UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 31, 2002

MEMORANDUM

SUBJECT: **Revised** EFED RED Chapter for **Lindane**
PC Code No. 009001; Case No. 818566; DP Barcodes: D254764

TO: B. Shackleford, Branch Chief
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The EFED Integrated Environmental Risk Assessment for Lindane is attached. The following is an overview of our findings:

Major Conclusions

Lindane is a persistent and moderately mobile organochlorine compound. Lindane is a potential endocrine disruptor in birds, mammals and possibly fish. There is a possibility of acute and chronic risk to avian and mammalian species consuming a majority of their body weight in treated seed per day. Based on a Tier I screening assessment (using GENEEC), the aquatic assessment resulted in risks to aquatic organisms. For estuarine/marine invertebrates, possible high acute risk may occur even at the low application rates for seed-treatment uses. Restricted use LOC's were exceeded for estuarine/marine invertebrates and freshwater fish. Endangered species LOC's are exceeded for freshwater fish and invertebrates. Chronic risk to estuarine/marine organisms could not be assessed due to a lack of data. Modeling studies showed that lindane concentrations in both surface and ground water may reach environmentally significant levels (> MCL), even when lindane is restricted to seed-treatment uses only. However, the modeling assumption that 100% of the compound will disassociate from the seed surface may have produced highly conservative estimates and has thus overestimated the EEC's and resulting risks. Nevertheless, due to the compound's persistence, residues continue to last in various environmental media and probably is associated with long-range transport.

Risk Factors

- Produces significant reproductive effects in birds (including eggshell thinning) and small mammals.
- Lindane is a lipophilic compound and has been found in milk from exposed lactating females.
- Based on available literature, lindane has shown endocrine disrupting effects in birds, mammals and possibly in fish.
- Very persistent and moderately mobile**.** In aerobic soil systems, lindane degrades very slowly. The registrant-calculated half-life was 980 days (MRID 406225-01).
- Very highly toxic to a broad spectrum of aquatic species.

Possible Mitigating Factors

- Seeds that are incorporated in soil may reduce exposure rates to terrestrial wildlife.
- Low use rates.
- It appears that at least two bird species (quail and red-winged blackbird) were averse to consuming lindane-treated seeds in laboratory studies, which may decrease exposure, thus reducing risk.
- Lindane is bio-concentrated rapidly in microrganisms, invertebrates, fish, birds and mammals, however bio-transformation and elimination are relatively rapid when exposure is discontinued
- The modeling assumption that 100% of the compound will disassociate from the seed surface has likely produced highly conservative estimates and has thus overestimated the EEC's and resulting risks. EFED believes that a seed leaching study would greatly increase certainty regarding a more realistic estimate of the amount of available lindane on the seed surface and leaching from the seed surface. This in turn would allow a refinement of exposure estimates and environmental concentration values (EECs).

Risks to Terrestrial Organisms

- Seed treatment uses present acute and chronic risk to birds and mammals. Also, due to lindane's potential endocrine-disrupting character, mammals and birds that ingest seeds may be at some additional risk. Also, in addition, there is a possibility of acute risk to small mammals with high metabolic rates that dig and cache seeds. Chronic risk to these species may be greater during breeding season due to high seed consumption over time and the persistence of the compound in soil.
- There is a reduced acute risk to waterfowl and upland gamebirds from seed treatment. However, there is acute risk to songbirds (passerines) and other similar seed eating avian species.
- Lindane is highly toxic (0.2 to 0.56 µg/bee) to honeybees. However, since this is a seed treatment application, low risk is assumed to flying insects, although beneficial soil dwelling insects may be at some risk.

Risks to Aquatic Organisms

- Restricted use and endangered species LOC's are exceeded (RQ= 0.40) for freshwater fish. No chronic LOC's are exceeded for freshwater fish.
- The acute endangered species LOC is slightly exceeded (RQ= 0.07) for freshwater invertebrates. No chronic LOC's are exceeded for freshwater invertebrates.
- No acute LOCs were exceeded for estuarine/marine fish. Chronic risk to estuarine/marine fish could not be assessed due to a lack of toxicity data.
- Acute, restricted use and endangered species LOC's were exceeded (RQ= 8.7) for estuarine/marine invertebrates. However, there are no estuarine/marine invertebrates listed as endangered. Chronic

risk to estuarine/marine invertebrates could not be assessed due to a lack of toxicity data.

Risks to Endangered Species

- Endangered birds and especially small mammals that eat a large daily proportion of seeds may be at risk from the proposed seed treatment use pattern. Endangered freshwater fish and invertebrates may also be at acute risk. Also, exposed endangered birds, mammals and possibly fish may be at risk due to the potential endocrine disrupting properties of lindane combined with already limited population sizes and/or losses in critical habitat.

Incident reports

Incident reports submitted to EPA involving lindane have been tracked by Incident Data System (IDS), microfiched, and then entered into a second database, the Ecological Incident Information System (EIIS). Since 1971, only four incidents which involve fish kills have been reported that are related to lindane use. The most recent incident occurred in 1995 in which hundreds of trout were killed on a tree farm in North Carolina after a spill close to a nearby stream. In 1993, an incident was reported that involved approximately 60 trout in California, and the other two incidents were reported 1971 and 1983. However, no aquatic incidents have been reported as having occurred under the normal use conditions of seed treatment under soil incorporated use patterns.

Water Resource Assessment

Fate studies show that lindane is both moderately mobile (mean K_{oc} = 1368) and highly persistent (soil half life of 2.6 years). Even considering lindane's very low use rate under the current use restriction to seed treatment (maximum of 0.0512 lb a.i./acre), lindane concentrations may be expected to reach water resources at environmentally significant levels. Modeling studies showed that lindane concentrations in both surface and ground water may reach environmentally significant levels (> MCL), even when lindane is restricted to seed-treatment uses only. This conclusion is based solely on lindane's use as a seed treatment and does not consider past uses of lindane. However, note that lindane continues to persist in the environment from past uses.

Endocrine Disruption

Based on available scientific literature, lindane has the potential to be an endocrine disrupting compound in birds, mammals, and possibly in fish. Thus the following language is recommended:

<u>EPA’s Interim Policy for Potential Endocrine Disruptors</u>

EPA is required under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen- and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, lindane may be subjected to additional screening and or testing to better characterize effects related to endocrine disruption.

Other Concerns

Formulations: Many formulated products containing lindane also contain other active ingredients (Pentachloronitrobenzene, Captan, Diazanon, Metalaxyl, Thiram, Carboxin, Maneb and Mancozeb) which can be as toxic or more toxic than lindane alone. It is not known if the combination of lindane and these other actives ingredients are more toxic than either is separately or if there may be toxic synergism. Thus, testing with certain formulated products may be required. The registrant is requested to submit any available information on the toxic synergism of these chemicals.

Data Gaps

Environmental Fate: The environmental fate database for lindane is largely complete and adequate for the present risk assessment. However, an anaerobic soil metabolism study is required for outdoor seed treatment uses (Memo from Denise Keehner re: EFED policy guidance for eco-risk and drinking water assessments of seed treatment pesticides, 7/30/99).

EFED also believes that a seed leaching study would greatly increase certainty regarding a more realistic estimate of groundwater leaching and runoff. This in turn would allow a refinement of exposure estimates and environmental concentration values (EECs). EFED has issued a guidance for this study (Memo from Denise Keehner re: Standard Method for Determining the Leachability of Pesticides from Treated Seeds, 7/6/2000).

Ecotoxicity: The environmental toxicity database for lindane is largely complete and adequate for the present risk assessment. However, Tier I plant toxicity studies (850.4100-Seedling emergence in 10 species and 850.5400-Aquatic plant toxicity tests in 5 species) are required for outdoor seed treatment uses (Memo from Denise Keehner re: EFED policy guidance for eco-risk and drinking water assessments of seed treatment pesticides, 7/30/99).

In addition, the avian reproduction study (Mallard duck) needs to be repeated. Although the submitted study (MRID 448671-01) was classified as being supplemental due to guideline deviations as well as the low hatching success in the control group, the study should be repeated to determine if 15 ppm is a valid NOAEL value. The NOAEL value of 15 ppm will be used in risk assessments until further data is provided.

Also, due to the acute toxicity of lindane (LC50s or EC50s < 1 mg/l) to estuarine/marine fish and invertebrates, and concentrations that may reach estuarine/marine systems, chronic studies are required (72-4 a and b: Estuarine/Marine Fish Early Life-Stage and Estuarine/Marine invertebrate life-cycle). An estuarine/marine fish early life-stage and estuarine/marine invertebrate life-cycle toxicity test using the TGAI are required for lindane because the end-use product may be expected to be transported to an aquatic environment from the intended use site, aquatic acute LC50/EC50s were less than 1 mg/l and studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected. Also, the persistence of lindane is > 900 days. The preferred test species are sheepshead minnow and mysid shrimp. Aquatic testing will be held in reserve until a seed leaching study is submitted.

Lastly, there is evidence that seed-eating birds may not be exposed due to aversion to the compound. However, The Agency does NOT have any such data for seed-eating mammals. Thus, it may be beneficial for submission of such data to better characterize risk to seed-eating mammals.

Labeling Recommendations

EFED recommends that the labels for all lindane products carry the following statements:

Environmental Hazards

Manufacturing Use:
This pesticide is toxic to fish, birds, and other wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the USEPA.

End Use Products:

Granular/Seed Treatment
This product is toxic to fish, birds, and other wildlife. Exposed treated seeds may be hazardous to birds and other wildlife. Dispose of all excess treated seeds by burial away from bodies of water. Do not apply directly to water. Do not contaminate water by disposing of equipment washwaters. Apply this product only as specified on the label.

LINDANE RED Chapter: Environmental Fate and Ecological Risk Assessment: Seed treatment

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EXECUTIVE SUMMARY

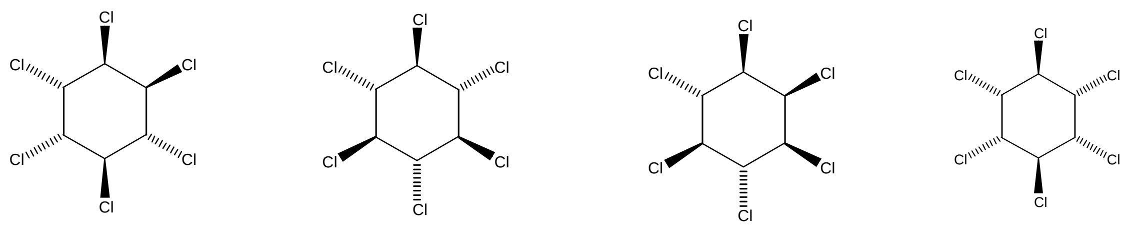
Lindane is a persistent and moderately mobile organochlorine compound. At present, there is only one agricultural use (seed treatment) that might affect the environment. Lindane is a potential endocrine disruptr in birds, mammals and possibly fish. There is a possibility of acute and chronic risk to granivorous avian and mammalian species. However, at least two bird species (quail and red-winged blackbird) were averse to consuming lindane-treated seeds in a laboratory environment, which may drastically decrease exposure, thus reducing risk. In the field , Blus et al. (1985) found that when lindane was substituted for heptaclor (HE) for treatment of seed (Columbia Basin near the Umatilla NWR, in Oregon and Washington State, USA), lindane did not produce adverse effects in birds and residues were not detected in either their eggs or brains. Also, coincidental with the decrease in HE residues in Canada geese, mortality decreased, reproductive success improved, and the population increased rapidly (Blus et al. 1984). There was no evidence for either bio-magnification of lindane residues from treated seeds to goose tissues or eggs, or for induction of adverse effects to avian species. This may be due to the fact that Canada geese, as well as other avian species, may have been repelled by lindane treated seed as a submitted study has suggested with quail and red-winged blackbirds. A Tier I screening assessment (using GENEEC) indicated risks to aquatic organisms. For estuarine/marine invertebrates, high acute risk may occur even at the low application rates for seed-treatment uses. Restricted use LOC's were exceeded for estuarine/marine invertebrates and freshwater fish. Endangered species LOC's are exceeded for freshwater fish and invertebrates and estuarine/marine invertebrates. However, there are no estuarine/marine invertebrates listed as endangered. Chronic risk to estuarine/marine organisms could not be assessed due to a lack of data. Screening level Tier I modeling studies showed that lindane concentrations in both surface and ground water may reach environmentally significant levels (> MCL), even when lindane is restricted to seed-treatment uses only. The modeling assumption that 100% of the compound will disassociate from the seed surface may have produced highly conservative estimates and may have overestimated the EEC's and resulting risks. A seed leaching study would greatly increase certainty regarding a more realistic estimate groundwater leaching and runoff. This in turn would allow a refinement of exposure estimates and environmental concentration values.

Mode of Action

Technical HCH consists of a number of isomers: alpha (α), beta (β), and gamma (γ) (known as lindane). The approximate composition of technical HCH is 55-70% α- HCH, 5-14%, β-HCH, 10-18%, γ-HCH and impurities. Lindane (99.5% γ-HCH) is the most biologically active insecticidal isomer.

In insects, lindane acts through the inhibition of the gamma-aminobutyric acid (GABA) receptor of the CNS. GABA operates by increasing chloride ion permeability into neurons thereby inhibiting neurostimulation inducing overstimulation of the CNS causing rapid violent convulsions. The a isomer is much less active at inhibiting binding to the GABA receptor than lindane and the beta isomer seems not to exhibit inhibiting binding at all.

Figure 1: Chemical Structure of Lindane and Isomers



Alpha-HCH | Beta-HCH | Delta-HCH | Lindane (gamma-HCH)

Use Characterization

Although the only current agricultural use of lindane is for seed treatment, lindane has been extensively used in the past as an insecticide on a variety of crops, for home termite control, and as a wood preservative. Table 1 summarizes the current use rates for seed treatment that were used in this risk assessment.

Table 1. Lindane seed-treatment uses and application rates.

Seed Type	Label Rate [lb a.i./100 lb seed]	Typical Seeding[a] [lbs seed/acre]	Estimated Application Rate, based on label rate and maximum seeding [lb. a.i./acre]
Barley	0.0375	60-96	0.036
Corn	0.125	10-14	0.018
Oats	0.03125	50-80	0.025
Rye	0.0328	56-84	0.0276
Sorghum	0.0628	6.76	0.00425
Canola	1.075-1.456	4	0.043-0.059
Wheat	0.0426	40-120	0.0512

[a] Based on information from BEAD.

