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OFFICE OF
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MEMORANDUM

SUBJECT: EFED Registration Review Problem Formulation for Sodium Cyanide (M-44)
PC Code No. 074002; Case No. 143-33-9

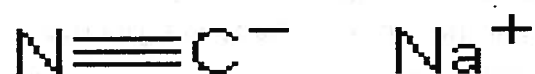
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This memo summarizes the draft registration review problem formulation for sodium cyanide (M-44). After reviewing the available fate and toxicity data, no changes in risk conclusions are anticipated relevant to the 2009 response to the petition to cancel M-44. However, as outlined in the Agency's response to the petition and addenda (filed January 24, 2007, March 20, 2007, July 27, 2007 and January 7, 2008) requesting that EPA suspend and cancel the registration of the predator control uses of sodium cyanide (M-44), the Agency will conduct an endangered species risk assessment for all uses of sodium cyanide. In this assessment, risk to listed species will be re-evaluated in terms of the twenty-six use restrictions added to the labels to reduce the risk to listed animals.

Problem Formulation
for the Ecological Risk Assessment
of Sodium Cyanide (M-44)



Environmental Fate and Effects Division
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1. Purpose

The purpose of this problem formulation is to provide the foundation for the ecological risk assessment being conducted for the registered uses of sodium cyanide (M-44). As such, it articulates the purpose and objectives of the forthcoming risk assessment, evaluates the nature of the problem, and provides a plan for analyzing the data and characterizing the risk (EPA, 1998). Additionally, this problem formulation is intended to identify data gaps, uncertainties and potential assumptions needed to address those uncertainties in characterizing the ecological risk associated with the registered uses of M-44.

M-44 is used to target coyotes, red foxes, gray foxes and wild dogs. The M-44 device's base is buried in the ground. The capsule holder is inserted into the unit's base and the capsule is loaded into the capsule holder. The capsule holder is then treated with a scent used to attract canids to the unit. When an animal tugs at the capsule holder, a spring-driven plunger ejects the sodium cyanide capsule into its mouth. Primary exposure occurs when the injection device containing powdered M-44 is activated and M-44 is released directly into the mouth of the target animal. Rapid death occurs following the inhalation of newly formed hydrogen cyanide from the reaction of M-44 (sodium cyanide) with water contained in available moisture.

2. Problem Formulation

2.1. Nature of Regulatory Action

This report summarizes the Environmental Fate and Effects Division's (EFED) Problem Formulation for the Registration Review of M-44. Previous risk assessments were completed for the uses of the chemical, through 1994, which serve as the basis for this assessment.

The Food Quality Protection Act of 1996 mandated the EPA to implement a new program, *i.e.*, registration review (http://www.epa.gov/oppsrrd1/registration_review/). All pesticides distributed or sold in the United States generally must be registered by the EPA. The decision to register a pesticide is based on the consideration of scientific data and other factors showing that it will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. The registration review program is intended to ensure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health and the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the new registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely.

As part of the implementation of the new Registration Review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Agency is beginning its evaluation to determine whether M-44 continues to meet the FIFRA standard for registration. This problem formulation for the environmental fate and ecological risk assessment chapter in support of the registration review is intended for the initial docket opening the public phase of the review process.

2.2. Regulatory History

Sodium cyanide was initially registered as a pesticide on December 23, 1947, to control ants on uncultivated agricultural and non-agricultural areas. Sodium cyanide was also registered to control certain bacteria, insects, and commensal rodents in human residences; railway cars; food marketing, storage, and distribution facilities; and commercial institutional and industrial premises.

Prior to 1972, sodium cyanide was used to control predators in a gunpowder-fired unit called the "Humane Coyote Getter." Executive Order 11643, issued in 1972, banned the use of M-44 on federal land. All predator control uses of M-44 were cancelled and suspended in 1972 (37 Fed. Reg. 5718, March 1972). Experimental use permits were issued to DOI, CA, ID, KS, MT, SD, and TX in 1974. In 1975, the US Fish and Wildlife Services requested the re-registration of M-44. In response to that request, the executive order was amended to allow experimental uses of the M-44 ejector device with twenty-six use restrictions requested by the administrative law judge. The order was amended again in 1976 to allow use on federal lands.

In 1985, the DOI petitioned EPA to modify the 1972 cancellation order to include a modification to allow the use of M-44 in wildlife refuges for the protection of threatened or endangered species subject to predation by coyotes and other wild canids. The decision (August, 1987) recommended that the registration be modified to allow the proposed use to protect threatened or endangered species.

M-44 is used to protect endangered species as well as to protect livestock and poultry. Labels for M-44 were modified to identify specific endangered species as one of the twenty-six use restrictions (Appendix A) following the receipt of the 1993 Biological Opinion (BO) (U.S. Department of Interior 1993). Listed species identified on the label included the Hawaiian crow, Mariana crow, California condor, Florida panther, ocelot, jaguarondi, San Joaquin kit fox, Louisiana black bear, gray wolf and grizzly bear. One label specifically protects listed species from the Arctic fox in the Aleutian Islands.

On, January 24, 2007, ten non-governmental organizations, Sinapu, Public Employees for Environmental Responsibility (PEER), Beyond Pesticides, Forest Guardians, Predator Defense, Western Wildlife Conservancy, Sierra Club, The Rewilding Institute, Animal Defense League of Arizona, and Animal Welfare Institute, petitioned the Agency for cancellation of all registered uses of M-44. The request for cancellation was based on purported unreasonable adverse effects on the environment, misuse, inability of the

registrant to secure the pesticide (prevent unauthorized access) and harm to endangered species. Following review of this petition, the Agency determined use of M-44 does not create unreasonable adverse effects on the environment under FIFRA and its registration meets the FIFRA eligibility standards as indicated in a memo available on the docket dated January 16, 2009.

However, as part of this registration review action, the Agency will reconsult with US Fish and Wildlife Services in accordance with Section 7 of the Endangered Species Act (USFWS/NMFS, 1998) based on additional species identified and potential changes in ranges/habitat boundaries for previously identified species. A letter initiating formal consultation will be delivered to USFWS. In addition, EPA will confirm that the measures in place remain adequate to protect listed species identified from the 1993 BO and recommend additional measures for new listed species identified if necessary.

2.3. Previous Risk Assessments

A Reregistration Eligibility Decision (RED) that included an ecological risk assessment for fish, invertebrates, and plants in aquatic habitats, as well as birds, mammals, invertebrates and plants in terrestrial habitats, was issued in 1994 for M-44 (USEPA, 1994). At this time, the data were considered sufficient to allow the Agency to assess the registered uses and to determine that the pesticide could be used without resulting in unreasonable adverse effects to humans and the environment.

Based on the 1994 RED, a potential risk of direct effects on non-target birds and mammals was identified when the device is triggered and M-44 is injected into the animal's mouth. The RED also indicated that open literature provided support for the low risk of secondary poisoning due to the amount of time M-44 remains in the carcass and the amount in the tissues. Furthermore, it was assumed in the 1994 RED that exposure to M-44 from run-off, leaching or spray drift was negligible because M-44 is buried in the soil in a containment device which released only when triggered. Based on available data at that time, any releases of M-44 to the soil (e.g., following triggering of the device) were assumed to be subject to rapid degradation by bacteria or volatilization and dissipation due to formation of hydrogen cyanide gas.

3. Stressor Source and Distribution

Sodium cyanide (M-44) is used to target coyotes, red foxes, gray foxes and wild dogs. Primary exposure occurs when the device is activated and M-44 is released directly into the mouth and is considered as the stressor in this assessment. Exposure is also possible from accidental spills.

