentrations in soils for the metals are 14.4 p/m for tungsten, 8.43 p/m for copper, 0.94 p/m for tin, and 0.24 p/m for iron. The EEC for tungsten is lower than the value for ITN shot, and considerably lower than the values for previously approved shot types. As noted earlier, the ceiling concentration limit for biosolids application for copper is 4,300 p/m (EPA 2000). The EEC for iron from TB shot is extremely small.

TTI Shot

The EEC for tungsten in TTI shot in soil (the increase in soil concentration) is 12.77 mg/kg or p/m. This is below the EEC for several other tungsten-based shot types that we have previously approved. We are not aware of any problems associated with those shot types. The EPA does not have a biosolids application limit for tungsten. Data from biosolid studies indicate that tungsten generally is present at 40 to 180 p/m, about four times the worst EEC for tungsten from ITN shot. Therefore, it is unlikely that tungsten from the shot would exceed concentrations obtained from biosolid applications.

The EEC for tin in dry soils is 8.37 p/m. In general, soil concentrations in the United States are between 1 and 5 p/m; the suggested maximum concentration in surface soil tolerated by plants is 50 p/m dry weight (Kabata-Pendias and Pendias 1984), about six times the worst-case concentration to be expected from TTI shot.

If the shot are completely dissolved in dry, porous soil, the maximum EEC for iron is 0.88 p/m. Iron is naturally widespread, comprising approximately 2 percent of the composition of soils and sediments in the United States. The EEC for iron from TTI shot is much lower than that level.

Though data on iron concentrations in biosolids are unavailable, natural soil background concentrations range from 5,000 to 50,000 p/m. This is equivalent to 32,500 to 325,000 kg per hectare. We do not believe that the extremely small addition of the insoluble iron from TTI shot would have any effect on plants or animals, especially because the iron in the shot is not in a soluble form.

Possible Environmental Concentrations for Metals in the Four Shot Types in Aquatic Systems

The EEC for water assumes that 69,000 number 4 shot are completely dissolved in 1 hectare of water 1 foot (ft) (30.48 cm) deep. The submitter then calculates the concentration of each metal in the shot if the shot pellets dissolve completely. For our analyses, we assume complete dissolution of the shot type containing the highest proportion of each metal in the range of alloys submitted.

TICN Alloys

For TICN shot, the EEC for tungsten is 4.541 milligrams per liter (mg/l). The EPA has set no acute or chronic criteria for tungsten in aquatic systems.

The EEC for iron from TICN shot in water is 1.579 mg/l. The chronic water quality criterion for iron in fresh water is 1 mg/l (EPA 1986). EPA has no criterion for salt water.

For copper, the aquatic EEC is 0.717 mg/l. This value is above both the acute and chronic criteria for freshwater and saltwater. This issue is discussed in the "In Vitro Solubility Evaluation of TICN Shot" section.

The aquatic EEC for nickel from TICN shot is 0.346 mg/l. The EPA (1986) acute criterion for nickel in fresh water is 1,400 micrograms per liter (μ g/l); the chronic criterion is 160 μ g/l. The acute and chronic criteria for salt water are 75 and 8.3 μ g/l, respectively. Based on the EEC, the maximum release of nickel from TICN shot would be well below the fresh water acute criterion for protection of aquatic life.

For the tin in TICN shot, the aquatic EEC is 0.280 mg/l. The lowest published standard for tin in water is the 4 mg/l water quality standard for the state of Minnesota. Even in the worst case, the tin concentration from dissolved TICN shot would be well below this standard.

ITN Alloys

The aquatic EECs for the metals in ITN shot are shown in table 3. The EEC for nickel exceeds aquatic water quality criteria (table 4). However, corrosion studies demonstrated that corrosion rates for all types of ITN shot are relatively low in both fresh water and seawater. This corrosion is discussed under "In Vitro Solubility Evaluation of ITN Shot."

TABLE 3.—EXPECTED AQUATIC ENVIRONMENTAL CONCENTRATIONS OF THE METALS IN ITN ALLOYS

Alloy	Shot weight (kg)	Deposition (kg)			Aquatic EEC (p/m)			
(% I/T/N)		Iron	Tungsten	Nickel	Iron	Tungsten	Nickel	
1 (70/20/10)	11.446	8.01	2.29	1.15	2,629	751	376	
2 (40/20/40)	11.706	4.68	2.34	4.68	1,536	768	1,536	
3 (44/33/23)	12.746	5.61	4.21	2.93	1,840	1,380	962	
4 (10/50/40)	14.700	1.47	7.35	5.88	482	2,411	1,929	
5 (20/70/10)	17.299	3.46	12.11	1.73	1,135	3,973	568	
6 (10/70/20)	17.624	1.76	12.34	3.52	578	4,048	1,156	

TABLE 4.—AQUATIC LIFE CRITERIA AND WORST-CASE CONCENTRATIONS OF METALS IN ITN SHOT

Metal	Acute water quality criterion for aquatic life (μg/l)	Chronic water quality criterion for aquatic life (μg/l)	Maximum EEC from ITN alloys
	No Criterion 1,400	1,000 No Criterion 160 8.3	, (- ,)

TB Shot

The aquatic EECs for metals in TB shot are shown in table 5. The EEC for

copper is considerably above the criteria for protection of fresh water and salt water life. However, a solubility study for this shot type demonstrated that corrosion of TB shot is low. This is discussed under "In Vitro Solubility Evaluation of TB Shot."

TABLE 5.—AQUATIC LIFE CRITERIA AND CONCENTRATIONS OF METALS IN TB SHOT

Metal	Acute water quality criterion for aquatic life (μg/l)	Chronic water quality criterion for aquatic life $(\mu g/l)$	Maximum EEC from TB shot
Tungsten Copper (Fresh Water) Copper (Salt Water) Tin Iron	No Criterion 13.0 4.8 4,0001 ¹ No Criterion	No Criterion 9.0 3.1 No Criterion 1,000	3,073 1,797 1,797 199.7 51.2

¹ Minnesota water quality standard, no federal standard for comparison.

TTI Shot

The EEC for tungsten is 2.72 milligrams per liter (mg/1). The EPA has set no acute or chronic criteria for tungsten in aquatic systems.

The aquatic EEC for tin is 1.78 mg/1. The lowest published standard for tin in water is the 4 mg/1 water quality standard for the state of Minnesota. Tin concentration from dissolved TTI shot would be well below this standard.

The EEC for iron from TTI shot in water is 0.19 mg/1. The chronic water quality criterion for iron in fresh water is 1 mg/1 (EPA 1986). EPA has no criterion for salt water.

