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Ecological Risk Assessment

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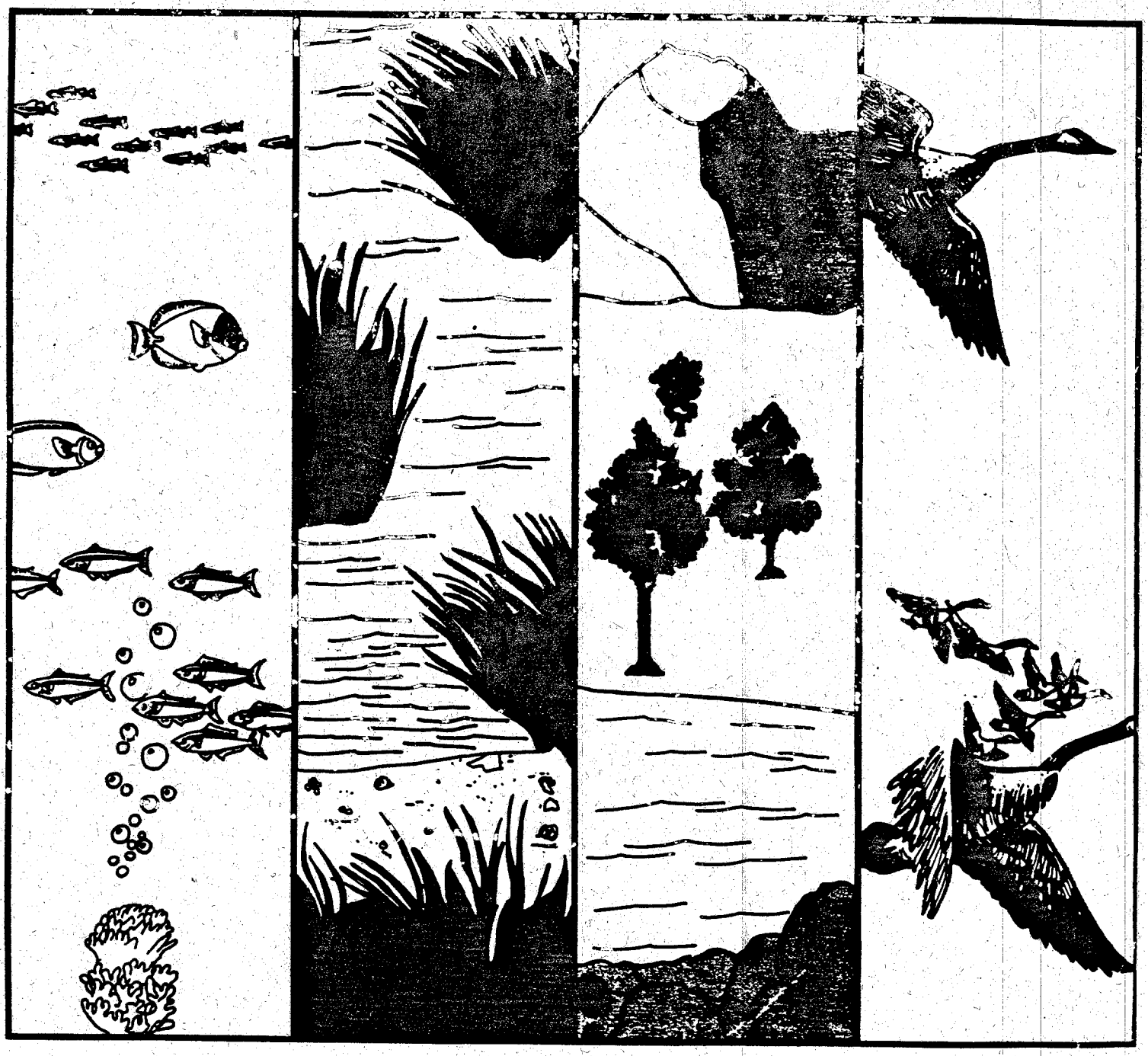

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would like to define ecological risk assessment from the use of pesticides as estimating the likelihood or probability that adverse effects (e.g., mortality to single species of organisms, or reductions in populations of non-target organisms due to acute, chronic, and reproductive effects, or disruption in community and ecosystem level functions) will occur, are occurring, or have occurred. This definition encompasses the final criteria for initiation of special review (see 40 CFR Part 154: 49005; 49007; 49016 - § 154.7(a)(3), (4), (5), and (6); Attachment A). Community and ecosystem level functions, while not specifically covered in the proposed regulations, would be covered under Section 154.7 (a)(6) above.

As stated by Johnson (1982), risk is a function of hazard and exposure. Similarly, ecological risk is a function of toxicological hazard and environmental exposure. Toxicological hazard is the intrinsic quality of a pesticide to cause an adverse effect under a particular set of circumstances. Toxicological hazard data would include, for example, laboratory fish, aquatic invertebrate, or bird LC_{50} values, and effect levels for fish and avian reproduction tests. Environmental exposure is a function of two data components. The first is the estimated amount of the pesticide residue that will be in the environment and available to non-target organisms. We call this the estimated environmental concentration or EEC. The second consists of the numbers, types, distribution, abundance, dynamics, and natural history of non-target organisms which will be in contact with these residues. Information on the proposed label use of the pesticide is essential for such exposure estimates. We first estimate toxicological hazard and environmental exposure separately, and then compare them.

III. RISK ASSESSMENT METHODS

Barnthouse, et al., (1982 a, b) describe five methods for "environmental risk analysis" (i.e., quotient method, analysis of extrapolation error, fault tree analysis, analytic hierarchy method, and ecosystem uncertainty analysis). Their "quotient method" is most similar to EEB's current risk assessment method. However, there are some subtle differences. In their quotient method, an EEC is directly compared to an effect level such as an LC_{50} value (e.g., 10 ppm/10 ppm). The resultant quotient, 1, can then be compared to some relative quotient ranking to indicate possible adverse effects to non-target organisms. For example, where quotient = Q:

$$Q \leq 0.1 = \text{No Adverse Effects}$$
$$0.1 \leq Q \leq 10 = \text{Possible Adverse Effects}$$
$$Q > 10 = \text{Probable Adverse Effects}$$

ECOLOGICAL RISK ASSESSMENT

I. INTRODUCTION

Since 1970, the regulatory authority and basis for pesticide risk assessment has rested with the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under this Act, EPA must determine whether a pesticide can be registered for a particular use. FIFRA, as amended, states that the Administrator shall register a pesticide if he determines that, "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment" (P.L.95396, Sec. 3 (c)(5)(D)). It also states that, "the Administrator may conditionally amend the registration of such pesticide ... if the Administrator determines that ... amending the registration ... would not significantly increase the risk of any unreasonable adverse effects on the environment" (ibid. Sec. 3(c)(7)(B)).

The term "unreasonable adverse effects on the environment" means 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 (ibid. Sec. 2(bb)). Under FIFRA the process of determining whether or not a risk is unreasonable (i.e., factoring in benefits along with risks) is a risk management function. For this discussion, the important term used in FIFRA is "risk to the environment." In order for the Administrator to determine if there will be an unreasonable risk to the environment from the use of a pesticide, an environmental risk assessment or more specifically, an ecological risk assessment, is required. The term 'ecological' better describes the broad scope of adverse effects that are of concern from the use of pesticides. In the past, the adverse effects of greatest concern have been mortality to single species of non-human, non-target organisms, including endangered or threatened species. The Ecological Effects Branch (EEB) in the Hazard Evaluation Division (HED) in the Office of Pesticide Programs (OPP) has primary responsibility for developing environmental risk assessments for pesticides. It should be noted that the state-of-the-art in ecological risk assessment is rapidly evolving and EEB is striving to broaden our risk assessment concerns to include not only single species and populations of wildlife, aquatic organisms, plants, and beneficial insects, but also community and ecosystem level concerns, as well.

II. DEFINITION OF TERMS

Risk assessment has been described as estimating the probability or likelihood of undesirable events such as injury, death, or decrease in the mass or productivity of game fish, wildlife, etc. (Suter II, et al., 1983; Rodericks and Tardiff, 1982). We

We, on the other hand, compare an EEC and an effect level (e.g., an LC_{50}) based on regulatory risk criteria. The regulatory risk criteria, as specified in the 1975 Regulations for the Enforcement of the FIFRA (40 FR (129): 28260-28265; 28281-28284) and in Special Review of Pesticides; Criteria and Procedures; Final Rule (40 CFR Part 154: 49005; 49007; 49016 § 154.7(a)(3), (4),(5), and (6)) are summarized and presented in Table 1. 1/

Many of these risk criteria contain specific safety factors that were derived from a toxicological model presented in the 1975 regulations. The model was designed to provide a safety factor that would allow for differential variability and sensitivity among fish and wildlife species. It was assumed that the slope of the dose/response curve for the effects of a pesticide on most fish and wildlife species would be unknown. (It is impossible to test every non-target species that might be exposed to a pesticide.) Therefore, as the 1975 regulations state:

> From a cross section of existing dose-response data it has been estimated that a typical slope is 4.5 probits per log cycle, and a minimum slope is about 2 probits per log cycle. The latter situation corresponds to a very variable test population with some individuals displaying high sensitivity to the toxicant. From this model it can be estimated that a dose or exposure 10 times lower than the LD_{50} or LC_{50} would be expected to lead to a mortality rate of about 0.01 percent under typical slope conditions, but to a mortality rate of 4 percent under minimum slope conditions. A dose-response 5 times lower than the LD_{50} or LC_{50} would be expected to lead to mortality rates of about 0.1 percent and 10 percent respectively. These figures were used as the basis for selecting a safety factor of 5-10 for setting the classification criteria for protecting wildlife. These factors would be expected to provide an ample margin of safety for a typical species, but only marginal protection to the most variable species. Even larger safety factors than 10 would be desirable to ensure protection of species in which even a single death is of special concern, for instance the death of an endangered species (40 FR (129): 28261). (Also see Attachment H concerning endangered species.)

1/ Special Review is a formalized Agency process for determining whether currently registered pesticides present unreasonable adverse effects to humans or the environment.

TABLE 1 Regulatory Risk Criteria A/

	Presumption of No Risk	Presumption of Risk that may be Mitigated by Restricted Use B/	Presumption of Unacceptable Risk	
			Non-Endangered Species	Endangered Species C/
I. Acute Toxicity				
1) Mammals	EEC < 1/5 LC_{50} mg/kg/day < 1/5 LD_{50} LD_{50} > 50 mg/kg *	EEC ≥ 1/5 LC_{50} mg/kg/day > 1/5 LD_{50} LD_{50} ≤ 50 mg/kg *	EEC ≥ LC_{50}	EEC ≥ 1/10 LC_{50} OR EEC ≥ 1/5 LC_{10}
2) Birds	EEC < 1/5 LC_{50} LD_{50} > 50 mg/kg *	1/5 LC_{50} ≤ EEC < LC_{50} LD_{50} ≤ 50 mg/kg *	EEC ≥ LC_{50}	EEC ≥ 1/10 LC_{50} OR EEC ≥ 1/5 LC_{10}
3) Aquatic Organisms	EEC < 1/10 LC_{50}	1/10 LC_{50} ≤ EEC < 1/2 LC_{50} EEC ≥ 1/10 LC_{50}	EEC ≥ 1/2 LC_{50}	EEC > 1/20 LC_{50} OR EEC > 1/10 LC_{10}
II. Chronic Toxicity	EEC < Chronic No Effect Level	N/A	EEC ≥ Chronic Effect Levels Including Reproductive Effects	EEC ≥ Chronic Effect Levels Including Reproductive Effects; Also any Adverse Habitat Modification

A/ Source: Part 162 - Regulations for the Enforcement of the FIFRA (FR 40 (129): 28260-28265; 28281-28284; Thursday, July 3, 1975).
Source: Proposed Change in Section 3 Regulations - Restricted Use Criteria (See Attachment B).
Source: Parts 154, 162 and 172 Special Reviews of Pesticides; Criteria and Procedures; Final Rule (40 CFR(229): 49005; 49007; 40016; Wednesday, November 27, 1985).

B/ Restricted Use is a classification of a pesticide whereby its use is limited to applicators who have been certified by EPA through EPA approved training programs.

C/ Interagency agreement between EPA/OPP, U.S. Department of Interior (USDI), Office of Endangered Species (OES), and U.S. Department of Commerce (USDC), National Marine Fisheries Service (NMFS), 1980

The following equations describe this model:

(1) $\log LC_k = \log LC_{50} + (\text{probit } k - 5)/b$

where k = the new percentage mortality
b = the slope
5 = the probit of 50%
(Hill, et al., 1975)

and the antilog of $\log LC_k$ = the estimate of the dosage of the new percentage mortality, LC_k.

(2) LC_{50}/LC_k = Safety Factor

For example, the following calculations resulted in the acute safety factors for wild mammals and birds.

Example (A): if b = 4.5; LC_{50} = 100 ppm; k = 0.1; probit k = 1.91;

then, $\log LC_{0.1} = 2 + (1.91 - 5)/4.5$

$\log LC_{0.1} = 1.31$; Antilog (1.31) = 20.4 = $LC_{0.1}$

and, $LC_{50}/LC_{0.1}$ = Safety Factor

where 100/20.4 = 4.9 or approximately 5.

Therefore, pesticides which result in residues exceeding 1/5th an LD_{50} or LC_{50} value for non-target organisms with "typical slopes" will be candidates for restricted use (i.e., use restricted to certified applicators). It is not stated in the regulations, but an acceptable interpretation of the situation is this: based on that cross section of data and accepting the assumptions of the model, 0.1% (or one in 1000) of the typical population exposed to the pesticides are likely to die when the safety factor of 5 is used. These criteria also specify that the residues are to be determined at the time of maximum residues (i.e., immediately after application). This adds an additional (albeit unknown) safety factor to the criteria since these residues may degrade over time.

It was felt that a slightly higher safety factor was needed for many aquatic organisms because they cannot easily limit their exposure to pesticides by moving out of treated areas or by switching to alternate food items as can birds and mammals. Therefore, an additional safety factor of 2 was applied. Consequently, pesticides which result in residues exceeding 1/10th an LC_{50} value for non-target aquatic organisms with "typical slopes" will be candidates for restricted use.

We can use the previous model to determine the probability of 50 percent mortality in the typical aquatic non-target organism population.

Example (B): if $b = 4.5$; $LC_{50} = 100$ ppm; $LC_k = 10$;

then, LC_{50}/LC_k = Safety Factor, where $100/10 = 10$

$\log LC_k = 1$;

and, $\log LC_k = \log LC_{50} + (\text{probit } k - 5)/4.5$

$1 = 2 + (\text{probit } k - 5)/4.5$

probit $k = 0.5$

therefore, $k = 0.00000339767$, the new percentage mortalit

As above, we can state that pesticides which result in residues exceeding 1/10th an LC_{50} value for non-target aquatic organisms with "typical slopes" will be candidates for restricted use. Again, an acceptable interpretation of this situation is this: based on that cross section of data and accepting the assumptions of the model, approximately 0.000034% (or one in 30,000,000) of the typical population exposed to the pesticide are likely to die when the safety factor of 10 is used. This obviously provides a large margin of safety for aquatic organisms with "typical slopes."

We realize that many theoretical questions can be raised about the use of risk criteria and safety factors in general. Currently, we do not use the model to predict the probability of a pesticide to cause significant acute adverse effects to non-target organisms. This simple model for ecological risk assessment does not provide a mechanism for estimating model uncertainty or the probability of adverse effects. We have come to view the risk criteria with their safety factors as "rough" estimates of potential risk to non-target organisms. We should note that an attempt is currently being made to re-visit the model based on up-to-date data bases in both EEB and the Office of Research and Development (ORD).

IV. DATA REQUIREMENTS

Specific information and testing data are necessary in order to conduct an ecological risk assessment. FIFRA states that "The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide ... " (P.L. Sec. 3(c)(2)(A)).

Under FIFRA the Agency is not responsible for producing the data needed to make an ecological risk assessment. That burden is placed upon the applicants for registration. OPP has published regulations which specify the data that are required for registration (40 CFR Part 158), and guidelines which provide recommended testing methods that are needed to produce the required data (Pesticide Assessment Guidelines - Subdivision E).

Further, we are in the process of developing Standard Evaluation Procedures (SEPs) for each kind of data that is required for an ecological risk assessment. These SEPs explain the procedures used to evaluate ecological effects data submitted to OPP, and ensure comprehensive and consistent treatment of the science in reviews as well as providing interpretive policy guidance. SEPs already developed and published through the National Technical Information Service (NTIS) include:

- Avian Single-Dose Oral LD_{50};
- Avian Dietary LC_{50};
- Acute Toxicity Test for Freshwater Fish;
- Acute Toxicity Test for Freshwater Invertebrates;
- Wild Mammal Toxicity Test;
- Acute Toxicity Test for Estuarine and Marine Organisms (Estuarine Fish 96-Hour Acute Toxicity Test);
- Acute Toxicity Test for Estuarine and Marine Organisms (Shrimp 96-Hour Acute Toxicity Test);
- Acute Toxicity Test for Estuarine and Marine Organisms (Mollusc 96-Hour Flow-Through Shell Deposition Study);
- Acute Toxicity Test for Estuarine and Marine Organisms (Mollusc 48-Hour Embryo-Larvae Study);
- Honey Bee - Acute Contact LD_{50}; and
- Honey Bee - Toxicity of Residues on Foliage.

Additional SEPs for reviewing chronic and field testing data will be completed and include:

- Avian Reproduction;
- Fish Early-Life Stage;
- Aquatic Invertebrate Life-Cycle;

° Fish Life-Cycle; and

° Field Testing for Pollinators.

V. APPROACH TO ASSESSING ECOLOGICAL RISK

Under their definition of risk assessment, Rodericks and Tardiff (1982) present four procedural steps: (1) the review and evaluation of hazard data to identify the nature of the hazards; (2) identifying and evaluating the observed quantitative relationship between dose and response (this frequently requires the imposition of assumptions regarding the quantitative relationship between the test organisms and the nontarget organisms that will be protected); (3) the identification of the conditions of exposure (e.g., intensity, frequency, and duration of exposure); and (4) combining the information on dose-response with that on exposure to derive estimates of the probability that the hazards associated with the use of the chemical will be realized under the conditions of exposure that will be experienced by the non-target population(s) under consideration. The authors state further that: "Risk assessment involves integration of the information and analysis associated with these four steps to provide a complete characterization of the nature and magnitude of risk, and the degree of confidence associated with this characterization."

In EEB, we generally follow these four steps. As outlined in Figure 1, toxicological hazard data and exposure data are compared using the regulatory risk criteria. Typically, the toxicological hazard data may consist of acute LD_{50} and LC_{50} values, or chronic no-effect-levels for the most sensitive indicator species. Exposure data normally consist of model-based estimated environmental concentrations in important media of concern (i.e., water, soil, non-target organism food items). As the ratio of these input data equals or exceeds the restricted use criteria, a risk is inferred. If the ratio approaches or exceeds the special review criteria, then a high risk is inferred. For non-endangered non-target organisms, this generally means that the ratio approaches or exceeds one. The criteria for endangered species are more rigorous. They are presented in Attachment H and consist of safety factors applied to acute toxicity values such as the LC_{10} or LC_{50}.

We recognize that the ratio method for assessing risk has numerous weaknesses. For example: (1) it does not adequately account for effects of incremental dosages; (2) it does not compensate for differences between laboratory tests and field populations; (3) it cannot be used for estimating indirect effects of toxicants (e.g., food chain interactions); (4) it has an unknown reliability; (5) it does not quantify uncertainties; and (6) it does not adequately account for other ecosystem effects (e.g., predator-prey relationships, community metabolism, structural shifts, etc.). At the present time, therefore, the state-of-the-

FIGURE 1

Flow Chart for Ecological Risk Assessment for Pesticides

INPUTS

TOXICOLOGICAL HAZARD DATA

(Laboratory)

- Ecotoxicological data (e.g., LD_{50}s; LC_{50}s; EC_{50}s; NELs; MATC)
- Human Toxicology data (e.g., Rat, Mouse, Rabbit, LD_{50}s; LC_{50}s, NELs)

(Field)

- Ecotoxicological data (e.g., mortality; sublethal effects; population effects)

EXPOSURE DATA

(Laboratory)

- Chemical fate and transport data (e.g., 1/2-life data; K_d values; residue decline curves; fish accumulation)
- Chemistry data (e.g., solubility; vapor pressure; molecular weight; structure)

(Field)

- Residue Chemistry data (e.g., plant and soil residues; metabolic products)
- Chemical data and transport data (e.g., field dissipation rates; fish rates; fish residues)

- Pesticide use information (e.g., label rate; frequency timing; method of application; site characteristics; potential geographic extent of use)
- Non-target organism information (e.g., types; distribution; abundance; dynamics; natural history)

Estimated Environmental Concentrations (EECs) for water, soil, non-target food items; plus profile of non-target organisms at risk

INTEGRATION

Compare Toxicological Hazard Data to Exposure Data Based on Regulatory Risk Criteria (See Table 1)

OUTPUTS

1. Statement Assessing Ecological Risk from the Use of the Pesticide
2. Regulatory Actions

- Require Additional Data
- Require Restricted Use Classification to Reduce Risk
- Require Use Restrictions on Label to Reduce Risk
- Initiate Special Reviews based on Risk Criteria (See Attachment A)
- Recommend against Registration

art cannot provide a complete characterization of the magnitude of risk nor the degree of confidence associated with the characterization.