3.1. Description of Properties of M-44 (Sodium Cyanide)

A summary of chemical information and physicochemical properties of sodium cyanide is included in **Table 3.1** below. Factors influencing transport include solubility,

adsorption on soil components and clay and interactions with biomass. Sodium cyanide appears to be degraded rapidly in soil where it readily hydrolyzes to hydrogen cyanide. The hydrogen cyanide, which is formed by reaction with moisture, will diffuse to the atmosphere and be diluted into the air. The hydrolysis reaction is as follows:



Reactions with soil compounds will convert cyanide into carbon dioxide and ammonia or other nitrogen containing compounds. Thus, the environmental impact of the pesticidal use of sodium cyanide is expected to be minimal because of its mode of application as well as its degradation pattern in the environment. Sodium cyanide works by converting to hydrogen cyanide gas when it comes in contact with moisture, which inhibits an enzyme reaction that is essential to mammalian cellular respiration. This results in central nervous system depression, cardiac arrest and gross respiratory failure.

Table 3.1 Summary of chemical information and physicochemical properties of M-44 (Sodium Cyanide)

Chemical Formula	NaCN
Chemical Structure	$\text{N}\equiv\text{C}^- \text{Na}^+$
Synonyms:	Hydrocyanic acid, sodium salt; Cyanogran
CAS No.:	143-33-9
Product Codes:	J.T. Baker: 3662, 3663 Mallinckrodt: 7616
Appearance:	White deliquescent granular solid.
Odor: ³	Almond odor. Bitter almonds.
Molecular Weight: ³	49.0072 g / mol
Solubility in Water: ³	48 g / 100 cc @ 10 ⁰ C (50 ⁰ F), 58 g / 100 cc @ 20 ⁰ C (68 ⁰ F), 82 g / 100 cc @ 34.7 ⁰ C (94.5 ⁰ F)
Specific Gravity: ⁴	1.60 @ 25 ⁰ C / 4 ⁰ C
Density: ³	1.595 g / cm ³
pH:	Aqueous solutions are strongly alkaline.
% Volatiles by volume @ 21C (70F):	0
Boiling Point: ¹	1496 ⁰ C (2724.8 ⁰ F)
Melting Point: ¹	563 ⁰ C (1045.4 ⁰ F)
Vapor Pressure (mm Hg):	1.0 @ 817 ⁰ C (1503 ⁰ F)
Stability:	Very stable when dry. Moisture will cause slow decomposition, releasing poisonous hydrogen cyanide gas.
Hazardous Decomposition Products:	Emits toxic fumes of cyanide and oxides of nitrogen when heated to decomposition.
Henry's Law Constant	0.132 atm-l/mol
Hazardous Polymerization:	Will not occur

Incompatibilities:	Acid. nitrates, nitrites, chlorates, fluorine, magnesium, and strong oxidizers. Reacts with acids to liberate toxic and flammable hydrogen cyanide gas. Water or weak alkaline solutions can produce dangerous amounts of hydrogen cyanide in confined areas. Reacts with carbon dioxide in air to form hydrogen cyanide gas.
Conditions to Avoid:	Heat, moisture, incompatibles.
¹ (Material Data Safety Sheet: http://www.sciencelab.com/msds.php?msdsId=9927711) ² (Centers Disease Control and Prevention: http://www.cdc.gov/niosh/npg/npgd0562.html) ³ (http://www.answers.com/topic/sodium-cyanide) ⁴ (IPCS: http://www.ilo.org/legacy/english/protection/safework/cis/products/icsc/dtasht/_icsc11/icsc1118.htm)	

3.2. Mechanism of Action

The sodium cyanide capsule is only allowed for use in the M-44 spring-loaded ejector. The capsule is loaded into a capsule holder which is screwed onto the ejector mechanism and treated with a scent formulated to attract canids. When an animal pulls the capsule holder, a spring-driven plunger ejects the sodium cyanide into the animal's mouth. The active ingredient (NaCN) reacts with moisture in the mouth to form hydrogen cyanide (HCN) gas, which is then inhaled. Hydrogen cyanide strongly inhibits oxidative phosphorylation in mitochondria and subsequent ATP production. The inhibition of oxidative metabolism puts increased demands on anaerobic glycolysis, which results in lactic acid production and may produce severe acid-base imbalance. The central nervous system is particularly sensitive to the toxic effects of cyanide, and exposure to hydrogen cyanide generally produces symptoms within a short period of time (<http://www.atsdr.cdc.gov/mhmi/mmg8.pdf>). In animals, death occurs from ten seconds to two minutes after the device is triggered (http://www.aphis.usda.gov/lpa/pubs/fsheet_faqs_notice/fs_wsm44.html).

3.3. Overview of Pesticide Usage

Current Use

M-44 is a restricted use pesticide registered to control canid predators (*coyotes* (*Canis latrans*), red fox (*Vulpes vulpes*), gray fox (*Urocyon cinereoargenteus*), and wild dogs (*Canis latrans*). One registration is used to control arctic foxes that prey on listed species in Alaska. Analysis of labeled use information is the critical first step in evaluating the federal action. The current label for M-44 represents the FIFRA regulatory action; therefore, labeled use and application rates specified on the label form the basis of this assessment. The assessment of use information is critical to the development of the action area and selection of appropriate modeling scenarios and inputs.

The USDA/APHIS and Navajo Fish and Wildlife Department are federal agencies with current M-44 registrations. States with current registrations include Montana, New Mexico, South Dakota, Texas and Wyoming. The registration for Kansas has been cancelled according to the information in Office of Pesticide Programs Information

Network (OPPIN). Although specific states have current registrations and are limited to geographical locations, APHIS is not limited geographically. Therefore, the spatial extent of the potential use areas include the habitat of target carnivores indicated above, based on a nation-wide assessment for registration review. Habitat ranges will be updated through EPA's Bulletins Live! web site (<http://www.epa.gov/espp/bulletins.htm>). This will be defined in detail in the forthcoming risk assessment.

M-44 uses are presented in **Table 3.3** with label maximum application rates. All baits have the same amount of the active ingredient for both federal and state labels. Although the label allows M-44 to be used when needed, for this assessment, one application per year is used. The restrictions include a statement identifying the maximum number of devices to be used. Although the minimum number of devices necessary to reduce losses is the label requirement, the maximum number of devices allowed is 10 devices in any 100 acre pasture or 12 devices in any one square mile of open range.

The twenty-six restrictions provide instructions for geographical placement of the device as well as the maximum number allowed. The restrictions indicate that the device is not to be placed within 200 feet of any lake, stream, or other water body. Further, the device is required to be placed more than 50 feet from the public road or pathway and to be removed from the sight of people or domestic animals. The device is not to be placed in areas where food crops are planted.

Table 3.3. Summary of M-44 Uses¹ and Application Information			
USE	Target	Max Appl Rate	Maximum Number of Devices
Forest/Pasture/Rangeland	Coyotes, red foxes, gray foxes and wild dogs	0.97-9.7g (0.97g per capsule)	No more than 10 devices are to be placed in 100A of pastureland ² .
		10.67-11.64g (0.97g per capsule)	No more than 12 devices may be placed in one square mile of open range ² .
Aleutian Islands	Artic Fox	10.67-11.64g (0.97g per capsule)	No more than 12 devices may be placed in one square mile of open range ² .
<ol style="list-style-type: none"> 1. Uses assessed based on LUIS report Table 1 and EFED label data report. 2. Maximum Number of Devices based on Use Restriction Bulletin. 			

