

Regulatory Basics for Researchers.

National Alliance of Independent Crop Consultants

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Jack Arthur
Manager U.S. Regulatory Affairs

Regulatory Basics for Researchers



- Definitions and Key Points
- Types of Pesticide Registrations
- The Registration Process
- The Evolution of Pesticide Regulation in the U.S.



Regulatory Basics for Researchers



■ Definitions and Key Points.

■ A **Pesticide** is substance that will prevent, destroy, repel, or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant.

■ A **Tolerance** is the legal level of a pesticide that can occur in food or feed commodities.

■ **FIFRA** is the **F**ederal **I**nsecticide **F**ungicide and **R**odenticide **A**ct

■ **FFDCA**, is the **F**ederal **F**ood Drug and **C**osmetic **A**ct

■ All pesticide products must be registered by the U.S. EPA, Office of Pesticide Programs.

<http://www.epa.gov/pesticides/>

■ In addition all pesticide products must be registered in the states.

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■ Definitions and Key Points.

- **40 CFR 172.3** “ Pesticides can be tested without an EUP or a registration on a cumulative total of up to 10 acres per pest on land and one acre surface water.
 - All food and feed must be destroyed if there are no supporting Tolerances.
 - Water can not be used for harvesting fish and shellfish, recreation, or irrigation.
 - If multiple pests occur at a test location the 10 acre limit shall encompass all of the target pests.
- Laboratory and Greenhouse tests do not require a permit.
- Testing inhabited structures generally requires an Experimental Use Permit.
- Formulations that are not approved must follow the research rules regardless of how similar it may be to an approved formulation.

Types of Pesticides Registrations

- FIFRA **Section 3** Full registration
 - Can be conditional requiring additional data.
 - Restricted Use, limits use to licensed applicators due to potential hazard to humans or the environment.

- FIFRA **Section 5** Experimental Use Permits (EUP)
 - Requires tolerance for food crops
 - Limited to <5000 acres.
 - Have reporting and record keeping requirements.

Types of Pesticides Registrations; (State Registrations)

■ FIFRA **Section 18** Emergency Exemptions

- Requires a tolerance
- There are 4 types
 - Specific
 - Quarantine
 - Public Health
 - Crisis

■ FIFRA **24C** Special Local need

- There is a special local need within the state.
- Tolerances or exemptions from tolerances are in place.
- Product was not denied registration

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EPA Review of Applications by the Office of Pesticide Programs

■ **Registration Division (RD)** is the primary contact for registration actions.

- RD screens submission for completeness.
- RD coordinates all Registration and Preregistration meetings.
- Distributes data to science divisions for evaluation and to monitor progress
- When review is complete RD coordinates the resolution of any outstanding issues and approves the label.

■ **Health Effects Division (HED)** Conducts human risk assessments

■ **Environmental Fate and Effects Division (EFED)** Conducts the environmental risk assessments

OCT 21 '99 10:30AM BASF CORP-C-KEEPER P.2/9 2049
wjm 10-21-99

BASF

ACCEPTED
with COMMENTS
In EPA Letter Dated
OCT 25 1999

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
7969-150

Distinct®

herbicide

For use in field corn and non-crop areas

Active Ingredient:
Sodium salt of diflufenzopyr: 2-[1-[[3,5-difluorophenylamino] carbonyl]-
hydrazono]ethyl-3-pyridinecarboxylic acid, sodium salt 21.4%
Sodium salt of 3,6-dichloro-g-anic acid 55.0%
Inert Ingredients: 23.6%
Total: 100.0%

* This product contains 20% 2-[1-[[3,5-difluorophenylamino] carbonyl]-hydrazono]ethyl-3-
pyridinecarboxylic acid (diflufenzopyr) or 0.20 pounds acid equivalent per pound of product.
** This product contains 50% 3,6-dichloro-g-anic acid or 0.50 pounds acid equivalent per
pound of product.

EPA Registration Number 7969-150 EPA Est. Number _____

**KEEP OUT OF REACH OF CHILDREN.
CAUTION**

See additional Precautionary Statements and Statement of Practical Treatment.

