Addendum to the 2002 Lindane Reregistration Eligibility Decision (RED)

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Case No. 315

Approved by:

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Date

I. Introduction

This document serves as an addendum to the July 2002 Lindane Reregistration Eligibility Decision document (2002 RED). This document addresses whether pesticide products containing the active ingredient lindane are eligible for reregistration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and whether existing tolerances for residues of lindane in food and feed are safe under the provisions of the Federal Food, Drug and Cosmetic Act (FFDCA).

This RED Addendum reflects the Agency's conclusions on the remaining lindane seed treatment uses in light of the information gathered since the 2002 RED. The seed treatment use is a source of human exposure to lindane, and it will add to the reservoir of lindane already present in the environment. EPA believes that dietary exposure to lindane from the seed treatment use may pose a risk to nursing infants who consume breast milk contaminated with lindane. EPA, however, is not able to quantify that risk at this time or determine whether current exposures result in any harm. Lindane's persistent and bioaccumulative nature is also of concern to the Agency. In addition, the Agency's updated analysis of the seed treatment use indicates very minor benefits to growers. In light of these factors, EPA now concludes that the six lindane seed treatment uses are ineligible for reregistration.

As of July 27, 2006, the Agency had received requests from all lindane technical and end-use product registrants to voluntarily cancel all lindane product registrations. Once the cancellation process is complete, EPA will propose to revoke the existing lindane fat tolerances pursuant to section 408(l)(2) of the Food Quality Protection Act (FQPA).

II. Background

In July 2002, EPA issued a RED for lindane that captured the Agency's then-current analysis of the registered uses of lindane as well as the existing tolerances. The 2002 RED concluded in part that existing tolerances for lindane were no longer needed as the uses associated with those tolerances had all been cancelled, or voluntary cancellation had been requested. The 2002 RED also concluded that the current uses of lindane for seed treatment would be eligible for reregistration under FIFRA provided several conditions were met. First, EPA determined that a number of changes to the terms and conditions of registration of the seed treatment products were necessary to prevent "unreasonable adverse effects on the environment." These changes are specified in the 2002 RED. Second, EPA determined that the use of lindane for seed treatment was likely to result in residues in raw agricultural commodities derived from plants grown from seeds treated with lindane. Therefore, new tolerances for the existing seed treatment uses were needed. Third, EPA identified additional data that were needed to characterize lindane metabolites in order to establish appropriate tolerances for lindane. In summary, EPA determined that the currently registered lindane seed treatment products would be eligible for reregistration if: 1) the registrants amended product labels to reflect the terms and conditions specified in the 2002 RED; 2) the registrants provided the metabolism data set forth in the 2002 RED; and 3) EPA was able to establish all required tolerances for residues of lindane in food.

Following the 2002 RED, the registrants submitted revised labels for all end-use products reflecting the risk mitigation measures specified in the 2002 RED. The Agency has reviewed and approved these labels. The registrants also submitted the required product and residue chemistry data, and the Agency reviewed these data and found them to be acceptable. To satisfy generic data requirements, Crompton (now Chemtura) submitted a required seed leaching study; a nature of the residue study, also known as a plant metabolism study, originally required in the 1985 Lindane Registration Standard Data Call-In (DCI); and an anaerobic aquatic metabolism study to satisfy an anaerobic soil metabolism data requirement also originally required under the 1985 Lindane Reregistration Standard DCI.

The Agency has taken a number of actions with respect to lindane since the 2002 RED. EPA received and reviewed a number of comments on the 2002 RED. EPA also revoked all current tolerances of lindane, except for fat tolerances, because the associated uses had been cancelled (70 FR 55282, Sept. 21, 2005). EPA did not revoke the fat tolerances because residue data suggested that livestock that were fed lindane-treated seeds would bear residues of lindane in meat commodities (i.e., fat). In February 2006, EPA prepared and released for public comment a document titled "Assessment of Lindane and Other Hexachlorocyclohexane Isomers" (2006 Assessment). This assessment provided information on potential health effects of lindane as well as its associated isomers.

III. Lindane's toxicity

The Agency's conclusions regarding effects of lindane in humans are largely based on studies in animals. Lindane primarily affects the nervous system. In acute, subchronic, and developmental neurotoxicity studies and chronic toxicity/oncogenicity studies, lindane was found to cause neurotoxic effects. Lindane also appears to cause renal and hepatic toxicity. In addition, there is evidence that lindane may act as an endocrine disruptor. Moreover, infants and children are expected to be more susceptible to the potential adverse effects of lindane than adults. In both a developmental neurotoxicity study and a 2-generation reproduction study, offspring demonstrated increased susceptibility to lindane's adverse effects. The 2002 RED and its supporting documents provide a detailed summary of lindane's toxicity.

