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Study Classifications Used by EFED in
Data Evaluation Records (DERs)

Studies submitted to EFED in support of pesticide registration or re-registration are categorized as to their usefulness in a risk assessment. While different sets of terms have been used over the years to describe the quality and value of environmental fate and ecological effects studies, there has been consistency in the general meaning of the classifications and their application.

The three general categories used for classifying studies are:

Core or **Acceptable**
Supplemental, **Upgradeable**, or **Ancillary**
Invalid or **Unacceptable**

Core or Acceptable means that all essential information was reported, the data are scientifically valid, and the study was performed according to recommended protocols. Minor inconsistencies with guidelines may be apparent, but they do not detract from the guideline's intent. Studies in this category fulfill the corresponding data requirement in 40 CFR Part 158, and are appropriate for use in a risk assessment.

Supplemental is a somewhat broad category. Studies in this category are scientifically valid, however, they were either performed under conditions that deviated from recommended guideline protocols or certain critical data necessary for complete verification are missing. Supplemental studies may be useful in a risk assessment and can, at the scientist's discretion, fulfill the corresponding data requirement in 40 CFR Part 158. A subset of these studies might be referred to as Upgradeable. These studies may be upgraded to Core/Acceptable with additional information. Other Supplemental studies may be referred to as Ancillary. These studies appear to provide scientifically sound information, but the data cannot be verified under EPA's criteria, and/or the study is not upgradeable.

Invalid or Unacceptable studies are not scientifically valid, or deviated substantially from recommended protocols such that they are not useful for risk assessment. These studies do not fulfill the corresponding data requirement in 40 CFR Part 158.

Soon we hope to implement new terminology and definitions that will apply to both ecological effects and environmental fate studies and thus will harmonize the way in which the two disciplines describe the status of the data. In addition, the proposed terminology is consistent with what is being used by the Health Effects Division in the Office of Pesticide Programs in their toxicology data evaluation records. The suggested new terms and definitions are:

- **Acceptable/Guideline**: All essential information was reported and the study was performed according to Office of Pesticide Programs' recommended protocols. Minor inconsistencies with guidelines may be apparent, however, the deviations do not detract from the guideline's intent. Studies in this category fulfill the corresponding data requirement in 40 CFR Part 158 and are appropriate for use in a risk assessment.

- **Acceptable/Non-Guideline**: These studies may or may not have been performed according to Office of Pesticide Programs' recommended guidelines. The studies are scientifically valid, but deviated from OPP-recommended protocols. Results are useful in a risk assessment and can, at the scientist's discretion, fulfill the corresponding data requirement in 40 CFR Part 158.

  Some of the conditions that may place a study in this category include: a) inappropriate test species, b) deviations from recommended test solution characteristics, c) inappropriate soils, or d) insufficient sampling intervals. Furthermore, a study that meets other guidelines (e.g., ASTM, BBA, etc.), could be included in this category.

- **Unacceptable**: These studies are not scientifically valid, or critical information required to determine the validity of the study is missing. Also in this category are those studies that deviated substantially from OPP-recommended protocols such that they are not useful for risk assessment. These studies do not fulfill the corresponding data requirement in 40 CFR Part 158.

  If these studies are upgradable, the data needed to resolve the deficiencies should be specified.

Studies in the peer-reviewed open literature often provide valuable information that can be useful for risk characterization. Because these studies are usually conducted for purposes other than satisfying FIFRA regulatory requirements, they rarely meet the study objectives as outlined in the Pesticide Assessment Guidelines. Also, access to the raw data needed to evaluate the study is generally not available. Therefore, it is unlikely that open literature studies can fulfill the requirements of 40 CFR Part 158. Separate guidance on assessing data from the open literature and when this information may be used in our risk characterizations will be forthcoming.