PROCESS TO ASSESS A NEW REQUEST FOR BIOPESTICIDE REGULATORY ASSISTANCE

The IR-4 Project Executive Director will assign a staff member who will be responsible for processing new requests for Biopesticide Regulatory Assistance Platform utilizing the following steps:

1. PRELIMINARY ASSESSMENT
    a. Assess if the Request for Assistance (PCR) differs from any existing request.
        - IF YES, establish a new PCR entry in the IR-4 Biopesticide Regulatory Assistance Database (BRAD).
        - If the Request for Assistance is substantially similar to an existing request, add a comment to the BRAD about the submission of a substantially similar request, including additional submitter(s) and additional requesting state(s).
    b. Assess if the PCR is relevant in the IR-4 Biopesticide Regulatory Support platform, which includes
        - Is the Request for Assistance from someone in the public sector or associated with that crop (i.e. commodity association) and
        - Will the technology be regulated by EPA's Biopesticide and Pollution Prevention Division?

    If YES to both, proceed to Step 2. If NO, seek guidance from the IR-4 Executive Director

2. COMPANY/SUPPORTING GROUP COMMITMENT TO REGISTER
    a. Solicit input from the company that manages the technology to assess if they are willing to cooperate/partner with IR-4 in facilitating the registration, including (but not limited to): providing necessary data required by EPA and their willingness to register the product/use once approved. If the company is willing to cooperate/partner with IR-4, make a note in the BRAD and proceed to Step 3.
    b. If the company that manages the technology has the proposed use(s) as a registration objective or is not willing to cooperate with IR-4, make an appropriate note in IR-4 BRAD and stop further assessment of PCR.

3. SECONDARY VETTING
    a. The Executive Director will establish an ad hoc review team for Secondary Vetting of new requests for biopesticide regulatory support.
    b. The review team members will be asked to complete one or more sections of the “IR-4 Project Biopesticide Regulatory Support Secondary Vetting Survey. This Survey will assist the reviewers in assessing each new PCR on a 0-100 scale. If there are multiple reviews for a section, their scores for that section will be averaged
    c. The review team will provide the Executive Director with a comprehensive score and additional comments.
    d. IR-4 will only provide regulatory assistance it the TOTAL score exceeds 66. The higher the score, the higher the project is in IR-4 Biopesticide Regulatory Assistance Que. If a PCR is below 66, the stakeholder submitting the PCR can request a reassessment every 12 months.

IR-4 Project Biopesticide Regulatory Support Secondary Vetting Survey

Section 1- Biology

Part A -Does the product effectively control or suppress the target pest? Include documentation or reference to support the conclusion (assign a maximum of 10 points).

Guidelines:

- If deemed "Control" assign between 7-10 points
- If deemed "Suppress" assign between 3-6 points
- If deemed "Not Effective" or no hard data is available, assign between 0-2 points

Part B - What is the importance of the pest (assign a maximum of 10 points).

Guidelines:

- If deemed "Always Damaging," assign between 7-10 points
- If deemed "Under Certain Conditions can be Damaging," assign between 3-6 points
- If deemed "Damage is Limited" or no data is available, assign 0-2 points

Section 2 –Product Support (assign a maximum of 10 points)

Guidelines:

- Product was discovered/developed by a United States public sector entity that is working with a company that is an experienced registrant in the United States (10 points)
- Product was discovered/developed by a private sector entity that is working closely with a public sector scientist and an experienced registrant in the United States (5-7 points)
- Product was discovered/developed by a United States public sector entity that is working with a company that is not an experienced registrant in the United States (3-6 points)
- Product was discovered/developed by a private sector entity that is working closely with a public sector scientist that is working with a company that is not an experienced registrant in the United States (1-4 points)

Section 3-EPA'Experience with Technology (assign a maximum of 10 points)

Guidelines:

- Known technology/Known data requirements(7-10 points)
- Novel technology/with known data requirements (3-6 points)
- Novel technology/with unknown data requirements (0-2 points)

Section 4-Estimate of Financial Support for Product (assign a maximum of 10 points)

Guidelines:

- Company/group has significant resources to develop data needed for registration (7-10 points)
- Company/group has some resources to develop data needed for registration (3-6 points)
- Company/group has no resources available to develop data needed for registration (0-2 points)

Section 5-Path Forward to Registration/Likelihood of Waivers (assign a maximum of 50 points)

Guidelines:

- All required studies are acceptable (50 points)
- Most (>75%) of the required studies are acceptable; other required studies in progress (40 – 45 points)
- Some (<74%) of required studies are acceptable, other required studies in progress (30 -40 points)
- Testing for all studies in progress (25 points)
- Testing for most (>75%) required studies in progress (20 points)
- Testing for some <74%) in progress (5-15 points
- None of the required studies are available or in progress (0 points)