

The IR-4 Process (cont'd)

Planning/conducting the residue program, field & lab (including ChemSAC proposals to reduce data required & joint projects with AAFC/PMC)



Agenda:

Food Use Workshop
Sept

NRPM
Nov

Chem SAC
Proposals
Oct-March

Agenda:

Protocol
Development
Nov to April

Field Trials
March to Nov

Lab Analyses
1 year

Agenda:

Field Data Books

Analytical
Summary
Report

ALL DATA
RECEIVED!

PRE NRPM Planning

National Research Planning Meeting

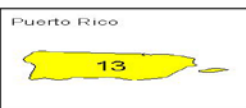
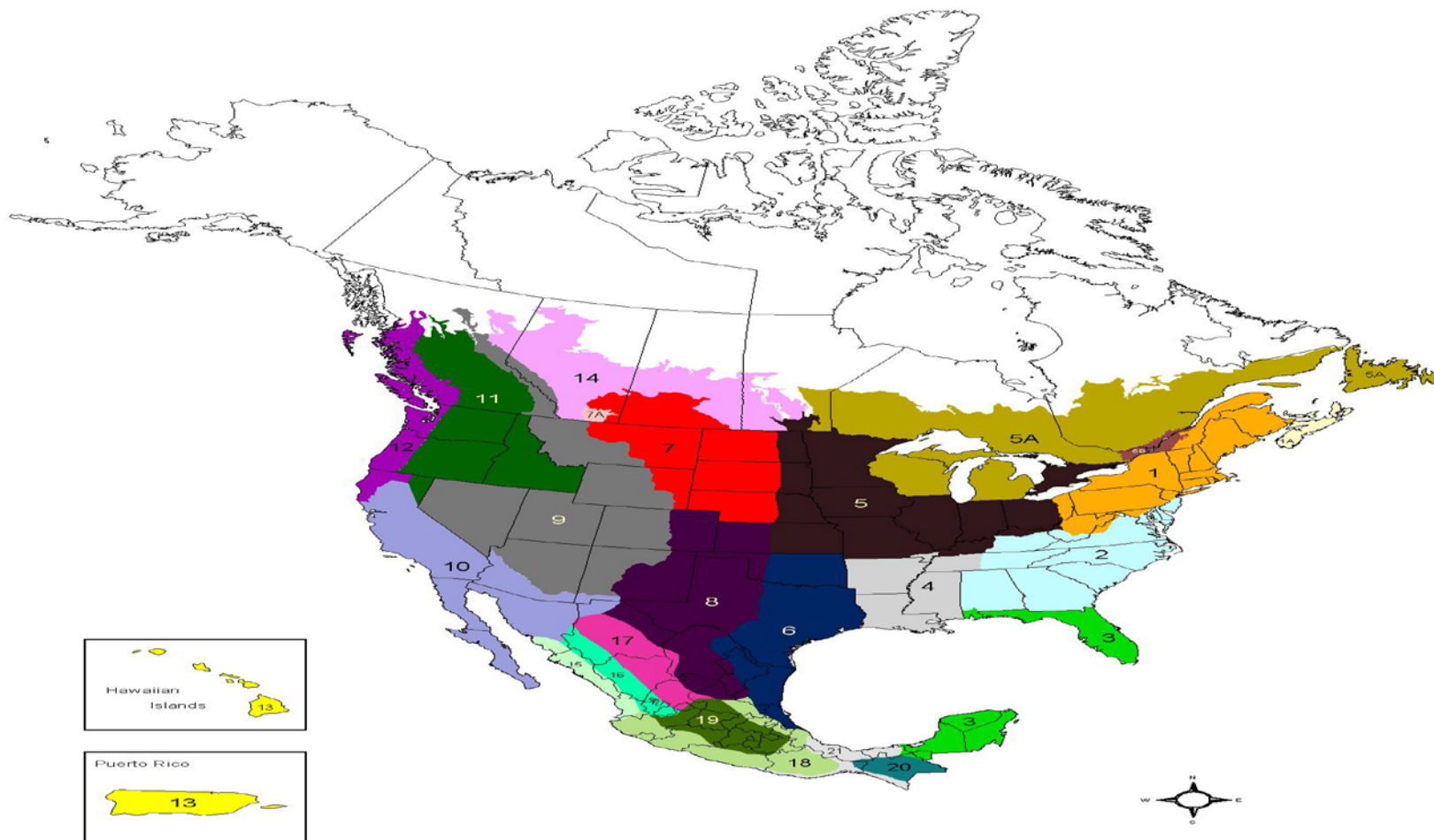
- Number of trials needed
- Decline and/or Processing trials
- Location of trials – EPA Regions
- Database entries