IV. Sources of Lindane Exposure

A. Seed Treatment Use

The seed treatment use is a source of human exposure to lindane. There are several possible routes by which this exposure may occur. First, individuals may be exposed to lindane residues when eating plants grown from treated seeds. Residue data demonstrate that the aerial portion of a growing crop will uptake lindane residues present on treated seed (2002 RED, pp. 44-45). Second, consumption of meat is a potential source of lindane exposure. It is possible that livestock feed may be derived from grain grown from lindane-treated seed. EPA expects that livestock fed lindane-treated seed will bear residues of lindane in meat commodities (i.e., fat). USDA annual pesticide monitoring data show one detection of lindane residues in milk in 1998, one detection in the fat of poultry in 2000, and three detections (one from imported cows) in the fat of livestock (e.g., cows) in 2001 and 2002 (USDA Pesticide Data Program). In addition, the USDA's Food Safety and Inspection Service (FSIS) detected lindane in the fat of domestic and imported meat products in 1998, 1999 and 2000. For example, in 2000, four imported samples (three calf and one pig) and 16 domestic samples (cow, sheep, turkey, goat, veal) contained lindane. EPA acknowledges these detections cannot be attributed solely to treated seeds.

Third, treated seeds are a potential source of lindane in drinking water. Modeling also shows that lindane concentrations in both surface water and groundwater may reach environmentally significant levels (greater than the Maximum Contaminant Level [MCL] of 0.2 ppb), even when lindane is restricted to seed-treatment uses only. Even considering lindane's very low use rate for seed treatment, lindane may be expected to reach water resources at environmentally significant levels because of its mobility and high persistence. Based on a screening-level assessment, lindane from seed treatment may reach water resources at levels above the MCL of 0.02 ppb (U.S. EPA 2002 EFED RED Chapter at p. 3). This conclusion is based solely on lindane's use as a seed treatment and does not consider past uses of lindane (U.S. EPA 2002 EFED RED Chapter). Water monitoring data, to be discussed in Section IV.B.i. of this addendum, show that residues of lindane are present in surface water in the United States.

Exposure to lindane may also occur through volatilization from treated seeds. Field studies from Canada report an increase in lindane in the atmosphere in areas where lindane-treated seeds are used (2006 Assessment at p. 20). Due to lindane's persistence and mobility, these lindane releases may contribute to human exposure via any route.

B. Other Sources of Exposure

In addition to the seed treatment use, U.S. populations may be currently exposed to lindane from several other sources.

i. Past/historical uses

Lindane was first registered in the U.S. in the 1940s. Since that time, lindane has been registered for use on a wide variety of fruit and vegetable crops (including seed treatment), ornamental plants, tobacco, greenhouse vegetables and ornamentals, forests, Christmas tree plantations, log dips, livestock dips, household sprays, domestic outdoor and indoor use by homeowners (including dog dips, household sprays, and shelf paper), commercial food or feed storage areas and containers, wood or wooden structures sites, and human skin/clothing (a military use). In 1977, EPA initiated a Rebuttable Presumption Against Registration (RPAR) review of lindane, now called a Special

Review, that resulted in the cancellation of lindane uses in smoke fumigation devices for indoor domestic use. Following the RPAR, EPA issued a Registration Standard for Lindane in September 1985 that included a requirement for the submission of additional data to support lindane registration and to address exposure concerns. Between 1993 and 1998, long-range transport and environmental concerns about lindane increased; in response to these concerns, lindane registrants voluntarily cancelled all registered uses of lindane in 1998 and 1999, except for seed treatment uses on 19 agricultural crops and a dog mange treatment. The dog mange use was voluntarily cancelled in December 2001. Finally, in 2001 and 2002, the registrants voluntarily cancelled all but the following six lindane seed treatment uses: barley, corn, oats, rye, sorghum, and wheat. As of 2002, the only remaining agricultural uses for lindane were the six seed treatment uses that are being addressed in this document.

Any of these past uses potentially result in continued exposures to lindane today due to its persistent, bioaccumulative nature and potential for long-range transport. Indeed, as shown below, lindane has been detected in a variety of foods as well as surface waters. EPA cannot link these residue detections with particular uses of lindane.

The Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN)'s Total Diet Study summary of residues from 1991 to 2001 indicates that many food items contain residues of lindane (http://www.cfsan.fda.gov/~acrobat/tds1byps.pdf). The summary shows almost 50 types of food items in which lindane has been detected at least once between 1991 and 2001. The food items with the most detects were plain milk chocolate candy bars, yellow mustard, and commercial chocolate chip cookies. In addition, FDA's pesticide residue monitoring program indicates that, between 1993 and 2003, lindane is consistently detected in 2% to 3% of foods tested (http://www.cfsan.fda.gov/~dms/pesrpts.html).

The United States Geological Survey (USGS) National Water Quality Assessment program (NAWQA) database includes 373 surface-water samples in which lindane was detected. Four of these samples had lindane concentrations of 0.1 ppb or greater, with a maximum concentration of 0.219 ppb detected in a sample from the agricultural "Harding Drain" in Stanislaus County, California in February 2000. The samples were collected between 1992 and 2004, with 199 of the samples with detections collected in 1999 or later. The USGS classified 115 of the samples with detections as having come from water bodies in areas of agricultural land use, 101 from water bodies in mixed land-use areas, and 49 from water bodies in urban land-use areas. Eight samples were classified as having been collected from areas classified as "other."

ii. Imported meats

Lindane may currently be used in other countries to directly treat livestock against external parasites. Because U.S. tolerances currently exist for lindane in livestock fat, livestock or meat products that have been treated with lindane and containing lindane residues can be legally imported into the United States. Approximately 8 percent of red meat and 5 percent of animal fat consumed by the U.S. population is imported, and red meat is among the fastest growing U.S. imports (Jerardo 2003).

iii. Subsistence diets

Indigenous populations are exposed to lindane via consumption of subsistence diets. As noted in the 2006 Assessment, indigenous populations rely heavily on animal fats and protein in their subsistence diets. For example, EPA reported high harvest amounts of walrus, seal and whale for Alaska communities. Residues of lindane and other HCH isomers are present in these animals even though they are not in areas where lindane is manufactured or used. As explained in Section V of this addendum, lindane and other HCH isomers are mobile once released into the environment and can be transported long distances. Lindane and other HCH isomers tend to accumulate in colder climates, such as the arctic, and concentrate in the food chain. Thus any manufacture or use of lindane, or other HCH isomers, is a potential source of exposure to indigenous populations (2006 Assessment at pp. 26, 44-45).

iv. Pharmaceutical use

Lindane is also used as a treatment for lice and scabies. Individuals who use lindane pharmaceutical products will be exposed to lindane in amounts that will exceed exposure from the seed treatment use. The pharmaceutical use, though, is also a source of exposure to the general population. EPA believes that lindane from the pharmaceutical use may reach drinking water via "down the drain" release; that is, lindane enters drinking water when individuals using the pharmaceutical products wash off their hands/bodies. Based on information from Los Angeles County, California, EPA estimated average effluent concentrations of lindane discharged from publicly owned treatment works to be 0.03 ppb (2002 RED at p. 23). In fact, California banned the pharmaceutical uses of lindane due to concerns about water contamination and acute neurotoxicity concerns from direct application. Although FDA has recommended that lindane be prescribed as a second line treatment since 1995, these products remain a source of exposure.

v. Use in foreign countries

As far as EPA is aware, lindane is still being used in a few other countries. For example, EPA believes that lindane is still used in India. In addition, lindane is registered for use in Bolivia, Burkina Faso, Cameroon, Cape Verde, Chad, Kenya, Malaysia, Mali, Mauritania, Mexico,[1] Papua New Guinea, Syria, Tanzania, Togo, and Zimbabwe (Lindane NARAP Annex B). Because of lindane's persistence and potential for long range transport, EPA believes that releases of lindane in these other countries could result in exposures in the United States. Bailey et al. (2000) demonstrated that organochlorine pesticides including lindane can travel from eastern Asia to North America in as little as five days.

[1] Mexico, however, has stated that it intends to phase out all uses of lindane.

V. Environmental Fate

Lindane is a persistent organochlorine compound that is widely distributed in the environment with a long half-life in various environmental compartments. The presence of lindane and other HCH isomers (namely α- and β-HCH) in the environment and human and wildlife tissues, as well as the environmental fate and exposure routes of lindane, have been documented in detail in scientific literature as well as in the Agency's 2002 RED and 2006 Assessment. The fate characteristics of lindane, including persistence, bioaccumulative potential, and potential for long-range transport, are the key elements to understanding the extent and scope of exposures associated with the use of lindane. Lindane's toxicity in association with these fate characteristics results in risks of concern for the Agency. Below is a summary of these concerns.

