STANDARD OPERATING PROCEDURE		
SOP NO.: GLP-S-05		Page No.: 1 of 23
Title: **GLOSSARY OF GLP AND SELECTED EPA TERMS AND ACRONYMS**		
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1. **PURPOSE**

To ensure correct and consistent usage of the specialized terminology relating to the Toxic Substances Control Act (TSCA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practices (GLP) Standards regulations [40 CFR Parts 792 and 160, respectively].

2. **SCOPE**

This SOP provides a glossary of terms which should be used by inspectors and auditors in the TSCA and FIFRA GLP inspection program. Consistency in usage of these terms is necessary in order to avoid confusion and misinterpretation of information presented in inspection reports and summaries, as well as in letters, memoranda, and professional papers.

3. **OUTLINE OF PROCEDURES**

- Acronyms and abbreviations
- Glossary of GLP terms
- Selected EPA terms

4. **REFERENCES**

4.1 TSCA GLP Standard Regulations, 40 CFR Part 792
4.2 FIFRA GLP Standards Regulations, 40 CFR Part 160

5. **SPECIFIC PROCEDURES**

5.1 Acronyms and Abbreviations

The following acronyms are sufficiently well known that they may be used in most written documents without further definition:

- **EPA** (U.S. Environmental Protection Agency)
- **FDA** (U.S. Food and Drug Administration)
- **CFR** (Code of Federal Regulations)
- **FIFRA** (Federal Insecticide, Fungicide, and Rodenticide Act)
- **TSCA** (Toxic Substances Control Act)

The following should be defined (by writing the full name or term and giving the accepted acronym in parentheses immediately following) when first used in a written communication, and redefined if a significant gap occurs between usages (accepted acronyms are shown in parentheses):

- Office of Prevention, Pesticides, and Toxic Substances (OPPTS)
- Office of Enforcement & Compliance Assurance (OECA)
- Office of Pesticide Programs (OPP)
- Office of Compliance (OC)
- Agriculture & Ecosystems Division (AgED)
- National Enforcement Investigations Center (NEIC)
- Organization for Economic Cooperation and Development (OECD)
- National Toxicological Program (NTP)
- Other government departments, offices, divisions, branches, etc., when used
- Premanufacture Notification (PMN)
- Good Laboratory Practice (GLP)
- Standard Operating Procedure (SOP, plural SOPs)
- Curriculum vitae, plural curricula vita (CV, CVs)
- Quality Assurance Unit (QAU)
- Quality Assurance (QA)
- Company names, when abbreviated, i.e.:
  - E.I. duPont deNemours (duPont)
  - Analytical Development Corporation (ADC)
- Chemical names, when abbreviated, i.e.:
  - Pentachlorophenol (PCP)
  - Ethylenebisdithiocarbamates (EBDCs)
- Instruments and techniques, when abbreviated, i.e.:
  - Thin-layer chromatography (TLC)
  - Liquid scintillation counter (LSC)

5.2 Glossary of GLP Terms

The following terminology is to be utilized in all documents related to the TSCA or FIFRA GLP programs, particularly when preparing inspection reports. An index of terms defined in this SOP is attached. Authors and reviewers should be consistent in the usage of these terms.

Active Ingredient (AI) The chemical or substance in a pesticide product that can kill, repel, attract, mitigate or control a pest, or that acts as a plant growth regulator.

Administrative Record The permanent, reviewable record of the Agency's regulatory review and decision process. It consists of a statement of the Agency's decision (i.e., position documents); science reviews and chapters; the associated supporting bibliography; and non-technical documents (e.g., decision packets, internal and external correspondence). These documents detail the evolution of the Agency's decision on a pesticide's status.

ai/A The amount of pure pesticide active ingredient applied per acre.

Applicant The term given to a chemical company or other organization that has applied to OPP to obtain registration of a pesticide product.

Association of American Pesticide Control Officials (AAPCO) An association of state pesticide regulatory officials dedicated to the effective enforcement of laws and implementation of programs that relate to proper and safe use of pesticides.

Application for Research or Marketing Permit: (1) An application for registration, amended registration, or reregistration of a pesticide product under FIFRA sections 3, 4, or 24(c). (2) An application for an experimental use permit under FIFRA section 5. (3) An application for an exemption under FIFRA section 18. (4) A petition or other request for establishment or modification of a tolerance, for an exemption for the need for a tolerance, or for other clearance under FFDCA section 408. (5) A petition or other request for establishment or modification of a food additive regulation or other clearance by EPA under FFDCA section 409. (6) A submission of data in response to a notice issued by EPA under FIFRA section 3(c)(2)(B). (7) Any other application, petition, or submission sent to EPA to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide.

Auditor: A person responsible for conducting all or part of a study audit. The study auditor may also be the inspector, and may be an EPA employee, an employee of another Federal agency (e.g., HEW), or a contractor employee. An

auditor may, if requested by the inspector, assist in the conduct of the GLP compliance review of the facility.

Association of Official Analytical Chemists (AOAC) An association devoted to the development, testing, validation and publication of analytical methods for foods, feeds, drugs, fertilizers, pesticides and other substances.

Association of State and Territorial Health Officials (ASTHO) Association of state health professionals dedicated to effective health care and who work with OPPT on health issues related to pesticides.

Batch: A specific manufactured or formulated quantity or lot of test, control, or reference substance used in a study, that has been characterized by source, identity, purity, composition, stability, and solubility (if appropriate). Batch can also include a discreet quantity of carrier, such as feed, prepared in a single procedure, in which the test or control substance has been mixed for administration to the test system.

Cancellation A process authorized under FIFRA section 6 whereby the Agency stops the sale, distribution and use of a pesticide product.