In Vitro Solubility Evaluation of TICN Shot

When nontoxic shot is ingested by waterfowl, both physical breakup of the shot, and dissolution of the metals that comprise the shot, may occur in the highly acidic environment of the gizzard. In addition to the standard Tier 1 application information, Spherical Precision provided the results of an in vitro gizzard simulation test conducted to quantify the release of metals in solution under the prevailing pH conditions of the avian gizzard. The metal concentrations released during the simulation test were, in turn, compared to known levels of metals that cause toxicity in waterfowl. The evaluation followed the methodology of Kimball and Munir (1971) as closely as possible. The average amount of copper and nickel released from eight TICN shot per day are 1.87 mg and 1.77 mg, respectively.

The maximum tolerable level of dietary copper during the long-term growth of chickens (*Gallus domesticus*) and turkeys (*Meleagris* species) has been reported to be 300 p/b (Committee on Mineral Toxicity in Animals (CMTA) 1980). At the maximum tolerable level for chronic exposure of 300 ppb for poultry, a 1.8 kg chicken consuming 100 g of food per day (Morck and Austic 1981) would consume 30 mg copper per day (16.7 mg of copper per kg of body weight per day). The average amount of copper released from eight TICN shot is 1.87 mg per day, which is well below concentrations that cause copper toxicosis in waterfowl. A bird would have to ingest 129 TICN shot to exceed the maximum tolerable level.

No reproductive or other effects were observed in mallards that consumed the equivalent of 102 mg of nickel as nickel sulfate each day for 90 days (Eastin and O'Shea 1981). Therefore, the average amount of nickel released from eight TICN shot/day of 1.77 mg will pose no risk of adverse effects to waterfowl. Additionally, metallic nickel likely has a lower absorption from the gastrointestinal tract than does the nickel sulfate used in the mallard reproduction study, further decreasing the absorbed dose of TICN shot compared to the published toxicity study described above.

We concluded that TICN shot is very resistant to degradation, and that it poses no risk to waterfowl if ingested in the field. The slow breakdown rate of 49546 Federal Register/Vol. 70, No. 163/Wednesday, August 24, 2005/Proposed Rules

1.53 mg per shot per day only permits the release of 0.233 mg of copper and 0.221 mg of nickel per shot per day, both of which are concentrations that are orders of magnitude below toxic levels of concern for copper and nickel in waterfowl.

In Vitro Solubility Evaluation of ITN Shot

Fresh water, seawater, and an "artificial gizzard" environment (Kimball and Munir, 1971) were evaluated to determine their corrosion rates on each of the six alloys, plus steel as a standard. The "artificial gizzard" test, although developed for lead alloy evaluation, proved to reliably simulate the mallard gizzard for both steel and ITN alloys and constitutes a very conservative approach for evaluation of nontoxic shot. This test resulted in corrosion/erosion rates up to twice those measured in steel and Tungsten-Nickel-Iron mallard in-vivo studies (January 4, 2001, 66 FR 737).

The ITN alloys with relatively low concentrations of tungsten and nickel corrode in a manner similar to that of steels. Corrosion rates of such steels are roughly linear over a wide range of exposure time. This corrosion is in contrast with that of alloys such as stainless steel, tungsten-nickel iron, or

"high-alloy" varieties of ITN, which readily form passivating oxide layers that impede further corrosion. Assuming that the short-term rate of shot weight loss would continue for one month in a static aqueous environment (a conservative assumption, because natural fresh water and seawater environments are dynamic, and because corrosion products forming on metal surfaces tend to progressively retard corrosion rates), the actual EECs are presented in table 6. These data show that the nickel concentration from ITN shot actually will be well below both the acute and chronic criteria for nickel in aquatic settings.

TABLE 6.- ENVIRONMENTAL CONCENTRATIONS OF METALS IN ITN SHOT BASED ON SOLUBILITY TESTING

Alloy (% I/T/N)		Fresh Water EEC (µg/l)			Salt Water EEC (µg/l)		
		Tungsten	Nickel	Iron	Tungsten	Nickel	
1 (70/20/10)	27.16	7.76	3.87	3.36	0.97	0.23	
2 (40/20/40)	1.95	0.97	1.95	0	0	0	
3 (44/33/23)	12.61	9.69	6.70	10.66	7.99	2.60	
4 (10/50/40)	1.45	7.27	5.82	0	0	0	
5 (20/70/10)	6.79	23.77	3.40	2.72	20.37	2.90	
6 (10/70/20)	0	0	0	0	0	0	

ENVIRON-Metal also provided the results of an in-vitro gizzard simulation test conducted to quantify the release of metals in solution under the prevailing pH conditions of the avian gizzard (table 7). These data also demonstrate that the hazards from these alloys to wildlife would be very minimal.

TABLE 7.—METAL LOSS FROM ITN ALLOYS IN A SIMULATED GIZZARD OVER A 14-DAY PERIOD.

	Initial weight of 10	V				
Alloy (% I/T/N)	number 4 shot (g)	Iron	Tungsten	Nickel	Percent weight loss	
1 (70/20/10)	1.994	179.90	51.40	25.70	12.9	
2 (40/20/40)	2.687	64.00	32.00	64.00	5.9	
3 (44/33/23)	2.766	72.60	54.45	37.95	5.9	
4 (10/50/40)	3.479	13.10	65.50	52.40	3.7	
5 (20/70/10)	3.462	18.80	65.80	9.40	2.7	
6 (10/70/20)	3.418	19.40	135.80	38.8	5.7	

In Vitro Solubility Evaluation of TB Shot

The EEC for copper EEC was over 138 times the freshwater acute criterion of 13 g/l, and 200 times the freshwater chronic criterion of 9.0 g/l. However, Olin noted that the very conservative assumptions used to calculate the copper EEC are only an indication of the likely effect of deposition of TB shot in an aquatic setting. Therefore, as an addendum to the application for TB shot, Olin had an in-vitro dissolution test in water conducted. The test was conducted to quantify the release of metals from TB shot at pH values of 5.6, 6.6, and 7.6 in synthetic buffered waters. The highest EEC for copper from

the dissolution evaluations was $0.15 \mu g/l$ at pH 5.6. The hardness-adjusted chronic water quality criterion for copper was $9.7 \mu g/l$, approximately 65 times the worst-case EEC. Therefore, detrimental effects in aquatic systems from dissolution of TB shot would be highly unlikely.

