Quarterly PRIA 3 Report

November 19, 2013

PRIA 3 Status: October 1, 2012 – September 30, 2013

- Number of application submissions since Oct. 1, 2012 -- September 30, 2013
    - Antimicrobials – 319
    - Biopesticides – 134
    - Conventionals – 1028
    - Inerts – 37 [32 food use; 5 non-food use]
    - Miscellaneous – 600 [593 are Gold Seal letter requests]
    - Total -- 2,118

- Number of completed decisions since Oct 1, 2012 – September 30, 2013
    - Antimicrobials – 329
    - Biopesticides – 111
    - Conventionals – 1,039
    - Inerts – 43 [28 food use inerts cleared; 15 non-food use inerts cleared]
    - Miscellaneous – 562 [561 are Gold Seal Letters]
    - Total -- 2,084

- Number of completed decisions with due date extensions since Oct. 1, 2012 – September 30, 2013
    - Antimicrobials – 73 (22.2%)
    - Biopesticides – 34 (30.6%)
    - Conventionals – 205 (19.7%)
    - Inerts – 1 (14.3%)
    - Miscellaneous – 0
    - Total – 313 (15.3%)

% of completed PRIA decisions with due date extensions

FY	Antimicrobials	Biopesticides	Conventionals	Misc.	Inerts
2009	68/342 = 19.9%	42/124 = 33.9%	193/1104 = 17.5%		
2010	108/310 = 34.8%	85/138 = 61.6%	277/1069 = 25.9%		
2011	85/346 = 24.6%	48/134 = 35.8%	236/1074 = 22.0%		
2012	86/333 = 25.8%	74/133 = 42.8%	235/1068 = 22.0%		
2013	73/329 = 22.2%	34/111 = 30.6%	205/1039 = 19.7%	0/562 = 0%	1/7 = 14.3%

- Amount of PRIA net fees collected (Oct. 1, 2012 to September 30, 2013) -- $14.751 M
- Amount of maintenance fees collected in FY 2013 – $27.015 M

- 2-Day label Review status
    - Purchase and deployment of Comparedocs software - completed
    - Training - completed
    - Experience with use - limited
    - Performance to date: RD

        -33% of RD PRIA FY'13 completions occurred before Pre-decisional Determination Due Date;

        - 51% of RD PRIA FY'13 completions occurred between Pre-decisional Determination and PRIA Due Dates;

        -14% of RD PRIA FY'13 completions occurred on the PRIA Due Date;

        - 2% of RD PRIA FY'13 completions were late (most were PRIA 2 applications)

        -2 RD PRIA 3 completions occurred after the PRIA Due Date under the 2-day label review process and were completed in 1 day.

    - Performance to date: AD

        23% of AD PRIA FY'13 completions occurred before Pre-decisional Determination Due Date;

        - 54% of AD PRIA FY'13 completions occurred between Pre-decisional Determination and PRIA Due Dates;

        - 22% of AD PRIA FY'13 completions occurred on the PRIA Due Date;

        -1% of FY'13 completions were late (PRIA 2 submissions)

- **Status of short term strategy to deal with PRIA backlog due to government shutdown**

    - AD
        - # of PRIA decisions due by October 31st -- 34
        - # of October PRIA decisions completed to date – 18

        - # of PRIA decisions due between November 1 – November 30th -- 27
        - # of November PRIA decisions completed to date – 5

        - # of PRIA decisions due between December 1 – December 31st – 25

        - # of new AI/new use PRIA decisions where Division Director has communicated new timeframes – 0

- BPPD
  - # of PRIA decisions due by October 31st -- 6
  - # of October PRIA decisions completed to date – 4

  - # of PRIA decisions due between November 1 – November 30th -- 16
  - # of November PRIA decisions completed to date – 4

  - # of PRIA decisions due between December 1 – December 31st – 20

  - # of companies where Division Director has communicated new timeframes for new AI/new use PRIA decisions – 5
- RD
- **Not New AI nor New Use PRIA Actions (NOTE: These numbers are for all PRIA codes except those for new chemicals and new uses.)**

