
Part III

Environmental Protection Agency

40 CFR Part 745

Lead **Fishing Sinkers**; Response to Citizens' Petition and Proposed Ban;
Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 745
[OPPTS-62134; FRL-4643-3]
RIN 2070-AC21

Lead **Fishing Sinkers**; Response to Citizens' Petition and Proposed
Ban

AGENCY: Environmental Protection Agency (EPA).
ACTION: Proposed rule.

SUMMARY: On October 20, 1992, the Environmental Defense Fund (EDF), Federation of Fly Fishers, Trumpeter Swan Society, and North American Loon Fund petitioned EPA under section 21 of the Toxic Substances Control Act (TSCA), and the Administrative Procedure Act (APA), to initiate rulemaking proceedings under section 6 of TSCA to require that the sale of lead **fishing sinkers** be accompanied by an appropriate label or notice warning that such products are toxic to wildlife. EPA granted the petition; however, the Agency believes that a labeling provision would not adequately address the risk of injury to waterfowl and other birds (waterbirds), from ingestion of lead **fishing sinkers**. In addition, EPA also believes that zinc **fishing sinkers** adversely affect waterbirds, and can cause mortality. Therefore, EPA is proposing this rule under section 6(a) of TSCA to prohibit the manufacturing, processing, and distribution in commerce in the United States, of certain smaller size **fishing sinkers** containing lead and zinc, and mixed with other substances, including those made of brass. The Agency also requests that persons with information relevant to the issues outlined in this document submit that information to EPA.

DATES: Written comments in response to this proposed rule must be received by May 9, 1994. If persons request time for oral comment, EPA will hold an informal hearing in Washington, DC. The exact date, time, and location of the hearing, if held, will be announced in the Federal Register. For further information regarding the hearing, see Unit XV. of this preamble.

ADDRESSES: Comments should be submitted in triplicate to: TSCA Docket

Receipt (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-G99, 401 M St., SW., Washington, DC 20460, Attention: Docket No. 62134. For information regarding the submission of comments containing information claimed as confidential business information (CBI), see Unit XIV. of this preamble.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Rm. E-545, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554-1404, TDD: 202-554-0551.

SUPPLEMENTARY INFORMATION:

I. Authority

If EPA determines that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture of chemical substances, or that any combination of such activities, presents or will present an unreasonable risk of injury to human health or the environment, section 6(a) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(a), authorizes EPA to apply one or more of the following requirements to such substance or mixture to the extent necessary to protect against the risk: (1) Prohibit or limit the amount of a chemical substance or mixture manufactured, processed, or distributed in commerce; (2) prohibit or limit the amount of chemical substance or mixture manufactured, processed, or distributed in commerce for particular uses or at particular concentration levels; (3) require labeling or warning rules; (4) require manufacturers and processors to make and retain records of the process used to manufacture or process a chemical substance or mixture, and to conduct tests to monitor compliance with regulatory requirements; (5) prohibit or otherwise regulate any manner or method of commercial use; (6) prohibit or otherwise regulate any manner or method of disposal of such substance or mixture or articles containing such substance or mixture; (7) require that manufacturers notify the public of unreasonable risk associated with a chemical substance or mixture, and to replace or repurchase the product. Section 6 of TSCA requires EPA to apply the least burdensome requirements to protect adequately against the risk. Section 6(a)(2)(A) of TSCA, prohibiting the manufacturing, processing, or distribution in commerce of a chemical substance or mixture for a particular use or at a particular concentration level, provides EPA the authority to issue this proposed rule. Section 8(a)(1) of TSCA gives EPA authority to require persons who manufacture or process chemical substances and mixtures to maintain records for manufacturing purposes, including records necessary for effective enforcement of TSCA requirements.

Section 12(a) of TSCA exempts from regulation under the Act any chemical substance, mixture, or article containing a chemical substance or mixture that is manufactured, processed, or distributed in commerce solely for export and bears or is enclosed in a container bearing a stamp or label stating that is intended for export. However, this exemption does not apply to any of the situations enumerated in TSCA section 12(b), nor to any recordkeeping requirements promulgated pursuant to TSCA section 8.

Section 12(b) of TSCA requires that any person who exports or intends to export a chemical substance or mixture for which a rule has been proposed or promulgated under section 6 must notify EPA of such exportation or intent to export.

II. Background

A. TSCA Section 21

Any person may petition EPA under section 21(a) of TSCA to initiate proceedings for the issuance, amendment, or repeal of a rule or order under section 4, 5, 6, or 8 of TSCA. As required by section 21(b), the petition must set forth the facts which the petitioner claims establish that it is necessary for the Agency to issue, amend, or repeal a rule

or order under those sections of TSCA. Section 21(b) also directs EPA to decide either to grant or deny the petition within 90 days after a petition is filed. If EPA denies a petition, the Agency must publish the reasons for the denial in the Federal Register. If the Agency grants the petition, EPA must promptly commence an appropriate proceeding in accordance with section 4, 5, 6, or 8 of TSCA.

B. Petition Claims and Request

EPA received a petition under TSCA section 21 and the APA on October 20, 1992, from the EDF, Federation of Fly Fishers, Trumpeter Swan Society, and North American Loon Fund requesting EPA to initiate rulemaking proceedings under section 6 of TSCA to require that the sale of lead **fishing sinkers** be accompanied by an appropriate label or notice warning that such products are toxic to wildlife (Ref. 5). The petition claims that trumpeter swans and common loons are dying from ingestion of lead **fishing sinkers**. The petition did not specify the particular type, shape, or size of lead **fishing sinkers** that are the source of the problem, therefore requiring a label or warning notice. The petitioners also submitted a letter to the Agency on December 10, 1992, which reported that a Mississippi Sandhill Crane was discovered dead on the Mississippi Sandhill Crane National Wildlife Refuge in 1992, and a flat, well-worn object was recovered from its gizzard (Ref. 6). The letter also stated that a necropsy of the bird revealed a lead concentration of 69 parts per million (ppm) (wet weight) in the liver, and in response to an inquiry to the Fish and Wildlife Service (FWS) about the nature of that object, EDF was advised that it was a lead **fishing sinker** (Ref. 6).

C. Summary of Studies Cited in Petition

The petition cited a number of studies which reported mortality in trumpeter swans, mute swans, and common loons due to ingestion of lead **fishing sinkers**. The petitioners also cited a recent bulletin from the FWS reporting that an immature Mississippi sandhill crane died from lead poisoning (Ref. 19).

1. Common loons (*Gavia immer*). A 2.5 year study of mortalities of common loons in New England found that lead toxicity from ingested **fishing sinkers** was the most common cause of death in adult breeding birds (Ref. 13). The study reported that 64 percent of adult common loons (*Gavia immer*) received for analysis from New Hampshire, and 44 percent of adults received from Maine, had ingested **fishing sinkers**. Thirty-one adults were examined, and of these, 16 (52 percent) were shown to have died from lead poisoning. The authors of the study concluded that due to adverse effects on breeding adults, lead poisoning may be an important factor in limiting loon populations in some areas.

Levels of lead found in the blood of loons that had ingested **sinkers** averaged 1.4 ppm. The study indicated that scientists consider 0.35 to 0.60 ppm lead in the blood to be indicative of lead poisoning in many species. Levels of lead in the livers of 4 loons that had lead **sinkers** in their gizzards ranged from 5.03 to 18.0 ppm, while levels in 10 loons that did not have **fishing sinkers** in their gizzards ranged from <0.05 to 0.11 ppm. The study also states that 5 or 6 ppm in the liver is considered a toxic level in waterbirds. Toxic effects of lead to loons were found to be similar to those seen in other waterbirds.

Lead poisoning was diagnosed as the cause of death in 7.3 percent of common loons necropsied (total of 7 adult loons) in a Minnesota study (Ref. 4). Five of the seven lead poisoned birds contained lead **sinkers**. Lead concentrations in the liver of the loons ranged from 7.12 to 35 ppm, wet weight. Although the incidence of lead **sinkers** was low in all necropsied birds, it is relatively high in relation to those birds found to have died from lead poisoning. In addition, only those birds whose body condition during necropsy indicated potential lead poisoning were actually analyzed for lead. Therefore, the incidence of lead poisoning in the study could be an underestimate of the actual number of loons exposed to lead **sinkers** and suffering from lead

poisoning in Minnesota.

The petitioners also cited a case report involving three common loons found dead in New Hampshire, Wisconsin, and Maine that were submitted to a wildlife health laboratory for necropsy (Ref. 12). Two adult loons died of lead poisoning (lead liver levels were 20.6 ppm and 46.1 ppm), and a lead **fishing** sinker was found in each bird. One of these loons had ingested an oval shaped lead **fishing** sinker which measured 5 mm by 4 mm (or roughly 1/5 inch) in size. The third loon had a lead liver level of 38.52 ppm and three fragments of a **fishing** line were found in the loon's stomach.

Results from necropsies conducted on 222 common loon carcasses from 18 States submitted to the National Wildlife Health Research Center from 1975 through 1991 were also cited in the petition received by EPA (Ref. 10). Lead poisoning was responsible for 14 (6 percent) common loon deaths. Eleven of these birds had **fishing sinkers** in their gizzards (Ref. 17). Post mortem examinations, or necropsies performed on the loons that died from lead poisoning indicated that although the lead **sinkers** differed in shape and length, the largest reported diameter was 7 mm, or approximately 1/4 inch (Ref. 17). These data also revealed that two common loons ingested what appeared to be lead jigs (weighted hooks used for **fishing**).

While not listed as a threatened or endangered species under the Federal Endangered Species Act (ESA), 16 U.S.C. 1531, common loons are listed as an endangered or threatened species in some New England States (Ref. 5).

2. Trumpeter swans (*Cygnus buccinator*). Mortality due to lead poisoning was investigated for 72 trumpeter swans found dead in 7 western States (Ref. 2). Ingestion of lead pellets or **fishing sinkers** accounted for approximately 20 percent of the known deaths in Idaho, Montana, and Wyoming, and nearly 50 percent in western Washington. The maximum lead concentration in livers of swans found dead was 37 ppm (wet weight). Concentrations of 3 to 4 ppm expressed as wet weight in livers was considered by various researchers to be toxic to birds. Four swans were diagnosed to have signs of lead poisoning due to ingestion of **fishing** weights. The four birds ingested a total of eight lead **fishing sinkers**. The study postulated that trumpeter swans are particularly susceptible to lead poisoning because they feed by digging up large amounts of bottom sediments of streams and lakes, and ingesting large amounts of plant material in this manner.

3. Mute swans (*Cygnus olor*). Two studies were cited that examine mortality in mute swans, a species introduced into the United States that is similar to trumpeter swans. In the first study, lead **fishing** weights were found (an average of 11 per bird, one bird contained 43) in the gizzards of 16 out of 18 (88 percent) mute swans found dead or dying along the Trent River in England (Ref. 16). The mean concentration of lead in the kidney of these swans was 1,734 ppm dry weight. The area along the river where they fed was heavily contaminated with lead **fishing** split shot.

Mute swans were also examined along the Thames River in another study (Ref. 1). Out of 94 dead swans examined, 57 percent, or 53 were shown to have died from ingesting **fishing** weights. The average number of lead **sinkers** found in the gizzards of these swans was seven. The median lead level in the liver of these swans was 105 ppm dry weight and 908 ppm dry weight in the kidney.

4. Mississippi sandhill crane (*Grus canadensis pulla*). The petitioners also submitted a FWS technical bulletin which reported that a Mississippi sandhill crane, a Federally endangered species, was found dead on the Mississippi Sandhill Crane National Wildlife Refuge in 1992 due to lead poisoning (Ref. 19). The lead concentration in the crane's liver was 69.41 ppm wet weight (Ref. 18). The object found in the gizzard resembled lead, was triangular in shape although flattened, and approximately 8 by 10 mm, or approximately 1/2 inch in size (Ref. 18). Although a definitive identification of the object was not made, based on the size and shape of the object, the bird may have ingested a lead **fishing** sinker.

D. Summary of EPA Response to Petition and EDF Lawsuit

EPA granted the petition on January 14, 1993 (Ref. 22). After reviewing the petition, the accompanying studies, and other information gathered by EPA, the Agency preliminarily determined that certain lead **fishing sinkers** present an unreasonable risk of injury to waterbirds, and that rulemaking under section 6(a) of TSCA to ban the manufacture, processing, and distribution in commerce of certain lead **sinkers** would be necessary to protect against that risk. EPA informed EDF by letter on March 11, 1993, that it was planning to issue a proposed rule to address these concerns (Ref. 23).

Despite EPA's expressed intent to issue a proposed rule to address the risks posed by certain lead **fishing sinkers**, including regulatory options more stringent than the labeling requested in the petition, EDF sued EPA on March 15, 1993, in the U.S. District Court for the District of Columbia, alleging EPA's failure to promptly publish a notice of proposed rulemaking under section 6 of TSCA (Ref. 8).

EPA subsequently informed EDF that, as an outgrowth of developing the proposed rule, EPA's preliminary analysis indicated that not only were lead **fishing sinkers** toxic to waterbirds, but that **sinkers** made of some other materials likely to be used as substitutes for lead in **sinkers** might also present unreasonable risks to waterbirds (Ref. 24). EPA also indicated that to analyze these other risks adequately, the schedule for proposal would be delayed until January 1994.

Based on EPA's commitment to utilize its best efforts to issue a proposed rule by January 14, 1994, to ban lead in certain **fishing sinkers**, EPA and EDF filed a joint motion for continuance with the U.S. District Court, requesting suspension of all legal proceedings until late January 1994 (Ref. 9). The court granted this motion and ordered the parties to submit a joint status report to the court by January 21, 1994 (Ref. 20).

In accordance with EPA's regulations for issuing a regulation under section 6 of TSCA, 40 CFR part 750, EPA is now proposing this rule under section 6(a) of TSCA to address unreasonable risk of injury to waterbirds (such as the trumpeter swan, common loon, and sandhill crane). This rule as proposed would prohibit the manufacture (including import), processing, and distribution in commerce of certain size lead- and zinc-containing **fishing sinkers** for use in the United States. The manufacture, processing, and distribution in commerce of these lead- and zinc-containing **fishing sinkers** solely for export would not be prohibited.

In granting the petition, EPA agreed to examine the appropriateness and feasibility of a TSCA section 6(a)(3) labeling requirement requested by the petitioners. However, EPA believes that a labeling provision would not adequately reduce the unreasonable risk of injury from lead- and zinc-containing **fishing sinkers** to waterbirds. EPA believes that a label would not result in a sufficient decline in consumer purchases of lead- or zinc-containing **fishing sinkers** such that waterbirds would be adequately protected. EPA also believes that since **fishing sinkers** typically become deposited in the environment accidentally, (i.e., even when carefully handling or using **fishing sinkers**, they may be accidentally lost or discarded into the environment), labels would have little effect on how **sinkers** are used in practice and would not significantly affect the environmental risks of using **sinkers**.

EPA also considered a number of other regulatory options, however, the Agency does not believe those options would adequately reduce the unreasonable risk of injury to waterbirds. A further discussion of all options considered, including EPA's determination why labeling would be minimally effective in this case, can be found in Unit VI. of this preamble.

If EPA finds that a final TSCA section 6 rule is warranted after evaluation of the public comments received, the Agency will use its best effort to promulgate such a regulation within 3 years of this proposed rule.