Carcinogenicity The capacity to induce cancer (e.g., malignant tumors).

Carrier: Any material, including but not limited to feed, water, soli, nutrient media, with which the test substance is combined for administration to a test system.

Chemical Case For purposes of review and regulation, OPP has grouped individual pesticide active ingredients that are chemically similar (e.g., salts and esters of the same chemical) into chemical cases.

Chemical Manufacturers Association (CMA) A trade organization that represents the industrial chemical industry.

Chemical Producers and Distributors Association (CPDA) A trade organization whose members include smaller pesticide formulators, manufacturers and distributors.

Chemical Specialties Manufacturers Association (CSMA) Originally named the National Association of Insecticide and Disinfectant Manufacturers, CSMA is a pesticide industry trade organization which sponsors the Chemical Specialties Manufacturers Association Political Action Committee.

Child-Resistant Packaging (CRP) FIFRA regulations (40 CFR 162.16) require that certain residential use pesticides meeting or exceeding specified toxicity criteria be packaged so as to offer protection to children and adults from injury or illness resulting from accidental ingestion or contact.

Cholinesterase Inhibition An inhibition in the effectiveness of cholinesterase, often caused by a chemical such as an organophosphate or

carbamate pesticide. This inhibition can result in nervous system disorders such as excess salivation, cramps, dyspnea, anxiety, and death. See also, cholinesterase.

Cholinesterase Enzymes, which when situated in the nervous system, help regulate the transmission of nerve impulses. There are two common types: that which is found in the brain peripheral nervous system and red blood cells; and pseudo cholinesterase, which is found in plasma.

Chromatography A process that separates a chemical mixture into its component parts for subsequent identification and quantification.

Code of Federal Regulations (CFR) The categorized set of regulations that implement federal statutes. Regulations that pertain to EPA are at 40 CFR.

Colorimetric Analysis A method of chemical analysis by which the concentration of a compound in solution can be determined by measuring the strength of its color by visual or photometric methods.

Confidential Business Information (CBI) Material that contains trade secrets or commercial or financial information that has been claimed as confidential by the submitter (usually the registrant). Procedures for handling CBI are described in the CBI manual for OPP.

Confidential Statement of Formula (CSF) A list showing the identity of the ingredients contained in a pesticide formulation. The list is submitted by a registrant or applicant at the time of application for registration or change in formulation.

Control Substance: Any chemical substance or mixture other than a test substance, which is administered to the test system in the course of a study for the purpose of establishing a basis for comparison with the test substance. For the purposes of compliance with the FIFRA or TSCA regulations, EPA will accept the convention followed by FDA, which is that positive controls (such as are used in skin sensitization tests and other toxicology tests) are considered to be control substances. The definition of control substances does not include negative controls such as the diluents, carriers, vehicles, etc., in which the test substance was dissolved or suspended before it was applied to the test system, and which has itself also been applied to part of the test system.

Co-operator: The owner or operator of an individual study field site or group of field sites in a limited geographic area. The responsibilities of the cooperator should be defined in the protocol or a written agreement with the sponsor or coordinator, but typically may include: preparation of the study site, planting of any crops, and routine care and maintenance of the test system. Responsibilities may or may not include application of the test substance and collection of samples or specimens.

Coordinator: A middleman organization between the sponsor and the test facility. The coordinator is responsible for organizing and setting up the study, and contracting with field sites and laboratories for the conduct of the study. The coordinator may also write the study protocol, provide quality assurance oversight and/or write the final report.

CORT Studies The set of toxicology studies consisting of **chronic feeding (C)**; **oncogenicity**, which is now referred to as **carcinogenicity (O)**; **reproduction (R)**; and **teratology (T)**, which now is referred to as developmental toxicity. These studies are required for all food/feed use pesticides and one or more may also be required for non-food/feed use pesticides. Chronic feeding effects, carcinogenicity, and developmental toxicity must be tested in two species, reproduction in one.

Data Call-In (DCI) Notice A DCI notice, as provided by FIFRA §3(c)(2)(B), is a notice that is issued by RD or SRRD to registrants. A DCI Notice requires the submission of specific data to support the reregistration or continued registration of a pesticide. Failure to submit these data can result in suspension of the registered products.

Delaney Clause Found in Section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (FFDCA), the Delaney clause prohibits food additive or drug tolerances for any substance (including pesticides) that causes cancer in test animals or in humans, if the substance is added to or concentrates in processed food or feed.

Dermal Absorption/Penetration A process by which a chemical enters the skin (e.g., a pesticide enters the skin of an applicator) and then moves into the body as an internal dose; it usually is expressed as a percentage of an amount applied to the surface of the skin.

Domestic Application Pesticide application in and around houses, office buildings, motels and other living or working areas; now termed residential use. See residential use.

Dosimetry Process of measuring a dose (i.e., of a pesticide, radiation, medicine, etc.).

Downstream Processors Industries dependent on crop production, such as canneries and food processors.

Emergency Suspension Suspension of pesticide product registration under FIFRA section 6(c) due to an imminent hazard. Emergency suspension immediately halts distribution, sale and sometimes use of effected pesticides. See also, Suspension of Registration.

Emulsifiable Concentrate (EC) A type of pesticide formulation that contains the active ingredient, one or more petroleum solvents, and an emulsifier that allows the formulation to be mixed with water. The strength of this concentrate usually is stated in pounds of active ingredient per gallon of concentrate.

Emulsifier A chemical that aids in suspending one liquid in another, usually an organic chemical in an aqueous solution.

End-Use Product (EP) A pesticide formulation for field or other end use. The labeling bears instructions for using or applying the product (as packaged and sold, or after dilution by the applicator) for controlling pests or regulating plant growth. The term excludes products with labeling that allows use of the product to formulate other pesticide products.