Branch	**Month Due**	**TOTAL DUE**	**Completed**	**Pending as of 11-12-13**	
FB	OCTOBER	3	1	2	
	NOVEMBER	5	1	4	
	DECEMBER	11	0	11	
FB BRANCH TOTALS		19	2	17	
HB	OCTOBER	5	0	5	
	NOVEMBER	15	2	13	
	DECEMBER	19	4	15	
HB BRANCH TOTALS		39	6	33	
IB	OCTOBER	6	3	3	
	NOVEMBER	22	5	17	
	DECEMBER	21	0	21	
IB BRANCH TOTALS		49	8	41	
IRB	OCTOBER	11	8	3	
	NOVEMBER	9	2	7	
	DECEMBER	14	0	14	
IRB BRANCH TOTALS		34	10	24	
GRAND TOTALS	**OCTOBER**	**25**	**12**	**13**	
	NOVEMBER	**51**	**10**	**41**	
	DECEMBER	**65**	**4**	**61**	
	TOTALS				

■ RD New Chemicals and New Uses with Original Due Dates Between Oct-Dec 2013

[*Notes the registrants that were sent an email on status. Only one to still follow up on.]

Chemical	New Chem(NC) or New Use (NU)	Original PRIA Due Date	New Due Date	# of Decisions
1*	NC	11/1/13	1/30/14	3
2*	NC	11/15/13	1/15/14**	2
3*	NU	10/31/13	11/15/13	2
4*	NU	12/21/13	1/15/14	3
5*	NU	12/2/13	12/19/13	2
6*	NU	10/18/13	12/18/13	3
7*	NU	11/27/13	12/18/13	2
8*	NU	11/1/13	11/23/13	1
9*	NU	11/27/13	12/18/13	2
10*	NU	10/31/13 and 11/16/13	3/20/14	2
11*	NU	10/17/13 12/9/13 12/20/13	12/20/13	4
12*	NC – import	10/12/13	12/12/13	1
13*	Import	11/10/13	12/6/13	1
14*	Import	12/19/13	12/19/13	1
15	Import	10/31/13	12/8/13	1
16*	1st Food Use	12/15/13	12/15/13	3
17*	NU	11/12/13 11/18/13	11/30/13	7
18*	NU	10/11/13 11/27/13 11/15/13 11/6/13	11/27/13	17
19*	NU	11/7/13	12/7/13	3
20*	NU	12/19/13	12/19/13	2
21*	NU/GMO	12/1/13	11/17/14	2
22*	NU	10/18/13	11/30/13	2
23*	NU	10/23/13	4/30/14	1
24*	NU	10/19/13 10/23/13	11/30/13	3
25*	NU/GMO	10/15/13		1
26*	Import	11/14/13	11/21/13	1

27*	NU/GMO	12/30/13	On hold	2
28*	NU	12/28/13	12/18/13	3
29*	NU	11/27/13	11/27/12	1
30*	NU/GMO	10/30/13	7/7/14	3
31*	NU	11/10/13	11/30/13	1
32*	NU	10/21/13	Needs renegot.	1
33*	NC	10/15/13	12/15/13	16
34*	NC	12/1/13		2
35*	NU	11/1/13		2
36*	NU	10/26/13		10
37*	NU	10/26/13		4
38*	NU	11/1/13	11/15/13	1
39*	NU	12/13/13	12/13/13	3
40*	NU	12/30/13	12/17/13	5
41*	NU	11/23/13	11/23/13	1
42*	NU	12/17/13		2
43*	NU	11/30/13	1/30/13	1
44*	NU	10/22/13 12/12/13	12/12/13	2

- Inerts
  - # of PRIA decisions due by October 31st -- 8
  - # of October PRIA decisions completed to date – 5

  - # of PRIA decisions due between November 1 – November 30th – 3
  - # of November PRIA decisions completed to date – 2

