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July 29, 2004

Schedule for New Use (Not First Food Use)

(Usually Necessary 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.}

<table>
<tr><td rowspan="2">Name of ai:</td><td colspan="2" rowspan="2">Process: (e.g. Std, ARIA, Low Tox.)</td><td colspan="2">Last Possible Science Due Date:</td></tr>
<tr><td colspan="2">Science Due Date:</td></tr>
<tr><td>RD Branch:
Risk Manager:

Phone #:</td><td>HED Branch:
Risk Assessor:

Phone #:</td><td>EFED Branch:
Risk Assessor:

Phone #:</td><td colspan="2">BEAD:
Phone #:

FEAD:
Phone #:</td></tr>
<tr><td colspan="3">MILESTONE</td><td>Scheduled Completion Date</td><td>Actual Completion Date</td></tr>
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Package Sent to Science Divisions	**HED:**	
	HED:	
Obtain/Verify Team Members		
Team Meeting 1 (Introductory meeting; risk manager reviews available regulatory background/information and labels, team determines schedule for completeness check, and reduced risk and NAFTA decisions, if necessary; team discusses how preparations for the second team meeting will happen–e.g. how information on drinking water and mammalian tox data will be shared; what scoping meetings will occur and how they will be organized and determines the schedule up to the point of the second team meeting) [RD, HED, EFED, BEAD]		
Determine if it is a Workshare (or possible Workshare?)		
Up-Front Steps: Publish Notice of Filing (& Public Interest Finding)		
Publish Notice of Receipt of New AI		
Open E-Docket [Include BEAD if Public Interest Finding Involved]		
Completeness (Science) Screen (Determine if all guidelines met and that there are no "show-stoppers" in the studies. RD needs write up of results) [HED, EFED, RD]	**HED:**	
	EFED:	
Reduced Risk Decision (if necessary) [RD, HED, EFED, BEAD]		
NAFTA Joint Review Candidate Decision (if necessary)		
Studies Sent to Contractor (EFED)	**EFED:**	
The following three blocks address some of the additional preparatory work that should happen before the second team meeting.		
Determine if New Water Assessment is Required (for use in RARC and HED Scoping Meeting–a new assessment would be required if, for example, the rates are different or the use includes a new type of geographic area with different run-off or leaching potential or if the risk cup is getting full and HED needs a more refined assessment than previously done)		

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Determine if Any New Mammalian Toxicity Information Should be Sent to EFED (for use in RARC and HED Scoping Meeting)		
Scoping/Planning– ***EXTREMELY IMPORTANT FOR NEW USES*** (Risk manager should participate in all relevant scoping meetings; raise issues with management (e.g. IRAD) as necessary–Must determine if a previous assessment covers the new use or if a new assessment is needed (EFED); for EFED and HED must determine what the differences in a new assessment would be and decide the format in which to present them, e.g. if only residue data review is needed you might attach new tables X, Y, and Z to a previous assessment along with a short explanation of the new tolerance). This scoping step may eliminate the need for some of the following steps. [RD, HED, EFED, BEAD]		
TEAM Meeting 2 (Team reviews/integrates results of each division's initial scoping exercises; reviews results of completeness check and reduced risk and NAFTA decisions, if these were necessary; makes sure that all available information has been shared (on water and mammalian toxicity); discusses how initial risk picture looks; finalizes initial scoping as a team; if there are possible ESA concerns risk manager notifies FEAD; prepare for meeting w/ registrant; identify any issues to raise with RD/OPP management; team determines schedule up to at least Team Meeting 3.) [RD, HED, EFED, BEAD]		
Risk Manager Sends Letter to Registrant: States deficiencies/issues identified in science screen and at second team meeting; results of reduced risk/NAFTA decisions.		
Registrant Meeting (Registrant gives briefing on package, potential risk issues including ESA issues, provides input on problem formulation, addresses issues arising from completeness check and risk manager's letter; team reviews plan for the chemical and solicits up-front input, e.g. verify current use and usage information and verifies identified target pests.)		
Studies Sent to Contractor (HED)	**HED:**	
HED Requests Necessary Method Validations from BEAD BEAD Due Date	**HED:** **BEAD:**	
EFED Problem Formulation		
RARC 1 [RD, HED, EFED, BEAD]		

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Team Meeting 3 (Review results of problem formulation (EFED) and RARC 1 HED; discuss any remaining questions and issues; provide avialable degradate information to EFED; finalize the scope of the assessments; define next steps and determine the rest of the detailed schedule as outlined below; prepare for meeting with registrant/stakeholders; identify any issues to raise with RD/OPP management.)		
NOTE: 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 members should *immediately* inform the team of the change (or the likelihood of a change in that information) *as soon as the change is discovered*. 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.		
Brief RD Management (Review plan for chemical and detailed schedule; raise any issues that require management input)		
Team Meeting 4 (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 may be ESA issues; if there are likely to be ESA issues FEAD invited to meeting and plays integral part in determining refinement strategy.) [RD, HED, EFED, BEAD]	**HED:**	
	EFED:	
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).		
"Problem" DERs Provided to RD (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)	**HED:**	
	EFED:	
Degradate Information to HED (fate profile that is necessary for metabolism portion of HEXARC meeting)		
HEXARC (Risk Manager attends.)		
Final Water #'s to HED (for use in risk assessment)		

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RARC 2 (Risk Manager attends.) [RD, HED, BEAD]		
EFED Internal Peer Review (Risk Manager attends.)		
HED Final Risk Assessment Document and Complete Set of DERS to RD		
EFED Final Risk Assessment Document and Complete Set of DERS to RD		
Team Meeting 5 (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; FEAD–if necessary]		
Risk Management Completed: Brief Management		
Documentation Completed (FR Notice for tolerance; label review; decision document package; registration notice prepared; FR for registration notice)		
Risk Assessment/DERs (whole record) Placed in Docket		

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