To further illustrate the approach shown in Figure 1 consider the following example: a hypothetical organophosphate insecticide is applied to cotton at 1 pound active ingredient up to 3 times per growing season, as a foliar spray when insects appear. Cotton is a major crop in the U.S. with approximately 8,000,000 acres planted in 1983 (U.S. Department of Agriculture, 1984). Gusey and Maturgo (1972) list the following species or groups as utilizing cotton fields for feeding from June through October: quail, pheasants, doves, prairie chickens, passerines, rabbits, deer, raccoons, and antelope. Roach (1973) observed orioles, hummingbirds, bobwhites, mourning doves, towhees, cardinals, and thrashers using more mature, shadier cotton fields in a Mississippi study. In June and July, before most soil was shaded, purple grackles were observed. Other birds were observed to a lesser extent. Among mammals, rabbits and deer browsed incidentally on cotton; cotton rats, house mice, white-footed mice, cotton mice, beavers, armadillos, raccoons, and foxes were also observed. A limited number of species of snakes, lizards, turtles, toads, and frogs were also seen. Therefore, there is significant potential for exposure of the insecticide to terrestrial wildlife, especially birds. The most likely result of exposure to birds is via the diet (versus oral ingestion of the pesticide *per se*). The maximum and typical expected residue concentrations of the insecticide immediately after application on vegetation, insects, soil (after Hoerger and Kenaga, 1972; 1 lb, ai/A) and water (see Table 2) are:

Vegetation Type	Residue (ppm) Maximum	Typical
Short grass	240	125
Long grass	110	92
Leaves and leafy crops	125	35
Forage, e.g., alfalfa; also estimate for small insects	58	33
Pods containing seeds; Legumes	12	3
Grain	10	3
Fruit (e.g., cherries, peaches)	7	1.5

Soil	Residue (ppm)
0.1 acre-inch in depth	22

Water	Residue (ppm)
0.5 acre-foot in depth	0.734

TABLE 2: EECs (ppb) of Pesticides in Bodies of Water Immediately Following Direct Applications of from 0.1 to 10.0 lbs ai/A

		Water Depth (ft)										
Lb/A	mg/ft^2	0.5	1	2	3	4	5	6	7	8	9	10
0.10	1.04	73.4	36.7	18.3	12.2	9.1	7.3	6.1	5.2	4.5	4.0	3.7
0.20	2.08	147	73.5	36.7	24.5	18.3	14.7	12.2	10.5	9.1	8.1	7.4
0.25	2.60	184	91.9	45.9	30.6	22.9	18.3	15.3	13.1	11.4	10.2	9.2
0.30	3.12	220	110.2	55	36.7	27.5	22.0	18.3	15.7	13.7	12.2	11.0
0.40	4.16	294	147.0	74	49.0	36.7	29.4	24.5	21.0	18.3	16.3	14.7
0.50	5.20	367	183.7	91.9	61.2	45.9	36.7	30.6	26.2	22.9	20.4	18.4
0.75	7.80	551	275.6	137.8	91.8	68.9	55.1	45.9	39.3	34.4	30.6	27.6
1.00	10.41	734	367.5	183	122	91	73	61	52	45	40	37
1.25	13.01	919	459.7	230	153	115	92	77	66	57	51	46
1.50	15.61	1100	551.6	276	184	138	110	92	78	69	61	55
1.75	18.21	1280	643.5	322	214	161	128	107	92	80	71	64
2.00	20.82	1471	735.7	368	245	184	147	122	105	92	81	74
2.25	23.42	1650	827.6	414	276	207	165	138	118	103	92	83
2.50	26.02	1838	919.41	459	306	229	183	153	131	114	102	92
3.00	31.23	2200	1103.5	552	368	276	220	184	157	138	122	110
4.00	41.64	2940	1471.4	735	490	367	294	245	210	183	163	141
5.00	52.05	3680	1839	919	612	459	367	306	262	229	204	184
6.00	62.46	4415	2207	1103	735	551	441	367	315	275	245	220
7.00	72.87	5150	2575	1287	858	643	515	429	367	321	286	258
8.00	83.28	5885	2943	1471	981	735	588	490	420	367	327	294
9.00	93.69	6622	3311	1655	1103	827	662	551	473	413	367	331
10.00	104.10	7356	3678	1839	1226	920	736	613	525	460	409	368

Weight of 1 cubic foot of water = 28,293,000 mg
= 62.36 lb

Weight of 1 acre-foot of water = 2,716,402 lb

Concerning exposure to aquatic organisms, we can assume that a typical runoff scenario for cotton growing areas would include a 10-acre basin draining into a 1-acre pond with an average depth of 6 feet (USDA, 1982). Further, Wauchope (1978) suggests that water-soluble pesticides applied as aqueous solutions usually show runoff losses of 0.5% (or less) to 3 times this amount (1.5%) if a large, early runoff event occurs. Therefore, a generalized maximum runoff figure is 1.5%. Using the general equation where EEC (ppb) = pesticide loading to the body of water/weight of the water, a maximum estimated concentration due to runoff would be 9 ppb. An additional source of the insecticide to the pond is spray drift. There is little information from which to estimate this source of contamination. Nigg, et al., (1984) found a mean of 140 ppb in a 0.25 acre pond three hours after spraying a Florida citrus orchard with 10 lbs ai/A phenthoate. The sole source of contamination was determined to be drift. Extrapolating for 1.0 lb ai/A of the insecticide, the value would be 14 ppb. When the drift estimates are added to runoff estimates, the total initial concentration of the insecticide in the pond is estimated to be 23 ppb. Thus, preliminary EECs for the environment would range from 1.5 ppm to 240 ppm for terrestrial exposure and 23 ppb to 734 ppb for aquatic exposure.

The laboratory toxicological hazard data for this hypothetical insecticide is as follows: Bobwhite quail (adult) LD_{50} = 2 mg/kg and bobwhite quail (14 days old) LC_{50} = 3 ppm; mallard duck (10 days old) LC_{50} = 30 ppm; avian reproduction NEL = 300 ppm; bluegill sunfish LC_{50} = 100 ppm; rainbow trout LC_{50} = 57 ppm; *Daphnia magna* LC_{50} = 100 ppm; fathead minnow life-cycle MATC = 50 ppm; *Daphnia magna* life-cycle NEL = 35 ppm.

When comparing the exposure EECs to the toxicological hazard data based on the criteria in Table 1, it is clear that the risk to aquatic organisms is low. The highest EEC, 734 ppb, is less than 1/10th the lowest acute LC_{50} value (i.e., 57 ppm/10 = 5.7 ppm) and the lowest chronic value (i.e., 35 ppm/10 = 3.5 ppm). The risk to avian wildlife, however, is high. The EECs for common avian diet components like insects, seeds, grain (i.e., 3 ppm to 58 ppm) are greater than or equal to the lowest avian acute LC_{50}, 3 ppm. Further, exposure to contaminated insects alone poses a risk of unacceptable levels.

The nature of the risk is that significant acute avian effects are possible. The magnitude of the effects, while unquantified, could be quite large since cotton is a major crop in the U.S., especially in the Southeast, Texas, and California. Avian populations could be adversely affected on a local or regional level, including members of endangered species.

Finally, to further validate this conclusion, field effects data are usually required. Specifically, these data are terrestrial field studies that will investigate and quantify acute effects to avian populations in actual field situations.

At this time, we cannot provide a reliable estimate of the probability for significant reductions in populations of non-target organisms. However, based on an increasing body of historical field effects data, we believe that the risk assessment scheme does enable us to distinguish between pesticides that pose a significant high risk and those that pose a low risk.

A. Aquatic Risk Assessment

1. Introduction

EEB's aquatic hazard assessment process has been discussed from a regulatory viewpoint elsewhere (Akerman and Coppage, 1979). This report will concentrate primarily on EEB's risk assessment procedures and the supporting scientific rationale. In the aquatic risk assessment, we examine the potential risks of the proposed pesticide uses to non-target fish and aquatic invertebrates, in both the freshwater and estuarine/marine environments. These groups of organisms were chosen because there are well defined testing protocols available for fish, crustaceans, molluscs, and aquatic insects. In addition, certain species within these groups are important food and recreation resources, and consequently are of great economic and aesthetic value.

Risks to non-target algae and aquatic plants are not addressed here because the Agency has determined that phytotoxicity data will be requested only on a case-by-case basis. Examples when such data may be requested are: (1) for pesticides used in forests and natural grasslands, (2) when hazards are posed to federally endangered or threatened plants, (3) at the initiation of a Special Review where a phytotoxicity problem may exist, (4) where a specific phytotoxicity problem arises and when general open literature data are not available to address the problem (see 40 CFR 158.150). When such hazards are addressed, they are considered in a separate review.

2. Indicator Species

EEB requests certain toxicity data prior to the completion of an aquatic risk assessment. Considering that there are more than 2000 species of freshwater and saltwater fish in North America and tens of thousands of species of aquatic invertebrates, certain indicator species were selected for the toxicity testing that were most useful for risk assessment. The selection criteria included the following:

- the test species should be one which has demonstrated sensitivity to the known effects produced by toxic chemicals;
- the dose-response of the test species to a variety of pesticides;
- the test species should be ecologically significant, occurring naturally in large numbers and in widespread habitats;
- the test species should be aesthetically and/or economically important;
- the test species should be readily available for test purposes; and
- the test species should have a life-cycle short enough to permit reasonably short (1 year) life-cycle tests.

While no single species meets all these criteria, test species should meet a majority of these criteria to qualify. In addition, we are continually seeking better indicator species. An example of this is the recent development of early life-stage toxicity test methodology using three Atherinid fishes (silversides). It was generally recognized that an established estuarine/marine fish that has been widely used as the indicator species for toxicity testing, the sheepshead minnow (Cyprinodon variegatus), is relatively insensitive to known toxic chemicals. Therefore, EPA's Environmental Research Laboratory at Gulf Breeze, Florida, proceeded to develop partial life-cycle testing methods using more sensitive and better representative marine/estuarine test species (i.e., Menidia beryllina, M. menidia, and M. peninsulae) (Goodman, et al., 1985 a, b). When these methods are finalized and tested, Subdivision E of the Pesticide Assessment Guidelines will be updated.

The indicator species that EEB has selected for acute toxicity testing are consistent with the recommendations in: (1) ASTM Standard E 729-80 for freshwater/marine fish and macroinvertebrates, (2) Committee on Methods for Toxicity Tests with Aquatic Organisms, 1975, for freshwater/marine fish and macroinvertebrates, (3) ASTM Standard E 724-80 for static acute tests with larvae of bivalve molluscs, and (4) Bioassay Procedures for the Ocean Disposal Permit Program (anonymous, 1978) for oyster shell growth tests, static acute tests using mysid and grass shrimp and Acartia tonsa. More specifically, the species most often preferred for acute testing are:

- freshwater/coldwater fish - rainbow trout (Salmo gairdneri)
- freshwater/warmwater fish - bluegill sunfish (Lepomis macrochirus)

- freshwater crustacean - Daphnia magna
- estuarine/marine fish - sheepshead minnow (Cyprinodon variegatus)
- estuarine/marine shrimp - mysid, penaeid or grass
- estuarine/marine oyster - eastern oyster (Crassostrea virginica)

The indicator species that EEB has selected for chronic toxicity testing are consistent with the recommendations in (1) National Water Quality Laboratory Committee on Aquatic Bioassays (1971 a, b) for fathead minnow and brook trout, (2) Bioassay Procedures for the Ocean Disposal Permit Programs for mysid and grass shrimp and sheepshead minnow (anonymous, 1978), (3) ASTM Standard E 1022-84 Practice for Conducting Bioconcentration Tests with Fishes and Salt Water Bivalve Molluscs, (4) Macek, et al., 1975, for bioconcentration in bluegill, and (5) Branson, et al., 1975, for bioconcentration in rainbow trout. More specifically, the species most often preferred for chronic testing are:

- freshwater fish - rainbow or brook trout Salvelinus fontinalis), and fathead minnow (Pimephales promelas)
- freshwater crustacean - Daphnia magna
- estuarine/marine fish - sheepshead minnow (Cyprinodon variegatus)
- estuarine/marine shrimp - mysid (Mysidopsis bahia)
- estuarine/marine mollusc - eastern oyster (Crassostrea virginica)

3. Toxicological Hazard Data

The following aquatic toxicological hazard data represent the full complement of aquatic testing that could be requested for an aquatic risk assessment:

Tier 1

(1) 96-hour coldwater fish LC_{50};
(2) 96-hour warmwater fish LC_{50};
(3) 48-hour (or 96-hour) freshwater aquatic invertebrate LC_{50}

Tier 2

(4) 96-hour estuarine/marine fish LC_{50};
(5) 96-hour estuarine/marine shrimp LC_{50};
(6) 48-hour oyster embryo-larvae EC_{50};

(7) 96-hour oyster shell deposition EC_{50};
(8) Fish early life-stage MATC or Effect/No Effect Level;
(9) Aquatic invertebrate life-cycle MATC or Effect/No Effect Level;
(10) Fish bioaccumulation factor, e.g., 1000X;
(11) Special aquatic organism test data (e.g., fish acetylcholinesterase levels).

Tier 3

(12) Fish full life-cycle MATC or Effect/No Effect Level;

Tier 4

(13) Fish/aquatic invertebrate population effects in the field;
(14) Simulated and actual field effects data on aquatic organisms.

These laboratory and field data describe the potential of a pesticide to cause adverse effects (i.e., mortality, reduction in growth or impairment of reproduction in aquatic non-target organisms and their populations). They are compared to the estimated or actual measured pesticide residue in the aquatic environment in order to estimate the ecological risk to populations of aquatic non-target organisms from the use of the pesticide.

The actual amount of aquatic toxicological hazard data that would be required is determined by the "when required" testing criteria found in the footnotes to Part 158.145 of the Data Requirements for Pesticide Registration; Final Rule (40 CFR 49 (207): 42894-42895; Wednesday, October 24, 1984) and in the "when required" paragraphs in Subdivision E of the Pesticide Assessment Guidelines. The criteria are identical in both documents. Basically, pesticides that are persistent in any media, are highly toxic to non-target organisms, require repeat applications, are applied directly to water, or are likely to transport to water from the intended use sites, will require substantial additional data. Also, the fewer criteria that are met, the fewer data that are generally required.

4. Aquatic Residues

Measured pesticide concentrations in water are usually not collected by the registrant at this stage of the registration process in support of a registration action. If such data are available, they are included in the exposure component of EEB's ecological risk assessment. Normally, however, EEB must estimate aquatic exposure to pesticide residues.

Figure 2 AQUATIC ESTIMATED ENVIRONMENTAL CONCENTRATION (EEC) TIER SYSTEM

Level 1

GO TO EEC TABLE FOR DIRECT APPLICATION TO WATER (See Table 2)

DIRECT APPLICATI MODEL (Lentic)

EEC < Risk Criteria → No Risk

EEC > Risk Criteria

Level 2

Modify Variables in Basic Equation (1) From Level 1

1. Chemical Site Dependent Variables:
   - drainage basin size (A)
   - surface area (A)
   - average depth (ft)
   - % runoff (decimal)
2. How?
   Use Literature References:
   - Benchmark Chemicals (e.g., Wauchope, 1978: 462-468; McElroy, et al., 1976)
   - Typical Runoff figures (e.g., Wauchope, 1978: 460-464; Spencer, et al., 1985)
   - Site Characteristics (e.g., U.S. Dept. of Agriculture, 1982)
   - Spray Drift (e.g., Nigg, et al., 1984)

SIMPLE RUNOFF MODEL (Lentic)

EEC < Risk Criteria → No Risk

EEC > Risk Criteria

Level 3

Request EEC Estimation from Exposure Assessment Branch (EAB)
Computer, Simulation Models (SWRRB and EXAMS)

SWRRB predicts pesticide concentration in the runoff (Attachment C)
EXAMS predicts pesticide concentration in aquatic systems receiving runoff. It has two versions: (A) steady state input and (B) pulse loading. The latter is more representative of most agricultural use sites. Both pond and river scenarios available (Attachment D).

EXAMPLES: (See Attachment F).

COMPUTER RUNOFF AN EXPOSURE MODEL SIMULATIO (Lentic and Lotic)

EEC < Risk Criteria → No Risk

EEC > Risk Criteria

Level 4

Request Actual Field Residue Monitoring Studies

FIELD DATA (Lentic)

EEB's current approach to estimating exposure (i.e., how much pesticide will be in the water [Estimated Environmental Concentration or EEC]) is similar to the hierarchical or tier system presented in Subdivision E of the Pesticide Assessment Guidelines (EPA-540/9-82-024, p. 2). Figure 2 illustrates the current EEB "Aquatic EEC Tier System." It is generally agreed that lentic aquatic systems represent more of a worst-case analysis than lotic systems. Therefore, the lentic system (e.g., ponds) is often chosen as the aquatic system initially evaluated. We use state-of-the-art models to develop EECs for streams and rivers when the analysis in lentic systems indicates potential for risk. (See Attachment F.)

Pesticide registrants normally supply EPA with data on the fate and transport of the pesticide in the environment. These data are used by EEB to, among other things, estimate how long an EEC calculated in Level 1 or 2 will be present in the water. The fate data can be divided into five categories of data requirements and results, as reported in Table 3.

In addition, EEB also receives information on the physical and chemical properties of the pesticide. The important information for consideration in the ecological risk assessment includes: color, physical state, odor, melting point, bulk, density or specific gravity, solubility, vapor pressure, dissociation constant, octanol/water partition coefficient, pH, molecular weight, and chemical structure.

Initially, EEB considers the worst possible risk situation (i.e., direct application to water). This worst-case scenario is described in Figure 2, Level 1. All pesticide uses are considered under this scenario first, whether or not a direct application to water is proposed. If there is no risk determined at Level 1, then no further exposure analyses are necessary.

In Level 1, a "worst-case" EEC is determined by solving the following mass balance equation:

(1) EEC (ppb) = A (pesticide loading to the body of water)/B (weight of the water)

Where, A = maximum application rate (lbs ai/A) x size of the drainage basin (A) x % runoff (decimal);

and B = surface area of the body of water (A) x average depth (ft) x 43,560 ft^2/A x 62.36 lbs/ft^3

For example, if the application rate is 0.10 lbs active ingredient per acre, the drainage basin is estimated to be 1 acre, the percent runoff for a direct application is 100 or 1 when changed to a decimal, the surface area of the body of

Table 3: Environmental Fate and Transport Data

Data Requirements	Reported Results
1. Degradation	
a. Hydrolysis	1a. - hydrolytic half-life at pHs 5, 7 & 9
b. Photodegradation - water - soil	b. - photolytic half-life in water and soil
2. Metabolism	
Aerobic Soil Anaerobic Soil Anaerobic Aquatic Aerobic Aquatic	2. - half-life estimates and residue decline curves
3. Mobility	
Leaching	3. - Soil/water relationship (Kd values); i.e., adsorption/desorption
4. Field Dissipation	
Soil Water Forest	4. - Residue decline curves
5. Accumulation	
Rotational Crop Irrigated Crop Fish Aquatic Non-Target	5. - Significant residues accumulated, rates of accumulation, residue decline curves

REFERENCE: Environmental Fate Branch, HED, OPP. 1982. Pesticide Assessment Guidelines Subdivision N, Chemistry: Environmental Fate. EPA-540/9-82-021.

water is 1 acre, and the average depth of the body of water is 0.5 ft, then equation (1) can be solved as follows:

$$EEC\ (ppb) = (0.1 \times 1 \times 1)/(1 \times 0.5 \times 43560 \times 62.36) = 73\ ppb$$

This number appears in the third column in Table 2. A worst-case EEC, like the one calculated above, is then compared to the lowest acute aquatic LC_{50} value, chronic effect level or chronic no effect level (NEL). These values are determined from the toxicological hazard data outlined above. If the EEC is less than the acute and chronic aquatic risk criteria, then EEB presumes that there will be no risk to aquatic organisms from the proposed pesticide use because there is little likelihood of significant exposure to non-target aquatic organisms. There would be no need to proceed any further on the EEC Level System. Alternately, if the EEC is equal to or greater than these risk criteria, then EEB would proceed to Level 2.

In Level 2, surface runoff (including both water and sediment) and spray drift are considered the major mechanisms for pesticide loss to the aquatic environment. The other principal mechanisms of pesticide transport away from the application site (i.e., leaching, degradation and volatilization) (Rumker, et al., 1975: 104) are not directly included in this Level 2 estimation, but will be included in Level 3. In some instances, an estimate of pesticide spray drift can be crucial in the aquatic risk assessment, especially for pesticides that are applied by air or by mist blower (see Nigg, et al., 1984). Preliminary spray drift scenarios have been developed (see Attachment E). We estimate that approximately 10% of the amount of pesticide applied will reach the aquatic environment via spray drift. It is important to note here that lipophilic pesticides have a tendency to become tightly bound to soil. They are, therefore, less likely to be transported via water runoff, but could be transported via soil erosion. However, aquatic contamination via spray drift could be an even more important factor in aquatic risk assessment for these pesticides.

Concerning surface runoff, the same basic equation used in Level 1 (see equation (1)) is used again in Level 2 to determine the EEC. However, this time the variables in the equation are modified to better describe a typical field use site. The "chemical and site dependent variables," (i.e., drainage basin size, surface area of the pond, average depth of the pond, and, runoff percent) are selected from appropriate literature references (Figure 2). The resultant EEC is again compared with the aquatic hazard data as modified by the aquatic risk criteria (Table 1). If the comparison still results in a conclusion of potential risk to aquatic organisms, then EEB would proceed to Level 3.

At this point, EEB performs an estimate of an aquatic EEC using state-of-the-art exposure models (e.g., EXAMS). At the same time, EEB requests the direct assistance of the Exposure Assessment Branch (EAB) if any modifications to the model or use scenario are needed. Scientists from both branches meet and agree upon the appropriate use site characteristics that should be entered into the computer runoff and exposure model in Level 3 (Attachments C and D). All the principal mechanisms of pesticide transport are considered in this model simulation including pesticide drift. However, the leaching, or adsorption/desorption (K_d) factor is one of the most important parameters. A number of computer estimated EECs have been completed. The most appropriate input made for the EXAMS model is the "pulse loadings" (versus "steady state" or slow build-up from a single input). These are considered to be more "real" situations for agrichemical use sites. Pesticides are usually applied at various times throughout the growing season, and rainstorms, and irrigation, which result in pesticide runoff, are periodic in nature. Both lentic (pond) and lotic (river) scenarios have been evaluated.

It should be noted that these simulations are still being field validated and are often rebutted by pesticide registrants either with simulations of their own or arguments that certain crucial data parameters are biased and need to be changed. These issues are addressed as they arise, but when disagreements cannot be resolved, EEB requests actual field residue monitoring studies (Level 4). Also, at times such studies are offered by the pesticide applicants in order to verify or refute the model estimates.

The report of EEC Model results received by EEB often consists of a brief summary of the expected concentrations in different components of soil and water, and a series of tables and graphs containing the estimated residues over time. In addition, the report may also contain a page containing a summary of the chemical properties of the chemical, as shown in Table 4, and a drift add-on component to the SWRRB/EXAMS model (Attachment E, Output from Spray Drift Model). The difference between steady state and pulse loading can be very important. In at least one case, the pulse loading model produced residue quantities five times greater than the steady state model. It appears that the quantity dynamics of the water column and sediments of the pulse load mode are closer aligned to those conditions found in nature for agricultural runoffs. Considering these factors, EEB usually requests at least the pulse loading estimate. Interpretation errors can result with all these estimates and caution is urged when they are used in ecological risk assessment.

Perhaps the best approach to date for summarizing and using the EEC computer model data is found in Attachment G. Of particular importance is the tabular summary of the SWRRB/EXAMS EEC

Table 4: Summary of Chemical Fate Properties

Common Name: _____

Chemical Name: _____

Structure:

Chemical Properties:

Molecular Weight: _____

Solubility (ppm): _____

Partitioning:

K_{ow} _____ K_{oc} _____ $K_d = K_{abs} = K_{ps}$ _____

Hydrolysis (half-life hrs.)

(pH 5?) _____ (pH 7?) _____ (pH 9?) _____

K_{ah} _____ K_{nh} _____ K_{bh} _____

Photolysis (half-life hrs.)

_____ K_{dp} _____

Degradation (half-life hrs.)