ENVIRONMENTAL FATE AND TRANSPORT ASSESSMENT

Summary

Laboratory studies indicate that lindane is persistent and moderately mobile. It is resistant to photolysis and hydrolysis (except at high pH), and degrades very slowly by microbial actions. Table 2 summarizes the physical-chemical and environmental fate properties of lindane. Since most degradation pathways occur slowly, the presence of the degradates is generally at relatively low levels. There is possible evidence that lindane transforms to the alpha isomer of hexachlorocyclohexane by biological degradation although this issue remains to be conclusively resolved. Possible degradates could include isomers of pentachlorocyclohexene, 1,2,4,-trichlorobenzene, and 1,2,3-trichlorobenzene.

Lindane is transported through the environment by both hydrologic and atmospheric means. Lindane has often been detected in surface and ground water, and in areas of non use (e.g., the arctic), indicating global atmospheric transport (see long-range transport section). Most of these detections have likely resulted from a combination of lindane's past widespread use and its extreme persistence. Currently, U.S. agricultural uses of lindane are restricted to seed treatments, and application rates are quite low. Based on a screening level assessment, lindane may reach water resources at levels above the MCL of 0.2 µg/L.

Table 2. Physical-chemical properties of lindane.

Parameters	Value
Chemical name	γ-1,2,3,4,5,6-hexachlorocyclohexane
CAS No..	58-89-9
Molecular Weight	290.82
Solubility	7 mg/l
Vapor Pressure	9.4×10^{-6} torr
Henry's Law Constant @ 2 5 C	$10^{-2.49}$
pH 5 Hydrolysis half life	stable
pH 7 Hydrolysis half life	stable
pH 9 Hydrolysis half life	43-53 days
Soil Photolysis half life	stable
Aquatic photolysis half life	stable
Aerobic soil dissipation half life	980 days
Soil organic carbon partitioning (K_{oc})	1368 mL/g (mean of 4 soils)
Octanol-water partition coefficient (K_{ow})	$10^{3.78}$

Hydrolysis
Lindane is stable to hydrolysis at pH 5 and 7 and has a half life of from 43 -53 days at pH of 9 (MRID 00161630). At pH 9, the degradates were pentachlorocyclohexane, 1,2,4,-trichlorobenzene, and 1,2,3-trichlorobenzene. Quantitative data were not provided for the degradates in the submitted document.

Aqueous Photolysis
Lindane is stable to photolysis in aqueous systems. These studies (MRIDs 0016457; 001645545; 447931) showed no evidence of aqueous photodegradation during the 30-day study period, even when acetone was used as a photosensitizer **(**MRID 001645545)**.**

Soil Photolysis
Lindane in contact with soil does not photodegrade significantly. On a 1-mm thick soil specimen exposed to artificial sunlight for 12 hour per day, lindane degraded only very slightly over the 30-day test period. The extrapolated half-life was greater than 150 days (MRID 444406-05). The dark control showed a 5% loss over the 30-day study. The soil degradation half life with consideration for the dark control losses is 200 days. Because of the extreme extrapolation to obtain a half life, this study essentially gives no evidence of lindane photodegradation on soil.

Aerobic Soil Metabolism
In a 336-day aerobic soil metabolism study, lindane degraded very slowly, with a registrant-calculated half life of 980 days (MRID 406225-01). Minor degradation products were PCCH and BHC, which reached maximums of 3.84% and 0.77% of applied radioactivity, respectively. Total CO_2 production was 4.81% of the applied parent radioactivity at day 336. It was confirmed that both compounds were present at the beginning of the study; however, it was also observed that, even though there was some variability in the data, pentachlorocyclohexene (PCCH) showed a continuous increment in concentration from day 0 to day 336 (last test interval) of the study. In general, it appeared that there was metabolic transformation during

the study, where pentachlorocyclohexene was formed slowly. Although microbial transformation of lindane to α-HCH is technically possible, it does not occur to a significant extent. Lindane can isomerize to α-HCH by both photolysis and microbial degradation, although significant conversion under typical environmental conditions has not been demonstrated for either pathway.

Anaerobic Soil Metabolism

This study is at best considered only marginally useful, mainly because the material balances generally decreased throughout the study period and were unacceptably low, and because there was variability of in the data for the parent compound. Lindane degraded with a DT_{50} of 36.5 days in anaerobic (nitrogen) flooded sandy loam soil that was incubated in darkness up to 60 days following a 31-day aerobic incubation period. During the aerobic phase, the parent compound was sampled only at the initial, 14 days, and 31 days (prior to flooding). During that time, the parent decreased from 97.6% of the applied radioactivity to 69.6% at 31 days post-treatment. The registrant proposed to estimate the half-life of the aerobic soil metabolism of lindane based on the extrapolation of the 31 day aerobic portion of the study. However, close inspection of the data indicates poor recovery of the radioactivity (from 103.0% at the initial to 85.74% at 31 days. Furthermore, only three data points are available for the calculation. EFED believes that to estimate a half-life of aerobic soil metabolism under these conditions is inappropriate. After anaerobic conditions were induced by flooding and nitrogen gas, the parent compound in the total soil/water system was initially 69.6% (at day 0 prior to flooding), but it increased to 77.1% of the applied radioactivity by 3 days. Total volatiles (including CO_2) were 39.2% at 60 days; $^{14}CO_2$ (NaOH trap only) was a maximum of 6.0% by 60 days. At 60 days following initiation of anaerobic conditions, 12.5% of the applied radioactivity was present as volatile parent compound. In the volatile phase, a major degradate to 11.8% by 60 days following the initiation of anaerobic conditions. The registrant attempted to identify the degradate. It eluted on GC trials at 10.1 minutes. When the sample was spiked with α-HCH, it eluted with the unknown, suggesting the presence of α-HCH. However, this could not be confirmed by a second analytical technique, namely, HPLC. In addition, the registrant provided another study, MRID# 44867107, which is a non-guideline study.

Mobility

The registrant-calculated organic carbon partitioning coefficient (K_{oc}) ranged from 942 to 1798 mL/g with a mean of 1368 mL/g for the four soils tested (MRID 00164346). EFED considers compounds with this range of K_{oc} values to be moderately mobile. Sorption of lindane was assessed in 24-hour batch sorption studies. Soil characteristics and results are presented in Table 3.

Table 3. Soil descriptions and results of 24-hour batch adsorption studies of lindane.

Texture	Clay Loam	Loam	Loamy Sand	Sand
Sand	46	46	82	88
Silt	25	29	8	7
Clay	29	25	10	5
Organic Carbon (%)	0.99	1.58	1.58	0.39
CEC [meq/100 g]	19.4	22.2	18.2	8.9
pH	7.84	7.22	6.9	7.75
K_f [(ml/g)(mg/L)$^{1-n}$] [a]	16.8	14.9	28.4	3.83
N [a]	0.96	0.92	0.93	0.89
K_{oc} [mL/g] [b]	1696	942	1798	1037

[a] Defined by the Freundlich isotherm: $S=K_FC^N$ where S is sorbed concentration [mg/kg], and C is aqueous concentration [mg/L].

[b] K_{oc} is taken as the organic carbon partitioning coefficient at an aqueous concentration of 1 mg/L.

Laboratory Volatility

The submitted study provides only supplemental information about the volatility of lindane. The study was initially designed and submitted to European agencies. The registrant submitted supplemental calculations along with the original submission. Lindane volatilized moderately after application. Immediately after application, a 1.5 cm layer of soil was placed on top of the treated soil (according to the registrant this would simulate soil incorporation similar to the actual use as a seed protectant). During the first hour 2.19% of the applied lindane was found in the volatile traps. The calculated mean volatilization rate of lindane was 0.290 $\mu g/cm^2/hr$. The rate of volatilization decreased with time to an average of 0.0347 $\mu g/cm^2/hr$ in the 6-24 hour interval. After 24 hours, about 13% of the applied radioactivity was volatilized. Lindane represented >86% of the radioactivity extracted from the traps (MRID# 44445301).

Terrestrial Dissipation

Lindane, at 0.61 lbs a.i./A, was applied at once to two test plots (loamy sand, pH 5.2) cropped with peaches and bareground, located in Georgia. Lindane dissipated slowly, with calculated half-lives of 65 and 107 days for cropped and bareground soils, respectively, based on the average of 3 values of lindane in the 0-5 cm soil depth. Lindane was reported to be in the 5-10 cm soil depth between days 120 and 185, at levels between 0.04-0.05 ppm. (MRID 40622502)

In another terrestrial field dissipation study (MRID 448671-03), lindane was applied uniformly to a field in California at a target rate that was 8 times higher than the label application rate for seed treatment. Results from day 0 measurements indicated that 58% of the target rate was actually applied. Lindane residues were not detected below 6 inches. However, the quantification limit was 0.02 ppm, which is only about 5% of the original concentration; thus lindane in this study that leached below the 6 inches could have easily remain unquantified, and thus dissipation half lives may be underestimated. The registrant-calculated dissipation half life was 25 days. Dissipation half-lives are typically shorter in the field than data from laboratory studies due to volatilization, run-off and other such variables. Degradates were not monitored.

Bioconcentration

Lindane bioconcentrates appreciably, but depurates rapidly. Bioconcentration studies were conducted with bluegill sunfish (*Lepomis macrochirus*) at nominal concentration of 0.54 $\mu g/L$ of lindane for 28 days, followed by 14 days of depuration (MRID 400561-01). Bioconcentration factors were 780 for fillet, 2500 for viscera, and 1400 for whole fish tissues. After the 14 days of depuration, ^{14}C levels were reduced by 96% in fillet, 95% in viscera, and 85% in whole fish.

Once released into the environment, lindane can partition into all environmental media. Lindane has been detected in air, surface water, groundwater, sediment, soil, ice, snowpack, fish, wildlife and humans. Lindane can bio-accumulate easily in the food chain due to its high lipid solubility and can bio-concentrate rapidly in microrganisms, invertebrates, fish, birds and mammals, however bio-transformation and elimination are relatively rapid when exposure is discontinued (WHO 1991).

Water Resource Assessment

Lindane may reach surface and ground waters when used as a seed treatment, although concentrations are expected to be low. Fate studies show that lindane is both moderately mobile (mean K_{oc} = 1368) and persistent (soil half life of 2.6 years). Based on a screening level assessment, even at its very low use rate under the current use restriction to seed treatment (maximum of 0.0512 lb a.i./acre), lindane may reach water resources at environmentally significant concentrations.

Surface Water (Farm Pond)

Surface water concentrations resulting from lindane use as a seed treatment were predicted with the Tier1 assessment model, GENEEC. Table 4 presents a summary of GENEEC inputs and results. The entire output file can be found in **Appendix III**.

Table 4. GENEEC input parameters and results for lindane.

Application Rate	1 x 0.051 lb ai/acre*
Aerobic Soil Half Life	980 days (single value)
Organic Carbon Partitioning Coefficient (K_{oc})	942 mL/g (lowest value)
Peak	0.67 µg/L
4-day average	0.66 µg/L
21-day average	0.58 µg/L
56-day average	0.48 µg/L

*The highest effective application rate was for wheat at 0.0512 lb a.i. /acre (see Table 1).

Ground Water

Ground water concentrations were predicted with SCIGROW. Input parameters and output and the resulting EEC are summarized in Table 5. The entire SCIGROW output file is located in **Appendix III**.

Table 5. SCIGROW input parameters and results for lindane.

Application Rate	1 @ 0.051 lb/acre
Aerobic Soil Half Life	980 days (mean Value)
Organic Carbon Partitioning Coefficient (K_{oc})	1367 mL/g (median Value)
EEC	0.011 µg/L

Drinking Water Recommendations to HED

EFED recommends that the Health Effects Division (HED) use the concentrations presented in Table 6 for drinking water EECs. The drinking water EECs were based on the GENEEC (surface water) and SCIGROW (groundwater) simulations described above.

Table 6. Drinking water EECs for lindane for use by HED.

	Acute	Chronic
Groundwater	0.011 µg/L	0.011 µg/L
Surface Water	0.67 µg/L	0.48 µg/L

Monitoring Data

The presence of lindane in the environment, due to previous widespread agricultural use, is well documented in U.S. data bases. For example, In the U.S. EPA STORET data base, 720 detections (after culling of data to eliminate dubious data, e.g. K and U codes) in ground water were reported between the years 1968 and 1995, in nearly all regions of the country, with especially high numbers of detections in the South and West. For these 720 detections, the median and mean concentrations were 0.01 and 11 µg/L, respectively. For surface waters, 8775 detections were reported with median and mean concentrations of 0.005 and 0.18 µg/L. STORET Dectections were reported in nearly all regions of the conterminous U.S. In the USGS NAWQA study, lindane was detected in 2.58% of surface water samples (0.67% at levels greater than 0.05 µg/L, maximum concentration reported was 0.13 µg/L). For groundwater, USGS NAWQA reported a detection frequency of 0.1 % (0.07% at levels greater than 0.01 µg/L, maximum concentration reported was 0.032 µg/L).

EFED would like to stress some basic general parameters when considering the possible use of these types of monitoring data for lindane:

- EFED believes that utilizing “NAWQA” and/or “STORET”data exclusively to establish exposures or to define aquatic risk is not appropriate in most cases. Both databases indicate that lindane has been found in surface and ground water. There is no indication that this has changed.

- The models used by EFED (FIRST and GENEEC2) assume the chemical is applied in the area surrounding the water body from which exposures may occur. Random monitoring of agricultural areas does not automatically assure that lindane was used in the basin surrounding the body of water being sampled. Also, neither NAWQA nor STORET monitoring programs are designed or are intended to establish potential risk to aquatic organisms from agricultural chemicals.

- The NAWQA and STORET monitoring programs are not designed, nor are they intended to establish potential risk to human health. NAWQA and STORET are status and trends program for general water quality. Monitoring is not “targeted” to specific pesticides and no validated link to a pesticides’ use at the field level with an occurrence in either ground or surface water has been made.

- The Agency acknowledges that lindane’s use has decreased over time, and detections should decrease accordingly, but, once again, the purpose of the estimation of EEC’s is to obtain potential concentrations of a pesticide when they are applied in the proximity of surface water intakes.

- NAWQA and STORET data are limited by the extent of sampling conducted at any one site. Very few sites were sampled more than a few times in a year and still fewer for more than one year. Information such as, but not limited to, the timing of lindane application, proximity to the sampling site and proximity of sampling site to the nearest drinking water intake are necessary to better characterize the usefulness of the monitoring data.