Net contents: 7.5 pounds (3.4 kilograms)

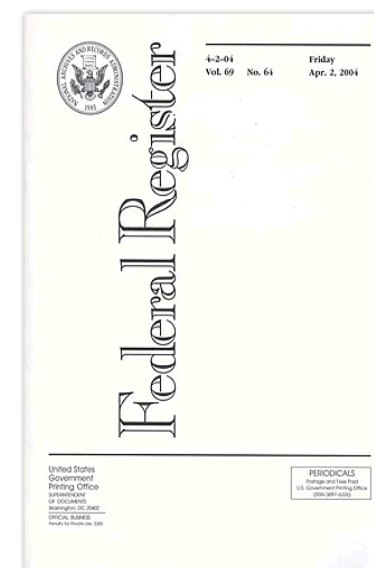
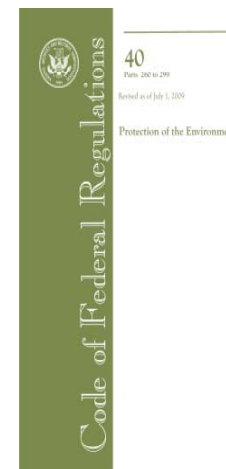
BASF Corporation
P.O. Box 13529, Research Triangle Park, NC 27709

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■ The Registration Process

- All regulations for the Office of Pesticide Programs with respect to FIFRA and FFDCA are Codified in 40 CFR Parts 150 to 189.
- All changes to the regulations must be published in the Federal Register
- Additional guidance is then provided as needed.
 - Pesticide Registration (PR) Notices
 - http://www.epa.gov/PR_Notices/
 - PR Notices are issued by the Office of Pesticide Programs to inform pesticide registrants and other interested persons about important policies, procedures and regulatory decisions



■ The Registration Process: Data Requirements

40 CFR Part 158 contains data tables that identify data requirements by use pattern.

http://www.epa.gov/pesticides/regulating/data_requirements.htm#requirements

- Guidelines for conducting studies. OPPTS harmonized guidelines.
 - <http://www.epa.gov/oppts/pubs/frs/home/guidelin.htm>
- Consultation with EPA is often required to determine the data requirements and clarify guidance.



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Guideline Number	Data Requirement	Use Pattern					Test substance	Test Note No.
		Terrestrial Food or Feed	Aquatic Food	Greenhouse Food	Indoor Food	Residential Outdoor		
Supporting Information								
860.1100	Chemical identity	R	R	R	R	R	TGAI	--
860.1200	Directions for use	R	R	R	R	R	--	--
860.1550	Proposed tolerance	R	R	R	CR	NR	--	1
860.1560	Reasonable grounds in support of petition	R	R	R	CR	NR	--	1
860.1650	Submittal of analytical reference standards	R	R	R	CR	NR	PAI and residue of concern	1, 2, 25
Nature of the residue								
860.1300	Nature of the residue in plants	R	R	R	CR	CR	PAIRA	3, 4, 25
860.1300	Nature of the residue in livestock	CR	CR	CR	CR	NR	PAIRA or radiolabeled plant metabolite	1, 6, 25
860.1850	Confined rotational crops	CR	CR	NR	NR	NR	PAIRA	7

6. Required for indoor uses where the pesticide is applied directly to food, in order to determine metabolites and/or degradates. Not required when only indirect contact with food would occur (e.g., crack and crevice treatments).

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OPPTS; Ecotoxicology Guidelines

