

US EPA ARCHIVE DOCUMENT

### Schedule for Non-Fast Tracks

(All steps not always necessary & not always sequential—to be determined by team)

{In what follows there is a lot of discussion about “scoping”—we were asked to provide a definition. Scoping is the process of examining and often re-examining the specific action to determine what specific work is required to complete it. Another aspect of scoping is determining how this work can be completed in the most efficient manner possible and defining a schedule for the action based on this determination. We want to encourage people to use existing alternative processes—ARIA, low tox, etc. where possible *and* to think of new and innovative ways to get work done more efficiently. We also want to support the science division’s scoping efforts, such as HED’s new scoping exercises and use of RARC I and EFED’s problem formulation. RD has a new risk management entity (IRAD) where teams can propose their ideas and get input up-front-- or in-put anywhere along the process, from the risk managers. If you think something can be done more efficiently than it is currently being done—propose your idea to IRAD. In this way we can direct the majority of time and resources to chemicals/issues with the most risk.

Finally, we have talked about “scoping the schedule”. The idea behind this concept is that as we schedule each action *individually*, we must look for potential problems and bottlenecks in the overall schedule, which includes all actions that must be done, to see if there are going to be obstacles to actually getting this particular action out on schedule. This is a continuing process that must involve management in all of the divisions. What we are asking individual teams to do is immediately identify these problems when they arise so they can be addressed. Under PRIA we can no longer afford the time lost when actions sit in various queues, therefore, we must address resource issues quickly.}

<i>Name of ai:</i>	<b>Process:</b> (e.g. Std, ARIA, Low Tox.)		<b>Last Possible Science Due Date:</b>	
			<b>Science Due Date:</b>	
<b>RD Branch:</b>	<b>HED Branch:</b>	<b>EFED Branch:</b>	<b>BEAD:</b>	
<b>RM:</b>	<b>Risk Assessor:</b>	<b>Risk Assessor:</b>	<b>Phone #:</b>	
<b>Phone #:</b>	<b>Phone #:</b>	<b>Phone #:</b>	<b>Phone #:</b>	
			<b>FEAD:</b>	
			<b>Phone #:</b>	
<b>MILESTONE</b>			<b>Scheduled Completion Dates</b>	<b>Actual Completion Dates</b>

<b>Package Sent to Science Divisions:</b>	<b>HED:</b>	
	<b>EFED:</b>	
<b>RD Scoping</b> (Clarifies with registrant what the action is and specifically what the registrant wants.)		
<b>Obtain/Verify Team Members</b> (only team members that are necessary–e.g. if it is only a PPE change, may only need an ORE person)		
<b>TEAM Meeting 1</b> (Team Scoping: discuss action, confirm what work is required or if additional information is needed.) [RD, HED, EFED, BEAD–as necessary]		
<b>Registrant Meeting</b> (If necessary team meets with registrant to clarify/discuss action and resolve any issues.)		
<i>For Simpler Actions--</i>		
<b>A. For actions without data that are resolved in the team and/or registrant meeting-- decision and rationale written up by risk manager, signed by team, and approved by IRAD.</b>		
<b>B. For actions with data that require some, but not lengthy analysis, relevant team member does analysis and provides write-up to risk manager; risk manager writes up decision and rationale, signed by team, and approved by IRAD.</b>		
<i>For More Complicated Actions--</i>		
<b>If the action is more complicated follow a modified new use process, using the steps outlined below <i>as necessary</i>.</b>		
<b>Studies Sent to Contractor</b>	<b>EFED:</b>	
<b>Determine what information EFED and HED need from each other and when it will be delivered</b> (i.e. water information for HED and mammalian toxicity information for EFED).	<b>HED:</b>	
	<b>EFED:</b>	
<b>Scoping/Planning (in each division if necessary)</b> (Risk manager should participate in all relevant scoping meetings; raise issues with management (e.g. IRAD) as necessary.) [RD, HED, EFED, BEAD–as necessary]		