Long-range Transport Potential of Lindane

Hexachlorocyclohexane (HCH) is an organochlorine pesticide used throughout the world and is commonly available in two formulations: technical-grade HCH, consists of mainly α-HCH (55-70%), γ-HCH (10-18%) and trace amounts of β-, δ-, and ε-HCH isomers (5-14%) and lindane (almost pure, 99.5% γ-HCH). The United States and many other developed nations discontinued and banned α-HCH usage. Although the only current agricultural use of lindane in United States is for seed treatment, lindane has been extensively used in the past as an insecticide on a variety of crops, for home termite control, and as a wood preservative. Numerous studies of ambient air (Harner et al., 2001 and Waite et al., 1999), precipitation (Barrie et al., 1992 and Norstrom and Muir, 1994), and surface water (Harner, 1997 and Norstrom and Muir, 1994) have reported HCH residues, particularly α and γ isomers, throughout North America. One concern is whether the current use of lindane in the United States has the potential of atmospheric burdens that arise from secondary emissions owing to agricultural practices like seed treatment and consequently their potential for long-range transport and effects on the ecosystem. There are no specific studies that have been conducted in the United States to address this issue. Therefore, this section relied on available literature to address the relative influence of local and regional sources of lindane and their potential for long-range transport.

Lindane is a relatively volatile, persistence and lipophilic organochlorine pesticide and it can migrate over a long distance through various environmental media such as air, water, and sediment. Once lindane is applied to soil, it can either persist in soil as a sorbed phase or be removed through several physical, chemical, and biological processes. However, volatilization from soil and surface waters is the major dissipation route for lindane. The Henry's law constant for lindane suggests that it will volatilize into the air, although microbial and chemical degradation and uptake by crops can also occur (Walker et al., 1999). Lindane can also enter the air as adsorbed phase onto suspended particulate matter, but this process does not appear to be a major contributor like volatilization (Walker et al., 1999 and Bidlemen, 1998). Lane et al. (1992) reported that 95% of the HCH isomers in ambient air were the gaseous phase. Brubaker and Hites (1998) measured the gas phase kinetics of the hydroxyl radical with α-HCH and γ-HCH, and reported that these compounds have long atmospheric half-lives in air and therefore can be transported long distance. Recently, soil and air samples were collected for organochlorine pesticides in northwest Alabama to estimate soil-to-air fluxes and their contribution to the atmospheric concentration (Harner et al., 2001). They attributed that the atmospheric concentration of lindane in northwest Alabama is possibly due to atmospheric advections or regional sources rather than the studied soils. A field study conducted by Waite et al. (2001) in Saskatchewan, Canada demonstrated volatilization of lindane from fields planted with lindane-treated canola seed. They reported that significant quantities (12-30%) of applied lindane volatilize from treated canola seed to the atmosphere during the growing seasons and have direct implications on regional atmospheric concentrations of lindane. They have also estimated that a range of 66.4 to188.8 tons of atmospheric load of γ-HCH occurred during 1997 and 1998 following the planting of canola in the region of the Canadian-prairies. Poissant and Koprivnjak (1996) reported that 90% of elevated γ-HCH concentration in the atmosphere at Villeroy, Quebec in 1992 was from secondary emissions of applied lindane-treated corn, while the rest was from the volatilization of residual lindane from the previous year seed treatment.

The production and usage of HCH isomers (especially α-HCH) have declined worldwide (except India) significantly in recent years (Li et al., 1998). However, many studies suggest that secondary emissions of residual lindane continue to recycle in the global system while they slowly migrated and redeposited in the northern Hemisphere. Harner et al. (1999) attributed the substantial increase of α-HCH compared to lindane in the Arctic to the differences in deposition and photochemical degradation of lindane to α-HCH. However, many other studies did not find substantial evidence of photoisomerization of lindane to α-HCH (Walker et al., 1999). They also suggested that the conversion of lindane to α-HCH in soil and sediment might occur and contribute a small fraction of α-HCH accumulation in atmosphere. Cleeman et al. (1995) measured the deposition of HCH isomers at four sites during 1990 to 1992 in Denmark. Elevated levels of α- and γ-HCHs were detected in the spring and summer and were attributed to continuing use of HCH isomers and long-range transport from European countries south and west of Denmark. Ockenden et al. (1998) observed a very similar trend in Norway. Iwata et al. (1993) compared surface water and air concentrations of HCH isomers. Results indicate that HCHs were primarily released from east Asia and India but were accumulating in the northern oceans. They suggested that HCH isomers were able to atmospherically transport to colder regions where it was deposited and became less volatile in colder sinks. Atmospheric concentrations of many organochlorine compounds have also been detected in the Arctic, but the highest concentrations are generally α- and γ-HCHs (Harner, 1997). Even though, high concentrations of HCH isomers were detected in surface waters of the Arctic, bioaccumulation in the aquatic food chains was significantly less than the other organochlorine compounds (Norstrom and Muir, 1994).

The behavior of HCH isomers in the environment is complex because they are multimedia chemicals, existing and exchanging among different compartments of the environment such as atmosphere, surface water, soil and sediment. Post-application residual volatilization of lindane takes place over a much longer period. Once airborne, lindane may move into the upper troposphere for more widespread regional, and possibly transcontinental distribution as a result of large-scale vertical perturbations that facilitate air mass movement out of the near surface. Also, it may reversibly deposit on terrestrial surfaces close to the source and still be transported over large distances, even global scales, through successive cycles of deposition and re-emission as result of ambient temperature and latitude differences known as “global distillation or fractionation” (Wania and Mackay, 1996). In order to understand the long-range transport potential of a compound, a necessary step needs to consider if multimedia environmental partition and degradation processes can substantially remove the substance. In response, a number of multimedia models have emerged. Detailed information of multimedia model evolution and their significance can be found in a recent article by Wania and Mackay (1999).

Recently, a workgroup was initiated by Wania and Mackey (2000) to compare the persistent and long-range transport potential estimated by models developed and used by various research groups. Even though there are some specific differences among the participants’ models, all participants used essentially the basic multimedia Level III fugacity model developed by Mackey (1991). The Level III model is more complex and realistic than Level I and Level II fugacity models. A Level I model is a closed system mass balance of a defined quantity of chemical as it partitions at equilibrium between compartments. A Level II model is a steady-state open system description of chemical fate at equilibrium with a constant chemical emission rate. The Level III model is a steady-state of chemical fate between a number of well-mixed compartments which are not at equilibrium. This model also assumes a simple, evaluative environment with user-defined volumes and densities for the following homogeneous environmental media (or compartments): air, water, soil, suspended sediment, sediment, fish and aerosols. This model gives a more realistic description of a chemical's fate including the important degradation and advection losses and the intermedia transport processes.

All participants of the workgroup evaluated the persistent and long-range transport of lindane and 25 other chemicals using a set of physical, chemical, and environmental fate data by Mackey et al. (1992-1997). They calculated values termed “fugacity capacities” for selected environmental media (air, water, soil) in the model, based on the chemical and physical properties of the modeled substances. There are large differences in the absolute persistence value estimated by the various models ranging from 546 days to 1219 days for lindane and 368 days to 925 days for α-HCH. Similarly, the absolute atmospheric transport distances calculated by the participants are also large ranging from1000 km(621 miles) to58396 km (36287 miles) for lindane and 1014 km (630 miles) to 72441 km (45014 miles) for α-HCH. Despite the large difference in the absolute values, the correlation between the overall persistence and long-range transport values obtained by various models were high, with correlation coefficients averaging higher than 0.80. The differences between models can be attributed to the differences in the numbers and relative dimensions of the model compartments. In addition, environmental degradation rates, which can vary with temperature, humidity, and other environmental properties, may have significant influence on the variation among model results.

Currently, the EPA is developing a PBT Profiler that estimates environmental persistence (P), bioconcentration potential (B), and aquatic toxicity (T). When a user accesses the PBT Profiler on the Internet, the program prompts the user to enter the Chemical Abstract Service (CAS) number of chemicals under consideration. The PBT Profiler is linked to a database containing CAS numbers and associated chemical structure for more than 100,000 discrete chemical substances. If the CAS number is in the database, the PBT Profiler will translate the CAS number into a chemical structure, predict the PBT characteristics, and provide a PBT Profile in an easy to understand format. The PBT profiler also uses the Level III fugacity model as described earlier to determine the percentage of a chemical in defined media. More information can be obtained from EPA’s website (www.epa.gov/opptintr/p2framework/docs/profile.htm). A beta test of the PBT Profiler has been completed and the peer review phase is in progress. The PBT profiler was used to estimate PBT characteristics of lindane. The following italicized or underlined highlights in PBT outputs of lindane indicate that the persistence and aquatic toxicity criteria have been exceeded and characteristics travel distance (CTD) or a half-distance (analogous to half-life) was 15000 km (9321miles).

In summary, the presence of α-HCH and lindane in surface water, atmosphere and precipitation from sites remote from industrial and agricultural activities implies long-range atmospheric migrations of these compounds. Concerns have been raised for their potential effects on human and ecosystem health of the northern hemisphere. It is conceivable that the elevated levels of lindane and α-HCH in the northern

Results

Italicized or **underlined** highlights indicate that the PBT Profiler criteria have been exceeded.
Color version

Persistence			Bioaccumulation	Toxicity

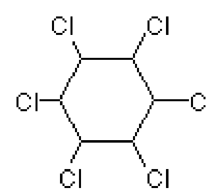
58899 gamma-Hexachlorocyclohexane

PBT Profiler Estimate = P b *T* P2 considerations

Media	Half-Life (days)	Percent in Each Medium	BCF	Fish ChV (mg/l)
Water	**180**	6%	**310**	***0.3***
Soil	**360**	89%		
Sediment	**1,600**	4%		
Air	**120**	1%		

CTD in air = **15,000** Km

Overall Persistence = 440 days



hemisphere, especially in the Arctic, resulted from long-range transport. Persistence and long-range transport of lindane was also reflected in monitoring data and various modeling efforts. Despite the progress made in recent years in estimating the persistence and long-ranged transport using models for chemicals, a validated global model has not yet been published because of uncertainties involved in the source inventories, chemical fate data, degradative pathways and exposure analyses. Future work should be aimed at developing a comprehensive screening tool that can be used reliably in risk assessments for regulatory purposes.

ECOLOGICAL EFFECTS TOXICITY ASSESSMENT

Toxicity testing reported in this section does not represent all species of bird, mammal, or aquatic organism. Only two surrogate species for both freshwater fish and birds are used to represent all freshwater fish (2000+) and bird (680+) species in the United States. For mammals, acute studies are usually limited to the Norway rat or the house mouse. Estuarine/marine testing is usually limited to a crustacean, a mollusk, and a fish. Also, neither reptiles nor amphibians are tested. The assessment of risk or hazard makes the assumption that avian and reptilian toxicity are similar, and that fish and amphibians toxicity are similar. Generally, the most toxic endpoints for the technical grade active ingredient (TGAI) are used in the assessment to represent each group of organism.

Based on ecological effects data, the toxicity endpoints[+] used in the assessment of lindane can be characterized as follows:

* Avian acute oral - Moderately toxic (LD50= 56 mg/Kg)
* Avian acute dietary - Highly toxic (LC50= 425 ppm)
* Avian chronic (reproduction)- (NOAEC= 15 ppm)
* Mammalian acute oral - Moderately toxic (LD50= 88 mg/Kg)
* Mammalian chronic (reproduction)-(NOAEL= 20 ppm)
* Honey bee acute - Highly toxic (LD50= 0.2 ug/bee)
* Fish (freshwater) acute - Very highly toxic (LC50= 1.7 ppb)
* Fish (freshwater) chronic - Reduced larval growth (NOAEC= 2.9 ppb)
* Fish (estuarine) acute - Very highly toxic (48 hr LC50= 23.0 ppb)
* Fish (estuarine) chronic - No data
* Invertebrate (freshwater) acute - Very highly toxic (96 hr LC50= 10.0 ppb)
* Invertebrate (freshwater) chronic- Decreased reproduction (21-day NOAEC= 54.0 ppb)
* Invertebrate (estuarine) acute - Very highly toxic (96 hr LC50/EC50= 0.077 ppb)
* Invertebrate (estuarine) chronic - No data
* Plants - No data

+ For a complete listing of these and other toxicity studies for lindane, please see Appendix I.

Toxicity to Terrestrial Organisms

Bird and mammal overview

Lindane is moderately toxic to birds and mammals on an acute exposure basis. Chronic reproductive effects include significant reductions in egg production, growth and survival parameters in birds, and decreased body weight gain in mammals.

Avian Species (Acute Oral, Subacute Dietary and Reproduction)
In acute oral toxicity studies conducted on bobwhite quail, starlings, red-winged blackbirds and sparrows, the LD_{50s} for lindane are 122, 100, 75 and 56 mg/kg, respectively. The results suggest that lindane is moderately toxic to birds on an acute oral basis. Subacute dietary toxicity studies conducted on mallard duck, bobwhite quail, ring-necked pheasant, and Japanese quail suggest that lindane is practically non-toxic to highly toxic, with LC_{50s} of >5000, 882, 561 and 425 ppm, respectively. An avian reproduction study on bobwhite quail indicated that significant reductions occurred in the number of eggs laid, eggs set, viable embryos, live 3-week embryos, normal hatchlings and 14-day old survivors, percentage of normal hatchlings/eggs laid, normal hatchlings/eggs set, normal hatchlings/live 3 week embryos, 14-day

survivors/eggs set, 14-day survivors/normal hatchlings, eggshell thickness and hatchling weights. The No Observable Adverse Effect Concentration (NOAEC) and the Lowest Observable Adverse Effect Concentration (LOAEC) were determined to be 80 and 320 ppm, respectively.

Also, an avian reproduction study using mallard ducks showed significant reductions in the number of viable embryos, live 3-week embryos, and normal hatchlings at the two highest concentrations (45 and 135 ppm). The NOAEC and the LOAEC were determined to be 15 and 45 ppm, respectively. However, due to low hatching success in the control group, the study should be repeated to determine if 15 ppm is a valid NOAEL value. The NOAEL value of 15 ppm will be used in risk assessments until further data is provided.

In addition, the registrant submitted two 14-day free choice avian dietary toxicity studies (400561-03 and 400561-04). Results suggested that bobwhite quail and red-winged blackbirds were repelled by treated sorghum seed. These studies clearly suggested that birds avoided lindane treated food when given a choice and even in a no-choice situation, birds did not readily eat and were emaciated at study termination.