  - # of PRIA decisions due between December 1 – December 31st – 3

- **Status on implementing automated registration tracking system**
  - Seven milestones:
    1. Application receipt date; receipt number assigned
    2. PRIA category(ies) assigned; waiver decision, if applicable, completed; payment completed; 21-day screen timeframe expired; PRIA start date; PRIA due date; pre-decisional determination due date, if applicable;
    3. Contact information for PM assigned to your application; date data sent into review;
    4. 45/90 technical screen timeframe expired;
    5. Actual last science review completion date;

6. Pre-decisional determination date reached, if applicable
7. Regulatory decision completed

- Automated emails sent out at each milestone
- Registrant must supply an email address for each application to receive email tracking milestones
- Will not replace current registrant-PM communications
- Intent is to go live as soon as possible and "learn by doing", making modifications "on the fly"

- **45/90 Preliminary Technical Screen – Summary of FY'13**
  - # of actions completed screen – 1,152
    AD – 260
    BPPD –104
    RD – 788
  - # of 10-day deficiency letters sent out – 110
    AD - 63
    BPPD – 7
    RD - 40
  - # of rejections/withdrawals – 22
    AD – 5 [2 withdrawals]
    BPPD – 0
    RD – 17 [10 withdrawals]

- **Case studies regarding 45/90 Technical Screen Process**

BPPD Case Study – B670:

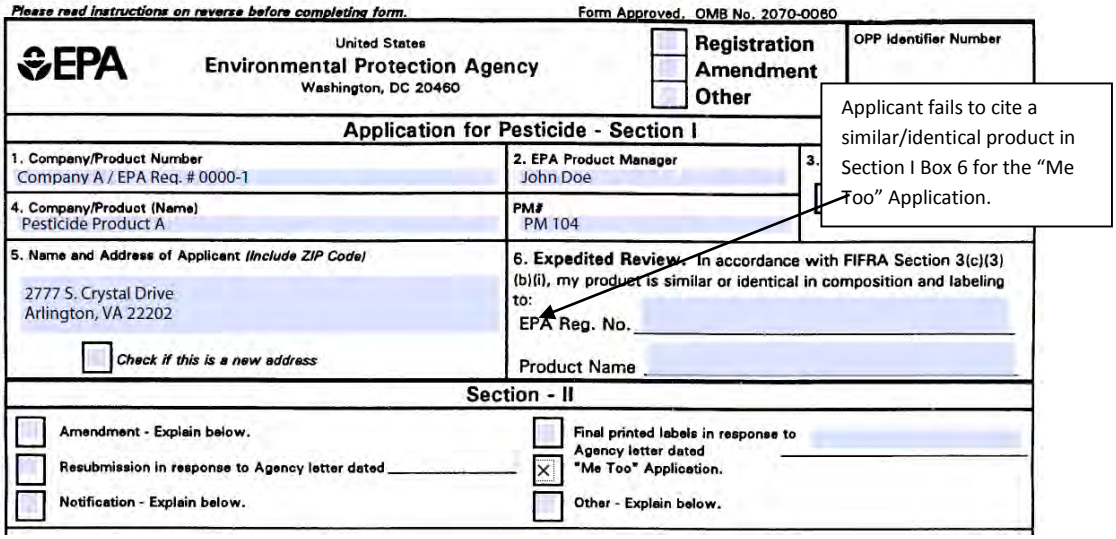
- The action is a new product; old AI with a PRIA 3 timeframe of 7 months
- 12/14/2012 Coded
- 12/31/2012 Passed 21-day
- 1/8/2013 passed 11-3
- 1/8/2013 in for 90-day tech screen
- 1/9/2013 out of tech screen, FAILED. Acute Toxicity deficiencies (Acute Oral, Acute Inhalation, Acute Dermal, Primary Eye Irritation, Primary Skin Irritation, Skin Sensitization). Scientific rationale submitted (in lieu of guideline studies) is not robust enough. Data requirements not satisfied.
- 1/17/2013 tech screen failure letter signed by DD and sent by Team Leader via certified mail
- 1/22/2013 lettered delivered to applicant
- 2/5/2013 Response due to EPA
- 2/4/2013 OPP received response to letter (pin-punch date)
- 2/21/2013 Received from 11-3
- 2/21/2013 Placed in for review w/ tech screen team