- [850.1000 - Special Considerations for Conducting Aquatic Laboratory Studies \(PDF\)](#) (13 pp, 45K)
- [850.1010 - Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids \(PDF\)](#) (10 pp, 36K)
- [850.1020 - Gammarid Acute Toxicity Test \(PDF\)](#) (11 pp, 36K)
- [850.1025 - Oyster Acute Toxicity Test \(Shell Deposition\) \(PDF\)](#) (9 pp, 32K)
- [850.1035 - Mysid Acute Toxicity Test \(PDF\)](#) (10 pp, 34K)
- [850.1045 - Penaeid Acute Toxicity Test \(PDF\)](#) (9 pp, 32K)
- [850.1055 - Bivalve Acute Toxicity Test \(Embryo Larval\) \(PDF\)](#) (7 pp, 27K)
- [850.1075 - Fish Acute Toxicity Test, Freshwater And Marine \(PDF\)](#) (13 pp, 45K)
- [850.1085 - Fish Acute Toxicity Mitigated By Humic Acid \(PDF\)](#) (10 pp, 35K)
- [850.1300 - Daphnid Chronic Toxicity Test \(PDF\)](#) (12 pp, 42K)
- [850.1350 - Mysid Chronic Toxicity Test \(PDF\)](#) (10 pp, 36K)
- [850.1400 - Fish Early-Life Stage Toxicity Test \(PDF\)](#) (15 pp, 66K)
- [850.1500 - Fish Life Cycle Toxicity \(PDF\)](#) (4 pp, 16K)
- [850.1710 - Oyster BCF \(PDF\)](#) (14 pp, 50K)
- [850.1730 - Fish BCF \(PDF\)](#) (25 pp, 74K)
- [850.1735 - Whole Sediment Acute Toxicity Invertebrates, Freshwater \(PDF\)](#) (19 pp, 65K)
- [850.1740 - Whole Sediment Acute Toxicity Invertebrates, Marine \(PDF\)](#) (14 pp, 50K)
- [850.1790 - Chironomid Sediment Toxicity Test \(PDF\)](#) (16 pp, 57K)
- [850.1800 - Tadpole/Sediment Subchronic Toxicity Test \(PDF\)](#) (15 pp, 49K)
- [850.1850 - Aquatic Food Chain Transfer \(PDF\)](#) (4 pp, 16K)
- [850.1900 - Generic Freshwater Microcosm Test, Laboratory \(PDF\)](#) (28 pp, 76K)
- [850.1925 - Site-Specific Aquatic Microcosm Test, Laboratory \(PDF\)](#) (21 pp, 91K)
- [850.1950 - Field Testing For Aquatic Organisms \(PDF\)](#) (7 pp, 21K)
- [850.2100 - Avian Acute Oral Toxicity Test \(PDF\)](#) (11 pp, 38K)
- [850.2200 - Avian Dietary Toxicity Test \(PDF\)](#) (12 pp, 42K)
- [850.2300 - Avian Reproduction Test \(PDF\)](#) (16 pp, 53K)

- [850.2400 - Wild Mammal Acute Toxicity \(PDF\)](#) (5 pp, 18K)
- [850.2450 - Terrestrial \(Soil-Core\) Microcosm Test \(PDF\)](#) (19 pp, 123K)
- [850.2500 - Field Testing For Terrestrial Wildlife \(PDF\)](#) (43 pp, 115K)
- [850.3020 - Honey Bee Acute Contact Toxicity \(PDF\)](#) (8 pp, 27K)
- [850.3030 - Honey Bee Toxicity of Residues on Foliage \(PDF\)](#) (6 pp, 23K)
- [850.3040 - Field Testing for Pollinators \(PDF\)](#) (5 pp, 18K)
- [850.4000 - Background-Nontarget Plant Testing \(PDF\)](#) (15 pp, 50K)
- [850.4025 - Target Area Phytotoxicity \(PDF\)](#) (15 pp, 51K)
- [850.4100 - Terrestrial Plant Toxicity, Tier I \(Seedling Emergence\) \(PDF\)](#) (8 pp, 29K)
- [850.4150 - Terrestrial Plant Toxicity, Tier I \(Vegetative Vigor\) \(PDF\)](#) (8 pp, 28K)
- [850.4200 - Seed Germination/Root Elongation Toxicity Test \(PDF\)](#) (8 pp, 29K)
- [850.4225 - Seedling Emergence, Tier II \(PDF\)](#) (10 pp, 36K)
- [850.4230 - Early Seedling Growth Toxicity Test \(PDF\)](#) (9 pp, 33K)
- [850.4250 - Vegetative Vigor, Tier II \(PDF\)](#) (10 pp, 35K)
- [850.4300 - Terrestrial Plants Field Study, Tier III \(PDF\)](#) (8 pp, 27K)
- [850.4400 - Aquatic Plant Toxicity Test Using Lemna Spp., Tiers I and II \(PDF\)](#) (10 pp, 36K)
- [850.4450 - Aquatic Plants Field Study, Tier III \(PDF\)](#) (9 pp, 30K)
- [850.4600 - Rhizobium-Legume Toxicity \(PDF\)](#) (14 pp, 73K)
- [850.4800 - Plant Uptake and Translocation Test \(PDF\)](#) (13 pp, 35K)
- [850.5100 - Soil Microbial Community Toxicity Test \(PDF\)](#) (11 pp, 46K)
- [850.5400 - Algal Toxicity, Tiers I and II \(PDF\)](#) (11 pp, 42K)
- [850.6200 - Earthworm Subchronic Toxicity Test \(PDF\)](#) (13 pp, 43K)
- [850.6800 - Modified Activated Sludge, Respiration Inhibition Test for Sparingly Soluble Chemicals \(PDF\)](#) (9 pp, 37K)
- [850.7100 - Data Reporting for Environmental Chemistry Methods \(PDF\)](#) (9 pp, 30K)

