

§ 158.2000 Biochemical pesticides definition and applicability.

This subpart applies to all biochemical pesticides as defined in paragraphs (a), (b), and (c) of this section.

(a) *Definitions.* The following terms are defined for the purposes of subpart U of this part.

(1) A *biochemical pesticide* is a pesticide that:

(i) Is a naturally-occurring substance or structurally-similar and functionally identical to a naturally-occurring substance;

(ii) Has a history of exposure to humans and the environment demonstrating minimal toxicity, or in the case of a synthetically-derived biochemical pesticides, is equivalent to a naturally-occurring substance that has such a history; and

(iii) Has a non-toxic mode of action to the target pest(s).

(2) A *Pheromone* is a compound produced by a living organism or is a synthetically derived substance that is structurally similar and functionally identical to a naturally-occurring pheromone, which, alone or in combination with other such compounds, modifies the behavior of other individuals of the same species.

(i) An *Arthropod Pheromone* is a pheromone produced by a member of the taxonomic phylum Arthropoda.

(ii) A *Lepidopteran Pheromone* is an arthropod pheromone produced by a member of the insect order Lepidoptera.

(iii) A *Straight Chain Lepidopteran Pheromone* is a lepidopteran pheromone consisting of an unbranched aliphatic chain (between 9 and 18 carbons) ending in an alcohol, aldehyde, or acetate functional group and containing up to three double bonds in the aliphatic backbone.

(b) *Examples.* Biochemical pesticides include, but are not limited to:

(1) Semiochemicals (insect pheromones and kairomones),

(2) Natural plant and insect regulators,

(3) Naturally-occurring repellents and attractants, and

(4) Enzymes.

(c) *Applicability.* The Agency may review, on a case-by-case basis, naturally-occurring pesticides that do not

clearly meet the definition of a biochemical pesticide in an effort to ensure, to the greatest extent possible, that only the minimum testing sufficient to make scientifically sound regulatory decisions would be conducted. The Agency will review applications for registration of naturally-occurring pesticides to determine whether to review the pesticide under this subpart U.

§ 158.2010 Biochemical pesticides data requirements.

(a) Sections 158.2030 through 158.2070 identify the data requirements that are required to support registration of biochemical pesticides. Sections 158.2080 through 158.2084 identify the data requirements that are required to support Experimental Use Permits (EUPs). Variations in the test conditions are identified within the test notes. Definitions that apply to all biochemical data requirements can be found in § 158.2000.

(b) Each data table includes “use patterns” under which the individual data are required, with variations including food and nonfood uses for terrestrial and aquatic applications, greenhouse, indoor, forestry, and residential outdoor applications under certain circumstances.

(c) The categories for each data requirement are “R”, which stands for required, and “CR” which stands for conditionally required. Generally, “R” indicates that the data are more likely required than for those data requirements with “CR.” However, in each case, the regulatory text preceding the data table and the test notes following the data table must be used to determine whether the data requirement must be satisfied.

(d) Each table identifies the test substance that is required to be tested to satisfy the data requirement. Test substances may include: technical grade active ingredient (TGAI), manufacturing-use product (MP), end-use product (EP), typical end-use product (TEP), residue of concern, and pure active ingredient (PAI) or all of the above (All). Commas between the test substances (*i.e.*, TGAI, EP) indicate that data may be required on the TGAI or