- 2/27/2013 re-screen complete, PASSED. The rationale was re-written to adequately address the data requirements and was supported with scientific justification/citations.
- 2/27/2013 Assigned to BPPD Regulatory Action Leader (RAL)
- 8/8/2013 PRIA due date
- 8/7/2013 REGISTERED

AD Case Study:

Event 1: Applicant Submits Application to EPA -- Category A530- substantially similar new product

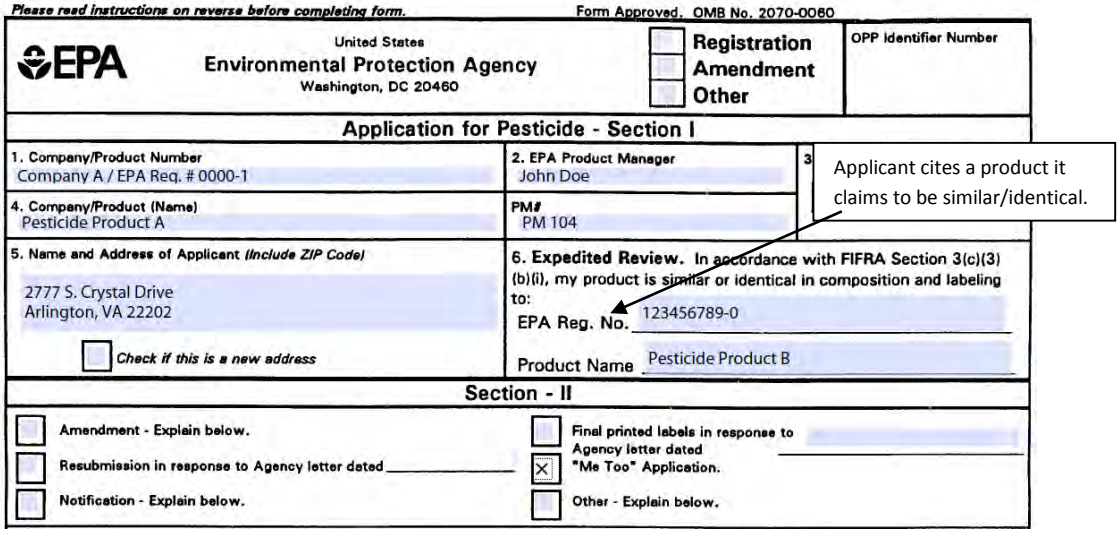
- The applicant, Company A, submits to EPA an Application for Pesticide (EPA Form 8570-1) for its product "Pesticide Product A" (EPA Reg. No. 0000-1). As shown in Figure 1, the company indicates in Section II of Form 8570-1 that the application is a "Me Too" Application; however, the company does not provide sufficient information in Section I Box 6 (i.e., the EPA Reg. No. and Product Name of a product that is similar or identical in composition) to allow EPA to conduct its review.
- Figure 1. Incomplete EPA Form 8570-1



- **Event 2: EPA Notifies Applicant of Preliminary Technical Screen Deficiency/Failure**
- During the Preliminary Technical Screen (also known as the "45-/90-day screen"), EPA staff identified the application deficiency. As soon as possible and no later than 45 days into EPA's decision time, EPA notified the applicant in writing that the application is deficient. In the written notification, EPA specified that the application would be rejected if the applicant did not correct the failure before the date that is 10 business days after the applicant received the notification of the failure.
- **Event 3: Applicant Responds to Deficiency/Failure**
- Within 10 business days of receiving EPA's written communication of the Preliminary Technical Screen failure, the applicant resubmitted the application to EPA and identified the

EPA Reg. No. and Product Name of a product that is claimed to be substantially similar or identical in composition (see Figure 2).