Based on the submitted environmental fate data, physical and chemical properties, lindane is a persistent, moderately mobile, and relatively volatile compound. Selected physical-chemical properties of lindane are summarized in Table 1. Lindane can migrate over a long distance through various environmental media such as air, water and sediment. Due to the persistent nature and long-range transport, lindane has been detected in air, surface water, groundwater, sediment, soil, ice, snowpack, fish, wildlife and humans. The source of these lindane detections is unclear; but it may be the result of a combination of past widespread use in the U.S. and other countries, lindane's extreme persistence, current seed treatment use, current use in foreign countries, and use as a pharmaceutical.

Table 1. Fate and Physical-Chemical Properties of Lindane

Parameter	**Value**
Molecular Weight	290.82
Solubility (25 ^{o}C)	7 mg/L
Vapor Pressure (25 ^{o}C)	9.4 x 10-6 torr
Henry's Law Constant (atm-m^3/mol)	3.5 x 10^{-6} @ 25°C
Hydrolysis Half-life (pH 5, 7, 9; 25 ^{o}C)	Stable, stable, 43-53 days
Aqueous Photolysis Half-lives (pH 5)	Stable
Soil Photolysis Half-life	Stable
Aerobic Soil Metabolism Half-lives	980 days
Organic Carbon Partition Coefficients (K_{oc})	1368 mL/g (mean of 4 soils)
Octanol – Water Partition Coefficient (log K_{ow})	3.78
Bioconcentration Factors (BCF)	In fish bluegill sunfish, 780 (fillet), 2500 (viscera), 1400 (whole fish tissues)

A. Persistence

Once released into the environment, the primary process by which lindane dissipates is volatilization into the air, although abiotic and biotic degradation as well as uptake by crops can also occur. However, lindane is resistant to abiotic processes like photolysis and hydrolysis (except at high pH), and degrades very slowly by microbial actions. The hydrolysis half-lives of lindane were reported to be stable at pH 5 and pH 7, and ≥ 43 days at pH 9 (U.S. EPA 2002 EFED RED Chapter). Since lindane does not contain chromophores that absorb light >290 nm, direct photolysis is not expected to occur. In an aerobic soil metabolism study, lindane degraded very slowly, with a calculated half-life of 980 days (U.S. EPA 2002 EFED RED Chapter). Since most degradation pathways occur slowly, the presence of degradates is generally low. Possible lindane degradates could include pentachlorocyclohexene, 1,2,4,-trichlorobenzene, and 1,2,3-trichlorobenzene (U.S. EPA 2002 EFED RED Chapter).

Additional evidence of its persistence is the fact that lindane has been found at numerous hazardous waste sites which have been abandoned. Of the 1,662 current or former industrial sites on the National Priorities List, lindane was found in 189 (ATSDR 1997 at p. 1).

B. Bioaccumulation and Bioconcentration

Lindane can bio-accumulate easily in the food chain due to its high lipid solubility and can bioconcentrate rapidly in microorganisms, invertebrates, fish, birds and mammals (WHO 1991). The octanol-water partition coefficient (log Kow = 3.78, Table 1) for lindane indicates that it has the potential to bioaccumulate. Lindane has potential to enrich in lipid-containing biological compartments. However, lindane is a multimedia chemical, existing and exchanging among different compartments of the environment such as the atmosphere, surface water, soil and sediment. In addition, temperature, humidity, and other environmental properties may have significant influence on environmental degradation rates. These properties likely affect the presence of lindane in the environment as well as the variability in the bioaccumulation, bioconcentration and biomagnification in the various biological compartments. Differences in accumulation are also likely due to different modes of uptake, metabolism and sources of contamination.

The estimated bio-concentration factors (BCF) of lindane were 780x in fillet, 2500x in viscera and 1400x in whole fish (U.S. EPA 2002 EFED RED Chapter). Although lindane may bioconcentrate rapidly, most data suggest that bio-transformation, depuration and elimination are relatively rapid once exposure is eliminated. After 14 days of depuration, lindane levels were reduced by 96% in fillet, 95% in viscera, and 85% in whole fish.