Mammalian Species (Acute Oral and Reproduction)
In toxicity studies conducted on laboratory rats for the Agency's Health Effects Division (HED), lindane is moderately toxic to small mammals on an acute oral basis (LD_{50} of 88 mg/kg). Results from a chronic reproduction study indicate reproductive toxicity at a LOAEL of 150 ppm (NOAEL of 20 ppm) with decreased body weight gain, viability up to PP4 in both generation offspring and delayed onset and completion of tooth eruption and hair growth in F2 pups being the endpoints affected.

Insects
Lindane is highly toxic to bees on an acute contact basis (LD_{50s} ranged from 0.20 to 0.56 µg/bee).

Toxicity to Non-target Aquatic Animals

Freshwater organism toxicity overview
Lindane exhibits high to very high acute toxicity to freshwater fish (LC_{50} ranges of 1.7 to 131 ppb) and freshwater aquatic invertebrates (LC_{50} ranges of 10.0 to 520 ppb). Chronic effects include reduction in larval growth in freshwater fish (NOAEC=2.9 µg/L) and decreased reproduction in aquatic invertebrates (NOAEC=54 µg/L).

Freshwater fish
In acute toxicity studies conducted on coldwater and warmwater species, the 96-hour LC_{50} values for the technical grade material ranged from 1.7 to 131 ppb, suggesting that lindane will be highly to very highly toxic to freshwater fish on an acute basis. Early life-stage toxicity tests conducted on rainbow trout show that lindane significantly affected larval growth at concentrations greater than or equal to 6.0 µg/L.

Freshwater invertebrates
Acute toxicity studies conducted on a variety of freshwater aquatic invertebrates suggest that the active ingredient of lindane is highly to very highly toxic on an acute basis. 48- and 96-hour LC_{50} or EC_{50} values ranged from 10.0 to 520 µg/L in 6 studies. A life-cycle toxicity test conducted with the active ingredient (99.5% ai) on waterflea (*Daphnia magna*) found a 21-day NOAEC of 54.0 µg/L and a LOAEC of 110.0 µg/L. Decreased reproduction was the affected endpoint in the study.

Estuarine/Marine organism toxicity overview

Lindane exhibits high to very high acute toxicity to estuarine/marine fish and ranges from moderately to very highly toxic to estuarine/marine aquatic invertebrates. No data were submitted to assess chronic effects to either estuarine/marine fish or estuarine/marine aquatic invertebrates.

Estuarine/Marine fish

Testing on a variety of species resulted in 48- and 96-hour LC_{50} range of 23.0 to 190.0 µg/L, which is considered to be very highly to highly toxic on an acute basis. No data on the chronic effects of lindane estuarine/marine fish have been submitted.

Estuarine/Marine invertebrates

Acute toxicity testing on a variety of estuarine/marine invertebrate species with the technical product resulted in 48- and 96-hour LC_{50}/EC_{50} values ranging from 0.077 to 2800.0 µg/L which fall into the highly to very highly toxic acute classes for estuarine/marine invertebrates. No data on the chronic effects of lindane have been submitted.

Toxicity to Plants

Currently, plant testing is not required for pesticides other than herbicides and fungicides except on a case-by-case basis (e.g., labeling bears phytotoxicity warnings, incident data or literature that demonstrates phytotoxicity). Because of the current low application rate, lack of incident data on plants and no available literature suggesting phytotoxicity, no plant data would normally be required. However, Tier I plant toxicity studies (850.4100-Seedling emergence in 10 species and 850.5400-Aquatic plant toxicity tests in 5 species) are required for outdoor seed treatment uses (Memo from Denise Keehner re: EFED policy guidance for eco-risk and drinking water assessments of seed treatment pesticides, 7/30/99).

Ecological Incident Data

Incidents have been reported from the use of lindane and are on the USEPA incident database. These incidents are listed in a table in **Appendix II.** The incidents all involved fish and lindane was not the definite cause for most, however, one definite incident was an accidental spill that did kill trout.

ENVIRONMENTAL RISK ASSESSMENT

In order to evaluate the potential risk to aquatic and terrestrial organisms from the use of lindane, risk quotients (RQs) are calculated from the ratio of estimated environmental concentrations (EECs) to generally the most toxic ecotoxicity value (acute) or no-effect level (chronic) for that group of organisms. These RQs are then compared to levels of concern (LOCs) used by OPP to indicate potential risk to nontarget organisms and the need to consider regulatory action. EECs are based on the maximum application rates (worst case) for selected modeled crop uses for lindane.

Ecological effects data requirements and assessments for seed treatment pesticides are normally based on the granular risk assessment strategy. The seed treatment assessment process is designed to assess toxicological endpoints according to application rates, application method, and soil incorporation depth. Granules (seeds) are assumed to be consumed by terrestrial wildlife, and exposure may be limited by type of application method.

Risk to Nontarget Terrestrial Organisms

Ecological risks from seed treatments can be assessed by the same methods used for granular and bait products. The standard assessment is to calculate the number of LD50 per square foot of seeds exposed at the soil surface, accounting for incorporation of the seeds in the soil (Felthousen 1977). The number of seeds that must be consumed by the non-target organism to reach the LD50 can be calculated if the amount of active ingredient (AI) on each seed is known or can be estimated. If the concentration of active ingredient on the seed is known or can be estimated, then this concentration can be used as an EEC to assess risk to granivorous birds and mammals. For avian species, this EEC can be compared directly to the dietary LC50 value. For mammals, this EEC can be compared to the concentration of toxicant in food lethal to 50% of the population, which is calculated by dividing the LD50 value by the fraction of body weight consumed per day (McCann 1987).

Birds and small mammals actively probe the soil while searching for food. While foraging, they are known to ingest soil, both intentionally and incidentally. Beyer, et al. (1994) estimated the soil content of the diet of a number of bird and mammal species to range from <2% to 30%. Nevertheless, soil incorporation will reduce overall species risk and/or access to the compound.

Terrestrial assessment
The labels with the highest rates (lb lindane/100 lb seed) were used to evaluate potential maximum consumption of lindane by terrestrial animals. The current approach uses daily food intake calculated using the relationships described in Nagy (1987 as cited in USEPA, 1993). Acute risk quotients (RQ) were then calculated based on animals receiving their full diet from lindane-treated seeds for a 1-day time period–that is,

$$\mathbf{RQ} = \frac{\textbf{mass of lindane consumed in 1 day from treated seeds}}{\textbf{species-specific mass of lindane required to reach } \mathbf{LD_{50}}}$$

An **RQ $\geq$ 0.5** is defined as the level of possible acute risk. Details of the calculations are given in Appendix II. Results suggest that there may be potential acute and chronic risk to both endangered and non-endangered birds and mammals. Smaller birds and mammals (i.e., those with high food intake rates per body mass) are at greater risk than larger animals. The calculation pertains to consumption of food in dry weight. Seeds used for planting are expected to possess low water content, thus no adjustments were made for wet weight.

Aquatic assessment
The EFED model GENEEC was used to determine aquatic EECs. Wheat has the highest application rate in terms of lbs a.i per acre (see Table 1) and was used as the model crop scenario. Results of this assessment are listed in **Appendix II** and the GENEEC output file is in **Appendix III**. An analysis of the results suggest that for estuarine/marine invertebrates, high acute risk (RQ = 8.7) may occur even at the low application rates for seed-treatment uses. Restricted use LOCs were exceeded for estuarine/marine invertebrates and freshwater fish. Endangered species LOCs are exceeded for freshwater fish and invertebrates and estuarine/marine invertebrates. Chronic risk to estuarine/marine organisms could not be assessed due to a lack of data.

Exposure and Risk to Endangered Species
In 1983, the Agency requested a “case-by-case” opinion for a Section 18 (emergency use exemption) for sugarcane use in Florida. Jeopardy to the snail kite, bald eagle and Florida panther was found from potential lindane use. The Agency agrees with the jeopardy to the snail kite due to reductions to its food source (apple snails) from the sugarcane use. However, even though lindane exhibits toxicity to birds and mammals, under the proposed seed treatment use patterns, low risk is assumed for most endangered species of these taxa based on their lifestyles, feeding habits and natural environments.

When the regulatory changes recommended in this IRED are implemented and the ecological effects and environmental fate data are submitted and accepted by the Agency, the Reasonable and Prudent Alternatives may need to be reassessed and modified based on the new information.

The Agency is currently engaged in a Proactive Conservation Review with FWS and the National Marine Fisheries Service under section 7(a)(1) of the Endangered Species Act. The objective of this review is to clarify and develop consistent processes for endangered species risk assessments and consultations. Subsequent to the completion of this process, the Agency will reassess the potential effects of lindane use to federally listed threatened and endangered species. At that time the Agency will also consider any regulatory changes recommended in the IRED that are being implemented. Until such time as this analysis is completed, the overall environmental effects mitigation strategy articulated in this document and any County Specific Pamphlets described in Section IV which address lindane, will serve as interim protection measures to reduce the likelihood that endangered and threatened species may be exposed to lindane at levels of concern.

RISK CHARACTERIZATION

Summary of Risk

Lindane is a persistent, moderately mobile organochlorine and a potential endocrine disruptor in birds, mammals and possibly fish. There is a possiblity of acute and chronic reproductive risk from the use of lindane-treated seed to endangered and non-endangered avian and especially mammalian species consuming a majority of their body weight in seed per day. The assessment suggests acute risk to endangered and non-endangered freshwater fish may occur even at the low application rates for seed-treatment uses. However, the aquatic assessment is based on the conservative assumption that 100% of the compound will disassociate from the seed surface. Thus, these risks may be overestimated somewhat.

Based on a screening level assessment, both surface and ground water simulations show that lindane concentrations in water resulting from seed treatments may reach levels of environmental concern and may exceed the MCL for drinking water (0.2ppb). Lindane in water bodies due to past uses will likely remain for long periods, due to lindane’s extreme persistence.

Avian and Mammalian Species

Based on available scientific literature, lindane has shown adverse endocrine effects in mammals (Raizada et al. 1980; Uphouse 1987; Cooper et al. 1989) and has been reported to disturb male mammalian reproductive functioning (Chowdhury et al., 1987; Chowdhury and Gautam 1994; Dalsenter et al. 1997; Dalsenter et al. 1996). Lindane is also known to accumulate in fat tissues and to be slowly eliminated in milk during lactation (Pompa et al. 1994). Neurological and behavioral alterations are principal toxic effects of lindane in animals (Hulth et al. 1976; Joy 1982). Chakravarty et al. (1986) and Chakravarty and Lahiri (1986) found that when domestic ducks were force fed lindane (20 mg/kg of body weight for 8 wks), significant egg-shell thinning, reduced clutch size, and reduced laying frequencies were observed. They suggested that lindane induced estradiol insufficiency which causes inhibition of hepatic RNA and yolk protein synthesis, thereby preventing transformation of moderately differentiated oocytes to mature vitellogenic follicles, delaying ovulation and thus drastically reducing clutch size. Hoffman and Eastin (1982) found that lindane was teratogenic to mallard ducks only at doses that were greater than five times the field level of application, but did find that lindane was much more toxic on a lbs per acre basis when administered in oil. However, lindane in the diet of laying hens at 100 ppm caused reduced hatchability (Whitehead et al. 1972) and at 25 ppm the same effect was noted in Japanese quail (Dewitt and George 1957). In the field , Blus et al. (1985) found that when lindane was substituted for heptaclor (HE) for treatment of seed (Columbia Basin near the Umatilla NWR, in Oregon and Washington State, USA), lindane did not produce adverse effects in birds and residues were not detected in either their eggs or brains. Also, coincidental with the decrease in HE residues in Canada geese, mortality decreased, reproductive success improved, and the population increased rapidly (Blus et al. 1984). There was no evidence for either bio-magnification of lindane residues from treated seeds to goose tissues or eggs or for induction of adverse effects to avian species. This may be due to the fact that Canada geese, as well as other avian species, may have been repelled by lindane treated seed as a submitted study has suggested with quail and red-winged blackbirds.

The registrant submitted two 14-day free choice avian dietary toxicity studies (400561-03 and 400561-04) using 40% lindane. Results suggested that bobwhite quail and red-winged blackbirds were repelled by treated sorghum seed. These studies clearly suggested that birds avoided lindane treated food when given a choice and even in a no-choice situation, birds did not readily eat and were emaciated at study termination. Other avian species may possibly also show aversion to lindane treated seed. However, birds of prey that consume small mammals that have accumulated lindane may be at risk from some level of secondary toxicity from chronic exposure over time. Also, lindane can be stored in the fat of birds; birds of prey in the Netherlands contained up to 89 ppm in their fat (Ulman 1972).

Earthworms are known to accumulate lipophilic substances (such as lindane) through the epidermis and the intestine (Belfroid et al. 1994). In nature, worms constitute a link in the transport of environmental pollutants from soil to organisms higher up in the terrestrial food web. Avian and mammalian species may eat worms that have accumulated lindane, thus providing some level of risk to those species. Also, many young birds eat diets rich in animal foods (including worms), even though they may be strict vegetarians as adults. Many newly-hatched young that feed themselves, instinctively select protein-rich foods such as worms.

Lindane-treated seed will most likely be planted in the spring during, or just prior to, breeding season. Higher energy expenditures and higher caloric need in mammals during gestation and lactation imply a need for either more total food and/or food with a higher caloric content. Conditions during breeding season present a need to keep in close proximity to the den and subsequent offspring. Because of this, mammals living near fields planted with lindane treated seed may not have the option of traveling to non-treated areas and may in fact cache these readily available treated seeds. Most uses do not present high acute risk to larger seed eating mammals. However, due to the compound exhibiting endocrine-disrupting effects and being lipophilic and eliminated in milk during lactation, mammals in general that may ingest seeds may be at some risk. Milk is known to be a major route of elimination for lipophilic persistent substances stored in adipose tissue. The milk:plasma concentration ratio for lindane indicates a much more efficient excretion of the compound in milk (Dalsenter et al. 1997). Milk possesses a great affinity on liposoluble substances due to its high fat content. The presence of lindane in mammalian milk exposes nursing offspring during critical periods of post-natal development (Dalsenter et al. 1997). Small mammals with high metabolic rates that dig and cache seeds, may be at acute and especially chronic risk, due to consumption over time and the persistence of the compound in soil. Dalsenter et al. (1997) indicated that treatment of female rats on day 15 of pregnancy with only a single dose (30 mg lindane/Kg of body weight) affects the sexual behavior of adult male offspring by altering libido and by reducing testosterone concentration without compromising fertility. Effects to offspring may be due to the indirect interference of lindane on hormonal regulation in males. Pertubation of the endocrine system during early stages of development can be influenced by small changes of hormonal imbalance.