There is a Special Local Needs registration for California to use sodium cyanide as a

fumigant (Registrant number CA84000600) on citrus. This use will also be evaluated in this assessment.

3.4. Environmental Fate and Transport

No acceptable fate or transport studies were submitted for sodium cyanide (M-44). Based on the available information, the exposure route appears to be directly through ingestion with a low risk of secondary poisoning.

The Agency does not anticipate significant environmental exposure to sodium cyanide when used as an encapsulated material together with the M-44 ejector device and when the directions specified on the label are followed.

Should an accidental spill of sodium cyanide from the capsules occur in the field, several processes would contribute to the dissipation of cyanide. Hydrogen cyanide formed by reaction with moisture will diffuse to the atmosphere and be diluted into the air compartment. Reactions with soil components (including microorganisms) will convert cyanide to carbon dioxide and ammonia or other nitrogen containing compounds. Groundwater contamination by cyanide from M-44 ejectors is not anticipated. The environmental exposure of the pesticidal use of sodium cyanide is expected to be minimal because of its mode of application (encapsulated in ejector devices).

Sodium cyanide (M-44) and subsequent formation of hydrogen cyanide are considered as the stressor in this assessment. With a K_{ow} of only -1.69, bioaccumulation of this compound is not expected to be a significant route of exposure and therefore, the data requirement to evaluate bioaccumulation was waived.

The transformation products will not be evaluated in this assessment because they are not expected to occur in significant quantities due to the transformation of sodium cyanide hydrogen cyanide gas when mixed with moisture.

4. Receptors

The receptor is the biological entity that is exposed to the stressor (EPA, 1998). Due to the forest, pasture and rangeland uses of M-44, the types of receptors that may be exposed include terrestrial receptors such as birds, reptiles and terrestrial-phase amphibians. Although toxicity studies for aquatic animals were received, no aquatic receptors will be evaluated based on low exposure expected for aquatic environments. Consistent with the process described in the Overview Document (EPA, 2004), this risk assessment uses a surrogate species approach in its evaluation of M-44. Toxicological data generated from surrogate test species, which are intended to be representative of broad taxonomic groups, are used to extrapolate to potential effects on a variety of species (receptors) included under these taxonomic groupings.

Table 4.1 provides a summary of the taxonomic groups and the surrogate species tested based on the indoor nonfood use pattern to help understand potential ecological effects of pesticides to these non-target taxonomic groups. The forestry and terrestrial feed crop

use patterns for M-44 indicate that no animal toxicity tests are required because the pesticide is in the form of a gas. No plant studies are required under Part 158 because M-44 is a contained pesticide. No acute oral avian studies were submitted or requested based on the known toxicity of sodium cyanide. M-44 is classified as very highly toxic to birds.

One aquatic supplemental study was reviewed. The rainbow trout study (MRID 13701) resulted in an $LC_{50}=0.188\text{mg/L}$. This classifies M-44 as highly toxic to fish. Studies for aquatic invertebrates and plants were waived due to the use patterns and low volume. No chronic toxicity studies are available because M-44 is not expected to be persistent.

Table 4.1. Test Species Evaluated for Assessing Potential Ecological Effects of M-44 and the Associated Acute Toxicity Classification		
Taxonomic Group	Example(s) of Surrogate Species	Acute Toxicity Classification
Bird ¹	Bobwhite (<i>Colinus virginianus</i>)	Very Highly Toxic ⁴
		Chronic toxicity data not requested based on use pattern ⁵ , chemical properties and expected lack of long-term exposure potential.
	Mallard (<i>Anas platyrhynchos</i>)	Very Highly Toxic ⁴
		Chronic toxicity data not requested based on use pattern ⁵ , chemical properties and expected lack of long-term exposure potential.
Mammals	Laboratory rat (<i>Rattus norvegicus</i>)	$LD_{50} = 7.5 \text{ mg/kg-bw}$ (MRID 426108-01) Very Highly Toxic
		Chronic toxicity data not requested based on use pattern ⁵ , chemical properties and expected lack of long-term exposure potential.
Insects	Honey bee (<i>Apis mellifera</i> L.)	Data not requested based on use pattern ⁵ , chemical properties and lack of expected exposure of bees to M-44.

Table 4.1. Test Species Evaluated for Assessing Potential Ecological Effects of M-44 and the Associated Acute Toxicity Classification

Taxonomic Group	Example(s) of Surrogate Species	Acute Toxicity Classification
Freshwater Fish ²	Bluegill (<i>Lepomis macrochirus</i>)	Data not requested based on use pattern ⁵ , chemical properties and lack of expected exposure of aquatic organisms to M-44.
	Rainbow trout (<i>Oncorhynchus mykiss</i>)	Rainbow trout LC ₅₀ =0.188 mg/L (MRID 13701) Highly Toxic
	Fathead minnow (<i>Pimephales promelas</i>)	Data not requested based on use pattern ⁵ , chemical properties and lack of expected exposure of aquatic organisms to M-44
Aquatic Invertebrates	<i>Daphnia magna</i>	Data not requested based on use pattern ⁵ , chemical properties and lack of expected exposure of aquatic organisms to M-44
Estuarine/marine fish	Sheepshead minnow (<i>Cyprinodon variegatus</i>)	
Estuarine/marine invertebrates	Mysid shrimp (<i>Americamysis bahia</i>)	
	Eastern oyster (<i>Crassostrea virginica</i>)	
Terrestrial plants ³	Vegetative Vigor Monocots – Wheat (<i>Tritum gestivum</i>)	Data not requested based on use pattern ⁵ , chemical properties and lack of expected exposure of terrestrial plants organisms to M-44.
	Dicots – Rape (<i>Brassica napur</i>)	
	Seedling Emegence Monocots – Sorghum (<i>Sorghum bicolor</i>)	
	Dicots – Tomato (<i>Lycopersicon esculentum</i>)	
Aquatic plants and algae	Duckweed (<i>Lemna gibba</i>)	Data not requested based on use pattern ⁵ , chemical properties and lack of expected exposure of aquatic plants organisms to M-44.
	Green algae (<i>Pseudokirchneriella subcapitata</i>)	
	Blue green Algae (<i>Anabaena flos-aquae</i>)	
	Freshwater Diatom (<i>Navicula pelliculosa</i>)	
	Marine Diatom (<i>Skeletonema costatum</i>)	

¹ Birds represent surrogates for terrestrial-phase amphibians and reptiles in the absence of data for these taxa.

² Freshwater fish may be surrogates for aquatic-phase amphibians in the absence of data for these taxa.

Table 4.1. Test Species Evaluated for Assessing Potential Ecological Effects of M-44 and the Associated Acute Toxicity Classification

Taxonomic Group	Example(s) of Surrogate Species	Acute Toxicity Classification
³ Four species of two families of monocots, of which one is corn; six species of at least four dicot families, of which one is soybeans. ⁴ Toxicity data for birds was waived by FEAD because there is sufficient evidence to categorize sodium cyanide as very highly toxic to birds when administered orally on an acute basis. In addition, conducting a study using sodium cyanide poses a hazard to the technicians.. ⁵ Toxicity Study is not required under the forestry or terrestrial feed crop use patterns because M-44 is a contained pesticide treatment.		

