The IR-4 Process (in the beginning!)

Tracking stakeholder needs (PCRs), developing the annual plan for residue and performance research

The IR-4 Food Use Regulatory Clearance Process

Stakeholder:

Define Pest Problem

Identify Pest Management Solution

Request Assistance from IR-4

https://www.ir4project.org/fc/submit-a-request-food-crops/

The Process Starts with Requests

Submitted from:

- **Growers**
- **Grower Groups**
- **State/Federal Research & Extension Personnel**

Request Reviewed by Manufacturer

Requests Prioritized

Top Priorities Researched That Year

Other Priorities Researched as Money Allows

Field and Lab Research

- **Measure residue levels in crop samples (EPAregions.pptx)**
- **Top priorities completed in ~30 months**

Data Submitted to EPA

Risk Assessment

Tolerance Established by EPA

Manufacturer Adds Crop to the Product Label

Stakeholder Requests (new PCRs)

- Submitted on-line from website and received electronically at HQ (https://www.ir4project.org/fc/submit-a-request-food-crops)
- Received throughout the year, with a mad rush in the weeks prior to the Food Use Workshop deadline
- Internal review by HQ discipline experts to decide if the request is **NEW**, or duplicates an existing PR#
- If it is **NEW** - next sequential PR# in database is assigned, the request is emailed to the appropriate registrant(s) for review/response, PCR info is entered into database, “Project Status” is “Under Evaluation”

PCR questions to registrant

- Manufacture Representative Completing Questions Below: _____

- **1.** Is the subject use your registration/re-registration objective and no IR-4 research is needed to support the use? ____ (if NO go to Question 2)
  2. Are you willing to register/maintain the registration for the subject use if IR-4 obtains the appropriate data? _____ (if YES answer Questions 3 to 6)
  3. What data does IR-4 need to generate? Residue only _____ Residue and Efficacy/Crop Safety _____ Efficacy/Crop Safety only _____
  4. Are you aware of any data IR-4 can use in support of the subject minor use? _____
  (if YES please provide a summary of the supporting data)
  5. Are there any EPA data requirements that could significantly delay or preclude regulatory clearance of the proposed use? _____ (if YES briefly describe)
  6. Can you assist with IR-4's research efforts by providing one or more of the following:
  Conduct some/all of the field research?____ Analysis of residue samples? ____ Financial grant to offset costs? _____
  7. Will you be able to provide IR-4 with GLP characterized test substance and analytical reference standards? _____
  (if YES, will you also be able to provide confirmation of the location of retain samples and characterization data? ____
  8. Are you pursuing registration or an import tolerance on this crop in other countries? _____
  Please note requestor Int'l info in item 4 of the request below.
  Are you prepared to secure import MRLs in global markets specified by the requestor?_____

Registrant Response = Project Status

- Based on registrant response, “Project Status” can be:
  - MFG Objective – no need for IR-4 research
  - MFG will not support – pursue response from a secondary MFG(s)
  - Potential, E/CS data needed before approval for residue study
  - Researchable, only residue data needed
  - Researchable, residue and E/CS data needed
  - Only E/CS data needed (to add a crop/pest to the current label)
  - HOLD – use not supportable now, but in future?

Project Requests' Status Regularly Reviewed

- Typically there are ~350-400 project requests in our database that could be prioritized for the next year's research plan, either for residue or performance data (or both)
- These are all reviewed, at least once a year, during 25-30 meetings the HQ team has with registrants (most in the late April to early August timeframe), and the database is continually updated with the most current information for each project request
- As we approach the Sept. priority-setting workshop each year, the PMC determines (based on expected funding & other HQ/ regional costs) how many new GLP residue studies can be prioritized, and how much funding can be targeted for performance research

Plans/Deadlines for 2020 FUW

- Aug. 14 – EPA red/yellow/green light PCR assessment complete (list to be provided 7/7/20)
- Aug. 17 – last day for receipt of new PCRs, for consideration at FUW
- Aug. 21-Sept. 3 – on-line project nominations (organized by discipline)
- Sept. 9 – project reports/spreadsheets for workshop available on IR-4 website
- Sept 14-17 – Food Use/IS/Global priority-setting workshops, Bloomington, MN

2020 FUW to NRPM Schedule

- Aug. 18-Sept. 28 – Priority Upgrade Proposals (PUPs) accepted
- Sept. 25 – tentative project list available for on-line 2021 field site entries (labs are assigned during/after protocol development)
- Sept. 28 – deadline for proposed regional upgrades & PUPs
- Oct. 1 – HQ/RFC conf. call to confirm carryover trials/studies & upgraded additional priorities (regional and PUPs) for 2021 research plan
- Oct. 16 – deadline for on-line field site assignments
- Week of Oct. 26 – National Research Planning Meeting (NRPM)

Addressing Performance Needs (E/CS research)

A Very Different Process than for Residue Research

- Project performance requirements are captured in database year round, and also efficacy & crop safety trial reports
- IR-4 P-team continually determines what performance trials are needed to “fill-in the blanks” for ongoing projects, and confirms what trials are needed to support new residue “A” and performance “H+” priorities
- P-team works with RFC to identify researchers for all of the next year’s trials
- After multiple conference calls before and after NRPM face-to-face meetings, the trial plan is established to meet the funding target set by the PMC

The IR-4 Process

- Dan Kunkel - overview and global impact
- Van Starner – tracking stakeholder needs (PCRs), developing the annual plan for residue and performance research
- Debbie Carpenter – planning/conducting the residue program (field and lab)
- Tammy Barkalow – organizing and implementing the QA monitoring program
- Bill Barney – using crop grouping, compiling final reports, submissions to EPA, securing labels