Biopesticides and Pollution Prevention Division Technical Screen Checklist

Last Updated October 2023

General Application Content Checklist

EPA Form 8570-1 (Application Form)
The application form is accurate and complete (consistent with other parts of the application - e.g., box 6 is complete if requesting "me-too" expedited review, CSF(s) list film and ink if proposing water-soluble packaging, etc.)
Cover Letter/Data Transmittal Document
The cover letter/data transmittal document clearly explains the applicant's proposal and lists all accompanying forms and data to support the application
Data compensation requirements **EPA Form 8570-27 (Formulator's Exemption Statement)** **EPA Form 8570-34 (Certification with Respect to Citation of Data)** **EPA Form 8570-35 (Data Matrix)**
If citing to compensable data, offers-to-pay and forms (Certification with Respect to Citation of Data and Data Matrix) indicating the companies (Pesticide Data Submitters List) to whom offers of compensation were made, are included and complete If applicant qualifies for a formulators' exemption, formulators' exemption form is included, accurate, and complete Note: use of some inert ingredients is subject to data compensation If exclusive use or task force data are cited and applicant has permission or is a member of the task force, proof of permission or evidence of membership is documented and provided If any of the data are exclusive use, Letters of Authorization are included (40 CFR § 152.116(c))
EPA Form 8570-4 (Confidential Statement of Formula (CSF))
All CSFs are accurate and complete (e.g., CSF and label ingredient statement match, calculations are accurate, ingredients are cleared, etc.) – See detailed CSF checklist (below)
Petition (Tolerance or Exemption from the Requirement for a Tolerance)
All petition sections are accurate and complete (e.g., sections provide adequate information to cover the tolerance/exemption, all cited references are provided, etc.), **Pesticide Registration Manual: Registrant Summary of Pesticide Petitions for EPA's Notice of Filing**
The Tolerance/Exemption from the Requirement of a Tolerance Petition and the Notice of Filing Petition Summary are both submitted.
Label
All labels are accurate and complete (e.g., CSF and label ingredient statement match, any required physical/chemical hazards are present, precautionary statements and first aid statements match, Worker Protection Standard labeling requirements are met, etc.) – See detailed label checklist (below) and the Agency's Label Review Manual.
Data Requirements
Data/information to support the application is included, accurate, and complete (e.g., data matrices for AIs and products are complete, all data requirements are adequately addressed, bridging rationale and data adequately demonstrate similarity, rationales appear to be sufficiently robust to address the data requirement, test substances are clearly identified and appropriate, all references and supporting material are provided and clearly marked/annotated, etc.) – See detailed data matrix and data requirements checklist (below)
Agency Actions
Identify any unresolved issues from the 21-day Content Screen (e.g., PR Notice 11-03 Compliance)

Identify if the proposed action requires the publication of a Notice of Receipt • new pesticide active ingredient or new use pattern (FIFRA section 3(c)(4)) • Agency should prepare for NOR publication if needed
Identify if the proposed action requires the publication of a Notice of Filing • establishing, modifying, suspending, or revoking a tolerance or exemption from the requirement of a tolerance (FFDCA section 408) • Agency should prepare for NOF publication if needed
Identify if the proposed action requires a public comment period • new active ingredients, first food use, first outdoor use, first residential use, or other action of significant public interest
Consolidate existing records (e.g., pre-submission meeting notes) related to the submission - link or upload to case records
Annotate CSFs with PC Codes and food-use citations (e.g., § 180.910, § 180.920, § 180.930, § 180.940, and § 180.950)
For registered products, identify any unresolved product issues (e.g., overdue terms of registrations) and work with registrant to resolve or establish a schedule to resolution
For registered products, work with registrant to consolidate (or close) outstanding non-PRIA actions (as appropriate)
Determine if any review committees may need to be involved (e.g., HASPOC, CATSAC, ToxSAC, DESAC, CHEMSAC, etc.)
Determine if any of the submitted data/information involve human studies (thereby triggering HSRB/ethics review and possible recode of PRIA action)
For active ingredients in currently registered products, check most recent Registration Review document for any outstanding data requirements, required label mitigation, or additional/unique data/information.

Detailed Label Technical Screen Checklist

Ingredient Statement Label Review Manual Ch. 5 Ingredient Statement
If a registered product is used as the source of active ingredient in the formulation, the source registration must support the uses on the proposed label.
For a new product: If an unregistered source of active ingredient is being used, is the active ingredient approved for the uses on the proposed label?
Ingredients total 100% and decimal points are aligned
CSF and label ingredient statement match
Check microbial active ingredients for strain designation, potency/viability, inhalation sensitizer precautionary statement, and respirator statement
Precautionary Language (For new product registrations, the following information will not be known until after the acute tox review is completed.) Label Review Manual Ch. 7 Precautionary Statements
The signal word, precautionary statements, and First Aid statements are correct based on the expected acute toxicity profile and arranged according to most severe route of exposure (PRN 2001-1)
Environmental Hazards Label Review Manual Ch. 8 Environmental Hazards
Should there be a nontarget toxicity statement based on the ecological effects data on the active ingredient(s)?
Are the statements in agreement with PRNs 93-10 and 95-1
Directions for Use Label Review Manual Ch. 12 Directions of Use
Are the use patterns on the proposed product the same for the similar product(s)?
Are the application rates and exposure scenarios consistent with the approved rates and exposure scenarios on similar labels for this active ingredient and in U.S. units? Are application rates appropriate for intended uses (e.g., smaller units for residential products)?