Environmental Fate Data Scientific data that characterize a pesticide's fate in the ecosystem, considering its degradation inducers (light, water, microbes), pathways and resultant degradation products.

Epidemiology The branch of medicine that deals with the frequency and occurrence of diseases in populations and the establishment of causal relationships between these diseases and environmental (including pesticide exposure) and other factors.

Estimated Environmental Concentration (EEC) The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.

Experimental Start Date: The first date the test substance is applied to the test system.

Experimental Termination Date: The last date on which data are collected directly from the study.

Experimental Use Permit (EUP) A permit authorized under FIFRA section 5 that is granted by the Agency to allow a pesticide producer to conduct testing of a new pesticide, product and/or use, outside of the laboratory. The testing is generally conducted on ten or more acres of land or water surface. EUPs are most commonly used for large-scale testing of efficacy and gathering of environmental fate, ecological effects, and crop residue chemistry data.

F_0 Adult Initial parent in a multi-generational reproduction study.

F_1 Adult Adult of the first generation (i.e., an F_1 pup reared to sexual maturity and used for breeding the next generation).

F_1 Pup First generation pup.

F_{1a} or F_{1b} Pup First generation pup; a or b indicates the first or second litter, respectively.

F_2 Pup Second generation pup.

Federal Food, Drug, and Cosmetic Act (FFDCA) FFDCA regulates, among other things, the use of drugs (human and veterinary), and chemicals in cosmetics and human and animal foods. It includes the legal requirement that tolerances (maximum residue limits) be established for pesticide residues in and on raw agricultural commodities, processed food and feed items (see sections 408 and 409). These tolerances are established by EPA.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) FIFRA sets forth regulations for the sale, distribution and use of pesticides in the U.S.

Federal Record Center A repository for archived records and out-of-date data; the information is retrievable.

Federal Register (FR) A daily government publication where all federal regulatory actions, including proposed rules, final rules, and notices, are published.

FIFRA Scientific Advisory Panel (SAP) An independent group of scientists, authorized under FIFRA, to render scientific opinions on pesticide issues and advise the Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances.

FIFRA Section 6(a)(2), Adverse Effects Data The provision in FIFRA which requires the registrant to submit to EPA any studies or other information regarding unreasonable adverse effects of a pesticide, at any time after its registration.

FIFRA Section 18 (Emergency Exemption) A provision in FIFRA under which EPA can grant an emergency exemption to a state or another federal agency that allows the use for a limited period (usually one year) of a pesticide product that is not registered for that particular use. The exemption is requested and authorized because a pest problem is unanticipated and/or severe and there is no time or interest by a registrant to register the product for that use. Registrants cannot apply for emergency exemptions.

FIFRA Section 24(c) Special Local Need (SLN) Registration Registration of a pesticide product under FIFRA section 24(c) by a state agency for a specific use that is not federally registered (however, the active ingredient must be federally registered for other uses). The special use is specific to that state and is often minor; thus, it may not economically warrant a full federal registration by the registrant. SLNs have full federal registration status; they are processed by product manager teams in RD. SLN registrations cannot be issued for new active ingredients, food-use active ingredients without tolerances, or for a registration that has been canceled or suspended under FIFRA section 3(c)(2)(B). A 24(c) registered product cannot be shipped across state lines, and may be used only in the state of issuance.

FFDCA: The Federal Food, Drug, and Cosmetic Act, as amended.

Flowable Formulations in which the active ingredients are finely ground insoluble solids mixed with a liquid as a suspension. Flowables are mixed with water for application.

FOIA Freedom of Information Act. Legislation that ensures the availability of federally generated information to the public.

Food and Drug Administration (FDA) The federal agency responsible for carrying out the provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which includes pesticide tolerance enforcement. See also, Federal Food, Drug, and Cosmetic Act.

Food Quality Protection ACT (FQPA) The Food Quality Protection Act (FQPA), passed by Congress in 1996, amends prior pesticide legislation to establish a more consistent protective regulatory scheme, based on sound science. It mandates a single, health-based standard for all pesticides in all foods; special protections for infants and children; expedites approval of safer pesticides; and creates incentives for the development and maintenance of effective crop protection tools for American farmers. It also requires periodic re-evaluation of pesticide registration will remain up to date in the future.

Generally Recognized as Safe (GRAS) Designation by FDA that a chemical or substance (including certain pesticides) added to food is considered safe by experts, and so is exempted from the usual food additive tolerance requirements of FFDCA section 409.

Genetic Engineering Directed transfer of permanent genetic information between species. This may include organisms that the Agency considers to be microbial pest control agents. Some higher plants have been "genetically engineered" to produce a pesticide or other compound not produced by the native plant.

GLP Compliance Review: A review of a facility's current procedures and practices to determine that the Good Laboratory Practice Standards regulations of TSCA or FIFRA are being observed for pertinent studies being conducted at the facility. One or more ongoing TSCA - or FIFRA - regulated studies will normally be selected from the master schedule to serve as a partial basis for the review.

GLP Inspection: An inspection or investigation conducted at a testing facility, which consists of a GLP compliance review and/or a study audit of one or more final reports. It is possible that a GLP inspection may consist only of study audits, without the conduct of a formal facility GLP compliance review. Generally, an inspection will be conducted as a result of the neutral scheme for targeting facilities. An investigation differs from an inspection in that it will consist of a more detailed review of facility policies,

procedures, or data as - a result of suspected data deficiencies and/or violations of the FIFRA or TSCA regulations.

Good Laboratory Practice (GLP) Protocols established in 40 CFR 160 and 40 CFR 792 to assure the quality and integrity of data submitted by registrants. Provisions of the GLP standards include record keeping, personnel, and laboratory equipment requirements.