Aquatic Organisms

Generally, from the results of the aquatic assessment, risks to aquatic organisms were low. The highest use rate (wheat) was modeled. Based on a Tier I screening assessment (using GENEEC) and assuming that 100% of the compound will disassociate from the seed surface, the aquatic assessment resulted in risks to aquatic organisms. The greatest risk, due mainly to the toxicity of the compound, was to estuarine/marine invertebrates from an acute exposure (RQ=8.7). There were no data available to assess chronic risk to these invertebrates. These data are especially important since the compound is persistent and can result in significant bio-accumulation (bioconcentration factor is 1400 times the ambient water concentration). Acute risk to endangered and non-endangered freshwater fish may also occur even at the low application rates for seed-treatment uses. In addition, Petit et al. (1997) found that lindane exhibited estrogenic activity in two *in vitro* bioassays. Thus, lindane may also be an endocrine disrupting compound in aquatic species. EFED believes that a seed leaching study would greatly increase certainty regarding a more realistic estimate of the amount of available lindane on the seed surface. This in turn would allow a refinement of exposure estimates and environmental concentration values (EECs). However, the assumption that 100% of the compound will disassociate from the seed surface has likely produced highly conservative estimates and has thus overestimated the EEC's and resulting risks.

Reproductive and population effects in other species of invertebrates have also been suggested. Blockwell et al. (1999) found that populations of *H. azteca* (a detritivorous crustacean) exposed to (LOAEL=13.5 ug lindane/L; NOAEC=6.9 ug lindane/L) lindane were significantly (ANOVA, $p < 0.001$; Tukey-Kramer, $p < 0.05$) smaller than control populations in a 35 day chronic study. Reduction in population growth was observed and resulted from a combination of toxicant effects: disruption of the reproductive behavior patterns of adult *H. azteca* and a reduction in the growth of recruited individuals and consequently their delayed sexual development. This value is similar to the LOAECs produced from other chronic lindane toxicity studies conducted with freshwater crustaceans: 19 µg/L for *Daphnia magna* in a 64-d study and 8.6 µg/L in a 17-week study conducted with *Gammarus fasciatus* based on survivorship and reproductive success (Macek et al., 1976). Furthermore, an LOAEC of 9.9 ug lindane/L was generated in a life cycle study conducted using *Chironomous riparius* (Insecta) (Taylor et al. 1993). Lindane has also previously been reported to reduce juvenile growth of the European amphipod *Gammarus pulex (L.)* at 6.1 µg/L in a 14-d study (Blockwell et al. 1996). However, data shows that concentrations of lindane above 2.5 µg/L (found in Lake Michigan tributary stream) were not reported as occurring in any aquatic system tested (ATSDR 1997).

Incidents have been reported from the use of lindane and are in the EPA incident database. An incident classified as "highly probable" was reported as killing hundreds of trout on a tree farm in Watauga, North Carolina after a spill close to a nearby stream. However, no aquatic incidents have been reported as having occurred under normal use conditions of seed treatment under soil incorporated use patterns.

Endocrine Disruption

EPA is required under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disrupting Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen- and thyroid-hormone systems, in addition to the estrogen-hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticidal chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA has authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

Based on available scientific literature, lindane has characteristics of an endocrine disrupting compound. The compound exhibits effects on birds, mammals and possibly fish. As stated previously, effects included disruption in male reproductive behavior and functioning in mammals (LD50=88 mg/kg with levels of only 30 mg/kg resulting in effects), eggshell thinning possibly from estrogen deficiency in female birds, and estradiol insufficiency which may cause a delay in ovulation resulting in a drastic reduction in clutch size in birds (NOAEL/LOAEC=80/320 ppm with calculated EEC levels of 51.5 to 206.2 ppm resulting in a possibility of effects). In the submitted avian reproduction study using the mallard duck (MRID 448671-01), thyroid weights for males in the 135 ppm test concentration were significantly higher than those measured in the control. Histopathology revealed microscopic lesions in the thyroid glands consisting of thyroid follicular distension and coalescence, follicular hypertrophy and follicular hyperplasia. These lesions were more apparent at the 135 ppm than at 45 ppm. Analysis of the gonads of either sex were unremarkable with the exception of the possibility of reduced spermatogenesis in the group receiving 45 ppm. Exposure of mammalian neonates to lindane during lactation induces reproductive hazards to male offspring rats which are detectable at adulthood.

Based on all these data, EFED recommends that when appropriate screening and or testing protocols being considered under the Agency's EDSP have been developed, lindane be subjected to more definitive testing to better characterize effects related to its endocrine disruptor activity under the current use pattern.

Presence in the Environment

Lindane, as well as other HCH isomers, do not naturally occur in the environment. Once released into the environment, lindane can partition into various environmental media. Because of long-range transport, lindane has been detected in air, surface water, groundwater, sediment, soil, ice, snowpack, fish, wildlife and humans. HCH- isomers (mainly α and γ) were the major organochlorine insecticide detected in arctic air, snow and seawater (Barrie et al. 1991). The Arctic is considered a "sink" for persistent organic pollutants. Once in the Arctic, lindane bio-accumulates in the food chain due to its high lipid solubility. Lindane is bio-concentrated rapidly in microrganisms, invertebrates, fish, birds and mammals, however bio-transformation and elimination are relatively rapid when exposure is discontinued (WHO 1991).

Lindane is strongly adsorbed on soils that contain large amounts of organic matter, however it can leach with water from rainfall or artificial irrigation. Lindane sorbed to soil can get into the atmosphere either by wind erosion of the soil particulates or by volatilization. Volatilization seems to be an important route of dissipation under higher temperature conditions such as those occurring in tropical regions (WHO 1991). Levels of lindane in the atmosphere seem to be seasonal and temperature dependent, with the highest air concentrations in the summer and lowest during winter, as would be expected from agricultural uses (Whitmore et al., 1994). Removal of foliar and broadcast type applications and uses in favor of low rate seed treatments will most likely limit the amount of available lindane for release into the environment. However, Waite et al. (1998) did find that release of lindane to the atmosphere begins within the first week the treated seed is sown. Most recently, Waite et al. (2001) found that between 30% (in 1997) and 12% (in 1998) of the lindane applied to canola fields (as treated seed) was lost through volatilization that began immediately after planting.

Lindane is more soluble in water than most other OC compounds, therefore it has a greater possibility of remaining in the water column. Agricultural run-off is likely the major contamination route of lindane to surface water. The three main transport pathways for atmospheric input to surface waters are wet deposition, dry deposition and gas exchange across the air-water interface, although evaporative loss from surface water is not considered significant. Apart from atmospheric deposition and surface run-off, point source discharges are also contributors of surface water contamination. In Canada, run-off from canola fields was reported to contaminate surface water with maximum concentrations of 0.011 ppb and 0.004

ppb for lindane and α-HCH, respectively (Donald et al., 1997). As stated previously, both surface and ground water simulations, based on a screening level assessment, show that lindane concentrations in water resulting from seed treatment may reach levels of environmental concern and may exceed the MCL for drinking water (0.2 ppb). Lindane in water bodies due to past uses will likely remain for long periods, due to lindane's extreme persistence.

Persistence and long-range transport of HCH-isomers were also reflected in monitoring data and various modeling efforts. The most common hexachlorocyclohexane isomers found in the environment are lindane (γ-), α-, and β-HCHs, with α-HCH as the predominant isomer in air and ocean water and β-HCH the predominant isomer in soils, animal tissues and fluids (Willett et al., 1998). Recent data suggest that the declines of α-HCH isomer concentrations in the environment have resulted from reduced use of technical HCH, especially in Asian countries (Iwata et al., 1993). However, Oehme et al., (1995) have suggested that while there are some indications that total HCH in Arctic air has declined, mean levels of lindane have increased slightly, which likely reflects the increase in lindane use in northern hemisphere after the ban of technical HCH was imposed.

Literature cited

Agency for Toxic Substances and Disease Registry (ATSDR). 1997. Toxicological profile for Alpha-, Beta-, Gamma-, and Delta-Hexachlorocyclohexane. U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry. September 1997.

Barrie L.A., D. Gregor, B. Hargrave, R. Lake, D. Muir, R. Shearer, B. Tracey and T. Bidleman. 1991. Arctic contaminants: sources, occurrence and pathways. The Science of the Total Environment 122:1-74.

Belfroid A., J. Meiling, D. Sijm, W. Hermens, K. van Gestel. 1994. Uptake of hydrophobic halogenated aromatic compounds from food by earthworms (*Eisenia andrei*). Archives of Environmental Contaminants and Toxicology 27:260-265.

Beyer, W.N., E.E. Conner and S. Gerould. 1994. Estimates of soil ingestion by wildlife. J. Wild. Management 58(2):375-382.

Blockwell, S.J., D. Pascoe , and S.J. Maund. 1999. Effects of the organochlorine insecticide lindane on the population responses of the freshwater amphipod *Hyalella azteca*. Environmental Toxicology and Chemistry 18(6):1264-1269.

Blockwell SJ, D. Pascoe, E.J. Taylor. 1996. Effects of lindane on the growth of the freshwater amphipod *Gammarus pulex (L.)*. Chemosphere 32:1795-1803.

Blus, L.J., C.J. Henny, and A.J. Krynitsky. 1985. The effects of heptachlor and lindane on birds, Columbia Basin, Oregon and Washington, 1976-1981. Science of the Total Environment 46:73-81.

Blus, L.J., C.J. Henny, D.J. Lenhart, and T.E. Kaiser. 1984. Effects of heptachlor and lindane treated seed on Canada geese. Journal of Wildlife Management 48(4):1097-1111.

Brubaker, W.W., and R.A. Hites Jr. 1998. OH reaction kinetics of gas-phase a- and g-hexachlorocyclohexane and hexachlorobenzene. Environ Sci Technol. 32:766-769.

Chakravarty, S. and P. Lahiri. 1986. Effect of lindane on eggshell characteristics and calcium level in the domestic duck. Toxicology 42:245-258.

Chakravarty, S., A. Mandal, and P. Lahiri. 1986. Effect of lindane on clutch size and level of egg yolk protein in domestic duck. Toxicology 39:93-103.

Chowdhury, A.R. and A.K. Gautam. 1994. Steroidogenic impairment after lindane treatment in male rats. Sangyo-Ika-Daigaku-Zasshi 16:145-152.

Chowdhury, A.R., H. Venkatakrishna-Bhatt, and A.K. Gautam. 1987. Testicular changes of rats under lindane treatment. Bulletin of Environmental Contamination and Toxicology 38:154-156.

Cleemann, M., Poulsen M.E., and G. Hilbert. 1995. Deposition of lindane in Danmark. Chemosphere 30:2039-2049.

Clench, M.H. and R.C. Leberman. 1978. Weights of 151 species of Pennsylvanian birds analyzed by month, age and sex. Bulletin of the Carnegie Museum of Natural History:5; Tomlinson, R.E. 1975. Weights and wing lengths of wild Sonoran Masked bobwhites during fall and winter. Wilson Bulletin 87:180-18

Cooper, R.L., R.W. Chadwick, G.L. Goldman, K.C. Booth, J.F. Hein, and W.K. McElroy. 1989. Effect of lindane on hormonal control of reproductive function in the female rat. Toxicology and Applied Pharmacology 99:384-394.

Dalsenter, P.R., A.S. Faqi, J. Webb, H-J. Merker and I. Chahoud. 1997. Reproductive toxicity and toxicokenetics of lindane in the male offspring of rats exposed during lactation. Human and Experimental Toxicology 16:146-153.

Dalsenter, P.R., A.S. Faqi, J. Webb, H-J. Merker and I. Chahoud. 1996. Reproductive toxicity and tissue concentrations of lindane in adult male rats. Human and Experimental Toxicology 15:406-410.

Dalsenter, P.R., A.S. Faqi, and I. Chahoud. 1997. Serum testosterone and sexual behavior in rats after prenatal exposure to lindane. Bulletin of Environmental Contamination and Toxicology 59:360-366.

Dewitt, J.B. and J.L. George. 1957. Pesticide wildlife review. U.S. Fish and Wildlife Service, USDI, Washington, D.C.

Donald, D.B., H. Block and J. Wood. 1997. Role of groundwater on lindane detections in surface water in western Canada. Environmental Toxicology and Chemistry 16(9):1867-1872.

Felthousen, R.W. 1977. Classification of granulated formulations. Internal EPA memo: Environmental Safety Section, 9/9/77, USEPA, pp. 1-20.

Harner T. 1997. Organochlorine contamination of the Canadian Arctic, and speculation on further trends, Int. J. Environ. And Poll. 8:51-73.

Harner, T, T.F. Bidleman, L.M.M Jantunen, and D. Mackay. 2001. Soil-air exchange model of pesticides in the United States cotton belt. Environ Toxi Chem 20:1612-1621.

Harner, T., H. Kylin, T.F. Bidleman, and W.M.J. Strachan. 1999. Removal of (-and (-hexachlorocyclohexane and enentiomers of (-hexachlocyclohexane in the eastern Arctic ocean. Environ Sci Technol. 33:1157-1164.

Hoffman, D.J. and W.C. Eastin. 1982. Effects of lindane, paraquat, toxaphene, and 2,4,5-trichlorophenoxyacetic acid on mallard embryo development. Archives of Environmental Contamination and Toxicology 11(2):79-86.

Hulth, L., R. Larsson, R. Carlsson, and J.E. Kihlstron. 1976. Convulsive action of small single oral doses of the insecticide lindane. Bulletin of Environmental Contamination and Toxicology 16:133-137.

Iwata, H., S. Tanabe, N. Sakai and R. Tatsukawa. 1993. Distribution of persistent organochlorines in the oceanic air and surface seawater and the role of ocean on their global transport and fate. Environmental Science and Technology 27:1080-1098.

Joy, R.M. 1982. Mode of action of lindane, dieldrin and related insecticides in the central nervous system. Neurobehavioral Toxicology and Teratology 4:813-823.