- Figure 2. Complete EPA Form 8570-1



- **Event 4: Because the Failure was not Corrected, EPA Rejected the Application**
- Based on the applicant's response, EPA retrieved product information on the cited product which contains 90% cuprous oxide and 10% irgarol. EPA compared the information provided on the proposed product (50% cuprous oxide and 50% irgarol) to the information on file for the cited product and determined that, because the product referenced in Section II Box 6 of the registration application was not substantially similar to the proposed product, the cited acute toxicity data were not acceptable. As soon as was possible, EPA notified the applicant in writing that the application had been rejected because the deficiency previously identified (i.e., that the applicant did not cite a substantially similar or identical product) was not corrected within 10 business days after the applicant received the notification of the failure.

RD case studies

(1) R315 – new non-food animal product

Date	Who	Action item
May 12, 2013	Similarity Clinic/RD	Received 2 new products for review
May 28, 2013	Similarity Clinic/RD	Both products contained 3 active ingredients. Both cited the same studies to support registration. First time all three actives have been mixed together in a product. **Problems with cited studies:** Acute oral - supplemental – only conducted with 1 active. Acute dermal – only conducted with 1 active. Acute inhalation – data matrix stated waiver but no justification for a waiver. Primary eye, primary skin, and skin sensitization studies all conducted with 2

Date	Who	Action item
		actives. Both new products contain a solvent that is not in test material used in the cited studies. Email sent/10 day letter requesting registrant to cite or submit another set of acute tox data to support registration of both products. Registrant was given until 6/11/13 (10 business days) to submit/cite new data or withdraw product
June 11, 2013	Registrant	Email received from Registrant containing a white paper justifying the acute toxicity citations written by an independent consultant
July 9, 2013	Similarity Clinic/RD	Email sent to registrant stating that the independent consultants justification did not change the initial finding that the data cited was unacceptable and that the registrant should withdraw or rejection process would be started
Between 7/9/13 and 7/17/13	RD staff and Registrant	Multiple phone calls discussing the issue Registrant argued that it was not a similarity issue – RD sent package for full acute tox (6 pack) review and Companion Animal review.
July 17, 2013	RD scientist	Completed acute tox review and Companion Animal Safety Study (CASS) – both found to be unacceptable
July 25, 2013	Similarity Clinic/RD, PRIA Managers Meeting _____ Similarity Clinic & OGC	Issue presented at PRIA Managers meeting – they agreed that the product should be rejected _____ Email discussion with OGC about the registrant's products and writing up the rejection letter. OGC advised RD to send the registrant a letter stating that the CASS was unacceptable first followed then by the final rejection letter
July 26, 2013	Similarity Clinic	Letter sent to Registrant re CASS review – stating that it was unacceptable
July 30, 2013	Similarity Clinic	Rejection Letter signed by Deputy Office Director & sent out to registrant

Date	Who	Action item
August 8, 2013	Registrant	Requested meeting with Deputy Office Director (see Sept 4, 2013)
August 28, 2013	Registrant	Sent another white paper written by a 2nd independent consultant for EPA to consider.
August 28, 2013	Deputy Office Director, RD Division Director, PRIA coordinator, RD Ombudsperson, Similarity Clinic	Pre-registrant meeting – internal discussion clarifying EPA's position
Sept 3, 2013	Deputy Office Director, RD Division Director, PRIA Coordinator, RD Ombudsperson, PM, Similarity Clinic	Pre-registrant meeting – more internal discussion talking about options
Sept 4, 2013	Internal RD meeting – RD Branch Chiefs, Similarity Clinic, RD scientist	Pre-registrant meeting (toxicology) – consensus on options for registrant to move forward after rejection
Sept 4, 2013	Registrant and OPP	Meeting between registrant and OPP. Registrant given 2 options to move forward: 1) resubmit packages citing the appropriate data for CASS and acute tox or 2) resubmit packages doing new acute tox data and citing appropriate data for CASS. Timeline discussed
Sept 6, 2013	Registrant	Sent meeting summary of 9/4 meeting
Sept 25, 2013	RD Division Director	Sent corrections of meeting summary back to registrant
Nov 8, 2013	Similarity Clinic	registrant decided on option 1 (see 9/4/13) Two new registrant packages received – same products as before w/new acute tox data citations and new CASS data citation to support product registrations – RD scientist reviewing both products coded as R315