Soil (Aerobic)(25 C) _____ hr K _____

Soil (Anaerobic)(25 C) _____ hr K _____

Water (Type _____ pH _____) _____ hr K _____

Bacteriological

Soil (Type _____) _____ hr K _____

Water (Type _____) _____ hr K _____

Vapor Pressure: _____

Evaporation: _____

Values. The information on the number of days that the EEC exceeds a critical risk criteria (e.g., 1/2 LC_{50}, which is the 1975 criteria for Presumption of Unacceptable Risk for Aquatic Organisms in Table 1), and the identification of the day that the minimum and maximum EECs occurred clearly shows whether EEB should have a concern for risk to non-target aquatic organisms, which non-target organisms are at risk, and what the duration of the risk is. Attachment G is a good written assessment of risk, integrating exposure data and toxicological hazard data.

5. Aquatic Non-Target Exposure

Concurrent with the aquatic EEC determination is an analysis of the use pattern and use site characteristics. This is done in order to determine which aquatic non-target organisms are likely to be exposed to the proposed use of the pesticide.

Information on the use pattern and the use site are collected from a wide variety of sources. The following contains a number of information sources that are used: proposed pesticide label; 1978 Census of Agriculture, Vol. 1, Parts 1-50; EPA Label File; USDA Statistical Reporting Service, Crop Reports by State; EPA Compendium of Registered Pesticides; EEB Crop Index and Chemical File; USDA Economic Research Service (Staff Reports on Pesticide Use for Crop: National, Regional and State Level); EEB Agricultural Crop Information File; USDA County Extension Agents; and personal contacts and personal experience of Agency personnel.

Once the specific treatment areas are identified, then EEB describes the aquatic non-target organisms that are associated with the treatment areas and which would likely be exposed to the pesticide due to their natural history characteristics, (e.g., food habits, breeding requirements and behavior, resting behavior). We rely on personal contacts with experts in the field and on a staff member's personal experience to complete this analysis, as well as consulting appropriate references:

Lagler, 1956. Freshwater Fishery Biology.

EPA-670/4-73-001, Biological Field and Laboratory Methods for Measuring the Quality of Surface Waters and Effluents.

Scott and Crossman, 1973. Freshwater Fishes of Canada.

Usinger, 1956. Aquatic Insects of California.

Lee, et al., 1980. Atlas of North American Freshwater Fishes.

Pflieger, 1975. The Fishes of Missouri.

Trautman, 1981. The Fishes of Ohio.

Hutchinson, Vol. I (1957), II (1967), III (1975). A Treatise on Limnology.

Hoese and Moore, 1977. Fishes of the Gulf of Mexico.

Holt, Ed. 1969 & 1971. The Distributional History of the Biota of the Southern Appalachians, Part I: Invertebrates, and III: Vertebrates.

EPA, 1972, Biota of Freshwater Ecosystems, Water Pollution Control Research Series 18050 ELD 05/72, Manual No. 1-10.

Galtsoff, Ed. 1957. The Gulf of Mexico, Its Origin, Waters and Marine Life. Fishery Bull. No. 89, Vol. 55.

Carlander, K.D. 1969. Handbook of Freshwater Fishery Biology. Vol 1. Iowa State Univ. Press, Ames Iowa.

Carlander, K.D. 1977. Handbook of Freshwater Fishery Biology. Vol. 2. Iowa State Univ. Press, Ames Iowa.

Gosner, K.L. 1971. Guide to Identification of Marine and Estuarine Invertebrates. Wiley-Interscience, N.Y.

Lauff, G.H., ed. 1967. Estuaries. Amer. Assoc. Adv. Sci. Washington, D.C.

Pennak, R.W. 1953. Freshwater Invertebrates of the United States. Ronald Press, N.Y.

Smith, R.I., F.A. Piteka, D.P. Abbot and F.M. Wessner. 1970. Intertidal Invertebrates of the Central California Coast. Univ. Calif. Press., Los Angeles.

Zingmark, R.G., ed. 1978. An Annotated Checklist of the Biota of the Coastal Zone of South Carolina. Univ. S. Carolina Press, Columbia, S.C.

At this point, EEB has reviewed and summarized (1) the toxicological hazard data for various indicator species of aquatic non-target organisms and (2) the estimated exposure of the pesticide from the proposed use. The latter is described in terms of its residues in the aquatic environment and the aquatic organisms that are likely to be exposed to the pesticide. The next step is to actually perform the assessment of risk.

6. Risk Assessment

By relating the known biological and ecological responses elicited by known concentrations of a pesticide to the actual or estimated environmental concentration of that pesticide, it is possible to determine the likelihood of adverse effects and, thus, to make an ecological risk assessment. EEB's approach to using and comparing hazard and exposure data is largely based upon an approach recommended by an Aquatic Hazards of Pesticides Task Group of the American Institute of Biological Sciences (Cairns, Jr., et al., 1978). Part of the charge to the Task Group was to develop criteria and rationale for the use of the basic test data already required (acute toxicity data and environmental fate data), and to determine the need for additional testing (life-cycle, early life-stage, accumulation, simulated and actual field). From the many criteria that were considered, this Task Group selected six criteria that they considered to be of primary importance for making decisions concerning the need for additional data:

- LC_{50} less than (<) 1 mg/liter (ppm);
- Estimated environmental concentration greater than (>) 0.01 of the LC_{50};
- Pesticide used on a major crop or otherwise to be broadly used;
- Water solubility value less than (<) 0.5 ppm or octanol: water partition coefficient greater than (>) 1000;
- Half-Life in water greater than (>) 4 days; and
- Avian safety, mammalian safety, or efficacy test results produce abnormal, reproductive, and/or other unusual effects at low dosages or concentrations.

If any one or more of these criteria are met, then additional testing, beyond the basic test data, is needed. EEB has incorporated these criteria into Subdivision E of the Pesticide Assessment Guidelines and into the footnotes of Part 158.145 of the regulations. Many of EEB's pesticide risk assessments end with the conclusion that there is a great potential for risk because pertinent hazard and exposure data are lacking. Therefore, before a more detailed ecological risk assessment can be completed, additional data are needed. When all required data have been requested, received, reviewed and summarized by EEB, the toxicological hazard data are compared to the exposure data and the risk is characterized on the basis of the risk criteria in Table 1. The risk assessment is generally broken down into acute and chronic risk to fish and aquatic invertebrates.

a. Fish Acute Risk

In assessing the acute risk of a proposed pesticide to non-target fish, EEB uses biological response data from acute bioassays on fish:

- Coldwater fish LC_{50};
- Warmwater fish LC_{50}; and
- Estuarine/marine fish LC_{50}

The lowest LC_{50} value for each ecosystem which will be impacted by the pesticide (freshwater and/or estuarine or marine) is selected from the toxicological data. The typical approach is to directly compare the aquatic EEC with the selected LC_{50} value(s). If the EEC is less than 1/10th the aquatic LC_{50}(s), then EEB presumes no acute risk to fish (see Table 1). If the EEC is between 1/10th LC_{50} and 1/2 LC_{50} (see Table 1), then EEB presumes that there is risk to fish which may be mitigated by some precautionary labeling statements (e.g., "This pesticide is toxic to fish. Drift and runoff from treated areas may be hazardous to fish in neighboring areas") or through labeled use restrictions (e.g., for a mosquito larvicide, "Do not apply to fish bearing waters").

If, however, the EEC is equal to or greater than a lethal concentration, which results in significant acute effects on the population, or the EEC is equal to or greater than 1/2 the aquatic LC_{50} (see Table 1), then EEB presumes that the acute risk from the use of the pesticide is significant. The anticipated effects are described with as much detail as possible, sometimes referring to previous significant pesticidal effects on fish from requested field studies, fish kill data or field effects from the use of similar pesticides. If the data are sufficiently compelling, a special review may then be initiated.

b. Aquatic Invertebrate Acute Risk

Biological response data from tests shown here are used to assess the acute risk of a proposed pesticide to aquatic invertebrates. These include:

- Daphnia or aquatic insect LC_{50}/EC_{50};
- Shrimp LC_{50}/EC_{50};
- Oyster embryo-larvae LC_{50}; and
- Oyster shell growth EC_{50}.

The approach is the same as that described for risk to fish.

c. Fish and Aquatic Invertebrate Chronic Risk

In order to assess the chronic risk of a proposed pesticide use to fish, the following biological response data are used:

- Fish (early life-stage or life-cycle) effect level, NOEL, or MATC;
- Aquatic Invertebrate Effect Level and NOEL; and
- Fish/Aquatic Invertebrate Bioconcentration Factor and Depuration Rate.

If the EEC is less than or equal to the chronic no observable effect levels for fish and aquatic invertebrates (see Table 1), then EEB presumes no chronic risk to fish and aquatic invertebrates. If the pesticide use causes significant adverse effects on the physiology, growth, population levels or reproductive rates, as indicated in laboratory tests and confirmed in field tests, or the EEC is equal to or greater than a level which results in significant chronic effects on aquatic non-target populations, then the presumption is that the chronic risk from the use of the pesticide is significant. At times labeled use restrictions such as "Do not use in the following counties/states ... " and "This is a Restricted Use Pesticide" may mitigate the presumed chronic risk. Although there have been few documented population reductions due to chronic pesticide effects (e.g., reproduction impairment), one of particular note was reported during the EPA Cancellation hearings for DDT.

> Evidence presented in the hearings indicated that DDT was responsible for the death of lake trout fry hatched from eggs taken from Lake George, a tributary of Lake Champlain. It has also been implicated in excessive mortality of Lake Michigan coho salmon fry, and salmon eggs from a Maine lake exhibited lowered hatchability when DDT levels reached 3 ppm in the eggs. In 1969, residues of DDT in sea trout in the Laguna Madre (Texas) were correlated with residues in menhaden, a major food of the trout. Reproductive impairment had been observed since 1964 as evidenced by a decline from 30 to 0.2 juvenile trout per acre. After residues in menhaden declined, the sea trout populations returned to 1964 levels. (See EPA-540/1-75-022.)

7. Endangered Species

The above discussion on the aquatic risk assessment procedures did not specifically address risks to endangered species. This is a normal component of the review, and the approaches to assessing risk are identical except for two items: (a) the risk criteria, and (b) consultation with USDI, Office of Endangered Species (see Attachment H).

a. Endangered Species Risk Criteria

More stringent criteria are used in the risk assessment for endangered species in order to provide greater protection to populations of aquatic organisms already severely reduced to levels where their survival as a species is questionable. The criteria were developed to provide an estimate of a no-effect-level or at least a minimal-effect-level based on the data provided for non-endangered species. If the EEC is less than 1/10th the lowest aquatic acute LC_{10} (when a slope is available) or less than 1/20th the lowest aquatic LC_{50} (when no slope is available) or less than the lowest aquatic chronic no-effect-level, then EEB presumes that there will be minimal risk to endangered aquatic organisms from the use of the pesticide. If, however, the EEC is greater than the levels set by the above criteria, then EEB presumes that there will be a risk to aquatic endangered species and, thus, a formal consultation with OES is initiated.

b. OES Formal Consultation

This communication is needed to elicit written opinion from OES concerning our presumed risk, the extent of the risk, and whether labeling can mitigate the risk. It is typically requested after an informal consultation with the U.S. Fish and Wildlife Service (USFWS) or National Marine Fisheries Service (NMFS) personnel is made and takes the form of a written communication between EEB and USFWS or NMFS personnel. Specifically, the request is in the form of a letter from the Chief of EEB to the NMFS or the region of the USFWS where the effects may occur. If more than one region is involved, EEB contacts USFWS Headquarters in Washington, D.C., to arrange for one of the regions to receive the request for formal consultation and to contact the other regions.

EEB provides information to the USFWS or NMFS to allow them to determine if jeopardy may occur to endangered species from the proposed use. At a minimum the following information is included, either in the letter or as an addendum:

- Chemcial name;
- Type of pesticide (insecticide, herbicide, etc.);
- Proposed use(s) of the pesticide (e.g., crop/site, label use rates, methods of application, geographical location of proposed use site);
- Toxicity data of the pesticide (only valid data are included;

- Exposure information (exposure levels for environmental compartments applicable to each toxicity category value provided in (d) are presented);
- Environmental fate data; and
- A discussion of the potential hazards (a list of the endangered species EEB has identified as possibly affected is included).

When the USFWS or NMFS Biological Opinion is received, EEB determines, based on the recommendations in the Opinion, the appropriate course of action. If the Opinion concludes jeopardy, the viable options are:

- Label restrictions designed to eliminate risk to endangered species;
- Recommendation against registration of the pesticide; or
- Further contact with the USFWS or NMFS for clarification if there appears to be an inconsistency in the Biological Opinion.

Also, if EEB disagrees with the Opinion, then EEB reinitiates consultation with the USFWS or NMFS providing documentation to support its position.

B. Terrestrial Risk Assessment

1. Introduction

The terrestrial risk assessment involves an examination of the potential hazards of proposed pesticide uses to non-target mammalian and avian wildlife. Mammalian and avian wildlife are given more emphasis in the assessment, primarily, because of two factors: (1) established protocols for toxicity testing exist for certain mammalian and avian species; and (2) mammals and birds are usually the organisms of greatest economic value, if lost or harmed, because they generally constitute the "game species" of local, state, and federal governments or agencies. However, two items must also be considered: (1) it is assumed that when birds and mammals are "protected" via the risk criteria of the assessment, some "protection" is afforded reptiles and amphibians by these same criteria; (2) as the state-of-the-art of toxicity testing develops, other organisms, such as reptiles and amphibians, can be considered more accurately in the risk assessment process. Non-target insects will be considered in a later section of this report.

2. Indicator Species/Test Species

The avian indicator organisms used in the terrestrial toxicity tests are usually the bobwhite quail, ring-necked pheasant, and mallard duck. The mammals most often used are domestic ones (e.g., laboratory rat) and are those utilized in the human risk assessment process. As needed, certain non-domestic mammals are used, generally those representative of areas where pesticide applications are likely to occur. Also, avian organisms such as red-winged blackbirds, starlings, mourning doves, sparrows, and Canada geese are also used depending on use site and pesticide application.

3. Terrestrial Residues

The estimated terrestrial residue profile developed for pesticides is based primarily upon the works of Hoerger and Kenaga (1972) and Kenaga (1973). In the earlier article the authors examined the residue levels from literature sources and tolerance data of twenty-eight different pesticides in or on sixty crops (totaling more than two hundred and fifty different pesticide crop combinations) at various time intervals after application. (For the pesticides and plant categories considered in this publication see Attachment I.) From these levels Hoerger and Kenaga developed maximum expected residue levels and typical limit residue values (apparently, mean values) for the time period immediately after application (see Table 5). From their findings EPA staff developed a criteria paper and nomograph (see Attachment J) for use within the Agency. Therefore, it should be noted that the resultant residue profile for pesticides in or on vegetative and/or invertebrate (insect) surfaces now in use within EEB represents a maximum expected residue profile for day zero of application (i.e., immediately after application). This approach, though empirical, is considered reasonable since: (a) in most instances pertinent residue data (particularly, for insects) are not available to EPA; (b) the residue values of Hoerger and Kenaga (1972) appear to correlate well with those of other researchers; (c) the pesticides/crops considered by Hoerger and Kenaga (1972) cover the major classes of pesticides and the crops on which they are used typically (see Attachment I); and (d) whenever possible, this approach is coupled with an examination of the pesticide registrant's residue data.[2/]

2/ The Agency utilizes a registrant's residue data when said data pertains to levels in or on feed items likely to be consumed by non-target organisms.

Table 5. Maximum Expected Residues and Typical Residues of Pesticides on Differing Categories of Vegetation Types (from Hoerger and Kenaga, 1972)

ppm Residue on the Basis of a Pesticide Dosage of 1 lb Per Acre

Plant Category	Immediately After Application		6 Weeks After Application	
	Upper Limit	Typical Limit	Upper Limit	Typical Limit
Range Grass	240	125	30	5
Grass	110	92	20	1-5
Leaves and Leafy Crops	125	35	20	< 1
Forage Crops	58	33	1.0	< 1
Pods Containing Seeds	12	3	1.5	< 1.0
Grain	10	3	1.5	< 1.0
Fruit	7	1.5	1.5	< 0.2

Concerning the estimated residues likely to be found in or on insects, EEB utilizes the approach proposed by Kenaga (1973). In his article Kenaga states that residues on insects can be estimated from residue data for plants with a similar surface area-to-mass ratio as the insects in question. He indicates that for small insects the residue data available for dense foliage situations (alfalfa, clover, trefoil: 1.0 lb active ingredient per acre corresponds to a maximum expected residue of 58 ppm) are relevant whereas for large insects the data for seeds and pods (1.0 lb active ingredient per acre corresponds to maximum expected residues of 10 to 12 ppm) are pertinent. EEB finds this approach reasonable, particularly since: (a) insect residue data are lacking for most pesticides; (b) insects constitute a major portion of the diet of certain non-target organisms and, therefore, should be considered in a non-target organism hazard evaluation; and (c) certain residue data for insects presented by other researchers support Kenaga's proposal. For example, McEwen, et al., (1972) found that 0.25 lb active ingredient Guthion per acre sprayed ultra low volume (ULV) to control grasshoppers resulted in a residue of 14 ppm Guthion in grasshoppers on the day of application, and this correlates with 56 ppm Guthion RUD (Residue from a Unit Dosage).3/

In another spray program involving Toxaphene to control range caterpillars, these same researchers found a range of 7.2 to 34 ppm Toxaphene in range caterpillars from an application rate of 1.0 lb active ingredient Toxaphene per acre (or RUD). These results, therefore, tend to support Kenaga's hypothesis regarding foliar/insect residue correlations (10 ppm for large insects/seeds, pods, fruit and 58 ppm for small insects/dense foliage).

Whenever possible, EEB utilizes actual residue data as supplied by the registrant or found in the literature. Often such data are lacking, particularly, residues in or on non-target organism food items such as insects, other invertebrates, seeds, pods or nuts.

4. Risk Assessment

The next step is to determine the likelihood of exposure and hazards by correlating the information on residues, food

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3/ Hoerger and Kenaga (1972) define RUD as "Residue from a Unit Dosage" or:

$$\text{RUD} = \frac{\text{actual residue}}{\text{treatment rate}} = \frac{\text{ppm}}{\text{lb pesticide/A}}$$

items consumed, and wildlife utilization of crop areas with the toxicity data available for mammalian and avian species. The terrestrial toxicity data usually available for assessment are as follows:

TIER 1

1. The mammalian toxicity data submitted in support of (human) toxicology data requirements (e.g., rat acute oral LD_{50}; acute dermal toxicity; 90-day feeding studies -- rodent and non-rodent);

2. Avian acute oral LD_{50} (upland gamebird or water fowl species);

3. Avian dietary LC_{50} (upland gamebird); and

4. Avian dietary LD_{50} (upland gamebird);

TIER 2

5. Wild mammal toxicity data (generally, an acute oral LD_{50} study);

6. Avian reproductive studies (upland gamebird or water fowl species); and

7. Special studies with avian or mammalian species (e.g., non-target mammalian reproduction studies, avian acute dermal LD_{50}, avian cholinesterase test, avian or mammalian secondary toxicity);

TIERS 3 and 4

8. Simulated and actual field testing with avian and/or mammalian species.

With these data EEB correlates the estimated residues in or on mammalian and avian food items the number of granules likely to be ingested, or the quantity of pesticide which may directly contact non-target organisms and develops estimates concerning potential risks. The various approaches which can be taken are discussed below.

a. Mammalian Species

(1) Acute Risks

In assessing the acute hazards of pesticide uses to non-target mammals, the EEB typically utilizes the data from mammalian (human) toxicity studies, wild mammal LD_{50} studies, simulated and actual field testing with mammalian species, or special studies with mammalian species. In most risk assessments, though, the

laboratory rat acute oral LD_{50} is exclusively used. EEB correlates these data with maximum expected numbers of granules, numbers of seeds, numbers of baits, or vegetative/insect residues to obtain estimates of hazard. Table 6, for example, provides the typical approach for determining granular, seed, or bait hazards. Typically, rat LD_{50} data on the technical grade of the active ingredient are available. These data are converted first to an LD_{50} based on active ingredients (ai) relative to the animal's body weight (see columns 1 through 4, Table 6). This LD_{50} is then used to develop the lethal amount of product (usually a formulation of lesser percent active ingredient than technical grade) estimated to produce such an LD_{50} (see column 5, Table 6). Then the quantity of pesticide product available to the organism (represented as milligrams, baits, granules, or seeds) is generated using the application rate(s) and use site information. The calculations typically address a one square foot area, but daily feed consumption values and estimates of the multiples of lethal dose which may be consumed daily also provide a perspective to the potential risk picture (see columns 6 through 10, Table 6). (It should be noted however, that granular hazards to mammals should, in most cases, be minimal, especially considering the greater hazards for avian species. Theoretically, such risks are possible, particularly for small mammals such as insectivores which may accidentally ingest granules directly or granules that may adhere to earthworms or soil insects). As can be seen, the final analysis correlates the quantity of product, seeds, baits or granules available in a square foot (i.e., 52.11 baits, seeds, or granules) with the amount of product, seeds, baits or granules needed to produce an LD_{50} on a per animal body weight basis (i.e., 20 baits, seeds, or granules).

These LD_{50}/seed, bait, granular correlations can be carried further as shown in Table 7. This attachment presents a species sensitivity profile (a subject discussed in more detail under avian species) which points out that smaller mammals, simply based on body weight comparisons, require ingestion of fewer granules than larger mammals to reach an LD_{50}. For example, a 20-day-old eastern cottontail theoretically has to ingest 91.3 granules of a 10G (10% ai granular) formulation to reach an LD_{50}. An adult cottontail, however, needs to ingest 1,182 granules of the same 10G formulation.

Correlation of acute mammalian toxicity data with estimated or actual residues is usually performed as shown in Table 8. The rat LD_{50} data must first be converted to an LC_{50} value based upon the relationship from Lehman (1959), and once this is done, the correlation of converted LC_{50} and residue data can be made. For example, if the rat LD_{50}, body weight, and food consumption values are 100 mg/kg ai, 0.40 kg, and 0.02 kg, respectively, the following relationship exists:

Table 6. Mammalian Toxicity/Use Rate Correlation: 10% ai Granular Formulation Applied at 1 lb ai/A

(1) Organism	(2) Body Weight	(3) LD_{50} (mg/kg ai)	(4) LD_{50} (mg/animal ai)1/	(5) Lethal Amount of Product to Produce LD_{50}/Animal2/
Rat	0.4 kg	10 mg/kg	4 mg/animal	40 mg

(6) Quantity of Product Sq. Ft.	(7) Lethal Number of Baits, Seeds or Granules/Animal4/	(8) Number of Baits, Seeds, or Granules/Sq. Ft.5/	(9) Daily Feed Consumption	(10) Multiples of Lethal Dose Which May Be Consumed Daily6/
104.22 mg	20	52.11	20,000 mg	500X

1/ 10 mg/kg ai x 0.4 kg = 4 mg ai/animal.

2/ (4 mg/animal)/(10% product) = 40 mg product.