Group A, B_1, B_2, C, D, E Carcinogen Qualitative classification of chemicals for human carcinogenic potential based on the Agency's Carcinogen Assessment Guidelines. Group A includes known human carcinogens. Group B, which is subdivided into categories B_1 and B_2, contains probable human carcinogens. B_1 is reserved for agents that have limited evidence of carcinogenicity from epidemiologic studies and sufficient evidence from animal studies; B_2 is for agents for which there is sufficient evidence from animal studies and inadequate or no data from epidemiologic studies. Group C contains possible human carcinogens for which there is limited animal evidence; Group D includes chemicals that have no carcinogenic information or insufficient information to classify the chemicals; and Group E consists of chemicals that are not expected to be human carcinogens.

Hazard Inherent toxicity of a compound. Hazard identification of a given substance is an informed judgment based on verifiable toxicity data from appropriate animal models or information from human studies.

Hazard Ratio A term used to compare an animal's daily dietary intake of a pesticide to its LD_{50} value. A ratio greater than 1.0 indicates that the animal is likely to consume an amount of pesticide exceeding the dose at which 50 percent of animals of the same species would be killed.

Highest Dose Tested (HDT) The highest dose of a chemical or substance tested in a study.

Hydrolysis The decomposition of organic compounds by interaction with water.

Hyperplasia An increase in the number of cells in a tissue or organ (excluding tumor formation) that increases the bulk of the organ. Hyperplasia is sometimes a precursor to tumor formation.

Hypoplasia A condition of arrested development in which an organ or part remains below the normal size or in an immature state.

Imminent Hazard A situation that exists when the continued use of a pesticide during the time required for a cancellation proceeding would be likely to result in unreasonable adverse effects on humans or the environment or will involve unreasonable hazard to the survival of an endangered species.

Indemnification A provision of FIFRA section 15 that requires EPA to pay end-users, dealers, and distributors for the cost of stock on hand at the time a

pesticide registration is suspended under section 6(c). Only certain end-users are entitled to an automatic indemnity.

Inert Ingredient An ingredient in a pesticide product's formulation that has no direct pesticidal activity but can be biologically active (such as water, solvents, emulsifiers, surfactants, clay, or propellants).

Information Collection Request (ICR) EPA prepares an ICR for rules, proposed rules, surveys, or guidance documents that contain information gathering requirements. The ICR is a description of what information is needed, why the information is needed, how it will be collected, and how much the information collection will cost. The Agency submits each ICR to OMB for approval.

Inspector: The single individual with overall responsibility for the conduct of the inspection. The inspector is the leader of the inspection team, is responsible for presenting inspection credentials and the Notice of Inspection to the responsible facility representative, and for preparing the Receipt for Samples and Documents, and TSCA Confidentiality Claim. The inspector is responsible for the collection and quality of all evidence necessary to support any potential enforcement action. The inspector must be present at the facility whenever other inspection team members are present. If he/she cannot be present at the facility, the inspector may delegate one of the team members to temporarily assume the responsibilities of the inspector. However, the delegated person must also have inspector credentials.

Integrated Pest Management (IPM) The concept and practice of using a variety of methods (cultural, pesticidal, biological, etc.) to control pests.

Interregional Research Project No. 4 (IR-4) A program sponsored by the U.S. Department of Agriculture (USDA). IR-4 provides national leadership and coordination for information on the clearance of minor use pesticides and generates data to support minor-use registrations.

In Vitro Testing or occurring outside an organism (e.g., in a test tube or a culture dish).

In Vivo Testing or occurring inside an organism.

IR-4 Project: Interregional Research Project No. 4, national headquarters located at the New Jersey Agricultural Experiment Station, Cook College, Rutgers University, New Brunswick, New Jersey. A cooperative government/industry effort by the State Agricultural Experiment Station (SAES); U.S. Department of Agriculture (USDA), Agriculture Research Service (ARS) and Cooperative State Research Service (CSRS); U.S. EPA; U.S. FDA; and manufacturers of pesticides and animal drugs. Within the context of the GLP program, IR-4 is working to register pesticides for use on minor crops, where the volume of usage does not justify commercial development. Within the next decade, IR-4 has a strategy to register 2,600 new minor uses and reregister 1,000 minor uses. Most of the GLP-regulated studies being conducted by the IR-4 project are being done by universities and the USDA-ARS.

LC_{50} Lethal concentration of a substance that is expected to cause death in 50 percent of a test population. Usually used for birds or aquatic organisms, or for mammalian inhalation toxicity studies.

LD_{50} Lethal dose taken by mouth or absorbed through the skin that is expected to cause death in 50 percent of the test animals treated. If a chemical has an LD_{50} of 10 mg/kg, it is more toxic than one having an LD_{50} of 100 mg/kg.

LD_{lo} Lethal dose, low. The lowest dose in an animal study at which lethality occurs.

LDT The lowest dose tested in a study.

Leaching Movement of a substance downward or out of the soil as the result of water movement.

Letter of Entry: A letter provided by the Director, AED, authorizing a non-EPA employee to participate in an inspection, normally as an auditor or observer. The letter is presented by the inspector to the testing facility at the time of the inspection.

Lifetime Average Daily Dose (LADD) Used for estimating excess lifetime cancer risk.

List A Pesticides The statutorily defined list that originally contained 350 active ingredients (grouped into 194 chemical cases) subject to reregistration. These chemicals, for which Registration Standards were written prior to FIFRA '88, are primarily food-use chemicals. They account for 85 to 90 percent of the total volume of food use pesticides used in the U.S.. See also, List B, C, and D pesticides, and reregistration.