E. Summary of EPA's Analysis and Proposed Rule

EPA based this proposed regulatory action on a number of factors such as the scientific evidence regarding the toxicity of lead and zinc, exposure to **fishing sinkers**, the economic consequences of the rule as proposed, and availability of substitutes. These factors are discussed further in Units III., IV., and V. of this preamble.

Extremely low amounts of lead and zinc adversely affect waterbirds. Lead causes damage to the liver, kidney and central nervous system, and adversely affects reproduction and growth in waterbirds. Zinc is also toxic to waterbirds and can damage the central nervous system.

Studies have shown that exposure to both lead and zinc can cause death in waterbirds. Ingestion of a small sinker can result in the death of a waterbird. Various species have died from ingestion of lead **fishing sinkers** such as sandhill cranes, trumpeter, mute, and tundra swans, and common loons found in different areas of the United States.

Waterbirds may ingest **fishing sinkers** for a number of reasons. Small **sinkers** (1 inch and under) may appear most like pieces of grit necessary to break down food, or as food items such as seeds which waterbirds ingest. Waterbirds such as swans may ingest **sinkers** as they sift through sediments, and loons may ingest **sinkers** when eating fish with attached **fishing** tackle, or pick up **sinkers** from the bottom of waterbodies. Lead **fishing sinkers** up to and including 1 inch have been found in the gizzards, or digestive tracts of waterbirds. Studies have reported cases of **sinkers** ingestion in birds found in different parts of the United States.

EPA does not believe that the use of lead- and zinc-containing **sinkers** is essential. Several available or commercially viable substitutes for lead and zinc **sinkers** exist which are less toxic to waterbirds (e.g., bismuth, tin, antimony, steel, and tungsten). The economic impact (purchase price of **sinkers**) of the proposed regulation on consumers is estimated to be less than \$4.00 for the average angler per year. This is minimal in comparison to other **fishing** expenditures such as rods, reels, licenses, etc.

The benefit of the proposed rule is measured in terms of number of **sinkers** removed from the market or reduced for exposure to waterbirds. Each sinker which does not enter the environment reduces the number of **sinkers** available for ingestion and potential waterbird mortality or death. The rule as proposed would prevent an estimated 450 million lead- and zinc-containing **fishing sinkers** from being produced each year, and potentially from entering the environment.

Not only would the proposed rule serve to reduce risks posed to waterbirds, but it would also assist in reducing human health risk to home manufacturers of lead **fishing sinkers**. While EPA has not analyzed the risks to human health due to the manufacture of lead **fishing sinkers** at home, the health effects of lead are well documented. Lead can cause learning disabilities in children, miscarriages, and may contribute to hypertension or high blood pressure. Persons who make lead **sinkers** at home may receive harmful exposures during the melting and pouring of lead through the inhalation of dust or vapors.

III. Regulatory Assessment

A. Lead

Lead is a soft, bluish metallic element mined from rock and found naturally all over the world. Its malleability, low melting point, ease of processing, abundance, low cost, density, and durability give lead good functional value. Accordingly, it has been used to manufacture, or as an ingredient in many different products including paint, gasoline, batteries, solder, and radiation shielding.

Lead affects nearly every system of the human body. While it is harmful to individuals of all ages, lead exposure is especially detrimental to children, fetuses, and women of childbearing age. Lead enters the bloodstream and may cause lead poisoning, a disease which can cause learning disabilities, interfere with growth, cause permanent hearing and visual impairment, and cause other damage to the brain and nervous system in children. In large doses, lead can cause blindness, brain damage, convulsions, and even death. Lead exposure before or

during pregnancy can affect fetal development and can cause miscarriages. In adult males, lead exposure may contribute to hypertension and infertility. Both adults and children can receive harmful exposures to lead by inhaling the fine dust or vapors produced when **sinkers** are made at home.

As indicated in Unit II. of this preamble, lead exposure may produce harmful effects and even death in wildlife as well. Lead adversely affects the function and structure of the kidney, central nervous system, bones, and production and development of blood cells in waterbirds. Exposure to lead can cause lead poisoning in waterbirds, producing convulsions, coma, and death. Waterbirds may be directly exposed to lead through ingestion of lead **fishing sinkers**.

B. Use, Production, and Distribution of Lead **Sinkers**

Lead is also used to manufacture **fishing sinkers**. **Sinkers** are used to assist in casting, and to carry the **fishing** line with attached lures and hooks to a certain depth in the water. There are no universal sizes or shapes of lead **fishing sinkers** due to differences in the type of fish being sought, the equipment being used, and the environmental conditions. However, all **sinkers** are attached in some manner to the **fishing** line, and provide weight so that the hook, bait, or lure is below the surface of the water.

The **sinkers** which may be lost or discarded in aquatic (freshwater) or terrestrial habitats vary in shape and range in weight from 1/100 of an ounce, to 8 ounces, and in size from under 1/16 inch up to 3 inches. They may be round split shot, or triangular, egg, cone, tear-drop, or elongated oval shapes. The Agency's examination focused on the types of **sinkers** used for freshwater **fishing**, which include: (1) Split shot, (2) worm weights, (3) egg **sinkers**, (4) bass casting, (5) pyramid **sinkers**, (6) rubber core, (7) pinch grip, and (8) slip shot.

EPA's evaluation also focused on **sinkers** under 2 inches in length or width regardless of weight. This size was chosen because the Agency believes this size sinker would be the largest readily ingested by waterbirds, and commonly available in the environment. It is estimated that approximately 2,500 metric tons of lead, zinc, and brass **sinkers** (over 98 percent of the volume represented by lead), an estimated 480 million **sinkers**, are manufactured each year in the United States (Support Document 2).

Split shot **sinkers**, a round sinker with a slice through a small portion of it, are estimated to account for almost half of the total lead sinker market in terms of numbers of **sinkers**. **Fishing** line is placed into this sliced area and then the sinker is ``pinched'' onto the line. The majority of lead **sinkers** produced are equal to or less than 1 inch in any dimension.

Fewer than 10 major manufacturing companies account for most of the domestic production of lead **fishing sinkers**. Production by individuals at home (home manufacturers) is estimated to be substantial. Home manufacturers buy lead ingots, which are available at retail stores or through catalogues, melt the lead, and then pour it into molds. Home manufacturers either use these **sinkers** for their personal use, or they sell these lead **sinkers** within the local area to other persons, or retailers, such as **fishing** tackle stores (Support Document 2). Home manufacture for sale is referred to as the ``cottage industry'' in this proposed rule. The majority of home manufacturers produce non-split shot **fishing sinkers**. It is estimated that between .8 and 1.6 million anglers may produce their own lead **sinkers**.

Lead **fishing sinkers** are imported into the United States in small volumes. The amount of lead **fishing sinkers** exported each year is also minimal.

Lead **fishing sinkers** are distributed from manufacturing companies to large retail establishments directly, or are furnished to a distributor who then supplies **sinkers** to smaller retailers. Distributors range from individuals to national distribution operations. A significant amount of lead **fishing sinkers** is also supplied directly to mail-order companies for purchase by individuals

through a catalogue. It is estimated that there are currently 31 million freshwater anglers nationwide.

C. EPA's Concerns

The studies cited by the petitioners are supported by other studies in showing that lead **fishing sinkers** have been ingested by a number of different species of waterbirds in various parts of the country, and have caused mortality of those birds. This is not a localized occurrence, nor has only one type of lead sinker been ingested. However, no matter the specific type of sinker, lead is toxic and produces adverse effects in avian species.

EPA recognizes that United States waterbird populations migrate to other countries and can potentially ingest **fishing sinkers** that are exported from the United States. Although EPA is concerned about adverse effects exported **sinkers** may have on migratory waterbirds, EPA does not at this time have information indicating that use of exported **fishing sinkers** poses an unreasonable risk to waterbird populations in the United States. Therefore, EPA is not taking action at this time to prohibit the export of lead- or zinc-containing **fishing sinkers**.

EPA is required under TSCA section 6 to examine substitutes when exploring regulatory actions concerning chemical substances or mixtures. In the course of its analysis, the Agency discovered that some substitute materials for lead **fishing sinkers** could also pose an unreasonable risk of injury to waterbirds. There is evidence that zinc, a material presently used in **fishing sinkers**, can cause waterbird mortality based on a study involving mallards (Support Document 1). Brass contains a notable amount of lead and zinc (as much as 8 and 20 percent by weight respectively), as well as copper, aluminum, and antimony. Due to the low concentrations at which lead and zinc produce toxic effects in waterbirds, EPA believes that brass **fishing sinkers** could also present an unreasonable risk of injury to waterbirds. EPA is concerned that unless the Agency takes action to address these other **fishing sinkers** (e.g., zinc and brass), the rule would not reduce risk sufficiently. Therefore, the Agency is proposing restrictions on all **sinkers** containing lead and zinc of a size that are ingestible by waterbirds, as a necessary measure to prevent future exposures and mortality to those species.

EPA is also concerned about potential human exposures resulting from the home manufacture of lead **fishing sinkers**. While the Agency has not characterized or determined the extent of human exposure, EPA is aware that individuals and their family members may be exposed to potentially harmful airborne lead particles or vapors while pouring lead into lead **fishing** sinker molds. As discussed previously in this unit, lead can cause learning disabilities, impaired hearing, and behavioral changes in children, and hypertension and miscarriages in adults. EPA is concerned about exposures to lead, particularly lead poisoning in young children, and in conjunction with other Federal Agencies, has established a National Lead Information Center. For more information, persons may call 1-800-LEADFYI (532-3394).

This proposed rule, if implemented, may also reduce potential human exposures. As proposed, EPA's rule would prohibit the manufacture of lead **fishing sinkers** by persons at home (home manufacturers and the cottage industry). These parties are included in the provisions of the rule because of the potential for human exposure, and because EPA believes that a lead sinker, whether manufactured at home or by a large manufacturer, presents unreasonable risks to waterbirds when discarded in the environment. The rule as proposed, would also prohibit the production of **fishing sinkers** by individuals who purchase lead shot (ammunition), and cut a groove in the shot creating a split shot **fishing** sinker. This activity would be considered processing for the purposes of the rule.

D. Hazard to Waterbirds

For more detailed discussion of the studies reviewed by EPA and utilized in the discussion presented in Units III.D. and III.E. of this

preamble, see Support Document 1 ('`Ecological Hazard and Exposure Assessment of Lead **Fishing Weights** to Birds'). Although zinc-containing and brass **fishing sinkers** are subject to the provisions of this proposed rule, they are presented here as substitutes for lead **sinkers** due to the manner in which EPA conducted its analysis. EPA's investigation examined the toxicity of substitutes and compared their toxicity to lead. Those substitutes found to be toxic (i.e., zinc and brass) are also subject to this proposed regulatory action.

1. Summary. EPA's evaluation primarily focused on routes of exposure involving direct ingestion of **fishing sinkers** by waterbirds, but also considered uptake (not ingestion) and toxicity of metals contained in **fishing sinkers** to birds and aquatic organisms in laboratory studies. EPA also examined the toxicity of lead and other sinker materials to mammalian species (rats and mice) to determine if there were additional risks to other organisms in the environment.

Based on the conclusions of EPA's analysis which examined existing studies and laboratory data, zinc, and brass (with and without lead) could potentially result in greater toxicity to aquatic organisms (fish, invertebrates and algae) than lead. Copper is also toxic to aquatic organisms, however, copper metal may be less bioavailable in the environment because it can easily bind with materials such as sediment or organic particulate matter which would serve to mitigate copper's toxicity to aquatic organisms. The toxicity of lead and zinc to aquatic organisms in freshwater may also be mitigated to some degree, although to a lesser extent than copper. Available studies indicate that other substances used in **fishing sinkers** (i.e., bismuth, tin, tungsten, steel, and antimony) are less toxic to aquatic organisms than lead.

In comparing toxicities to avian species (mainly mallard ducks), zinc, brass, tin, copper, bismuth, tungsten, steel, and antimony, would be less toxic than lead. However, zinc is toxic at very low levels, and has been shown to produce zinc intoxication, and mortality of waterbirds (mallards).

With regard to toxicity to mammals (rats and mice), bismuth, tungsten, steel, and tin are less toxic than lead, while zinc, antimony, copper, and brass, are more toxic to mammals than lead.

EPA believes that polypropylene, terpene resin putty, and iron (also potential sinker substitutes) are less toxic than lead to aquatic, avian, and mammalian species.

2. Toxicity of lead. Lead causes adverse effects to birds through a variety of aquatic and terrestrial pathways. Lead is neither beneficial nor essential to animals, and studies commonly show its metabolic effects on birds to be adverse. The metal may cause several sublethal effects such as adversely modifying the function and structure of kidney, bone, the central nervous system, and the production and development of blood cells. It produces adverse behavioral, biochemical, histopathological, neuropsychological, fetotoxic, teratogenic, and reproductive effects. Ingested lead can impair antibody production and lower numbers of white blood cells and spleen plaque-forming cells in mallards. Severe damage to the central nervous system results in stupor, convulsions, coma, and death. Other signs of lead poisoning include loss of appetite (and resulting weight loss), lethargy, weakness, emaciation, drooped wings, green liquid feces, impaired locomotion and an inability to fly, and impaired balance and depth perception. Fat deposits in the body are eventually exhausted, and there is a marked atrophy of the bird's pectoral muscles. There is a definite progression of symptoms after **sinkers** are ingested, ending in most cases in death.

After ingestion, lead **sinkers** are reduced in size and shape by dissolution in the acidic environment of the digestive system such as the stomach, as well as the physical grinding in the gizzard. Soluble toxic salts are formed that are absorbed into the circulatory system causing toxicosis, neurological, and behavioral changes, and eventual death. Once lead passes through the gut it binds to red blood cells. It is stored in bones and soft tissues, and is excreted in the bile to the small intestine and feces. Dietary deficiencies in calcium, iron, zinc, copper, vitamin E, thiamin, phosphorus, magnesium, fat, protein,

minerals, and ascorbic acid or diets low in these components, may increase absorption of lead, and thus, its toxic effects.

The level of lead in the blood of waterbirds considered toxic by most researchers is 0.5 ppm, and toxic symptoms may begin to appear at 0.2 ppm lead. The level of lead in the liver that is considered to be lethal to waterbirds is 5.0 ppm or more (3 to 4 micrograms per gram (ug/G) expressed as wet weight, or 10 to 14 ug/G expressed as dry weight).

For some sensitive species of birds, survival was reportedly reduced at lead doses of 75 to 150 ppm body weight; reproduction was affected at dietary levels of 50 ppm. Sublethal signs of lead poisoning were present at doses of 7.5 ppm body weight. Mortality in waterbirds is usually caused at dose concentrations of 20 to 40 ppm of lead in experimental studies, and lethal levels range from doses of 5 to 80 ppm of lead. In 1 study, 16 mallard ducks (11 males and 5 females) received 2 number 4 lead shot. This dose resulted in mean lead levels in the liver of 32.16 ppm (wet weight) in the males, and 13.85 ppm (wet weight) in the females, and blood lead levels of 3.47 ppm in the males, and 4.15 ppm in the females. Thus, ingesting only two lead shot can result in blood and liver levels considerably higher than those reported to be lethal.