3/ (1 lb ai/A)/(10% product) = 10 lb product/A
(10 lb prod/A) x (454,000 mg/1 lb) = 4,540,000 mg prod/A
(4,540,000 mg prod/A)/(43,560 ft^2/A) = 104.22 mg/ft^2

4/ (40 mg lethal amt. of prod.)/(2 mg granule, seed, or bait weight) = 20 granules, seeds, or baits

5/ (104.22 mg prod./ft^2)/(2 mgs granule, seed, or bait weight) = 52.11 granules, seeds, or baits/ft^2

6/ (20,000 mg food cons.)/(40 mg lethal amount prod.) = 500X.

Table 7. Mammalian Species Sensitivity Profile 1/

Pesticide 10G (10% ai)/15G (15% ai)
Hazard to Four Species of Non-Target Mammals

Species	Body Weight (g)	Mg/2/ Animal (g)3/	Number of Granules Equal to LD_{50} 4/ 10G	LD_{50} 4/ 15G	1/5th LD_{50} 5/ 10G	1/5th LD_{50} 5/ 15G
Rat	200	2.0	215.0	142.8	43.0	28.5
Eastern Cottontail (Adult)	1100	11.0	1,182.0	785.7	236.5	157.1
Weaned Young 20 days old	85	0.85	91.3	60.7	18.2	12.1
Grey Squirrel (Adult-Female)	520	5.2	559.1	371.4	111.8	74.2
Weaned Young 10 weeks old	200	2.0	215.0	142.8	43.0	28.5
Delmarva Fox 6/ Squirrel (Adult-Female)	795	7.95	816.1	567.8	163.2	113.5
Weaned Young 8-10 weeks old	454	4.54	483.8	324.2	96.7	64.8

1/ Utilizing rat LD_{50} of 10 mg/kg ai from empirical data

2/ Weight of one 15G granule = 0.093 mg
Weight of one 10G granule = estimated to be same as 15G granule
Weight of pesticide in one granule:
0.093 mg x 15% = 0.0139 mg ai/granule
0.093 mg x 10% = 0.0093 mg ai/granule

3/ Rat LD_{50} = 10 mg/kg ai
10 mg/kg ai x 0.2 kg body wt. = 2 mg ai/animal
(LD_{50} for Rat on per body wt. basis)
All other values in this column based on the assumption that each organism has the same sensitivity as the rat (i.e., LD_{50} for each organism is 10 mg/kg ai)

4/ Number of 15G granules required to equal LD_{50} = $\frac{2 \text{ mg ai/animal}}{0.014 \text{ mg ai/granule}}$ = 142.8 granules

5/ 1/5th the LD_{50} = restricted use classification trigger (see Table

6/ Weight data obtained via personal communication with Gary Taylor and Dr. Vagan Flyger of the Delmarva Fox Squirrel Recovery Team

Table 8. Mammalian Food Factor/Residue Calculations

Diet Types	Residue Contamination of Diet (ppm) (From Kenaga, 1973)		Food Consumed By Organism (Hypothetical)		Maximum Adjusted Residues (ppm)		Total Dietary Residues (ppm)
Dense foliage	58 ppm	x	100%	=	58 ppm	=	58 ppm
Small insects and	58 ppm	x	50%	=	29 ppm		
Seeds	10 ppm	x	50%	=	5 ppm	=	34 ppm
Seeds	10 ppm	x	100%	=	10 ppm	=	10 ppm

Summary:

Organism	LD_{50} (mg/kg/ai)	Estimated LC_{50} (ppm ai)	Diet Situation	Total Dietary Residue (ppm)
Rat	100 mg/kg	2000 ppm	100% dense foliage	58 ppm
Same	Same	Same	50% small insects 50% seeds	34 ppm
Same	Same	Same	100% seeds	10 ppm

$$\frac{\text{food consumption (kg)}}{\text{body weight (kg)}} \times \frac{\text{residue (mg)}}{\text{food (kg)}} = \text{mg/kg/day}$$

Using this relationship, the reviewer can develop a theoretical LC_{50} for the rate of 2000 ppm ai and then correlate this value with residues estimated to be on available food items (in some cases, however, actual LC_{50} data are available (McCann, et al., 1981), but these are rare since the requirement for such testing has not been developed. An excellent discussion of this approach, including an examination of the use of converted LC_{50}s as opposed to actual LC_{50}s, is presented in the reference just cited. It shows the problems encountered when utilizing LD_{50} toxicity data and residue data in the estimation of hazards. In this paper it shows that out of 17 chemicals tested only one (EPN) had a converted LC_{50} value (660 ppm) similar to an actual dietary LC_{50} value (603 ppm). Further, it points out that different hazard decisions were reached 35 percent of the time when the converted LC_{50} values and the actual LC_{50} values were compared (McCann, et al., 1981).

It should be noted in Table 8 that food factors are briefly discussed. A more lengthy discussion is presented below under the avian species risk discussion, but it should be recognized that for mammalian organisms food factors typically have not been used in EEB. One possible reason for this is that the main body of mammalian data used concerns rodents. Rodents, at least the smaller ones (and these are the ones for which the greater pesticide hazard may exist), are primarily vegetarian (Martin, et al., 1951). Thus, the food factor for small rodents usually has been treated as 100% (i.e., 100% of the organism's total diet is contaminated with pesticide; see Table 8). Also, a species sensitivity profile (as developed in Table 7) was not developed in Table 8. This is because a lengthy discussion of such a profile (when utilizing LC_{50} data) is presented in the avian species section.

Other approaches to a determination of acute mammalian hazards are possible but in most instances these have not been utilized in EEB. Mammalian dermal LD_{50} data have been utilized for an assessment of acute dermal risks by correlating the dermal LD_{50}, adjusted to a per animal body weight basis (as shown in Table 7 using acute oral LD_{50} data), with the estimated quantity of pesticide per square foot (usually mg ai/ft^2 as shown in Table 6). Some pesticide studies with penned rabbits (to determine dietary as well as dermal hazards) have been performed, but these are not common. Development of other mammalian risk assessment techniques has been minimal, possibly due to a lack of acceptable protocols or an apparent lack of field mortality (with the exception of certain pesticides).

Special mammalian studies to assess acute risks are not commonly used by EEB. However, special tests, which are usually modifications of existing protocols (e.g., extending the observation period in LD_{50} studies performed with anti-coagulant rodenticides), have been utilized for rodenticides and predacides, but only on a case-by-case basis.

(2) Subchronic/Chronic Risks

The assessment of subchronic or chronic hazards to mammals correlates the available data from the mammalian toxicity data submitted in support of human toxicity data requirements (e.g., 90-day feeding, chronic feeding, oncogenicity, or reproductive studies) and any other pertinent effects data (such as avian reproduction effects data), with estimated or actual field residues data. Such a correlation usually integrates the available no-effect-levels (NELs) and/or effect levels with the residues in question. The weakest link in this process, however, is the accurate determination of residues, particularly their extent and duration. In most instances, field dissipation data, especially for residues in or on pertinent mammalian food items, are not available. Such dissipation data usually concern residues in soil, water, and in or on crop parts intended for human consumption.

It should be noted that, at least historically, few risk assessments have been performed that address subchronic or chronic adverse effects to non-target mammals. The emphasis in this area of terrestrial effects has been on avian species. The reasons for this are, possibly, that: (1) there is a general lack of field evidence concerning chronic adverse effects to mammalian wildlife from long-term exposure to pesticides; and (2) established protocols which address such effects on non-target mammalian wildlife are not readily available. Zepp and Kirkpatrick (1976) and Gilbertson (1975) are two references where reproductive effects in non-target mammals (i.e., cotton-tails and minks, respectively) are addressed.

(3) Secondary Hazards

The majority of EEB's secondary risk assessment for mammals (and birds) concerns pesticides used to control rodents, carnivores, or other mammalian organisms. These pesticides, generally categorized as rodenticides and predacides, can be divided into three groups: (1) acutely toxic compounds such as 1080, strychnine, and zinc phosphide, (2) first generation anticoagulants, or those compounds which require multiple feedings to produce a toxic effect (e.g., warfarin, diphacinone, and chlorophacinone), and (3) second (sometimes called third) generation anticoagulants -- those

chemicals, which via a single feeding or limited feedings, produce an anticoagulant toxic effect ((e.g., brodifacoum, bromadiolone, and difenacoum) Kaukeinen, 1982; Kaukeinen, 1984). Reviews, therefore, focus on these types of compounds because of their strong potential to produce secondary toxicity and risks. However, the review of secondary toxicity has broadened to include the assessment of the potential secondary hazards associated with the use of other pesticides (e.g., carbamates and organophosphates). This is the result of findings by Balcomb (1983) who concluded that the use of Furadan® 10 granules (10% carbofuran) in a Maryland cornfield resulted in the poisoning (including one death) of several raptors which apparently fed on small mammals or birds that had been killed or immobilized by ingestion of carbofuran granules. Although these findings on secondary toxicity relate to birds, EEB considers such toxicity and risks likely for non-target mammals and birds. Further, the potential for similar effects appears plausible for organophosphates and, possibly, other classes of compounds.

Another aspect of secondary toxicity/risk assessment important to this discussion is that EEB generally recognizes secondary toxicity among organisms higher in the food chain. That is, the branch does not consider mammalian (or avian) effects (including mortality) from the ingestion of pesticide-contaminated invertebrates such as insects as secondary toxicity. The distinction may seem minor, but White, et al., (1979) present the mortality of laughing gull chicks, chicks, from the ingestion of parathion-contaminated insects carried to the chicks by adults, as secondary toxicity. EEB considers this form of toxicity as primary, recognizing, of course, that the actual primary poisoning occurred at the insect level. With prey and predators higher in the food chain (e.g., rodents consumed by owls), however, EEB recognizes toxicity at the predator (owl) level as secondary. The following shows the distinction:

Primary Versus Secondary Toxicity

LEVEL AT WHICH TOXICITY OCCURS		RECOGNIZED TOXICITY/ HAZARD ASSOCIATED WITH (B)
Primary (A)	Secondary (B)	
Insect	Quail	Primary
Insect	Mouse	Primary
Rodent	Owl	Secondary
Rodent	Ferret	Secondary

In performing a secondary risk assessment for non-target mammals, EEB uses the approaches outlined earlier for acute and subchronic/chronic risks, but carries the assessment further by developing a larger toxicity data base, for both primary and secondary (and addressing both acute and chronic) toxicity and risks. For example, a typical review of a rodenticide proposed for use in and around agricultural buildings could include data requirements (for mammals) that address:[4]

- The primary acute toxicity for the target organisms (rodents);
- The primary chronic toxicity for the target organisms (rodents);
- The primary acute toxicity to non-target mammals (e.g., species from several wild mammal families such as felidae, mustelidae, or canidae);
- The primary chronic toxicity (if the rodenticide is persistent in the environment) to non-target mammals (e.g., species from several wild mammal families such as felidae, mustelidae, or canidae);
- The secondary acute (and chronic if the rodenticide is persistent) toxicity to representative species from several wild mammal families such as felidae, mustelidae, or canidae; and
- Residue analyses which address:
  - Levels of toxicant in proposed formulations such as baits;
  - The rate of degradation of toxicant in proposed formulation(s) under typical use conditions;
  - Levels of toxicant in target organisms feeding on the proposed formulations;
  - The rate of depuration for the toxicant after a rodent stops feeding on the proposed formulation(s); and
  - Body residues and rate of depuration for predators feeding on contaminated rodents.

4/ These requirements would be in addition to those determined for avian, aquatic, and, in some cases, reptilian and/or amphibian species.

With these data EEB would attempt to correlate expected environmental and body residues with toxic effect levels found in the toxicity studies. Extrapolation to field situations would be undertaken, but in most cases field studies would be required to determine the primary and secondary toxic effects likely under actual use conditions.

This approach is similar to that presented by Kaukeinen (1982) where he states:

> Parameters associated with such studies include: 1) prey selection, 2) prey intoxication, 3) prey residue determination, 4) prey preparation for predator consumption, 5) presentation, 6) predator selection, 7) predator health and handling, 8) predator captive conditions, 9) predator acclimation, 10) predator intoxication, 11) predator observation and evaluation, 12) pathology and residue analysis.

As the above discussion indicates, EEB's secondary toxicity/risks assessment is a highly complex one -- one in which the toxicity data base analyzed and the number of use/exposure variables and variety of organisms at different trophic levels considered is extensive. Each facet of information is critical, and testing must be pertinent to proposed use situations, for as Savarie, P.J., et al., (1978) and Kaukeinin (1982) point out, extrapolation of laboratory toxicity results to field situations is extremely difficult, if not questionable. Thus, with these types of pesticides (i.e., those exhibiting secondary toxic effects) simulated field and/or actual field testing is normally a requirement. Such field testing is highly complex, expensive, time-consuming, and typically requires the employment of highly trained, experienced personnel. Protocols for such testing are developed on a case-by-case basis and are pertinent to the pesticide, the proposed use situation, and the non-target organisms likely to be exposed and potentially affected. Further, development of such protocols requires close cooperation between registrants and branch personnel. It should also be noted that to date only a minimal number of acceptable field studies for mammalian species have been received. Thus, EEB's efforts are presently directed towards standardization of testing procedures and secondary risk assessment methods.

b. Avian Species

(1) Acute Risks

The use of the avian toxicity data in the assessment of acute risks to avian wildlife is similar to and generally better defined than for mammals. Use of the avian acute oral LD_{50} to assess granular bait or seed risks is undertaken following the procedures outlined in Tables 6 and 7. However, the LD_{50} data can also be used as shown in Table 8 (i.e., conversion to estimated LC_{50}s and correlation of

such LC_{50}s with actual or estimated residues can be made). Usually, though, a species sensitivity profile as shown below (see Table 9) is developed. Then conclusions for potential effects to various non-target avian species can be made.

As an example of the use of the avian acute oral LD_{50}, Table 9 presents the theoretical number of granules (of a hypothetical pesticide) needed to produce an LD_{50} in a variety of bird species. For a house sparrow, a bird one-fifth the size of a mourning dove, only 2.8 15G (15% ai) granules are needed to produce an LD_{50}. The mourning dove, however, requires five times the same amount or approximately 14 granules. The calculations shown are similar to those in Tables 6 and 7. An excellent discussion on this approach is presented in three articles (Balcomb, 1979; Balcomb, 1980; Balcomb, et al., 1984). The first two discuss the Agency's basis for classifying certain granular insecticides as "Restricted" (i.e., for use by certified applicators) based on their toxicity and palatability to avian species, their exposure on soil surface following soil incorporation, and reported bird kills. Of particular interest are the application of Agency risk criteria (i.e., one-fifth the avian LC_{50}) to the data base and calculations which estimate the number of granules required to produce an avian LD_{50} from available toxicity data (Balcomb, 1979; Balcomb, 1980). The third paper further examines the use of LD_{50}/granule toxicity data by correlating field effects data with laboratory toxicity data. For example, by the use of the acute oral LD_{50} granule data and the observed field effects information, the researchers concluded that almost any ingestion of the granular pesticide studied (carbofuran) by smaller bird species may be fatal. Larger species, however, might survive because of the increased quantity of carbofuran needed to cause mortality and the reversible nature of carbamate poisoning (Balcomb, et al., 1984).

When using avian LC_{50} data from avian dietary studies, EEB typically makes a direct comparison of the LC_{50} value with actual or estimated residue levels developed from Kenaga (1973). For example, if the bobwhite quail LC_{50} were 50 ppm ai and the maximum expected residues in or on seeds were 10-12 ppm ai from a 1 lb ai/A application, then the 50 ppm LC_{50} value (or one-fifth the LC_{50} value (10 ppm) (the hazard criterion which theoretically approaches the no-effect-level (0.1-10% depending on the dose-response data): see FR 40(129): 28261; July 3, 1975) is compared with the 10-12 ppm ai maximum expected residue. This approach, of course, is based on the assumption that all, or 100%, of the quail's diet is seeds and the total diet is contaminated with the pesticide in question.

Table 9. Avian Species Sensitivity Profile To A Hypothetical Pesticide 1/

Pesticide 10G (10% ai)/15G (15% ai)
Hazard to Seven Species of Non-Target Birds

Species	Body Weight (g)	Mg/2/ Animal (g)3/	Number of Granules Equal to LD50 4/ 15G	LD50 4/ 10G	1/5th LD50 5/ 15G	1/5th LD50 5/ 10G
Bobwhite (adult)	200	0.40	4.3	6.4	0.9	1.3
Bobwhite (14-day)	30	0.06	0.6	1.0	0.1	0.2
Robin	80	0.16	1.7	2.6	0.3	0.5
Mourning Dove	100	0.20	2.2	3.2	0.4	0.6
House Sparrow	20	0.04	0.4	0.6	0.1	0.1
Redwing Blackbird	50	0.10	1.1	1.6	0.2	0 3
Grasshopper Sparrow	13.9	0.027	0.3	0.4	0.1	0.1
Attwater's 6/ Prairie Chicken (adult)	1000	2.00	21.5	32.3	4.3	6.5
Prairie Chicken (14-day)	50	0.10	7.1	1.6	0.2	0.3

1/ Utilizing Bobwhite Quail LD_{50} of 2 mg/kg (15G) or 0.3 mg/kg (converted to ai)

2/ Weight of one 15G granule = 0.093 mg
Weight of one 10G granule = estimated to be same as 15G granule
Weight of pesticide in one granule:
= 0.093 x 15% = 0.0139 mg ai/granule.
= 0.093 x 10% = 0.0093 mg ai/granule.

3/ Bobwhite quail LD_{50} = 2 mg/kg (15G) = 0.3 mg/kg ai
2 mg/kg (15G) x .2 kg = body wt. = .4 mg/animal (15G)
(LD_{50} for 15G to bobwhite quail on per body wt. basis)
All other values in this column based on the assumption that each organism has the same sensitivity as the bobwhite quail (i.e., LD_{50} for each organism is 2 mg/kg (15G))

4/ Number of 15G granules required to equal LD_{50} $= \frac{0.4 \text{ mg/animal}}{0.093 \text{ granule wt.}} = 4.3$

Or

LD_{50} = 2 mg/kg (15G) x 15% = 0.3 mg/kg ai
.2 kg x 2 mg/kg = 0.4 mg/animal (15G)
.2 kg x 0.3 mg/kg ai = 0.06 mg/animal ai

$$\frac{\frac{0.06 \text{ mg/animal ai}}{15\%}}{.093 \text{ mg granule wt.}} = \frac{0.06 \text{ mg/animal ai}}{(15\%)\ (.093)} = 4.3 \text{ granules}$$

5/ 1/5th LD_{50} = restricted use classification trigger (see Table 1)

6/ Weight data obtained via personal communication with Wayne Shifflet, Refuge Manager, Attwater's Prairie Chicken Refuge, Aransas, TX

Another approach utilizing the avian LC_{50} data considers species sensitivity and food factors. This approach develops the potential acute avian risks for various species via dietary exposure and incorporates the food consumption habits (based on summer diets) of each species. In Table 10 the theoretical LC_{50} values of three species are calculated from the LC_{50} value for the adult bobwhite quail. These values are developed based upon the assumption that each species has the same sensitivity to a hypothetical pesticide as the adult bobwhite quail (i.e., the daily intake which will produce 50% mortality is 2.68 mg/kg/day).

This approach is similar to that used in human risk assessments (see Attachment K) and the one proposed by Kenaga (1973) for birds. For use with avian species Kenaga (1973) indicated that:

(a) The classical approach in animal toxicological research is to determine the average daily intake of a toxicant which can be consumed by an organism without adverse effect(s). This quantity of toxicant consumed is commonly expressed as "milligrams of toxicant consumed per kilogram of body weight of the organism per day" or mg/kg/day.

(b) The mg/kg/day data (from the dietary LC_{50} study) for a particular avian species can be correlated with the feed consumption/body weight data of another avian species to predict a safe dietary (or residue level) of the pesticide to that species. And after these correlations are made, then residue levels in the field (i.e., in or on feed items) can be compared to the safe levels determined for each species.

EEB uses this approach to address the potential acute hazards of a pesticide use to those avian species likely to be exposed (by typically extrapolating from the bobwhite quail). However, in utilizing the mg/kg/day data, as proposed in (b) above and as shown in Attachment K (where a NOEL dietary level for humans -- 0.1 mg/kg/day or 6 mg/person/day or 4 ppm -- is determined from a rat NOEL dietary level 10 mg/kg/day or 4 mg/animal/day or 200 ppm), EEB chose to predict a toxic (or theoretical LC_{50}) dietary level of a pesticide for avian species rather than a "safe" NEL or NOELs. Table 10 presents this approach, and as indicated above, the initial assumption is that the species considered will have the same sensitivity to a pesticide via dietary exposure as bobwhite quail.

Table 10. Avian Species Sensitivity to A Hypothetical Pesticide and Use of Food Factors[1/]

Species[2/]	Body Weight (gms)	Food Cons. (gms)	F. Cons./B.Wgt. (%)	Calculated LC_{50} (ppm)[3/]	Toxicant mg/kg/day	Consumed mg/animal/day
1. Bobwhite Quail	170.00	15.20	8.94	30.00	2.68	0.46
2. Mourning Dove	100.00	11.20	11.20	23.93	2.68	0.27
3. Field Sparrow	13.90	4.65	33.45	8.01	2.68	0.04
4. Carolina Wren	19.00	6.53[4/]	34.37[4/]	7.80	2.68	0.05

1/ All of the calculations for calculated LC_{50} (ppm), except for 30 ppm which is the reference LC_{50}, are based upon the assumption that each species has the same sensitivity to a hypothetical pesticide as bobwhite quail (i.e., the daily intake which will produce 50 percent mortality is 2.68 mg/kg/day; see Kenaga (1972 and 1973)).

2/ All species considered are adult organisms, and the body weight and food consumption values are from Kenaga (1973), Nice (1938), and USDI, USFWS, Circular 199, 1964.

3/ These are the theoretical dietary levels which should cause 50 percent mortality (LC_{50}) using the assumption stated in (1) above (See Kenaga (1972 and 1973)). The procedure used is:

$$\frac{\text{Food Consumption}}{\text{Body Weight}} (\%) \times \text{Toxicant Residue Level} (\text{ppm}) = \text{Toxicant (mg/kg) Body Weight/Day}$$

4/ The food consumption value and, consequently, the food consumption/body weight (as %) value were developed from Kenaga (1973). In this article the food consumption values for a 19.0 gm tree sparrow (Spizella arborea) are given as 7.11 and 5.95 gm, the x equaling 6.53 gm. This value is considered suitable for use with the Carolina wren's body weight of 19.0 gm (from Nice (1938)).

Theoretical (or calculated) LC_{50} values are then developed for the other species by use of Lehman's (1959) relationship for ppm and mg/kg/day.[5/] As can be seen, this procedure is the same recommended by Kenaga (1973) and used by toxicologists for human risk assessments. The only difference is that effect levels (LC_{50} values) are utilized in EEB's approach whereas NOELs, NELs, or safe levels are used in the other.