Reported incidents to terrestrial species are also considered in determining risk. A preliminary review on April 26, 2010 of the Ecological Incident Information System (EIIS, version 2.1), maintained by the Agency's Office of Pesticide Programs, and the Avian Monitoring Information System (AIMS), maintained by the American Bird Conservancy, indicates forty-four reported ecological incident associated with the use of M-44. This total excludes incidents classified as 'unlikely' and only includes those incidents with certainty categories of 'highly probable', and 'probable' and 'possible' (for EIIS) and 'certain', 'highly likely', 'likely', 'probable', and 'possible' (for AIMS). In the EIIS and AIMS databases, the "unlikely" category is used when a chemical is not likely to be responsible for the incident. For example, an 'unlikely' classification might be applied in situations where a given chemical is practically nontoxic to the category of organism killed and/ or there is evidence that another pesticide or stressor likely caused the incident. Incidents classified as 'unlikely' for M-44 will not be included in this Problem Formulation or forthcoming ecological risk assessment.

Incident reports for non-target organisms typically provide information only on mortality events and plant damage incidents. Except for phytotoxic effects in terrestrial plants, sub-lethal effects for organisms such as reduced growth or impaired reproduction are rarely reported. EPA's changes in the registrant reporting requirements for incidents in 1998 may account for a reduced number of reported incidents. Registrants are now only required to submit detailed information on 'major' fish, wildlife, and plant incidents. Minor fish, wildlife, and plant incidents, as well as all other non-target incidents, are generally reported aggregately and are not included in EIIS. In addition, there have been changes in state monitoring efforts due to lack of resources.

Table 4.2 reports EIIS incidents for M-44. No aquatic incidents or plant incidents are reported in the EIIS database for M-44. The EIIS database describes forty-five terrestrial animal incidents, covering a period from 1983-2009. There were three incidents classified as misuses of M-44. The database records mortality for twenty-six birds, fifteen dogs, ten wolves, three fox and two bear. Incidents reported in the AIMS data base cover the period from 1998-2000. All ten bird incidents reported in the AIMS data base are also reported in the EIIS data base.

Table 4.2 EIIS Terrestrial Incidents

Incident ID	Use Site	Legality	Certain y	State	Year	Total No.	Appl. Method	Species
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Table 4.2 EIS Terrestrial Incidents								
Incident ID	Use Site	Legality	Certainty	State	Year	Total No.	Appl. Method	Species
I019079-001		Undetermined	Probable	MT	1978	1	Animal control device	Grizzly Bear
I014411-001	Rangeland	Registered use	Highly Probable			1	Animal control device	Raven
I019079-002		Undetermined	Probable	CA	1983	1	Animal control device	California Condor
I001940-001	Rangeland	Misuse (accidental)	Probable	ID	1995	1	Animal control device	Gray Wolf
I011688-002	Rangeland	Registered Use	Highly Probable	MT	1997	1	Explosive	Gray Wolf
B0000-400-6	Agricultural Area Rangeland	Misuse (accidental)	Probable	MT	1998	1	Mechanical Firing	Wolf
I011688-003	Rangeland	Registered Use	Highly Probable	MT	1998	1	Explosive	Wolf
I011688-004	Rangeland	Registered Use	Highly Probable	WY	1998	1	Explosive	Wolf
I009048-005	Rangeland	Registered Use	Probable	NM	1998	1	Device	American Crow
I008909-001	Rangeland	Registered Use	Highly Probable	NM	1998	5	Capsule	American Crow Raven
I009048-004	Rangeland	Registered Use	Probable	NM	1998	1	Device	Not Reported
I009048-006		Registered Use	Probable	TX	1999	1	Device	American Crow
I009782-001	Agricultural Area Rangeland	Registered Use	Highly Probable	VA	1999	3	Gas Release	Raven
I009048-003	Rangeland	Registered Use	Probable	NM	1999	1	Device	Not Reported
I009048-001		Registered Use	Probable	NM	1999	1	Device	Raven

Table 4.2 EIIS Terrestrial Incidents								
Incident ID	Use Site	Legality	Certainty	State	Year	Total No.	Appl. Method	Species
I009443-001	Agricultural Area	Registered Use	Highly Probable	VA	1999	5	Bait	Raven Vulture Dog
I010353-001	Rangeland	Registered Use	Probable		1999	1		American Crow
I010696-001	Rangeland	Misuse (accidental)	Highly Probable	NM	2000	1	Capsule	American Crow
I012953-001	Rangeland	Registered use	Highly Probable	SD	2001	1	Animal control device	Wolf
I011656-003	Agricultural Area	Registered Use	Probable	SD	2001	1	Bait	Gray Wolf
I013411-001	Rangeland	Registered use	Highly Probable		2002	1		Fox
I019441-001	Pasture	Undetermined	Probable	NM	2005	1	Animal control device	Dog
I019441-002	Pasture	Undetermined	Probable	NM	2005	1	Animal control device	Dog
I019441-003	Pasture	Undetermined	Probable	NM	2005	1	Animal control device	Dog
I019441-005	Rangeland	Undetermined	Probable	UT	2005	1	Animal control device	Dog
I019441-006	Pasture	Undetermined	Probable	VA	2006	1	Animal control device	Dog
I019441-008	Pasture	Undetermined	Probable	UT	2006	1	Animal control device	Dog
I017723-001	Pasture	Registered Use	Probable	TX	2006	1	Animal control device	Raven Dog
I019441-011	Rangeland	Undetermined	Probable	UT	2007	1	Animal control device	Dog
I019441-017	Rangeland	Undetermined	Probable	ND	2007	1	Animal control device	Dog
I019194-001	Rangeland	Registered Use	Highly Probable	ND	2007	1	Animal control device	Dog

Table 4.2 EHS Terrestrial Incidents								
Incident ID	Use Site	Legality	Certainty	State	Year	Total No.	Appl. Method	Species
I018365-002	Bait, carcass/meat	Registered Use	Highly Probable	ID	2007	2	Animal control device	Gray Wolf
I019441-012	Rangeland	Undetermined	Probable	VA	2007	1	Animal control device	Dog
I019441-013	Rangeland	Undetermined	Probable	VA	2007	1	Animal control device	Dog
I018646-003		Registered Use	Probable	VA	2007	1	Animal control device	Black bear
I019441-016	Rangeland	Undetermined	Probable	NM	2007	1	Animal control device	Dog
I019826-001	Pasture	Registered Use	Highly Probable	NE	2008	2	Animal control device	Swift Fox
I019826-002	Rangeland	Registered Use	Highly Probable	ND	2008	1	Animal control device	Common Raven
I019826-003	Rangeland	Registered Use	Highly Probable	VA	2008	1	Animal control device	Common Raven
I019961-002	Pasture	Undetermined	Highly Probable	ND	2008		Animal control device	Dog
I019961-001	Pasture	Registered Use	Probable	VA	2008	1	Animal control device	Dog
I020409-001	Rangeland	Registered Use	Highly Probable	WY	2008	1	Animal control device	Gray Wolf
I020675-001	Rangeland	Registered Use	Highly Probable	ND	2009	1	Animal control device	Common Raven
I020940-001	Rangeland	Registered Use	Highly Probable	ND	2009	1	Animal control device	Common Raven
I020940-002	Rangeland	Registered Use	Highly Probable	NM	2009	1	Animal control device	Common Raven

In the forthcoming risk assessment, the incidents will be further evaluated to determine if they represent current patterns of use for M-44. Examples of additional considerations are mitigation (e.g., reduced application rates), product cancellations, and changes in use

patterns that have occurred since the date of the reported incidents.

M-44 is not among the constituents monitored by the National Water Quality Assessment Data Warehouse (NAWQA), maintained by the U.S. Geological Survey.