Lane, D.A., N.D. Johnson, M.J. Hanley, Schroeder W.H., and D.T. Ord . 1992. Gas- and particle -phase concentrations α-hexachlorocyclohexane and γ-hexachlorocyclohexane and hexachlorobenzene in Ontario air. Environ Sci Technol. 26:126-133.

Li, Y.F., T.F. Bidleman, L.A. Barrie, and L.L. McConnell. 1998. Global hexachlorocyclohexane use trends and their impact on the arctic atmospheric environment. Geophys Res Lett. 25:39-41.

Macek K.J., K.S. Buxton, S.K. Derr, J.W. Dean, and S. Sauter. 1976. Chronic toxicity of lindane to selected aquatic invertebrates and fishes. EPA-60013-76-047. U.S. Environmental Protection Agency, Washington, DC.

Mackey, D. 1991. Multimedia environmental models. The fugacity approach. Lewis Publication, Boca Raton, FL.

Mackey, D., W.Y. Shiu, K.C. Ma. 1992-1997. Illustrated handbook of physical-chemical properties and environmental fate for organic chemicals. Vol. I to V. Lewis Publication, Chelsea, MI

McCann, J.A., W. Teeters, D.J. Urban, and N. Cook. 1981. A short-term dietary toxicity test on small mammals. In Avian and Mammalian Wildlife Toxicology: Second Conference, ASTM STP, pp. 132-142.

Nagy, K.A. 1987. Field metabolic rate and food requirement scaling in mammals and birds. Ecology Monographs 57:111-128.

Norstrom, R.J., and D.C.G. Muir. 1994. Chlorinated hydrocarbon contaminants in arctic marine mammals. Sci Total Environ. 154:107-128.

Ockenden, W.A., E. Steinnes, C. Parker, and K.C. Jones. 1998. Observations on persistent organic pollutants in plants: implications of their use as passive air samplers and POP cycling. Environ Sci Technol. 33:3482-3488.

Oehme, M., J.-E. Haugen and M. Schlabach. 1995. Ambient levels of POPs in spring 1992 at Spitzbergan and the Norwegian mainland:comparison with 1984 results and quality control measures. Sci Total Environment 160/161:139-152.

Petit, F., P. Le Goff, J.P. Cravedi, Y. Valotaire, and F. Pakdel. 1997. Two complementary bioassays for screening the estrogenic potency of xenobiotics: recombinant yeast for trout estrogen receptor and trout hepatocyte cultures. Journal of Molecular Endocrinology 19(3):321-335.

Poissant, L. and J.F. Koprivnjak. 1996. Fate and atmospheric concentrations of a- and g-hexachlorocyclohexane in Quebec, Canada. Environ Sci Technol. 30:845-851.

Pompa, G., L. Fadini, F. Di-Lauro, and F. Caloni. 1994. Transfer of lindane and pentachlorobenzene from mother to newborn rabbits. Pharmacology and Toxicology 74:28-34.

Raizada, R.B., P. Misra, I. Saxena, K.K. Datta, and T.S. Dikshitt. 1980. Weak estrogenic activity of lindane in rats. Journal of Toxicology and Environmental Health 6:483-492.

Taylor E.J., S.J. Blockwell, S.J. Maund, and D. Pascoe. 1993. Effects of lindane on the life-cycle of a freshwater macroinvertebrate *Chironomous riparius Meigen* (Insecta:Diptera). Archives of Environmental Contaminants and Toxicology 24:145–150.

Ulman, E. 1972. Monograph of an insecticide. Schillinger Verlag, Federal Republic of Germany.

Uphouse, L. 1987. Decreased rodent sexual receptivity after lindane. Toxicology Letters 39:4-14.

USEPA. 1993. Wildlife exposure factors handbook (Volume I). EPA/600/R-93/187a.

Waite, D., N.P. Gurprasad and T. Thompson. 1998. Atmospheric studies of Hexachlorobenzene (HCB) and y-Hexachlorocyclohexane (lindane or y-HCH) in the prairies. EAD Seminar 10/22/98.

Waite, D., N.P. Gurprasad, J.F. Sproull, D.V. Quiring and M.W. Kotylak. (2001). Atmospheric movements of lindane from canola fields planted with treated seed. Journal of Environmental Quality 30:768-775.

Walker, K., D.A. Vallero and R.G. Lewis. 1999. Factors influencing the distribution of lindane and other hexachlorocyclohexanes in the environment. Environ Sci Technol 33, pp. 4373-4378.

Wania, F. and Mackay, D. 2000. A comparison of overall persistence values and atmospheric travel distances calculated by various multimedia fate models. WECC Report2/2000. WECC Wania Environmental Chemists Corp. Toronto, Canada.

Wania, F. and Mackay, D. 1999. The evolution of mass balance models of persistent organic pollutant fate in the environment. Environ Poll. 100:223-240.

Wania, F. and Mackay, D. 1996. Tracking the distribution of persistent organic pollutants. Environ Sci Technol. 30:390A-396A.

Whitehead, C.C., A.G. Downing, and R.J. Pettigrew. 1972. The effects of lindane on laying hens. Br. Poultry Science 13:293

Willet, K., E.M. Ulrich and R.A. Hites. 1998. Differential toxicity and environmental fates of hexachlorocyclohexane isomers. Environmental Science and Technology 32 (15): 2197-2207.

Whitmore, R.W., F.W. Immerman, D.E. Camann, A.E. Bond, R.G. Lewis and J.L. Schaum. 1994. Non-occupational exposures to pesticides for residents of two US cities. Archives of Environmental Contaminants and Toxicology 26:47-59.

World Health Organization (WHO). 1991. Lindane (Environmental Health Criteria 124). 208 pp.

Appendix I: Ecological Effects Data

Ecological toxicity studies required by the Agency for the registration/re-registration of a pesticide, and the rational behind these requirements, are listed in 40 CFR 158. The following studies submitted by the registrant were used to develop an ecological toxicity assessment for lindane.

Toxicity to Terrestrial Animals

Birds, Acute and Subacute

Avian Acute Oral Toxicity

Species	*% ai*	*LD50 (mg/kg)*	*Toxicity Category*	*Acc No. Author/Year*	*Study Classification*[1]
Bobwhite quail *(Colinus virginianus)*	95.5	122	Moderately toxic	00263944 Bio-life, 1986	Core
Red-winged BB *(Agelaius phoeniceus)*	Tech	75	Moderately toxic	00020560, Schafer, 1972	Supplemental
Starling *(Sturnus vulgaris)*	Tech	100	Moderately toxic	00020560, Schafer, 1972	Supplemental
House Sparrow *(Passer domesticus)*	Tech	56	Moderately toxic	00020560, Schafer, 1972	Supplemental
Common Grackle (*Quiscalus quisula)*	Tech	>100	Moderately toxic	00020560, Schafer, 1972	Supplemental
Mallard Duck *(Anas platyrhynchos)*	25	2000	practically non-toxic	00160000 Hudson et al, 1984	Supplemental

[1] Core (study satisfies guideline).

Since the LD50s using the technical grade range from 56 to 122 mg/kg, lindane is considered to be moderately toxic to avian species on an acute oral basis. The guideline (71-1) is fulfilled (ACC# 00263944).

Avian Subacute Dietary Toxicity

Species	*% ai*	*5-Day LC50 (ppm)*[1]	*Toxicity Category*	*Acc No. Author/Year*	*Study Classification*
Mallard duck *(Anas platyrhynchos)*	$\geq$95	>5000	prac. non- toxic	00022923 Hill et al, 1975	core
Northern bobwhite quail *(Colinus virginianus)*	$\geq$95	882	moderately toxic	00022923 Hill et al, 1975	core
Ring-necked pheasant (*Phasianus colchicus*)	$\geq$95	561	moderately toxic	00022923 Hill et al, 1975	core
Japanese quail (*Coturnix japonica*)	$\geq$95	425	highly toxic	00022923 Hill et al, 1975	supplemental

[1] Test organisms observed an additional three days while on untreated feed.

Since the LC50 falls in the range of 425 to >5000 ppm, lindane is considered to be highly to practically non-toxic to avian species on a subacute dietary basis. The guideline (71-2) is fulfilled. (ACC# 00022923).

In addition, the registrant submitted two 14-day free choice avian dietary toxicity studies (MRIDs 400561-03 and 400561-04). Results suggested that bobwhite quail and red-winged blackbirds in a laboratory environment were repelled by treated sorghum seed. When given a choice and even in a no-choice situation, these birds did not readily eat and were emaciated at study termination.

Birds, Chronic

Avian Reproduction

Species/ Study Duration	*% ai*	*NOAEC/LOAEC[1] (ppm)*	*LOAEC Endpoints*	*MRID No. Author/Year*	*Study Classification*
Northern bobwhite quail *(Colinus virginianus)*	99.8	80/320	egg production, survival, eggshell thickness and hatchling wt.	448122-01 Dreumel and Heijink, 1999	Core
Mallard duck *(Anas platyrhynchos)*	99.8	15/45	viable embryos, live 3wk embryos and normal hatchlings	448671-01 Dreumel and Heijink, 1999	Supplemental

1 NOAEC = No Observed Effect Concentration; LOAEC = Lowest Observed Effect Concentration, ND = Not Determined

The guideline (71-4) is not fulfilled (MRID 448122-01 and 448671-01). The avian reproduction study (Mallard duck) needs to be repeated. Although the submitted study (MRID 448671-01) was classified as being supplemental due to guideline deviations as well as the low hatching success in the control group, the study should be repeated to determine if 15 ppm is a valid NOAEL value. The NOAEL value of 15 ppm will be used in risk assessments until further data is provided.

Mammals, Acute and Chronic

In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. These toxicity values are reported below.

Mammalian Toxicity: Acute and Chronic

Species	*% ai*	*Test Type*	*Toxicity Value*	*Year*	*MRID/ Acc No.*
Laboratory rat *(Rattus norvegicus)*	technical	LD50	88 (males);91 (females); moderately toxic	Gaines 1969. Tox. & Appl. Pharm. 14:515-534	00049330
Laboratory rat *(Rattus norvegicus)*	99.5	2 Generation reproduction	NOAEL= 20 ppm LOAEL= 150 ppm	1991	422461-01

Insects

Nontarget Insect Acute Contact Toxicity

Species	*% ai*	*LD50 (μg/bee)*	*Toxicity Category*	*ACC No. Author/Year*	*Study Classification*
Honey bee *(Apis mellifera)*	technical	0.56	Highly toxic	00036935,1975	core
Honey bee *(Apis mellifera)*	technical	0.20	Highly toxic	05001991,1978	core

The results indicate that lindane is highly toxic to bees on an acute contact basis. The guideline (141-1) is fulfilled. (ACC# 00036935 and 05001991).

Terrestrial invertebrates

Nontarget Terrestrial Invertebrate Acute Toxicity

Species	*% ai*	*LC50 (ppb)*	*Toxicity Category*	*ACC No. Author/Year*	*Study Classification*
Sowbug (*Asellus brevicaudus*)	99	10.0	Moderately toxic	400946-02	Supplemental

The results indicate that lindane is moderately toxic to terrestrial invertebrates on an acute dietary basis. There are no guideline requirements for terrestrial invertebrates (MRID# 400946-02).

Toxicity to Aquatic Organisms

Freshwater Fish, Acute

Freshwater Fish Acute Toxicity

Species	*% ai*	*96-hour LC50 (ppb)*	*Toxicity Category*	*MRID/ Acc No.*	*Study Classification*
Goldfish (*Carassius auratus*)	99	131.0	Highly toxic	400946-02	Supplemental
Rainbow trout *(Oncorhynchus mykiss)*	99	18.0	Very highly toxic	400980-01	Core
Brown trout *(Salmo trutta)*	99	1.7	Very highly toxic	400946-02	Core
Bluegill sunfish *(Lepomis macrochirus)*	99	25.0	Very highly toxic	400980-01	Core
Black bullhead *(Ictalurus melas)*	99	64.0	Very highly toxic	400946-02	Core
Brown trout (*Salmo trutta*)	99	22.0	Very highly toxic	400980-01	Core

Freshwater Fish Acute Toxicity

Species	*% ai*	*96-hour LC50 (ppb)*	*Toxicity Category*	*MRID/ Acc No.*	*Study Classification*
Channel catfish *(Ictalurus punctatus)*	99	44.0	Very highly toxic	400946-02	Core
Yellow perch *(Perca flavescens)*	99	68.0	Very highly toxic	400946-02	Core
Fathead minnow (*Pimephales promelas*)	99	77.0	Very highly toxic	400980-01	Core
Fathead minnow (*Pimephales promelas*)	99	67.0	Very highly toxic	400980-01	Core
Lake trout (*Salvelinus namaycush*)	99	32.0	Very highly toxic	400946-02	Core
Lake trout (*Salvelinus namaycush*)	99	24.0	Very highly toxic	400980-01	Supplemental
Carp (*Cyprinus carpio)*	99	90.0	Very highly toxic	400946-02	Supplemental
Coho salmon (*Oncorhynchus* kisutch*)*	99	23.0	Very highly toxic	400946-02	Core
Green sunfish (*Lepomis cyanellus)*	99	70.0	Very highly toxic	400980-01	Core
Largemouth bass (*Micropterus salmoides)*	99	32.0	Very highly toxic	400946-02	Core

MRID 400946-02= Macek and McAllister. 1970. Insecticide susceptibility of some common fish family representatives. Trans. Amer. Fish Soc. 99:20-27.

Because the 96-hour LC50 for the technical grade material falls in the range of 1.7 to 131 ppb, lindane is considered to be highly to very highly toxic to freshwater fish on an acute basis. The guideline (72-1) is fulfilled (MRID/Acc# 400946-02 and 400980-01).

Freshwater Fish, Chronic

Freshwater Fish Early Life-Stage Toxicity Under Flow-through Conditions

Species	*% ai*	*NOAEC/LOAEC (ppb)*	*MATC[1] (ppb)*	*Endpoints Affected*	*MRID No.*	*Study Classification*
Rainbow trout *(Oncorhynchus mykiss)*	99.5	2.9/6.0	4.2	Larval wet wt.	444054-01 and 400561-05	Supplemental

[1] MATC = Maximum Allowed Toxic Concentration, defined as the geometric mean of the NOAEC and LOAEC.

This study was scientifically sound but did not fulfill guideline requirements. The study contained enough information that if repeated, would not add further information. The guideline (72-4) is fulfilled (MRID# 444054-01 and 400561-05). The data indicate that lindane significantly affected larval growth at concentrations equal to or greater than 6.0 ppb. In a memo dated 8/27/98, after review by the EFED Aquatic Biology Technical Team, it was concluded that the study produced a valid NOAEC and LOAEC even with the problems encountered during the course of this study, thus, even though the study was classified as being supplemental, the study does not need to be repeated.

