

**RESPONSIVENESS SUMMARY FOR THE
STUDY PLAN FOR MINK INJURY INVESTIGATIONS
FOR THE HUDSON RIVER**

**HUDSON RIVER NATURAL RESOURCE
DAMAGE ASSESSMENT**

HUDSON RIVER NATURAL RESOURCE TRUSTEES

STATE OF NEW YORK

U.S. DEPARTMENT OF COMMERCE

U.S. DEPARTMENT OF THE INTERIOR

FINAL

DECEMBER 31, 2006

Available from:

U.S. Department of Commerce
National Oceanic and Atmospheric Administration
Hudson River NRDA, Lead Administrative Trustee
Damage Assessment Center, N/ORR31
1305 East-West Highway, Rm 10219
Silver Spring, MD 20910-3281



TABLE OF CONTENTS

INTRODUCTION **1**

PUBLIC COMMENTS RECEIVED **2**

REFERENCES **7**

This *Responsiveness Summary for the Study Plan for Mink Injury Investigations for the Hudson River* was prepared by the Hudson River Natural Resource Trustees (Trustees) — New York State, the U.S. Department of Commerce, and the U.S. Department of the Interior. The Trustees are working cooperatively to conduct a Natural Resource Damage Assessment (NRDA) for the Hudson River. This Responsiveness Summary provides Trustee agency responses to public comments on and questions about the Trustees' *Study Plan for Mink Injury Investigations for the Hudson River, Draft for Public Review and Comment*, dated June 13, 2006, released by the Trustees for public review and comment.

INTRODUCTION

Pursuant to the Hudson River Natural Resource Damage Assessment (NRDA) Plan (Hudson River Natural Resource Trustees 2002), the Trustees developed a *Study Plan for Mink Injury Investigations for the Hudson River, Draft for Public Review and Comment* (Draft Mink Injury Study Plan) (Hudson River Natural Resource Trustees 2006a), and engaged in public review of that Draft Mink Injury Study Plan.

On June 16, 2006, the Draft Mink Injury Study Plan was released by the Trustees to the public. In that Draft Mink Injury Study Plan, the Trustees asked the public and the party(ies) responsible for the contamination to review the Draft Mink Injury Study Plan and provide feedback on the proposed approach. The Draft Mink Injury Study Plan noted that the Trustees sought public input to help them in planning and conducting an assessment that is scientifically valid, cost effective, and that incorporates a broad array of perspectives. Peer review of the Draft Mink Injury Study Plan had been conducted prior to release of the study plan for public review and comment.

A Notice of Availability of the Draft Mink Injury Study Plan was published in the Federal Register on June 20, 2006. Availability of the Draft Mink Injury Study Plan was also announced by the Trustees on the Hudson River NRDA web site maintained by the U.S. Fish and Wildlife Service (FWS). The Draft Mink Injury Study Plan noted that comments were to be submitted by July 15, 2006. However, the public comment period was subsequently extended through July 20, 2006 via notice on the FWS Hudson River NRDA web site on June 20, 2006, where the Draft Mink Injury Study Plan was posted. This provided a full 30-day public review period following issuance of the Federal Register Notice of Availability.

All comments received on the Draft Mink Injury Study Plan, as part of the peer and public review process, were considered. The Trustees appreciate the input represented by these comments. The Trustees evaluated peer and public comments and, where warranted, incorporated these comments in the Draft Mink Injury Study Plan to produce the *Study Plan for Mink Injury Investigations for the Hudson River, Hudson River Natural Resource Damage Assessment, Final, Public Release Version*, dated August 15, 2006 (Final Mink Injury Study Plan) (Hudson River Natural Resource Trustees 2006b). In the remaining instances, public comments on the Draft Mink Injury Study Plan were addressed by letter to the commentor, acknowledging receipt of comments and providing an initial response and noting that a more detailed Responsiveness Summary (this document) would be provided by the Trustees in the near future.

PUBLIC COMMENTS RECEIVED

One letter from the public was received in response to the Draft Mink Injury Study Plan: a letter from The General Electric Company (GE), the Potentially Responsible Party, dated July 20, 2006. No other comments were received from the public.

The text of the GE comment letter is provided below, along with the Trustee response (in italicized text) to comments.