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■ OPPTS Environmental Fate and Transport

■ Group A — Laboratory Transport Test Guidelines

- [835.0001 - Principles and Strategies Related to Biodegradation Testing of Organic Chemicals under the Toxic Substances Control Act \(TSCA\) \(November 2008\) \(PDF\)](#) (17 pp, 155K)
- [835.1110 - Activated Sludge Sorption Isotherm \(January 1998\) \(PDF\)](#) (9 pp, 25K)
- [835.1210 - Soil Thin Layer Chromatography \(January 1998\) \(PDF\)](#) (8 pp, 21K)
- [835.1220 - Sediment and Soil Adsorption/Desorption Isotherm \(January 1998\) \(PDF\)](#) (20 pp, 56K)
- [835.1230 - Adsorption/Desorption \(Batch Equilibrium\) \(November 2008\) \(PDF\)](#) (55 pp, 680K)
- [835.1240 - Leaching Studies \(November 2008\) \(PDF\)](#) (16 pp, 275K)
- [835.1410 - Laboratory Volatility \(November 2008\) \(PDF\)](#) (6 pp, 103K)

■ Group B — Laboratory Abiotic Transformation Test Guidelines

- [835.2120 - Hydrolysis \(November 2008\) \(PDF\)](#) (15 pp, 174K)
- [835.2130 - Hydrolysis as a Function of pH and Temperature \(January 1998\) \(PDF\)](#) (16 pp, 40K)
- [835.2210 - Direct Photolysis Rate in Water by Sunlight \(January 1998\) \(PDF\)](#) (37 pp, 127K)
- [835.2240 - Photodegradation in Water \(November 2008\) \(PDF\)](#) (6 pp, 45K)
- [835.2310 - Maximum Direct Photolysis Rate in Air from UV/Visible Spectroscopy \(January 1998\) \(PDF\)](#) (21 pp, 91K)
- [835.2370 - Photodegradation in Air \(November 2008\) \(PDF\)](#) (5 pp, 42K)
- [835.2410 - Photodegradation in Soil \(November 2008\) \(PDF\)](#) (6 pp, 44K)

■ Group C — Laboratory Biological Transformation Test Guidelines

- [835.3100 - Aerobic Aquatic Biodegradation \(January 1998\) \(PDF\)](#) (10 pp, 53K)
- [835.3110 - Ready Biodegradability \(January 1998\) \(PDF\)](#) (55 pp, 156K)
- [835.3140 - Ready Biodegradability – CO₂ in Sealed Vessels \(Headspace Test\) \(November 2008\) \[SUPERSEDES 3120\] \(PDF\)](#) (26 pp, 223K)
- [835.3160 - Biodegradability in Sea Water \(January 1998\) \(PDF\)](#) (33 pp, 111K)
- [835.3170 - Shake Flask Die-Away Test \(January 1998\) \(PDF\)](#) (11 pp, 30K)
- [835.3180 - Sediment/Water Microcosm Biodegradation Test \(January 1998\) \(PDF\)](#) (14 pp, 38K)
- [835.3190 - Aerobic Mineralization in Surface Water – Simulation Biodegradation Test \(October 2008\) \(PDF\)](#) (28 pp, 226K)
- [835.3200 - Zahn-Wellens/EMPA Test \(January 1998\) \(PDF\)](#) (10 pp, 46K)
- [835.3210 - Modified SCAS Test \(January 1998\) \(PDF\)](#) (8 pp, 21K)
- [835.3215 - Inherent Biodegradability – Concawe Test \(October 2008\) \(PDF\)](#) (16 pp, 152K)
- [835.3220 - Porous Pot Test \(January 1998\) \(PDF\)](#) (24 pp, 129K)
- [835.3240 - Simulation Test – Aerobic Sewage Treatment: A. Activated Sludge Units \(October 2008\) \(PDF\)](#) (39 pp, 350K)
- [835.3260 - Simulation Test – Aerobic Sewage Treatment: B. Biofilms \(October 2008\) \(PDF\)](#) (16