Olin provided the results of an invitro gizzard simulation test conducted to quantify the release of metals in solution under the prevailing pH conditions of the avian gizzard. The simulation test demonstrated that a number 4 TB shot would release about 0.67 mg of the alloy per day. This, in turn, would mean release of approximately 0.24 mg of copper per day.

Olin pointed out that the theoretical availability of copper from this in-vitro gizzard simulation test should be considered maximal when compared to the Irby et al. (1967) study results or the CMTA (1980) guideline. Unlike the invivo gizzard, which resembles an open corrosion system in which the products of the corrosion process are constantly being eliminated (Kimball and Munir 1971), the test design for this in-vitro gizzard simulation was a closed corrosion system. Therefore, fine pieces of shot that would be released, and normally discarded from the gizzard, remained in the dissolution medium and potentially yielded more copper. Additionally, the analytical samples were analyzed for total metals with no

filtration or centrifugation prior to analysis. As a result, the fine pieces of shot that were not fully dissolved and would normally be excreted were included in the total copper concentrations reported.

Summary: Solubility Evaluations

We have previously approved as nontoxic other shot types that contain tungsten, iron, and tin. Previous assessments of nontoxic shot types indicated that the potential release of iron, tungsten, or tin from TICN, ITN, or TB shot should not harm aquatic or terrestrial systems and we believe the small amount of tin in TB shot is not likely to harm waterfowl. The solubility testing further indicates that the release of nickel from ITN shot and copper from TICN or TB shot is not sufficient to present a hazard to aquatic systems or to biota. We propose to approve the four shot types as nontoxic. Our approval is based on the toxicological report, acute toxicity studies, reproductive/chronic toxicity studies, and other published research. The available information indicates that the four shot types are nontoxic when ingested by waterfowl and that they pose no significant danger to migratory birds, other wildlife, or their habitats.

Impacts of Approval of the Four Shot Types

Effects of the Metals

Iron

Iron is an essential nutrient. Iron toxicosis in mammals is primarily a phenomenon of overdosing of livestock. Maximum recommended dietary levels of iron range from 500 p/m for sheep to 3000 p/m for pigs (National Research Council [NRC] 1980). The amount of iron in any of the four shot types would not pose a hazard to mammals.

Chickens require at least 55 p/m iron in the diet (Morck and Austic 1981). There were no ill effects on chickens fed 1,600 p/m iron in an adequate diet (McGhee et al. 1965), and chicks tolerated 1,600 p/m iron in the diets that included adequate copper, although decreased weight gains and increased mortality were observed in copperdeficient diets (McGhee et al. 1965). At the maximum tolerable level for chronic exposure of 1,000 p/m for poultry (NRC 1980), a 1.8 kg chicken consuming 100 grams of food per day (Morck and Austic 1981) would consume 100 mg iron per day (56 mg per kg of body weight per day)

Deobald and Elvehjem (1935) reported that 4,500 p/m iron in the diet produced rickets in chicks. Adverse effects were not observed when turkey poults were fed diets amended with 440 p/m iron (Woerpel and Balloun 1964).

Turkey poults fed 440 p/m in the diet suffered no adverse effects. The tests, in which eight number 4 tungsten-iron shot were administered to each mallard in a toxicity study indicated that the 45 percent iron content of the shot had no adverse effects on the test animals (Kelly *et al.* 1998).

We are not aware of acute toxicity data for iron in waterfowl. Zinc-coated iron shot appeared to have little or no effect on ducks dosed with eight number 6 shot; mortality and weight loss for treated ducks were comparable to those for control animals (Irby *et al.* 1967).

Game-farm mallards administered eight number 4 pellets of tungsten-iron shot, indicated no adverse effects from either the tungsten or the iron (Kelly *et al.* 1998). This shot formulation has a much greater iron content (45 percent) than do the shot types considered here.

Tungsten

Tungsten salts are toxic to mammals. Lifetime exposure to 5 p/m tungsten as sodium tungstate in drinking water produced no discernible adverse effects in rats (Rattus species) (Schroeder and Mitchener 1975). However, with 100 p/ m tungsten as sodium tungstate in drinking water, rats had decreased enzyme activity after 21 days (Cohen *et al.* 1973).

Tungsten may be substituted for molybdenum in enzymes in mammals. Ingested tungsten salts reduce growth, and can cause diarrhea, coma, and death in mammals (e.g. Bursian et al. 1996, Cohen et al. 1973, Karantassis 1924, Kinard and Van de Erve 1941. National Research Council 1980, Pham-Huu-Chanh 1965), but elemental tungsten is virtually insoluble and therefore essentially nontoxic. Tungsten powder added to the food of young rats at 2, 5, and 10 percent by mass for 70 days did not affect health or growth (Sax and Lewis 1989). A dietary concentration of 94 p/m did not reduce weight gain in growing rats (Wei et al. 1987). Exposure to pure tungsten through oral, inhalation, or dermal pathways is not reported to cause any health effects (Sittig 1991).

Acute tungsten toxicosis results in death from respiratory paralysis, often preceded by diarrhea and coma. Chronic intoxication is most evident in reduced growth rates. However, the most sensitive sign is reduced xanthine oxidase activity. Xanthine oxidase is an enzyme that is dependent upon molybdenum for proper functioning. It is thought that tungsten readily substitutes for molybdenum, with subsequent reduction in enzyme activity; supplemental dietary molybdenum will reverse the symptoms. The National Research Council Committee on Animal Nutrition recommends a maximum tolerable dose of 20 p/m tungsten in the diet for effective rearing of livestock (NRC 1980).

The LD50 of tungsten as sodium tungstate (Na_2WO_4) administered by intraperitoneal injection is 112 p/b body weight in male rats and 79 p/b body weight in mice (Mus species) (Pham-Huu-Chanh 1965). This would classify tungsten as "very toxic" when administered intraperitoneally as a soluble salt. Kinard and Van de Erve (1941) showed that Na_2WO_4 is the most toxic tungsten salt, when compared with tungsten oxide and ammonium paratungstate.

Tungsten administered in the diet had no effects on rats until reaching 150 p/ m diet when carcinoma incidence was increased in female Sprague-Dawley rats (Wei et al. 1987). Higgins et al. (1956a, b) noted that dietary concentrations of 45 or 94 p/m tungsten produced no adverse effects on weight gain in growing rats. Other studies with rats indicate that dietary exposure to 5,000 p/m tungsten oxide (WO₃) or Na₂WO₄ results in 90 percent and 80 percent mortality, respectively, by the 70th day of exposure (NRC 1980). However, lifetime exposure of rats to 5 p/m tungsten as Na₂WO₄ in drinking water resulted in no observable adverse effects (Schroeder and Michener 1975). At 100 p/m tungsten as Na₂WO₄ in drinking water, rats had decreased enzyme activity after 21 days of exposure (Cohen et al. 1973).

