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Understanding Challenges in Microbial Pesticide Terrestrial Estimated Environmental Concentrations (EECs)

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The US EPA defines the estimated environmental concentration (EEC) for exposure in terrestrial environments as the highest concentration of product as applied to the field, either what will come out of the sprayer during foliar applications or during drip/or drench applications.[1]

For microbial pesticides, this value is calculated from the maximum application rate (e.g. pounds of product per acre), minimum dilution volume (e.g. gallons of solution per acre) from the specimen label, and the viability (count) of the microbe in the product to be tested.

$$\frac{\text{Minimum Application Rate}\left(\frac{\text{lbs}}{\text{acre}}\right) X \frac{454\text{g}}{\text{lbs}} X \text{ Viability}\left(\frac{\text{CFU}}{\text{g}}\right)}{\text{Minimum Dilution Volume}\left(\frac{\text{gallons}}{\text{acre}}\right) X \frac{3785\text{ mL}}{\text{gallon}}} = \text{EEC CFU/mL}$$

1. **U.S. Environmental Protection Agency.** *Microbial Pesticide Test Guidelines: OPPTS 885.4000. Background for Nontarget Organism Testing of Microbial Pest Control Agents;* EPA 712–C–96–354; Office of Prevention, Pesticides and Toxic Substances: Washington, DC, 1996.

It is generally understood that for any dietary terrestrial animal testing performed under EPA 885 series (i.e. 885.4340 or 885.4380), the maximum test concentration should be 10x or 100x the EEC.

These test concentrations, however, can prove problematic or physically impossible, particularly when minimum dilution volumes are low and maximum application rates are high (see examples, below).

All calculations are based on a batch count of 1.0 x 10^9 CFU/g.

Example 1:

Based on the specimen label, the maximum application rate is 5 pounds/acre, and the minimum dilution volume is 10 gallons/acre, so the EEC is determined to be 6.0 x10^7 CFU/mL.

If 25 mL of diet (e.g. sucrose solution for bees) is prepared, the diet preparation would be as follows:

EEC FACTOR	CONCENTRATION (CFU/mL)	AMOUNT OF MICROBE REQUIRED FOR DOSING (g)	PROPORTION OF DIET THAT WOULD BE MICROBE
10x	6.0 x 10^8	15	60%
100x	6.0 x 10^9	150	600%

Using the standard guidance, these diets would contain either a much higher proportion of test substance than recommended for normal feeding or would be physically impossible to prepare.

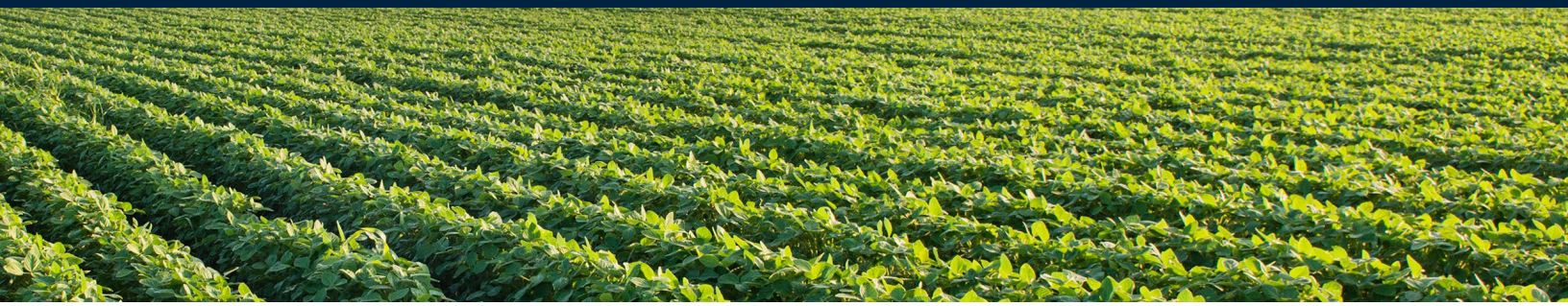
However, if the minimum dilution volume is increased from 10 gallons/acre to 20 gallons/acre, the preparation would change as follows:

EEC FACTOR	CONCENTRATION (CFU/mL)	AMOUNT OF MICROBE REQUIRED FOR DOSING (g)	PROPORTION OF DIET THAT WOULD BE MICROBE
10x	3.0 x 10^8	7.5	30%
100x	3.0 x 10^9	75	300%

Now, the amount of microbe required at the 10x EEC rate becomes a reasonable percentage of the final diet, while the amount required at the 100x EEC rate is still not physically possible.







Example 2:

From the specimen label, the maximum application rate of a product is 2 pounds/acre and the minimum dilution volume is 5 gallons/acre, so the EEC is determined to be 4.8 x10^7 CFU/mL.

If the same 25 mL of diet is prepared, the preparation would be as follows:

EEC FACTOR	CONCENTRATION (CFU/mL)	AMOUNT OF MICROBE REQUIRED FOR DOSING (g)	PROPORTION OF DIET THAT WOULD BE MICROBE
10x	4.8 x 10^8	12	48%
100x	4.8 x 10^9	120	480%

Once again, both rates would result in diets that would contain either a much higher proportion of test substance than recommended for normal feeding or would be physically impossible to prepare. But, if we increase the minimum dilution volume to 25 gallons/acre, the EEC would now be 9.6 x 10^6 CFU/mL and the preparation would instead look like this:

EEC FACTOR	CONCENTRATION (CFU/mL)	AMOUNT OF MICROBE REQUIRED FOR DOSING (g)	PROPORTION OF DIET THAT WOULD BE MICROBE
10x	9.6 x 10^8	2.4	9.6%
100x	9.6 x 10^9	24	96%

At these rates, both the 10x and 100x EEC rates are achievable, even if 100x EEC is above the recommended proportion of test substance to diet.

These examples show that the preferred maximum test rates (10x and 100x the EEC) may not be achievable or reasonable for use in testing microbial pesticides. To work around these limitations, lower maximum test concentrations (e.g. 1x the EEC) or increasing minimum dilution volumes on specimen labels need to be considered. Manufacturers for these agricultural products should take into account that minimum dilution volumes are not just applicable to field use but may impact laboratory testing and therefore regulatory risk assessments as well.

Smithers designs the appropriate studies to conduct environmental risk assessments for microbial pesticides to address these challenges. Contact us to schedule a meeting with our experts.

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