BPPD's Risk Assessment Elements "Cheat Sheet" for Applicants

Last updated: September 2019

When submitting a pesticide product registration application to EPA/OPP/BPPD, it is essential that you (applicant) address all applicable data requirements per the Code of Federal Regulations (CFR), part 158. However, it is also imperative that you (applicant) characterize your use sites, use patterns, rates and generally summarize your toxicity data so that a comprehensive risk assessment, taking into account all aspects of your product, can be performed by EPA. Often, when one or more of these pieces of information is missing from an application, the applicant is unsatisfied with the unavoidably conservative assessment that is performed. Further, presenting this information to EPA upfront can alleviate some unnecessary back-and-forth exchanges between EPA and the applicant and subsequent review time lost.

Hence, EPA/BPPD highly recommends that applicants answer the following questions in writing in either a cover letter, data volume, or both when submitting their new product application:

1. **What are the proposed uses for the product?**

   Please provide specific information on sites, application methods (i.e. equipment used), etc.

2. **What are the proposed use rates?**

   Please provide information on the maximum application rate for each use site/scenario as well as the maximum rates per season and the minimum reapplication time interval. For use in occupational and residential exposure assessments, depending on the use, it is helpful to provide application rates expressed in pounds active ingredient per acre, pounds active ingredient per gallon, pounds active ingredient per bottle or can, etc.

3. **What are the exposure scenarios?**

   Address exposure routes for human health toxicity: Will there be dietary exposure? Could there be incidental oral exposure? Will there be occupational (short-term, intermediate-term or long-term) dermal and/or inhalation exposure? Will there be dermal or inhalation post-application exposure? Will there be residential exposure?

   Address exposure routes for non-target organisms: Will the application methods, directions, use sites, etc results in drift or run-off in the environment? Will the product, as applied, be available to non-target organisms (e.g. birds may be exposed to pesticides applied to soil pre-plant from foraging for insects)?

4. **What are the toxic effects?**

   What are the toxic effects in the human health and non-target organism studies? What are the NOAELs/LOAELs of these effects? Please characterize the effects. Are there any NOAELs below the study limit dose? When NOAELs are below limit doses, depending on the type, severity and incidence of effects, additional data may be required. Please suggest endpoints for each exposure scenario (e.g. dietary, occupational, etc.). Is an FQPA safety factor required (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/determination-appropriate-fqpa-safety-factors)?

5. **What information on your compound can be found in the open scientific literature**?

   Please conduct a thorough search of the literature. Are there any additional toxicity, environmental fate, metabolism, etc. data on your active ingredient? Please do not exclude data just because they aren't relevant to the biochemical pesticide data requirements (i.e. if a carcinogenicity study is available, please provide the data). Fully characterize your literature search by identifying for EPA the search engine used, search terms, and your results.

6. **What is the risk? Depending on the hazard and exposure profiles, should the assessment be quantitative or qualitative?**

   Conducting a preliminary risk assessment could help you to identify and resolve any issues prior to submission of your package.

   For dietary exposure: are there residue data? If so, conduct a DEEM analysis to estimate dietary risk (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/deem-fcidcalendex-software-installer). Make sure to consider the appropriate safety factors (including FQPA). If there are no residue data, is IDEEM an appropriate tool to characterize this active ingredient? Please provide any environmental fate data you have on your active ingredient. Also, what are the byproducts and/or degradates of your active ingredient?

   For occupational and residential exposure: please consult the Agency's SOPs for occupational (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data. Note: an occupational exposure spreadsheet is not available online but can be provided upon request) and residential (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide AND https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/framework-assessing-non-occupational-non-dietary) exposure and risk assessment.

7. **Is an aggregate exposure and risk assessment required?**

   Once a toxicity endpoint has been identified (regardless of the route of exposure), ALL exposures to a chemical must be aggregated (i.e., accounted for) if:

   1. *the applicant is seeking to establish a tolerance or exemption from the requirement of a tolerance, OR*
   2. *if a new pesticidal non-food use is being added to a chemical that already has an established tolerance or tolerance exemption.*

   If an aggregate exposure and risk assessment is required, submission of as much exposure information as possible (e.g. exposure from other sources like cosmetics, foods, etc.) is useful and can speed up the Agency's review process. You may even want to conduct your own assessment to identify any issues prior to submission of your package. Refer to https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/general-principles-performing-aggregate-exposure-and for more information.