Goats (Capra hircus) appear to be less tolerant of dietary tungsten. A 5-month exposure to 22.5 p/m dietary tungsten as Na_2WO_4 resulted in depressed liver xanthine oxidase activity in growing kids. Milk production in goats and cows (Bos species) was unaffected by a single oral exposure to 25.0 p/b body weight of Na_2WO_4 (Owen and Proudfoot 1968). Anke and Groppel (1985) established that goats require at least 0.06 p/m tungsten in their diets for optimal reproduction.

Chickens given a complete diet showed no adverse effects of 250 p/m sodium tungstate administered for 10 days in the diet. However, 500 p/m in the diet reduced xanthine oxidase activity and reduced growth of day-old chicks (Teekell and Watts 1959). Adult hens had reduced egg production and egg weight on a diet containing 1,000 p/m tungsten (Nell *et al.* 1981). Ecological Planning and Toxicology (1999) concluded that the No Observed Adverse Effect Level for tungsten for chickens should be 250 p/m in the diet; the Lowest Observed Adverse Effect Level should be 500 p/m. Kelly *et al.* (1998) demonstrated no adverse effects on mallards dosed with tungsten-iron or tungsten-polymer shot according to nontoxic shot test protocols.

Breeder hen exposure to 250 p/m tungsten as sodium tungstate for 10 days had no adverse effects, but increasing the diet to 500 p/m tungsten for an additional 20 days resulted in decreased xanthine oxidase activity (Teekell and Watts 1959). Similarly, day-old chicks on a 500 p/m tungsten diet with adequate molybdenum showed reduced rate of gain (Selle 1942).

Nell *et al.* (1981) fed laying hens diets containing 1,000 p/m tungsten (unspecified salt) for five months; control diets contained 0.4 p/m tungsten. Hens were artificially inseminated and eggs were collected and set weekly. Three of 40 hens on the high-tungsten diet died, and the remaining 37 had reduced egg production and egg weight. Egg fertility and hatchability were not affected. Liver tungsten was significantly elevated in treated birds, although there was no effect on body weight.

Day-old white leghorn chickens placed on a molybdenum-deficient diet for 35 days showed a decreased rate of growth and increased mortality at 45 p/m tungsten as sodium tungstate (Higgins *et al.* 1956a, b). However, this is not an accurate reflection of tungsten toxicity because low molybdenum levels potentiate the effects of tungsten (NRC 1980).

Ecological Planning and Toxicology (1999) concluded that the No Observed Adverse Effect Level (NOAEL) for tungsten for chickens should be 250 p/m in the diet; the Lowest Observed Adverse Effect Level should be 500 p/m. An adult chicken fed a diet of 1,000 p/m tungsten for 150 days would ingest about 100 mg of tungsten per day, or a total of 15 grams. In the USFWS guidelines for a reproduction study for shot, mallards would receive eight number 4 shot on four dosing periods. A total of 32 TICN shot during the course of the study, each containing 0.2006 grams of tungsten, would result in a total exposure of 6.42 grams of tungsten, if the tungsten in the shot is totally dissolved. This estimated exposure of 6.42 grams of tungsten during a TICN shot mallard reproductive study is about 43 percent of the 15 grams demonstrated to cause reproductive effects in chickens.

The effects of ingestion of tungsten by mallards as elemental metal in a shot pellet were studied by Ringelman *et al.*

(1993). Birds were given pellets of 39 percent tungsten, 44.5 percent bismuth, and 16.5 percent tin by weight, per bird. No evidence of toxicity or other histological changes were reported. Tungsten was not detected in liver or kidney tissue.

Dosing mallards with eight number 4 Iron-Tungsten shot (with 55 percent tungsten) also produced no tungsten toxicity in the ducks (Kelly et al. 1998). In that study, birds received eight number 4 pellets by oral gavage and were observed for changes in serum enzymes, organ weights, histology of tissues and accumulation of metals in bone. Tungsten was detected in femur, liver, and kidneys of dosed ducks, but no other significant changes were measured. Iron-Tungsten shot eroded by 55 percent and Tungsten-Polymer shot eroded by 80 percent over the course of the study; however, tissue concentrations were lower in the Tungsten-Polymer birds than in the Iron-Tungsten group. The shot were 55 percent tungsten for the Iron-Tungsten formulation and 95.5 percent tungsten for the polymerized shot. The amount of tungsten in TICN shot (40-76 percent) is similar to that in the Iron-Tungsten shot (55 percent). Tungsten-Nickel-Iron shot in the study by Ecotoxicology & Biosystems Associates, Inc. (2000), conducted with a proportion of tungsten similar to that in TICN shot, was not toxic.

Kraabel *et al.* (1996) surgically embedded tungsten-bismuth-tin shot in the pectoralis muscles of ducks to simulate wounding by gunfire and to test for toxic effects of the shot. The shot produced no toxic effects nor induced adverse systemic effects during the 8week study.

Copper

Copper is a dietary essential for all living organisms. In most mammals, ingestion of one TICN shot pellet would result in release of 8 to 25 mg of copper, not all of which would be absorbed. In humans, ingestion of a pellet could mobilize approximately 8 mg of copper. These low levels of copper would not pose any risk to mammals.

Copper requirements in birds may vary depending on intake and storage of other minerals (Underwood 1971). The maximum tolerable level of dietary copper during the long-term growth of chickens and turkeys is 300 p/m (CMTA 1980). Eight-day-old ducklings were fed a diet supplemented with 100 p/m copper as copper sulfate for eight weeks. They showed greater growth than controls, but some thinning of the caecal walls (King 1975). Studying day-old chicks, Poupoulis and Jensen (1976) reported that no gizzard lining erosion could be detected in chicks fed 125 p/m of copper for four weeks, but they detected slight gizzard erosion in chicks fed 250 p/m copper. The authors found that it required 500 to 1,000 p/m of copper to depress growth and weight gain of chicks. Jensen *et al.* (1991) found that 169 p/m copper in the diet produced maximal weight gain in chickens.

Stevenson and Jackson (1979) studied the influence of dietary copper addition on the body mass and reproduction of mature domestic chickens. Hens fed on a diet containing 250 p/m copper for 48 days showed a similar rate of food intake as control hens that had no copper in their diet. Additionally, the mean number of eggs laid daily did not differ between hens fed 250 p/m copper and the controls. After 4 months of being fed at dietary copper levels in excess of 500 p/m, negative effects on the daily food intake, body mass loss, and egg-laying rates were observed.