EPA examined lead shot in its analysis because there is a substantial body of information concerning this form of lead (fate, transport, and distribution in the environment), and its toxicity may be similar in some cases to those for lead **fishing sinkers**. Younger birds and waterfowl are more susceptible to lead from shot or **sinkers** than older animals. A single shot or two swallowed with food or taken up as grit in the gizzard of birds may introduce enough lead into the bloodstream to be fatal. Based on this information, EPA scientists believe that a single **fishing** sinker which is usually larger and typically contains much more lead than a single shot, could be fatal to waterbirds. Death of waterbirds follows exposure to lethal amounts of lead by an average of 2 to 3 weeks. During this time, affected birds become less mobile, are limited in their ability to forage for food and seek cover, tend to avoid other birds, and, as a result, become increasingly susceptible to predators, adverse climate changes, and other causes of mortality.

It is very difficult to derive a dose-response relationship for lead **fishing sinkers**. No studies were found in which increasing doses of lead were given to laboratory bird species that would enable a concentration-response curve to be derived. EPA believes that it is difficult to determine such a dose-response level due to a number of factors, such as species, age, size, sex of the bird, diet habits, and time of year. However, based on available studies, and the similarity between lead **fishing sinkers** and lead shot, EPA believes that ingestion of the smallest lead **fishing** sinker (1/100th of an ounce) is sufficient to cause adverse, and even lethal effects in waterbirds.

3. Toxicity of substitutes. To determine the effect of lead **fishing** sinker substitutes on the environment, EPA evaluated their toxicity to terrestrial (rats, mice, and ducks) and aquatic organisms (fish, oysters, crustaceans, clams, worms, insects, and algae) using available studies. However, EPA believes avian species are most likely to be directly exposed to **fishing sinkers** (by ingestion) and therefore become adversely affected.

The possible substitute metals examined in available studies, as individual metals or in combination with other metals, which were compared to lead were steel, zinc, tungsten, tin (inorganic form), antimony, copper, bismuth, brass without lead (zinc/copper, assumed to be a 50/50 alloy), and brass with lead (zinc/copper/lead in a 12 percent/80 percent/8 percent alloy). No avian toxicity information was discovered for tungsten, information on the toxicity of bismuth to avian and aquatic species was not found, and no mammalian or aquatic toxicity information was found for steel. No aquatic, avian, or mammalian toxicity information was found for other substitutes such as polypropylene, and terpene resin putty, and no toxicity information for aquatic or avian species on iron was found.

The hazards of these substitutes, based on available data, to

aquatic invertebrates, fish, and algae, and to birds and mammals were compared with lead, to determine if they were any more or less toxic than lead. The Agency did not evaluate the direct ingestion of **sinkers** by fish or other aquatic organisms, which is assumed to be low in frequency. Measured endpoints in the aquatic toxicity analysis were lethality or death (acute exposure), reduction in cell numbers (algal tests), and changes in reproduction/growth (chronic exposure). Measured endpoints in the terrestrial tests were lethality (LD₅₀), changes in reproduction, the lowest published toxic dose, and the lowest published lethal dose. These laboratory effects were extrapolated to what could occur in the environment were these substitutes to be used in place of lead.

a. Substitutes subject to regulatory action.--i. Zinc. Zinc is more toxic to aquatic organisms (fish and crustaceans) than lead, may be bioconcentrated by invertebrates (insects and oysters) and algae, and may be more bioavailable to aquatic organisms. EPA believes that environmental conditions could mitigate the toxicity of zinc to a certain extent in freshwaters to aquatic organisms because it is more soluble than lead.

Zinc is toxic to mammals (rats and mice) and avian species. In one study, 15 mallard ducks were dosed with 8 number 6 zinc shot. Three of the dosed ducks died within 30 days, with an average time to death of 20 days. Weight loss, also a symptom of lead poisoning, was associated with zinc ingestion. Two of the 3 mallards that died, and 10 of the 12 surviving mallards developed evidence of zinc intoxication before the end of 30 days. These signs began with stumbling while walking, and progressed to an inability to run, a complete loss of muscular control of the legs, loss of the ability to move wings normally, and spasmodic movement of wings. Birds showing signs of zinc intoxication would, as with lead intoxication, be more susceptible to predation.

ii. Brass. It is problematic to determine the aquatic and terrestrial toxicities of brass with and without lead, because of the difficulty of apportioning the toxic contribution of each metal (zinc, copper, and lead) to the overall ``total toxicity'' of each alloy. Each metal may not contribute equally to the total toxicity of the alloy and the total toxicity may not be an average of the individual metal toxicities. Total toxicity of the alloy can be less than the sum of the parts, or more than additive (i.e., synergistic). Mixtures of zinc and copper are generally more-than-additive in aquatic toxicity to a number of different freshwater and marine fish and invertebrates. There is some evidence that zinc and lead mixtures may also be more-than-additive to some marine invertebrates. In addition, the alloys may vary in the percentage of a particular metal present. Also, the individual metals may leach into aquatic environments and at different rates.

The aquatic toxicity and fate of a brass dust consisting of copper, zinc, and lead (as an impurity) was studied. Daphnid crustaceans that were tested died, and the growth of algae was adversely affected after exposure to brass dust in a laboratory study. The brass mixes with and without lead was more toxic to aquatic organisms than lead alone assuming that each metal contributed to the total toxicity of the alloy, based on the percentage of each metal in the alloy. Brass with and without lead was calculated to be more toxic to mammals (rats and mice) than lead alone.

Even though the toxicity of brass to waterbirds has not been tested, based on the toxicity of lead and zinc, brass with and without lead would also be very toxic to waterbirds.

b. Substitutes not subject to regulatory action.--i. Steel. No adverse toxicological effects (mortality) from steel have been indicated as a result of a research program conducted by the FWS to replace lead shot with steel shot, which examined relative toxicity to ducks of five proposed substitute shot metals. Fifteen mallards were dosed with eight number 6 teflon-coated steel shot. No mortalities or significant body weight losses were reported over the 30-day study period. In contrast, all 15 mallards dosed with 8 number 6 lead shot died within 15 days, and an average 22 percent of their body weight was lost. No information was found regarding the toxicity of steel to aquatic and mammalian organisms. However, EPA believes that steel would have low potential toxicity to those species.

ii. Tin. Tin, in the inorganic form, is generally much less toxic to aquatic organisms (crustaceans and fish) than lead because of its low solubility, poor absorption, low uptake rate, and rapid excretion. Based only on limited information, it appears that tin is also much less toxic to waterbirds (mallards) and mammals than lead. No mortality was reported, over 30 days, in mallards exposed to 8 number 6 tin shot. Body weight losses in treated birds were not significantly different from control birds.

iii. Antimony. Laboratory studies indicate that antimony is less toxic to aquatic organisms such as fish, crustaceans, worms, and algae than lead. Even though antimony is not considered to be persistent, it bioaccumulates in invertebrates, but not in fish. Laboratory data indicate that antimony is more toxic to mammals (rats and mice) than lead. No information was found which indicates that antimony is toxic to avian species.

iv. Copper. Laboratory studies indicate that copper is more toxic to aquatic organisms, such as fish, crustaceans, and algae than lead. However, the Agency believes that copper may act differently in the environment than in laboratory studies due to the physical and chemical nature of the aquatic ecosystem. EPA believes that environmental conditions in freshwaters where substitute **fishing sinkers** would likely be used, would mitigate the toxicity of copper metal (as cupric ions) to aquatic organisms. Copper chemistry, availability, and mobility in surface waters is complex, but the cupric ion has been found to be highly reactive to many inorganic and organic constituents of natural waters, and the proportion of copper present as the free cupric ion is generally low. For example, moderate to strong complexes and precipitates of carbonates, phosphates, amino acids, and humates are formed. Cupric ions are readily absorbed onto surfaces of suspended solids. These inorganic and organic copper and precipitates are generally less toxic than free cupric ions and tend to reduce the total toxicity of copper.

Toxicity of copper to avian species such as mallards is less than lead. In 1 study where 24 mallards were dosed with 8 number 6 copper shot, 1 death occurred after 41 days, but the authors concluded that this death could not be attributed to the copper pellet. Metallic copper was also viewed as non-toxic to mammals in this study. However, studies indicate that many copper salts are highly toxic to mammals, and copper is more toxic to mammals than lead.

v. Bismuth. No aquatic toxicity or avian toxicity studies were found regarding bismuth. EPA has no information to indicate that bismuth is toxic to avian species. However, information on the toxicity of bismuth to mammals (rats and mice) is available. The lethal dose of bismuth (chloride oxide salt) to 50 percent of rats tested is much higher than that for lead.

vi. Tungsten. Tungsten was found to have low toxicity to aquatic organisms (crustaceans and algae). EPA found no information which indicates that tungsten is toxic to avian species. The toxicity of tungsten to aquatic organisms (daphnids and algae), and mammals (rats) is less than lead based on laboratory studies.

vii. Iron. No aquatic, or avian toxicity information or studies could be found for iron. EPA found no information which indicates that tungsten is toxic to aquatic organisms or avian species. The toxicity of iron chloride and iron sulfate to mammals (rat) was examined. Both forms of iron exhibited low toxicity to rats based on lethal (LD₅₀) and lowest toxic dose data.

viii. Terpene resin putty. No aquatic, avian, or mammalian toxicity information or studies could be found for terpene. EPA found no information which indicates that terpene resin putty is toxic to avian species. However, terpene resin putty contains approximately 92 percent tungsten. Based on the low toxicity of tungsten to aquatic and mammalian, EPA believes that terpene resin putty may also present a low potential toxicity to these species.

ix. Polypropylene. No aquatic, avian or mammalian toxicity information or studies could be found for polypropylene. Polypropylene is a polymer and has a high molecular weight. EPA believes that this property would mitigate the transport of polypropylene through biological membranes, tissues, and cells of the gizzard or gut of avian

species. Therefore, the polypropylene would not be absorbed and bioaccumulated by organisms such as waterbirds, but rather would be excreted after passage through the digestive system. EPA believes that polypropylene would present a low potential toxicity to avian, aquatic, and mammalian species.

E. Exposure

1. Summary. **Fishing sinkers** are used throughout the United States, easily lost or discarded into the environment and, therefore, are available for exposure to waterbirds. **Sinkers** may be found in areas fished, such as along shorelines, embankments, rock barriers, and piers. **Sinkers** may be lost in aquatic habitats if the hook or line gets tangled in weeds or other obstructions, and when the line breaks, **sinkers** may still be attached or fall off the line. **Sinkers** may also be lost or discarded in terrestrial habitats if dropped by anglers. Any sinker discarded in these areas could easily be ingested by waterbirds feeding on seeds or other vegetative matter.

For example, a recent study involving a lake dredging project that focused on lead shot in upstate New York, reported that for a period of 5 months in 1990, the average number of **fishing** weights extracted from the lake's sediment during dredging was 4.2 per day. The lake is approximately 60 acres in size and 125 cubic meters of sediment were dredged each day.

An area along the river Trent in England, where one of the studies took place that examined lead **fishing** sinker ingestion by mute swans, was heavily fished and contaminated with lead **sinkers**. Over a 100 meter stretch near the river, 1,100 lead split shot **sinkers** were collected by 2 persons in 1 hour.

Another study which examined deposition of lead split shot by anglers in South Wales and in England reported that a range of 5 to 300 **sinkers** per square meter were found in the water along the shoreline, and along the bank of several small ponds and lakes. The authors calculated that each person **fishing** dropped 4 to 7 **sinkers** per visit to the waterbody. While this area in Great Britain may experience heavy **fishing** pressure, it further demonstrates that **sinkers** enter the environment, and can be available for exposure to waterbirds.

Sinkers may be accidentally dropped along the shoreline, or can be caught on items in the water, such as waterside or submerged branches and vegetation. Waterbirds may intentionally pick them up, mistaking them for seeds, or to use them as grit (materials birds use to aid in digestion such as small pebbles), or may inadvertently ingest them along with food such as discarded bait fish with a line and sinker attached. It is necessary for birds to pick up and use grit to grind up food items because birds lack teeth.

Fishing sinkers discarded in shallow areas of aquatic habitats are readily available for ingestion by waterbirds for perhaps several years. Lead **sinkers** persist in the environment and may not completely degrade for a period of at least 100 to 300 years. Zinc and brass **sinkers** would also remain in the environment for many years.

Natural deposition and sedimentation processes operate to eventually cover the discarded **sinkers** with detritus and sediments. However, activities such as boating or dredging may disturb sediments and uncover discarded **sinkers**. Also, receding water levels due to drought, tidal effects, natural subsidence, or intentional drawdowns would make **sinkers** readily available.

The size of the waterbird, especially the size of the gizzard or esophagus may determine the size of the **fishing** sinker that can potentially be swallowed.

EPA believes that larger birds such as sandhill cranes could swallow **sinkers** which are 2 inches in diameter, however, smaller **sinkers** (1 inch and under) would be more readily ingested by most species. The Agency believes that **sinkers** 1 inch or less more closely resemble food sources or pieces of grit.

Limited data are available regarding the size of **fishing sinkers** ingested by waterbirds. While **sinkers** approximately 1/4 inch (7 mm) in diameter have been found in the gizzard of common loons, EPA believes

that these **sinkers** were probably larger when initially ingested. This is because **sinkers** are eroded in the gizzard by the mechanical grinding of the sinker with other materials such as grit, and chemically by acidic substances present in the gizzard or digestive tract. As the sinker is broken down and the metal materials are rubbed from the sinker surface, lead, zinc, or other metals are released into the bloodstream, tissues, and organs of the bird. Even if a **fishing sinker** is excreted from a bird after it has been ground down to a small size, the lead already absorbed into the tissue of the bird could still cause adverse effects and death.

A scientist who has studied lead poisoning in common loons has found lead **sinkers** up to, and including 1 inch in length in the gizzard of common loons which died from lead poisoning. These particular **sinkers** ingested appear to be worm weights, egg **sinkers**, and bass casting **sinkers**. Lead jigs were also found in these common loons.

The frequency of ingestion of **sinkers** may differ between species, geographic region, and time of year. Data are not currently available to determine to what extent ingestion of lead or other **fishing sinkers** is incidental, accidental, or selected.

The number of lead- or zinc-containing **sinkers** that waterbirds are likely to ingest cannot be quantified. There are differences among species of waterbirds, variations in feeding, mating, and migration behavior, as well as in other factors such as age and sex of the bird that can affect ingestion. In addition, accurate estimates of this sort would depend on a number of conditions such as the extent of **fishing** in a certain area, number of **sinkers** and waterbirds present in the area, and many factors relating to bird behavior.

Due to all these factors, a model is not available to predict the probability of ingestion of **fishing sinkers** by waterbirds or the extent of the exposure to birds over a specific time period (number of waterbirds at risk or number of **fishing sinkers** available for ingestion). In addition, an accurate number of waterbirds that could receive a lethal dose of lead or zinc from **fishing sinkers**, or the probability of consuming a lethal dose, cannot be estimated.

Areas subject to **fishing** each year will continue to pose a threat of sinker ingestion to waterbirds occurring or returning to migrate in that area. However, whether accidental or intentional, ingestion of **sinkers** does occur and is assumed to be proportional to availability. Therefore, as the number of lead- and zinc-containing **fishing sinkers** entering the environment increases, so does the probability of ingestion by waterbirds.