(2) New AI R010

DATE	COMMENT
3/7/13	Submission of New Active Ingredient applications (PRIA Code R010). • One technical application • One End use application (from a separate company) Proposed uses: Seed treatment uses on corn, soybean, and wheat for the active ingredient as well as an import tolerance on tomatoes and grapes. • One petition for tolerances: Proposed tolerances on corn, soybean, wheat, tomatoes and grapes.
3/21/13	21-Day Screen complete: Several deficiencies were noted with the technical application. E-mail was sent to technical registrant notifying them of deficiencies.
4/10/13	EPA front end confirmed receipt of technical registrant's revised application addressing the 21-day screen deficiencies.
4/17/13	Package was assigned to IRB
5/1/13	Studies beaned to Science Division for 90-day technical screen. Due date for 90-day screen was 6/26/13.
5/21/13	Met with technical registrant. Company said they would send in additional toxicity information to address some preliminary tox concerns. (Neurotoxicity data gap)
6/5/13	Technical registrant submitted additional toxicity data to be included in the HED 90-day technical screen.
6/5/13	First team meeting. Potential EFED deficiencies were discussed.
6/13/13	Internal meeting with EFED to further discuss potential deficiencies and possible solutions to see if the issues could be resolved without rejecting the application.
6/18/13	Internal meeting with EFED to further discuss potential deficiencies and possible solutions.
6/20/13	HED finalized 90-day technical screen memo and confirmed that there are no deficiencies identified.
6/20/13	Presented case at PRIA managers meeting to discuss possible options.
6/20/13	Called technical registrant to let them know about EFED deficiencies.
6/25/13	EFED finalized 90-day technical screen memo outlining deficiencies.
6/25/13	EPA called the end use company to determine their agency contact. (The contact that was provided in the application no longer worked for the company).
6/25/13	Sent out 10-day letters to the technical registrant and the end use registrant. A response was due by 7/11/13. Deficiencies included: For the Technical Application: Environmental Fate and Effects Data Deficiencies • 835.2410: Photodegradation in Soil • 835.4300: Aerobic Aquatic Metabolism

	• 835.4400: Anaerobic Aquatic Metabolism • 850.1300: Freshwater Invertebrate Life-Cycle (daphnid) • 850.1400: Freshwater Fish Early Life-Stage (same species as acute study) • 850.4400: Vascular Aquatic Plant (duckweed) • 850.5400 (updated to 850.4500 and 850.4550): Non-vascular Aquatic Plants (required on four separate species) • 850.1025: Estuarine/Marine Invertebrate Acute (oyster shell deposition) • 850.1035: Estuarine/Marine Invertebrate Acute (mysid) • 850.1075: Estuarine/Marine Fish (sheepshead minnow) • 850.2100: Acute Oral Toxicity Study with Passerines • 835.6100: Terrestrial Field Dissipation • 835.6100: Environmental Chemistry Methods (ECM) and Independent Laboratory Validation for soil • 850.1730: Bioconcentration in Fish • 850.1350: Chronic Toxicity Test (mysid) • 850.1735: Whole Sediment Acute Toxicity (freshwater invertebrate) • 850.1740: Whole Sediment Acute Toxicity (marine invertebrate) Deficiencies for the End Use Application: EPA would not be able to grant a registration for your technical source based on the application before it at this time."
6/26/13	Companies confirmed receipt of 10-day deficiency letters.
6/26/13	EPA called the end use registrant to make sure they understood that the problem we had was with his technical source and that he would have to contact his technical source for details.
6/28/13	End use registrant sent an e-mail saying they are in contact with and are working with the technical registrant to resolve the deficiencies. The end use company is relying on the technical registrant to fix their technical application.
7/9/13	Called technical registrant to confirm that they would be sending in a response.
7/9/13	Additional teleconference with technical registrant to answer questions regarding their response.
7/10/13	Follow-up call with technical registrant to answer further questions and to discuss options.
7/11/13	Technical registrant submitted their response to the deficiencies (35 volumes of data/information).
7/24/13	RD met with EFED to discuss preliminary findings of technical registrant's response to the 10-day letter. In looking at the response EFED identified four guidelines that were still deficient. 835.6100 Terrestrial Field Dissipation 860.6100 ECM Method 850.1025 Estuarine/marine invertebrate acute 850.2100 Acute oral tox passerines
7/25/13	EFED e-mail RD a summary of their findings regarding the four data gaps.