At the 300 p/m level for chronic exposure for poultry, a 1.8 kg chicken consuming 100 g of food per day (Morck and Austic 1981) would consume 30 mg of copper per day (16.7 mg of copper per kg of body weight/day). One number 4 TICN shot contains a maximum of 31.7 mg of copper. However, at the 0.233 mg of copper per shot per day release rate from the solubility testing, a bird would have to ingest at least 128 TICN shot to exceed the maximum tolerable level. Thus, the copper release from the TICN shot appears to be well below the level that could cause copper toxicosis in waterfowl. The average amount of copper released from 8 TB nontoxic shot per day is 7.87 mg, so a bird would have to ingest over 30 shot to exceed the maximum tolerable level.

Day-old poults fed diets containing 500 p/m ration for 24 weeks showed reduced growth and increased gizzard histopathology (Kashani et al. 1986). Growing domestic turkeys showed no long-term effects when fed 300 p/m copper in the daily diet, but 800 p/m of copper in the diet for 3 weeks inhibited growth with no adverse effects on survival (Supplee 1964). No effect of feeding 400 p/m of copper as copper sulfate to turkey poults in the daily diet for 21 weeks was reported, and it was concluded that poults could tolerate 676 p/m of copper without deleterious effects. Growth was reduced in poults fed 800 p/m and 910 p/m of copper over the same time (Vohra and Kratzer 1968). Their conclusion was supported by another study that found that copper in the diet of domestic turkeys had to rise to 500 to 750 p/m level before signs of slight toxicity appeared, assuming that

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adequate methionine also was present (Christmas and Harms 1979).

Henderson and Winterfield (1975) reported acute copper toxicity in 3week-old Canada geese (Branta canadensis) that had ingested water contaminated with copper sulfate. The authors calculated the copper intake to be about 600 mg copper sulfate/kg body weight, or 239 mg copper/kg. The amount of copper released from eight number 4 shot would be 42.26 mg, which is much less that the 239 p/b toxic level.

Irby *et al.* (1967) dosed 24 Mallard ducks with 8 number 6 pure copper shot to observe if they were toxic over a 60day exposure period. They calculated that the total mass of copper in the gizzard was 0.6 gram, and observed that none of the ducks died from copper toxicosis after 60 days. TB shot is 35.1 percent copper by weight, so eight shot would contain 0.64 grams of copper.

International Nontoxic Composites, Inc. (2003) reported that pure copper control shot breaks down at the rate of 18.42 mg copper per gram of shot per day, or 11.05 mg copper per day for 0.6 grams of copper shot, under in vitro gizzard simulation test conditions. However, TB shot releases only 4.35 mg copper per gram of shot per day or 7.87 mg of copper per day for 1.81 grams of shot under the same test conditions. This indicates that TB shot should not be a hazard for wildlife that consume it.

The EPA (2002) provided both acute and chronic freshwater quality criteria for copper, which are functions of water hardness. The freshwater acute criterion for a water body with hardness of 100 mg/l, for example, is 13 μ g/l, and the chronic criterion is 9.0 μ g copper per liter. The EPA acute and chronic saltwater quality criteria are not affected by hardness, and are 4.8 and 3.1 μ g/l.

Nickel

Deficiencies have been reported in diets ranging from 2 to 40 billion p/b nickel (NRC 1980). The dietary requirement for nickel has been set at 50 to 80 p/b for the rat and chick (Nielsen and Sandstead 1974). Humans consume up to 900 µg per day as a normal dietary intake (Nieboer et al. 1988). Though it is necessary for some enzymes, nickel competes with zinc, calcium, and magnesium for binding sites on most of the metal-dependent enzymes, resulting in various levels of inactivation, although it is essential for functioning of some enzymes, particularly urease (Andrews et al. 1988, Nieboer et al. 1988). Water-soluble nickel salts are poorly absorbed from the gastrointestinal tract, averaging only 3

percent to 6 percent assimilation efficiency in rats (Nieboer *et al.* 1988).

Rats fed nickel carbonate concentrations up to 1,000 p/m for 3 to 4 months did not show treatmentrelated effects, nor was body weight of pups affected (Phatak and Patwardhan 1950). Elevated nickel concentrations in pups were observed in the 500 and 1,000 p/m treatment groups. Young rats were fed nickel catalyst (finely divided nickel suspended in vegetable oil and supported on kieselguhr) at 250 p/m for 16 months with no effects (Phatak and Patwardhan 1952).

Rats fed 1,000 p/m nickel sulfate for 2 years exhibited mild effects, such as reduced body weight and liver weight, but increased heart weight (Ambrose *et al.* 1976). Also, there was an increase in the number of stillborn pups and a decrease in weanling weights through three generations. Nickel chloride was most toxic to rats. Young rats decreased food consumption and lost body weight within 13 days in diets containing 1,000 p/m nickel as nickel chloride (Schnegg and Kirchgessner 1976).

Calves showed weight loss and decreased feed intake, organ size, and nitrogen retention when fed 1,000 p/m nickel and nickel carbonate for 8 weeks (O'Dell et al. 1970a, 1971). Calves fed 250 p/m nickel did not show effects. Lactating dairy cows were not affected by 50 or 250 p/m dietary nickel (Årchibald 1949, O'Dell et al. 1970b). Soluble nickel salts are very toxic to mammals, with an oral LD50 of 136 p/ b in mice, and 350 p/b in rats (Fairchild et al. 1977). Nickel catalyst (finely divided nickel in vegetable oil) fed to young rats at 250 p/m for 16 months, however, produced no detrimental effects (Phatak and Patwardhan 1952).

Water-soluble nickel salts are poorly absorbed if ingested by rats (Nieboer *et al.* 1988). Nickel carbonate caused no treatment effects in rats fed 1,000 p/m for 3 to 4 months (Phatak and Patwardhan 1952). Rats fed 1,000 p/m nickel sulfate for 2 years showed reduced body and liver weights, an increase in the number of stillborn pups, and decrease in weanling weights through three generations (Ambrose *et al.* 1976). Nickel chloride was even more toxic; 1,000 p/m fed to young rats caused weight loss in 13 days (Schnegg and Kirchgestiner 1976).