2. Feeding habits. Numerous species of waterbirds may intentionally or inadvertently ingest **fishing sinkers** during feeding. While it is not certain why waterbirds ingest small **sinkers**, perhaps it is due to a similarity in size and shape to grain, seeds or roots of some plants, or invertebrates, or they appear like pebbles or grit which aid in digestion. Waterbirds may also ingest **sinkers** when preying on fish still hooked to a broken line with a sinker attached.

Studies have documented ingestion of lead **fishing sinkers** by common loons, trumpeter swans, and mute swans. However, based on their feeding habits, and where they forage for food (locations where people fish), many other species could easily ingest lead- or zinc-containing **sinkers**, and could also be affected.

Loons can dive to a fairly substantial depth (up to approximately 30 feet) to capture fish, and may inadvertently ingest **sinkers** when eating fish with tackle still attached. Loons may also intentionally pick up **sinkers** for use as grit.

Cranes and herons wade in the shallow areas of inland and coastal aquatic habitats searching for prey. Both species dig into the sediment with their bills to extract food. They consume fish, crustaceans, and other benthic invertebrates, amphibians, insects, and vegetation (including grains), and may incidentally ingest lead **fishing sinkers**.

Bay diving ducks (e.g., canvasbacks) and grebes, feed on aquatic insects, fish, crustaceans, other invertebrates, and aquatic plants found on the bottoms of aquatic habitats.

Geese, ducks, and swans eat aquatic vegetation, plant shoots or roots, seeds, bulbs, insects, small mammals, roots, berries, and nuts.

Often they feed along shorelines and may be readily exposed to discarded or lost **fishing sinkers**. Swans frequently pull vegetation off the bottom sediments. These species can easily ingest **fishing sinkers** during feeding as they forage or sift through sediment on lake, pond, or river bottoms.

Raptors and scavengers such as hawks, osprey, and vultures consume fish, small mammals, birds, and crustaceans. Monofilament line and attached sinker weights hooked to bait such as worms or fish could also be easily ingested by other fish or fish-eating predators.

3. Affected species. EPA believes that over 75 individual species are potentially at risk from exposure to lead- and zinc-containing **fishing sinkers** based on their feeding habits and sources of food. These species fall into a number of groups such as surface feeding ducks, bay diving ducks, loons and grebes, sea ducks, cranes and their allies, geese and tree ducks, swans, herons and their allies, raptors and scavengers.

During the course of EPA's analysis, additional reports were found which document the ingestion of lead **fishing sinkers** and lead poisoning in sandhill cranes (not the endangered Mississippi sandhill crane), common loons, mute swans, and tundra swans.

Two wild sandhill cranes (*Grus canadensis*) found dying were submitted to the National Wildlife Health Research Laboratory for diagnosis (Ref. 26). One female sandhill crane, that died from lead poisoning shortly after capture, was found in Nebraska and contained a portion of a lead **fishing** sinker in its gizzard. The lead level (wet weight) in the crane's liver and kidney were 23 ppm and 29.8 ppm, respectively. Another female sandhill crane which was weakened and unable to fly was found in the Aransas National Wildlife Refuge in Texas. A portion of a lead **fishing** sinker was found in the gizzard, and lead poisoning was determined to be the cause of the moribund condition of the bird. The lead level (dry weight) in the kidney was 113.4 ppm and 258.8 ppm in the liver.

Tufts University Wildlife Clinic examined (necropsied) 21 adult common loons found dead or moribund in New England States from 1991 - 1993 (Ref. 30). Fourteen common loons had ingested either a lead **fishing** sinker, lead worm weight, or lead jig. Nine of these 14 loons died from lead poisoning; 5 were suspected of dying from lead poisoning (they showed necropsy and histopathologic lesions consistent with lead poisoning). Toxicological analysis of the 9 birds confirmed with lead poisoning had lead liver levels ranging from 6.05 ppm to 13 ppm. The lead **sinkers**, lead jigs, and lead worm weight that the loons had ingested were also examined (weighted and measured). These lead objects ranged in length from 0.27 to 1 inch; from 0.21 to 0.49 inches in width; and in weight from 1.5 grams to 16.5 grams.

Necropsy data from the Rose Lake Wildlife Research Center in East Lansing, Michigan report that from 1988 to 1993: (1) Out of 55 common loons examined, 3 died from lead poisoning due to lead **fishing sinkers**, (2) 5 out of 60 mute swans examined, ingested lead **fishing sinkers** and died from lead poisoning, and (3), 1 tundra swan (*Cygnus columbianus*) died from lead poisoning due to the ingestion of a lead **fishing** sinker (Ref. 15). Lead concentrations in the liver and kidney of the common loons ingesting **fishing sinkers** ranged from 6 to 13 ppm and 28 to 46 ppm respectively. The data also indicated that 12 common loons ingested what appeared to be lead jigs, which are weighted hooks. The lead levels in the liver of these loons ranged from 11.7 to 98.2 ppm in the liver and 18.1 to 124 ppm in the kidney.

Data from the New York State Wildlife Resources Center in Delmar, New York reported that seven common loons, and one mute swan necropsied, died from lead poisoning due to ingestion of lead **fishing sinkers** (Ref. 29). The common loon mortalities were as follows: (1) one common loon located along Lake Ontario in 1983, and later died, had a lead level in the liver of 9.3 ppm; a worn lead **fishing** sinker weighing approximately 2 grams was found in the stomach, (2) one debilitated common loon that died shortly after it was found in 1986 at Long Lake, had ingested a worn elongated split shot **fishing** sinker; the lead concentration in the liver was 41.2 ppm wet weight, (3) two common loons that died in 1989, each with a worn lead **fishing** sinker in their

gizzards, had lead liver levels of 26.4 ppm, and 30 ppm, (4) one common loon with a lead liver level of 9.8 ppm also died in 1989, and had ingested a lead **fishing** sinker, (5) a ``large'' split shot lead **fishing** sinker was found in a common loon that died in 1982 (2 assays were conducted indicating that lead liver levels were 21 and 23 ppm), and (6) one loon found dead on Kueka Lake had ingested an egg-shaped sinker approximately 8 mm in diameter; the lead liver level was 15.5 ppm. The New York State Wildlife Resources Center also reported that a female mute swan that had ingested a teardrop-shaped lead **fishing** sinker died from lead poisoning in 1986.

A male whistling swan (also referred to as the tundra swan, *Cygnus columbianus*) was found sick and extremely emaciated along the banks of a creek in Maryland (Ref. 11). It was brought to the Patuxent Wildlife Center for autopsy where it was found that the bird was lead poisoned. The swan had ingested a lead sinker contained in the gizzard. The level of lead found (on a wet weight basis) in the blood, liver, and kidney was 830 ppm, 40 ppm, and 2,440 ppm respectively. The study authors surmised that the very high levels of lead reflected a high level of lead absorbed from the ingested sinker.

Any endangered or threatened waterbirds, such as the Mississippi Sandhill Crane (See Unit II.C.4. of this preamble) that feed in areas with discarded or lost **fishing sinkers** may potentially ingest lethal quantities of lead or zinc. Each individual is important to the continued survival of an endangered or threatened species, and therefore, impacts on even single individuals are of special concern. Other listed endangered species, such as the whooping crane (*Grus americana*), wood stork (*Mycteria americana*), Aleutian Canada goose (*Branta canadensis leucopareia*), peregrine falcon (*Falco peregrinus peregrinus*), and possibly the bald eagle (*Haliaeetus leucocephalus*), may directly or indirectly ingest **fishing sinkers**.

4. Species ranges. Ranges of these potentially exposed waterbirds, as well as avian predators and scavengers include areas throughout the United States with suitable aquatic habitats for feeding and breeding activities. In some cases, these ranges correspond to areas subject to moderate to heavy use by fishermen (e.g., northwest, midwest, southeast, upper north central, and northeast U.S.). The range of a species often is complex and large and it can consist of a summer or breeding range, a winter range, and geographic areas where the species occurs throughout the year. Often portions of these three areas geographically overlap. The breeding ranges of the species with reported mortalities (common loon, trumpeter swan, mute swan, tundra swan, and sandhill crane) due to ingestion of lead **fishing sinkers**, the ranges of other potentially affected species discussed above, and the areas fished essentially cover the entire United States.

Bay diving ducks and mergansers are generally found throughout the United States during the year. Loons and grebes occur across the upper midwest, northeast, west coast, and Alaska. Surface feeding ducks, depending on the species, occur throughout the United States. Cranes, herons, and their allies, generally occur throughout the United States and along coastal areas. Sea ducks are commonly found along the United States coast. Geese and tree ducks are distributed along the west coast, northeast and Gulf coast. Swans are found in many areas of the United States including the northeast, upper midwest, west coast, Rocky Mountains, and Alaska. The distribution of raptors and scavengers is widespread throughout the United States.

5. Population effects. EPA recognizes that population effects cannot be measured accurately in this case, because of the many species that may be adversely impacted, and other complex variables involved. It is difficult to separate out the precise degree of the hazard posed by **fishing sinkers** to waterbird populations as opposed to that from natural or other man-made sources of population mortality and variability, or that caused by normal environmental change (e.g., drought, increased predation). Many waterbird populations have been decreasing progressively over the past several years and decades because of increased hunting and a decline in suitable nesting habitats (e.g., the net loss of 2.6 million acres of wetlands in the United States from the mid-1970's to the mid-1980's).

It is difficult to see the full effect on populations, as there have not been large reported die-offs due to ingestion of **fishing sinkers**. While the available studies may appear to indicate that a small number of common loons, trumpeter swans, mute swans, tundra swans, and sandhill cranes have died due to ingestion of lead **fishing sinkers**, EPA believes that the potential magnitude of the risk to waterbirds is greater than the number of known deaths indicates. Species with similar feeding habits in similar ecosystems such as those previously discussed (Unit III.E.2 of this preamble), are likely to also be at risk, although no deaths due to ingestion of **fishing sinkers** have been reported.

The potential risks to waterbird populations may not be fully reflected in the available data due to a number of factors. Birds that are seriously ill from ingesting lead- or zinc-containing **sinkers** may seek the cover of vegetation and are difficult to locate when they die. Common loons and trumpeter swans do not flock together and consequently, when individual birds seek cover they are often overlooked. Because they are susceptible to predation, most of the ill or dead birds may quickly disappear as they become meals for predators such as mink, weasels, raccoons, fox, coyotes, eagles, hawks, and owls. This complicates the ability to determine the magnitude of adverse effects to waterbirds due to sinker ingestion. Therefore, EPA believes that the true number of waterbird deaths is considerably larger than those that have been observed and reported. Even if a known number of carcasses are deliberately ``planted'' in known locations, it is difficult to locate all of them at a later time.

For example, in a study conducted in northwestern Missouri, 62 percent of 90 planted carcasses disappeared after only 4 days. In Texas coastal marshes, 89 percent of 47 carcasses had disappeared in 8 days. In a refuge in Missouri, 25 percent of ``planted'' carcasses were not located when the areas were searched. If the number of dead and lead- or zinc-affected waterbirds do not exceed the ability of predators to consume them, few carcasses will be present. Carcasses would become more evident when birds die in greater numbers, or if the number of predators decreased.

EPA also recognizes that naturally occurring populations of waterbirds do not exist in isolation. The health of one population is often dependent upon other populations within a natural community. As such, lead- and zinc-containing **fishing sinkers** may cause direct adverse effects on one population, but may also produce indirect effects, such as perturbations on food webs in ecosystems. For example, these perturbations could include disruptions in the predatory/prey and competition relationships between individuals in interacting populations within a community.

However, EPA did examine how **fishing sinkers** may affect individuals within a population. The number of individuals within the trumpeter swan, common loon, and Mississippi sandhill crane populations are as follows. Trumpeter swan populations are estimated to be approximately 13,000 in Alaska, 1,700 in the Rocky Mountain area, and 300 in the interior portion of the United States. Common loon populations are estimated to be 34,000 in Alaska and 47,000 in the rest of the United States. The population of the Mississippi sandhill crane, found on and near the Mississippi Sandhill Crane National Wildlife Refuge in Jackson County, Mississippi, is estimated to be 142 individuals.

Although the total population of trumpeter swans or common loons may appear large and geographically dispersed, it can consist of relatively small local breeding populations. The loss of a few members of these local populations may be of great consequence. For example, the common loon population in 4 New England States (Maine, New Hampshire, Vermont, and Connecticut) is estimated to be approximately 4,374 individuals; however, Vermont has only about 16 nesting pairs or 32 individuals. As mentioned previously (Unit II.C.1. of this preamble), common loons are listed as an endangered or threatened species in some New England States (Ref. 5).

If only a few of these loons die from poisoning due to ingestion of a lead- or zinc-containing **fishing sinker**, there will be fewer birds to reproduce, and less future offspring. This is of particular concern

regarding endangered species where both the total and local populations are low, and the loss of an individual is very significant. Therefore, deaths of individual birds may in turn impact the total population of avian species. However, direct effects may only be seen concerning individuals, or local breeding populations. Regardless of the difficulty in fully determining the impacts on waterbird populations, lead- and zinc-containing **fishing sinkers** remain as one source of unnecessary adverse pressure on already stressed populations. This is especially true if local breeding populations, made up of individuals, have to cope with other adversities such as loss of habitat. In addition, **fishing** sinker ingestion may result in toxic effects, thereby significantly reducing or eliminating the opportunity for reproductive effects to occur.

Although the effects of lead- and zinc-containing **fishing sinkers** on waterbird populations are impacts of concern, EPA does not believe it is necessary to demonstrate population effects before taking regulatory action (Ref. 3). Since most endangered species have very low population numbers, concern would be high if even one individual was adversely affected or died as a result of lead or zinc ingestion. By the time such effects were conclusively shown, it might be too late to mitigate any adverse effects to these species. In fact, the Mississippi sandhill crane, a Federally endangered species, is in danger of extinction due to a number of factors such as loss of habitat, human predation, and presence of other toxins in the environment.

EPA has previously implemented regulatory programs that protect birds without estimating population effects. The Agency took action to phase out most uses of granular carbofuran, an agricultural insecticide and nematicide (Ref. 27), and to cancel certain registrations of the pesticide diazinon, based solely on concerns about acute risks posed to birds (Ref. 28).

F. Risk Characterization

EPA believes that lead- and zinc-containing **fishing sinkers** pose an unreasonable risk to waterbirds for the following reasons.

Fishing sinkers are used and can be found in ponds, lakes, and streams, and along the shores and banks of these aquatic habitats throughout the United States. They are available for ingestion by waterbirds. The actual number of **sinkers** located in the environment cannot be quantified; however, approximately 477 million lead, zinc, and brass **sinkers** are sold each year in the United States. As more **sinkers** are discarded or lost in the environment each year, more will be potentially available to waterbirds, and additional waterbird deaths may occur. Based on the toxicity of lead and zinc, one **fishing** sinker can be sufficient to cause mortality in waterbirds.

As previously discussed, the actual number of waterbirds that will likely ingest **fishing sinkers**, and the definite number of **fishing sinkers** ingested by each waterbird, cannot be estimated. However, the true number of deaths may be higher than the number of documented cases due to: (1) The lack of a national incident reporting system (in addition, the studies and research conducted specifically to assess the ingestion of **fishing sinkers** are small in number), (2) the difficulty of locating carcasses in the field, and (3) limited resources and staff to conduct necropsies.