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- [835.3280 – Simulation Tests to Assess the Primary and Ultimate Biodegradability of Chemicals Discharged to Wastewater \(October 2008\) \(PDF\)](#) (59 pp, 344K)
- [835.3300 - Soil Biodegradation \(January 1998\) \(PDF\)](#) (10 pp, 38K)
- [835.3400 - Anaerobic Biodegradability of Organic Chemicals \(January 1998\) \(PDF\)](#) (10 pp, 31K)
- [835.3420 - Anaerobic Biodegradability of Organic Compounds in Digested Sludge: By Measurement of Gas Production \(October 2008\) \(PDF\)](#) (24 pp, 262K)

■ Group D — Transformation in Water and Soil Test Guidelines

- [835.4100 - Aerobic Soil Metabolism / 835.4200 – Anaerobic Soil Metabolism \(October 2008\) \(PDF\)](#) (19 pp, 250K)
- [835.4300 - Aerobic Aquatic Metabolism / 835.4400 – Anaerobic Aquatic Metabolism \(October 2008\) \(PDF\)](#) (20 pp, 463K)

■ Group E — Transformation Chemical-Specific Test Guidelines

- [835.5045 - Modified SCAS Test for Insoluble and Volatile Chemicals \(January 1998\) \(PDF\)](#) (7 pp, 19K)
- [835.5154 - Anaerobic Biodegradation in the Subsurface \(January 1998\) \(PDF\)](#) (12 pp, 31K)
- [835.5270 - Indirect Photolysis Screening Test: Sunlight Photolysis in Waters Containing Dissolved Humic Substances \(January 1998\) \(PDF\)](#) (24 pp, 76K)

■ Group F — Field Dissipation Test Guidelines

- [835.6100 - Terrestrial Field Dissipation \(October 2008\) \(PDF\)](#) (50 pp, 512K)
- [835.6200 - Aquatic \(Sediment\) Field Dissipation \(October 2008\) \(PDF\)](#) (7 pp, 49K)
- [835.6300 - Forestry Dissipation \(October 2008\) \(PDF\)](#) (7 pp, 48K)
- [835.6400 - Combination and Tank Mixes Field Dissipation \(October 2008\) \(PDF\)](#) (5 pp, 42K)

■ Group G — Ground Water Monitoring Test Guidelines [Reserved]

■ Group H — Volatility from Soil Test Guidelines

- [835.8100 - Field Volatility \(November 2008\) \(PDF\)](#) (6 pp, 44K)

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■ OPPTS Health Effects Testing Guidelines.

■ Group A – Acute Toxicity Test Guidelines

- [870.1000 - Acute Toxicity Testing--Background \(December 2002\) \(PDF\)](#) (9 pp, 23K)
- [870.1100 - Acute Oral Toxicity \(December 2002\) \(PDF\)](#) (10 pp, 27K)
- [870.1200 - Acute Dermal Toxicity \(August 1998\) \(PDF\)](#) (10 pp, 24K)
- [870.1300 - Acute Inhalation Toxicity \(August 1998\) \(PDF\)](#) (11 pp, 21K)
- [870.2400 - Acute Eye Irritation \(August 1998\) \(PDF\)](#) (8 pp, 22K)
- [870.2500 - Acute Dermal Irritation \(August 1998\) \(PDF\)](#) (8 pp, 23K)
- [870.2600 - Skin Sensitization \(March 2003\) \(PDF\)](#) (9 pp, 29K)