PRE NRPM Planning

National Research Planning Meeting

- “Why did I get those trials?”
- Review of Guidance Documents
 - 860 Guidelines (EPA)
 - NAFTA Joint Review Guidance
 - Codex Field Trial Guidance

North American Major and Minor Crop Field Trial Regions



Lambert Conformal Conic Projection

Major and Minor Crop Field Trial Regions



PRE NRPM Planning

National Research Planning Meeting

Crop	1	2	3	4	5	6	7	8	9	10	11	12	13	Adj. Sum
Alfalfa, forage		2	0	0	0	5	0	0	0	0	1	0	0	8
Alfalfa, hay		1	0	0	0	5	0	2	1	1	1	1	0	12
Alfalfa, seed		0	0	0	0	0	0	0	0	1	2	2	0	5
Almond		0	0	0	0	0	0	0	0	0	5	0	0	5
Amaranth, grain						3 trials in any area where the crop is grown								3
Apple		4	1	0	0	3	0	0	0	0	2	6	0	16
Apricot		0	0	0	0	0	0	0	0	0	4	1	0	5
Artichoke, Globe		0	0	0	0	0	0	0	0	0	3	0	0	3
Asparagus		0	0	0	0	1	0	0	0	0	2	2	0	5
Avocado		0	0	0	0	0	0	0	0	0	4	0	0	5
Bahiagrass, seed		0	1	1	0	0	1	0	0	0	0	0	0	3
Banana		0	0	0	0	0	0	0	0	0	0	0	5	5
Barley, grain		1	0	0	0	3	0	3	0	2	0	3	0	12
Bean, dried		0	0	0	0	7	0	2	1	0	1	1	0	12
Bean, Lima, dried		0	0	0	0	0	0	0	0	0	8	0	0	8

EPA/NAFTA Guidelines for number of field trials

Cucumber

Zones	1	1A	2	3	4	5	5A	5B	6	7	7A	8	9	10	11	12	13	14	Total
Cucumber			3	1		3								1					8
Canada						2		2								1			5
US			3	1		2			1					1					8
Savings						1		2	1							1			5

Joint Projects

- Canadian Partnership (PMC) started in 1996, fully funded program in Canada in 2003.
- IR-4 and PMC have Minor Use Priority-Setting Workshops annually.
- Where residue projects are of mutual interest, IR-4 and PMC conduct the research together with a single protocol, study director and sponsor. All research done under GLPs
- Field projects are initiated on both side of the border with the intent to satisfy both the US and Canada data requirements.
- Submitted to EPA or PMRA at approximately the same time.



PRE NRPM Planning

National Research Planning Meeting

- Number of trials needed
- Decline and/or Processing trials
- Location of trials – EPA Regions
- Is the study needed?

Chem SAC Proposals

- What is EPA Chem SAC?
- IR-4 prepares a proposal.
- Proposal uses existing data to eliminate some of the data requirements.
- EPA Chem SAC reviews the proposal.

