



Greenhouse, Lab, and Field Testing with Biological Products: High Throughput Testing

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Are validated analytical methods available?

Is a GAP or maximum application rate available?

- Microbial
 - Form and concentration of the organism in the test sample?
 - Biosafety category level? USDA permit required?
 - Attenuated or method-specific controls?
- Protein/Peptide
 - Solubility in water?
 - HPLC-DAD, HPLC-UV, LC-MS/MS, ELISA, Western blot
- RNA/DNA Product
 - ID/Sequence
 - Is there a primer or probe sequence available?
 - Is the product manufactured using living cells?

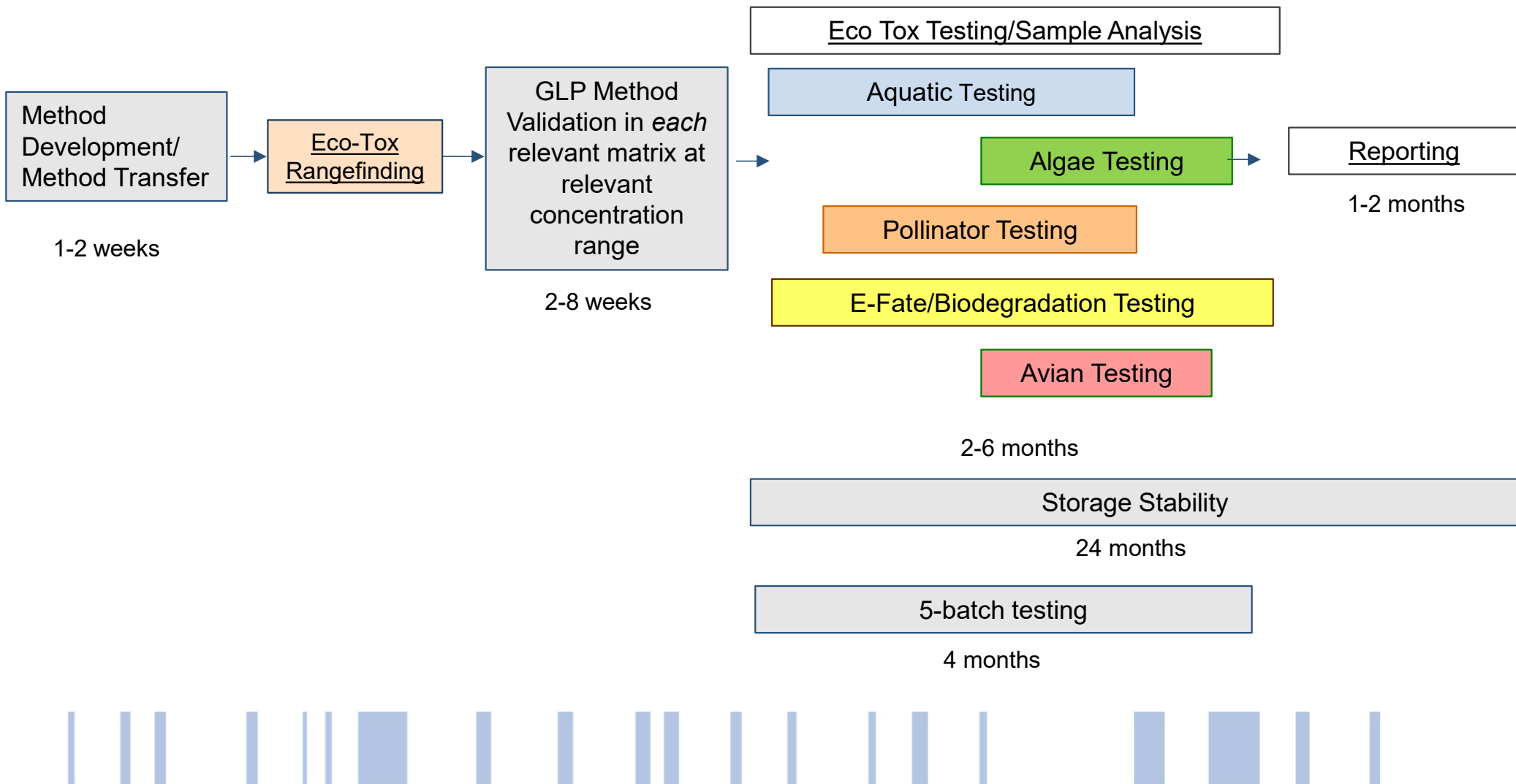
Typical Field Testing Timeline

Field Testing is limited by season and associated crop/target

Crop	Target	Time	Location
Cole Crops	Cabbage Looper, Diamondback moth, Beet Armyworm, Aphid, and Whitefly	Feb-Nov	Field
Eggplant	Whitefly, Mites, Thrips, and Leafhopper	April-Nov	Field
Lettuce	Whitefly and Aphids	Feb-May, Oct-Dec	Field
Corn	Corn Earworm	May-Sept	Field
Tomato/Pepper	Whitefly, Thrips (pepper), and Aphids	April-Oct	Field
Almond	Mites, Nematodes, and Navel Orangeworm	June-Aug and Year-Round	Field
Grape	Mites, Leafhopper, and Mealybugs	April-Aug	Field
Walnut	Aphids	April-Aug	Field
Citrus	Nematode, Thrips, and Citrus Red Mite, California Red Scale	Year-Round	Field
Alfalfa	Pea Aphid, Alfalfa Weevil, and Leafhopper	Feb-Oct	Field



Typical Laboratory Testing Timeline



Microbials

- Viability Assessment upon receipt
- Validated Methods for CFU determination
- Appropriate controls for exposure refinement
- Practical standardization of study guidelines on case-by-case basis
- Containment in field and greenhouse based on BSL level

DNA/RNA products

- Challenges with qPCR analysis – potential SANTE deficiencies
- Quantitation of active substance or representative sequence has regulatory implications

Proteins/Peptides

- Align more closely with conventional test guidance and risk assessment
- Delivery and maintenance difficult for larger molecules in aqueous systems



GLP

- Upfront analytical work, Quality Assurance, and Reporting time significantly extends time to complete
- Comprehensive assessment of potential toxicity. Full report.
- Required for risk assessment
- Higher cost

non-GLP

- Faster to complete
- Screening assays are high throughput and provide data quickly to derisk discovery process
- Less comprehensive – wider spacing of test concentrations and lack of verification of exposure concentrations creates datagaps
- Lower cost

Success in the field/laboratory depends on effective communication between the testing facility and client.