Once species sensitivity is established then the next step, using appropriate food factors, is to correlate actual or expected residues with the theoretical LC_{50}s. Table 11 presents the food factor calculations and the correlation of total adjusted residues with the theoretical LC_{50} values. This approach may appear cumbersome, but it does emphasize that, even from one application rate, different exposures and different potential hazards exist for organisms with different body weights, food consumption rates, and/or feeding patterns. A case in point is the LC_{50} and total adjusted residue values (see Tables 10 and 11) for the carolina wren. Because of its relatively large food consumption in relation to body size, the theoretical LC_{50} value calculated is 7.80 ppm, a value approximately one-fourth the LC_{50} value of 30.00 ppm for the reference organism, bobwhite quail. Further, the relative hazard from residues in or on food items appears much greater, primarily due to the wren's large consumption of small insects. The bobwhite quail, however, has a lower dietary residue due to its greater consumption of plant matter.

Relative to the above discussion on species sensitivity, it is recognized that the approach is a theoretical one -- one used to estimate potential acute hazards to non-target avian species. It is considered a logical one, however, for a one-to-one sensitivity ratio is being utilized between organisms of similar size and food habits and with similar chances for exposure to the pesticide. Some of the avian research done to date indicates that all possible variations in species and/or age sensitivity occur from exposure to the same or similar pesticides (Friend and Trainer, 1974; Hudson, et al., 1972; Tucker and Haegele, 1971; Schafer, 1972). Other avian research, however, indicates that although such variations in species sensitivity to chemicals can occur, smaller species are generally more sensitive to toxicants than larger species (Hill, et al., 1975).[6/] These latter findings are supported further by the research of Hill (1971). Hill examined the toxicity of four

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5/ See Table 10, footnote 3.

6/ Note that this research represents approximately ten years of testing with an examination of greater than 130 compounds, of which 39 were organophosphates.

Table 11. Avian Species/Toxicity/Residue Correlations for a Hypothetical Pesticide

Species	Calculated LC_{50} (ppm) 1/	Food Consumed (%) 2/ Animal	Food Consumed (%) 2/ Plant	Maximum Expected Residues 3/ Animal	Maximum Expected Residues 3/ Plant	Maximum Adjusted Residues 4/ Animal	Maximum Adjusted Residues 4/ Plant	Total Residues (ppm) 5/ For Both Animal and Plant
1. Bobwhite Quail	30.00	27% Beetles, Weevils, Grasshoppers, etc.	73% Seeds: Ragweed, Lespedeza, Corn, etc.	58.0 ppm	10.0 ppm	15.7 ppm	7.3 ppm	23 ppm
2. Mourning Dove	23.93	0%	100% Seeds: Corn, Pigweed, etc.	0.0 ppm	10.0 ppm	0.0 ppm	10 ppm	10 ppm
3. Field Sparrow	8.01	51% Beetles, Grass-hoppers, Caterpil-lars, etc.	49% Seeds: Crabgrass, Bristle-grass, Panic-grass, etc.	58.0 ppm	10.0 ppm	29.6 ppm	4.9 ppm	34.5 ppm
4. Carolina Wren	7.80	99% Ants, Flies Milli-pedes, etc.	1% Seeds: Poison Ivy, Pine, Oaks, etc.	58.0 ppm	10.0 ppm	57.4 ppm	0.1 ppm	57.5 ppm

1/ Refer to Table 12 for an explanation of how the "calculated LC_{50}" values were obtained.
2/ This information is taken from: Martin, Alexander C., et al. (1951)
3/ Based upon 1.0 lb active ingredient per acre application to expected food items using following references:
a. Hoerger and Kenaga (1972)
b. Kenaga (1973)
c. Kenaga (1972)
4/ Residue values adjusted to reflect % animal/plant matter consumed.
Example: Bobwhite Quail: 58 ppm x 0.27 (27%) = 15.7 ppm
10 ppm x 0.73 (73%) = 7.3 ppm
5/ Reflects total residues expected in the diet: animal or plant alone or a total of animal and plant food items.
Example: Mourning Dove: 10 ppm total expected in food items consumed (i.e., 1.00 (100%) x 10 ppm = 10 ppm).

mosquito larvicides to blue jays, house sparrows, cardinals, wild bobwhites, and to farm-reared bobwhites in dietary LC_{50} studies. His results suggest that the larger species were more tolerant to the pesticides than the smaller ones.[7/]

Further, the farm-reared bobwhites were not only heavier than wild-captured ones but also were more tolerant to several of the pesticides because of their larger size. Therefore, relative to these two bodies of research, it can be seen that a one-to-one sensitivity ratio approach is not biased one way or the other, but gives EEB an opportunity to observe on paper the potential risks of different dietary residues to different species of birds.

Other avian data, such as simulated and actual field testing and special studies to assess acute avian risks, are also used. Simulated and actual field testing or monitoring, plus available field mortality data, are routinely utilized by EEB. In these situations, the known rates, available (or estimated) residue data, and observed effects (toxicological symptoms, as well as mortality) are all integrated. Usually, for the simulated field testing, brain acetylcholinesterase data are available, and these provide another important clue as to whether exposure actually occurred. As for special studies such as acute dermal LD_{50} or inhalation tests, few have been done or used by EEB in its risk assessments. Dermal and inhalation risks have been tentatively linked to certain carbamates (fenthion and fenitrothion, respectively), and, of course, avicides are well known for their dermal effects to birds.

In those cases where acute or chronic avian data are lacking, then EEB is usually forced to utilize any other available information and, particularly, data for mammals. In doing so, the approaches outlined above for mammals are typically followed.

(2) Subchronic/Chronic Risks

Typically, the assessment of subchronic and/or chronic avian hazards involves the correlation of NELs and effect levels found in the avian reproduction studies with actual or expected residue levels. This process requires a close examination of the avian reproductive data to see which reproductive parameters were most affected and whether such effects are likely in the field. It is a difficult assessment simply because of the number of variables found not only in the studies themselves but also in the field

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7/ Only blue jays were the exception to the size-toxicity relationship, being more sensitive than the other species in almost all of the studies performed.

conditions under which the pesticide will be used. The present laboratory study addresses the effects of chronic low levels of pesticides on eggs, embryos, and hatchlings. Difficulties have arisen with the study's fairly common use in examining organophosphate and carbamate (or other acutely toxic) compounds which break down rapidly, but are repeatedly applied and, therefore, pose a subchronic or chronic hazard to birds. In these instances the main reproductive hazard appears to be mortality to the breeding adults or newly-hatched or young chicks rather than effects on eggs and developing embryos. Also, the laboratory reproductive study has been required more readily for persistent herbicides, but for herbicides which are minimally toxic, on an acute basis, to mammals and birds. In these situations, EEB usually puts greater emphasis on the chronic mammalian data and on requests to the registrants for pertinent residue, including dissipation, data.

Even with the laboratory reproductive study's shortcomings, they are requested and utilized in the review process. At this point, this study is EEB's strongest reference for assessing chronic avian risks. Field studies (large pen) and monitoring are also utilized to a much lesser degree, and the variability in these is even greater, making interpretation of results very difficult. However, the use of avian reproductive studies, whether laboratory or field, is well established and a definite, formalized approach is presented in the Agency's Pesticide Assessment Guidelines - Subdivision E.

Other studies or data utilized by EEB include tests where birds' eggs were sprayed with pesticides. Usually these data are lacking, but the available ones can show the percent hatching success for treated eggs versus controls. However, the use of mammalian data by EEB occurs readily since these data are usually available and, possibly, are the best chronic data available for use.

Probably the weakest point in the chronic avian review is the residue information. As discussed under mammals, pertinent residue, including field dissipation, data usually are lacking, thus forcing EEB to extrapolate and estimate the residues likely to be found over time. Under these conditions, Hoerger and Kenaga's (1972) and Kenaga's (1973) data are of minimal value since the residues presented in these articles primarily concern those found immediately after application of the pesticide.

(3) Secondary Hazards

In assessing the secondary risks of pesticides to non-target avian species EEB takes the same approach outlined earlier for determining secondary risks to non-target mammals. Data requirements, primary risk, secondary risk, and acute and chronic toxicity

concerns for avian species are similar to those for mammals, and the full discussion presented earlier is applicable here. The only major difference concerns those organisms likely to be exposed and those chosen for use in the various toxicity and field tests. EEB normally requires an upland gamebird and a waterfowl species (as indicated earlier under acute risks), but also requires a variety of other avian species depending upon the proposed use in question. Most often, raptors (hawks, eagles, owls, and vultures) are used, particularly in secondary toxicity studies where pesticide contaminated organisms (such as rodents) are fed to the birds. However, free-ranging individuals are utilized in field studies designed to address potential secondary risks under typical pesticide use conditions. Other species utilized in the primary toxicity tests include: crowned guinea fowl, laughing doves, pheasants, geese, horned larks, mourning doves, blackbirds, magpies, pintails, chickens, chukars, sparrows, Gambel's quail, and domestic turkeys (Tietjen, 1976; Atzert, 1971). Of course, EEB requires that testing be done on representatives of wild avian species likely to be exposed under typical use conditions.

With the toxicity data, both laboratory and field, developed on appropriate avian species, the reviewer correlates these data with expected environmental and body residue levels (in target and non-target organisms) to assess the potential impacts. As discussed in the mammals section, these reviews are highly complex and, in most cases, the field effects data provide the major information pertinent to the risk determination. However, these studies are generated on a case-by-case basis, and to date EEB has received a minimal number of adequate field studies for review. Consequently, EEB is working towards standardization of testing methodologies and secondary risk assessment procedures.

5. Risk Criteria

The above discussion on terrestrial hazard assessment procedures did not include an application of risk, regulatory, or safety criteria to the LD_{50} or LC_{50} data presented because these criteria were discussed extensively in earlier sections. Tables 7 and 9 show the use of one of these criteria (1/5th the LD_{50} or LC_{50}), but this criterion is only intended for use with non-endangered wildlife. For endangered wildlife, 1/5th the LD_{10} or LC_{10} (if a slope value is available) or 1/10th the LD_{50} or LC_{50} (when no slope value is present) are used (see Attachment H). Both of these criteria, the nonendangered and endangered, are used by EEB, basically, to determine NELs or levels at which minimal mortality is likely. They were developed over the years to provide consistency and are somewhat supported by LD_{50}/LC_{50} dose-mortality data. Another approach, which is essentially the same as that discussed, consists of an examination of the raw dose-mortality data and the dose-mortality curve in order to calculate a minimal-effect level or NEL.

This level can then be compared with the safety criteria (1/5th LD_{50}/LC_{50}, 1/5th LD_{10}/LC_{10}, or 1/10th LD_{50}/LC_{50}) used. Heath, et al., (1972) provide a formula for this technique but point out that extrapolating from a probit regression line can produce erroneous results, particularly, if there is some curvature to the line.[8/] They indicate that specially designed studies, for example, ones to determine LC_{10}s, are more appropriate. Also, it should be noted that examination of the dosemortality curve along with its correlation with actual or measured residues provides EEB with a better understanding of potential hazards than the mere use of risk criteria and LD_{50}, LC_{50}, LD_{10} or LC_{10} values.

6. Risk Assessment - Non-Target Insects

At present, risk assessment for non-target insects is limited to honey bees. Sections on non-target aquatic insects and on insect predators and parasites in Part 158 are reserved, pending Agency decision as to whether these data requirements should be established.

The first step in risk assessment is to determine whether honey bees will be exposed to the pesticide as a result of the proposed use(s). EEB examines all proposed use situations to make this determination. Generally, bee exposure may occur in two major use areas: foliar application to crops attractive to bees, and adult mosquito control. Because the probability of exposure can usually be determined, the number of uses which require bee testing is narrowed considerably. For example, use of granular formulations and preplant soil applications does not usually result in bees being exposed to the pesticide; thus, no testing would be required in these cases.

If the proposed use will result in bee exposure, the Agency requires data on acute toxicity to honey bees. If acute tests show no or low toxicity, no further testing is normally required. If acute tests show moderate or high toxicity, the Agency requires data on the extent of residual toxicity of the pesticide to honey bees.

On the basis of this information, in conjunction with any other pertinent information, the Agency will do one of two things. If there is any information which indicates properties of the

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8/ The formula presented by Heath, et al., (1972) is:

$$\log LC_K = (5 - \text{probit}^{K})/b - \log LC_{50}$$

with the antilog of $\log LC_K$ the result wanted.

pesticide other than direct toxicity, and which indicates that the pesticide might cause unique problems in honey bees, the Agency may require field testing. This testing would be designed to apply specifically to the potential problem. Normally, however, field testing is not required. In the usual case, the Agency will use the acute and residual toxicity data to determine appropriate bee precaution statements to be placed on the product label.

VI. RISK ASSESSMENT - SHORTCOMINGS AND IMPROVEMENTS

There are a number of weaknesses in EEB's aquatic and terrestrial risk assessments. As mentioned previously, the ratio or quotient method for assessing risk (1) does not adequately account for effects of incremental dosages, (2) does not compensate for differences between laboratory test and field populations, (3) cannot be used for estimating indirect effects of toxicants (e.g., food chain interactions), (4) has an unknown reliability, (5) does not quantify uncertainties, and (6) does not adequately account for other ecosystem effects (e.g., predator-prey relationships, community metabolism, structural shifts). Further, we have no terrestrial exposure model comparable to the aquatic exposure models (e.g., SWRRB/EXAMS). There is no integrated air component to the exposure models, and the simple spray drift models need improvements. The current aquatic exposure models are still being validated by EPA's Office of Research and Development (ORD). Their utility is limited somewhat because they do not provide an estimate of uncertainty of their results. Finally, the risk criteria currently being used by EEB need a stronger empirical data base for support. The data base should consist of laboratory and field effects data.

For 1986 and beyond, EEB is planning to improve in-branch EEC calculations and continue to develop a better understanding of available EEC models. In addition, EEB has taken 3 steps to improve the risk assessment as a whole, and the risk criteria in particular. First, EEB and ORD have initiated an analysis of pertinent in-house and published acute and chronic toxicity data in order to modify the risk criteria. This analysis is based on the relationship between dose/concentration of the pesticide and the response of the test organisms.

Second, ORD has two major research projects that have been designed with EEB's input, to improve the scientific basis for, and the process of, conducting ecological risk assessments. These two projects are titled: Field Validation and Ecological Risk Assessment Research. Under the field validation project, three field and simulated field studies are designed to determine whether EEB's predictions of risk of pesticides to non-target organisms based on our risk criteria are verified in actual field use situ-

ations. The ecological risk assessment project is in the advanced planning stage, and is scheduled to begin in 1986. It is being viewed as a long-term research project (5-10 years). The assessment methodology to be developed will contain many components including data bases, models, and software to coordinate the components. This integrated system will permit problem solving through coordinated access to appropriate computational tools, data bases, and presentation of results. Components that will be contained in the risk system include:

- sets of frequently used environmental scenarios, and a capability to generate new scenarios from large data bases;

- data bases of species, populations, and ecosystems at risk; of environments; of chemical parameters for exposure and toxicity modeling; and of comparative toxicology for prediction effects;

- models of chemical fate to calculate expected residues based on chemical concentration distribution and organism behaviors;

- computational tools for existing specific methods, such as the ratio method;

- several models that compute effects based on susceptibility and exposure, to be used to predict consequences of exposure to toxicants:

  - a steady-state model to calculate ultimate effects of long-term exposure;
  - population-specific models that calculate the effects on populations of particular scenarios of chemical loadings on their environment;
  - models for interacting subsets of biotic communities (predator-prey associations);
  - large ecosystem models that include representations of all major ecological processes for a selected scenario; and

- a probability analysis that estimates probabilities associated with result in two forms: (1) calculated probability values for portions of an analysis for which uncertainties and inherent variation can be quantified and (2) descriptions of the nature of additional uncertainties.

The risk assessment research program described above will provide improved capabilities to calculate risk using existing methods, such as the quotient method or other techniques. The

program proposed ultimately to develop integrated assessment procedures that will predict ecological consequences for many exposure scenarios with an associated evaluation of uncertainty.

Finally, EEB is moving in the direction of testing and evaluating ecosystem response in addition to individual responses of surrogate species. Traditional single-species, clean environment bioassays will still be required (e.g., LC_{50} in fish and LC_{50} in birds) because they provide valuable baseline information for comparative purposes. Working closely with EPA's ORD, the regulated community, and academia, EEB will be developing test methods and analysis schemes that measure ecosystem impact from an integrated, rather than from a single-species viewpoint. When lower tier testing indicates potential risk, small-scale or full-scale field testing will be required of pesticides manufacturers to negate the potential risk. These field tests will not only measure the traditional end points (e.g., mortality), they will also assess impact on populations of organisms and impacts on community structure and function. These complex test requirements will hopefully account for the basic resiliency of healthy ecosystems, identify problems with stressed ecosystems, and help the Agency better understand the ecological risk of the pesticide.

ATTACHMENT A: Final Criteria for Initiation of Special Review

The Administrator may conduct a Special Review of a pesticide use if he determines, based on a validated test or other significant evidence, that the use of the pesticide (taking into account the ingredients, impurities, metabolites, and degradation products of the pesticide):

- May result in residues in the environment of non-target organisms at levels which equal or exceed concentrations acutely or chronically toxic to such organisms, or at levels which produce adverse reproductive effects in such organisms, as determined from tests conducted on representative species or from other appropriate data.

- May pose a risk to the continued existence of any endangered or threatened species designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act of 1973, as amended.

- May result in the destruction or other adverse modification of any habitat designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act as a critical habitat for any endangered or threatened species.

- May otherwise pose a risk to humans or to the environment which is of sufficient magnitude to merit a determination whether the use of the pesticide product offers offsetting social, economic, and environmental benefits that justify initial or continued registration.

Reference: 40 CFR 50 (229): § 154.7 (a)(3), (4), (5), and (6).

ATTACHMENT B: Proposed Restricted Use Criteria for Hazard to Non-Target Organisms

(c)(1) All Products. A pesticide product intended for outdoor use will be considered for restricted use classification if:

(i) When used as according to label directions, application results in residues in the diet of exposed mammalian wildlife, immediately after application, such that:

(A) The level of residues equals or exceeds 1/5th of the acute dietary LC_{50}; or

(B) The amount of pesticide consumed in one feeding day (mg/kg/day) equals or exceeds 1/5th of the mammalian acute oral LD_{50};

(ii) When used according to label directions, application results, immediately after application, in residues in the diet of exposed birds at levels that equal or exceed 1/5th of the avian subacute dietary LC_{50};

(iii) When used according to label directions, application results in residues in water that equal or exceed 1/10th of the acute LC_{50} for non-target aquatic organisms likely to be exposed; or

(iv) Under conditions of label use or widespread and commonly recognized practice, the pesticide may cause discernible adverse effects on non-target organisms, such as significant mortality or effects on the physiology, growth, population levels or reproduction rates of such organisms, resulting from direct or indirect exposure to the product ingredients or residues.

(2) Granular Products. In addition to the criteria of (c)(1) of this section, a pesticide intended for outdoor use and formulated as a granular product will be considered for restricted use classification if:

(i) The formulated product has an acute avian or mammalian oral LD_{50} of 50 mg/kg or less as determined by extrapolation from tests conducted with technical material or directly with the formulated product; and

(ii) It is intended to be applied in such a manner that significant exposure to birds or mammals may occur.

(d) Other Evidence. The Agency may also consider evidence such as field studies, use history, accident data, monitoring data, or other pertinent evidence in deciding whether the product or use may pose a serious hazard to man or the environment that can reasonably be mitigated by restriction to use by certified applicators.

ATTACHMENT C: Model Name: Simulator for Water Resources in Rural Basins

Model Acronym: SWRRB

Type of Model: SWRRB is basically a hydrology model combined with a pesticide runoff model.

Developed by: Agricultural Research Service, Temple TX

Contact: Robert F. Carsel, U.S. EPA Environmental Research Laboratory, Athens, GA

Application: SWRRB is a ~~hybrid~~ pesticide runoff model to predict the concentration of pesticide in the runoff and that available for leaching. The model combines the original Simulator for Water Resources in Rural Basins (SWRRB) model, which is a hydrology model, with a pesticide quantification runoff model. The model utilizes a Soil Conservation Service (SCS) curve number technique with actual daily rainfall data. The model structure is based on the water balance equation, evapotranspiration, percolation, return flow and pesticide function which accounts for the loss of applied pesticide to the atmosphere. The pesticide inputs include soil persistence and partition constants. The model output data predicts daily runoff volume and peak rate, sediment yield, evapotranspiration, percolation, return flow and pesticide concentration in the runoff. There are seventeen river basins data sets based on actual field observations available in SWRRB to predict pesticides behavior.

Model Accessed Through: EPA National Computer Center (NCC)

Status: The SWRRB model has been evaluated by comparison with actual pesticide runoff data from the fields in the basins and with other runoff models. SWRRB predicts quantities of an event very well while prediction of individual event occurrence, as with similar models, is somewhat weak. This latter prediction is not used in the determination of estimated pesticide environmental concentrations.

User's Manual: A manual is available from ERL Athens, GA. It contains both a user's manual and the hydrology information for each basin.

(ATTACHMENT C, CONTINUED)

LIST OF AVAILABLE RIVER BASINS

1. Coshocton, Ohio, 115
2. Coshocton, Ohio, 118
3. Coshocton, Ohio, 129
4. Coshocton, Ohio, 130
5. Riesel, Tx. M, SW-2
6. Riesel, Tx., 1, SW-2
7. Riesel, Tx., 2, Y-6
8. Riesel, Tx., 3, Y-8
9. Riesel, Tx., 4, SW-12
10. Tifton, Ga., Z
11. Vega, Tx., M-W-1
12. Watkinsville, Ga., P-1
13. Watkinsville, Ga., M
14. Watkinsville, Ga., P, P-1
15. Watkinsville, Ga., 2, P-2
16. Yazoo, Mississippi

ATTACHMENT D: Model Name: Exposure Analysis Modeling System

Model Acronym: EXAMS

Type of Model: Hydrologic model to predict "steady-state" or "pulse-load" behavior of organic toxicants in aquatic ecosystems.

Developed by: U.S. EPA Environmental Research Laboratory, Athens, Georgia

Contact: Dr. Lawrence Burns, EPA ERL, Athens, GA

Applications: EXAMS couples the fundamental characteristics of the environment to the physical and chemical properties of the toxicant, using process models (mathematical relationships) appropriate to each aspect of chemical behavior considered by the model. These include an equilibrium partitioning of the chemical into (up to 5) ionic species, each of which may occur as a dissolved, sediment-sorbed, or biosorbed molecule, and a kinetic treatment of volatilization, transport, direct photolysis, hydrolysis (specific acid, base, and neutral), oxidation, and bacterial degradation in the water column and bottom sediments of the ecosystem.

Four general impact environments are available: pond, river, and oligotrophic and eutrophic lakes. Other impact environments may be generated where specific situations are to be analyzed. The environmental parameters are those that have an effect on the pesticide concentration (e.g., volume of the environment and flow of the water) and on degradation (e.g., biomass and water chemistry).

