

Pesticide Ecological Effects Database

Guidance Manual-Updated 10/26/05

Introduction

This guide has been prepared to explain the documentation procedures utilized in the pesticide ecotoxicity database developed by the Environmental Fate and Effects Division of the Office of Pesticide Programs, USEPA. The database incorporates summaries of ecological toxicity data which have been reviewed and categorized as fully or partially acceptable for fulfillment of pesticide registration and reregistration guideline requirements as explained under FIFRA Subdivision E, Parts 158.145 and 158.150.

Purpose and Goals

The purpose for development of this database has been to make more readily accessible a current up to date summary of EPA reviewed data corresponding to the ecotoxicological effects of all pesticide active ingredients presently registered or previously manufactured in the U.S. for the greatest diversity of species possible. Data on newly proposed chemicals are not entered until U.S. registration is granted by the Agency.

1. The database was originally initiated in 1991 to assist toxic chemical modeling procedures being developed by the Chesapeake Bay Program Office in Region III. Though originally designed as an risk assessment tool for use by Divisions within the Office of Pesticide Programs and various other offices within the Agency, it has also been provided to other government agencies and the public for general use in researching the toxicity of pesticides to wildlife, aquatic organisms and plantlife.
2. It is not the first attempt to electronically store this information. Past attempts were abandoned due to lack of funding to employ entry personnel, lack of FTE allocation to carry through the oversight, and use of obsolete systems which could not be transferred to new software.
3. The present database appears to have secured adequate funding to continue the effort through the upcoming fiscal year. Eventually this system will be integrated into a Office of Pesticide Programs Information Network (OPPIN) system presently under development by OPP as well incorporated into an OPP website.

Data Sources

Unlike many ecotoxicity databases, the Pesticide Ecotoxicity Database is composed primarily of unpublished data that has been carefully reviewed by the Agency. Most current databases primarily summarize published literature. Toxicity data for this database are drawn from several sources.

1. Toxicological studies conducted a commercial laboratories and submitted by pesticide companies in support of their products. EPA's Office of Compliance and Monitoring conducts periodic audits of these laboratories. These studies are funded by the chemical

companies.

2. Published studies conducted by United States EPA, Dept. of Agriculture, and Fish and Wildlife Service research laboratories over the last 25 years. This data must be evaluated by Agency biologists and considered to meet our guideline criteria for acceptability before it's use in the regulatory process.
3. Published studies obtained and evaluated by OPP biologists for criteria mentioned above.

Major EPA Accepted Toxicological References Used in the Pesticide Ecotoxicity Database

1. Hudson, R.H., R.K. Tucker, and M.A. Haegle. 1984. Handbook of Toxicity of Pesticides to Wildlife. USFWS Publication No. 153
2. Hill, E.F., R.G. Heath, J.W. Spann, and J.D. Williams. 1975. Lethal Dietary Toxicities of Environmental Pollutants to Birds. USFWS Publication No. 191
3. Johnson, W.W., and M.T. Finley. 1980. Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates. USFWS Publication No. 137
4. Mayer, F.L., and M.R. Ellersieck. 1986. Manual of Acute Toxicity: Interpretation and Database for 410 Chemicals and 66 species of Freshwater Animals. USFWS Publication No. 160.
5. Mayer, F.L. 1986. Acute Toxicity Handbook of Chemicals to Estuarine Organisms. USEPA Environmental Research Laboratory, Gulfbreeze, Florida. EPA Publication 600/x-86/231.

In addition, other studies conducted by USFWS and studies conducted by J.A. McCann for USDA, and later USEPA, at the Agricultural Research Center in Beltsville, Maryland are included in the database for aquatic species. Acute oral and contact honeybee toxicity studies conducted by Atkins at the University of California, Riverside are generally considered acceptable in fulfilling nontarget insect toxicity study requirements.

