the plant metabolism study show differing metabolites in plants form those found in animals, an additional livestock metabolism study involving dosing with the plant metabolite(s) may also be required.

8. Livestock feeding studies are required whenever a pesticide residue is present in livestock feed or when direct application to livestock uses occurs.

9. Required if indoor use could result in pesticide residues in or on food or feed.

10. Data are required to determine whether FDA/USDA multiresidue methodology would detect and identify the pesticides and any metabolites.

11. Data are required whenever a pesticide may be applied directly to water, unless it can be demonstrated that the treated water would not be available for human or livestock consumption.

12. Data on fish are required for all pesticides applied directly to water inhabited, or which will be inhabited, by fish that may be caught or harvested for human consumption.

13. Data are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.

14. Data are required whenever a pesticide may be used in food/feed handling establishments.

15. Data on the nature and level of residue in processed food/feed are required when detectible residues could potentially concentrate on processing thus requiring the establishment of a separate tolerance higher than that of the raw agricultural commodity.

16 Anticipated residue data are required when the assumption of tolerance level residues would result in predicted exposure at an unsafe level of exposure. Data, using single serving samples of a raw agricultural commodity, on the level or residue in food as consumed would be used to obtain a more precise estimate of potential dietary exposure. These data may also include washing, cooking, processing or degradation studies as well as market basket surveys for a more precise residue determination.

17. The proposed tolerance must reflect the maximum residue likely to occur in crops, in meat, milk, poultry, or eggs.

18. Required when a residue analytical method is required.

§ 158.2083 Experimental use permit biochemical pesticides human health assessment data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the human health assessment data requirements for a particular biochemical pesticide product.

(2) The data in this section are not required for straight chain lepidopteran pheromones when applied up to a maximum use rate of 150 grams active ingredient/acre/year.

(b) *Use patterns.* (1) Food use patterns, in general, include products classified under the following general uses: terrestrial food crop use; terrestrial feed crop use; aquatic food crop use; greenhouse food crop use.

(2) Nonfood use patterns include products classified under the general use patterns of terrestrial nonfood crop use; aquatic nonfood residential use; aquatic nonfood outdoor use; aquatic nonfood industrial use; greenhouse nonfood crop use; forestry use; residential outdoor use; residential indoor use; indoor food use; indoor nonfood use; indoor medical use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental use permit biochemical pesticides human health assessment. The test notes are shown in paragraph (e) of this section.

TABLE—EUP BIOCHEMICAL PESTICIDES HUMAN HEALTH ASSESSMENT DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns		Test Substance		Test Notes
		Food	Nonfood	MP	EP	
Tier I						

TABLE—EUP BIOCHEMICAL PESTICIDES HUMAN HEALTH ASSESSMENT DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns		Test Substance		Test Notes
		Food	Nonfood	MP	EP	
Acute Testing						
870.1100	Acute oral toxicity - rat	R	R	TGAI and MP	TGAI and EP	1
870.1200	Acute dermal toxicity	R	R	TGAI and MP	TGAI and EP	1, 2
870.1300	Acute inhalation toxicity - rat	R	R	TGAI and MP	TGAI and EP	3
870.2400	Primary eye irritation - rabbit	R	R	TGAI and MP	TGAI and EP	2
870.2500	Primary dermal irritation	R	R	TGAI and MP	TGAI and EP	1, 2
none	Hypersensitivity incidents	R	R	All	All	4
Subchronic Testing						
870.3100	90-day oral (one species)	R	NR	TGAI	TGAI	--
Developmental Toxicity						
870.3700	Prenatal developmental - rat preferably	R	CR	TGAI	TGAI	5
Mutagenicity Testing						
870.5100	Bacterial reverse mutation test	R	CR	TGAI	TGAI	6
870.5300	*In vivo* mammalian cell assay	R	CR	TGAI	TGAI	6, 7
Tier II						
Developmental Toxicity						
870.3700	Prenatal developmental	CR	CR	TGAI	TGAI	5

(e) *Test notes.* The following test notes are applicable to the data requirements for experimental use permit biochemical pesticides human health assessment as referenced in the last column of the table in paragraph (d) of this section.

1. Required unless the test material is a gas or highly volatile (vapor pressure $>10^{-4}$torr (mm/Hg)).

2. Required unless the test material is corrosive to skin or has pH <2 or >11.5.

3. Required when the pesticide, under conditions of use, would result in respirable material (e.g., gas, volatile substance or aerosol/particulate), unless it is a straight chain lepidopteran pheromone.

4. Hypersensitivity incidents must be reported as adverse effects data.

5. Required if the use of the product under widespread and commonly recognized practice may reasonably be expected to result in significant exposure to female humans (e.g., occupational exposure or repeated application of insect repellents directly to the skin). Tier II data is required on a different test species from Tier I data when developmental effects are observed in the first study and information on species-to-species extrapolation is needed.

6. Required to support nonfood uses if either:

i. The use is likely to result in significant human exposure; or

ii. The active ingredient (or its metabolites) is structurally related to a known mutagen or belongs to any chemical class of compounds containing a known mutagen.

Additional mutagenicity tests that may have been performed plus a complete reference list must also be submitted. Subsequent testing may be required based on the available evidence.

7. Choice of assay using either:

i. Mouse lymphoma L5178Y cells, thymidine kinase (tk) gene locus, maximizing

assay conditions for small colony expression or detection;

ii. Chinese hamster ovary (CHO) or Chinese hamster lung fibroblast (V79) cells, hypoxanthine-guanine phosphoribosyl transferase (hgprt) gene locus, accompanied by an appropriate *in vivo* test for clastogenicity; or

iii. CHO cells strains AS52, xanthine-guanine phosphoribosyl transferase (xprt) gene locus.

§ 158.2084 Experimental use permit biochemical pesticides nontarget organisms and environmental fate data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget organisms and fate data requirements for a particular biochemical pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section. In general, for all outdoor end-use products including turf, the following studies are required: one avian acute oral, one avian dietary, one acute freshwater fish, and one acute freshwater invertebrate study.

(2) The data in this section are not required for arthropod pheromones when applied at up to a maximum use rate of 150 grams active ingredient/acre/year except when the product is expected to be available to avian species (*i.e.*, granular formulation).

(b) *Use patterns.* The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood/nonfeed crop. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and nonfood use. The remaining terrestrial uses include forestry and residential outdoor use. Data are also required for the general use patterns of aquatic food and nonfood crop use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental use permit biochemical pesticides nontarget organisms and environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—EUP BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/Feed/Nonfood	Food/Nonfood	Food/Nonfood		Food/Nonfood		
Tier I								
Avian Testing								
850.2100	Avian acute oral toxicity	R	R	NR	R	NR	TGAI, EP	1, 2, 3
850.2200	Avian dietary toxicity	R	R	NR	R	NR	TGAI, EP	1, 2, 3
Aquatic Organism Testing								
850.1075	Fish acute toxicity, freshwater	R	R	NR	R	NR	TGAI, EP	2, 3, 4