Accordingly, this Responsiveness Summary documents comments that were received, that those comments were considered by the Trustees, and how the Trustees addressed those comments.

LETTER FROM GENERAL ELECTRIC, DATED JULY 20, 2006

General Comments:

The Mink Study Plan provides an overview of the trustee's design for a laboratory toxicity test intended to evaluate the reproductive effects of feeding PCB-containing carp from the Hudson River to farm-raised mink. As addressed further in the attached comments, the experimental mink diet proposed in the Plan does not appear to be representative of the natural diet of resident Hudson River mink and does not ensure that the experimental mink diet will reflect the PCB concentration, congener mix or nutritional content of prey items most likely to be consumed by resident mink. As a result, we question whether the proposed study will provide reliable evidence regarding actual exposures and potential injuries to mink residing in the Hudson River watershed when compared to site-specific PCB concentrations of typical prey items and hepatic concentrations of PCBs in resident mink.

The DOI regulations at 43 CFR Section 11.62 (f)(4)(i)(E) explicitly approve the use of laboratory experiments as acceptable proof of biological injury in the field. Additionally, see response to Specific Comment A.

In addition, similar to prior trustee study plans (e.g., the 2004 Avian Egg Injection Investigation Study Plan), the release date and comment period of the Mink Study Plan allows little or no time for the trustees to consider or implement any comments prior to initiation of the work.

The Trustees' desire to keep the assessment moving along in a timely fashion and to provide an opportunity for public input into the process, while taking into consideration the life histories of the mammalian species of interest, necessitated a tight schedule for planning. The Trustees completed peer and public review activities, and developed a Final Mink Injury Study Plan, before feed preparation began, ensuring time to make any revision of the work warranted by consideration of the peer and public reviews.

Unless the study design is modified to address the concerns outlined in the attached comments and the public is afforded the opportunity to comment on the modified plan, the trustees should not proceed with implementation of the Mink Study Plan.

None of the public comments received on the Draft Mink Injury Study Plan warrants revision of the Study Plan to the extent that a new public notice and comment period is needed. Nor are the revisions and additional detail that are part of the Final Mink Injury Study Plan so significantly different from the Draft Mink Injury Study Plan that a second public review process is justified.

Specific Comments:

A. Dietary Treatments - The Mink Study Plan rationalizes the use of mink as a test species in that they are a "semi-aquatic piscivorous species native to the area" (Appendix A, Section 1, Introduction). However, as the Trustees note in the introductory text to Appendix A (Section 1, Background), mink have a very broad diet that can include a wide range of aquatic and terrestrial vertebrate and invertebrate species, depending on local availability. Furthermore, the fish component of the mink diet is primarily comprised of species other than carp (U.S. EPA 1993). Therefore, the implicit assumption made in the Study Plan that an experimental diet where PCB exposure is derived from Hudson River carp is representative of the natural dietary exposure of mink in the wild is unfounded. The Trustees should evaluate the option of collecting fish species for the feeding study that are more representative of the fish component of the diet of Hudson River mink. If carp are used in the study, then a comparative evaluation should be performed of PCBs in carp and other fish and mink prey species to determine how concentration and congener distribution of PCBs in carp reflect the actual diet of Hudson River mink, and how this may relate to any effects observed in the feeding study.

Use of an experimental diet where PCB exposure is derived from Hudson River carp is entirely appropriate for the mink PCB-feeding study. In order to develop a dose-response curve mink need to be exposed to dietary treatments containing varying levels of PCBs, including a high PCB level, which can be achieved by the use of fish in the diet that are anticipated to be highly-contaminated with PCBs, such as carp.

The carp from the Hudson River used in the mink feed serve to represent the components of the diet of Hudson River mink that contain PCBs. As noted in the Study Plan, mink are opportunistic hunters, feeding on other small mammals such as mice, rats, rabbits and muskrats; aquatic prey including frogs, fish, and crayfish; and terrestrial prey including birds, snakes, insects, and other invertebrates. As part of the NRDA, the Trustees have analyzed a number of Hudson River animals that are potential components of the mink diet – including shrews and mice, birds and their eggs, frogs and tadpoles, fish, and muskrats – and found them all to be contaminated with PCBs. The use of Hudson River carp in the mink study diet thus represents the exposure of Hudson River mink to PCBs in their diet through these, and potential other, sources.