Criteria Employed by EPA In The Review Process for Registration/ReRegistration Product Data

Though the requirements are broadly outlined under the 1988 Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Pesticide Assessment Guidelines, more detailed summaries of the procedures utilized by Agency scientists in determining ecotoxicity data acceptability has been developed by the Agency through our Standard Evaluation Procedures manuals (EPA Publication 540 Series) and currently finalized 850 guideline series publications.

Criteria for Acceptance of Published Data

In general, published data must show evidence of satisfying all criteria needed for acceptable data as explained in our Standard Evaluation Procedural Manuals and/or as accepted by the American Society for Testing and Materials (ASTM). They must qualify as being conducted under Good Laboratory Practices (GLP) requirements.

Data Rejection Criteria

Though the Agency SEP's and ASTM are relatively specific as to what data must be reported and what study designs are preferred, the Agency scientist who initially reviews the study must determine the degree of compliance with these requirements.

1. Any omissions of data required to independently confirm the study author's conclusions may lead to rejection of the study.
2. Some deviations may be allowed if it is felt the study is still scientifically reliable for risk assessment and provides some useable information.
3. If the Agency determines that data omissions or study design weaken the overall validity or scientific acceptability of a study (e.g., significant deviations from ASTM or Agency recommended testing methodology), then the study is rejected for use in supporting registration of the test material.
4. Study submissions used to support pesticide registration must generally include the actual raw data recorded by the laboratory and meet GLP requirements.
5. Exceptions are published or unpublished data compiled by federal or university laboratories in which protocol guidelines are explained, studies were conducted according to scientifically accepted methods utilized at the time, and a quality assurance process has been completed prior to publication. The Agency does have laboratory records associated with many of these federally sponsored studies.

Data Entry Fields for Ecotoxicity Database

When data for a particular field has not been reported in the data evaluation report then **N.R.** is entered. When data for a field does not apply to the study in question then **N.A.** is entered to represent "Not Applicable".

Chemical Name: The common name associated by the Agency with this particular active ingredient. Product names are not generally utilized. If two or more common names are associated with the same active, the user may be referred to the other name(s) under which the toxicity data has been entered (e.g., Dacthal data is entered under DCPA). Chemical names with over 40 characters are avoided if possible.

Shaughnessy Code: This 6 number code (also referred to as the PC Code in the Agency) is used to distinguish each pesticide active ingredient on record in the Office of Pesticide Programs. Shaughnessy codes do not include chemicals which have no uses as a pesticide. They may include canceled or as yet unregistered pesticides, however this database does not include unregistered chemicals for confidential business information reasons.

-Degradates of a pesticide may be entered under the same shaughnessy code unless an independent one has been assigned.

-Dual active pesticide mixtures are entered under the chemical PC Code of the highest % chemical contained in the mixture.

Inert Ingredients which may not have a current PC Code assigned are currently entered under

999999 in the PC Code field, but under their currently accepted common name.

CAS Number: Chemical Abstract System number associated with this particular active ingredient. CAS numbers are not specific to pesticides and include industrial as well as agricultural chemicals that have no pesticidal uses. However, all PC Codes are associated with a CAS number if they have been assigned.

Use Pattern: The major use pattern generally associated with this active ingredient. If more than one use pattern applies then the heaviest or most common use pattern will be entered. Use patterns included are insecticide, herbicide, fungicide, algicide, fumigant, microbiocide, miticide, nematocide, molluscicide, growth regulator and rodenticide. Others may be entered as needed.

Taxa: This field refers to the general taxa for the species tested in each study. Taxa fields included in the database are mammalia, aves, insecta, fishes, amphibia, mollusca, aquatic plant, terrestrial plant and crustacea. This field allows a general sorting of all entered data by taxonomic group.

Common Name: The generally accepted common name for the test species when there is one. Generally, such guides as the American Fisheries Society Guide to Common and Scientific Names of Fishes are utilized for species where more than one common name may apply. If a common name is not applicable a general descriptive name is used(eg. freshwater algae).

Scientific Name: Genus and species of tested organism. If only genus is provided "sp." is entered for the tested species.