7/25/13	RD called the technical registrant to notify them of EFEDs findings and e-mailed them EFEDs summary. RD discussed options with the company.
8/1/13	Technical registrant called to ask questions about how the refund would work if they chose to withdraw. RD Ombudsperson was able to address their questions.
8/2/13	Teleconference with technical registrant to further discuss options.
8/6/13	Conference call with company to discuss withdrawal option and amendments to their import tolerance petition.
8/7/13	Technical registrant sent an e-mail to withdraw their technical application and let EPA know that they would be sending in an amended application for the import tolerance petition.
8/8/13	RD notified technical registrant of receipt of their withdrawal e-mail and explained refund.
9/3/13	EPA sent letter of confirmation of withdrawal to technical registrant.
9/4/13	EPA sent a letter of rejection to end use registrant because the agency was not able to grant a registration for their technical source.

Lessons Learned from this AI submission:

- EPA encourages pre-submission meetings to make sure everyone is on the same page and it is clear to all participants what the application package should contain, especially if there are questions on how to fulfill any guideline requirements in Part 158.

- The registrant should go through Part 158 and address all required guidelines in their submission package. Their matrix should include every required guideline study and an indication of how that guideline will be fulfilled (waiver request, study, a study on similar chemical with bridging argument). Make sure each required guideline is clearly accounted for on the matrix.

- "Cite-all" should not be used for new active ingredients.

- If more than one company is involved in an application, the companies should work out ahead of time who the contact person will be for all companies involved. EPA would like one contact person who will represent all parties in order to avoid communication barriers due to CBI concerns.

- Summary of reasons for rejections/withdrawals from 45/90 screen
    - Not substantially similar
    - Lack of efficacy data to support public health claim
    - Efficacy data tested above nominal concentration
    - Efficacy testing cited was inadequate
    - Inadequate rationale for changing signal word
    - Unacceptable bridging arguments

- New product with multiple AIs where acute tox data submitted on individual AIs and not on mixture
- New AI rejected for the following deficiencies: hydrolysis data submitted not adequate, independent lab validation for aquatic field dissipation studies not submitted, mysid chronic tox study not submitted, fish early-life stage study not submitted, multi-residue methods study not submitted (registrant stated that the study was still ongoing at time of submission), product specific description of the production process not submitted;
- New AI withdrawn for the following deficiencies; photodegradation in soil, aerobic aquatic metabolism, anaerobic aquatic metabolism, freshwater invertebrate life-cycle, freshwater fish early life-stage, vascular aquatic plant, estuarine/marine invertebrate acute, estuarine/marine fish, terrestrial field dissipation, environmental chemistry method & independent lab validation;

- 45/90 Preliminary Technical Screen Process Timeline
  - PRIA Decision Review Time Period begins 21 days after receipt of **both** the application and proof of payment except:

    When IR-4 or small business fee waiver/reduction is requested in the application;

    Then PRIA Decision Review Time Period begins when waiver is granted or 60 days after the application's pin punch date whichever occurs first.
  - The Preliminary Technical Screen begins on the date that the PRIA Decision Review Time Period begins and expires either:

    (a) 45 days later for PRIA actions with Decision Review Time Periods ≤ 6 months, or

    (b) 90 days later for PRIA actions with Decision Review Time Periods > 6 months

  - Significant Deficiencies identified during this 45 or 90-day screening time period are communicated to the registrant who has 10-business days to correct the deficiencies.

  - Failure to correct the deficiencies within 10-business days will result in the rejection of the application.

  - Deficiencies identified **after** the expiration of the 45/90 screening time period will be communicated to the registrant via a 75-day deficiency letter but **cannot** result in the application's rejection.