Ingestion of lead **fishing sinkers** by waterbirds has been documented. There is clear evidence that ingestion of lead **fishing sinkers** has resulted in toxic and often fatal effects to avian species such as common loons, trumpeter, mute, and tundra swans, and sandhill cranes.

The size of lead **fishing sinkers** which have been ingested by waterbirds has been documented. **Sinkers** up to and including one inch in size have been found in common loons.

Research has also demonstrated that zinc is toxic, and zinc pellets have produced mortality when ingested by waterbirds such as mallards. Therefore, ingestion of zinc **fishing sinkers** may also pose risks to waterbirds.

Other avian species that have similar feeding habits and breed or

migrate in areas containing lead- or zinc-containing **fishing sinkers** are at risk.

IV. Provisions of the Proposed Rule and Rationale

The rule would impose a ban on all manufacture, import, and processing of **fishing sinkers** containing any lead or zinc and which are 1 inch or less in any dimension for use in the United States 1 year after promulgation of the final rule. The distribution in commerce of such **fishing sinkers** would be prohibited 2 years after promulgation of the final rule. The rule would not prohibit the manufacture and processing of lead and zinc-containing **fishing sinkers** 1 inch or less in any dimension solely for export. Manufacturers and processors of those **sinkers** for export would be required to maintain records regarding the production, inventory, and shipment of those **sinkers**. This would allow EPA to track the distribution of regulated **sinkers**, and effectively enforce the rule.

EPA is proposing to prohibit the manufacture, processing, and distribution in commerce of any lead- or zinc-containing **fishing sinker** because EPA believes they pose an unreasonable risk of injury to avian species such as waterbirds. Extremely small amounts of lead and zinc (at the ppm level) adversely affect waterbirds, and ingestion of even one **fishing sinker** can result in their death. If **fishing sinkers** were allowed to contain a small amount of lead or zinc, although a trace amount may not produce toxic effects, the cumulative impacts due to ingestion of more than one sinker could result in mortality. In addition, lead- and zinc-containing **fishing sinkers** are very persistent in the environment and can be accessible for ingestion by waterbirds for a number of years. Therefore, EPA is proposing to regulate the production and sale of **fishing sinkers** containing any amount of lead or zinc.

EPA's economic analysis indicates that there are several available or commercially viable substitutes for lead- or zinc-containing **fishing sinkers**. This analysis, discussed further in Unit V. of this preamble, indicates that the average increase in annual costs to each individual person who fishes from this proposal would be substantially less than \$4.00 per year. EPA believes the scientific evidence demonstrating the severe adverse effects to waterbirds from the ingestion of lead- and zinc-containing **fishing sinkers**, the economic, social, and environmental value of these birds, and the low costs and availability of substitutes for these **sinkers**, outweigh any costs that would result from imposition of the proposed regulation. Therefore, EPA believes the continued manufacturing, processing, and distribution in commerce of small size lead- and zinc-containing **fishing sinkers** presents an unreasonable risk of injury to the environment.

EPA does not believe that the use of lead- and zinc-containing **fishing sinkers** is essential. Substitutes which the Agency determined were less toxic to waterbirds are available, albeit at a somewhat higher cost. These substitutes include tin, copper, antimony, bismuth, steel, tungsten, and terpene resin putty. EPA believes these substitutes for lead- and zinc-containing **fishing sinkers** would perform as well as lead or zinc.

This ban, as proposed, would greatly eliminate future entry of these **fishing sinkers** into the environment, and therefore limit the number of lead- and zinc-containing **fishing sinkers** available for exposure. EPA believes this would ensure that any unreasonable risk posed to waterbirds would be adequately reduced.

EPA is proposing to regulate all **sinkers** 1 inch or less in any dimension because those size **sinkers** resemble pieces of grit or small food items such as seeds which waterbirds may ingest. The majority of **sinkers** most likely to be used for recreational **fishing** are also 1 inch and less in size.

The Agency evaluated banning different types of **sinkers** 1 inch or less in size (split shot and non-split shot). While a ban on split shot type **sinkers** is the most economical option in terms of cost per sinker, it would only account for 68 percent of the **sinkers** 1 inch or less on

the market. Therefore, an additional 32 percent of **sinkers** 1 inch or less, or approximately 152 million **sinkers**, would still be manufactured per year and potentially available for exposure to waterbirds. EPA believes that it is important to capture this significant market segment because regardless of type, **sinkers** 1 inch or less pose a risk to waterbirds. In addition, the majority of home manufacturers produce non-split shot **sinkers**. Therefore, the prohibition on all **sinkers** 1 inch or less in any dimension would assist in reducing human health risks as well.

It is estimated that the proposed ban would prevent over 450 million lead- and zinc-containing **fishing sinkers** 1 inch or less from being produced each year, and potentially from entering the environment.

The provisions of this proposed rule concerning the ban on manufacturing and processing would become effective 1 year after promulgation of the final rule. EPA chose a 1-year delay, rather than an immediate ban which the Agency believed to be too burdensome on industry, to enable manufacturers of lead- and zinc-containing **fishing sinkers** time to retool their equipment to produce other types of **sinkers**.

The proposal, if implemented, would also prohibit the distribution in commerce of lead- or zinc-containing **fishing sinkers**, and that have any dimension less than or equal to 1 inch, by any person effective 2 years after promulgation of the final rule. The sale of these types and sizes of **fishing sinkers** in the United States by any person, including retail stores or catalogues, would not be allowed. The Agency believes restrictions on the distribution in commerce are necessary to eliminate the continued availability and usage of lead- and zinc-containing **fishing sinkers** less than or equal to 1 inch in size.

The prohibition on the distribution in commerce of lead and zinc-containing **sinkers** would become effective 2 years after promulgation of the final rule, in order to allow an adequate interval for distributors to sell their remaining inventory of those **sinkers**. Although EPA evaluated options which would further delay the regulatory requirements (ban the manufacture, processing, and distribution after 3 or 5 years), the Agency does not believe that these options would be justified in light of the continued and increasing risk to waterbirds. If EPA further delayed the ban, a potentially large number of lead- and zinc-containing **fishing sinkers** could enter the environment.

EPA evaluated a number of options before choosing to prohibit the manufacture, processing, and distribution in commerce of lead- and zinc-containing **fishing sinkers** 1 inch or less in any dimension. While the other options, discussed further in Unit VI. of this preamble, would restrict a segment of the **fishing sinkers** available for exposure to waterbirds, the Agency does not believe that these other options would adequately reduce the availability of **sinkers** for exposure or adequately reduce the unreasonable risk to waterbirds. To adequately reduce this risk, EPA believes a ban on the manufacture, processing, and distribution of lead- and zinc-containing **sinkers** 1 inch or less in any dimension is necessary. EPA also evaluated the option of a comprehensive ban on all **fishing sinkers**. While a comprehensive ban on all lead- and zinc-containing **sinkers** would accomplish the greatest degree of risk reduction, EPA did not select that option because the burden placed on society associated with that option would be too severe. Therefore EPA chose a limited ban targeting those **sinkers** which EPA believes pose the greatest harm to waterbirds.

The rule, as proposed would not prevent individuals from engaging in **fishing** or from using **sinkers**, but rather would prohibit the manufacture, processing and distribution of **fishing sinkers** of a certain type and size to prevent unreasonable risk of injury to waterbirds.

This rule would not prohibit the use of **fishing sinkers** containing lead and zinc by any person. TSCA section 6 (a)(5) authorizes EPA to prohibit or otherwise regulate any manner or method of commercial use of a substance or mixture. Because the **fishing sinkers** at issue are those used in recreational **fishing**, EPA's proposal would not extend to

the recreational use of these **fishing sinkers**.

The total cost of the proposed regulation for consumers is \$71.6 million over 10 years. The cost to persons who fish is minimal (average 2 cents per **fishing** day).

V. Economic Impacts

All references and background information reviewed in this Unit of the preamble are found in the ``Regulatory Impact Analysis of Options for Regulating Lead and Other Toxic **Fishing Sinkers**,'' referred to in this proposal as Support Document 2. EPA concentrated its analysis on lead **fishing sinkers** as they account for the majority of **sinkers** presently on the market. There is a small volume of brass **sinkers** currently produced domestically, and a very small volume of zinc **sinkers** which are imported. EPA estimates that approximately 477 million split shot and non-split shot lead, zinc, and brass **sinkers** are sold each year and used for freshwater **fishing**.

A. Availability, Application, and Cost of Substitutes

1. Summary. EPA has investigated a number of possible substitute materials for lead **fishing sinkers**. The substitutes considered suitable for lead **fishing sinkers**, are also appropriate for zinc and brass **fishing sinkers**. Substitutes were evaluated on the basis of availability, application, and cost, in addition to toxicity relative to lead and zinc (as detailed in Unit III.D. of this preamble). Availability refers to the current market for **sinkers** made of the various types of materials, while application refers to the sinker types that could be manufactured from a particular material. EPA is aware that there may be other substitutes which are being developed, but are not yet on the market, and others which may only be available locally such as glass and ceramic. The Agency has not analyzed these substitutes in detail, mainly because there is a lack of information regarding them.

As evaluated by the Agency, the costs of substitutes include raw materials, energy, operations and maintenance, capital, and conversion costs. These costs, along with toxicity considerations, were used to estimate the market share of various substitutes which would result following implementation of the proposed regulatory option.

The identified substitutes for split shot **sinkers** are different from those identified for non-split shot **sinkers**. Substitutes for lead split shot need to be malleable and have a soft edge so that **fishing** lines are not damaged when substitute weights are crimped or squeezed onto the line. The same considerations are not important for larger weights (i.e., non-split shot) that are tied onto the line. Hence, the list of feasible substitutes is different for the split shot segment of the market than it is for non-split shot **sinkers**.

Substitutes for lead **fishing sinkers**, which are identified as being currently commercially available and are subject to this proposed rule are zinc, and brass. Other potential substitute materials which are not subject to this proposal are: (1) Tin, (2) tin/antimony, (3) bismuth, (4) terpene resin putty, (5) copper, (6) stainless steel, and (7) polypropylene tungsten composite.

Finally, the suitability of lead jigs as a substitute was examined. While a jig basically accomplishes the same objective as a **fishing** sinker, the Agency does not believe they are viable substitutes for lead or zinc **sinkers**. Generally, jigs are used as artificial lures which require the angler to manipulate it such that it appears life-like. **Sinkers** are generally used with live bait and do not require such handling. Accordingly, it is estimated that lead jigs would substitute for less than 1 percent of lead **fishing sinkers** currently in use. Several of the substitutes are described below.

2. Substitutes subject to regulatory action.--i. Zinc. Zinc **fishing sinkers** under 1 inch are not currently manufactured in the United States. Non-split shot **sinkers** such as worm weights are presently imported for use. EPA does not believe that zinc **sinkers** are produced at home. Zinc is more expensive than lead, and could replace lead for a

few product forms such as worm weights.

Disadvantages of zinc relative to lead are that it is more expensive, is more difficult to manufacture, can damage the manufacturing equipment, and has a harder edge, and therefore may damage the **fishing** line. Also, zinc has a lower density, and is not as soft and easy to work with as lead.

ii. Brass. Brass **sinkers** are currently available in the United States for purchase, and are slightly more expensive than comparable lead **sinkers**. Primarily non-split shot brass **sinkers** such as those used for bass casting are produced in the United States. EPA does not believe that brass **sinkers** are produced at home. Brass **sinkers** can be plated with silver, zinc, or with zinc plus black chromate.

One disadvantage of brass is that it cannot be crimped onto the line as easily as lead shot because of the hardness of brass. It is therefore considered too hard for use as split shot, and mechanical crimping methods such as rubber appendages must be used. Also, brass may contain 7 to 8 percent lead, and 5 to 20 percent zinc. Furthermore, brass is less dense than lead and has a higher melting point than lead and other substitutes, making processing more difficult.

3. Substitutes not subject to regulatory action.--i. Tin. Tin, although less dense than lead, is suitable for use as split shot due in part to its softness. Tin split shot is currently available in the same weights as lead split shot. It appears that tin **sinkers** are easier to affix to the line than are lead **sinkers**. The tin shot is opened with the thumbnail, but has no ears for release, as does removable lead shot. Raw material costs for tin are approximately 10 times the cost of lead. Because of this higher cost, tin is not considered practical for use in **sinkers** other than split shot.

The main disadvantage of tin **sinkers** is that they are less dense than lead **sinkers**, resulting in roughly a 50 percent increase in material to achieve the same effect as for typical split shot. Also, although tin is soft, it requires greater precision methods to manufacture so that it will not damage the **fishing** line. Tin **sinkers** could be produced by home manufacturers; however, the relatively high cost of tin would likely discourage this activity, and home-manufactured tin split shot could cause line damage due to the relatively hard edge.

ii. Bismuth. **Sinkers** that are 99.99 percent bismuth are manufactured and distributed to retail stores. Five types of bismuth **sinkers** have been identified including bell **sinkers**, bass casting (swivel) **sinkers**, walking **sinkers**, egg **sinkers**, and worm weights.

Bismuth **sinkers** generally costs approximately twice as much as comparable lead **sinkers**. Bismuth **sinkers** could be manufactured at home, using a lead sinker mold. However, if home-manufacturers were to use bismuth, the resulting **sinkers** would be considerably more expensive than lead **sinkers** and hence, probably would not be purchased by retailers.

The advantages of using bismuth rather than lead, zinc, or brass include its slightly lower melting point, which means that it requires slightly less energy to manufacture than lead. The melting point of bismuth is also lower than the melting points of the possible substitutes copper and steel. Furthermore, the density of bismuth is high relative to other substitute materials like tin and copper.

Bismuth can be used to replace all lead, zinc, and brass sinker types except split shot. Bismuth cannot effectively replace lead for split shot because of its brittleness, which results in breakage when it is crimped onto the line. The small density difference compared to lead is overcome by making the sinker slightly larger.

iii. Terpene resin putties. A putty of terpene resins containing 92 percent tungsten by weight is currently manufactured. It has approximately 80 percent of the density of lead. The product is sold wholesale to retail outlets and distributors.

Terpene resin putty is approximately three to four times as expensive as lead split shot. Although the putty is more expensive than lead shot, in the fly **fishing** market, the only market into which it currently is marketed, this higher cost of the putty is insignificant compared to the high costs of other fly **fishing** equipment (e.g., a

person fly **fishing** may purchase 100 flies at \$1.20 each for one **fishing** trip). The product is not, however, an economically viable choice for most types of **fishing** that require weights larger than split shot.

Terpene resin putty currently is marketed only for fly **fishing**, although it can substitute for all sizes of split shot and most sinker sizes. The putty is not suitable for use as a heavy weight since it cannot be tied onto the line. However, like removable split shot, the putty can be reused many times. The major disadvantage of putty relative to lead is its higher cost.

iv. Steel and copper. Steel and copper theoretically could also be used as substitutes for lead, zinc, or brass **fishing** weights. However, for various reasons these substitute materials are not considered as practical alternatives at this time. Steel rusts unless expensive non-corrosive alloys are used. Steel generally costs more and is less dense than lead. Furthermore, steel products usually have very high melting points and are hard, making these materials impractical for manufacture with traditional technologies. Steel could not be injection molded; it could be stamped, but only with very heavy equipment. Typically, forging and foundry operations are required for processing steel into shapes. Copper has a density of approximately 79 percent of lead and a melting point greater than lead, zinc and brass. These factors may make copper unsuitable for use as a substitute for lead in **fishing sinkers**.

v. Polypropylene, iron, and tungsten mixtures. One company is currently developing an iron and tungsten impregnated polypropylene mixture that can be molded into **fishing sinkers** of the same size, shape, and dimensions as lead **fishing sinkers**. These weights have the same ``look'' as lead **fishing** weights, although they have roughly 50 percent of the specific gravity of lead. Raw material costs are estimated at \$1.50 to \$1.75 per pound or approximately five times greater than lead.