Age: If possible, some indication of the age of the organism will be given. N.R. will be entered when not reported.

- The ages of mammals and birds are generally given in days, weeks, months, or years.
- For acute studies the age/size of the tested fish is generally expressed as mean average weight in grams, as reported in the stud evaluation. If mean weight is not reported mean length is used.
- If no size is given for a vertebrate test species, but a lifestage such as "juvenile" or "adult" is indicated, this will be entered for age.
- Crustacean shell deposition study organism age is generally entered as "spat" vs "emblrv." for embryo larval studies.
- Ages of crustaceans, insects, and mollusks are generally expressed as year class, lifestage, instar, or size.
- Ages of aquatic plants are generally not given (not reported), though terrestrial plant studies may report age as "seedling" for Seedling Emergence study vs "juvenile plant" for Vegetative Vigor studies.
- Chronic studies generally test early life stages or a full life cycle of a test species. Age is referred to as early life stage (ErlyLf) or full lifecycle (LifCyc) for these studies.

Guideline Number: Guideline codes as explained under FIFRA Subdivision E, Part 158. These

codes will allow the user to sort by the specific type of study such as avian dietary, freshwater fish acute, estuarine organism acute, etc.

Wildlife and Aquatic Organisms Data Requirements FIFRA 158.490	
71-1	Avian Acute Oral-Game Bird or Waterfowl TGAI/TEP*
71-2	Avian Dietary-Waterfowl and Game Species
71-4	Avian Reproduction-Chronic Toxicity
71-5	Simulated or Actual Field Test Mammals & Birds
72-1	Freshwater Fish Acute-warm and coldwater species with TGAI or TEP
72-2	Freshwater Invertebrate Acute TGAI or TEP
72-3	Estuarine/ Marine Fish, Shellfish, Shrimp Acute using TGAI or TEP
72-4a	Freshwater or Marine/Estuarine Fish Early Life Stage Chronic Toxicity using TGAI or TEP
72-4b	Freshwater Invertebrate Life Cycle Chronic Toxicity using TGAI or TEP
72-5	Full Fish Life Cycle TGAI
72-7	Simulated or Actual Aquatic Field Study TEP

Plant Protection Data Requirements FIFRA 158.540	
122-1	Tier I Seed Germination-single dose
122-1	Tier I Seedling Emergence-single dose
122-1	Tier I Vegetative Vigor-single dose
122-2	Tier I Aquatic Plant Growth-single dose
123-1	Tier II Seed Germination-multi-dose
123-1	Tier II Seedling Emergence-multi-dose
123-1	Tier II Vegetative Vigor-multi-dose
123-2	Tier II Aquatic Plant Growth-multi-dose
NonTarget Insect Toxicity Data FIFRA 158.590	
141-1	Honey Bee Acute Contact LD50
141-2	Honey Bee Toxicity of Residues on Foliage

* **TGAI**= Technical Grade Active Ingredient

TEP=Typical End-Use Product

Test Type: This field further defines the method of administering the dose. A one or two letter code is entered here. Code explanations are as follows:

Avian, Aquatic, and Some Insect Studies

O = Oral gavage or capsule administration of the toxicant to produce an LD50

D = Administration of the toxicant ad libitum in the diet to produce an LC50

R = Reproductive study - generally a multi-week dietary administration for birds or mammals

S = Static system method (used in aquatic studies)

SR = Static renewal system (used in acute or chronic aquatic studies)

F = Flow through system (used in acute or chronic aquatic studies)

Plant Studies

SG = Seedling germination-terrestrial plants

SE = Seedling emergence-terrestrial plants

VV = Vegetative vigor-terrestrial plants

and often followed by PH=Phytotoxicity effect (ie chlorosis)

SH=Shoot height

SL=Shoot length

DW=Dry weight

RL=Root length

RW=Root weight (fresh or dry)

HT=Plant Height

C = Acute Contact Study (insect studies generally)-pesticide topically applied or dermally adsorbed

FO = Foliar residue feeding study -nontarget insects are exposed to treated foliar surfaces

% AI: The percent of active ingredient contained in the test material.