4.1 Ecosystems Potentially at Risk

Although the current registration review problem formulation develops an ecological risk assessment based on nation-wide use, it may not be possible to identify specific ecosystems. The scope of this assessment is limited based on the restricted use pesticide and method of application (capsules and ejector device). In general terms, terrestrial ecosystems potentially at risk due to the use of M-44, could include the treated area (rangeland, forests, pastures).

The primary exposure is terrestrial from ingestion directly into the mouth where the powder is changed to a gas. Based on the restricted use pattern, low volume, chemical properties and mode of action of M-44, biologically significant exposures in aquatic ecosystems are not expected.

5. Assessment Endpoints

Assessment endpoints are defined as “explicit expressions of the actual environmental value that is to be protected.” Defining an assessment endpoint involves two steps: 1) identifying the valued attributes of the environment that are considered to be at risk; and 2) operationally defining the assessment endpoint in terms of an ecological entity (i.e., a community of birds, mammals and terrestrial invertebrates) and its attributes (i.e., survival and reproduction). Therefore, selection of the assessment endpoints is based on valued entities (i.e., ecological receptors), the ecosystems potentially at risk, the migration pathways of pesticides, and the routes by which ecological receptors are exposed to pesticide-related contamination. The selection of clearly defined assessment endpoints is important because they provide direction and boundaries in the risk assessment for addressing risk management issues of concern. Changes to assessment endpoints are typically estimated from the available toxicity studies, which are used as the measures of effects to characterize potential ecological risks associated with exposure to pesticides, such as M-44.

To estimate exposure concentrations, the ecological risk assessment considers a single application at the maximum application rate applied as bait. Exposure will be evaluated at 100% of the application rate, which is the most conservative estimate. The most sensitive toxicity endpoints are used from surrogate test species to estimate treatment-related direct effects on acute mortality assessment endpoints. Toxicity tests are intended to determine effects of pesticide exposure on birds and mammals, as well as terrestrial-phase amphibians and reptiles using birds as surrogates. These tests include short-term acute studies and are typically arranged in a hierarchical or tiered system that progresses from basic laboratory tests to applied field studies. The toxicity studies are used to evaluate

the potential of a pesticide to cause adverse effects, to determine whether further testing is required, and to determine the need for precautionary label statements to minimize the potential adverse effects to non-target animals.

An open literature search will be conducted to determine any relevant endpoints. The search will focus on survival, growth and reproductive effects for terrestrial effects of M-44. More sensitive endpoints from acceptable open literature studies will be included in this risk assessment.

6. Conceptual Model

For a pesticide to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a pesticide moves in the environment from a source to an ecological receptor. For an ecological pathway to be complete, it must have a source, a release mechanism, an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure.

A conceptual model provides a written description and visual representation of the predicted relationships between M-44, potential routes of exposure, and the predicted effects for the assessment endpoint. A conceptual model consists of two major components: risk hypothesis and a conceptual diagram (EPA, 1998).

6.1 Risk Hypothesis

Risk hypotheses are specific assumptions about potential adverse effects (i.e., changes in assessment endpoints) and may be based on theory and logic, empirical data, mathematical models, or probability models (EPA, 1998). For this assessment, the risk is stressor-initiated, where the stressor is the release of M-44 into the environment. For M-44, the following ecological risk hypothesis is being employed for this risk assessment:

M-44, when used in accordance with the label, results in potential adverse effects upon the survival of non-target terrestrial vertebrates. Given the potential for poisoning from M-44 after being directly injected into the animal's mouth and from secondary poisoning from carcasses, there is a likelihood of exposure to terrestrial vertebrates.

The conceptual model is a generic graphic depiction of the risk hypothesis. It includes the potential pesticide or stressor (M-44), the source of the pesticide and/or transport pathways, exposure media, exposure point, biological receptor types, and attribute changes.

6.2 Conceptual Diagram

The conceptual site model is a generic graphic depiction of the risk hypothesis, and assumes that M-44, having forest, pasture and rangeland uses, is capable of affecting terrestrial animals provided that environmental concentrations are sufficiently elevated as a result of proposed label uses. Based on an examination of the physico-chemical properties of M-44, the fate and disposition in the environment, and mode of application, a conceptual model was developed that represents the possible relationships between the stressors, ecological receptors, and the assessment endpoints. Through a preliminary iterative process of examining available data, the conceptual model (i.e., the representation of the risk hypothesis) may be refined to reflect the likely exposure pathways and the organisms that are most relevant and applicable to this assessment (see **Figure 6.1**, below). It includes the potential pesticide or stressor (M-44), the sources and/or transport pathways, exposure media, exposure points, biological receptor types and attribute changes.

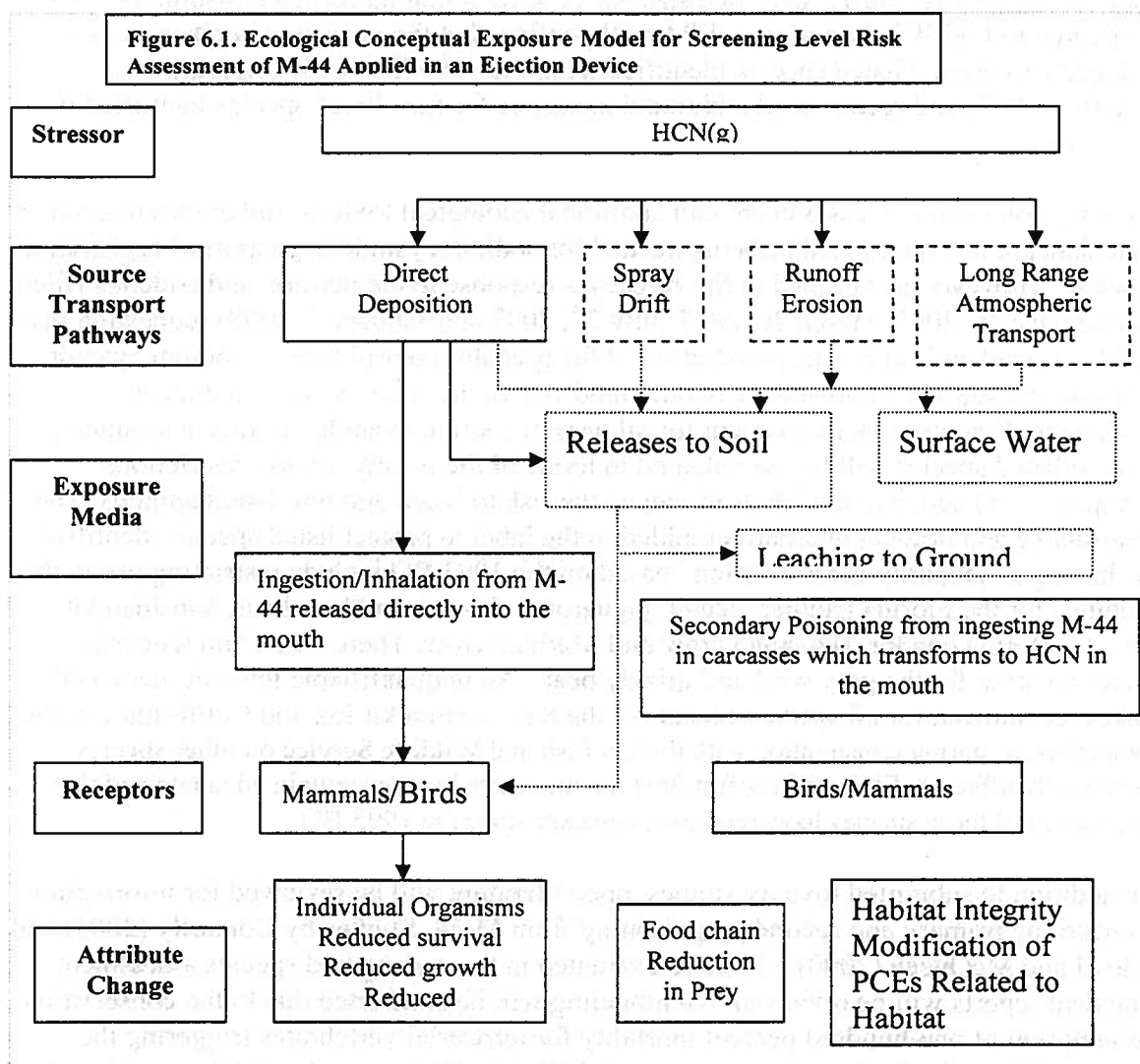
In order for a chemical to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a pesticide moves in the environment from a source to an ecological receptor. For an ecological exposure pathway to be complete, it must have a source, a release mechanism, an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure. In addition, the potential mechanisms of degradation/transformation (i.e., which degradation/transformation products may form in the environment, in which media, and how much) must be understood, especially if for the chemical, its metabolites/transformation products are of greater toxicological concern than the parent compound. The assessment of ecological exposure pathways, therefore, includes an examination of the source and potential migration pathways for constituents, and the determination of potential exposure routes.