In chicks from hatching to 4 weeks of age, 300 p/m nickel as nickel carbonate or nickel acetate in the diet produced no observed adverse effects, but concentrations of 500 p/m or more reduced growth (Weber and Reid 1968). A diet containing 200 p/m nickel as nickel sulfate had no observed effects on mallard ducklings from 1 to 90 days of age. Diets of 800 p/m or more caused significant changes in physical condition of the ducklings (Cain and Pafford 1981).

Mallard ducklings fed 1,200 p/m nickel as nickel sulfate from 1 to 90 days of age experienced reduced growth rates, tremors, paresis, and death (71 percent within 60 days) (Cain and Pafford 1981). Weights of ducklings receiving 200 and 800 p/m nickel were not significantly different than controls, but the humerus weight/length ratio, a measure of bone density, was significantly lower than controls among females in the 800 p/m group and all birds in the 1,200 p/m group. There was no mortality in the 200 and 800 p/m groups.

Breeding pairs of mallards were fed diets containing 0, 12.5, 50, 200, and 800 p/m nickel as nickel sulfate for 90 days (Eastin and O'Shea 1981). No treatment-related effects were observed on egg production, hatchability, or survival of ducklings. At the end of the 90-day treatment period, there were no significant differences in hematocrit, concentrations of hemoglobin, plasma triglycerides, cholesterol, or plasma activities of ornithine carbamoyl transferase and alanine aminotransferase. The only treatmentrelated observation was a black, tarry feces in the 800 p/m group. Assuming a mean daily consumption of 128 grams per bird (Heinz 1979), the 800 p/mtreatment group would have consumed 102 mg nickel each day and 9.2 grams of nickel during the course of the 90-day study. In the nontoxic shot Tier 2 approval process, birds could be given eight number 4 shot. For ITN shot, each shot would contain 0.02206 grams of nickel, so each duck would receive 0.176 grams of nickel, assuming complete solubilization of the nickel from the shot during the study. This is a very small fraction of the 9.2 grams of total nickel exposure or 102 mg per day experienced by the mallards in the Eastin and O'Shea (1981) study. Therefore, we expect no effect of the nickel on birds ingesting the shot.

No reproductive or other effects were observed in mallards consuming the equivalent of 102 mg of nickel as nickel sulfate each day for 90 days (Eastin and O'Shea 1981). Therefore, the 15.3 mg of nickel in each TICN shot, if completely eroded and absorbed in 24 hours, would not be expected to affect waterfowl. Based on the 0.221 mg of nickel per shot per day rate of release from the solubility study, a mallard would have to ingest in excess of 450 TICN shot to exceed the 102 mg nickel amount. Additionally, metallic nickel likely has a lower absorption from the 49550

gastrointestinal tract than does the nickel sulfate used in the mallard reproduction study, further decreasing the absorbed dose of TICN shot compared to the published toxicity study described above.

Adult mallards dosed with eight tungsten-nickel-iron number 4 pellets were fed a whole kernel corn and grit and observed for signs of toxicity for 30 days following dosing (January 4, 2001; 66 FR 737). No adverse effects were observed on body weight, food consumption or clinical chemistry, hematology, and histopathology. The tungsten-nickel-iron pellets lost an average of 7.9 percent of their initial weight during the study, releasing nickel at a rate of 1.85 mg per day per bird, for a total of 55.5 mg over the 30day study.

In a Tier 2 dosing study under the regulations governing approval of nontoxic shot, mallard ducks would each be given eight number 4 TICN shot (each containing 0.02206 grams of nickel) during the study. A duck would be exposed to 0.176 grams of nickel during the study if the nickel were completely dissolved. This is much less than the nickel exposure experienced by the mallards in the Eastin and O'Shea (1981) study. We conclude that the nickel in TICN shot will not be significant to waterfowl that ingest the shot.

Water hardness is the dominant factor governing nickel effects on aquatic biota (Stokes 1988). Toxicity of nickel to aquatic organisms is dependent upon water hardness, pH, and organic content, as well as other minor environmental parameters (Allen and Hansen 1996). In soft water, as little as 7 p/b nickel may be acutely toxic to fish fry, while in harder waters toxicity thresholds may be an order of magnitude higher (Stokes 1988).

The EPA (1986) acute water quality criteria reflect this insensitivity of aquatic organisms to nickel. For a water body with hardness of 50 mg/l (generally associated with highly oligotrophic systems that would not support large numbers of waterfowl), the criterion is 1,400 μ g/l. However, early fish life stages are more sensitive to nickel (Stokes 1988), which is reflected in the order of magnitude lower Freshwater Chronic Criterion of 160 μ g/l at a hardness of 50 mg/l (EPA 1986).

The saltwater chronic criterion of 8.3 μ g/l is much lower than the measured mysid shrimp (Mysidopsis bahia) chronic value, which is from the only chronic saltwater study in the EPA guidelines (EPA 1986).

Toxicity of nickel to aquatic organisms is dependent upon water hardness, pH, and organic content, as well as other minor environmental parameters (Allen and Hansen 1996). In soft water, as few as 7 p/b may be acutely toxic to fish fry, but in harder waters toxicity thresholds may be an order of magnitude higher. General toxicity ranges for aquatic organisms are as variable, with an acute toxicity of as low as 82 μ g/l for some oligochaetes to 138,000 µg/l for some gastropods; chronic toxicity values range from fewer than 100 µg/l for some green algae to $10,000 \mu g/l$ for filamentous algae (Stokes 1988)

The freshwater criterion maximum concentration is dependent on hardness. For a water body with hardness of 50 mg/l (generally associated with highly oligotrophic systems that would not support large numbers of waterfowl), this results in a criterion of 1,400 μ g/l. However, because early fish life stages are more sensitive to nickel, the freshwater chronic criterion is 160 μ g/l at a hardness of 50 mg/l (EPA 1986).

Tin

It is generally agreed that inorganic tin and tin compounds are comparatively harmless (Eisler 1989). Inorganic tin and its salts are poorly absorbed, their oxides are relatively insoluble, and they are rapidly lost from tissues (see Eisler 1989 for reviews). Reviews indicate that elemental tin is not toxic to birds (Cooney 1988, Eisler1989). Tin shot designed for waterfowl hunting is used in several European countries. We are aware of no reports that suggest that tin shot causes toxicity problems for wildlife.

Tin (II) chloride was toxic to juvenile eels at 6.0 mg/l and 1.2 mg/l, with death coming at 2.8 and 50 hours, respectively. This inorganic tin salt was also toxic to daphnids, at concentrations of 2.5 mg/l or more. Metelev *et al.* (1971) found that 1 g/l of Tin (II) chloride dihydrate (530 mg of tin per liter) was lethal to all fish species tested (Bandman 1993).