Chem SAC Proposals

- If EPA agrees with our proposal –study may not be needed, or less work needed.
- Examples
 - Data translation for Quinoa - use existing tolerances for wheat or barley if use pattern is the same.
 - Triazole metabolites – for post harvest applications, do not need to analyze for metabolites.
- Saves money, time and effort.



National Research Planning Meeting

Headquarters and Regional Staff



Research project field sites are assigned for the coming year. Lab sites are assigned during protocol development.

Use Pattern

Protocol Development

- Study Director suggests use pattern based on:
 - PCR Request.
 - Discussion with submitter.
 - Efficacy/Crop Safety Data.
 - Other crops already registered – crop group completion.

Use Pattern

Protocol Development

- What the registrant can support.
 - Existing studies – toxicity and ecotox, environmental fate, metabolism.
 - Max use rate per season.
 - Established MRLs may impact whether IR-4 can raise the rate or shorten the PHI.

Protocol Development

- Protocol template is prepared prior to FUW.
- Draft protocols are prepared and reviewed internally.
- Drafts posted for review and comment.
- Registrant is notified of test substance needs and timing.
- Comments are incorporated.
- Registrant approves draft protocol including use pattern.
- Protocol is signed and study begins.



Field Trials

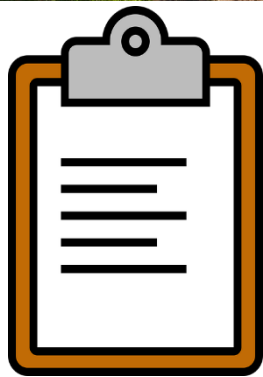


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Need your help to be successful:

Review draft protocol – does it make sense?
Can you carry out the use pattern as written.
Did you receive the correct test substance?
If there are questions – who do you call?

Field Trials



Field Trials

Help us submit the study as soon as possible:

Prompt completion of trials.

Impacts all if one trial is delayed.

Especially critical for repeat or replacement trials and expedited trials.

Field Data

Field Trials

Successful trials are critical to the success of the study.

If the harvested samples are not of commercial quality, the use pattern was not followed, or the documentation is insufficient to reconstruct what was done in the field, all further work on these samples is immaterial – the trial will have to be repeated.



Lab Analyses



Lab/Analytical Data

Lab Analyses



Lab Analyses



Need your help to be successful:

Review draft protocol – does it make sense?

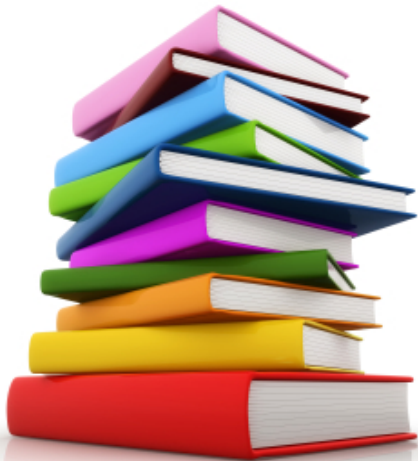
Request reference substance in a timely manner.

Send data to SD as it is generated.

Does the data make sense?

If there are questions – who do you call?

Field Data Books



- Finished in a timely manner.
- Information is complete.
- Clear and concise.

Analytical Summary Report

Trial ID (City, State)	NAFTA Growing Region	Trial Start Year	Crop/ Variety	Commodity	Total Rate lb ai/A	PHI (days)	Residues (ppm)
09190.06-ID03	11	2006	Hops/Nugget	Hops, Cones, Dried	0.158	6	0.69
(Parma, ID)							0.65
09190.06-OR02	12	2006	Hops/Willamette	Hops, Cones, Dried	0.167	6	0.67
(Hubbard, OR)							0.62
09190.06-WA16	11	2006	Hops/Nugget	Hops, Cones, Dried	0.161	8	0.34
(Prosser, WA)							0.36

Finished in a timely manner.
Information is complete.
Clear and concise.

ALL DATA RECEIVED!



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