C. Transport and Mobility

Lindane has often been detected in ambient air, precipitation, and surface water throughout North America, and it has also been detected in areas of non-use (e.g., the Arctic), indicating long-range transport of lindane occurs. The source of these lindane detections is unclear, but may be the result of a combination of manufacture (i.e., release during manufacture, disposal of HCH isomers), past widespread use in the U.S. and other countries, its extreme persistence, current seed treatment use, current use in foreign countries, and the pharmaceutical use of lindane. Once released into the environment, lindane can partition into various environmental media. Lindane present in soil can leach to groundwater, sorb to soil particulates and transport to surface water via runoff, or volatilize to the atmosphere. However, the Henry's law constant (Table 1) of lindane suggests that volatilization is the most important route of dissipation from water and moist soils followed by aerial long-range transport. Adsorption of HCH isomers to soil and sediments is generally a preferential partitioning process after volatilization. Leaching of HCH isomers through soil is governed by their water solubility and their propensity to bind to soil. The calculated Koc of lindane ranges from 942 to 1798 mL/g, with a mean of 1368 mL/g for four soils tested (U.S. EPA 2002 EFED RED Chapter). These data suggest that lindane has low leaching potential. Data also indicate that lindane is expected to adsorb to suspended solids and sediment in water. Based on the results of a number of laboratory soil column leaching studies that used soils of both high and low organic carbon content as well as municipal refuse, lindane has low subsurface mobility in soils (Melancon et al. 1986, Reinhart et al. 1991).

D. Volatility and Long-Range Transport

The behavior of lindane in the environment is complex because it is a multimedia chemical, existing and exchanging among different compartments of the environment such as the atmosphere, surface water, soil and sediment. Volatilization from soil and surface waters is a major dissipation route for lindane. The Henry's law constant for lindane suggests that it will volatilize from moist soil and surface water 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 Bidleman 2004). Brubaker and Hites (1998) measured the gas phase kinetics of the hydroxyl radical with lindane, and reported that it has long atmospheric half-lives in air and, therefore, can be transported long distance.

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 as cited in U.S. EPA 2002 EFED RED Chapter at pp 9-10). 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). The researchers concluded that the atmospheric concentration of lindane in northwest Alabama may be 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. Waite 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. The study also estimated that a range of 66.4 to 188.8 tons of atmospheric load of lindane 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 lindane 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 (U.S. EPA 2002 EFED RED Chapter at pp. 8-9).

Recently, seasonal air concentrations of lindane and other HCH isomers were monitored using Passive Air Samplers (PAS) along an urban to rural transect in Toronto, Canada (Motelay-Massei et al. 2005). The air concentrations of lindane were 159 pg/M^3 to 1020 pg/M^3 in the rural sites during the spring-summer monitoring period. A similar trend of air concentrations of lindane was also observed by Hoff et al. (1992) in Ontario, Canada. Both studies concluded that the continuing use of lindane during spring is likely associated with higher concentration of lindane in the air samples. Analysis of 1990 to 2001 data from the Integrated Atmospheric Deposition Network (IADN) also confirmed that annual agricultural application was a key variable in explaining the annual cycle of atmospheric lindane concentrations (Buehler et al. 2004). Jianmin et al. (2003) modeled lindane transport and deposition to the Great Lakes from usage areas in the Canada prairies and corn-belt regions of southern Ontario and Quebec. Results showed that lindane transport to the Great Lakes during spring-summer came mainly from application sites in the prairies, with minor contribution from the corn-belt. They compared the modeled concentration with the monitoring data of the IADN sites, which were within 50-134% of those measured during summer, 16-51% in fall and 3-20% in winter.

E. Surface Water, Sediments and Groundwater

Lindane is moderately mobile and can migrate over a long distance through various environmental media like water and sediment. Adsorption of lindane to soil and sediments is generally a preferential partitioning process after volatilization. The calculated Koc of lindane ranges from 942 to 1798 mL/g, with a mean of 1368 mL/g for four soils tested (U.S. EPA 2002 EFED RED Chapter). These data suggest that lindane has low leaching potential. Data also indicate that lindane is expected to adsorb to suspended solids and sediment in water. Lindane reaches water resources via surface runoff and through rain and snow deposition (ATSDR 1997 at p. 190 citing Tanabe et al. 1982; Wheatley and Hardman 1965). "For example, Lake Ontario received <2 kg/year of γ-HCH because of suspended sediment loading from the Niagara River between 1979 and 1981" (ATSDR 1997 at p. 190 citing Kuntz and Warry 1983). Studies also show that the

Great Lakes received 3.7 to 15.9 metric tons/year of lindane through atmospheric deposition (ATSDR 1997 at p. 190 citing Eisenreich et al. 1981). Lindane has also been detected in stormwater runoff in Denver, Colorado and Washington, D.C. (0.052–0.1 μg/L) (ATSDR 1997 at p. 190 citing Cole et al. 1984).