In the future the Trustees may propose additional work to supplement the work described in the Final Mink Injury Study Plan. Such work may include, but would not limited to, comparisons of the PCB and other contaminant mixture present in the test diet to PCBs in prey items more likely to be consumed by wild mink (e.g., smaller fish and other prey). Making such comparisons may require the collection of additional prey items likely to be part of the wild mink diet, and chemical analyses of those items.

The Mink Study Plan states that the congener makeup and non-PCB chemical composition of fish used in mink feeding studies reporting reproductive effects in mink exposed to diets contain less than 5 ppm differ from fish collected from the Hudson (Appendix A, Section 2.2, Dietary Treatments) as justification for sequentially lower exposure doses depending on the PCB concentration in carp collected from the Upper Hudson River. What contingencies are in place if the achievable upper dose range falls below 4 ppm?

While the Draft Mink Injury Study Plan notes that the congener makeup and non-PCB chemical composition of fish used in studies reporting reproductive impairment in mink fed diets containing PCB concentrations lower than 5.0 ppm (Heaton et al., 1995a; Restum et al., 1998) differs from the congener makeup and non-PCB chemical composition of fish collected from the Hudson River, this is not "justification" for sequentially lower exposure doses as the above comment indicates. Exposure doses have been selected to accomplish the purpose of the study and to inform the Trustees regarding injury to mink.

Available contaminants data on carp from the Upper Hudson River indicates it is highly unlikely that the Trustees will not be able to achieve a high dose of 4 to 6 ppm total PCBs, per Table 2 of the Final Mink Injury Study Plan. Fish for feed preparation were collected in June 2006 from the vicinity of Lock 2 (River Mile (RM) 162.1), from the first 2000 feet of the Moses Kill, and from the Northumberland Pool, with the majority (over 90%) of the fish coming from the former two sites. Contaminants data from 1999 for carp collected by New York State indicates that carp from the vicinity of Lock 2 contained from 9.9 ppm to about 69 ppm total PCBs (mean of about 34.7 ppm) (Sloan et al. 2002; DEC Biota Database 2006). The mouth of the Moses Kill is within approximately 1/4 mile of EPA Hot Spot 14. Carp collected in 1999 by New York State from approximately 1/4 mile north of the mouth of the Moses Kill at EPA Hot Spot 14 (River Mile 189.1) contained from 3.5 ppm to 208 ppm total PCBs (mean of about 45.8 ppm) (DEC Biota Database 2006).

B. Preparation of Diets - The Mink Study Plan notes that a mixer with a capacity of 454 kg will be used to prepare dietary treatments (Appendix A, Section 2.1, Collection of Fish and Feed Preparation) and that random grabs from each dietary treatment will be analyzed (Appendix A, Section 2.3, Preparation of Diets). Since the total quantities of fish required for several dietary treatments exceed the capacity of the mixer, an equal number of grab samples should be collected for analysis from each batch rather than each treatment to ensure that the dietary treatments are homogeneous.

The Trustees have given much thought and consideration to the preparation (grinding and mixing) of the fish that will be used in the mink diets and to subsequent preparation of the dietary treatments to ensure that these materials are homogenous and that sampling of these materials results in representative values for these materials. The process has been broken into two components - (1) Fish Preparation and (2) Dietary Treatment Preparation - described below, each of which has separate sampling steps appropriate to that component of work.

Fish Preparation

For feed preparation, when fish arrive at the mink study facility, they will be identified, sorted by collection site and weighed.

The total amount of Hudson River fish collected for the study is approximately 1500 kg. Because the capacity of the mixer that will be used to blend the ground fish is 500 kg, the fish will be ground and mixed in three loads (Loads 1 - 3). For Load 1, one third of the fish from each of the three collection sites will be ground, placed into a 500 kg capacity mixer, and mixed together for 30 minutes, such that the product of the mixer load is representative of the entire study area rather than a specific collection site. (Each mixer load will thus contain the same weight of fish from each location.) The ground, blended fish from Load 1 will be expelled from the mixer into approximately 20 plastic pans (approximate capacity of 30 kg) for freezing. Pans will be numbered consecutively from 1 to 20. One sample (of approximately 30 grams) associated with each pan will be collected and placed in a chemically clean glass container. There will be one glass container per set of four pans. Thus, there will be five samples of blended fish collected over 20 pans from Load 1. The glass containers will be labeled, reflecting the pan numbers associated with each, and frozen for subsequent analysis for total PCBs according to procedures outlined in the Hudson River Natural Resource Damage Assessment Analytical Quality Assurance Plan (Hudson River Natural Resource Trustees, 2005).