Under the possible uses of M-44, it is released from the ejection device directly into the animal's mouth causing death. There is also the potential for secondary poisoning from animals ingesting M-44 residue in carcasses, which transforms into the gas HCN.

Several potential exposure pathways are not expected to be evaluated in the forthcoming ecological risk assessment. These include direct deposition to soil and subsequent leaching to ground water, runoff to surface water, or direct exposure to terrestrial wildlife (soil ingestion). Based on previous risk assessment conducted in the 1994 RED, these exposure pathways are considered very unlikely due to the chemical properties, use patterns, and label use restrictions. Long-range atmospheric transport is also not expected to be a concern given the chemical properties and use pattern.

The representative terrestrial receptors are mammals and birds. The attribute changes used to assess risk to terrestrial receptors depend on the type of test (e.g., reduced survival, growth, or reproduction for animals). It should be noted, that these species do not cover all the possible species in the animal kingdom; certain taxa are considered as

surrogates for other taxa. For example, birds are considered surrogates for terrestrial-phase amphibians and reptiles.



7. Analysis Plan

In order to address the risk hypothesis, the potential for adverse effects on the environment is estimated. Usage, environmental fate and transport, and ecological effects of M-44 are characterized and integrated to assess the risks. This is accomplished using lines of evidence.

No aquatic exposure is expected based on the low concentrations in the device and fate properties indicating no spray drift, and a restriction that the M-44 device may not be placed within 200 feet of any lake, stream or other water body, therefore there is no potential risk for aquatic organisms.

Following a review of the petition to cancel M-44, the Agency initiated consultation with US Fish and Wildlife Services in accordance with Section 7 of the Endangered Species Act based on additional species identified and potential changes in ranges/habitat boundaries for previously identified species. A letter initiating formal consultation will be delivered to USFWS. In addition, EPA will confirm that the measures in place remain adequate to protect listed species identified from the 1993 BO (U.S. Department of Interior, 1993) and recommend additional measures for new listed species identified if necessary.

A new ecological risk assessment and additional ecological toxicity and environmental fate data are not anticipated as being needed for sodium cyanide in support of registration review. However, as outlined in the Agency's response to the petition and addenda (filed on January 24, 2007, March 20, 2007, July 27, 2007 and January 7, 2008) requesting that EPA suspend and cancel the registration of the predator control uses of sodium cyanide (M-44) and sodium fluoroacetate (Compound 1080), the Agency will conduct an endangered species risk assessment for all uses of sodium cyanide. In this assessment, risk to listed species will be re-evaluated in terms of the twenty-six use restrictions (Appendix A) added to the labels to reduce the risk to listed and non-listed animals. The reasonable and prudent alternatives added to the label to protect listed species identified as having a "jeopardy determination" based on the 1993 BO include restricting use in the habitats for the Florida panther, ocelot, jaguarondi, Louisiana black bear, San Juan kit fox, California condor, Hawaiian crow and Mariana crow. There was a "no jeopardy" determination for the gray wolf and grizzly bear. An unquantifiable level of incidental takes are allowed for all species except for the San Joaquin kit fox and California condor. Nonetheless, during consultation with the US Fish and Wildlife Service on other species potentially affected, EPA will confirm that the measures in place remain adequate and that the ranges of these species have remained constant since the 1993 BO.

In addition to submitted toxicity studies, open literature will be reviewed for information concerning primary and secondary poisoning from M-44. Studies by Connolly (2003) and Lloyd and McQueen (2000) will be re-evaluated in the endangered species assessment. Incident reports will be reviewed. No modeling will be conducted due to the conservative assumption of one-hundred percent mortality for terrestrial vertebrates triggering the device. Although, the Overview Document (USEPA, 2004) provides for determining the likelihood of effects to individual organisms from particular uses of a chemical by estimating the probit dose-response slope and either the level of concern or the actual calculated risk quotient value, no RQs are estimated for this assessment.

This analysis plan will be revisited and may be revised depending upon the data available in the open literature and the information submitted by the public in response to the opening of the Registration Review docket.

7.1. Stressors of Concern

The focus of this assessment is on the parent material, M-44 and subsequent formation of HCN gas. However, the Agency will review open literature to identify metabolite(s) of potential toxicological concern. Toxicity data for environmental mixtures of M-44 with other pesticides (those mixtures occurring in the environment following application), if available, may be presented as part of the ecological risk assessment. It is expected that the toxic effect of M-44, in combination with other pesticides used in the environment, is likely to be a function of many factors including, but not necessarily limited to: (1) the exposed species, (2) the co-contaminants in the mixture, (3) the ratio of M-44 and co-contaminant concentrations, (4) differences in the pattern and duration of exposure among contaminants, and (5) the differential effects of other physical/ chemical characteristics of the receiving waters (e.g. organic matter present in sediment and suspended water), although no aquatic exposure is expected. Quantitatively predicting the combined effects of all these variables on mixture toxicity to any given taxa with confidence is beyond the capabilities of the available data and methodologies. However, a qualitative discussion of implications of the available pesticide mixture effects data on the confidence of risk assessment conclusions will be addressed as part of the uncertainty analysis.

7.2. Measures of Exposure

In order to estimate risks of M-44 exposures in terrestrial environments, all exposure assumptions and resulting risk conclusions will be made based on maximum application rates for the current use patterns. Typically, the Agency evaluates risks to non-target birds and mammals based on consumption of foliage and prey items from treated fields (for foliar applications) and consumption of treated seeds or granules (for seed treatment and granular applications). However, the use pattern of M-44 (encapsulated ejection devices in the ground) combined with its chemical properties (rapid volatility and dissipation of HCN gas) and restrictions on the number of devices used per acre will result in substantially reduced exposures compared to conventional pesticide application methods. Measures of exposure anticipated in this assessment include: (1) direct ingestion in the mouth and subsequent inhalation of hydrogen cyanide by non-target terrestrial vertebrates that activate the ejection device and (2) indirect exposure through consumption of dead animals that have been killed by M-44 devices.

The agency currently expects to assume that 100% of the animals that activate the devices would experience rapid mortality. If feasible, indirect exposure will be quantified based on screening level estimates of the residues of M-44 in biota that have recently succumbed to its effects.