VI. Dietary Risk

A. Presence of Lindane in Breast Milk

Although there currently are no programs in the United States for monitoring lindane levels in human breast milk, EPA believes that lindane is present in the breast milk of at least some nursing mothers in the United States. In general, lindane is very persistent and highly soluble in fat or fatty tissue. Therefore, it has the potential to bio-accumulate in the food chain and bioconcentrate in microorganisms, invertebrates, fish, birds, and mammals. In practical terms, this means that when women are exposed to lindane through food, water, or the atmosphere, they will accumulate lindane residues in their fatty tissue, including breast milk and breast milk fat, and that these lindane residues will remain there for an undetermined amount of time.[2] Thus, to the extent women in the United States are exposed to lindane, EPA believes that that lindane likely will accumulate in their breast milk or breast milk fat.

Moreover, in the 1970s and 1980s, lindane was detected in breast milk in women in Binghamton, New York; Saint Louis, Missouri; several places in Mississippi, and in Philadelphia, Pennsylvania. Lindane also has been detected in breast milk of women in Argentina, Australia, Austria, Belgium, Bulgaria, Canada, the former Czechoslovakia, Denmark, the former Federal Republic of Germany (FRG), Greece, Finland, France, Hungary, India, Iran, Iraq, Ireland, Israel, Italy, Japan, Luxembourg, Mexico, Netherlands, Nigeria, Norway, Poland, Rwanda, Spain, Sweden, Switzerland, Taiwan, Thailand, Tunisia, Turkey, the United Kingdom, Vietnam, Yugoslavia, and Zaire (Jensen 1991). Several of these countries, like Canada, have had production and use patterns similar to those in the United States. Given the U.S. and world-wide presence of lindane in breast milk, EPA expects that, if U.S. monitoring programs existed, lindane would be detected in breast milk in other U.S. locales as well.

B. Lindane from Treated Seed Could Contribute to Breast Milk Contamination

EPA believes that lindane from the treated seed use could contribute to levels of lindane in breast milk. As discussed earlier, there are several routes by which women in the United States could be exposed to lindane from treated seed. These include: (1) eating food grown from treated seed; (2) eating the meat of animals fed with feed grown

[2] Several studies suggest, however, that once exposure stops, certain species may be able to eliminate lindane from their systems. EPA, however, cannot determine how quickly or slowly lindane may be eliminated from the human body. In comments, NRDC states that lindane is converted in to beta-HCH in the body (EPA NRDC Comments at p. 1). NRDC provides no support for this statement and EPA has found nothing independently to confirm or refute this statement. Beta-HCH accumulates to a greater extent than lindane and cannot be as efficiently eliminated (EPA 2006 Assessment at p. 19).

from treated seed; (3) consuming drinking water contaminated with lindane from the seed treatment use; and (4) being exposed to lindane that volatilizes from the seed treatment use. EPA believes that all of these are potential routes of exposure.

C. Infant Exposure to Lindane from Breast Milk and Resulting Risk

Infants will be exposed to lindane if they are fed contaminated breast milk. Indeed, for women, lactation is the most important route of elimination for persistent contaminants such as lindane (Jensen 1991 at p. 10). EPA is not able to conduct a scientifically quantitative assessment of the risks associated with exposure to lindane in breast milk due to the uncertainties regarding current monitoring data and the lack of a validated method for quantifying the infant exposure. In general, concentrations of man-made chemicals in human milk often are more than ten times higher than in cow's milk from the same area. Frequently, limit values established for contaminants in cow's milk are exceeded in human milk. Newborns and infants, whose main foodstuff is breast milk, may have a higher relative daily intake of these pollutants than adults (Jensen 1996).

As far as EPA is aware, there have been no overt illnesses in infants from exposure to lindane in breast milk. In addition, breast milk is the natural and superior foodstuff for newborns, and infants, and nursing provides important immunological and psychological benefits. Moreover, virtually all national and international experts agree that women should not forgo breast feeding even though breast milk may be contaminated with low levels of lindane, other organochlorine pesticides, and persistent industrial chemicals like PCBs (Jensen 1991 at p. 288).

Nevertheless, there is a dearth of long-term studies of the effects of infant exposure to lindane in breast milk. Thus, the potential long-term effects of newborn and infant exposure to lindane in breast milk are difficult to assess. EPA is currently unable to determine whether there are in fact adverse effects from exposure of infants to lindane in breast milk. However, EPA believes that, because of lindane's prior detections in breast milk, its physio-chemical properties, and its continued presence in the diet, the potential for adverse effects to infants from consumption of breast milk cannot be dismissed due to a lack of data.