If this is expressed simply as Technical Grade in the report then "TECH" is entered.

When formulations are tested the percent of active ingredient contained is entered. Mixes are entered with highest % active first followed by slash and the second major active %.

If % active ingredient is not indicated in a formulation test "FORM" is entered.

Granular formulations are entered as "G" after % ai number.

Emulsifiable concentrate formulations are entered as "EC" after % ai number.

Wettable powder formulations are entered as "WP" after % ai number.

Microencapsulated formulations are entered as "ME" after % ai

Study Length: The actual definitive study period expressed in hours, days, weeks or months as

appropriate. This includes the period of exposure and the post exposure observation period.

Dose Type: Reflects the endpoints the study has produced for the parameters it is designed to measure

EC25 = 25% Effect Concentration (plant studies)

EC50 = 50% Effect Concentration

LD50 = 50% Lethality from oral dose

LC25 = 50% Lethal Concentration in diet or water

LOEC or LOEL = Lowest Observed Effect Concentration (aquatic) or Observed Effect Level (dietary) for avian reproduction, aquatic early lifestage, or fish full lifecycle studies with both an NOEC and an LOEC

RT25= Residual Time to 25% mortality used in honeybee studies

TGL

“Greater than” or “less than” field for toxicity entries-this field was added to remove the < and > characters from the numerical toxicity field and allow mathematical manipulation of multiple entries.

If studies produced no lethal toxicity endpoint then Dose Type will be expressed as > highest dose tested.

If the LD50, LC50, EC50, or LOEC is below the lowest dose tested then the value will be entered as < than the lowest concentration in water or diet tested.

Toxicity: The numerical expression of the effect dosage types mentioned above under dose type field followed by the tox level (next field over).

Tox Level: Three letter code that expresses the dosage in orders of magnitude.

PPM: Parts Per Million

PPB: Parts per Billion

PPT: Parts per Trillion

UGB: Micrograms/bee (contact LD50 studies with honeybees)

UGG Micrograms of ai/gram of bee

MGK: milligrams/kg body wt(acute oral toxicity studies)

LBA: Equivalent concentration lbs ai/Acre (sometimes converted from grams ai/hectare)

This field provides a character field which can be used in conjunction with the toxicity field which is a numerical field. The user could thus sort individual data by magnitude levels of toxicity if needed.

95% Confidence Limits - as expressed by the study reviewer's independent statistical analysis. This field is entered as "N.R" if the study review does not state any confidence limits. In cases where the toxicity endpoint (ie LC₅₀) is greater than the highest dose tested "NA" (not applicable) may be entered. Many of the older studies may require that the Agency eventually repeat the statistical analysis of the raw data in order to replace any statistical information not included with the current study report.

Curve Slope: Probit slope if reported. If no probit slope is reported "NR."(not reported) is entered here. If it is not applicable to the study results then NA is entered in this field (eg no probit analysis possible)

NGL

Greater than(>) or less than(<) field for NOEL if not clearly established. For instance, if effects are observed at all tested dosages then < would precede the NOEL (lowest dose level). If no effects are observed at any concentration then the NOEL is the highest concentration tested.

NOEC or NOEL: No Observed Effect Concentration or Level- highest dose level where no effects (lethal, physical, or behavioral signs) are noted in this particular study.

Study Date: Year that the definitive study was completed by the laboratory.

Review Date: Year that the Agency completed its science review of the laboratory's final report.

Category: The three study categories used by the Agency to classify studies are core, supplemental, and invalid are represented by a letter code as C, S, or IN. Invalid studies are not entered into the database unless they are considered to be repairable at a later date by provision of additional data. Unrepairable studies will not be entered. The explanations for core, supplemental, and invalid studies are included in the SEP guidance documents. They are explained in attachments at the end of these guidelines.