List B Pesticides The second group of approximately 229 active ingredients (grouped into 149 cases) subject to reregistration. This list includes the food-use chemicals that are not on List A and other agricultural pesticides. See also, List A, C, and D pesticides, and reregistration.

List C Pesticides The third group of approximately 289 active ingredients (grouped into 150 cases) subject to reregistration. This list primarily includes antimicrobials. See also, List A, B, and D pesticides, and reregistration.

List D Pesticides The remaining approximately 288 active ingredients (grouped into 117 cases) subject to reregistration. This list includes many pesticide types including microbials and biochemicals. See also, List A, B, and C pesticides, and reregistration.

Lowest Acceptable Daily Dose (LADD) The largest quantity of a chemical that will not cause a toxic effect, as determined by laboratory animal studies.

Lowest Observed Effect Level (LOEL) The lowest dose in a study which produces an observable adverse effect.

Maintenance Fee An annual fee required of registrants for each pesticide product retained for registration.

Manufacturing Use Product (MP or MUP) Any product intended (labeled) for formulation or repackaging into other pesticide products.

Margin of Exposure (MOE) A numerical value that characterizes the amount of safety to a toxic chemical; a ratio of exposure to a toxicological endpoint, usually the NOEL. Formerly referred to as the Margin of Safety (MOS).

Master Record Identification Number (MRID #) A unique cataloging number assigned to an individual study at the time of submission to the Agency.

Maximum Contaminant Level (MCL) An enforceable concentration level for chemical contaminants that are often found in drinking water supplies; the MCL is based on technical and feasibility considerations and is set by the Agency's Office of Ground Water and Drinking Water.

Maximum Contaminant Level Goal (MCLG) A suggested limit on the concentration of chemical contaminants in water that will be protective of human health. An MCLG is not enforceable at the federal level; however, many states do enforce them.

Maximum Permitted Intake (MPI) An outdated term relative to daily human dietary exposure. The MPI was expressed in mg/day and was calculated by multiplying the acceptable daily intake by the body weight of a human (60 kg is a standard assumption).

Maximum Residue Level (MRL) Comparable to a U.S. tolerance, the Maximum Residue Level is recognized by many countries as an enforceable limit on pesticide residues in foods. MRLs are set by the Codex Alimentarius Commission, a United Nations agency staffed and funded jointly by the World Health Organization and the Food and Agriculture Organization.

Maximum Tolerated Dose (MTD) The maximum dose that an animal species can tolerate for a major portion of its lifetime without significant impairment or toxic effect other than carcinogenicity.

Metabolism The process by which chemicals are transformed and stored in an organism--animal or plant.

Metabolite Any substance produced by metabolism. See metabolism.

Microbial Pest Control Agent (MPCA) A microorganism (e.g., virus, bacterium, fungus, protozoan) that is used as a pesticidal agent, usually to infect and kill the target pest, or to compete with undesirable microbial pests in the environment. Test guidelines 885 of the OPPTS Harmonized Test Guidelines apply.

Miscible Capable of being mixed; often used to describe certain pesticide formulations.

MRID Number: The unique eight-digit identifier assigned by OPP to any submitted FIFRA documents. These can be an interim or supplemental report, additional data, the final study report, or other documents.

Mutagenic The property of a substance (or mixture of substances) to produce genetic changes.

National Pollutant Discharge Elimination System (NPDES) A provision of the Clean Water Act which prohibits discharge of pollutants into waters of the U.S. unless a special permit is issued by EPA, a state or, where delegated, a Native American tribal government.

National Pollutant Discharge Elimination System (NPDES) Permit A permit issued by the Office of Water that allows dischargers of pollutants (e.g., a chemical manufacturing facility) to purposely discharge contaminated effluent into waters of the U.S..

No Observable Effect Level (NOEL) The highest dose level (quantity) of a substance administered to a group of experimental animals that demonstrates the absence of effects observed or measured at higher dose levels. The NOEL should produce no biologically significant differences between the group of treated animals and a control group of unexposed animals maintained under identical conditions. See also, NOAEL.

NOAEL No observable adverse effect level. See no observable effect level.

Notice of Intent to Cancel (NOIC) Notification sent to registrants when the Agency decides to cancel (terminate) the registrations of products containing a pesticide, either for administrative reasons or because the chemical has been shown to cause unreasonable adverse effects. See also, suspension of registration.

Notice of Intent to Suspend (NOIS) Notification sent to a registrant when the Agency decides to suspend (halt) product sale and distribution because of failure to meet an obligation, such as submission of data in a timely and/or acceptable manner, or because of imminent hazard. See also, suspension of registration and emergency suspension.

Notification Letter: A letter from the Director, AED, to the facility contact person, notifying that person that the Agency intends to conduct a GLP Inspection. The letter normally identifies the date(s) of the inspection, the name of the inspector, the study or studies to be audited, whether a GLP compliance review will take place, and the types of data and records to be made available to the inspection team.

OECD Guidelines Testing guidelines prepared by the Organization of Economic and Cooperative Development of the United Nations. These guidelines assist in the preparation of protocols for toxicological, environmental fate, etc. studies.

Office of Pesticide Programs (OPP) OPP and the Office of Pollution Prevention and Toxics comprise the two offices within the Office of Prevention, Pesticides, and Toxic Substances.

Oncogenicity See carcinogenicity.

Pathogen Any disease-producing organism, bacteria, virus or fungus.

Person: Includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.

Personal Protective Equipment (PPE) Clothing and equipment worn by pesticide handlers (mixers, loaders and applicators) and re-entry workers, which is designed or intended to reduce their exposure to pesticides, during or after application.