Two versions of the model are available. The first version, "steady-state," is used primarily for long-term, constant-input with calculation of degradation and dissipation during steady-state and upon cessation of input. The second version allows for "pulse" loadings as may occur from field runoff during a rain storm.

Status: This model in all versions is being evaluated.

User's Manual: A manual is available from EPA publications in Cincinnati, OH, or NTIS, Springfield, VA. (EPA-600/3-82-023)

Model Accessed through: EPA National Computer Center (NCC) Compiler Language - FORTRAN/TSO (also available through OTS VAX computer at NCC and PDP 1170 at Athens, GA).

ATTACHMENT E: Output from Spray Drift Model

THIS IS A BALLISTIC MODEL WITHOUT DROPLET EVAPORATION.

1. CRITICAL LEVEL 0.10000 PPM
2. APPL. RATE 0.180 LB AI/ACRE
3. HEIGHT 10.00 FT
4. WIND SPEED 10.00 MPH
5. DROPLET TYPE NUMBER 2.0

DRIFT MAY RESULT IN WATER RESIDUES IN THE TOP SIX INCHES EQUAL TO THE CRIT. LEVEL OF 0.100000 AT A DISTANCE OF 78. FEET OR 24. METERS.

1. CRITICAL LEVEL 0.10000 PPM
2. APPL. RATE 0.180 LB AI/ACRE
3. HEIGHT 10.00 FT
4. WIND SPEED 10.00 MPH
5. DROPLET TYPE NUMBER 3.0

LARGE DROPS CAUSING MINIMAL DRIFT.

1. CRITICAL LEVEL 0.10000 PPM
2. APPL. RATE 0.180 LB AI/ACRE
3. HEIGHT 10.00 FT
4. WIND SPEED 10.00 MPH
5. DROPLET TYPE NUMBER 1.0

DRIFT MAY RESULT IN WATER RESIDUES IN THE TOP SIX INCHES EQUAL TO THE CRIT. LEVEL OF 0.100000 AT A DISTANCE OF 123. FEET OR 38. METERS.

1. CRITICAL LEVEL 0.01000 PPM
2. APPL. RATE 0.180 LB AI/ACRE
3. HEIGHT 10.00 FT
4. WIND SPEED 10.00 MPH
5. DROPLET TYPE NUMBER 2.0

DROPLETS EVAPORATED BEFORE REACHING THE GROUND. DUE TO DROPLET EVAPORATION, A LIKELY MAXIMUM DRIFT DISTANCE OF 244. FEET OR 75. METERS IS POSSIBLE YIELDING A CONCENTRATION OF 0.028800 PPM IN 6 IN. OF WATER.

1. CRITICAL LEVEL 0.00100 PPM
2. APPL. RATE 0.180 LB AI/ACRE
3. HEIGHT 10.00 FT
4. WIND SPEED 10.00 MPH
5. DROPLET TYPE NUMBER 2.0

(ATTACHMENT E, CONTINUED)

DROPLETS EVAPORATED BEFORE REACHING THE GROUND. DUE TO DROPLET EVAPORATION, A LIKELY MAXIMUM DRIFT DISTANCE OF 244. FEET OR 75. METERS IS POSSIBLE YIELDING A CONCENTRATION OF 0.028800 PPM IN 6 IN. OF WATER.

1. CRITICAL LEVEL 0.03000 PPM
2. APPL. RATE 0.180 LB AI/ACRE
3. HEIGHT 10.00 FT
4. WIND SPEED 10.00 MPH
5. DROPLET TYPE NUMBER 2.0

DRIFT MAY RESULT IN WATER RESIDUES IN THE TOP SIX INCHES EQUAL TO THE CRIT. LEVEL OF 0.030000 AT A DISTANCE OF 187. FEET OR 57. METERS.

1. CRITICAL LEVEL 0.05000 PPM
2. APPL. RATE 0.180 LB AI/ACRE
3. HEIGHT 10.00 FT
4. WIND SPEED 10.00 MPH
5. DROPLET TYPE NUMBER 2.0

DRIFT MAY RESULT IN WATER RESIDUES IN THE TOP SIX INCHES EQUAL TO THE CRIT. LEVEL OF 0.050000 AT A DISTANCE OF 125. FEET OR 38. METERS.

1. CRITICAL LEVEL 0.05000 PPM
2. APPL. RATE 0.180 LB AI/ACRE
3. HEIGHT 10.00 FT
4. WIND SPEED 10.00 MPH
5. DROPLET TYPE NUMBER 1.0

DROPLETS EVAPORATED BEFORE REACHING THE GROUND. DUE TO DROPLET EVAPORATION, A LIKELY MAXIMUM DRIFT DISTANCE OF 244. FEET OR 75. METERS IS POSSIBLE YIELDING A CONCENTRATION OF 0.090000 PPM IN 6 IN. OF WATER.

ATTACHMENT F: An Example of a More Sophisticated EEC Using State-of-the-Art Models

IA Purpose:

To calculate an aquatic EEC for the pesticide for its proposed new use in field and sweet corn.

II Directions for Use: Corn

III Data Discussion:

There were no studies to be reviewed. This is an analysis using existing data. Both a runoff scenario and two aquatic habitats will be examined.

Runoff:

Watersheds in three river basins (Tifton, GA; Yazoo, MS; Coshocton, OH) were chosen to determine the possible quantity of the pesticide in runoff as a function of meteorology and geography. The model river basins are part of the Simulator for Water Resources in Rural Basins (SWRRB).

Four applications at the time of silking were determined to occur about 1 July in Ohio and at anytime from early June to late August in Georgia and Mississippi. Applications were made on a 7- to 8-day schedule as per the label directions.

A K_d value of 1 was used even though the value has been reported to vary from 0.58 to 1.34 depending upon the clay content of the soil.

With each application that was followed by a storm within 1 to 5 days, significant pesticide runoff occurred. Quantities reached upwards of 0.100 lb/Acre with values of 0.010 to 0.050 fairly common. Two or three events of this magnitude occur each year and then no more pesticide runoff is predicted to occur.

Water Quality Analysis:

From the SWRRB data, a maximum of two runoff quantities 5 days apart (to account for 2 runoff events) were entered into the EXAMS (Exposure Analysis Modeling System) using both the Athens ERL Pond and River scenarios. The chemistry data for the pesticide used in the model is given in Table 2.

(ATTACHMENT F, CONTINUED)

The first input quantity of 0.00001 kg is to provide a better graphic plot of later results. Other quantities of 0.010 and 0.100 and 0.005 and 0.050 kg were those derived from the SWRRB data. The quantities were not adjusted to reflect large areas. (At present the effect of large field runoff is being studied with respect to the quantity of material that could enter an aquatic system.) If large field quantities are desired, multiply the outputs from the EXAMS model by that desired field size - the results are linear with respect to the pesticide inputs. It should be noted that the effective pesticide runoff quantity from a 100 acre field may only be equal to that released from a 5 to 10 acre field.

The maximum quantity of material that was predicted to occur in the Athens ERL model pond was 5 ppb dissolved in the water when .100 kg was introduced into the system. That quantity found sorbed onto suspended particles was about 10 ppb (mg/kg dry weight of suspended material). The pesticide has a calculated half-life of about 15 days for both dissolved and sorbed suspended material.

In the Athens ERL river model the pesticide does not exceed 5 ppb at the point of input and dissipates rapidly to less than 1 ppb by the time it reaches the third water compartment some 2 km downstream.

IV Conclusions:

The expected environmental concentration in an aquatic system should be no more than 5 ppb when the runoff input is 0.100 kg with no other inputs of this quantity for several weeks.

(ATTACHMENT F, CONTINUED)

Shaugh. No. _____

Common Name: _____

Chemical Name: _____

Structure: _____

Chemical Properties:

Molecular Weight: 365

Solubility (ppm): 25 (25 °C)

Partitioning:

K_{ow} 45 K_{oc} _____ $K_d = K_{abs} = K_{ps}$ _____

Clay Loam 1.34
Loamy Sand .58
Sandy Loam 1.22

Hydrolysis (halflife hrs.)

(pH 3) 206 hr (pH 7) long term study (>150 days) hr (pH 9) 22 hr

K_{ah} 3.36×10^{-3} K_{nh} 2×10^{-4}/hr K_{bh} 3.16×10^{-2}/hr

Photolysis (halflife hrs.)

194 hrs K_{dp} 8.6×10^{-3}/day (3.5×10^{-4}/hr)

Degradation (halflife hrs.)

Soil (Aerobic)(pH 6-8) 72-120 hr K 9.6×10^{-3} to 5.7×10^{-3}/hr

Soil (Anaerobic)(pH) _____ hr K _____

Water (Type Pond Sterile pH) 144-400 hr K 4.6×10^{-3} to 1.7×10^{-3}/hr

Bacteriological

Soil (Type _____) _____ hr K _____

Water (Type _____) _____ hr K _____

Vapor Pressure: 4.3×10^{-5} mmHg at 25°C

Evaporation: _____

(ATTACHMENT F, CONTINUED)

Table 1: SWRRB Input

K_d (sorption coefficient)	= 1.00
Washoff fraction	= 10%
Half life on foliage	= 2 days
Degradation Rate in soil	= 1.7×10^{-1} /day
Application Efficiency	= 75%

Table 2:

EXAMS — Exposure Analysis Modeling System — V2.0: Mode 2

Chemical:

TABLE 1.1. SH2 (NEUTRAL MOLECULE, SPECIES #1) INPUT DATA.

MWT= 365	SOL = 25.00	VAPR= 4.3000E-05	HENRY= 0.0000
KPS= 1.200	KPB = 0.0000	KOC = 0.0000	KOW = 45.00
KAH1= 3.3600E-06	EAH1= 0.0000	KNH1= 2.0000E-04	ENH1= 0.0000
KBH1= 3.1600E-07	EBH1= 0.0000	KOX1= 0.0000	EOX1= 0.0000
KBACW2= 0.0000	QTW2= 0.0000	KBACS2= 7.0000E-10	QTS2= 0.0000
KDP= 3.5000E-04	RFLAT= 40.00	LAMAX= 0.00	

(ATTACHMENT F, CONTINUED)

Table 3. Runoff quantities by Julian date for the three river basins. Quantities are expressed in lb ai/acre.

Yazoo MS

1971		
180	1.00	
187	1.00	
194	1.00	
197		.020
201	1.00	
206		.002
209		.006
210		.001
1972		
180	1.00	
182		.004
185		.035
186		.036
187	1.00	
195	1.00	
202	1.00	
1973		
180	1.00	
181		.008
185		.065
187	1.00	.024
188		.007
195	1.00	.069
202	1.00	
210		.002

Tifton GA

1971		
180	1.00	
183		.001
185		.001
187	1.00	
194	1.00	
201	1.00	
1972		
180	1.00	
187	1.00	
195	1.00	
198		.003
202	1.00	
206		.001
1973		
180	1.00	
187	1.00	
194	1.00	
199		.001
202	1.00	

Coshocton OH

1968		
180	1.00	
187	1.00	
194	1.00	
201	1.00	
206		.001
1969		
180	1.00	
186		.056
187	1.00	
188		.094
195	1.00	
201		.003
202	1.00	
208		.009
1970		
180	1.00	
187	1.00	
189		.011
194	1.00	
202	1.00	

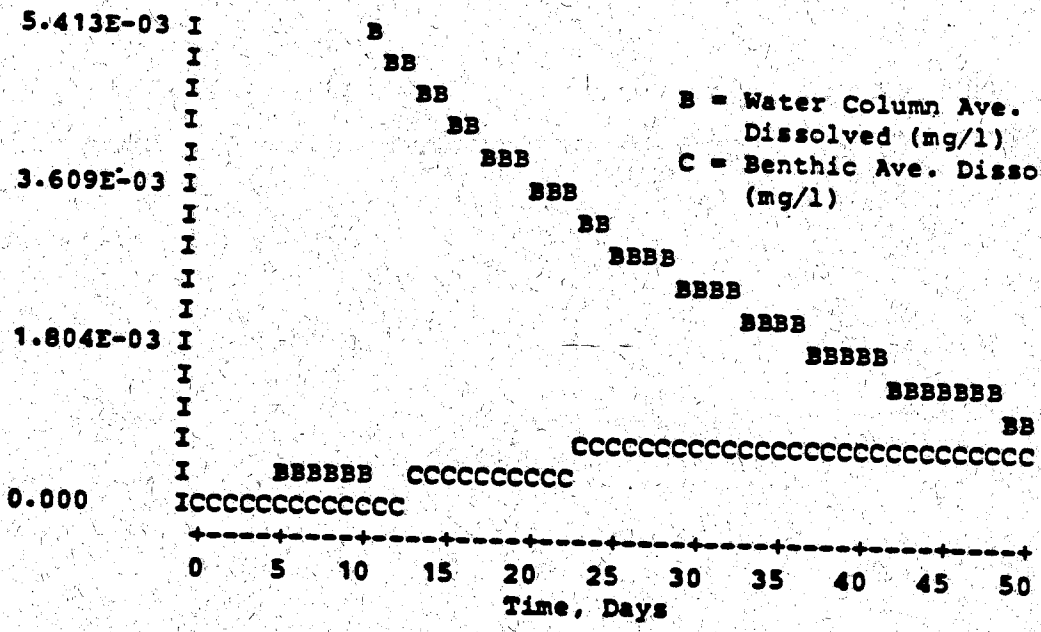
System: POND, AERL DEVELOPMENT PHASE TEST DEFINITION
Chemical:

Time	Water Column			Benthic		
(days)	Average Dissolved (mg/l)	Average Sorbed (mg/kg)	Total Mass (kg)	Average Dissolved (mg/l)	Average Sorbed (mg/kg)	Total Mass (kg)
Initial input 0.000001 kg						
0	5.000E-08	9.224E-08	1.000E-06	0.000E-01	0.000E-01	0.000E-01
1	4.812E-08	8.878E-08	9.624E-07	6.391E-10	1.179E-09	9.559E-10
2	4.631E-08	8.545E-08	9.263E-07	1.226E-09	2.261E-09	1.833E-09
3	4.458E-08	8.225E-08	8.916E-07	1.763E-09	3.253E-09	2.637E-09
4	4.291E-08	7.917E-08	8.582E-07	2.254E-09	4.159E-09	3.371E-09
5	4.130E-08	7.621E-08	8.261E-07	2.702E-09	4.985E-09	4.041E-09
Runoff input 0.010 kg						
5	5.000E-04	9.225E-04	1.000E-02	2.702E-09	4.985E-09	4.041E-09
6	4.812E-04	8.879E-04	9.625E-03	6.395E-06	1.180E-05	9.563E-06
7	4.632E-04	8.546E-04	9.264E-03	1.226E-05	2.262E-05	1.834E-05
8	4.458E-04	8.225E-04	8.917E-03	1.763E-05	3.253E-05	2.637E-05
9	4.291E-04	7.917E-04	8.583E-03	2.254E-05	4.159E-05	3.372E-05
10	4.131E-04	7.621E-04	8.262E-03	2.702E-05	4.986E-05	4.041E-05
Runoff input 0.100 kg						
10	5.413E-03	9.987E-03	1.083E-01	2.702E-05	4.986E-05	4.041E-05
11	5.210E-03	9.612E-03	1.042E-01	9.501E-05	1.753E-04	1.421E-04
12	5.014E-03	9.251E-03	1.003E-01	1.574E-04	2.903E-04	2.353E-04
13	4.826E-03	8.905E-03	9.653E-02	2.144E-04	3.956E-04	3.207E-04
14	4.646E-03	8.571E-03	9.292E-02	2.665E-04	4.917E-04	3.986E-04
15	4.472E-03	8.251E-03	8.944E-02	3.140E-04	5.793E-04	4.696E-04
16	4.305E-03	7.943E-03	8.610E-02	3.571E-04	6.589E-04	5.341E-04
17	4.144E-03	7.646E-03	8.289E-02	3.962E-04	7.310E-04	5.925E-04
18	3.990E-03	7.361E-03	7.980E-02	4.314E-04	7.960E-04	6.452E-04
19	3.841E-03	7.087E-03	7.682E-02	4.632E-04	8.545E-04	6.927E-04
20	3.698E-03	6.823E-03	7.396E-02	4.915E-04	9.069E-04	7.351E-04
21	3.560E-03	6.569E-03	7.121E-02	5.168E-04	9.536E-04	7.729E-04
22	3.428E-03	6.325E-03	6.857E-02	5.392E-04	9.949E-04	8.064E-04
23	3.301E-03	6.090E-03	6.602E-02	5.589E-04	1.031E-03	8.359E-04
24	3.178E-03	5.864E-03	6.357E-02	5.761E-04	1.063E-03	8.616E-04
25	3.061E-03	5.647E-03	6.122E-02	5.910E-04	1.090E-03	8.839E-04
26	2.947E-03	5.438E-03	5.895E-02	6.037E-04	1.114E-03	9.029E-04
27	2.838E-03	5.236E-03	5.677E-02	6.144E-04	1.134E-03	9.188E-04
28	2.733E-03	5.043E-03	5.467E-02	6.232E-04	1.150E-03	9.320E-04
29	2.632E-03	4.857E-03	5.265E-02	6.303E-04	1.163E-03	9.426E-04
30	2.535E-03	4.677E-03	5.071E-02	6.357E-04	1.173E-03	9.508E-04
31	2.442E-03	4.505E-03	4.884E-02	6.397E-04	1.180E-03	9.567E-04
32	2.352E-03	4.339E-03	4.704E-02	6.423E-04	1.185E-03	9.606E-04
33	2.265E-03	4.179E-03	4.530E-02	6.437E-04	1.188E-03	9.626E-04
34	2.182E-03	4.025E-03	4.364E-02	6.438E-04	1.188E-03	9.629E-04
35	2.102E-03	3.877E-03	4.203E-02	6.429E-04	1.186E-03	9.615E-04
40	1.743E-03	3.217E-03	3.487E-02	6.252E-04	1.154E-03	9.350E-04
45	1.447E-03	2.670E-03	2.895E-02	5.918E-04	1.092E-03	8.850E-04
50	1.202E-03	2.219E-03	2.405E-02	5.492E-04	1.013E-03	8.213E-04

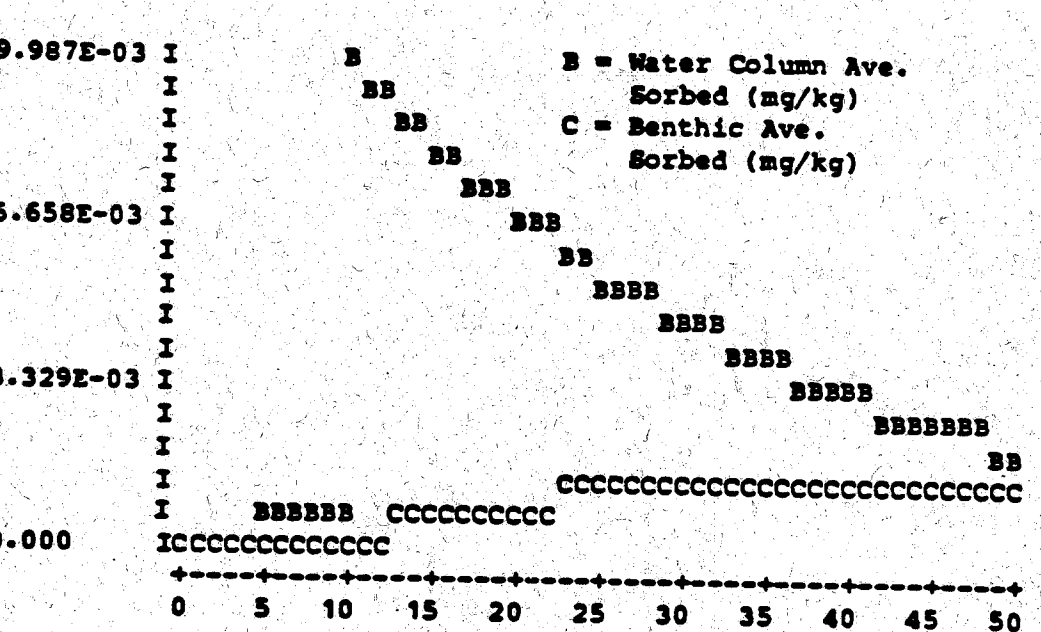
System: POND, AERL DEVELOPMENT PHASE TEST DEFINITION
Chemical:

Time (days)	Water Column Average Dissolved (mg/l)	Water Column Average Sorbed (mg/kg)	Water Column Total Mass (kg)	Benthic Average Dissolved (mg/l)	Benthic Average Sorbed (mg/kg)	Benthic Total Mass (kg)
Initial input 0.000001 kg						
0	5.000E-08	9.224E-08	1.000E-06	0.000E-01	0.000E-01	0.000E-01
1	4.812E-08	8.878E-08	9.624E-07	6.391E-10	1.179E-09	9.559E-10
2	4.631E-08	8.545E-08	9.263E-07	1.226E-09	2.261E-09	1.833E-09
3	4.458E-08	8.225E-08	8.916E-07	1.763E-09	3.253E-09	2.637E-09
4	4.291E-08	7.917E-08	8.582E-07	2.254E-09	4.159E-09	3.371E-09
5	4.130E-08	7.621E-08	8.261E-07	2.702E-09	4.985E-09	4.041E-09
Runoff Input 0.005 kg						
5	2.500E-04	4.613E-04	5.001E-03	2.702E-09	4.985E-09	4.041E-09
6	2.406E-04	4.440E-04	4.813E-03	3.199E-06	5.902E-06	4.784E-06
7	2.316E-04	4.273E-04	4.632E-03	6.132E-06	1.131E-05	9.171E-06
8	2.229E-04	4.113E-04	4.459E-03	8.819E-06	1.627E-05	1.319E-05
9	2.146E-04	3.959E-04	4.292E-03	1.127E-05	2.080E-05	1.686E-05
10	2.066E-04	3.811E-04	4.131E-03	1.351E-05	2.493E-05	2.021E-05
Runoff Input 0.050 kg						
10	2.706E-03	4.993E-03	5.413E-02	1.351E-05	2.493E-05	2.021E-05
11	2.605E-03	4.806E-03	5.210E-02	4.751E-05	8.765E-05	7.105E-05
12	2.507E-03	4.626E-03	5.015E-02	7.868E-05	1.452E-04	1.177E-04
13	2.413E-03	4.452E-03	4.827E-02	1.072E-04	1.978E-04	1.603E-04
14	2.323E-03	4.286E-03	4.646E-02	1.333E-04	2.459E-04	1.993E-04
15	2.236E-03	4.125E-03	4.472E-02	1.570E-04	2.897E-04	2.348E-04
16	2.152E-03	3.971E-03	4.305E-02	1.786E-04	3.295E-04	2.671E-04
17	2.072E-03	3.823E-03	4.144E-02	1.981E-04	3.655E-04	2.963E-04
18	1.995E-03	3.680E-03	3.990E-02	2.157E-04	3.980E-04	3.226E-04
19	1.921E-03	3.543E-03	3.841E-02	2.316E-04	4.273E-04	3.463E-04
20	1.849E-03	3.411E-03	3.698E-02	2.458E-04	4.535E-04	3.676E-04
21	1.780E-03	3.285E-03	3.561E-02	2.584E-04	4.768E-04	3.865E-04
22	1.714E-03	3.162E-03	3.428E-02	2.696E-04	4.975E-04	4.032E-04
23	1.650E-03	3.045E-03	3.301E-02	2.795E-04	5.156E-04	4.180E-04
24	1.589E-03	2.932E-03	3.179E-02	2.881E-04	5.315E-04	4.308E-04
25	1.530E-03	2.823E-03	3.061E-02	2.955E-04	5.452E-04	4.419E-04
26	1.474E-03	2.719E-03	2.947E-02	3.019E-04	5.569E-04	4.514E-04
27	1.419E-03	2.618E-03	2.838E-02	3.072E-04	5.668E-04	4.594E-04
28	1.367E-03	2.521E-03	2.733E-02	3.116E-04	5.749E-04	4.660E-04
29	1.316E-03	2.428E-03	2.632E-02	3.151E-04	5.814E-04	4.713E-04
30	1.268E-03	2.339E-03	2.535E-02	3.179E-04	5.865E-04	4.754E-04
31	1.221E-03	2.252E-03	2.442E-02	3.199E-04	5.901E-04	4.784E-04
32	1.176E-03	2.169E-03	2.352E-02	3.212E-04	5.925E-04	4.803E-04
33	1.133E-03	2.090E-03	2.265E-02	3.218E-04	5.938E-04	4.813E-04
34	1.091E-03	2.013E-03	2.182E-02	3.219E-04	5.939E-04	4.814E-04
35	1.051E-03	1.939E-03	2.102E-02	3.215E-04	5.931E-04	4.808E-04
40	8.717E-04	1.608E-03	1.744E-02	3.126E-04	5.768E-04	4.675E-04
45	7.237E-04	1.335E-03	1.447E-02	2.959E-04	5.459E-04	4.425E-04
50	6.012E-04	1.109E-03	1.203E-02	2.746E-04	5.066E-04	4.106E-04