EPA Ident: The EPA identification code used to retrieve a microfiche copy of the study as submitted to the Agency. These are expressed as an accession number "ACC" (6 digits) or MRID number (8 digits). These numbers are mainly for Agency use, but could be utilized to identify and obtain an actual copy of the Agency evaluation report from OPP's Freedom of Information Office in Arlington, Va. Prior to MRID numbers Accession numbers sometimes referred to single submission of multiple studies to the Agency for a single chemical. MRID numbers are now assigned individually to a single study. Accepted references of multiple studies have a single MRID assigned to the entire publication. If a study exposes more than one species in the same test then an MRID number may appear more than once in the database.

Doc # This is a new field and will pertain to identification numbers for pdf images of study evaluations which are currently being scanned by OPP. As scanning is completed for a data evaluation report this number will be added to the record for that study.

Lab Code: To avoid lengthy field entries a 3 letter code has been assigned by the database team to all laboratories which have conducted studies entered into the database to date.

Scientist: First initial and last name of the EPA scientist who evaluated the study. In the case of published compilations of pesticide toxicity data accepted by the Agency the first initial and last name of the main author(s) appears in the "scientist" field. In some cases the same data was independently reviewed by an Agency scientist prior to publication of these references.

Chronic Effect End Points

Many of these chronic endpoints apply to avian reproduction studies although growth, embryo and juvenile survival, and hatch success may also apply to chronic aquatic studies. If there is no entry in these fields then the endpoint for which chronic effects were observed has not been clearly stated in the report or there were no effects observed for that particular endpoint. When multiple effects are reported the LOEC for each individual endpoint may be reported in it's respective field.

Eggs laid - dosage at which the number of eggs laid or produced are affected

% Cracked - dose level at which significant increase in cracked eggs(avian) is noted

% Viable - dose at which % of viable eggs is affected

% Embryo Live - dose at which % of live embryos is affected

% Egg hatch - dose at which % hatch success is affected in avian or aquatic studies

14D Survive - dose level where chick survival in avian studies or larval/offspring survival in aquatic studies is effected.

Growth Effect - dose at which significant growth effects are noted for birds or aquatic organisms such as reduced weight or length.

Data Entry Procedures

1. EPA studies being entered into this database have already been reviewed by an Agency scientist as well as a second supervisory biologist. Therefore, determination of the study's validity is not required during the data entry process.
2. Toxicity data from acceptable published references. These data are reviewed to determine if any departures from required criteria are apparent (e.g., length of study, use of proper species). If there are clear departures, but the data is judged useable for risk characterization then the study is generally classified as supplemental data.
3. The entry process does not involve review of the actual laboratory data. The entry data is derived from the EPA scientist's Data Evaluation Report and independent statistical analysis. There may be gaps in the Data Evaluation Reports in regard to all 32 of the database entry fields or some may not apply due to the type of study or lack of response at tested dosages.
4. Additional information discovered during the secondary quality assurance effort by Agency scientists will be amended to the record.
5. If necessary an actual copy of the original submitted laboratory report will be retrieved in order to complete the entry process as a part of the tertiary quality assurance effort.

Avoiding Errors

The Ecological Effects Database entry program has been designed to aid the entry personnel in avoiding errors during the entry process.

Entry codes have been developed for each species being entered into the database. This code automatically triggers the system to correctly enter the Taxa, Common Name, and Taxonomic Name, thus avoiding spelling errors.

Menu selection boxes for dose type, use pattern, tox level, and the study category field speed entry of this information.

Points About Individual Records

Every record in the database represents a single toxicological study or portion of a study conducted

with a single species.

In cases where a laboratory report includes toxicity data for more than one species (e.g., terrestrial plant studies) an individual record is created for each tested species. The chemical information, EPA identification code, lab code, study completion date, review date, and reviewer data remain the same in such a case.

If published data compilations are used in the database the entry personnel use the FIFRA study quality criteria in determining the classification category for entered data (e.g., age, study length, etc).