B. Cost of Proposed Rule

The Agency developed estimates of the cost of the proposed regulatory option. The analysis, presented in Support Document 2, details the costs, methodology, and results for the proposed rule and for several additional regulatory alternatives.

In general, the approach of the cost analysis is to utilize a stepped demand function to depict demand for **fishing sinkers** and to estimate changes in consumer surplus resulting from various regulatory options. This type of function is appropriate where many substitutes are available and performance differences among the substitutes are not significant. The estimation of these functions incorporates basic information on the substitutes for lead- and zinc-containing **sinkers** and estimated market shares of the substitutes.

Stepped demand functions depict consumers as ceasing to demand certain quantities of a product when the cost of the product exceeds the cost of a comparable substitute. Therefore, there will be no reduction in the quantity demanded in the event of a price rise, unless the price rises sufficiently to be above the price of the next substitute. The cost of each substitute provides the height of each step, and the market share of substitutes provide the width. Demand is assumed to be relatively constant over the 10-year period--1993 to 2002.

While market shares are determined by a combination of toxicity and cost concerns to sensitivity analyses are performed, in the first market share is based predominately on cost concerns and, in the second, market share is based predominately on toxicity concerns. The base case market shares under the proposed regulatory option for non-split shot are estimated to be: Polypropylene-55 percent, bismuth-5 percent, tin-35 percent, steel-2 percent, and tin/antimony alloy-3 percent. The estimated base case market shares for split shot are: Tin-90 percent, tin/antimony alloy-2 percent, and terpene resin putty-8 percent. The supply of lead **sinkers** is assumed to be perfectly elastic in the long run, therefore, no producer surplus exists in these markets. Thus, most of the cost of the regulation will be borne in the long run entirely by consumers of these goods.

The present value social cost of the proposed regulatory option is estimated to be \$75.9 million discounted at 7 percent. The total costs over the 10-year period apportioned to consumers is estimated to be \$71.6 million discounted at 7 percent. This implies a cost of about \$9.6 million per year for the 31 million freshwater anglers that participate in freshwater **fishing** annually or only 2 cents per **fishing** day (average **fishing** days per individual per year are equal to 14). This does not mean to suggest however, that the increase in the purchase price of **sinkers** is 2 cents. EPA has estimated that the cost impact of the final rule per average angler would be approximately 31 cents per year. However, this figure does not include the markups associated with retail process. The purchase price paid for **sinkers** by the average angler could be \$1.50 to \$3.50 per year, or 10 to 25 cents per day of **fishing**. In any case, the increased price in **fishing sinkers** is relatively minimal in comparison to the total cost incurred by anglers for other expenditures such as **fishing** rods, reels, and other tackle, licenses, **fishing** trips, and boats.

C. Benefits of Proposal

Conducting a benefits analysis is complicated by a number of factors. First, the large number of bird species potentially at risk, the paucity of available data on local bird populations, deaths from all causes, and on deaths from lead- or zinc-containing sinker ingestion make it difficult to estimate current exposures and effects. Second, it is difficult to estimate the probability that a lost lead- or zinc-containing sinker will be picked up by an individual bird. Last, the accumulation of lead in the environment based on historical **fishing**, together with uncertainties about its continued availability to migratory waterbirds, creates problems for estimating the potential effectiveness of alternative regulatory options in reducing exposure and observed effects. Because of these difficulties, the approach taken in the benefits analysis is to illustrate the potential routes of exposure and describe the circumstances that suggest that significant numbers of waterbirds are potentially at risk.

The benefits are presented in terms of number of **sinkers** removed from the market. As indicated in Unit III.D. of this preamble, one lead- or zinc-containing sinker can generally lead to mortality. Following this assumption, this analysis provides estimates of the number of these ``toxic'' **sinkers** removed from the marketplace as a result of a regulatory option. This information provides an indication of the potential for a regulatory option to reduce exposure and risk to birds. While this approach cannot definitively describe absolute risk reduction, it is an effective means of comparing regulatory options.

For the regulatory options that EPA considered, the estimated number of ``toxic'' **sinkers** entering the environment which would be avoided over a 10-year period ranged from near zero to near 4.8 billion. The number of **sinkers** in the environment avoided over 10 years resulting from the regulatory option proposed in this rule, a ban on the manufacture, processing, and distribution in commerce, is approximately 4.2 billion **fishing sinkers** or 470 million **sinkers** per year. This estimate assumes that the regulation is effective in reducing the home manufacture of lead **fishing sinkers**. Therefore, this estimate represents a decrease in the number of lead **sinkers** alone of 89 percent. The remainder of lead, zinc, and brass **sinkers** left on the market will consist of **sinkers** greater than 1 inch in size.

EPA also reviewed relevant economic valuation literature for the variety and range of values associated with the loss of birds. The range of values which is developed in the analysis is used to produce an estimate analogous to a break-even estimate of the number of birds required to generate positive net benefits from the regulatory option. This range is based solely on the relative costs of each of the options and does not address the effectiveness or cost-effectiveness of any given option in terms of risk reduction.

Birds have value to society for a variety of reasons. Values include those from: bird watching; as part of and essential to the health of the ecosystem, its structure or function; biodiversity value;

aesthetic environment for hikers, campers, anglers, and nature walkers in national and state parks and other natural environments; potential future genetic or medical value; and game for hunting.

For example, approximately 58 million persons engaged in non-consumptive, non-residential recreation involving various forms of wildlife including birds. Recreational benefits or expenditure associated with birds including birdwatching, photography, and feeding is estimated to be \$18.1 billion, or approximately \$310 per spender. Other non-consumptive recreational benefits have examined endangered species such as the whooping crane. A valuation study found that persons were willing to pay \$21 to \$149 per year for a refuge that would help protect the crane which they could visit.

Because environmental benefits are usually not traded as market goods and services, estimating values for these benefits is difficult. However, economists have developed approaches with which to estimate these values.

Previously conducted valuation studies on birds are used in this analysis to produce an estimate of the number of non-endangered birds for which the regulatory costs would equal the value of birds for purposes of comparing regulatory options. This is similar in concept to a break-even point. Valuation studies which have been used focus primarily on use value and, thus, do not account for values which society places on endangered species, such as the Mississippi Sandhill Crane, which may be positively affected by the regulation. In addition, the estimates do not account for the value of risk reduction to human health which will occur as a result of the regulatory requirements. Thus, any ranges calculated can help to indicate the potential number of birds that would have to be saved to provide net benefits solely on the basis of benefits to non-threatened or non-endangered birds. The range offers useful guidance in comparing regulatory options, but does not measure absolute benefits or risk reduction.

To calculate the range, the costs of the selected regulatory option were divided by the estimated range of values for non-threatened or non-endangered birds. The results of EPA's analysis indicate that a likely breakeven range is equal to 367,000 to 3.4 million non-threatened or non-endangered birds. While not trivial, the upper bound of this estimate, 3.4 million birds, represents only 5 percent of the estimated fall population of game birds, which embody only a portion of the potentially affected species. Additionally, if as few as one percent of the **sinkers** removed from the market each year caused waterbird deaths, approximately 4.7 million birds could potentially be saved as a result of the regulation, well in excess of the high end of the estimated breakeven range.

While reductions in risk to human health and endangered species have not been quantified, they cannot be ignored. Because the proposed regulation encompasses home manufacture, human health benefits are expected because exposure to lead fumes and dust during the home manufacturing process are expected to be eliminated. Finally, several endangered species are potentially at risk from smaller lead- and zinc-containing **sinkers**. The values for these birds have not been accounted for, yet evidence suggests that society does place a high value on endangered species. For instance, in 1991, an estimated \$1.37 million was spent on preservation efforts for the Mississippi Sandhill Crane alone. While not necessarily a measure of the social value of individuals of this species, it does suggest that these values are real.

D. Cost-effectiveness

The Agency also compared the costs of various regulatory options relative to the benefits achieved by each option. For this analysis, cost-effectiveness was evaluated as cost per 1,000 ``toxic'' or lead- and zinc-containing **sinkers** removed from the market. This type of analysis can be useful in two ways: (1) For regulatory options yielding similar quantified benefits, it can assist EPA in identifying the most cost-effective options, and (2) for regulatory options yielding dissimilar or quantified and non-quantifiable benefits (as in this analysis), it can assist EPA in identifying the incremental increase in

cost per unit increase in quantifiable benefits. This analysis shows that a ban solely of split shot would have the lowest cost per 1,000 **sinkers** avoided. EPA is not proposing a ban on split shot alone because such a ban, on an annual basis, would address only 68 percent of lead **sinkers** 1 inch or less in size. EPA believes this option would be an inadequate response to the risks posed to waterbirds. The proposed option, however, increases benefits to include 100 percent of **fishing sinkers** 1 inch or less on an annual basis, at a still reasonable cost. In addition, the proposed option offers benefits to human health which would not accrue under a ban solely on split shot. EPA is not proposing a ban on **fishing sinkers** over 1 inch in any dimension, or an immediate ban of **sinkers**, in part, because this analysis showed that the incremental costs were high relative to the benefits achieved.

VI. Other Options Considered

A. Summary

In granting the petition, EPA agreed to examine labeling as one course of action. However, EPA also considered a number of other regulatory options such as: (1) A comprehensive ban on all sizes and types of lead- and zinc-containing **fishing sinkers**; (2) a geographic ban on lead- and zinc-containing **fishing sinkers**; (3) a prohibition on the manufacture, processing, and distribution in commerce of lead- and zinc-containing **fishing sinkers** under 2 inches in size; (4) a prohibition on the manufacture, processing, and distribution in commerce of lead and zinc-containing split shot **fishing sinkers**; (5) a prohibition or limitation on the amount of lead and zinc allowable in a **fishing** sinker; and (6) the use of an economic incentive or fee on the sale of lead- and zinc-containing **fishing sinkers**. These options are not mutually exclusive, and could be proposed in conjunction with one another. Although EPA did examine a combination of some options (e.g., labeling and ban), the Agency evaluated each individual option's ability to reduce the number of **sinkers** available for exposure to waterbirds. After consideration of the options and the available information, EPA believes that the proposal to prohibit the manufacture, processing, and distribution in commerce of smaller **fishing sinkers** that contain lead and zinc is the least burdensome means to adequately address the unreasonable risk of injury posed by **fishing sinkers** to waterbirds.

B. Labeling

The petitioners' section 21 petition requested that the Agency require a label on lead **fishing** sinker packaging. However, the petition also stated that depending upon the ``efficacy of the action requested of EPA today, it may at some point in the future be necessary for EPA to restrict further the manufacture, distribution, and sale of lead **fishing sinkers** under TSCA'' (Ref. 5).

A proposal to label could include the following: (1) Placing a label or warning notice on lead- and zinc-containing **fishing** sinker packaging stating that the product is toxic to waterbirds; (2) for **sinkers** sold in bulk, requiring retailers to post a sign with similar language; and (3) requiring catalogues selling **fishing sinkers** to contain language regarding the toxicity of the **sinkers**. This label could be placed on **fishing sinkers** manufactured and sold for use in the United States, and well as those for export. The goal of such a label would be to modify consumer behavior and cause anglers to purchase less toxic **sinkers**.

Labels generally provide consumers with information indicating how to use a product safely. However, in this case, labeling would have little effect on the quantity of toxic **sinkers** lost in the environment, regardless of how careful anglers are. One ingested lead- or zinc-containing sinker can be enough to cause death to a waterbird.

Additionally, labels provide consumers with information regarding the risks associated with the product. The Agency has reviewed studies regarding factors affecting labeling effectiveness and concludes that

consumers generally respond more readily to labels which state or suggest that an immediate and significant personal risk is associated with that product (Ref 31). In situations where the product would not pose such a risk (as is the case with anglers purchasing and using **fishing sinkers**), studies indicate that a label is often less effective in changing consumer response (Ref 31). Therefore, it is questionable whether a label would be effective in causing consumers to purchase other types of **fishing sinkers**.

EPA examined various rates of consumer response to a labeling provision in order to assess the impacts of such an option. The response rates evaluated include, 0, 5, and 10 percent, where a 0 percent response rate indicates that there would be no change in consumer purchasing behavior. EPA estimates that at a 5 percent response rate, approximately 22 million lead- and zinc-containing **sinkers** annually would not be purchased, and approximately 45 million **sinkers** annually would not be purchased at a response rate of 10 percent. In comparison, the proposed option, a ban on the manufacture, processing, and distribution in commerce of lead- and zinc-containing **fishing sinkers**, would result in removing over 450 million **sinkers** from the market on an annual basis, preventing them from entering the environment and becoming available for ingestion by waterbirds.

The Agency believes that labeling would not significantly affect the number of toxic **sinkers** lost in the environment and would only minimally affect consumer purchasing behavior. Therefore, the Agency believes that labeling would not adequately reduce any unreasonable risks of injury to waterbirds.

C. Comprehensive Ban, No Size Limit

This option would prohibit the manufacture, processing, and distribution in commerce of all types and sizes of lead- and zinc-containing **fishing sinkers**. This would guarantee the future elimination of all sizes and types of these **sinkers** in the environment. EPA believes this option would be unduly burdensome and would unnecessarily place restrictions on the types of **sinkers** that are not readily ingested by waterbirds, and, therefore do not pose a significant risk to those species. The Agency believes that there are less costly options which would effectively reduce the number of **sinkers** available for exposure to waterbirds. Therefore, EPA rejected this option.

D. Geographic Ban

EPA also considered a geographic ban to restrict the sale of lead- and zinc-containing **fishing sinkers** in certain areas such as those with freshwater habitats (e.g., near lakes, ponds, or rivers), or in habitats of affected species (see Unit III.E.3. of this preamble). The Agency rejected this option because these areas would essentially include the entire United States, and would be very difficult to enforce. In addition, waterbirds are migratory and could easily ingest **sinkers** in areas where the sale of these **fishing sinkers** was not prohibited. Anglers are also mobile, and could buy the **sinkers** in one location, and use them in another area where their sale is prohibited, thus defeating the purpose of the prohibition. For these reasons, EPA rejected this option.

E. Ban on **Sinkers** 2 Inches or Less in Size

EPA considered prohibiting the manufacture, processing, and distribution in commerce of lead- and zinc-containing **fishing sinkers** which were 2 inches and less in any dimension. EPA believes 2 inches is a diameter to which larger species, such as sandhill cranes, can expand their esophagus to swallow food or other items. However, after further consideration, although larger birds are physically capable of swallowing **sinkers** greater than 1 inch, EPA believes that most waterbirds would not likely ingest **sinkers** of that size. Moreover, the majority of **sinkers** over 1 inch in any dimension are used for **fishing** in the ocean, and would not be readily available for exposure to

waterbirds. This option is less cost effective than the proposed option in terms of removing lead- and zinc-containing **fishing sinkers** from the market. This generally occurs because the number of total **sinkers** between 1 and 2 inches is small compared with the cost of regulating them. For these reasons, EPA rejected regulating **sinkers** over 1 inch and less than 2 inches in any dimension.