This grinding and mixing process will continue for mixer Load 2 and Load 3 with the remainder of the Hudson River fish. Five samples of ground and blended fish will be collected over 20 pans from Load 2 and then from Load 3, as per the approach for Load 1 described above. This will result in a total of 15 samples -- from Loads 1, 2, and 3 - that will be analyzed for total PCBs pursuant to the Hudson River NRDA Analytical Quality Assurance Plan.

"Clean" ocean fish will be purchased from a supplier that routinely services the fur industry and will be shipped frozen to the mink study facility. This fish will be processed, sampled, and analyzed in the same manner as the Hudson River fish except that samples from approximately 10 pans will be composited, such that there will be two sample containers for each grind of the ocean fish. Four loads of ocean fish are anticipated altogether.

For dietary treatments, it is anticipated that the six dietary treatments will be prepared two or three times during the trial. Procedures for sampling and analysis will be identical for each batch of feed mixed, with the exception of the number of samples analyzed.

For the initial batch of feed, after thorough mixing of the dietary ingredients for 30 minutes, feed will be expelled into storage pails. As feed is being expelled into a storage pail, a sample of approximately 30 grams will be taken from the stream and placed into one of three chemically clean glass containers. The first grab will be placed into the first jar; the second into the second jar; the third into the third jar; and the fourth grab will again be placed into the first jar. This procedure will be continued during feed expulsion such that a sample from each bucket will be included in one of the three sample jars.

About 20 buckets of each dietary treatment will be produced, with three composite samples taken from each dietary treatment. These composite samples from the dietary treatments (18 composite samples total -- three samples from each of the six dietary treatments) will be frozen for subsequent chemical contaminant analysis (organochlorine pesticides [OCs], total PCBs, non-ortho PCB congeners, mono-ortho PCB congeners, polychlorinated dibenzo-p-dioxin [PCDD] isomers, polychlorinated dibenzofuran [PCDF] isomers, polybrominated diphenyl ether [PBDE] isomers and potentially toxic and bioaccumulative metals). An additional sample from each dietary treatment will be collected for nutrient analysis.

Results of chemical analyses of the three composite samples from each dietary treatment will be used to affirm the dose of PCBs to which mink fed the diet are being exposed. This will provide the Trustees assurance of the PCB doses in each mink dietary treatment.

During preparation of subsequent batches of feed, three composite samples from each of the dietary treatments will be collected as described above. One sample will be archived and two will be submitted for PCB analysis by high resolution mass spectrometry. An additional grab sample will be collected for nutrient analysis. Chemical analyses of grab samples will be completed prior to providing feed from the associated batch to the mink.

In addition to the sampling described above, for the first dietary batch, five grab samples of approximately 30 grams from each of three dietary treatments (1x, 0.5x, and control) will be collected. These samples will be collected at regular intervals as the feed is extruded from the mixer and will be analyzed for PCBs using low resolution mass spectrometry. These samples are intended to provide information about the variability of PCB exposure within a dietary group.

Will drinking water, dietary fillers and food of mink used prior to initiation of the proposed study be analyzed for the same suite of compounds as ocean-derived and Hudson River-derived fish to ensure that there is no unintentional exposure to these compounds?

Drinking water, dietary fillers and food of mink used prior to initiation of the study will not be analyzed. The Trustees have chosen an alternative approach to ensuring that there is not any unintentional exposure of mink to contaminants of concern. Specifically, prior to study initiation, three unexposed females and three unexposed males from the mink study facility breeding stock will be euthanized and the livers of those six animals will be analyzed for OCs, PCBs, PCDDs, PCDFs, PBDEs, and potentially toxic and bioaccumulative metals. This analysis should reveal any concerns regarding contamination of the drinking water, dietary fillers, feed, or any other sources, that would result in unintentional exposure of mink to contaminants of concern.