Freshwater Invertebrates, Acute

Freshwater Invertebrate Acute Toxicity

Species	*% ai*	*48-hour LC50/ EC50 (ppb)*	*Toxicity Category*	*MRID/Acc No.*	*Study Classification*
Waterflea *(Daphnia pulex)*	99	460.0	Highly toxic	400946-02	Core
Scud (*Gammarus fasciatus*)	99	10.0 (96 hr)	Very highly toxic	400946-02	Supplemental
Scud (*Gammarus fasciatus*)	100	88.0 (96 hr)	Very highly toxic	400946-02	Supplemental
Stonefly (*Pteronarcys californica*)	99	1.0 (96 hr)	Very highly toxic	400980-01	Core
Stonefly (*Pteronarcys californica*)	99	4.5 (96 hr)	Very highly toxic	400980-01	Core
Waterflea *(Simocephalus serrulatus)*	99	520.0	Highly toxic	400946-02	Supplemental

Because the LC50/EC50 of the TGAI ranges from 1.0 to 520 ppb, lindane is considered to be very highly to highly toxic to aquatic invertebrates on an acute basis. The guideline (72-2) is fulfilled (MRID# 400946-02).

Freshwater Invertebrate, Chronic

Freshwater Aquatic Invertebrate Life-Cycle Toxicity

Species	% ai	21-day NOAEC/ LOAEC (ppb)	MATC[1] (ppb)	Endpoints Affected	MRID No.	Study Classification
Waterflea *(Daphnia magna)*	99.5	54/110	77	Reproduction	444054-02/ 400561-06	Supplemental

[1] Maximum Allowed Toxic Concentration, defined as the geometric mean of the NOAEC and LOAEC.

The data indicate that lindane significantly reduced reproduction at concentrations equal to or greater than 110 ppb. This study was scientifically sound but did not fulfill guideline (72-4) requirements (MRID# 444054-02/400561-06). The study contained enough information that if repeated, would not add further information.

Estuarine and Marine Fish, Acute

Estuarine/Marine Fish Acute Toxicity

Species	*% ai*	*96-hour LC50 (ppb)*	*Toxicity Category*	*MRID No.*	*Study Classification*
Pinfish (*Lagodon rhomboides*)	100	31.0	Very highly toxic	402284-01	Supplemental
Sheepshead minnow *(Cyprinodon variegatus)*	100	100.0	Very highly toxic	402284-01	Supplemental
Longnose killfish (*Fundulus similis*)	100	190.0 (48 hr)	Highly toxic	402284-01	Supplemental
Spot (*Leiostomus xanthurus*)	100	23.0 (48 hr)	Very highly toxic	402284-01	Supplemental
Striped mullet *(Mugil cephalus)*	100	23.0 (48 hr)	Very highly toxic	402284-01	Supplemental

Since the 48 and 96 hr LC50s range from 23.0 to 190.0 ppb, lindane is considered to be very highly toxic to highly toxic to estuarine/marine fish on an acute basis. The data above, taken together, fulfill the guideline (72-3a) requirements (MRID 402284-01).

Estuarine and Marine Fish, Chronic

No data were submitted.

Estuarine and Marine Invertebrates, Acute

Estuarine/Marine Invertebrate Acute Toxicity

Species	*% ai.*	*96-hour LC50/EC50 (ppb)*	*Toxicity Category*	*MRID/Acc No.*	*Study Classification*
Eastern oyster (spat) *(Crassostrea virginica)*	100	240	Highly toxic	402284-01	Core
Eastern oyster (Emb/Larval) *(Crassostrea virginica)*	99.5	2820 (48hr EC50)	Moderately toxic	00264036/ 443555-01	Supplemental
Brown shrimp *(Penaeus aztecus)*	100	0.22 (48 hr EC50)	Very highly toxic	402284-01	Supplemental
Mysid *(Mysidopsis bahia)*	100	6.3	Very highly toxic	402284-01	Supplemental
Grass shrimp *(Palaemonetes vulgaris)*	100	4.4	Very highly toxic	402284-01	Supplemental
Seed Shrimp (*Cypridopsis vidua*)	99	3.2 (48 hr LC50)	Very highly toxic	400946-02	Supplemental
Pink Shrimp (*Penaeus duorarum*)	100	0.077	Very highly toxic	402284-01	Supplemental

Because the LC50s range from 0.077 to 2820 ppb, the TGAI of lindane is considered very highly to moderately toxic to estuarine/marine invertebrates on an acute basis. The guideline (72-3b and 72-3c) is fulfilled (MRID/Acc#s 264036, 400946-02, and 402284-01).

Estuarine and Marine Invertebrate, Chronic

No data were submitted.

Toxicity to Plants

Currently, plant testing is not required for pesticides other than herbicides and fungicides except on a case-by-case basis (e.g., labeling bears phytotoxicity warnings, incident data or literature that demonstrates phytotoxicity). Because of the current use pattern (incorporated seed treatment), low application rate, lack of incident data on plants and no available literature suggesting phytotoxicity, no plant data are required.

Appendix II: Risk Assessment

A means of integrating the results of exposure and ecotoxicity data is called the quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic.

RQ = EXPOSURE/TOXICITY

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories: (1) **acute high** - potential for acute risk is high, regulatory action may be warranted in addition to restricted use classification (2) **acute restricted use** - the potential for acute risk is high, but this may be mitigated through restricted use classification (3) **acute endangered species** - the potential for acute risk to endangered species is high, regulatory action may be warranted, and (4) **chronic risk** - the potential for chronic risk is high, regulatory action may be warranted. Currently, EFED does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to mammalian or avian species.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from the results of required studies. Examples of ecotoxicity values derived from the results of short-term laboratory studies that assess acute effects are: (1) LC50 (fish and birds) (2) LD50 (birds and mammals) (3) EC50 (aquatic plants and aquatic invertebrates) and (4) EC25 (terrestrial plants). An example of a toxicity test effect level derived from the results of long-term laboratory studies that assess chronic effects is: (1) NOAEC (birds, fish and aquatic organisms).

Risk presumptions, along with the corresponding RQs and LOCs are tabulated below:

Risk Presumptions for Terrestrial Animals

Risk Presumption	RQ	LOC
Birds		
Acute High Risk	EEC[1]/LC50 or LD50/sq ft or LD50/day[3]	0.5
Acute Restricted Use	EEC/LC50 or LD50/sq ft or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sq ft or LD50/day	0.1
Chronic Risk	EEC/NOAEC	1
Wild Mammals		
Acute High Risk	EEC/LC50 or LD50/sq ft or LD50/day	0.5
Acute Restricted Use	EEC/LC50 or LD50/sq ft or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sq ft or LD50/day	0.1
Chronic Risk	EEC/NOAEC	1

[1] abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

[2] $\frac{mg/ft^2}{LD50 * wt. of bird}$ [3] $\frac{mg of toxicant consumed/day}{LD50 * wt. of bird}$

Risk Presumptions for Aquatic Animals

Risk Presumption	RQ	LOC
Acute High Risk	EEC[1]/LC50 or EC50	0.5
Acute Restricted Use	EEC/LC50 or EC50	0.1
Acute Endangered Species	EEC/LC50 or EC50	0.05
Chronic Risk	EEC/MATC or NOAEC	1

[1] EEC = (ppm or ppb) in water

Risk Presumptions for Plants

Risk Presumption	RQ	LOC
Terrestrial and Semi-Aquatic Plants		
Acute High Risk	EEC[1]/EC25	1
Acute Endangered Species	EEC/EC05 or NOAEC	1
Aquatic Plants		
Acute High Risk	EEC[2]/EC50	1
Acute Endangered Species	EEC/EC05 or NOAEC	1

[1] EEC = lbs ai/A
[2] EEC = (ppm/ppb) in water

Terrestrial Exposure Assessment

The terrestrial exposure assessment for lindane seed treatment use is based on the calculation of the amount of seeds that a bird must ingest to receive a lethal LD50 dose compared to the amount of seeds a bird could ingests (if the diet consisted of only lindane-treated seeds).

Other Factors Affecting Risk

Only two bird species are usually required to be tested–one waterfowl species and one upland gamebird species–under the Fish and Wildlife Data Requirements listed in CFR 158. There is a great deal of uncertainty associated with extrapolating from the acute oral and subacute dietary data from two species to the large numbers of bird species associated with agricultural areas. Field surveys indicate that a large variety of birds are associated with these areas, including a multitude of songbirds and many others. Waterfowl are also likely to be present in these regions. As the EFED ecological database indicates that songbirds tend to be more sensitive than the two required test species, using the maximum estimated environmental concentration to calculate risk helps to compensate for this uncertainty in the toxicity data. However, in this case, actual acute data are available for songbirds (Sparrow LD50=56 mg/kg and Red-winged blackbird LD50=75 mg/kg).

The lack or small number of reported incidents involving birds or mammals does not prove that animals are not dying from pesticide exposure. Finding dead animals in the field is difficult, even when experienced field biologists are searching treated fields. Reporting of incident data is still rather accidental, and only carefully designed field studies can confidently indicate the likelihood of field kill incidents occurring.

ECOLOGICAL INCIDENTS SUMMARY

The number of documented kills in the Ecological Incident Information System is believed to be but a very small fraction of total mortality caused by pesticides. Mortality incidents must be seen, reported, investigated, and have investigation reports submitted to EPA to have the potential for entry into the database. Incidents often are not seen, due to scavenger removal of carcasses, decay in the field, or simply because carcasses may be hard to see on many sites and/or few people are systematically looking. Poisoned birds may also move off-site to less conspicuous areas before dying. Incidents seen may not get reported to appropriate authorities capable of investigating the incident because the finder may not know of the importance of reporting incidents, may not know who to call, may not feel they have the time or desire to call, may hesitate to call because of their own involvement in the kill, or the call may be long-distance and discourage callers, for example. Incidents reported may not get investigated if resources are limited or may not get investigated thoroughly, with residue and ChE analyses, for example. Also, if kills are not reported and investigated promptly, there will be little chance of documenting the cause, since tissues and residues may deteriorate quickly. Reports of investigated incidents often do not get submitted to EPA, since reporting by states is voluntary and some investigators may believe that they don't have the resources to submit incident reports to EPA.

Incident reports submitted to EPA since approximately 1994 have been tracked by assignment of I-#s in an Incident Data System (IDS), microfiched, and then entered to a second database, the Ecological Incident Information System (EIIS). This second database has some 85 fields for potential data entry. An effort has also been made to enter information to EIIS on incident reports received prior to establishment of current databases. Although many of these have been added, the system is not yet a complete listing of all incident reports received by EPA. Incident reports are not received in a consistent format (e.g., states and various labs usually have their own formats), may involve multiple incidents involving multiple chemicals in one report, and may report on only part of a given incident investigation (e.g., residues). While some progress has been made in recent years, both in getting incident reports submitted and entered, there has never been the level of resources assigned to incidents that there has been to the tracking and review of laboratory toxicity studies, for example. This adds to the reasons cited above for why EPA believes the documented kills are but a fraction of total mortality caused by lindane and other highly toxic pesticides.

Incidents entered into EIIS are categorized into one of several certainty levels: highly probable, probable, possible, unlikely, or unrelated. In brief, "highly probable" incidents usually require carcass residues, substantial ChE inhibition in avian and/or mammalian species, and/or clear circumstances regarding the exposure. "Probable" incidents include those where residues were not available and/or circumstances were less clear than for "highly probable." "Possible" incidents include those where multiple chemicals may have been involved and it is not clear what the contribution was of a given chemical. The "unlikely" category is used, for example, where a given chemical is practically nontoxic to the category of organism killed and/or the chemical was tested for but not detected in samples. "Unrelated" incidents are those that have been confirmed to be not pesticide-related.

Incidents entered into the EIIS are also categorized as to use/misuse. Unless specifically confirmed by a state or federal agency to be misuse, or there was very clear misuse such as intentional baiting to kill wildlife, incidents would not typically be considered misuse. Data entry personnel often do not have a copy of the specific label used in a given application, and would not usually be able to detect a variety of label-specific violations, for example.

Incidents have been reported from the use of lindane and are on the EPA incident database. These incidents are listed in the table below:

Incident #	Date	State	Organism	Tissue analysis	Tissue/soil Concentration	Use Site	Certainty index
I002166-001	4/28/95	NC	Trout (100s)	Yes+	0.43-10.74 ppm in tissue 0.12-1.6 ppm in soil	Tree farm	Highly Probable (Accident)
B0000-204	5/1/83	SC	Mullet (100)	No	N/A	Ag area	Possible
I004632-033	4/29/93	CA	Trout (60)	No	N/A	N/R	Probable
B0000-244-01	8/7/71	MA	Fish (15,000)	No	N/A	Cranberries	Probable

+ = positive

Exposure and Risk to Nontarget Terrestrial Organisms

Birds: Acute

Granular products/Seed Treatment:
Birds may be exposed to granular pesticides and seed treatments by ingesting granules or seeds when foraging for food or grit. They also may be exposed by other routes, such as by walking on exposed granules or drinking water contaminated by granules or treated seeds. The assessment below bases acute exposure on the quantity of seeds that a bird could ingest in one day and that the bird eats only lindane-treated seeds. This approach defines a risk quotient (RQ) as

$$RQ = Dose/LD_{50}$$

where Dose = the amount of lindane that a bird could receive by ingesting treated-seeds in a 24-hour period per bird mass (dose units in mg/Kg). Risk is assumed to occur for any RQ value greater than0.5.

The dose that a bird could receive by eating treated seeds can be approximated from the estimated amount of food that a bird can eat in a day. The dose can be described as

$$Dose = (FI)(C)(T)/M_{bird}$$

where FI = the food ingestion rate [kg/day]

C = active ingredient concentration on seed (mg/kg)

T = relevant duration time for food consumption (assumed to be 1 day in this assessment) [day].

M_{bird} = mass (wet) of bird [kg].