■ Group B – Subchronic Toxicity Test Guidelines

- [870.3050 - Repeated Dose 28-Day Oral Toxicity Study in Rodents \(July 2000\) \(PDF\)](#) (17 pp, 29K)
- [870.3100 - 90-Day Oral Toxicity in Rodents \(August 1998\) \(PDF\)](#) (13 pp, 33K)
- [870.3150 - 90-Day Oral Toxicity in Nonrodents \(August 1998\) \(PDF\)](#) (12 pp, 30K)
- [870.3200 - 21/28-Day Dermal Toxicity \(August 1998\) \(PDF\)](#) (15 pp, 36K)
- [870.3250 - 90-Day Dermal Toxicity \(August 1998\) \(PDF\)](#) (14 pp, 34K)
- [870.3465 - 90-Day Inhalation Toxicity \(August 1998\) \(PDF\)](#) (17 pp, 40K)
- [870.3550 - Reproduction/Developmental Toxicity Screening Test \(July 2000\) \(PDF\)](#) (13 pp, 89K)
- [870.3650 - Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test \(July 2000\) \(PDF\)](#) (17 pp, 89K)
- [870.3700 - Prenatal Developmental Toxicity Study \(August 1998\) \(PDF\)](#) (11 pp, 126K)
- [870.3800 - Reproduction and Fertility Effects \(August 1998\) \(PDF\)](#) (14 pp, 35K)

■ Group C – Chronic Toxicity Test Guidelines

- [870.4100 - Chronic Toxicity \(August 1998\) \(PDF\)](#) (18 pp, 44K)
- [870.4200 - Carcinogenicity \(August 1998\) \(PDF\)](#) (17 pp, 41K)
- [870.4300 - Combined Chronic Toxicity/Carcinogenicity \(August 1998\) \(PDF\)](#) (20 pp, 49K)

■ Group D – Genetic Toxicity Test Guidelines

- [870.5100 - Bacterial Reverse Mutation Test \(August 1998\) \(PDF\)](#) (13 pp, 36K)
- [870.5140 - Gene Mutation in *Aspergillus nidulans* \(August 1998\) \(PDF\)](#) (7 pp, 18K)
- [870.5195 - Mouse Biochemical Specific Locus Test \(August 1998\) \(PDF\)](#) (7 pp, 19K)
- [870.5200 - Mouse Visible Specific Locus Test \(August 1998\) \(PDF\)](#) (6 pp, 16K)
- [870.5250 - Gene Mutation in *Neurospora crassa* \(August 1998\) \(PDF\)](#) (6 pp, 17K)
- [870.5275 - Sex-linked Recessive Lethal Test in *Drosophila melanogaster* \(August 1998\) \(PDF\)](#) (6 pp, 16K)
- [870.5300 - *In vitro* Mammalian Cell Gene Mutation Test \(August 1998\) \(PDF\)](#) (14 pp, 37K)
- [870.5375 - *In vitro* Mammalian Chromosome Aberration Test \(August 1998\) \(PDF\)](#) (13 pp, 33K)
- [870.5380 - Mammalian Spermatogonial Chromosomal Aberration Test \(August 1998\) \(PDF\)](#) (11 pp, 28K)
- [870.5385 - Mammalian Bone Marrow Chromosomal Aberration Test \(August 1998\) \(PDF\)](#) (11 pp, 28K)
- [870.5395 - Mammalian Erythrocyte Micronucleus Test \(August 1998\) \(PDF\)](#) (12 pp, 31K)
- [870.5450 - Rodent Dominant Lethal Assay \(August 1998\) \(PDF\)](#) (6 pp, 15K)
- [870.5460 - Rodent Heritable Translocation Assays \(August 1998\) \(PDF\)](#) (7 pp, 17K)
- [870.5500 - Bacterial DNA Damage or Repair Tests \(August 1998\) \(PDF\)](#) (7 pp, 18K)
- [870.5550 - Unscheduled DNA Synthesis in Mammalian Cells in Culture \(August 1998\) \(PDF\)](#) (7 pp, 18K)
- [870.5575 - Mitotic Gene Conversion in *Saccharomyces cerevisiae* \(August 1998\) \(PDF\)](#) (6 pp, 16K)
- [870.5900 - *In vitro* Sister Chromatid Exchange Assay \(August 1998\) \(PDF\)](#) (7 pp, 18K)
- [870.5915 - *In vivo* Sister Chromatid Exchange Assay \(August 1998\) \(PDF\)](#) (6 pp, 15K)