C. Sample Size - The trustees conducted a power analysis to determine sample sizes needed to detect statistically significant differences in kit survival rates between control and treatment groups (Appendix A, Section 5.2, Sample Size Consideration). The power analysis indicated that between 15 and 20 mink are needed per treatment to maximize the probability of detecting differences. However, the Study Plan notes that the study facility lacks sufficient capacity to house that many individuals and instead notes that 10-15 mink will be used per group. In order to meet the sample size requirement for detecting statistically significant differences, and in consideration of space limitations, the Trustees should consider eliminating one of the treatment levels and re-assigning mink from that treatment to others to increase the sample sizes of the remaining treatments.

The Trustees have given much thought and consideration to samples sizes and statistical analyses, as discussed in section 5.2 of the Principal Investigators' Work Plan (Appendix A to the Trustees Final Mink Injury Study Plan). As noted in the Work Plan, the mink study facility has a limited capacity in terms of the number of animals that can be maintained. Part 11.64 of the DOI Regulations 43 CFR requires that, for selecting methodologies in the Injury Determination Phase, the testing and sampling performance be cost effective [see (a)(3)(ii)] and that the methodologies provide data consistent with the data requirements of the Quantification Phase [at (a)(3)(iv)]. The Trustees believe that the proposed combination of sample size and treatment groups best complies with the regulatory requirement to balance cost effectiveness with statistically valid study design.

D. Post-mortem Evaluation - The study notes that a certified veterinary pathologist will examine any mink that die during the trial period, except for unweaned kits (Appendix A, Section 2.7, Definitive Trial). In the unfortunate event that any kits should die prior to weaning, they should also be submitted for post-mortem evaluation to determine the cause of death.

The Principal Investigator indicates that disturbance to the kits and nest would likely result from attempts to identify and remove unweaned kits that die during the trial. The Principal Investigator strongly recommended against such attempts. It is a common mink ranch practice not to disturb the female until weaning. Further, the PI noted that dams (female parent) often eat young that die in the nest. Therefore, to find dead unweaned kits would require continual checking of the nest and associated disturbance.

REFERENCES

- DEC Biota Database: NYSDEC. 2006. Hudson River PCB Biota Database. NYSDEC, Bureau of Habitat, Albany, NY.
- Hudson River Natural Resource Trustees. 2002. Hudson River Natural Resource Damage Assessment Plan. September 2002. U.S. Department of Commerce, Silver Spring, MD.
- Hudson River Natural Resource Trustees. 2005. Analytical Quality Assurance Plan for the Hudson River Natural Resource Damage Assessment. Final. Public Release Version. September 1, 2005. Version 2.0. U.S. Department of Commerce, Silver Spring, MD.
- Hudson River Natural Resource Trustees. 2006a. Study Plan For Mink Injury Investigations for the Hudson River. Hudson River Natural Resource Damage Assessment. Draft for Public Review and Comment. June 13, 2006. U.S. Department of Commerce, Silver Spring, MD.
- Hudson River Natural Resource Trustees. 2006b. Study Plan For Mink Injury Investigations for the Hudson River. Hudson River Natural Resource Damage Assessment. Final. Public Release Version. August 15, 2006. U.S. Department of Commerce, Silver Spring, MD.
- National Research Council, 1982. Nutrient requirements of mink and foxes. In *Nutritional Requirements of Domestic Animals*, No. 7. National Academies Press, Washington, DC. 72 pp.
- Ringer, R.K., T.C. Hornshaw, and R.J. Aulerich, 1991. Mammalian wildlife (mink and ferret) toxicity test protocols (LC50, reproduction, and secondary toxicity). Report #600/3-91/043. U.S. Environmental Protection Agency, Washington, DC.
- Sloan, R. J., M. W. Kane, and L. C. Skinner. 2002. 1999 as a Special Spatial Year for PCBs in Hudson River Fish. New York State Department of Environmental Conservation, Bureau of Habitat, Division of Fish, Wildlife and Marine Resources. Albany, NY. 34 pp. plus tables and figures.