Pest Any insect, rodent, nematode, fungus, weed or any other form of terrestrial or aquatic plant or animal life, or any virus, bacteria, or other micro-organism which the Administrator declares to be a pest.

Pest Control Operator (PCO) A person or company that applies pesticides as a business (e.g., exterminator). Often used to describe such a service for household applications as compared to agricultural applications.

Pesticide Assessment Guidelines (PAG) Protocols listed in 40 CFR 158 that provide registrants with guidelines on how to do studies. They are published by EPA but are not legal documents. Copies of the Guidelines can be obtained from the National Technical Information Service.

Pesticide Document Management System (PDMS) The Agency-maintained collection of documents of regulatory significance to pesticides, including submitted studies. The documents are microfiched and indexed by an on-line retrieval system that anyone in OPP can use.

Pesticide Product Information System (PPIS) A data base that provides information on more than 60,000 currently and formerly federally registered pesticide products and other non-pesticide chemicals. For each federally registered product, PPIS can provide the product name, registrant name and address, EPA registration number, type of formulation, signal word, types of pesticide activity, active ingredient names and percentages, application sites, and pests controlled. Also, PPIS contains information on whether the product has been classified for general or restricted use.

Pesticide Registration Activity Tracking System (PRATS) An on-line tracking system to monitor the science reviews of data submissions. Also, PRATS is used to request actions (e.g., risk assessments, etc.) from the OPP science divisions.

Pesticide Regulation (PR) Notice A written notice from OPP to pesticide registrants that communicates important changes in regulatory policy, procedures, and/or regulations. Each PR Notice is assigned a two-part number beginning with the year issued followed by a cardinal number (e.g., 87-1, 87-2).

Phenology of Crops The development of crops through the seasons.
Pre-Harvest Interval (PHI) The time between the last pesticide application and harvest of the treated crop.
Protocol A study plan or method. Testing protocols for data requirements appear in the Pesticide Assessment Guidelines.
Pure Active Ingredient (PAI) Test substance required for certain pesticide studies. Pure active ingredients do not have inert ingredients added.

Q star, Q_1 star, Q_1* A mathematical value that represents the upper 95th percent confidence limit of the slope of a curve that describes the carcinogenic response of a tested compound; the curve is derived from the results of carcinogenicity studies. Q_1* represents potency of effect. It is expressed as: (mg of chemical/kg of body weight/day)$^{-1}$. The Q_1* is multiplied by an exposure value to give an estimate of excess cancer risk. (Q_1* also is used in conjunction with LADD.)
Quality Assurance Unit (QAU): Any person or organizational element, except the study director, designated by the testing facility management to perform the duties relating to quality assurance of a study. No QAU duties may be performed by any technical personnel directly involved with the conduct of the study. "Quality Assurance Unit" should be written with the initial letters capitalized only if this is the actual title given by the facility management to the organizational entity. When management uses any other title (i.e., Division of Quality Assurance, Quality Assurance and Regulatory Affairs Department), then the term "quality assurance unit" (in the GLP sense) is used without capitalizing, but is abbreviated as "QAU."
Qualitative Use Assessment (QUA) A report that provides a summary of the major uses of a pesticide including percent of crop treated, percent of pesticide used on a site, and other available usage information.

Raw Agricultural Commodity (RAC) A human food or animal feed crop that has not been processed (e.g., raw carrots, apples, corn or eggs).
Raw Data (Always plural): Any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. Raw data may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and data recorded from automated instruments. Raw data also include maintenance and calibration logs from instruments, receipt and distribution logs for test, control, and reference substances and samples, weather observations, records of environmental conditions, etc. Although, under the FIFRA and TSCA GLP Standards regulations, "raw data" is defined to include exact copies of original raw data, under FIFRA Books and Records

regulations [40 CFR, Part 169.2(k)] the original raw data must be retained for any registered pesticides.

Red Blood Cell (RBC) One of the formed cell types found in the blood; responsible for carrying oxygen from the external environment to all cells and tissues of the body. RBC is often used in conjunction with the type of cholinesterase that occurs in the red blood cell (e.g., RBC cholinesterase).

Reference Dose (RfD) An estimate of the level of daily exposure to a pesticide residue which, over a 70-year human life span, is believed to have no significant deleterious effects. RfDs are based upon data for noncarcinogenic effects of substances, even those which also may be carcinogenic. Formerly called the acceptable daily intake (ADI).

Reference Substance: Any chemical substance or mixture, or analytical standard, or material other than a test substance, feed, or water, that is administered to or used in analyzing the test system in the course of a study for the purposes of establishing a basis for comparison with the test substance for known chemical or biological measurements. Most commonly, reference substance refers to an analytical reference standard.

Registrant: The person who holds the registration from the Agency to market a pesticide. The registrant may be different from the sponsor, especially for minor use pesticides for which testing is being sponsored by the IR-4 project. In some instances, several different registrants or producers may form a task force or consortium to sponsor FIFRA or TSCA testing required for a specific chemical which they each market.

Registration The process and final Agency action that authorizes the legal sale, distribution, and use of a pesticide product. The process includes OPP's consideration of scientific, legal, and regulatory requirements of the product and results in issuance of a Notice of Registration to the registrant.

Registration Number A hyphenated, two-part number assigned by RD to identify each product registration (e.g., 1253-79). The first part of the number is the assigned company number (called the establishment number), which is specific to a given chemical company; the second part is the specific product number. The registration number must appear on the product's label, as required by 40 CFR 156.10.