Grandy *et al.* (1968) and the Huntingdon Research Centre (1987) conducted 30-day and 28-day, respectively, acute toxicity tests on mallard ducks by placing tin pellets inside the digestive tract or tissues of ducks. They reported that all treated ducks survived without deleterious effects.

Ringelmann *et al.* (1993) examined the effects of Tungsten-Bismuth-Tin shot consumption in ducks. The authors found no signs of toxicosis, and tin was not detected in the liver or kidney (<6 p/m) during the 32-day test period. In a 30-day dosing study of game-farm mallards dosed with eight number 4 size tin shot, there were no overt signs of toxicity or treatment-related effects on body weight. Tin was not detected in any tissues (Gallagher *et al.* 1999).

The 2 percent tin in bismuth-tin shot produced no toxicological effects in ducks during reproduction. It did not affect the health of ducks, the reproduction by male and female birds, or the survival of ducklings over the long term (Sanderson *et al.* 1997).

Chronic and acute studies documenting the nontoxic properties of 99.9 percent tin shot were conducted for the application for USFWS approval of tin shot as a nontoxic alternative. A 150day chronic toxicity/reproductive study conducted for tin shot revealed no adverse effects in mallards dosed with eight number 4 sized shot. Additionally, there were no significant changes in egg production, fertility, or hatchability of birds dosed with tin when compared to steel-dosed birds. A 30-day acute study was also completed by the International Tin Research Institute (Federal Register 64:17308, 1999). Treatment mallards were dosed with eight number 4 tin shot and hematocrit and hemoglobin concentrations, body weight and indications of toxicity were compared to those of control (no shot) and steel shotdosed birds. No adverse effects were seen in ducks dosed with tin. Hematocrit and hemoglobin concentrations did not differ from those of either negative control group, nor were there treatment-related effects on body weight. Ducks dosed with tin exhibited no sign of toxicity

In a study by Kraabel *et al.* (1996), shot pellets containing 39 percent tungsten, 44.5 percent bismuth, and 16.5 percent tin were embedded into the breast muscle of mallards. There were no adverse systemic effects observed in the study and the localized inflammatory reactions surrounding the shot were reduced in the tin-containing shot when compared to the steel shot control group.

Based on the toxicological report and toxicity tests, we concluded that shot that was 99.9 percent tin posed no significant danger to migratory birds or other wildlife and their habitats (65 FR 76886, December 7, 2000). Temporary approval was given because field detection techniques had not been approved, not due to any toxicity concerns. In support of the nontoxic application, chronic and acute toxicity tests demonstrated no adverse effects of tin shot on mallards. We do not believe the tin in any of the proposed shot types that contain it will pose toxicological risks due to wildlife.

Impacts of Approval of Alloys of Previously Approved Metals

We propose to extend the past approvals of some nontoxic shot types to broader alloys. We have, for example, approved nontoxic shot of almost 100 percent tungsten, and steel shot is essentially 100 percent iron. We are not aware of any synergistic effects of these metals, and approval of other shot types containing them in different proportions has indicated that negative effects on wildlife, fish, or their habitats from approval of alloys of these metals are very unlikely. Therefore, we propose to approve alloys containing any proportion of tungsten and 1 percent or more iron.

Similarly, as noted above, we gave temporary approval to shot of 100 percent tin (65 FR 76885), though the submitter did not seek final approval of that shot type. We also propose to approve shot alloys with any proportions of tungsten and tin and at least 1 percent iron.

Effects of the Approvals on Migratory Waterfowl

Approving additional nontoxic shot types will likely result in a minor positive long-term impact on waterfowl and wetland habitats. Approval of the four shot types and additional alloys as nontoxic would have a positive impact on the waterfowl resource.

Effects on Endangered and Threatened Species

The impact on endangered and threatened species of approval of the four shot types and the additional alloys would be very small, but positive. The metals in all four shot types and the additional alloys have been approved in other nontoxic shot types, and we see no potential effects on threatened or endangered species due to approval of these shot types.

Effects on Ecosystems

Previously approved shot types have been shown in test results to be nontoxic to the migratory bird resource, and we believe that they cause no adverse impact on ecosystems. There is concern, however, about noncompliance and potential ecosystem effects. The use of lead shot has a negative impact on wetland ecosystems due to the erosion of shot, causing sediment/soil and water contamination and the direct ingestion of shot by aquatic and predatory animals. Though we believe noncompliance is of concern, approval of the four shot types and the additional alloys will have little impact on the resource.

Cumulative Impacts

We foresee no negative cumulative impacts of approval of the four shot types and the additional alloys for waterfowl hunting. Their approval should help to further reduce the negative impacts of the use of lead shot for hunting waterfowl and coots.

Literature Cited

For a complete list of the literature cited in this proposed rule, contact the person listed under FOR FURTHER INFORMATION CONTACT.

Public Comments

In accordance with the Administrative Procedures Act and our nontoxic shot approval regulations, we seek comments on this proposal. Of particular relevance is information regarding the potential impacts of these shot types and the approval of alloys of metals already approved in other formulations on migratory birds, other wildlife, and their habitats.

In addition, Executive Order 12866 requires each agency to write regulations that are easy to understand. We invite comments on how to make this rule easier to understand, including answers to questions such as the following: (1) Are the requirements in the rule clearly stated? (2) Does the rule contain technical language or jargon that interferes with its clarity? (3) Does the format of the rule (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity? (4) Would the rule be easier to understand if it were divided into more (but shorter) sections? (A "section" appears in bold type and is preceded by the symbol "§" and a numbered heading; for example, "§ 20.134 Approval of nontoxic shot types.") (5) Is the description of the rule in the SUPPLEMENTARY INFORMATION section of the preamble helpful in understanding the rule? What else could we do to make the rule easier to understand?

You may submit written comments on this proposal to the location identified in the ADDRESSES section, or you may submit electronic comments to the internet address or the e-mail address listed in the ADDRESSES section. We must receive your comments before the date listed in the DATES section. While our normal practice is to open public comment periods on our proposed rules for 60 days, in this case we are opening the comment period for only 30 days. We believe a 30-day comment period will be sufficient because we have approved several other nontoxic shot types through the rulemaking process and have received very few comments

on those rulemaking actions and because the changes in this proposed rule should not be controversial. Following review and consideration of comments, we will issue a final rule on the proposed regulation changes.

When submitting electronic comments, please include your name and return address in your message, identify it as comments on the nontoxic shot proposed rule, and submit your comments as an ASCII file, preferably as part of the e-mail text. Include RIN 1018–AU04 in the subject line of your message. Do not use special characters or any encryption. Written comments on this proposed rule must be on 8¹/₂-inch by 11-inch paper.

