FAQs for EPA's Document:
Efficacy Testing Standards for Product Data Call-In Responses

1. **Should data be submitted/cited on both the basic (required) organisms as well as the supplemental (additional) organisms?**
   Yes, efficacy data should be submitted/cited for all basic (required) and supplemental (additional) organisms supporting any efficacy claims.

2. **The Efficacy Testing Standards for Product Data Call-In Responses document states that the basic formulation should be used for efficacy testing. What if the basic formulation is not used in commerce and the materials to batch the basic formula are not readily accessible?**
   If the basic formula cannot be tested, a currently marketed alternate formulation may be used instead. However, a rationale should be provided with this testing and the confidential statement of formula (CSF) changed to reflect the tested alternate as the new basic formula.

3. **This document states that the product needs to have full test material characterization data. Is a laboratory Certificate of Analysis (COA) sufficient to provide this information?**
   Yes, a laboratory Certificate of Analysis of the tested product lots is adequate.

4. **If cited studies or existing studies do not contain a COA as part of the original study, can a new COA be provided to support this data need?**
   Yes, but only if the product lots tested have not expired and have been maintained under appropriate storage conditions.

5. **The efficacy data supporting my product for supplemental (additional) bacteria uses minimum carrier counts of $1x10^4$ and 10 carrier per each of two lots, however the studies were performed with a version of the test method in place when the 2012 guidelines were published. Do I need to generate new data for these additional/supplemental bacteria?**
   The Agency recommends submitting studies performed under the test methods in place when the 2012 guidelines were published, as long as they conform to any updated standards identified in this guidance document.

6. **Do *Staphylococcus aureus* or *Pseudomonas aeruginosa* studies which comply with the product data call-in (DCI) guidance document but were performed under a pre-2013 AOAC use-dilution method need to be regenerated under the new, 2013 use-dilution method?**
   No, use-dilution data performed prior to the 2013 version of this method may be submitted in response to a reregistration data call-in as long as they conform to the updated standards identified in this guidance document.

7. **Can efficacy data performed under the Antimicrobial Testing Program (ATP) be cited to satisfy the DCI requirement?**
   Yes, a product lot tested under the ATP may be cited in response to a reregistration data call-in as long as the active ingredient concentration of the lot tested was at or below the nominal concentration.

8. **If a product has multiple active ingredients that are all covered by a single CAS number or trade name, is a single analytical assessment for that material adequate?**
   Yes, active ingredients with the same CAS number may be combined to determine a total analytical concentration.

9. **Why are non-food contact sanitizer requirements not addressed in this document?**
   This guidance document is intended to be a supplement which identifies certain updated standards since the 2012, 810 Series Guidelines. As a result, the document does not repeat all the testing requirements in the current 2012 Guidelines.

10. **Is there an acceptable active ingredient concentration range above the nominal concentration for previously-performed efficacy data? For instance, if the analytical method error is +/-2%, will testing on formulas at 2% above nominal be allowed?**
    No, the product lots tested in previously-performed (existing) efficacy data that is submitted in response to a reregistration product data call-in should be performed with active ingredient concentrations at or below the nominal concentration.

11. **Clarification is needed as to whether confirmatory data at the lower certified limit (LCL) can be submitted in support of the DCI. It is not clear if EPA understands that substantial confirmatory data on alternate formulas, performed at the LCL, can be submitted.**
    Confirmatory efficacy data should not be submitted in response to a reregistration data call-in except under the scenario described in question number 12, below. Otherwise, only efficacy data meeting the standard (non-confirmatory) data requirements are relevant to reregistration.

12. **If there is a need to repeat data because the previously-performed study batches were above the active ingredient nominal concentration, does the entire efficacy package need to be repeated or can confirmatory data be performed at the LCL for the basic (required) organisms?**
    In this situation, the basic (required) test organisms for disinfection and food contact surface sanitization may be supported with confirmatory data performed at the LCL. All additional organisms should be supported by appropriate testing data.

13. **Should claims which are not a part of the 810 guidelines such as non-public health claims be addressed in the DCI response (e.g. non-OIE list veterinary organisms [e.g. canine parvovirus])?**
    Antimicrobial efficacy responses to a reregistration product data call-in should address only public health efficacy data requirements.

Documents available online at:
www.epa.gov/pesticide-registration/efficacy-testing-standards-product-data-call-responses