Reregistration OPP's process of re-examining supporting scientific data, re-assessing human health and environmental risks, and making reregistration decisions for all pesticides initially registered before November 1, 1984. Reregistration priority is given to chemicals with the highest potential for exposure--high-volume and food-use chemicals (i.e., List A chemicals). Through this priority process, four lists of pesticides (Lists A, B, C, and D), were established under FIFRA '88. The reregistration process consists of the Agency identifying the studies necessary to conduct human health and environmental risk assessments; obtaining and reviewing these studies;

estimating potential risks; imposing any regulatory controls needed to manage those risks; and reregistering pesticide products whose risks are not unreasonable.

Reregistration Eligibility Decision (RED) Document RED documents summarize the findings of EPA's reregistration review process for individual chemical cases, and reflect the Agency's decisions on risk assessment and risk management for the uses of pesticides. Besides summaries of risk assessments, RED documents include requirements for risk reduction, product-specific data to support product reregistration, and any additional generic data needed on the active ingredient(s).

Residential Use Pesticide application in and around houses, office buildings, apartment buildings, motels, and other living or working areas.

Restricted Entry Interval (REI) The time after the end of a pesticide application during which entry into the treated area is restricted. Formerly called the reentry interval.

Restricted Use Pesticide A pesticide that is available for purchase and use only by certified pesticide applicators or persons under their direct supervision. This designation is assigned to a pesticide product because of its relatively high degree of potential human and/or environmental hazard.

Risk (Adverse Risk) for Endangered Species -- Aquatic Risk to species if anticipated pesticide residue levels equal 1/10 of LD_{10} or 1/20 of LC_{50}.

Risk (Adverse Risk) for Endangered Species -- Terrestrial Risk to species if anticipated pesticide residue levels equal 1/5 of LC_{10} or 1/10 of LC_{50}.

Risk Assessment A process in which the hazard and exposure potential of an environmental agent are described, and a risk characterization is developed. See also: Risk Characterization.

Risk Characterization In general, a determination of the likelihood of a hazard to occur in a population exposed to pesticide chemicals. This likelihood may be expressed as a numerical probability or as a margin of exposure. Simply stated: RISK = Hazard x Exposure.

Risk for Non-Endangered Species Risk to species if anticipated pesticide residue levels are equal to or greater than LC_{50}.

Solution A formulation or use dilution of a pesticide that dissolves in the carrier liquid or diluent and will not settle out or separate in an aqueous medium.

Special Review (SR) Special Review is the process through which existing pesticides suspected of posing unreasonable risks to human health, the environment, or non-target organisms are referred for review by the Administrator or the Assistant Administrator. The review requires intensive risk and benefit analyses with the opportunity for public comment. If the risk of any pesticide use is found to outweigh social and economic benefits,

regulatory action can be initiated. Regulations pertaining to Special Review procedures are found at 40 CFR Part 154.

Specimen: Any material derived from a test system for examination or analysis. Materials collected for analytical purposes may be referred to either as "specimens" or "samples."

Sponsor: The person (including an individual, partnership, corporation, association, scientific or academic establishment, government agency, or any other legal entity) who: (1) initiates and supports a study by providing financial or other resources; or (2) submits a study to EPA in support of an application for a research or marketing permit. The sponsor can be the testing facility only if it both initiates and actually conducts the study.

Standard Operating Procedure (SOP) A written procedure that conveys procedures for various functions performed by OPP staff. SOPs address both technical and administrative matters.

State FIFRA Issues, Research and Evaluation Group (SFIREG) SFIREG is a group of state pesticide regulatory officials who work with OPP staff to identify and resolve overlapping state and federal regulatory and research issues.

Study: Any experiment at one or more test sites, in which a test substance is studied in a test system. A study may be conducted under laboratory conditions or in the environment. The purpose of a study is to determine or help predict the effects, metabolism, product performance, environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media. When applied to efficacy studies, the term "study" applies only to those studies required by 40 CFR 158.640. The term "study" does not apply to basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility. For GLP purposes, a study will typically be considered to include the following discreet segments: (1) development and approval of a protocol; (2) provision of the test, control, and reference substances, including any required analyses, characterization, stability testing, etc.; (3) administration of test/control substances to the test system at one or more testing sites; (4) observation of the test system, and collection and analysis of specimens; (5) analysis of study results and preparation of the study report; and (6) quality assurance oversight.

> **Please note**: PR Notice 86-5 (OPTS, July 29, 1986, page 6) states that for residue chemistry, a single study report should be submitted in the following cases: (1) More than one commodity is derived from a single crop (i.e., beet tops and beet roots); (2) multiple field trials are associated with a single crop.

Study Audit: A review of a completed study, interim report, supplemental data, or other document which has been submitted to the Agency under the appropriate sections of TSCA or FIFRA. This is normally accomplished by reviewing available raw data, records and reports, interviewing study personnel or other facility officials, and reviewing laboratory operations. The study audit should be based on completeness of the raw data; conformance of the raw data to study report findings and conclusions; adherence to GLP Standards regulations, and to available and appropriate standard operating procedures and protocols.

Study Completion Date: The date the final report is signed by the study director.

Study Director: The single individual responsible for the overall technical conduct of a study. Practically speaking, the study director is the person who signs the protocol and final report, and coordinates the various phases of the study (see paragraph 2, definition of "Study," above). The study director need not be physically present at the test site or sites, nor be involved in the day-to-day aspects of the study conduct; he/she may rely on test site senior personnel (such as a senior investigator) and on the quality assurance units to keep him/her informed of the progress of the study and any problems encountered.

Study Initiation Date: The date the study director signed the protocol.

Supplemental Registration An arrangement by which a registrant licenses another company to market its registered name (i.e., distribute pesticide product under the second company's registration). A supplemental registration is identified by a three part number (e.g., 1342-6-2): the first and second parts are the primary registrant's registration number, and the third part is the supplemental registrant's company number.