■ Group E – Neurotoxicity Test Guidelines

- [870.6100 - Acute and 28-Day Delayed Neurotoxicity of Organophosphorus Substances \(August 1998\) \(PDF\)](#) (10 pp, 27K)
- [870.6200 - Neurotoxicity Screening Battery \(August 1998\) \(PDF\)](#) (13 pp, 32K)
- [870.6300 - Developmental Neurotoxicity Study \(August 1998\) \(PDF\)](#) (14 pp, 35K)
- [870.6500 - Schedule-Controlled Operant Behavior \(August 1998\) \(PDF\)](#) (8 pp, 20K)
- [870.6850 - Peripheral Nerve Function \(August 1998\) \(PDF\)](#) (9 pp, 22K)
- [870.6855 - Neurophysiology Sensory Evoked Potentials \(August 1998\) \(PDF\)](#) (14 pp, 35K)

■ Group F – Special Studies Test Guidelines

- [870.7200 - Companion Animal Safety \(August 1998\) \(PDF\)](#) (10 pp, 23K)
- [870.7485 - Metabolism and Pharmacokinetics \(August 1998\) \(PDF\)](#) (14 pp, 34K)
- [870.7600 - Dermal Penetration \(August 1998\) \(PDF\)](#) (14 pp, 37K)
- [870.7800 - Immunotoxicity \(August 1998\) \(PDF\)](#) (13 pp, 34K)

■ Group G – Health Effects Chemical-Specific Test Guidelines

- [870.8355 - Combined Chronic Toxicity/Carcinogenicity Testing of Respirable Fibrous Particles \(July 2001\) \(PDF\)](#) (17 pp, 181K)

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- **Residue chemistry guidelines.**
- [860.1000 - Background \(August 1996\) \(PDF\) \(42 pp, 128K\)](#)
- [860.1000 - Supplement: Guidance on Constructing Maximum Reasonably Balanced Diets \(MRBD\) \(June 2008\) \(PDF\) \(5 pp, K\)](#)
- [860.1100 - Chemical Identity \(August 1996\) \(PDF\) \(3 pp, 11K\)](#)
- [860.1200 - Directions for Use \(August 1996\) \(PDF\) \(9 pp, 29K\)](#)
- [860.1300 - Nature of the Residue--Plants, Livestock \(August 1996\) \(PDF\) \(34 pp, 126K\)](#)
- [860.1340 - Residue Analytical Method \(August 1996\) \(PDF\) \(14 pp, 45K\)](#)
- [860.1360 - Multiresidue Method \(August 1996\) \(PDF\) \(4 pp, 14K\)](#)
- [860.1380 - Storage Stability Data \(August 1996\) \(PDF\) \(17 pp, 54K\)](#)
- [860.1400 - Water, Fish, Irrigated Crops \(August 1996\) \(PDF\) \(5 pp, 16K\)](#)
- [860.1460 - Food Handling \(August 1996\) \(PDF\) \(6 pp, 20K\)](#)
- [860.1480 - Meat/Milk/Poultry/Eggs \(August 1996\) \(PDF\) \(16 pp, 53K\)](#)
- [860.1500 - Crop Field Trials \(August 1996\) \(PDF\) \(91 pp, 369K\)](#)
- [860.1520 - Processed Food/Feed \(August 1996\) \(PDF\) \(17 pp, 64K\)](#)
- [860.1550 - Proposed Tolerances \(August 1996\) \(PDF\) \(5 pp, 17K\)](#)
- [860.1560 - Reasonable Grounds in Support of the Petition \(August 1996\) \(PDF\) \(3 pp, 11K\)](#)
- [860.1650 - Submittal of Analytical Reference Standards \(November 2008\) \(PDF\) \(3 pp, 12K\)](#)
- [860.1850 - Confined Accumulation in Rotational Crops \(August 1996\) \(PDF\) \(12 pp, 55K\)](#)
- [860.1900 - Field Accumulation in Rotational Crops \(August 1996\) \(PDF\) \(11 pp, 39K\)](#)

Regulatory Basics for Researchers.