Based on the use pattern of M-44 (encapsulated ejection devices in the ground) combined with its chemical properties (rapid volatility and dissipation of HCN gas) and restrictions on the number of devices used per acre, exposure of aquatic ecosystems to M-44 is not expected to be biologically significant. Therefore, no aquatic exposure assessment is planned for M-44.

7.3. Measures of Effect

Ecological effects data are used as measures of direct and indirect effects to biological receptors. Data are typically obtained from registrant-submitted studies or from literature studies identified by ECOTOX. The ECOTOX database provides more ecological effects data in an attempt to bridge existing data gaps. ECOTOX is a source for locating single chemical toxicity data and potential chemical mixture toxicity data for aquatic life, terrestrial plants, and wildlife. ECOTOX was created and is maintained by the USEPA, Office of Research and Development, and the National Health and Environmental Effects Research Laboratory's Mid-Continent Ecology Division.

Information on the potential effects of M-44 on non-target animals is also collected from the Ecological Incident Information System (EIIS). The EIIS is a database containing adverse effect (typically mortality) reports on non-target organisms where such effects have been associated with the use of pesticides.

Where available, sub-lethal effects observed in both registrant-submitted and open literature studies will be evaluated qualitatively. Such effects may include behavioral changes (e.g., lethargy and changes in coloration). Quantitative assessments of risks, though, are limited to those endpoints that can be directly linked to the Agency's assessment endpoints of impaired survival, growth and reproduction.

The assessment of risk for direct effects to non-target organisms makes the assumption that the toxicity of M-44 to birds is similar to terrestrial-phase amphibians and reptiles. The same assumption is made for fish and aquatic-phase amphibians.

The acute measures of effect used for animals in this assessment are the LD₅₀, LC₅₀ and EC₅₀. LD stands for "Lethal Dose", and LD₅₀ is the amount of a material, given all at once, that is estimated to cause the death of 50% of the test organisms. LC stands for "Lethal Concentration" and LC₅₀ is the concentration of a chemical that is estimated to kill 50% of the test organisms. EC stands for "Effective Concentration" and the EC₅₀ is the concentration of a chemical that is estimated to produce a specific effect in 50% of the test organisms. Endpoints for chronic measures of exposure for listed and non-listed animals are the NOAEL/NOAEC and NOEC. NOAEL stands for "No Observed-Adverse-Effect-Level" and refers to the highest tested dose of a substance that has been reported to have no harmful (adverse) effects on test organisms. The NOAEC (i.e., "No-Observed-Adverse-Effect-Concentration") is the highest test concentration at which none of the observed effects were statistically different from the control. The NOEC is the No-Observed-Effects-Concentration.

7.4. Integration of Exposure and Effects

Risk characterization is the integration of exposure and ecological effects characterization to determine the potential ecological risk from the use of pesticides and the likelihood of direct and indirect effects to non-target organisms in terrestrial habitats. The exposure and toxicity effects data are integrated in order to evaluate the risks of adverse ecological

effects on non-target species. For the assessment of risks, a line of evidence approach is used to evaluate exposure and toxicity values. These criteria will be used to indicate when M-44 uses, as directed on the label, have the potential to cause adverse direct or indirect effects to non-target organisms. In addition, incident data from the EIIS and AIMS data bases, as well as information from the Biological Opinion will be considered as part of the risk characterization.

7.5. Endangered Species Assessments

Consistent with the Agency's responsibility under the Endangered Species Act (ESA), the Agency will evaluate risks to Federally-listed threatened and/or endangered (listed) species from registered uses of M-44. This assessment will be conducted in accordance with the Overview Document (USEPA, 2004), provisions of the ESA, and the Services' Endangered Species Consultation Handbook (USFWS/NMFS, 1998).

The assessment of effects associated with the registration of M-44 is based on an action area. The action area is considered to be the area directly or indirectly affected by the federal action, as indicated by the exceedance of Agency Levels of Concern (LOCs) used to evaluate direct or indirect effects. Because M-44 has a wide use pattern, the nationwide risk assessment is limited to the geographical areas identified on the labels. The action area will encompass those areas designated on all labels. It also takes into account the potential for direct and indirect effects and any modification to critical habitat based on ecological effect measures associated with reduction in survival, growth and reproduction as well as sub-lethal effects.

The nationwide action area does not imply that direct and/or indirect effects and critical habitat modification are expected to or are likely to occur over the full extent of the action area, but rather to identify all listed species and critical habitat that may potentially be affected by the action. The agency will use more rigorous analyses, including consideration of available land cover data, toxicity data and exposure information to determine areas where individual listed species and designated critical may be affected or modified via endpoints associated with survival, growth or reproduction.

The Agency's approach to defining the action area under the provisions of the Overview Document (USEPA, 2004) considers the results of the risk assessment process to establish boundaries for that action area with the understanding that exposures below the Agency's defined LOCs constitute a no-effect threshold. For the purposes of this assessment, attention will be focused on the footprint of the action (i.e., the area where M-44 application occurs), plus all areas where offsite transport may result in potential exposure that exceeds the Agency's LOCs. Specific measures of ecological effect that define the action area for listed species include any direct and indirect effects and/ or potential modification of its critical habitat, including reduction in survival, growth, and reproduction as well as the full suite of sub-lethal effects available in the effects literature. Therefore, the action area extends to a point where environmental exposures are below any measured lethal or sub-lethal effect threshold for any biological entity at the whole organism, organ, tissue, and/ or cellular level of organization.

Additional information is provided through the conclusions of a Biological Opinion (1993) that resulted in label changes. The 1993 Biological Opinion covers M-44 for control of coyotes, red foxes gray foxes and feral dogs and resulted in twenty-six restrictions that were included on the label. The opinion lists USDA/APHIS and Navajo Fish and Wildlife Department as federal agencies using M-44. (However, DOI is not listed). States listed include Montana, New Mexico, Texas and Wyoming. The label for Kansas has been cancelled according to the labels in OPPIN.

Three bird species and seven mammal species are covered under this opinion. The Alala (Hawaiian crow), California Condor and the Mariana crow are the bird species. Mammals include the gray wolf, grizzly bear, Louisiana black bear, Florida panther, ocelot, jaguarundi and San Joaquin kit fox.

The US Fish and Wildlife endangered species site details the geographic locations identified by USFWS for each species. The Alala, California Condor, Mariana crow, Florida panther and San Joaquin kit fox habitats are listed in states with no registered state agency uses.

The remaining species have habitats located in states with registered uses. The opinion allows incidental takes for the gray wolf in Montana, New Mexico, Texas and Wyoming under registered uses. The opinion allows incidental takes for the grizzly bear in Montana and Wyoming under registered uses. The opinion also allows incidental takes for the Louisiana black bear, jaguarundi and ocelot in Texas, under registered uses.

Species	USFWS Habitat	Used by State Agency
Alala (Hawaiian Crow)	Hawaii	No*
California Condor	California	No *
Mariana Crow	Guam	No*
Gray Wolf	Arizona, California, Colorado, Connecticut, Iowa, Idaho, Illinois, Indiana, Kansas, Massachusetts, Maine, Michigan, Minnesota, Missouri, Montana, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, Nevada, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Texas, Utah, Vermont, Washington, Wisconsin and Wyoming	Montana, New Mexico, Texas and Wyoming
Grizzly Bear	Alaska, Idaho, Montana, Washington and Wyoming	Montana, Wyoming
Louisiana Black Bear	Louisiana, Mississippi, Texas	Texas

Jaquarundi	Arizona and Texas	Texas
Ocelot	Texas	Texas
Florida Panther	Florida	No*
San Joaquin Kit Fox	California	No*
* However, USDA may use M-44 in any state.		