VII. Impact on Growers

Lindane is registered in the U.S. as a seed treatment use on wheat, barley, oats, rye, corn, and sorghum. An application to register lindane for use as a seed treatment for canola is pending before the Agency. In support of the 2002 RED, EPA assessed the potential impacts on growers of cancellation of the lindane seed treatment uses (U.S. EPA 2002 BEAD Analysis). At the time of the 2002 RED, there were registered alternatives for all lindane seed treatment uses except oats and rye. Imidacloprid and thiamethoxam were identified as the primary seed treatment alternatives to lindane (U.S. EPA 2002 BEAD Analysis at p. 1).

For the wheat, barley, corn, and sorghum seed treatment uses, grower-level effects of cancellation of lindane were expected to be minor. For these uses, EPA estimated an increased treatment cost to growers using lindane ranging from 0.3% of gross revenue to 4.4% of gross revenue. In some cases, these increased treatment costs would be offset by the effectiveness of alternatives on other pests. For example, for sorghum, EPA estimated increased treatment costs to growers using lindane of 3.5-4.4% of gross revenue. However, the Agency found that this increase would likely be offset by increased yields due to control of chinch bugs and aphids (U.S. EPA 2002 BEAD Analysis at p. 9). Overall, for uses for which alternatives are registered, EPA concluded the impact of cancellation of lindane to individual growers using lindane would be minor. Further, the Agency estimated that only 6% to 7% of total acres of wheat, barley, and corn planted and only 1% of total acres of sorghum planted were being treated with lindane.

At the time of the 2002 RED, no alternatives were registered for oats and rye. EPA estimated cancellation of the lindane seed treatment use could result in a 9% yield loss to growers using lindane; however, the Agency estimated that only 1% of total acres of oats and rye planted were being treated with lindane. For the growers affected, this crop loss would be partially offset by a lower treatment cost, but the Agency concluded that cancellation of the lindane seed treatment for oats and rye would have a major effect on individual growers using lindane (U.S. EPA 2002 BEAD Analysis at pp. 3-4).

Since the time of the 2002 RED, additional alternatives to the lindane seed treatment uses have been registered. Most notably, imidicloprid is now registered as a seed treatment use for oats and rye. Thus, there are now alternatives for all lindane seed treatment uses. The registration of imidicloprid for oats and rye significantly alters the Agency's 2002 assessment of grower-level impacts. A 9% yield loss to growers using lindane would no longer be expected if lindane were cancelled, though growers switching to imidicloprid would experience increased treatment costs of 0.52-1.7% of net revenues. The Agency considers this to be a minor effect (U.S. EPA 2005 BEAD Update). For all uses, the Agency expects an average increase in treatment cost of 0.29% of net revenues.

In addition, it appears that use of lindane-treated seeds is declining. In 2002, EPA estimated that approximately 4.8 million acres of corn crops were grown from lindane-treated seed (7 percent of the total corn acreage). This translated to approximately 52,000 pounds of lindane used for corn seed treatment. Updated information shows a substantial reduction in these figures. For 2004-2005, EPA estimates that less than three million acres of corn crops were grown from lindane-treated seed (less than 4 percent of the total corn acreage). This amounts to less than 30,000 pounds of lindane used for corn seed treatment. These revised figures suggest that use of lindane to treat corn seeds has declined by greater than 40 percent.

The Agency has received reports that some farmers using treated seeds will opt for lindane-treated seeds because lindane-treated seeds appear to repel sandhill cranes from corn crops. Two studies have estimated that sandhill cranes will damage 20 percent of corn crops grown near wetlands. It appears that this use is most common in

Wisconsin. EPA has no information indicating how much the potential 20 percent crop damage would be prevented by the use of lindane-treated seeds. As a result, the Agency is unable to quantify any resulting benefit from using lindane-treated seeds in this manner. Due to reduced availability of lindane-treated seeds, Wisconsin has submitted a FIFRA §18 emergency exemption request to use anthraquinone to control sandhill crane damage. EPA granted Wisconsin's FIFRA § 18 emergency exemption request and believes anthraquinone is an alternative for protecting crops from sandhill cranes.

VIII. Regulatory Determination

Pursuant to FIFRA, EPA must determine, after submission of relevant data, whether pesticide active ingredients are eligible for reregistration. (FIFRA § 4(g)(2)(A).) In order to be reregistered, EPA must find that an active ingredient meets the standard in section 3(c)(5) of FIFRA. (See FIFRA § 4(a)(2).) This requires EPA to examine, in part, whether a pesticide causes unreasonable adverse effects on the environment. Pursuant to section 2(bb) of FIFRA, "unreasonable adverse effects on the environment" is defined, in part, as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." In other words, to determine whether a pesticide causes unreasonable adverse effects on the environment, EPA must examine broadly the costs and benefits of the pesticide's use, including economic, social and environmental costs and benefits.