F. Ban on Split Shot **Sinkers** Only

EPA examined placing restrictions on the type of lead- and zinc-containing **fishing sinkers** which could be produced or sold. Specifically, EPA considered limiting split shot type **sinkers** because they constitute a significant market segment of the types of lead- and zinc-containing **sinkers** currently produced. However, while prohibiting the manufacture, processing, and distribution in commerce of these type **sinkers** would capture a large portion of **sinkers** available for exposure, EPA believes that regardless of shape, **sinkers** 1 inch or less in any dimension pose the same risk to waterbirds. As discussed earlier in this preamble, both split shot and non-split shot **sinkers** have been found in waterbirds that have died from lead poisoning. A ban solely on split shot would not adequately reduce the number of **sinkers** deposited in the environment.

In addition, EPA believes that the majority of the home manufacturers produce non-split shot **fishing sinkers**. An option to only restrict split shot **sinkers** would not reduce any human health risks associated with the home manufacture of non-split shot. For these reasons, EPA rejected this option.

G. Regulation of Lead and Zinc Content in **Sinkers**

EPA also examined regulating lead and zinc content by weight, or by percentage of lead and zinc present in each sinker. A specific weight or percentage limit would not effectively address the low level of lead or zinc which when ingested by waterbirds could result in a lethal dose (parts per million range). It may not be feasible to measure accurately such a small amount of lead or zinc, making it troublesome for industry to comply with the option, and difficult for the government to enforce adequately. EPA has therefore rejected this option.

H. Economic Incentive

The Agency considered placing a fee on the sale of lead- and zinc-containing **fishing sinkers**. While this option would encourage manufacturers, the cottage industry, or consumers to switch to substitutes, it is difficult to predict the risk reduction that would result from a given fee. In addition, home manufacturers would not be subject to a fee unless they sold the **sinkers**. As such, the quantity of **sinkers** manufactured at home would not be expected to decrease as a direct result of the fee (in fact it may increase as consumers attempt to avoid the fee on purchased **sinkers**) possibly undermining the intended change expected from the fee. For these reasons, EPA rejected this option.

VII. Other Federal Statutes

A. Endangered Species Act

The Endangered Species Act (16 U.S.C. 1531 to 1544) was enacted to protect and preserve plants and animals that have been designated by the Secretary of the Interior as endangered or threatened. The Mississippi sandhill crane is listed as an endangered species under 50 CFR 17.11. EPA has an obligation to conserve the Mississippi sandhill crane, and to consult with the Secretary of the Interior (through the FWS) to insure the action specified in this proposal is not likely to jeopardize the continued existence of the crane, or other endangered species, or result in the destruction or adverse modification of their habitats.

While this proposal is intended to protect and preserve all waterbirds, the Agency is especially concerned about the continued existence of the endangered Mississippi sandhill crane, and potential risk posed to other endangered and threatened species by lead- and zinc-containing **fishing sinkers**. Other endangered species such as the whooping crane, Aleutian Canada goose, peregrine falcon, and possibly the bald eagle could also benefit from this rule as proposed. A prohibition on the manufacture and sale of lead- and zinc-containing **fishing sinkers** would prevent future exposures and risks to these cranes and other endangered or threatened species. Although there has only been one reported death of a Mississippi sandhill crane due to lead poisoning, possibly from a lead **fishing** sinker, the Agency is concerned about each individual of an endangered species, and its importance to the continued survival of the species.

EPA has conferred with the FWS during the development of this proposed rule, to receive their input regarding the scientific aspects of this proposal, and to ensure that there is coordination between both agencies.

B. Migratory Bird Treaty Act

In considering this action under TSCA, EPA is also mindful of other statutes intended to protect birds such as the Migratory Bird Treaty Act (MBTA) (16 U.S.C. 703). Under the MBTA, it is unlawful to "take" migratory birds whether by killing, possessing, or trading except as permitted by regulations. Section 703 of the MBTA prohibits "by any means or in any manner, to . . . take, capture, kill, attempt to take, capture, or kill . . . migratory birds." The MBTA applies to ingestion of lead by birds as seen by action taken by the FWS to ban the use of lead shot to hunt certain waterfowl species. Numerous migratory waterfowl have died from lead poisoning due to ingestion of spent lead ammunition. Species such as sandhill cranes, and trumpeter, mute, and tundra swans are migratory birds which would be protected under the MBTA.

EPA believes that the MBTA is complimentary to the TSCA in potentially reducing risks to waterbirds. While this rule as proposed would regulate the manufacture, processing, and distribution in commerce of **fishing sinkers** in the United States, the Department of Interior has the authority to regulate the manner or method of **fishing** on lands under their control.

C. Other EPA Activities

EPA has been active in protecting migratory birds, and signed a Memorandum of Agreement along with the FWS, U.S. Forest Service, Bureau of Land Management, National Park Service, Department of the Navy, and the Agency for International Development on May 14, 1991, establishing the Neotropical Migratory Bird Conservation Program ("Partners in Flight"). This program, now comprised of many other Federal and State agencies, non-governmental organizations, and academia addresses noted population declines of migratory bird species which nest and breed in North America and winter in Mexico, Central and South America, and the Caribbean. In concert with other "Partners in Flight," EPA plays a major role in maintaining the environmental quality of migratory bird habitats.

VIII. Coordination with Other Federal Agencies

Concurrent with petitioning EPA under section 21 of TSCA, on October 20, 1992, the EDF, North American Loon Fund, Trumpeter Swan Society, and Federation of Fly Fishers also petitioned the Department of Interior (DOI) to utilize its authorities under the Migratory Bird Treaty Act, 16 U.S.C. sections 703-712, the National Wildlife Refuge System Administrator Act, 16 U.S.C. sections 668dd and 668ee, and the National Park Service Act, 16 U.S.C. sections 1-3, to prohibit, by regulation, the use of lead weights for **fishing** on any National Wildlife Refuge or National Park where the trumpeter swan or common

loon breeds or stops over during migration. On June 4, 1993, DOI published a Federal Register notice requesting comment on the petition (58 FR 31740). Comments were due by September 2, 1993. It is EPA's understanding that DOI is still developing its response to the petition.

Under section 9 of TSCA, EPA is directed to consider whether the risk to be addressed by regulatory action under TSCA may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by EPA. EPA recognizes that in the area of protection of wildlife, and specifically of waterbirds and other avian species, there are some areas of overlap between the statutory authorities administered by EPA and DOI. However, some activities, the regulation of which could protect wildlife (e.g., regulation of the manufacture, processing, and distribution in commerce of chemical substances), are clearly within the purview of EPA.

At this point, EPA has preliminarily determined that the potential unreasonable risks to waterbirds would not be sufficiently prevented or reduced through future regulatory initiatives by DOI so as to make regulatory action under TSCA unnecessary. As discussed above, EPA has worked closely in the past with a number of federal agencies, including DOI, to protect migratory birds. EPA has also conferred with the FWS of the DOI to ensure that there is coordination between the two agencies. EPA will continue to confer with and coordinate its activities with DOI in the course of this rulemaking to ensure a unified approach that adequately protects human health and the environment, and avoids unnecessary or duplicative Federal regulation.

IX. Unreasonable Risk

A. Standard

To promulgate a rule under TSCA section 6(a), EPA must find that there is a ``reasonable basis to conclude'' that activities involving a chemical substance or mixture present or will present ``an unreasonable risk of injury to health or the environment.'' The finding of unreasonable risk is a judgement under which the decision-maker determines that the risk of health or environmental injury from the chemical substance or mixture outweighs the burden to society of potential regulations.

It is important to note that section 6 of TSCA does not require a factual certainty, but only a ``reasonable basis to conclude'' that a risk is unreasonable. The legislative history of TSCA makes it quite clear that EPA may take regulatory action to prevent harm even though there are uncertainties as to the threshold levels of risk. Congress recognized that in addition to basing its decision on known facts, EPA must, of necessity, often base its action on scientific theories, consideration of projections from available data, modelling using reasonable assumptions, and extrapolations from limited data. (H.R. Rep. No. 1341, 94th Cong., 2d Sess. 32 (1976))

Although TSCA uses unreasonable risk as its basic standard for deciding on appropriate action regarding the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, TSCA does not define the term ``unreasonable risk.'' The only guidance in the statute is provided in section 6(c), which established the requirements that to make an unreasonable risk determination under section 6(a), EPA must consider the following: (1) The effects of the chemical on health and the magnitude of its exposure to humans; (2) the effects of the chemical on the environment and the magnitude of its exposure to the environment; (3) the benefits of the chemical for various uses and the availability of substitutes for such uses; and (4) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

Section 6(c) offers no further guidance to decisionmakers. In particular, it does not discuss how each of these factors are to be weighed in relationship to each other. Consequently, guidance on implementation of the unreasonable risk standard in regulatory decisionmaking requires consideration of the legislative history. The

House Report on TSCA (H.R. Rep. No. 1341, 94th Cong., 2d Sess. 13-15 (1976)) provides the most useful pertinent explanation. The House Report describes the finding of unreasonable risk as involving a balancing of the probability that harm will occur, and the magnitude and severity of that harm, against the adverse effects (social and economic) on society of the proposed Agency action to reduce the harm. In other words, unreasonable risk involves a weighing of the risks to be reduced by Agency action and the consequences of the action.

B. Finding

Utilizing this analysis, EPA has evaluated the following elements to make its preliminary ``unreasonable risk'' finding: (1) Evidence of the toxicity of lead and zinc, (2) effects of lead **fishing sinkers** on waterbirds, (3) species exposed and adversely affected by lead-containing and potentially affected by zinc-containing **fishing sinkers**, (4) potential magnitude of exposure to lead- and zinc-containing **fishing sinkers**, (5) substitutes for lead- and zinc-containing **fishing sinkers**, and (6) economic impacts of imposing the proposed rule. Each individual element is discussed in detail in Units III. and V. of this preamble.

EPA has weighed the risks of injury to waterbirds from continued use of smaller lead- and zinc-containing **fishing sinkers** against the costs of eliminating the manufacture, processing, and distribution in commerce of such **sinkers**. The Agency believes that the benefits of eliminating the effects to waterbirds of ingesting these **fishing sinkers** outweigh the costs to society of the rule as proposed based on the following:

1. The toxicity associated with lead exposure is well documented. A review of extensive research on the toxicity of lead to waterbirds leads to the conclusion that ingestion of lead **fishing sinkers** poses a significant hazard to waterbirds. Specifically, common loons, trumpeter swans, mute swans, sandhill cranes, and tundra swans have been demonstrated to ingest lethal amounts of lead, either intentionally, accidentally, or incidentally, while feeding in aquatic habitats containing discarded lead **sinkers**. Research has shown that one small lead **fishing** sinker is enough to cause mortality in these and other waterbirds. In addition, based on the toxicity of lead and zinc, other lead-containing or zinc-containing **fishing sinkers** such as brass would also pose a risk to waterbirds.

2. Lead and zinc are persistent in the environment. As more lead- and zinc-containing **sinkers** are produced and sold, more may enter ecosystems where they can become available to waterbirds.

3. The rule as proposed would create benefits by preventing potential waterbird deaths. It is estimated that the proposed ban would prevent over 450 million lead- and zinc-containing **fishing sinkers** that have any dimension 1 inch or less from being produced each year, and potentially from entering the environment.

4. Waterbirds have many benefits to society for reasons such as bird watching, photography, biodiversity, part of and essential to the health of the ecosystem, potential future genetic or medical value, contributing to the aesthetic environment for hikers, campers and anglers, and game for hunting. It is clear that significant public and private expenditures are made to protect and enjoy these birds.

5. Although the magnitude of the effect lead **fishing sinkers** have on waterbird populations is uncertain, it is reasonable to conclude that as more lead **fishing sinkers** are discarded or lost in the environment and are available for ingestion, further deaths will occur. In the case of endangered species particularly, each individual is valuable and vital to the continuation of the species.

6. Scientific evidence has demonstrated that zinc is also very toxic to waterbirds (exposure to mallards has resulted in their death), aquatic organisms, and mammals. Based on EPA's comparative toxicity analysis, ingestion of zinc-containing **fishing sinkers** could also cause death in waterbirds.

7. Substitutes for lead- and zinc-containing **fishing sinkers** are available which perform as well as lead and zinc, albeit at a higher

cost. These **sinkers** can be manufactured using existing technologies.

8. EPA's analysis indicates that the costs of this proposed rulemaking will not result in serious economic consequences for small businesses or the national economy, and would result in minimal economic consequences for anglers. The annual cost of the rule as proposed to the average angler is less than \$4.00.

9. A vast number of lead **fishing sinkers** are made by persons at home. Exposure to lead may cause severe adverse health effects such as brain damage in children, miscarriages, and hypertension. The rule as proposed may assist in preventing exposures which may result from the lead vapors or fumes created when making **sinkers**, and potential risks to human health.

After examination of these factors, EPA has preliminarily concluded that the continued manufacture, processing, and distribution in commerce of **fishing sinkers** that contain any lead or zinc, and that have any dimension 1 inch or less, presents or will present an unreasonable risk of injury to waterbirds.

X. Issues for Comment

While EPA solicits comment on all aspects of this proposal, the Agency specifically requests comments on the following issues: (1) The size of **fishing sinkers** prohibited from being manufactured, processed, and distributed in commerce; (2) whether the prohibitions will create difficulties for manufacturers of other types of **fishing sinkers** containing small amounts or impurities of lead and zinc; (3) the level at which lead or zinc impurities are present in other type of metals used for **fishing sinkers**; (4) additional avian or aquatic toxicity information for antimony, brass, tin, copper, bismuth, tungsten, terpene resin, polypropylene, and iron; (5) whether other types of **sinkers** should be included under the proposed ban; (6) whether the manufacture and sale of lead jigs should be prohibited or limited, and if so, how could the Agency distinguish jigs from other types of lures; (7) whether lead jigs are a likely or suitable substitute for lead **fishing sinkers**; (8) whether other suitable less toxic substitutes are available; (9) the effective date, or timing of the manufacture, processing, and distribution ban on lead- and zinc-containing **fishing sinkers**; (10) any further information which indicates that either lead- and zinc-containing **fishing sinkers**, jigs, lures, or other uses of lead in **fishing** equipment may be toxic to waterbirds, or other wildlife; (11) studies or any other information regarding the valuation or benefits of waterbirds, other birds, or endangered species (particular avian), or methods to estimate those benefits; (12) comments on the estimates of the cost associated with the proposed rule; (13) whether the proposal would inadvertently lead to greater human exposure due to increased illegal home production of lead **fishing sinkers**; (14) potential impacts of the proposed rule on small manufacturers and the cottage industry; (15) EPA's definition of **fishing sinker**; (16) information, studies, or comments on whether consumers' response to labels that do not warn of immediate and significant personal risk is likely to be small or uncertain compared to the response to labels that warn of personal risk; (17) whether warning labels on lead- or zinc-containing **fishing sinkers** are likely to reduce purchases of such **sinkers** by 0 to 10 percent; and (18) whether it is desirable or feasible to pursue any of the rejected options versus the one EPA has proposed.