The rate of food consumption (FI) of a bird can be estimated by the method of Nagy (1987; also see EPA, 1993). For passerines, the Nagy relationship is

$$FI = 0.141\ (M_{bird})^{0.850}$$

and for non-passerines the relationship is

$$FI = 0.054\ (M_{bird})^{0.751}$$

RQ results for this analysis are summarized in the table below. The results suggest that acute risk is highest for for birds eating seeds for broccoli, brussel sprouts, cabbage, and cauliflower. Small birds, which consume proportionally larger quantities of food with respect to their body weight, are at greater risk than larger birds. RQs exceeded 0.5 for the sparrow and the red-winged black bird under for all seed treatments. For the quail, RQ indicated risk only for the seeds with the highest application rate (broccoli, brussel sprouts, cabbage, and cauliflower).

Table Summary of RQ evaluation. RQs in bold indicate potential risk..

		Lindane Seed Conc (per label)		**Dose (mg ai consumed per day /kg bird)**			**RQ =Dose/LD_{50}**		
crop	example label #	lb ai/100 lb seed	mg ai/kg seed	sparrow (FI = 0.00613 kg/day)[a]	RWBB (FI = 0.0114 kg/day)[a]	quail (FI = 0.0148 kg/day)[a]	sparrow (LD_{50}=56 mg/kg)	RWBB (LD_{50}=75 mg/kg)	quail (LD_{50}=122 mg/kg)
barley	34704-658	0.0375	375	92.0	82.4	31.1	**1.64**	**1.10**	0.25
corn	71096-2	0.125	1250	307	275.	103.	**5.48**	**3.67**	**0.85**
oats	2935-0492	0.0313	313	76.6	68.7	25.9	**1.37**	**0.92**	0.21
rye	2935-0492	0.0328	328	80.4	72.1	27.2	**1.44**	**0.96**	0.22
sorghum	8660-53	0.0628	628	154.	138.	52.1	**2.75**	**1.84**	0.43
wheat	555-144	0.0426	426	104.	93.5	35.3	**1.87**	**1.25**	0.29

[a] Dose = seed concentration x food intake rate, where food intake rate (FI) is based on Nagy equation (see text), assuming the following typical bird weights: Sparrow wt = 25 g; Red winged BB wt = 52 g, Bobwhite quail wt = 178 g (Clench and Leberman. 1978).

Birds: Chronic

To determine chronic risk to birds, the concentration on the food item (seeds) was determined from the the label. Chronic RQ was calculated using the following equation: RQ = Concentration on seeds / NOAEC. Results are given in the table below and suggest a potential for chronic reproductive risk to avian species from the use of lindane-treated seed. Table summary of chronic RQ evaluation. RQs in bold indicate potential risk..

		Lindane Seed Conc (per label)		**RQ =Seed Conc./NOAEC**	
crop	example label #	lb ai/100 lb seed	mg ai/kg seed	mallard (NOAEC=15 mg/kg)	Quail (NOAEC = 80 mg/kg)
barley	34704-658	0.0375	375	**25**	**4.7**
corn	71096-2	0.125	1250	**83.3**	**15.6**
oats	2935-0492	0.0313	313	**20.8**	**3.9**
rye	2935-0492	0.0328	328	**21.9**	**4.1**
sorghum	8660-53	0.0628	628	**41.9**	**7.9**
wheat	555-144	0.0426	426	**28.4**	**5.3**

Mammals: Acute

Granular products/Seed Treatment:

Mammals may be exposed to granular pesticides ingesting granules or seeds when foraging for food or grit. They also may be exposed by other routes, such as by walking on exposed granules or drinking water contaminated by granules or treated seeds. The assessment was performed in a similar manner as for birds as given above. The Nagy relationship for the general case of all mammals is

$$FI = 0.0687\ (M_{mammals})^{0.822}$$

where $M_{mammals}$ is the mammal mass in kg. Results are summarized below. Since RQs above 0.5 indicate potential risk, the results indicate the possibility of acute risk to seed-eating mammals for all seed treatments, with smaller mammals being more vulnerable than larger mammals..

Table summary of RQ evaluation. RQs in bold indicate potential risk..

crop	example label #	Lindane Seed Conc (per label) lb ai/100 lb seed	mg ai/kg seed	Dose (mg ai consumed per day /kg mammal) 0.015 kg mammal (FI = 0.00218 kg/day)[a]	0.035 kg mammal (FI = 0.00437 kg/day)[a]	1 kg mammal (FI = 0.0687 kg/day)[a]	RQ =Dose/LD_{50} 0.015 kg mammal LD_{50}=88 mg/kg)b	0.035 kg mammal (LD_{50}=88 mg/kg)b	1 kg mammal (LD_{50}=88 mg/kg)b
barley	34704-658	0.0375	375	54	47	26	**0.62**	**0.53**	0.29
corn	71096-2	0.125	1250	181	156	86	**2.1**	**1.8**	**0.98**
oats	2935-0492	0.0313	313	45	39	21	**0.51**	0.44	0..24
rye	2935-0492	0.0328	328	47	41	23	**0.54**	0.46	0.26
sorghum	8660-53	0.0628	628	91	78	43	**1.0**	**0.89**	0.49
wheat	555-144	0.0426	426	62	53	29	**0.70**	**0.60**	0.33

[a] Dose = seed concentration x food intake rate, where food intake rate (FI) is based on Nagy equation (see text). Weights were chosen to represent typical small mammals.
b All LD_{50}s were based on the rat.

Mammals: Chronic

To determine chronic risk to mammals, the concentration on the food item (seeds) was determined from the the label. Chronic RQ was calculated using the following equation: RQ = Concentration on seeds / NOAEC. The NOAEC for the rat (20 mg/L) was used as an approximation for all mammals. Results are given in the table below and indicate a potential for chronic reproductive risk to mammalian species from the use of lindane-treated seed.

Table summary of chronic RQ evaluation. RQs in bold indicate potential risk..

crop	example label #	Lindane Seed Conc (per label) lb ai/100 lb seed	mg ai/kg seed	RQ =Seed Conc./NOAEC rat (NOAEC=20 mg/kg)
barley	34704-658	0.0375	375	**19**
corn	71096-2	0.125	1250	**63**
oats	2935-0492	0.0313	313	**16**
rye	2935-0492	0.0328	328	**16**
sorghum	8660-53	0.0628	628	**31**
wheat	555-144	0.0426	426	**21**

Insects

Currently, EFED does not assess risk to nontarget insects. Results of acceptable studies are used for recommending appropriate label precautions. As lindane is highly toxic (0.2 to 0.56 ug/bee) to honeybees, precautions in respect to spray drift to flowering plants should be followed. Since this is a seed treatment application, low risk is assumed to flying insects, however beneficial soil dwelling insects may be at risk.

Plants

No data was available for lindane to assess risk to terrestrial or aquatic plants.

Exposure and Risk to Nontarget Freshwater Aquatic Animals

EFED uses GENEEC to calculate Tier I EECs and assumed that 100% of the compound will disassociate from the seed surface. EECs are tabulated in **Appendix III.**

I. Freshwater Fish

Acute and chronic risk quotients are tabulated below.

Risk Quotients for Freshwater Fish Based On a bluegill LC50 of 1.7 ppb and a fathead minnow NOAEC of 2.9 ppb.

Site	LC50 (ppb)	NOAEC (ppb)	EEC Initial/Peak (ppb)	EEC 56-Day Ave. (ppb)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOAEC)
wheat	1.7	2.9	0.67	0.48	0.40	0.17

An analysis of the results indicate that restricted use and endangered species LOC's are exceeded for freshwater fish. No chronic LOC's are exceeded for freshwater fish.

ii. Freshwater Invertebrates

The acute and chronic risk quotients are tabulated below.

Risk Quotients for Freshwater Invertebrates Based On a daphnia EC50/LC50 of 10.0 ppb and a daphnia NOAEC of 54 ppb.

Site	LC50 (ppb)	21 day NOAEC (ppb)	EEC Initial/Peak (ppb)	EEC 21-Day Average	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOAEC)
wheat	10	54	0.67	0.48	**0.07**	0.01

An analysis of the results indicate that the acute endangered species LOC is exceeded for freshwater invertebrates. No chronic LOC's are exceeded for freshwater invertebrates.

iii. Estuarine and Marine Fish

The acute and chronic risk quotients are tabulated below.

Risk Quotients for estuarine/marine fish based on a striped mullet LC50 of 23 ppb. No data was submitted to assess chronic risk to estuarine/marine fish.

Site	LC50 (ppb)	NOAEC (ppb)	EEC Initial/ Peak (ppb)	EEC 56-Day Average	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOAEC)
wheat	23	N/A	0.67	0.48	0.03	N/A

An analysis of the results indicate that no acute LOCs were exceeded for estuarine/marine fish.

iv. Estuarine and Marine Invertebrates

Risk Quotients for Estuarine/Marine Aquatic Invertebrates Based on a pink shrimp LC50/EC50 of 0.077 ppb. No data was submitted to assess chronic risk to estuarine/marine invertebrates.

Site/ Application Method	LC50 (ppb)	NOAEC/ (ppb)	EEC Initial/ Peak	EEC 21-Day Average	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOAEC)
wheat	0.077	N/A	0.67	0.48	8.70	N/A

An analysis of the results indicate that high acute, restricted use and endangered species LOC's were exceeded for estuarine/marine invertebrates. Chronic risk to estuarine/marine invertebrates could not be assessed due to a lack of toxicity data.

Appendix III:

GENEEC OUTPUT (FOR SURFACE WATER ASSESSMENT)

```
RUN No.  1 FOR lindane     INPUT VALUES
--------------------------------------------------------------------
RATE (#/AC)  APPLICATIONS  SOIL  SOLUBILITY  % SPRAY INCORP
 ONE(MULT)   NO.-INTERVAL  KOC   (PPM)    DRIFT DEPTH(IN)
--------------------------------------------------------------------
.051(  .051)  1  1    942.0   7.0     .0   1.0


FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)
--------------------------------------------------------------------
METABOLIC DAYS UNTIL HYDROLYSIS  PHOTOLYSIS  METABOLIC COMBINED
(FIELD)  RAIN/RUNOFF  (POND)   (POND-EFF)  (POND)   (POND)
--------------------------------------------------------------------
980.00    2      N/A   .00-   .00  .00  *******


GENERIC EECs (IN PPT)
--------------------------------------------------------
  PEAK   AVERAGE 4   AVERAGE 21  AVERAGE 56
  GEEC   DAY GEEC    DAY GEEC   DAY GEEC
--------------------------------------------------------
 671.90   655.43    579.19    483.61
```

SCIGROW OUTPUT (FOR GROUND WATER ASSESSMENT

```
RUN No.  1 FOR lindane       INPUT VALUES
--------------------------------------------------------------------
APPL (#/AC) APPL. URATE  SOIL  SOIL AEROBIC
RATE     NO. (#/AC/YR) KOC  METABOLISM (DAYS)
--------------------------------------------------------------------
  .051   1    .051   1367.0   980.0


GROUND-WATER SCREENING CONCENTRATIONS IN PPB
--------------------------------------------------------
         .010993
--------------------------------------------------------
A=  975.000 B= 1372.000 C=   2.989 D=   3.137 RILP=   2.578
F=   -.668 G=   .215 URATE=   .051 GWSC=     .010993
```

Ecological Effects
Data Requirements for:
LINDANE

Guideline #	Data Requirement	Is Data Requirement Satisfied?	MRID #'s	Study Classification
71-1	Avian Oral LD_{50}	Yes	00263944	Core
71-2	2 Avian Dietary LC_{50}'s	Yes	00022923	Core
71-4	Avian Reproduction	Yes No	448122-01 448671-01	Core Supplemental
72-1	2 Freshwater Fish LC_{50}	Yes Yes	400946-02 400980-01	Core Core
72-2	Freshwater Invertebrate Acute LC_{50}	Yes	400946-02	Core
72-3(a)	Estuarine/Marine Fish LC_{50}	Yes in combination	402284-01 (5 studies)	Supplemental
72-3(b)	Estuarine/Marine Mollusk EC_{50}	Yes	402284-01	Core
72-3(c)	Estuarine/Marine Shrimp EC_{50}	Yes in combination	402284-01 400946-02 (5 studies)	Supplemental Supplemental
72-4(a)	Freshwater Fish Early Life-Stage	Yes	444054-01 400561-05	Supplemental
72-4(b)	Estuarine Fish Early Life-Stage	Required		
72-4(c)	Estuarine Invertebrate Life-Cycle	Required		
72-4(d)	Freshwater Invertebrate Life-Cycle	Yes	444054-02 400561-06	Supplemental
72-5	Freshwater Fish Full Life-Cycle	Reserved		
81-1	Acute Mammalian LD_{50}	Yes	00049330	Core
83-5	2-generation mammalian reproduction	Yes	422461-01	Core
122-1(a)	Seed Germ./Seedling Emergence	Required		
122-1(b)	Vegetative Vigor	Required		
122-2	Aquatic Plant Growth	Required		
123-1(a)	Seed Germ./Seedling Emergence	Reserved		
123-1(b)	Vegetative Vigor	Reserved		
123-2	Aquatic Plant Growth	Reserved		
144-1	Honey Bee Acute Contact LD_{50}	Yes Yes	00036935 05001991	Core Core
Non-guideline	14-day free choice avian dietary toxicity test (aversion)	Not required	400561-03; 400561-04	Supplemental

Environmental Fate
Data Requirements for:
LINDANE

Guideline #	Data Requirement	Is Data Requirement Satisfied?	MRID #'s	Study Classification
161-1	Hydrolysis	Yes	00161630	Accepted
161-2	Photodegradation in Water	Yes	00164547 00164545 44793101	Supplemental Supplemental Acceptable
161-3	Photodegradation on Soil	Yes	44440605	Acceptable
161-4	Photodegradation in Air	N/A	N/A	N/A
162-1	Aerobic Soil Metabolism	Yes	40622501	Accepted
162-2	Anaerobic Soil Metabolism	No	44867102	Unacceptable
162-3	Anaerobic Aquatic Metabolism	N/A	N/A	N/A
162-4	Aerobic Aquatic Metabolism	N/A	N/A	N/A
163-1	Leaching-Adsorption/Desorption	yes	00164346 00164538 40067301	Accepted
163-2	Laboratory Volatility	No	44445301	Unacceptable[1]
163-3	Field Volatility	N/A	N/A	N/A
164-1	Terrestrial Field Dissipation	Yes	44867103	Supplemental
165-4	Accumulation in Fish/ Bioconcentration	Yes	40056101 40056102	Accepted

1. Sorption properties of lindane and the soil were not reported. Additional volatility study submissions are not needed to assess this chemicals fate, since lindane's volatility is well documented in open literature.