Based on new information the Agency received since the 2002 RED, and the review of existing information, EPA has determined that the seed treatment uses of lindane are ineligible for reregistration under FIFRA because the current risks outweigh the benefits of the use of the pesticide. As of July 27, 2006, the Agency had received requests from all lindane technical and end-use product registrants to voluntarily cancel all lindane product registrations. Once the cancellation process is complete, EPA will propose to revoke the existing lindane fat tolerances pursuant to section 408(l)(2) of FQPA.

EPA believes the costs and benefits associated with the seed treatment use have changed significantly since the 2002 RED. At the time of the 2002 RED, there were no alternatives to the seed treatment use for oats and rye for control of wireworm. EPA estimated that without the availability of lindane-treated seeds, untreated plots might suffer as much as a 9% yield loss. The Agency considered this to be a major impact on growers who used lindane treatment for these crops. However, this was the only major impact on growers. For all other lindane seed treatment uses, alternatives existed and grower impacts were expected to be minor.

In March 2006, EPA registered imidicloprid as a seed treatment use on oats and rye for wireworm control. The Agency believes imidicloprid is as effective as lindane for control of wireworm. With the availability of imidicloprid, EPA no longer expects a yield loss in the absence of lindane. Growers are expected to see increased treatment costs of 0.52-1.7% of net revenues with use of imidicloprid. The Agency considers this to be a minor impact. In addition, at least with respect to corn, use of lindane-treated seeds has dropped by over 40 percent, from approximately 4.8 million acres to less than 3 million acres (less than 4 percent of total corn acreage).

Overall, the benefits of the lindane seed treatment uses are now negligible. For all uses, if lindane were cancelled, the Agency would expect to see average treatment costs increase by $1.82 per acre. This is equal to 0.29% of net revenues. For some crops, the increased treatment costs may be partially offset by better control of certain pests. In sum, the benefits of the lindane seed treatment use to growers are very minor, and cancellation of the lindane seed treatment uses is not expected to have an appreciable impact on growers.

Under FIFRA, EPA must balance the benefits of the lindane seed treatment use against the human health, environmental and social costs in determining whether the risk posed is unreasonable. EPA has identified a number of sources of exposure to lindane beyond the seed treatment. Past uses of lindane, consumption of imported meat, and pharmaceutical uses of lindane are all current sources of exposure. For indigenous populations who rely on subsistence diets, exposure to lindane or HCH isomers may result from current or past manufacture or use due to the long-range transport of lindane. EPA believes these sources of lindane have produced a reservoir of lindane in the environment that may remain for some time due to lindane's persistence.

The seed treatment use adds to this current lindane exposure. There are multiple routes by which individuals may be exposed to lindane from the seed treatment use. As discussed previously, consumption of crops grown from treated seed, consumption of livestock fed treated seed and consumption of drinking water are all routes of exposure to lindane from the seed treatment use. There may be additional exposure due to volatilization of lindane from treated seeds. The lindane seed treatment use will add to the existing reservoir of lindane in the environment.

EPA believes this potential ongoing exposure may be of particular concern to nursing infants. Due to lindane's tendency to accumulate in fatty tissues, it has been detected in the breast milk of women in the United States and in many other foreign countries. Although there is no current monitoring data for the U.S., EPA believes it is reasonable to conclude that lindane is present in the breast milk of U.S. women given ongoing exposure to lindane and the chemical's fate characteristics. EPA acknowledges there is uncertainty on the level of risk posed to nursing infants and that no adverse effects have been reported. However, the potential for adverse effects from consumption of lindane in breast milk cannot be dismissed.

EPA finds the overall costs of continued registration of lindane for seed treatment are high. The seed treatment use will only add to the existing sources of lindane exposure. Ongoing releases of lindane into the environment are of concern due to the environmental fate characteristics of the chemical. Lindane is persistent and mobile and will accumulate in human fat tissue. This potential for ongoing and future exposure to lindane is of particular concern for nursing infants because of the potential for exposure to lindane via breast milk.

In sum, EPA finds that these costs of continued lindane registration far outweigh the benefits of the seed treatment use. Therefore, the lindane seed treatment uses are not eligible for reregistration under FIFRA.

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