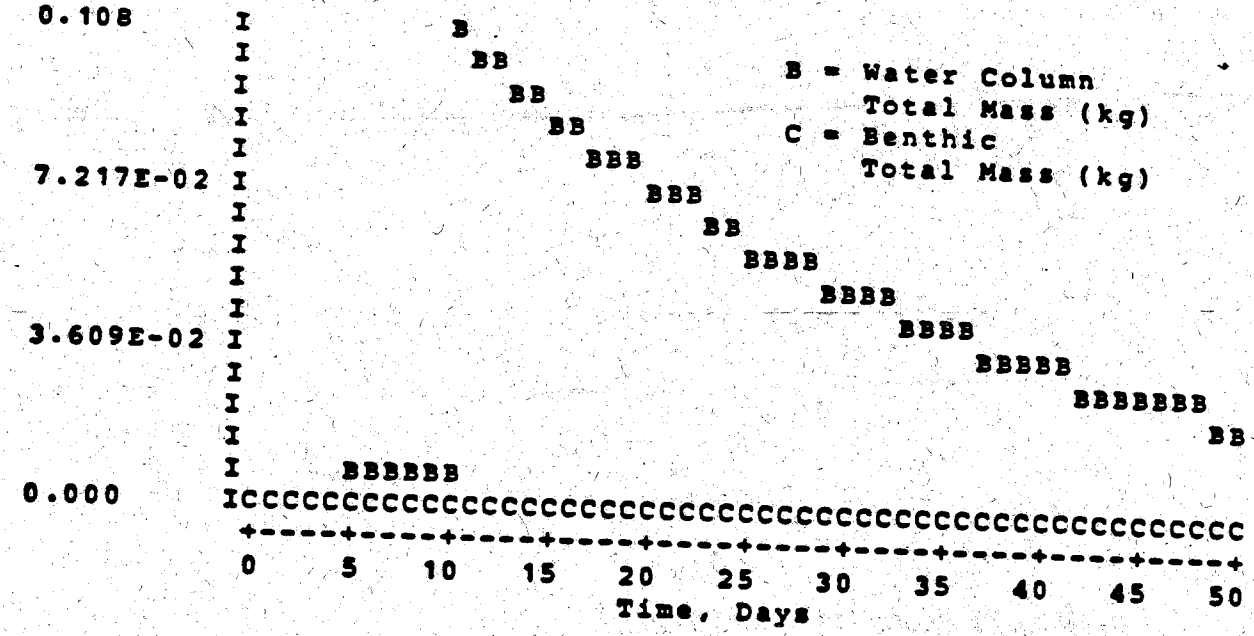
System: POND, AERL DEVELOPMENT PHASE TEST DEFINITION
Chemical:
Inputs: .000001 kg, day 0; .010 kg, day 5; .100 kg, day 10



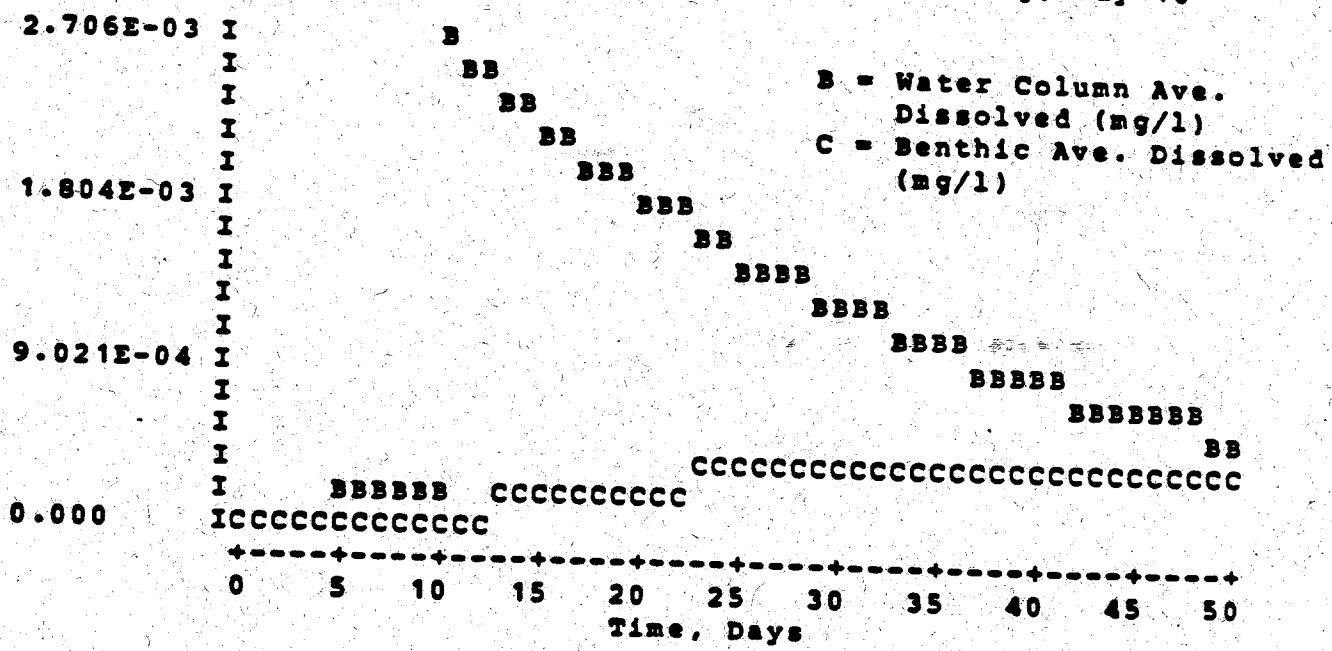
System: POND, AERL DEVELOPMENT PHASE TEST DEFINITION
Chemical:
Inputs: .000001 kg, day 0; .010 kg, day 5; .100 kg, day 10



System: POND, AERL DEVELOPMENT PHASE TEST DEFINITION
Chemical:
Inputs: .000001 kg, day 0; .010 kg, day 5; .100 kg, day 10



Compound:
Environment: POND, AERL DEVELOPMENT PHASE TEST DEFINITION
Inputs: .000001 kg, day 0; .005 kg, day 5; .050 kg, day 10



(ATTACHMENT F, CONTINUED)

ENVIRONMENT: RIVER, AERL DEVELOPMENT PHASE TEST DEFINITION
CHEMICAL:

day	Dissolved Water Ave.(?) (mg/l)	Dissolved Benthic Ave.(?) (mg/l)	Dissol. Water Comp. 5 (mg/l)	Sorbed Benthic Comp. 6 (mg/kg)	Total Concentration Water Comp. 5 (mg/l)	Total Concentration Benthic Comp. 6 (mg/kg)	Mass Water Comp. 5 (kg/m^2)	Mass Benthic Comp. 6 (kg/m^2)
Initial Input 0.000001 kg								
0	1.111E-09	0.000E-01	0.000E-01	0.000E-01	0.000E-01	0.000E-01	0.000E-01	0.000E-01
1	3.110E-07	-1.462E-10	9.481E-07	-8.086E-10	9.481E-07	-9.741E-10	2.844E-06	-6.577E-11
2	3.053E-07	-1.448E-10	9.230E-07	-7.944E-10	9.230E-07	-9.570E-10	2.769E-06	-6.461E-11
3	1.167E-07	-5.519E-11	3.520E-07	-3.034E-10	3.520E-07	-3.655E-10	1.056E-06	-2.468E-11
4	2.132E-08	-9.647E-12	6.419E-08	-5.492E-11	6.419E-08	-6.616E-11	1.926E-07	-4.467E-12
5	9.696E-07	4.652E-10	-2.917E-06	2.528E-09	-2.917E-06	3.045E-09	8.752E-06	2.056E-10
Runoff Input 0.005 kg								
5	4.586E-06	4.652E-10	-2.917E-06	2.528E-09	-2.917E-06	3.045E-09	8.752E-06	2.056E-10
6	7.802E-07	4.042E-09	2.377E-06	8.030E-09	2.377E-06	9.673E-09	7.132E-06	6.531E-10
7	1.054E-06	3.200E-09	3.186E-06	4.182E-09	3.186E-06	5.038E-09	9.558E-06	3.402E-10
8	8.483E-07	2.789E-09	2.557E-06	2.560E-09	2.558E-06	3.084E-09	7.673E-06	2.082E-10
9	5.251E-07	2.564E-09	1.581E-06	1.917E-09	1.581E-06	2.309E-09	4.743E-06	1.559E-10
10	1.854E-07	2.438E-09	5.576E-07	1.779E-09	5.576E-07	2.143E-09	1.673E-06	1.447E-10
Runoff input 0.050 kg								
10	5.574E-05	2.438E-09	5.576E-07	1.779E-09	5.576E-07	2.143E-09	1.673E-06	1.447E-10
11	5.559E-07	4.667E-08	-1.700E-06	1.036E-07	-1.700E-06	1.248E-07	5.101E-06	8.429E-09
12	2.147E-08	3.913E-08	6.499E-08	7.031E-08	6.500E-08	8.469E-08	1.950E-07	5.718E-09
13	-1.519E-06	3.464E-08	-4.584E-06	5.241E-08	-4.584E-06	6.313E-08	1.375E-05	4.263E-09
14	-8.992E-07	3.043E-08	-2.709E-06	3.571E-08	-2.709E-06	4.301E-08	8.126E-06	2.904E-09
15	-5.208E-07	2.725E-08	-1.567E-06	2.433E-08	-1.567E-06	2.931E-08	4.702E-06	1.979E-09
16	-1.648E-07	2.473E-08	-4.957E-07	1.625E-08	-4.958E-07	1.957E-08	1.487E-06	1.321E-09
17	-6.443E-09	2.275E-08	-1.937E-08	1.091E-08	-1.937E-08	1.314E-08	5.811E-08	8.872E-10
18	8.542E-08	2.114E-08	2.567E-07	7.277E-09	2.567E-07	8.766E-09	7.701E-07	5.919E-10
19	6.818E-10	1.985E-08	2.047E-09	5.162E-09	2.047E-09	6.219E-09	6.142E-09	4.199E-10
20	1.611E-07	1.862E-08	4.839E-07	3.136E-09	4.839E-07	3.778E-09	1.452E-06	2.551E-10
21	2.208E-08	1.767E-08	6.630E-08	2.391E-09	6.631E-08	2.880E-09	1.989E-07	1.945E-10
22	-7.943E-07	1.714E-08	-2.385E-06	3.757E-09	-2.385E-06	4.525E-09	7.156E-06	3.055E-10
23	-2.897E-07	1.605E-08	-8.698E-07	1.916E-09	-8.699E-07	2.308E-09	2.610E-06	1.559E-10
24	-3.801E-08	1.515E-08	-1.141E-07	8.986E-10	-1.141E-07	1.082E-09	3.423E-07	7.309E-11
25	5.422E-07	1.414E-08	1.628E-06	-8.629E-10	1.628E-06	-1.039E-09	4.884E-06	-7.018E-11
26	3.037E-10	1.372E-08	9.111E-10	3.783E-10	9.111E-10	4.557E-10	2.733E-09	3.077E-11
27	1.136E-09	1.308E-08	3.411E-09	2.581E-10	3.411E-09	3.109E-10	1.023E-08	2.099E-11
28	6.694E-07	1.215E-08	2.009E-06	-1.565E-09	2.009E-06	-1.885E-09	6.028E-06	-1.273E-10
29	1.732E-07	1.182E-08	5.199E-07	-3.277E-10	5.200E-07	-3.948E-10	1.560E-06	-2.665E-11
30	2.286E-08	1.134E-08	6.862E-08	2.572E-11	6.862E-08	3.098E-11	2.059E-07	2.092E-12
31	-7.866E-07	1.121E-08	-2.361E-06	2.109E-09	-2.361E-06	2.541E-09	7.083E-06	1.716E-10
32	-8.782E-12	1.034E-08	-2.688E-11	4.064E-11	-2.688E-11	4.896E-11	8.065E-11	3.306E-12
33	3.347E-13	9.872E-09	5.037E-13	2.866E-11	5.038E-13	3.452E-11	1.511E-12	2.331E-12
34	3.196E-13	9.430E-09	4.808E-13	2.068E-11	4.808E-13	2.492E-11	1.442E-12	1.682E-12
35	3.054E-13	9.015E-09	4.591E-13	1.541E-11	4.592E-13	1.857E-11	1.377E-12	1.254E-12
40	2.444E-13	7.222E-09	3.668E-13	3.899E-12	3.669E-13	4.697E-12	1.101E-12	3.171E-13
45	1.986E-13	5.872E-09	2.981E-13	1.437E-12	2.981E-13	1.731E-12	8.943E-13	1.169E-13
50	1.614E-13	4.772E-09	2.422E-13	5.406E-13	2.422E-13	6.512E-13	7.265E-13	4.397E-14

ATTACHMENT G: An Example of Summarizing and Interpreting Exposure Model Data and Integrating Exposure and Hazard Data for Risk Assessment

Aquatic Toxicity

The acute toxicity data indicates that this pesticide is very highly toxic to aquatic organisms. The most sensitive fish species is the bluegill which has an LC_{50} of 3.83 ppb. For aquatic invertebrates, the mysid shrimp had the lowest LC_{50} of 0.5 ppb, whereas the acute value for Daphnia was 1.4 ppb. Two chronic aquatic studies are available. The 32-day early-life stage with the fathead minnow which gave a MATC of > 2.5 and < 6.3 ppb, and the 21-day life-cycle with Daphnia produced a MATC of > 0.198 and < 0.495 ug/l. All of these values would place this pesticide in the very highly toxic range.

Aquatic Residues

EAB used the SWRRB-EXAMS models to determine the runoff EECs for turf. The scenario used was a 1 hectare pond, 2 meters deep with a runoff basin of 13 hectares. The spray regime for SWRRB was as follows:

Spray Regime

YEAR	JULIAN DATES	INTERVAL (days)
1970	139	
	151	12
	230	79
1971	133	
	168	35
	234	71
1972	134	
	168	34
	195	27
1973	135	
	166	30
	196	30
1974	140	
	174	34
	194	20
1975	129	
	179	48
	205	28

(ATTACHMENT G, CONTINUED)

The year selected for EXAMS was 1972 for the Tifton Turf I model.

SWRRB RUNOFF VALUES FOR THE TIFTON TURF I BASIN.

		Active Ingredient (lbs) per Acre			
Year	Day (Julian)	.001 - .004	.007 - .007	.007 - .009	> .009
1972	171	.002			
	173		.005		
	177				.013
	220	.001			

The concentrations for four portions of the pond were estimated. They were the chemical dissolved in the water column, chemical attached to sediment particles in the water column, chemical dissolved in the pores of the bottom sediment, and chemical attached to the bottom sediment. Below is a table which attempts to condense the results of this computer model.

SWRRB-EXAMS EEC VALUES

Sample Type	No. of Days EEC Exceeds 1/2 LC_{50} Fish	Daphnia	Estimated Concentration (ppb - Day) Min.	Max.
Bottom Porewater	0	51	0.0317 - 2	0.787-22
Water Dissolved	12	22	0.2146-149*	11.67-6
Bottom Sediment	149*	149*	33.82-4	204-22
Water Sediment Particles	149*	149*	55.52-149*	1210-2

* Data were given for 149 days only.

It should be pointed out that normally significant amounts of chemical would not be expected to reach ponds through spray drift when ground application is used. However, this case may be the exception. Direct application to our model pond would be expected to result in a concentration of 368 ppb. Hence, only spray drift 1/263th of the direct application would exceed the *Daphnia* LC_{50}.

(ATTACHMENT G, CONTINUED)

Aquatic Hazards

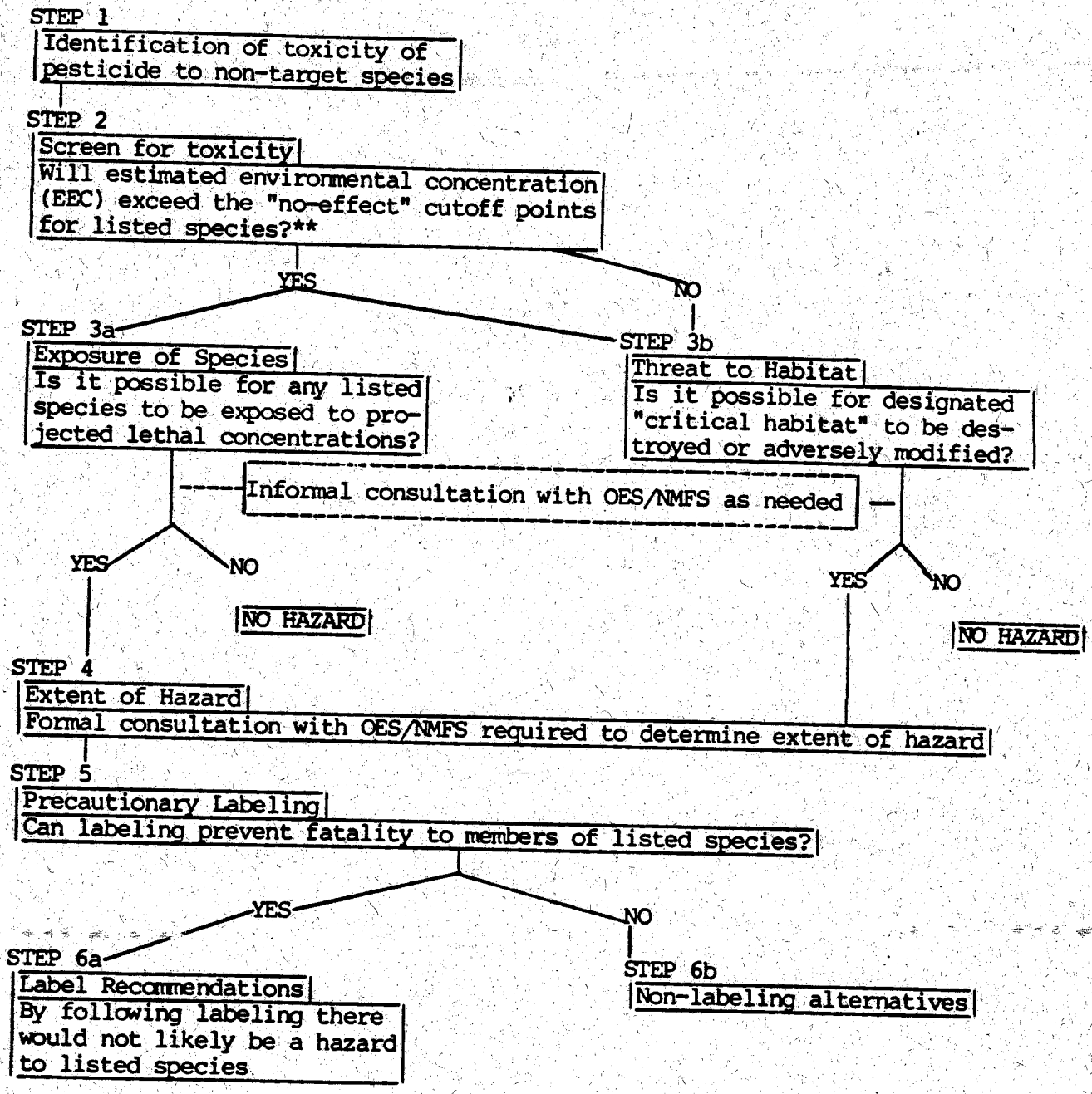
With the exception of the pore water the LC_{50} for both fish (bluegill LC_{50}-3.83 ppb) and Daphnia (LC_{50}-1.4 ppb) have been exceeded. The shortest duration of exposure among the remaining three sample types was the water-dissolved. However, this period is long enough to be of concern. From day 2 to 18, the concentration was greater than the 1/2 fish LC_{50} value. Within this period from day 6 to 10 the fish LC_{50} would be exceeded (11.67 ppb day 6 to 4.99 ppb on day 10).

Hazard would also be expected to benthic invertebrates under the residue levels proposed by these models. Though the exposure of daphnids in laboratory studies differs from the type of exposure to an invertebrate in a natural pond or stream sediment, (estimates are 33.82 to 204 ppb) the laboratory study has established that invertebrates are extremely sensitive to this chemical (the Daphnia LC_{50} is 1.4 ppb and MATC values are > 0.198 and < 0.495 µg/l). Unlike other animals, the primary route of exposure would be expected to be through their exoskeletons. Many insecticides are lipophilic. The available product chemistry data indicate this is the nature of the pesticide. Its solubility in water is only 150 ppb, and the octanol/water partition coefficient is 6310. These values would indicate a greater affinity for organic material and chitin (exoskeleton material) than soil or water. Thus, one would expect the organic runoff material to contain more pesticide than the soil portion. Also, one would expect invertebrates such as insects and crustaceans to be attracted to organic material as a potential food source. Therefore, by moving in and about the residue bearing material the animal's exoskeleton surface would be expected to contact directly with the chemical. This exposure would be in addition to that expected from feeding on contaminated organic material. In addition, benthic invertebrates would likely be exposed to the chemical dissolved in the water while feeding at the surface of the bottom sediments or in the water. Hazard would be expected under these conditions. Serious adverse effects on aquatic invertebrate populations would likely affect the higher trophic levels through starvation.