We make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. In some circumstances, we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish us to withhold your name or address, you must state this prominently at the beginning of your comment. We will not accept anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety. Comments will become part of the Administrative Record for the review of the application. You may inspect comments at the mailing address in ADDRESSES during normal business hours.

The Draft Environmental Assessment (DEA) for approval of the four shot types is available from the Division of Migratory Bird Management, U.S. Fish and Wildlife Service, 4501 North Fairfax Drive, Room 4091, Arlington, VA 22203–1610. You may call 703–358– 1825 to request a copy of the DEA.

The complete file for this rule is available, by appointment, during normal business hours at the same address. You may make an appointment at 703–358–1825 to review the files.

Required Determinations

NEPA Consideration

In compliance with the requirements of section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(C)), and the Council on Environmental Quality's regulations for implementing NEPA (40 CFR 1500– 1508), though all of the metals in these shot types have been approved in other shot types and are not likely to pose adverse toxicity effects on fish, wildlife, their habitats, or the human environment, we have prepared Draft Environmental Assessments for this action. We will finalize the Environmental Assessments before we publish a final rule on this action.

Endangered Species Act Considerations

Section 7 of the Endangered Species Act (ESA) of 1972, as amended (16 U.S.C. 1531 et seq.), provides that Federal agencies shall "insure that any action authorized, funded or carried out * * * is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of (critical) habitat." We have concluded that because all of the metals in these shot types have been approved in other shot types and will not be available to biota in significant amounts due to use of any of the four shot types, this action will not affect endangered or threatened species.

Executive Order 12866

This rule is not a significant regulatory action subject to Office of Management and Budget (OMB) review under Executive Order 12866. This rule will not have an annual economic effect of \$100 million or more or adversely affect an economic sector, productivity, jobs, the environment, or other units of government. Therefore, a cost-benefit economic analysis is not required. This action will not create inconsistencies with other agencies' actions or otherwise interfere with an action taken or planned by another agency. No other Federal agency has any role in regulating nontoxic shot for migratory bird hunting. The action is consistent with the policies and guidelines of other Department of the Interior bureaus. This action will not materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients because it has no mechanism to do so. This action will not raise novel legal or policy issues because the Service has already approved several other nontoxic shot types.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires the preparation of flexibility analyses for rules that will have a significant economic impact on a substantial number of small entities, which include small businesses, organizations, or governmental jurisdictions. This rule proposes to approve four additional types of nontoxic shot that may be sold and used to hunt migratory birds. We have determined, however, that this rule will have no effect on small entities since the approved shot merely will supplement nontoxic shot types already in commerce and available throughout the retail and wholesale distribution systems. We anticipate no dislocation or other local effects, with regard to hunters and others.

Small Business Regulatory Enforcement Fairness Act

This proposed rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule will not have an annual effect on the economy of \$100 million or more; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and does 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.

Paperwork Reduction Act

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. We have examined this regulation under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501) and found it to contain no new information collection requirements. OMB has assigned control number 1018-0067 to the collection of information that shot manufacturers are required to provide to us for the nontoxic shot approval process. This approval expires December 31, 2006. For further information, see 50 CFR 20.134.

Unfunded Mandates Reform

We have determined and certify pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.*, that this rulemaking will not significantly or uniquely affect small governments or produce a Federal mandate of \$100 million or more in any given year. Therefore, this rule does not constitute a significant regulatory action under the Unfunded Mandates Reform Act.

Civil Justice Reform—Executive Order 12988

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

Takings

In accordance with Executive Order 12630, this rule, authorized by the Migratory Bird Treaty Act, does not have significant takings implications and does not affect any constitutionally protected property rights. This rule will not result in the physical occupancy of property, the physical invasion of property, or the regulatory taking of any property. A takings assessment is not required.

Federalism Effects

This rule does not have a substantial direct effect on fiscal capacity, change the roles or responsibilities of Federal or State governments, or intrude on State policy or administration. In accordance with Executive Order 13132, this regulation does not have significant federalism effects, nor does it have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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) and 512 DM 2, we have determined that this rule has no effects on Federally recognized Indian tribes.

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 propose to amend part 20, subchapter B, chapter I of Title 50 of the Code of Federal Regulations as follows:

PART 20-[AMENDED]

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

Authority: 16 U.S.C. 703–712; 16 U.S.C. 742a–j; Pub. L. 106–108.

2. Section 20.21 is proposed to be amended by revising paragraph (j)(1) to read as follows:

§ 20.21 What hunting methods are illegal?

(j)(1) While possessing loose shot for muzzle loading or shotshells containing other than the following approved shot types.

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Approved shot type	Percent composition by weight	Field testing device
bismuth-tin	97 bismuth, 3 tin	Hot Shot®*.
iron (steel)	iron and carbon	Magnet or Hot Shot [®] .
iron-tungsten	any proportion of tungsten, ≥ 1 iron	Magnet or Hot Shot [®] .
iron-tungsten-nickel.	1 iron, any proportion of tungsten, up to 40 nickel	Magnet or Hot Shot®.
tungsten-bronze	51.1 tungsten, 44.4 copper, 3.9 tin, 0.6 iron and 60 tungsten, 35.1 copper, 3.9 tin, 1 iron.	Rare Earth Magnet.
tungsten-iron-copper-nickel.	40–76 tungsten, 10–37 iron, 9–16 copper, 5–7 nickel	Hot Shot [®] or Rare Earth Magnet.
tungsten-matrix	95.9 tungsten, 4.1 polymer	Hot Shot [®] .
tungsten-polymer	95.5 tungsten, 4.5 Nylon 6 or 11	Hot Shot [®] .
tungsten-tin-iron	any proportions of tungsten and tin, \geq 1 iron.	Magnet or Hot Shot [®] .
tungsten-tin-bismuth	49–71 tungsten, 29–51 tin; 0.5–6.5 bismuth, 0.8 iron.	Rare Earth Magnet.
tungsten-tin-iron-nickel	65 tungsten, 21.8 tin, 10.4 iron, 2.8 nickel	Magnet.

* The information in the "Field Testing Device" column is strictly informational, not regulatory. ** The "Hot Shot" field testing device is from Stream Systems of Concord, CA.

* * *

Dated: July 26, 2005.

Craig Manson,

Assistant Secretary for Fish and Wildlife and Parks. [FR Doc. 05-16718 Filed 8-23-05; 8:45 am]

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