XI. Exports

Section 12(b) of TSCA requires that any person who exports or intends to export a chemical substance or mixture for which a rule has been proposed or promulgated under section 6 of TSCA must notify EPA of such exportation or intent to export. In this proposed rule, EPA is addressing lead- and zinc-containing **fishing sinkers**. Since such **sinkers** may consist of lead and zinc in combination with any other material, EPA has concluded that it is proposing to regulate ``mixtures'' in the rule for purposes of applying section 12(b) export

notification requirements. Thus, as a result of this proposed rule, any person who exports or who intends to export any lead- or zinc-containing **fishing** sinker described in this proposed rule, to a foreign country, would be required under section 12(b) of TSCA to notify EPA of such exportation or intent to export. The export notification requirements are described in 40 CFR part 707.

EPA anticipates that the burden of the export notification requirements will be minimal. Exporters are required only to provide notification the first time they export or intend to export to each country in a calendar year. The notification requirements are set forth in 40 CFR part 707 and consist of the company's name and address, chemical name, TSCA section that triggered the notification (in this case section 6), countries that are the receivers, and the export date or intended export date. As described in Unit V. of this preamble, there is very little export of **sinkers**.

XIII. Recordkeeping

As discussed in Unit XI. of this preamble, TSCA section 12(a) authorizes EPA to impose recordkeeping requirements under TSCA section 8 on a chemical substance, mixture, or article containing a chemical substance or mixture even when it is manufactured, processed, or distributed in commerce and properly marked or labeled as being intended solely for export. Section 12(b) of TSCA permits EPA to require export notification for any substance or mixture regulated or proposed to be regulated under TSCA section 6.

EPA has the authority under section 8(a) of TSCA to require persons to engage in recordkeeping and reporting activities. Section 8(a)(1) of TSCA gives EPA authority to require persons who manufacture or process chemical substances and mixtures to maintain records for manufacturing purposes, including records necessary for effective enforcement of TSCA requirements. Small manufacturers and processors are generally exempt from recordkeeping under section 8(a). However, section 8(a)(3)(A)(ii)(I) provides that, when, as here, the chemical substance or mixture involved is subject of a rule proposed or promulgated under TSCA section 6, small manufacturers and processors also can be required to report and keep records.

Pursuant to these authorities and to ensure compliance with this proposed rule and TSCA section 12(b) export notification requirements, as applicable, and to assist in enforcement efforts, each person who manufactures or processes **fishing sinkers** that would be subject to the rule, after the effective date of the final rule, would be required to maintain manufacturing and shipment/distribution records for a period of 3 years from the date of manufacture or shipment, such as: (1) The product or brand name; (2) quantity and date of **sinkers** manufactured, processed, or shipped; (3) name, address, and telephone number of the person who shipped, and who received the sinker shipment; and (4) inventory records of **sinkers** manufactured or produced.

EPA believes that the recordkeeping requirements will be necessary for effective enforcement of the rule. This would enable EPA to ensure compliance with the rule and conduct inspections effectively. Examination of records would enable EPA to track distribution patterns and would aid in identifying sites where a potential violation of the final rule may exist.

XIII. Enforcement

Section 15 of TSCA makes it unlawful to fail or refuse to comply with any provision of a rule promulgated under section 6 of TSCA. In addition, section 15 of TSCA makes it unlawful for any person to: (1) Use for commercial purposes a chemical substance which such person knew or had reason to know was distributed in commerce in violation of a rule under section 6; (2) fail or refuse to establish and maintain records, submit reports or notices, or permit access to or copying of records, as required by TSCA; or (3) fail or refuse to permit entry or inspection as required by section 11 of TSCA.

Violators may be subject to both civil and criminal liability. Under the penalty provision of section 16 of TSCA, any person who

violates section 15 could be subject to a civil penalty of up to \$25,000 per day for each violation. Each day of operation in violation of the rule would constitute a separate violation. Knowing or willful violations of the rule could lead to the imposition of criminal penalties of up to \$25,000 for each day of violation or imprisonment for up to 1 year, or both. In addition, other remedies are available to EPA under sections 7 and 17 of TSCA, such as seeking an injunction to restrain violators of the rule and seizing any chemical substance or mixture manufactured or imported in violation of the rule.

Individuals, as well as corporations, could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to ``any person'' who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies. In particular, EPA may proceed against individuals who report false or misleading information or cause it to be reported.

XIV. Business Confidentiality

A person may assert a claim of business confidentiality for any public comments submitted to EPA in connection with the proposed rule. Any person who submits a public comment that contains information claimed as confidential, must also submit a nonconfidential version. Any claim of confidentiality must accompany the information when it is submitted to EPA. Persons may claim information confidential by circling, bracketing, or underlining it, and marking it with ``CONFIDENTIAL'' or some other appropriate designation. EPA will disclose information subject to a claim of business confidentiality only to the extent permitted by section 14 of TSCA and 40 CFR part 2, subpart B. If a person does not assert a claim of confidentiality for information in public comments at the time it is submitted to EPA, the Agency will put the comments in the public docket without further notice to that person.

XV. Hearing Procedures

If persons request time for oral comment, EPA will hold informal hearings in Washington, DC. Any informal hearing will be conducted in accordance with EPA's ``Procedures for Conducting Rulemaking under Section 6 of the Toxic Substances Control Act'' (40 CFR part 750). Persons or organizations desiring to participate in the informal hearing must file a written request to participate. The written request to participate must be sent to the Environmental Assistance Division at the address listed under FOR FURTHER INFORMATION CONTACT by [insert date 60 days after date of publication in the Federal Register]. The written request to participate must include: (1) A brief statement of the interest of the person or organization in the proceeding; (2) a brief outline of the points to be addressed; (3) an estimate of the time required; and (4) if the request comes from an organization, a non-binding list of the persons to take part in the presentation. Organizations are requested to bring with them, to the extent possible, employees with individual expertise in and responsibility for each of the areas to be addressed. Organizations which do not file main comments in the rulemaking will not be allowed to participate at the hearing, unless the Record and Hearing Clerk grants a waiver of this requirement in writing.

XVI. Rulemaking Record

In accordance with the requirements of section 19(a)(3) of TSCA, EPA has established a record for this rulemaking [docket number OPPTS-62134]. This record includes information considered by the Agency in developing the proposed rule, and will include comments on the proposed rule. A public version of the record which does not include information claimed as confidential business information is available to the public in the Nonconfidential Information Center (NCIC). The NCIC is located in Rm. E-G102, 401 M St., SW., Washington, DC 20460, and is open from noon to 4 p.m., Monday through Friday except legal holidays.

XVII. Support Documents

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7. Environmental Defense Fund, Mr. Bruce Manheim and Mr. Michael Bean. January 26, 1993. Letter to EPA Administrator Carol Browner.
8. Environmental Defense Fund, Inc. v. Carol Browner and the Environmental Protection Agency. Amended Complaint for Declaratory and Injunctive Relief filed in United States District Court for the District of Columbia. Civil Action Number 93-0532. May 18, 1993.
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12. Locke, L.N., S.M. Kerr, and D. Zoromski. 1981. Lead Poisoning in Common Loons (Gavia immer). Avian Diseases. 26(2):392-396.
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15. Rose Lake Wildlife Research Center. Wildlife Disease Laboratory. Mortality Summary Tables and Necropsy Records for Common Loon and Mute Swan Mortalities in Michigan 1988-1993.
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18. U.S. Department of the Interior, Fish and Wildlife Service, National Wildlife Health Research Center. Diagnostic Services Case Report Number 10625. April 20, 1992.
19. U.S. Department of the Interior, Fish and Wildlife Service. Endangered Species Technical Bulletin, Vol. 27 Nos. 3-8 1992. p. 16.

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29. New York State Department of Environmental Conservation. Wildlife Resources Center. Autopsy Reports. Case Numbers: 31-19, 82-70-8, 86-35-19, 86-26-24, 89-8-16, 89-66-29, 90-09-32, and 90-25-23.

30. Pokras, M.A., and H. Stern. Tufts University School of Veterinary Medicine. Personal communication to N. Laurson, EPA, Office of Pollution Prevention and Toxics. Common Loons found in New England between 1991 and 1993. February 1, 1994.

31. U.S. Consumer Product Safety Commission. Carol Pollack-Nelson. March 1991. Estimated Effectiveness of Warning Labels.

XIX. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients

thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

This proposed rule was submitted to OMB for review, and any comments or changes made in response to OMB suggestions or recommendations have been documented in the public record.

B. Regulatory Flexibility Act

Pursuant to the provisions of 5 U.S.C. 605(b), EPA is required to make a statement concerning the economic impact of this proposed rule on small businesses. This proposed rule, if promulgated, will have a significant economic impact on a number of small entities. A substantial number of small business entities will be affected by the proposed action such as the cottage industry.

The analysis indicates that the manufacturers of lead, zinc, and brass **sinkers** all fall under the Small Business Administration's definition of a small business. However, the analysis identified three distinct subgroups of these manufacturers, ``large'' manufacturers with significant capital, ``small'' manufactures which are often one or two person operations, and home manufacturers. The impacts on these segments were examined separately.

Large manufacturers are able to respond to the regulatory requirements and switch to alternative processes and/or materials and remain viable. While home manufacturers are unable to easily switch to alternatives, they would not be adversely impacted because retail sale of **sinkers** is not considered to be a primary source of income for these individuals. While small manufacturers may be adversely impacted, regulatory alternatives which may reduce the burden to these manufacturers could create unfair market advantages for them and their actions could continue to pose an unreasonable risk to the environment. An exemption for certain non-split shot **sinkers** would serve to reduce the burden on only some of the disproportionately impacted small businesses but not others. To conclude, it is difficult to devise a regulatory alternative which reduces the burden to this segment of the industry without compromising the intent of the regulation.

The selected regulatory option would impose recordkeeping requirements on industry; however, the overall impact of these requirements is expected to be minimal. The estimated maximum cost to industry is \$16,450 annually, or approximately .2 percent of the annual cost of the regulation overall.

C. Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act (44 U.S.C. 3501, et seq.), the information collection requirements in this proposed rule have been submitted to the OMB for approval. An Information Collection Request (ICR) has been prepared by EPA (identified as ICR Number 1671.01), and a copy may be obtained from Sandy Farmer (2136), Information Policy Branch, EPA, 401 M St., SW., Washington, DC 20460, or by calling (202) 260-2740.

This collection of information has an estimated annual recordkeeping burden of 54 hours per respondent. This estimate includes time for gathering and maintaining information needed.

EPA believes that the proposed rule provisions regarding maintenance of information poses a minimal burden. Manufacturers and processors of lead- and zinc-containing **fishing sinkers** for export would be required to keep records which establish the sale and/or transfer of **fishing sinkers** that would be banned for domestic consumption under this proposal. The type of information required should already be maintained as normal business records, and readily available. Therefore the information collection provision of this proposed rule would not impose a significant burden on the regulated entities.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch (2136), EPA, 401 M St., SW., Washington, DC 20460, and to the Office of Information and Regulatory

Affairs, OMB, Washington, DC 20503, marked ``Attention: Desk Officer for EPA.'' The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

List of Subjects in 40 CFR Part 745

Environmental protection, Hazardous substances, Lead, Recordkeeping and notification requirements.

Dated: February 28, 1994.
Carol M. Browner,
Administrator.

Therefore, it is proposed that 40 CFR part 745 be amended to read as follows:

1. The authority citation for part 745 would be revised to read as follows:

Authority: 15 U.S.C. 2605, 2607, and 2681-2692.

2. Subparts F-Q are reserved and subpart R is added consisting of Sec. 745.475 to read as follows:

Subparts F-Q--[Reserved]

Subpart R--Requirements for Specific Products Containing Lead

Sec. 745.475 Lead- and zinc-containing products.

(a) Scope, purpose, and applicability. (1) Scope. This subpart contains restrictions on the manufacture (including import), processing, and distribution in commerce of certain types of lead- and zinc-containing **fishing sinkers**. This subpart imposes requirements on persons who manufacture, process, or distribute **fishing sinkers** in commerce for use in the United States that contain any lead or zinc in combination with any other chemical substance, and are less than or equal to 1 inch in any dimension.

(2) Purpose. The purpose of this subpart is to protect waterbirds from unreasonable risk from ingestion of lead- and zinc-containing **fishing sinkers**.

(3) Applicability. This subpart applies to any person engaged in the manufacture, processing, or distribution in commerce of lead- and zinc-containing **fishing sinkers**, as defined in this subpart. Any person who manufactures or processes any such lead- or zinc-containing **fishing** sinker for export or intends to export any such **fishing** sinker to a foreign country will be subject to the export notification requirements of section 12(b) of TSCA. The notification requirements are set forth in 40 CFR part 707.

(b) Definitions. In addition to the terms defined in section 3 of TSCA, the following definition also applies for the purposes of this subpart:

(1) **Fishing** sinker means a weight which can be attached to a **fishing** line, not permanently affixed to a hook. This includes, but is not limited to split shot, worm weights, egg **sinkers**, bass casting, pyramid **sinkers**, rubber core **sinkers**, pinch grip **sinkers**, and slip shot **sinkers**.

(2) [Reserved]

(c) Manufacturing and processing limitations. Effective [insert date 1 year after promulgation of the final rule], all persons are prohibited from manufacturing or processing any **fishing** sinker for use in the United States which contains any lead or zinc, and is less than or equal to 1 inch in any dimension.

(d) Distribution in commerce limitations. Effective [insert date 2 years after promulgation of the final rule], all persons are prohibited from distributing in commerce any **fishing** sinker for use in the United States which contains any lead or zinc, and is less than or equal to 1 inch in any dimension.

(e) Recordkeeping. (1) Each person who manufactures or processes lead- and zinc-containing **fishing sinkers** less than or equal to 1 inch in any dimension for export shall maintain the following records: (i) Product name and/or brand name of such **fishing sinkers** manufactured or processed; (ii) location of where such **fishing sinkers** were manufactured or processed; (iii) quantity and date of such **fishing sinkers** manufactured or processed; (iv) product name and/or brand name of such **fishing sinkers** distributed (shipped); (v) quantities of such **fishing sinkers** shipped or delivered for shipment; (vi) date such **fishing sinkers** shipped or delivered for shipment; (vii) name, address, and telephone number of consignee; (viii) name, address, and telephone number of originating shipment carrier; and (ix) inventory records of the product and/or brand names, and quantity of such **fishing sinkers** manufactured or processed (these records may be disposed of when a more current inventory record is prepared by the manufacturer or processor). This information must be retained for a period of 3 years from the date of manufacture, processing or distribution in commerce. Shipping and receiving documents such as invoices, freight bills, and receiving tickets which provide the required information will be considered satisfactory for purposes of this section.

(2) [Reserved]

(f) Enforcement. (1) Failure or refusal to comply with any provision of this section is a violation of section 15 of TSCA (15 U.S.C. 2614).

(2) Failure or refusal to permit entry or inspection as required by section 11 of TSCA (15 U.S.C. 2610) is a violation of section 15 of TSCA (15 U.S.C. 2614).

(3) Violators are subject to the civil and criminal penalties specified in section 16 of TSCA (15 U.S.C. 2615), or specific enforcement and seizure as specified in section 17 of TSCA (15 U.S.C. 2616).

(g) Inspections. EPA will conduct inspections under section 11 of TSCA (15 U.S.C. 2610) to ensure compliance with this section.

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