

for evaluating such risk between agricultural and non-agricultural pesticides.” This part distinguishes the various classes of pesticide use (e.g., crop *vs.* non-crop) and the corresponding data necessary to support registration under FIFRA. This information is present in each data requirement table. In addition, the Use Pattern Index (appendix A) is a comprehensive list of pesticide use patterns, cross-referenced to the general use patterns appearing in the tables; the index will further assist the reader in distinguishing agricultural versus non-agricultural uses of pesticides.

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#### § 158.60 Minor uses.

(a) *Minor use policy.* A minor use of a pesticide is a use on a “minor crop” (a crop which is planted on a small total amount of acreage) or a use which is otherwise limited such that the potential market volume of the product for that use is inherently small. EPA’s policy concerning data requirements for minor uses of pesticides includes the following elements:

(1) Since the market volume for a minor use of a pesticide is intrinsically low, and the risk associated with the use often is also correspondingly low, EPA will adjust the data requirements concerning the minor use appropriately.

(2) A new data requirement pertinent to both an unregistered minor use and a registered major use will not be applied to a minor use applicant until it is applied to the major use registrations.

(3) EPA will accept extrapolations and regional data to support establishment of individual minor use tolerances.

(4) Group tolerances will be established to assist applicants for registration of products for minor uses as described in 40 CFR 180.34.

(b) *Advice on data requirements to support minor uses.* Applicants for registration are advised to contact the appropriate EPA Product Manager of the Minor Use Officer for advice on developing data to support new applications for minor uses of pesticides.

#### § 158.65 Biochemical and microbial pesticides.

Biochemical and microbial pesticides are generally distinguished from conventional chemical pesticides by their unique modes of action, low use volume, target species specificity or natural occurrence. In addition, microbial pesticides are living entities capable of survival, growth reproduction and infection. Biochemical and microbial pesticides are subject to a different set of data requirements, as specified in §§ 158.165 and 158.170, respectively.

(a) *Biochemical pesticides.* Biochemical pesticides include, but are not limited to, products such as semichemicals (e.g. insect pheromones), hormones (e.g., insect juvenile growth hormones), natural plant and insect regulators, and enzymes. When necessary the Agency will evaluate products on an individual basis to determine whether they are biochemical or conventional chemical pesticides.

(b) *Microbial pesticides.* (1) Microbial pesticides include microbial entities such as bacteria, fungi, viruses, and protozoans. The data requirements apply to all microbial pesticides, including those that are naturally-occurring as well as those that are genetically modified. Each “new” variety, subspecies, or strain of an already registered microbial pest control agent must be evaluated, and may be subject to additional data requirements.

(2) Novel microbial pesticides (*i.e.*, genetically modified or non-indigenous microbial pesticides) will be subject to additional data or information requirements on a case-by-case basis depending on the particular micro-organism, its parent microorganism, the proposed pesticide use pattern, and the manner and extent to which the organism has been genetically modified. Additional requirements may include information on the genetic engineering techniques used, the identity of the inserted or deleted gene segment (base sequence data or enzyme restriction map of the gene), information on the control region of the gene in question, a description of the “new” traits or characteristics that are intended to be expressed, tests to evaluate genetic stability and exchange, and/or selected Tier II environmental expression and toxicology tests.