Although specific states have current registrations and are limited to geographical locations, APHIS is not limited to specific states,

7.6. Drinking Water Assessment

A drinking water assessment will not be conducted for M-44. Although M-44 is thought to be very mobile, there is no route of exposure to either surface water or ground water which might serve as a potential source of drinking water supply. When the powder mixes with moisture and releases hydrogen cyanide gas. There is no run-off, leaching or spray drift because M-44 is buried in the soil. If M-44 is spilled and deposits in the soil, it is rapidly degraded by bacteria or dissipates as a gas when it mixes with moisture in the soil.

7.7. Preliminary Identification of Data Gaps

7.7.1. Fate

Although there are no acceptable registrant submitted fate studies, the environmental fate database for M-44 is considered adequate for risk assessment purposes based on open literature sources.

7.7.2 Effects

Studies provide information to reduce uncertainty for non-target and endangered species assessments. Study requirements are determined from the use pattern, and for forestry and terrestrial feed crop uses there are no required animal studies for end-use products that form a gas. Terrestrial plant studies are not required because M-44 is a contained pesticide.

Freshwater fish and freshwater invertebrate studies are conditionally required based on fate and transport data. An acceptable freshwater fish study (MRID 13701) was submitted. No honey bee study is required because the stressor for M-44 is a gas. No aquatic plant studies are required because M-44 is a contained pesticide treatment. In the event of a spill, M-44 is a salt (NACN) in the form of a powder, unless mixed with water, and which then forms a gas (HCN).

8. References

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U.S. Environmental Protection Agency (USEPA). 2004. Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, Endangered and Threatened Species Effects Determinations. Office of Prevention, Pesticides and Toxic Substances, Office of Pesticide Programs, Washington, D.C. January 23, 2004.

U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS). 1998. Endangered Species Consultation Handbook: Procedures for Conducting Consultation and Conference Activities Under Section 7 of the Endangered Species Act. Final Draft. March 1998.

U.S. Department of Interior 1993. Effects of 16 vertebrate control agents on threatened and endangered species. U.S. Fish and Wildlife Service Biological Opinion, March, 1993.

Appendix A. Sodium Cyanide Use Restrictions

1. Use of M-44 device shall conform to all applicable Federal, State and local laws and regulations.
2. Applicators shall be subject to such other regulations and restrictions as may be prescribed from time-to-time by the U.S. Environmental Protection Agency (EPA).
3. Each applicator of the M-44 device shall be trained in: (1) safe handling of the capsules and device, (2) proper use of the antidote kit, (3) proper placement of the device, and (4) necessary record keeping.
4. M-44 devices and sodium cyanide capsules shall not be sold or transferred to, or entrusted to the care of any person not supervised or monitored by the Animal and Plant Health Inspection Service (APHIS), Animal Damage Control (ADC) program or any agency not working under an ADC cooperative agreement.
5. The M-44 device shall only be used to take wild canids: (1) suspected of preying on livestock or poultry; (2) suspected of preying on Federally designated threatened or endangered species; or (3) that are vectors of a communicable disease.
6. The M-44 device shall not be used solely to take animals for the value of their fur.
7. The M-44 device shall only be used on or within seven miles of a ranch unit or allotment where losses due to predation by wild canids are occurring or where losses can be reasonably expected to occur based on recurrent prior experience of predation on the ranch or allotment. Full documentation of livestock depredation, including evidence that such losses were caused by wild canids, will be required before application of the M-44's is undertaken. This restriction is not applicable when wild canids are controlled to protect Federally designated threatened or endangered species or vectors of a communicable disease.
8. The M-44 device shall not be used: (1) in areas within national forests or other Federal Lands set aside for recreational use, (2) areas where exposure to the public and family and pets is probable, (3) in prairie dog towns, or (4) except for the protection of federally designated threatened or endangered species, in National and State Parks; National or State Monuments; federally designated wilderness areas; and wildlife refuge areas.
9. The M-44 device shall not be used in areas where federally listed threatened or endangered species might be adversely affected. Each applicator shall be issued a map, prepared by or in consultation with the U.S. Fish and Wildlife Service, which clearly indicates such areas.
10. One person other than the individual applicator shall have knowledge of the exact placement location of all M-44 devices in the field.
11. In areas where more than one governmental agency is authorized to place M-44 devices, the Agencies shall exchange placement information and other relevant facts to ensure that the maximum number of M-44's allowed is not exceeded.
12. The M-44 device shall not be placed within 200 feet of any lake, stream, or other body of water, provided that natural depression areas which catch and hold rainfall only for short periods of time shall not be considered "bodies of water" for purposes of this restriction.
13. The M-44 device shall not be placed in areas where food crops are planted.
14. The M-44 device shall be placed at least a 50-foot distance or at such a greater

distance from any public road or pathway as may be necessary to remove it from the sight of persons and domestic animals using any such public road or pathway.

15. The maximum density of M-44's placed in any 100 acre pasture land shall not exceed 10; and the density in any 1 square mile of open range shall not exceed 12.

16. No M-44 device shall be placed within 30 feet of a livestock carcass used as a draw station. No more than four M-44 devices shall be placed per draw station and no more than five draw stations shall be operated pr square mile.

17. Supervisors or applicators shall check the records, warning signs, and M-44 devices of each applicator at least once a year to verify that all applicable laws, regulations, and restrictions are being strictly followed.

18. Each M-44 device shall be inspected at least once every week, weather permitting access, to check for interference or unusual conditions and shall be serviced as required.

19. Damaged or nonfunctional M-44 devices shall be removed from the field.

20. An M-44 device shall be removed from an area if, after 30 days, there is no sign that a target predator has visited the site.

21. All persons authorized to possess and use sodium cyanide capsules and M-44 devices shall store such capsules and devices under lock and key.

22. Used sodium cyanide capsules shall be disposed of by deep burial or at a proper landfill site. Incineration may be used instead of burial for disposal. Place the capsules in an incinerator or refuse hole and burn until the capsules are completely consumed.

Capsules may be incinerated using either wood or diesel fuel.

23. Bilingual warning sign in English and Spanish shall be used in all areas containing M-44 devices. All such signs shall be removed when M-44 devices are removed.

A. Main entrances or commonly used access points to areas in which M-44 devices are set shall be posted with warning signs to alert the public to the toxic nature of the cyanide and to the danger to pets. Signs shall be inspected weekly to ensure their continued presence and ensure that they are conspicuous and legible.

B. An elevated sign shall be placed within 25 feet of each individual M-44 device warning persons no to handle the device.

24. Each authorized or licensed applicator shall carry an antidote kit on his person when placing/or inspecting M-44 devices. The kit shall contain at least six pearls of amyl nitrite and instructions on their use. Each authorized or licensed applicator shall also carry on his person instructions for obtaining medical assistance in the event of accidental exposure to sodium cyanide.

25. In all areas where the use of the M-44 device is anticipated, local medical people shall be notified of the intended use. This notification may be through a poison control center, local medical society, the Public Health Service, or directly to a doctor or hospital. They shall be advised of the antidotal and first-aid measures required for treatment of cyanide poisoning. It shall be the responsibility of the supervisor to perform this function.

26. Each authorized M-44 applicator shall keep records dealing with the placement of the device and the results of each placement. Such records shall include, but need not be limited to:

- a. The number of devices placed.
- b. The location of each device placed.
- c. The date of each placement, as well as the date of each inspection.
- d. The number and location of devices which have been discharged and the

apparent reason for each discharge.

- e. Species of animal taken
- f. All accidents or injuries to humans or domestic animals.