Surrogate Data Data from studies which involve test organisms or a test substance that are used to estimate the characteristics or effects on another organism or of another substance.

Suspension Finely divided solid particles mixed in a liquid.

Suspension of Registration An action authorized under FIFRA section 3(c)(2)(B) that temporarily halts further distribution and sales of a pesticide product. Suspension is commonly imposed because the registrant has failed to adequately meet data submission requirements. The registrant can request a hearing to discuss data issues and the suspension can be lifted when the requirements are met. A suspension of registration also can be issued under FIFRA section 6(c) due to an imminent hazard. This type of suspension halts distribution, sale and sometimes use of affected pesticide products. The registrant has the right to an expedited hearing on the question of whether an imminent hazard exists.

Systemic Poison Poison that travels through the body and affects one or more parts of the body, distant from the point of entry.

Technical Grade Active Ingredient (TGAI) The pesticide chemical in pure form (usually 95-100% active ingredient) as it is manufactured by a chemical company prior to being formulated into an end-use product (e.g., wettable powders, granules, emulsifiable concentrates).

Technical Grade Product A registered manufactured-use product that is composed of technical grade active ingredient.

Teratogenic The property of a substance or mixture of substances to produce structural deviations or malformations, not heritable, in or on an animal embryo or fetus.

Test: A subpart of a study. Examples include a phase of a study, such as clinical chemistry for a chronic toxicity study; or an acute dermal toxicity portion of a routine four-part (acute oral, acute dermal, eye irritation, and dermal irritation) battery of acute effects experiments.

Test Substance: A chemical substance or mixture of substances administered to or added to a test system as the subject of a study. Do not use "Test Chemical, "Test Material," etc. Note: The term "test substance" now includes mixtures, and the term "test mixture" should no longer be used except with specific reference to studies conducted under the original (pre-October 1989) GLP Standards regulations.

Test System: Any plant, animal, microorganism, chemical or physical matrix to which the test, control, or reference substance is administered or added for study. The test system also includes appropriate groups or components of the system not directly treated with the test, control, or reference substance.

Testing Facility: A person (including an individual, partnership, corporation, association, scientific or academic establishment, government agency, or any other legal entity) who actually conducts a study, encompassing those operational units which are being, or have been used to conduct studies. In elaborate studies, the testing facility may be comprised of one or more test sites, typically field sites and laboratories, in addition to offices and administrative units, computer laboratories and other facilities for analyzing data, and storage/archiving sites, any of which may be subcontracted.

Theoretical Maximum Residue Contribution (TMRC) The theoretical maximum amount of a pesticide in the daily diet of an average human. This theoretical amount assumes that the diet is composed of all food items for which there are tolerance-level residues of the pesticide. The TMRC unit is expressed as mg (of pesticide)/kg (of body weight)/day.

Tolerance Maximum permissible levels for pesticide residues allowed in or on commodities for human food and animal feed. Under the Federal Food, Drug, and Cosmetic Act, EPA is responsible for establishing tolerances. Whenever a

pesticide is registered for use on a food or feed crop, a tolerance or exemption from the requirement of a tolerance must be established. Established tolerances and exemptions for pesticide chemicals in or on raw agricultural commodities are listed in 40 CFR 180. Tolerances for pesticides in processed food are at 40 CFR 185; and tolerances for pesticides in processed animal feed are listed at 40 CFR 186. Tolerances are enforced by the Food and Drug Administration and the U.S. Department of Agriculture.

Tolerance Petition A formal request to establish a new tolerance or modify (raise, lower or revoke) an existing tolerance.

Toxic Concentration (TC) The concentration at which a substance produces a toxic effect.

Toxic Dose (TD) The dose at which a substance produces a toxic effect.

Toxicity, Acute The property of a substance or mixture of substances to cause effects in an organism through a single or short-term exposure. Acute toxicity is established through scientifically verifiable data from animal or human exposure tests. Values often are expressed as LD_{50} or LC_{50} in units mg/kg or mg/l. Acute toxicity studies include oral, dermal and inhalation studies.

Toxicity, Chronic The property of a substance or mixture of substances to cause effects of an extended duration in an organism, usually upon repeated or continuous exposure over most or all of the lifetime of that organism. Occasionally, chronic toxicity can result from single or very short duration exposures. Chronic toxicity is established through scientifically verifiable data from animal or human exposure tests. Values are expressed as NOEL, NOAEL, and LEL, usually in mg/kg/day. Chronic toxicity studies in mammalian species include carcinogenicity and chronic feeding.

Toxicity, Subchronic The property of a substance or mixture of substances to cause effects in an organism from (usually) more than one exposure (dosing) but less than lifetime exposure. For pesticides, subchronic studies are often for 90 days of exposure conducted in a rodent or the dog. Values are expressed as NOEL, NOAEL, or LEL in mg/kg/day. Subchronic studies may include oral, dermal, inhalation and reproduction studies.

Toxic Substances Control Act (TSCA) TSCA is a law administered by the Office of Prevention, Pesticides, and Toxics that governs the manufacture and use of toxic industrial chemicals. TSCA excludes drugs, pesticides, cosmetics and radioactive agents.

Typical End-Use Product (TEP) A term used in data requirements to convey direction to a data producer to use a commonly used end-use product as the test substance.

Vehicle: Any agent which facilitates the mixture, dispersion, or solubilization of a test substance with a carrier.

Volatility The property of a substance to become a vapor or gas without chemical change.

Water Soluble Packaging Packaging that dissolves in water; this type of packaging is used to reduce exposure risks to mixers and loaders.

Wettable Powder (WP) Dry formulation material that must be mixed with water or other liquid before it is applied.

/s/_____ 06/01/99
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