<p><b>Team Meeting 2 (if necessary)</b> (Team reviews/integrates results of each divisions’s scoping exercises; makes sure that all available information has been shared (on water and mammal toxicity); discusses how initial risk picture looks; finalizes initial scoping as a team; if there are possible ESA concerns risk manager notifies FEAD; prepares for meeting w/ registrant if necessary; identify any issues to raise with RD/OPP management; team determines schedule up to at least Team Meeting 3.) [RD, HED, EFED, BEAD–as necessary]</p>		
<p><b>Brief RD Management if Necessary</b> (Review plan for the action)</p>		
<p><b>PM Sends Letter to Registrant if Necessary:</b> States issues identified at second team meeting.</p>		
<p><b>Meeting with Registrant if Necessary</b> (Review plan for the chemical and solicit any necessary information; any input on problem formulation.) [RD, HED, EFED, BEAD–as necessary]</p>		
<p><b>Studies Sent to Contractor</b></p>	<p><b>HED:</b></p>	
<p><b>EFED Problem Formulation</b></p>		
<p><b>RARC 1</b> [RD, HED, EFED, BEAD–as necessary]</p>		
<p><b>Team Meeting 3:</b> Review results of problem formulation (EFED) and RARC 1 (HED); discuss any remaining questions and issues; provide available degradate information to EFED; finalize the scope of the assessments; define next steps and determine the rest of the detailed schedule as outlined below; identify any issues to raise with RD/OPP management. [RD, HED, EFED, BEAD–as necessary]</p>		
<p><b>NOTE:</b> If it appears that any information a team member provided to the team or to another Division up to this point (and from this point forward) turns out to be incorrect or in any way misleading the team member should <i>immediately</i> inform the team of the change (or the likelihood of a change in that information) <i>as soon as the change is discovered</i>. This may prevent someone from doing a lot of work for no reason-or doing work that will have to be redone. Examples include changes in degradates of concern, drinking water estimates, mammalian toxicity, need for further refinement of data, and need for additional information e.g. from BEAD, FEAD, or the registrant.</p>		
<p><b>Brief RD Management if Necessary</b> (Review plan for the action; raise any issues that require management input)</p>		

<p><b>Team Meeting 4</b> (After secondary review of studies—identify risk issues, plan refinement strategy, if necessary, or prepare for registrant meeting to discuss risk mitigation. Review, confirm and discuss with registrant, if necessary, any key exposure assumptions (from the label or from use of defaults) that may contribute to risk issues. Reconfirm schedule. Identify issues to raise with RD/OPP management. FEAD informed about whether there are ESA issues; if there are FEAD invited to meeting and plays integral part in determining refinement strategy.) [RD, HED, EFED, BEAD—as necessary]</p>	<b>HED:</b>	
	<b>EFED:</b>	
<p><i>Add any necessary steps to reflect due dates for additional information/refinements needed from BEAD (e.g. % crop treated, or FEAD, or HED and EFED e.g. sharing information on foliar residues for possible refinement of terrestrial eco-risk).</i></p>		
<p><b>“Problem” DERs Provided to RD</b> (DERs with problems e.g., study issues that need to be addressed by registrant or new study triggered, provided to Risk Manager for resolution and/or possible date extension)</p>	<b>HED:</b>	
	<b>EFED:</b>	
<p><b>Degradate Information to HED</b> (fate profile that is necessary for metabolism portion of HEXARC meeting)</p>		
<p><b>HEXARC</b> (Risk Manager attends.)</p>		
<p><b>Final Water #'s to HED</b> (for use in risk assessment)</p>		
<p><b>RARC 2</b> (Risk Manager attends.) [RD, HED, EFED, BEAD—as necessary]</p>		
<p><b>EFED Internal Peer Review</b> (Risk Manager attends.)</p>		
<p><b>HED Final Risk Assessment Document and Complete Set of DERs to RD</b></p>		
<p><b>EFED Final Risk Assessment Document and Complete Set of DERs to RD</b></p>		
<p><b>Team Meeting 5</b> (If necessary—identify remaining risk issues, plan further refinements, or prepare for registrant meeting to discuss risk mitigation. Reconfirm schedule. Identify issues to raise with RD/OPP management.) [RD, HED, EFED, BEAD—as necessary]</p>	<b>HED:</b>	
	<b>EFED:</b>	
<p><b>Documentation Completed</b> (label review; decision document package)</p>		