In references where a great number of studies are cited for the same species using the same identical grade test material under similar conditions (e.g., Mayer and Ellersieck) the study producing the lowest LC₅₀ or EC₅₀ value is entered.

When different ages or life stages for the same species are referenced in a study these are entered as separate record for each age level tested if a separate effect endpoint is produced.

If different formulations are tested on the same species then each formulation test is entered as a separate record.

In any case a representative study for each of the total number of species tested will be entered from the reference publication in order to increase the overall species diversity contained in the database for that particular pesticide.

Quality Assurance Procedures

Primary:

Primary quality assurance is considered to have been performed when the study was initially reviewed by Agency personnel. At this time the individual scientist reviewing the study examined all data reported to determine if the criteria required by the Agency at that time were met by this study. Individual criteria such as test material purity, age of tested species, test materials and design, and determination of acceptability of the final results are presented in the data evaluation record. The study review is secondarily reviewed by senior biologist whose signature also appears on the study evaluation report. These data are then extracted and entered into the database by the entry personnel.

Secondary:

Secondary quality assurance for this data is considered to be the review and comparison of the data endpoints entered into the database with the data presented in the actual data evaluation report. The secondary review process is conducted by EFED scientific personnel, but not by the person who initially entered the data. This quality assurance effort will be conducted on every record entered into the database. In addition, EFED scientists assist the database team in quality assurance by noting any entry data which is found to have errors during their day to day use of the system.

Tertiary:

Tertiary quality assurance will be implemented following a completed secondary review. The methods used in this third review will include random visual check of data entries, several methods of sorting by data fields to detect inconsistencies, and further investigation into records which contain these inconsistencies. Any data which were not reported in the original study review may eventually be filled by recalling the actual laboratory study report from the OPP document

processing center.

Classification Codes

The following criteria are used in classification of ecological effects data submitted to the US EPA Office of Pesticide Programs in support of pesticide registration.

Core: All essential information was reported and the study was performed according to recommended EPA or ASTM methodology. Minor inconsistencies with standard recommended procedures may be apparent; however, the deviations do not detract from the study's soundness or intent. Studies within this category fulfill the basic requirements of current FIFRA guidelines and are acceptable for use in a risk assessment.

Supplemental: Studies in this category are scientifically sound; however, they were performed under conditions that deviated substantially from recommended protocols. Results do not meet guideline requirements; however, the information may be useful in a risk assessment. Some examples of the conditions that may place a study in a supplemental category include:

- Unacceptable or non-native test species
- Test material not properly identified
- Dosage levels tested were less than 5000 ppm (or 100 ppm for aquatics), but not high enough to produce an effect on the tested organisms or a precise LC50/EC50 (exceptions sometimes made for highly insoluble chemicals).
- Deviations from recommended diet preparation measures
- Deviations from recommended water quality characteristics which may have stressed test organisms and affected toxicological response (e.g., low D.O. in aquatic studies)
- Tested organisms were older or younger than required age.

Invalid: These studies provide no useful information. They may not be scientifically sound, or they were performed under conditions that deviated so significantly from the recommended protocols that the results will not be useful in a risk assessment. Also studies where test materials are not clearly identified as to % ai, etc may receive invalid classification.

Examples of invalidated studies include those where there were problems with volatility of the test material or when a dry chemical was mixed without the use of a vehicle and precipitates are observed. Unless acceptable chemical analyses of actual toxicant concentrations were performed in studies such as these, the reviewer cannot be sure that the test organisms were actually exposed to nominally designated concentrations.

Rationale: This identifies what makes the study supplemental or invalid. It may be necessary to justify a higher category in spite of deviations. That is, a study may be called core or supplemental even though there were substantial deviations from recommended protocol. While all deviations should be noted, it may be that the deviations did not actually alter the response of the test organisms to the test material. The reviewer is expected to exercise judgement in this area.

Repairability: This indicates whether the study may be upgraded or given a higher validation category if certain conditions are met. Usually this would involve the registrant's submission of more data to clarify questions about the study conditions or results.