Evolution of Pesticide Regulation in the U.S

- **1910** - Insecticide Act of 1910
- **1947** - Federal Insecticide Fungicide and Rodenticide Act (FIFRA)
 - USDA regulated pesticide labeling
- **1954** – Miller Amendment to Federal Food Drug and Cosmetic Act (FFDCA)
 - Required FDA to set maximum residues levels of pesticides in food and feed
- **1970** – EPA was created
 - All pesticide and tolerance regulation consolidated.
- **1972-1990** - FIFRA was amended seven times.



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Evolution of Pesticide Regulation in the U.S



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- **1978** – EPA issues a policy statement that Efficacy data no longer had to be submitted. Except for public health applications. Data must still be collected but not submitted.
- **1996 – Food Quality Protection Act (FQPA).**
 - After years of debate and discussion the FQPA was rushed through Congress prior to mid term elections.
 - Activists successful Lawsuits against an important class of Fungicides under the **Delaney Clause** also drove the process.

“The Delaney Clause” was a 1958 amendment of FFDCA in response to a Cranberry contamination incident.

It prohibited the presence of “cancer causing” chemicals in processed commodities at levels higher than the raw commodity.

Regulatory Basics for Researchers. Evolution of Pesticide Regulation in the U.S



■ FQPA provisions

- Eliminated the Risk Benefit standard for human risk.
- Required the reevaluation of all tolerances and exemptions for tolerances in 10 years
- Required tolerances be established for Section 18 Emergency Exemptions
- Must consider an extra safety factor up to 10X in risk assessments for infants and children.
- Must consider aggregate exposure from all sources
- Must consider cumulative exposure for chemicals with a common mechanism of toxicity.

Regulatory Basics for Researchers. Evolution of Pesticide Regulation in the U.S



- **FQPA provisions (Continued)**
 - Must screen all pesticides for endocrine disruption
 - Requires re-review of all pesticides every 15 years.
 - Expedite antimicrobial approvals
 - Requires consultation with Health and Human Services before cancelling public health pesticides.

Regulatory Basics for Researchers. Evolution of Pesticide Regulation in the U.S



■ 2003 – Pesticide Registration Improvement Act (PRIA)

- Instituted a fee for service program. In exchange for a fee the Agency agrees to make a decision by standard date.
- Was renewed in 2007
- PRIA was developed in a cooperative effort between EPA, Industry and the Non Government Organizations (NGOs).

Pesticide Registration Improvement Renewal Act – PRIA II Fee Table – Effective October 1, 2007

EPA Number of Fee Category (EPA No.), corresponding number in the Congressional Record of July 21, 2007 (CR No., Title of Fee Category (Action), Decision Time Review Periods for FY 08, 09 and 10 in months, and the Registration Service Fee for FY08

EPA No.	CR No.	Action	Decision time (months)			FY 08 Registration Service Fee (\$)
			FY 08	FY 09	FY 10	
TABLE 1. Registration Division — New Active Ingredients						
R010	1	Food use (1)	24	24	24	516,300
R020	2	Food use; reduced risk (1)	18	18	18	516,300
R030	3	Food use; Experimental Use Permit application submitted simultaneously with application for registration; decision time for Experimental Use Permit and temporary tolerance same as #R040 (1)	24	24	24	570,700
R040	4	Food use; Experimental Use Permit application; establish temporary tolerance; submitted before application for registration; credit \$326,025 toward new active ingredient application that follows	18	18	18	380,500
R050	5	Food use; application submitted after Experimental Use Permit application; decision time begins after Experimental Use Permit and temporary tolerance are granted (1)	14	14	14	190,300
R060	6	Non-food use; outdoor (1)	21	21	21	358,700

Regulatory Basics for Researchers. Evolution of Pesticide Regulation in the U.S

FUTURE TRENDS

■ Currently the registration process is under Siege

NGO legal challenges under the Endangered Species and Clean Water Acts.

EPA is revisiting FQPA risk assessment policies

Increased Transparency and Stakeholder Input.

Increased Globalization of the process.





The Chemical Company