Are there proposed direct or indirect food use(s)? If so, is there a proposed or established tolerance or exemption for those uses? Are the proposed application rates for those uses consistent with an existing or proposed tolerance or exemption?
If uses fall under the scope of the Worker Protection Standard, label must have appropriate sections and language (see Chapter 10 and Chapter 12 of the LRM)
If organic claims (e.g., NOP, OMRI) are made, documents necessary for review (e.g., SDS for all ingredients, including starting materials, OMRI certificate, etc.) must be submitted, **EPA's National Organic Program Guidance**
Label claims are appropriate (e.g., no false/misleading, no elevated safety claims, etc. – see Chapter 12 of the LRM and the Pesticide Labeling Questions & Answers)
Product Performance (Efficacy) data must be submitted and included on the data matrix if claims are made for public health or structural pests on the product's label (biochemicals: refer to 40 CFR § 158.2070, microbials: refer to 40 CFR § 158.2160)
Storage and Disposal Label Review Manual Ch. 13 Storage and Disposal
Container handling and disposal statements must align with the container size(s), material(s), and use sites identified on the application form (EPA Form 8570-1) and the product label
Are the storage and disposal statements in agreement with PRNs 83-3 and 2007-4?

Detailed CSF Technical Screen Checklist (review all formulations)

For each product, ensure only one CSF is designated as the Basic Formulation and all others are easily distinguished by different alternate names (e.g., "Alternate 1" or "Alternate A")? Note: there is no standard for naming alternate CSFs
All Alternate Formulations are substantially similar (such that they would not be considered different products)
CSF is complete, signed, and dated
Units are in all applicable boxes
Supplier information adequately documented
All ingredients are correctly identified (e.g., CAS #s included for all chemicals)
Information on CSF(s) match product chemistry data
If an inert ingredient can also be considered an active ingredient, a clear explanation for how it is not acting as an active ingredient in the formulation/product is provided
If the formulation contains a conventional or antimicrobial active ingredient, the presence and purpose of the ingredient is explained in the application
All ingredients (and proprietary mixtures) have Agency approval/clearance for proposed use(s) (e.g., § 180.910, § 180.920, § 180.930, § 180.940, and § 180.950) or applications/petitions pending with the Agency. See EPA's InertFinder or Trade Name Database for approval statuses.
Check microbial active ingredients for culture collection reference, strain designation, and potency/viability
CSF and label (ingredient statement, physical/chemical hazard statements, etc.) match
Food-use formulations: if formulations and/or growth medium contain allergens (e.g., peanuts, tree nuts, milk, soybeans, eggs, fish, crustacea and/or wheat), the product uses must comply with any restrictions listed in 40 CFR § 180.1071
Final active ingredient percentage and weight totals are correctly calculated when using a manufacturing-use product (MP) registered source of active ingredient
Data compensation addressed for any ingredients subject to these requirements
Certified limits are standard, or an adequate explanation is provided

Detailed Data Matrix Technical Screen Checklist

The application contains a separate Data Matrix for each active ingredient (when the active ingredient is not from a registered source), and a Data Matrix for each product. All matrices are completely filled-out.
Active Ingredient (AI) Data Matrix
All TGAI product chemistry/product analysis data requirements are appropriately listed (biochemicals: refer to 40 CFR § 158.2030, microbials: refer to 40 CFR § 158.2120)
All TGAI human health (mammalian toxicology) data requirements are appropriately listed (biochemicals: refer to 40 CFR § 158.2050, microbials: refer to 40 CFR § 158.2140)
All TGAI nontarget organism/environmental fate data requirements are appropriately listed (biochemicals: refer to 40 CFR § 158.2060, microbials: refer to 40 CFR § 158.2150)
Product (MP or EP) Data Matrix [Note: a separate data matrix is needed for each product]
All product-specific product chemistry/product analysis data requirements are appropriately listed (biochemicals: refer to 40 CFR § 158.2030, microbials: refer to 40 CFR § 158.2120)
All product-specific human health (mammalian toxicology) data requirements are appropriately listed (biochemicals: refer to 40 CFR § 158.2050, microbials: refer to 40 CFR § 158.2140)
All product-specific nontarget organism/environmental fate data requirements are appropriately listed (biochemicals: refer to 40 CFR § 158.2060, microbials: refer to 40 CFR § 158.2150)
Product Performance (Efficacy) data must be submitted and included on the data matrix for the end-use product (EP) if claims are being made for public health or structural pests on the product's label (biochemicals: refer to 40 CFR § 158.2070, microbials: refer to 40 CFR § 158.2160)