The chronic toxicity data indicates an additional hazard. In this case the amount dissolved in water will exceed the lower level of the MATC for Daphnia for the duration of the reported sample (149 days).

Therefore, the concentrations and exposure periods estimated by the SWRRB-EXAMS model indicate a hazard to both the lentic and benthic fauna of the pond. This is particularly significant considering only three applications were assumed for the model and the pesticide label does not limit the number of applications per year. In addition, spray drift would be expected to contribute to the hazard, the extent of which we are unable to estimate at this time.

ATTACHMENT H: Ecological Effects Branch/HED Evaluating Risk To Endangered/ Threatened* Species From Pesticide Registration Actions (see attached written explanation for each step)



* also referred to as listed species

** 1/5th the lowest mammalian acute oral LD_{10} or LC_{10}; 1/5th the lowest avian subacute dietary LC_{10} or LD_{10}; 1/10th the lowest aquatic acute LC_{10}. Where LC_{10} or LD_{10} are not available, 1/10th the mammalian LD_{50} or LC_{50}, 1/10th the avian LC_{50} or LD_{50} or 1/20th the aquatic LC_{50}. Also, herbicides are initially considered to impact listed plants; consideration is given to whether it is a broadleaf, grasses, or non-selective herbicide. Insecticides are initially considered to impact listed insects.

(ATTACHMENT H, CONTINUED)

Step 1

Identification of toxicity of pesticide to non-target species

From test data submitted or referenced by the registrant, the toxicological impact, if any, upon non-target species is determined. Extrapolations are made from the results of basic required fish and wildlife studies and other validated test data.

Step 2

Screen for toxicity

The question is asked: "Will the estimated environmental concentrations (EEC) exceed the 'no-effect' cutoff points for listed species?"

Likelihood of hazard

Fish and wildlife are constantly being exposed to many naturally occurring compounds that would cause mortality or ecological disturbance if present at high enough concentrations. Therefore, even though the chemical is toxic to the organism and there is the likelihood of exposure to the organism, sufficient concentrations of the pesticide must be available to constitute a hazard. The obvious question: "How does one go about determining what is a sufficient concentration?"

Since it is impossible to obtain LC_{50} or LD_{50} data for listed species, we must assume that the sensitivity of these species is similar to that of indicator organisms used in current test protocols. Although this may or may not be the case, it would seem appropriate, when using these data for assessing hazard to listed species, that some "safety factor" be built into the evaluation process. Since even the loss of one individual of listed species may be unacceptable, some might argue that all hazard evaluations should be based on LC_1 (i.e., lethal concentration required to kill one percent of the population). However, due to the difficulty in actually determining an LC_1, it is proposed that the more reliable LC_{10} be used. The following risk criteria for establishing "no-effect" cutoff points would be:

1. Mammals - Occurs as a residue immediately following application in or on the feed of a mammalian listed species likely to be exposed to such feed in amounts equivalent to the average daily intake of said species, at levels less that 1/5th the acute oral LD_{10}, or LC_{10}, measured in mammalian test animals as specified in the Registration Guidelines.

(ATTACHMENT H, CONTINUED)

2. Birds - Occurs as a residue immediately following application in or on the feed of an avian listed species likely to be exposed to such feed in amounts equivalent to the average daily intake of said species, at levels less than 1/5th the subacute dietary LC_{10} or LD_{10} measured in avian test animals as specified in the Registration Guidelines.

3. Aquatic Organisms - Results in a maximum calculated concentration in (a) or (b) below of less that 1/10th the acute LC_{10} for aquatic organisms likely to be exposed as measured in test animals specified in the Registration Guidelines:

   (a) following direct application to a 6-inch layer of water, or

   (b) in the habitat(s) of concern (habitats of listed species).

4. Chronic Effects - There are no known reproductive or other chronic effects to indicator species at levels expected in the habitat(s) of concern.

Step 3a

Exposure of species

If the answer to 2 above is "yes," proceed to step 3a (Exposure of Species where the question is asked: "Is it possible for any listed species to be exposed to projected lethal concentrations?" A search is made of branch records and other available sources of information to identify listed species within proposed treatment areas. Branch reviewers may informally consult with OES and other persons knowledgeable of current listed species distribution. Based on the criteria indicated in Step 2, a determination is made whether or not that use of the pesticide product, as proposed, may affect any listed species.

If the answer to Step 2 above is "no," proceed to Step 3b - Threat to Habitat, and answer the question, "Is it possible for designated critical habitat to be destroyed or adversely modified?" Again, as needed, informal consultation may be made with OES and other pertinent sources to solicit the most current information on critical habitat. If there is a "No" answer to the questions asked in Steps 3a and 3b, a "No hazard" determination is made.

(ATTACHMENT H, CONTINUED)

Step 4

Extent of Hazard

If "Yes" is answered to Steps 3a or 3b, then a formal consultation, as required within the Endangered Species Act, is initiated by EEB. This consists of a letter of request to the Chief, Office of Endangered Species, accompanied by a copy of the branch review of the pesticide product and other supporting documentation (i.e., wildlife, fish kills attributable to the use of the pesticide).

OES or NMFS, upon acknowledgement of the consultation request, prepares a written "biological opinion" within 90 days. They may request clarification or more data to facilitate the preparation of the written opinion. On occasions they may request an extension of time beyond the 90 days.

Their written opinions summarize the nature of the request (pesticide toxicological properties, use patterns, listed species considered and listed species for which there is a jeopardy and no jeopardy opinion).

Step 5

Precautionary Labeling

When there is a jeopardy opinion the question is asked, "Can labeling prevent fatality to members of listed species?" If "Yes" proceed to Step 6a - Label Recommendations with appropriate labeling to avert jeopardy to the species identified within the "biological opinion."

If "No," nonlabeling alternatives must be investigated. These include, but are not limited to, the following: clarification of the reasonable and prudent alternatives with OES, involvement of the registrant to seek means to avert exposure of listed species (which may suggest an alteration in the use pattern, restriction of the pesticide to specific sites only and/or use by certified applicators only), suggest field studies to demonstrate safe usage at prescribed label rates exposing species most representative of listed species of concern, refer for Special Review.

ATTACHMENT I: Pesticides and Crops Considered by Hoerger and Kenaga (1972)

I. Pesticides Considered: > 20 different pesticides

A. From Literature

1. Dicamba, amine salt*
2. 2,4-D
3. Endosulfan
4. Picloram, amine salts
5. Parathion*
6. Methyl parathion*
7. EPN
8. Sulfotepp
9. Malathion
10. Dimethoate*
11. Methoxychlor
12. Captan
13. Phosdrin
14. Diazinon
15. Demeton*
16. Trithion
17. DDT*
18. Dieldrin
19. Endrin
20. Aldrin
21. Chlordane
22. Toxaphene*
23. Ovex
24. Dioxathion

B. From Tolerance Data

1. Carbaryl
2. Kelthane
3. Toxaphene*
4. DDT*
5. Malathion*
6. Parathion*
7. Methyl parathion*
8. Demeton*
9. Dicamba*
10. Disulfoton
11. Phorate
12. Dimethoate*

* Same pesticide examined twice

II. Crops Considered

A. From Literature Sources:

1. Grasses: (240 ppm)1/

a. Range grass
b. Range grass (dead undercover)
c. Fodder grass (W. Germany)

B. From Tolerance Data:

1. Grasses: (110 ppm)

a. Alfalfa
b. Barley
c. Clover
d. Corn forage
e. Cotton forage
f. Dandelion
g. Sorghum forage
h. Grass pasture or range grass
i. Pea forage
j. Cowpeas
k. Peppermint a Spearmint h
l. Sugarbeet t

1/ Numbers in parentheses are the highest pesticide residue values found on that crop category, based on an application rate of 1 lb per acre.

(ATTACHMENT I, CONTINUED)

2. Leaves & Leafy Crops:
(125 ppm)

a. Apples leaves
b. Tomato leaves
c. Bean leaves
d. Pear leaves
e. Spinach
f. Chard
g. Collard
h. Cauliflower leaves
i. Cauliflower head
j. Watercress
k. Celery
l. Celery leaves
m. Celery stalk
n. Cabbage
o. Carrot tops
p. Turnip greens
q. Lettuce (mature & immature)

2. Leaves & Leafy Crops:

None examined

3. Forage Crops:
(58 ppm)

a. Alfalfa (short)
b. Alfalfa (14-20 inches)
c. Red clover
d. Birdsfoot Trefoil

3. Forage Crops:
(110 ppm)

Same as 1 above

4. Pod Containing Seeds:
(12 ppm)

a. Beans: Snap
b. " : Green
c. " : French
d. " : Red Kidney

4. Pods Containing Seeds:
(10 ppm)

a. Shelled cowpeas
b. Beans
c. Green beans
d. Lima beans
e. Dry beans
f. Black-eyed peas
g. Shelled peas
h. Peas with pods

5. Fruits:
(6.6 ppm)

a. Apricots
b. Cherries
c. Peaches
d. Olives
e. Apples
f. Grapes
g. Strawberries
h. Oranges (Valencia)
i. Oranges (Navel)
j. Lemons

5. Fruits:
(6 ppm)

a. Blackberries & Boysenberries
b. Blueberries
c. Cherries
d. Cranberries
e. Currants
f. Dewberries & Loganberries
g. Gooseberries
h. Grapes
i. Plums
j. Raspberries
k. Strawberries

(ATTACHMENT I, CONTINUED)

6. Grain & Seeds:

None examined

6. Grain & Seeds:

a. Barley
b. Dry beans
c. Dry shelled lima beans
d. Corn
e. Cottonseed
f. Oats
g. Rice
h. Rye
i. Sorghum
j. Soybeans
k. Vetch se
l. Wheat

III. Classes of Pesticides Considered

A. Herbicides

1. Benzoic and Phenylacetic Acids:

a. Dicamba

2. Phenoxy Compounds

a. 2,4-D

3. Heterocyclic Nitrogen Derivatives (picolinic acid)

a. Picloram

B. Fungicides

1. Chlorinated Compounds

a. Captan

C. Insecticides

1. DDT Relatives (diphenyl aliphatics)

a. DDT
b. Methoxychlor
c. Kelthane (Dicofol)

2. Chlorinated Aryl Hydrocarbons (containing 6 or more chlorines)

a. Endrin
b. Aldrin
c. Dieldrin
d. Toxaphene
e. Endosulfan
f. Chlordane

(ATTACHMENT I, CONTINUED)

3. Phosphorous Compounds

a. Disulfoton
b. Phorate
c. Phosdrin
d. Malathion
e. Demeton
f. Dimethoate
g. Parathion
h. Methyl Parathion
i. EPN
j. Trithion
k. Dioxathion
l. Diazinon
m. Sulfotepp

4. Sulfonates

a. Ovex (Ovotran)

5. Carbamates

a. Carbaryl

IV. Pesticides Resulting in Highest Pesticide Residue Values Based on 1 lb Per Acre, According to Crop Category

A. Grasses (240 ppm):

Picloram, amine salts

B. Grasses (110 ppm):

Malathion

C. Leaves and Leafy Crops (125 ppm):

EPN

D. Forage Crops (58 ppm):

Endosulfan

E. Pods Containing Seeds (10 and 12 ppm):

10 ppm: Dimethoate 12 ppm: Methoxychlor

F. Fruits (6.6 and 6.0 ppm):

6.0: Carbaryl 6.6: Endosulfan

G. Grain and Seeds (110 ppm):

Parathion

Reference: Hoerger and Kenaga (1972)

ATTACHMENT J: Techniques for Estimating Pesticide Residues on Vegetation Immediately Following Application

The following techniques are designed to provide an estimate of pesticide residues which can occur on types of vegetation which are utilized by wildlife as forage.

It must be emphasized that actual residue values are always preferable to "calculated" or "typical" values and should be obtained and utilized whenever possible. Actual residue data become even more important in marginal cases. However, the techniques given below should normally be acceptable substitutes in most cases when residue data are available.

Method A

1. Determine the intended use rate in pounds per acre.
2. Determine on the nomograph the type of vegetation which is most appropriate for the non-target organism(s) of concern.
3. Place a horizontal straight edge on the appropriate application rate in lb/acre (Column No. 1) and read across to the most appropriate maximum expected residue column. Record this expected residue value (ppm).
4. Where subacute LC_{50} data are available for a bird or mammal, determine if the expected residue (ppm) exceeds 1/5th of the LC_{50} (ppm) as per the regulation.

Method B

Alternately, where only LD_{50} data are available, the following procedure can be used with reservation and restrictions.

1. Determine the intended use rate in pounds per acre.
2. Determine on the nomograph the type of vegetation which is most appropriate for the non-target organism(s) of concern.
3. Place a horizontal straight edge on the appropriate application rate in lb/acre (Column No. 1) and read across to the most appropriate maximum expected residue column. Record this expected residue value (ppm).
4. Locate on Table 1 the bird species whose body weight most closely approximates the species of concern. Note the bird weight and grams of feed eaten per day for this species.

(ATTACHMENT J, CONTINUED)

5. Using the above values, perform the following calculation:

$$\frac{\text{feed eaten per day (g)}}{\text{weight of bird (g)}} \times \text{pesticide residues (ppm)} = \frac{\text{mg pesticide}}{\text{kg bird weigh}}$$

6. Determine if the daily ingestion amount (mg pesticide/kg bird weight) exceeds 1/5th of the LD_{50} (mg/kg) as per the regulation.

Comments and Cautions

As with any oversimplification or extrapolation process, the techniques described herein should always be coupled with additional judgments. Several obvious flaws in the techniques are provided below. These should not be forgotten or overlooked in the use of the techniques.

1. The techniques outlined herein cannot be applied to insectivorous bird exposure because insects can be expected to contain considerably different residues than vegetation because they will inhale, walk upon, ingest, metabolize, and otherwise be exposed to greater amounts of pesticide than would vegetation.

2. Neither can these techniques be effectively used when a pesticide is applied in a granular form. When a formulation takes this form, first the amount of active ingredient per granule and then the number of granules equivalent to the LD_{50} in mg/kg for a species should be determined. A judgment can then be made, based on application rate and LD_{50} data, as to whether a species is likely to consume 1/5th of its LD_{50} in a day.

3. Certain seeds will not be eaten in toto. Instead, only the inside unexposed portions will be ingested, leaving the shell, hull or pod.

4. Further exposure beyond the oral route is likely. For example, compounds known to be dermally toxic can present additional hazard as a result of locomotion through dew (and pesticide) covered vegetation. For some toxicants, this route is as much or more the source of acute or subacute hazard as the oral route.

5. Young birds may be exposed to relatively greater amounts of ingested contaminated feed which also may be of smaller size and therefore contain greater residues. Table 1 refers only to adult birds. In addition, immature birds of many species go through a growth period when their diet is almost entirely insectivorous. These birds would be especially vulnerable during this critical period.

(ATTACHMENT J, CONTINUED)

6. Allowance should be made for at least a 2- to 3-fold difference in daily rate of food consumption from day to day, particularly in the case of large birds or inclement weather. Thus, if a pesticide had a short-acting nature (such as strychnine) which could kill quickly following short, high exposure levels, death could occur in birds gorging in contaminated feed which would normally be eaten over a longer time period. Therefore, the acceptable residues in vegetation would be 2 to 3 times less than those normally considered acceptable according to the techniques contained herein.

7. The "upper limit" residues presented in Kenaga's paper and employed in the nomograph were stated in terms of wet weight. The bird consumption values are presented in terms of dry weight. This is a discrepancy, but drift during application and other factors affecting residues should essentially offset this weight basis factor so that further correction need not be applied.

8. The techniques are only appropriate for initial surface deposited residues and do not account for the systemic uptake by plants which occurs with some pesticides.

9. The values in the nomograph are not necessarily appropriate for large fruit because birds will only peck at and consume the surface part of the fruit and the values in the nomograph pertain to the whole fruit. Since residues will be concentrated on the fruit surface and not distributed evenly throughout, the values are not representative of the amounts that could be expected to be consumed.

10. The techniques are useful only in the evaluation of acute and short-term subacute hazard. They are not intended for evaluation of chronic hazard.

11. When multiple applications are made, it is necessary to know degradation rates to properly assess the applicability of the techniques.

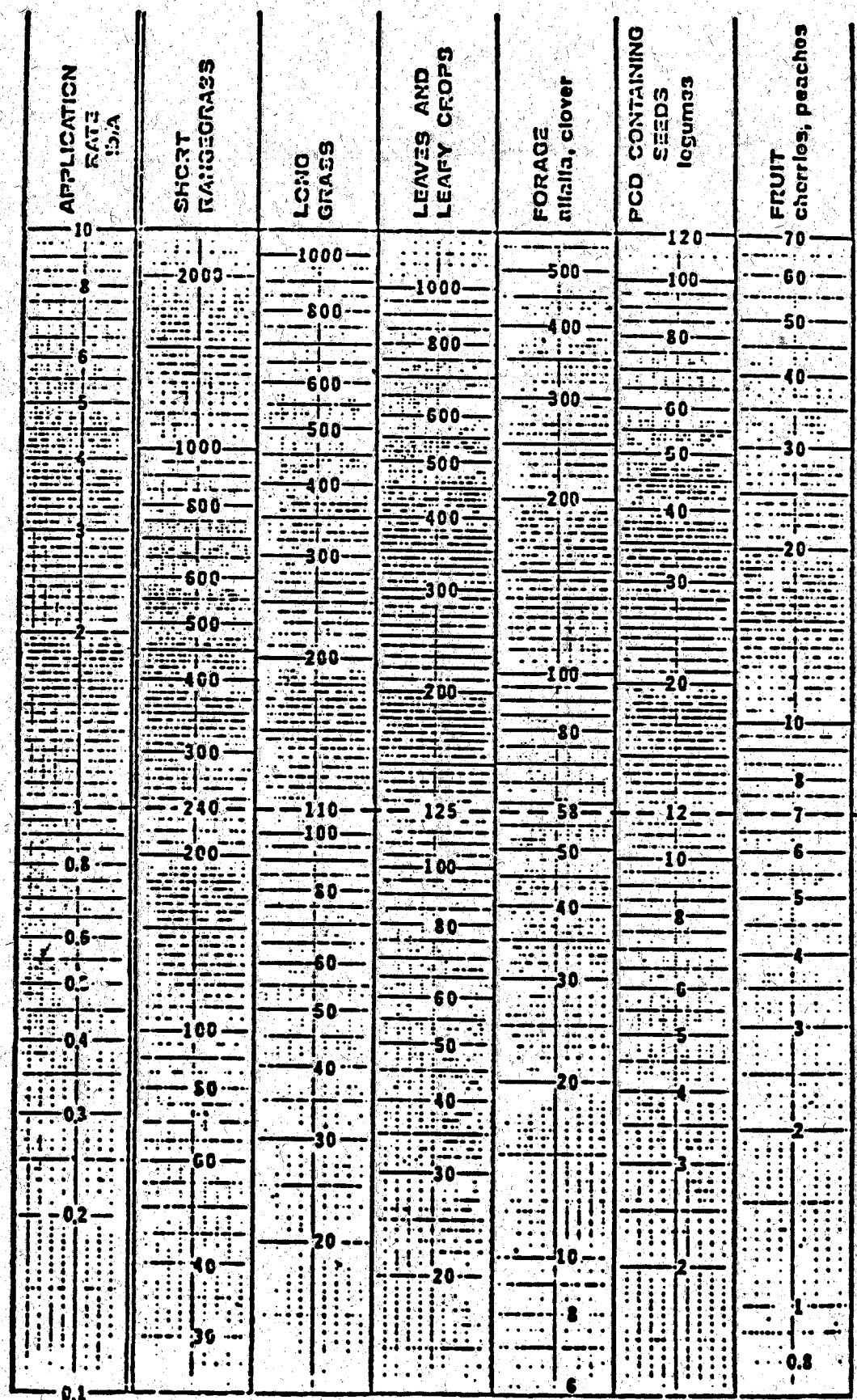
(ATTACHMENT J, CONTINUED)

TABLE 1. Relation of dry feed consumption to body weight of birds.

Bird Species	Adult Weight (g)	Mean Weight Dry Feed Eaten Per Day (g)
Blue tit	11	3.3
Robin (European)	16	2.35
Mourning dove	100	11.2
Bobwhite	170	15.2
Mallard, Pheasant	1200	50

MAXIMUM EXPECTED RESIDUES ON VEGETATION

ppm



ATTACHMENT K: Human Risk Approach Using Mammalian Data

A. Mammalian Data

1. Older rat 2-year NOEL = 200 ppm
2. Rat body weight = 0.4 kg
3. Rat food consumption = 20 gm or 0.02 kg
4. F. cons./b. wgt. = 5%

B. Calculations

1. Relationship (Lehman, 1959):

% body weight consumed x dietary residue = mg/kg/day consumed

5% x 200 ppm = 10/mg/kg/day = NOEL

2. Human risk calculations:

a. Man body weight = 60 kg

b. Man food consumption = 1500 g or 1.5 kg

c. Food consumption/body weight = 2.5%

d. Apply 100-fold safety factor: i.e., man is 100x more sensitive than rat:

i. NOEL x 1/100 = 10 mg/kg/day x 1/100 = 0.1 mg/kg/day

ii. $\frac{\text{Food consumption}}{\text{Body weight}}$ (%) x residues (ppm) = mg/kg/day

2.5% x ppm = 0.1 mg/kg/da
ppm = 4

iii. Also,

$$\frac{1.5\text{ kg}}{60\text{ kg}} \times \frac{6\text{ mg}}{1.5\text{ kg}} = 6\text{ mg/60 kg person/day}$$

[2.5% x 4.0 ppm = 0.1 mg/kg/day]

iv. Thus, safe level (or NOEL) established for man is 0.1 mg/kg/day or 6.0 mg/60 kg person/day or 4.0 ppm.

(ATTACHMENT K, CONTINUED)

C. Correlation of NOEL with residue (or tolerance) data

Crop or Food Item	Proposed Established Tolerance (ppm)	x	Food Factor (%)	x	Daily Diet (kg)	=	Contribution to NOEL[1/] (mg/day/1.5 kg)
Cottonseed	0.2 ppm	x	0.15%	x	1.5kg	=	0.00045 (0.00045 mg/1.5 kg = 0.0003 ppm)

These calculations indicate that a tolerance of 0.2 ppm on cottonseed, which constitutes only 0.15 percent of man's diet, will contribute 0.0075 percent (0.0003 ppm/4 ppm or 0.00045 mg/6 mg) towards the NOEL or ADI for man.[2/]

1/ Acutally considered an ADI (Acceptable Dietary Intake) by toxicologists.

2/ Tolerances are granted on all crops until, theoretically, the NOEL or ADI for man is reached.

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