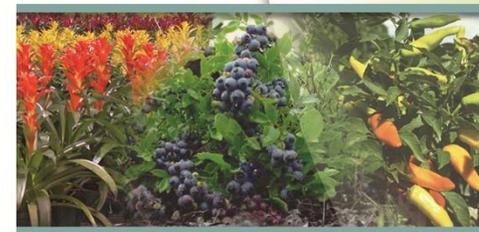




**Multi-Field Trial Differentiation, FDB Updates, Unused  
and Corrected FDB Pages, and Estimated Dates**

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## Multi-Field Trial Differentiation

- EPA had been informing us for about a decade that we needed to improve our trial independence when multiple field trials within a study were assigned to one individual.
- A clover study submitted to EPA was rejected because of the similarity of the trials conducted by one person.
- In 2012, IR-4 implemented the table of options that had been negotiated with EPA in 2011 to differentiate trials.
- PMRA (Canada) objected to some of the particulars; discussions are currently underway to make changes that will be acceptable to both agencies (and also to European regulators)



# Multi-Field Trial Differentiation

11.4 If a Field Research Director is assigned more than one trial in this study, the following requirements must be met:

An independently prepared tank-mix must be used in each trial. Also:

Choose one option from any 2 or 3 of the 5 sets below (depending on the PHI, for a minimum of 3 criteria met).

**This will probably change to: Choose one of the highlighted options or two of the other options**

Set	Option	Description
1	A	Spray volume must vary by at least 25% of the lower volume (minimum 10 GPA difference) Example 1, Trial A has a volume of 20 GPA and Trial B has a volume $\geq$ 30 GPA Example 2, Trial A has a volume of 60 GPA and Trial B has a volume $\geq$ 75 GPA The trial with the lowest spray volume for the first application must remain the lowest for each application; the trial with the highest must remain the highest for each, and so on
	2	Different adjuvant class: Crop oil concentrate or Nonionic surfactant (non-silicone) or Silicone surfactant (Do not contradict instructions on the label of either the adjuvant or the test substance) <b>(This will probably change to a choice of adjuvant vs. no adjuvant)</b>
3	A	Different foliar application type: foliar directed or foliar broadcast (Do not use this option if the label instructions for this commodity will specify one type or the other)
	B	Different types of application equipment be used in each trial (for example, tractor-pulled boom sprayer, tractor-pulled spreader, airblast sprayer, axial fan orchard sprayer, proptec sprayer, cannon mist sprayer, tower sprayer, over-row sprayer, tunnel sprayer, backpack sprayer, waist pack sprayer, hand gun, hand-held spreader, or shaker can)
	C	Different people make the applications, using hand-held equipment such as backpack sprayers, waist pack sprayers, hand guns, hand-held spreaders, or shaker cans <b>(This will disappear)</b>
	D	Different spray droplet size (fine, medium, coarse, very coarse, or extra coarse) This may be accomplished by changing nozzles and/or by changing spray pressure Document in the Field Data Book the droplet size that results from the pressure and nozzles used in the trial (nozzle catalog may be used as a reference) Coarse, very coarse, and extra coarse are appropriate for herbicides only
	E	Different granular application type: broadcast or banded (only if label supports both types)
	F	Different incorporation method for soil-applied test substance: mechanical or irrigation
	G	Different band width for soil applications: band width must vary by at least 50% of the lower width
4	A	<b>Different crop variety (different size at maturity, rough vs. smooth surface, different amount of foliage shielding the commodity, etc.)—confirm with Study Director if this option will be chosen (This will probably become a stand-alone option)</b>
	B	Different irrigation type (drip or furrow or sprinkler/over-the-top) (Irrigation must be applied at least once after each application, but over-the-top irrigation must not be applied within one hour of an application, and irrigation is not needed following the last application if samples are to be collected on the same day)
	C	Different planting arrangement for annual crops: single row beds or multi-row beds (two or more rows on each bed)
	D	For test substances that must be applied through drip irrigation: surface drip line or buried drip line
	E	One trial shall have trellised plants and the other shall not
	F	Different training system for fruit trees (for example, central leader or open center)
	G	Different maturity of trees or bushes in fruit and nut studies—young trees or bushes in one trial and mature trees or bushes in the other; minimum 5 year age difference
5	A	<b>Trial sites must be separated by at least 20 miles (32 km) (This will probably become a stand-alone option)</b>
	B	<b>First application in each trial is separated by at least 30 days (This will probably become a stand-alone option)</b>
	C	Different soil series, type, or texture (only in trials in which applications are made to the soil)

Possible new option: Different formulations (within types generally considered equivalent)



## Multi-Field Trial Differentiation

- You only need to fill out the differentiation options table (6L) once per trial; it does not need to be repeated for multiple applications.





# Some 2013 FDB Updates

- 6C (airblast)** PRESSURE OR OTHER STANDARD SETTING UTILIZED IN CALIBRATION (This has already been in the “regular” calibration 6C, and is now added to the airblast version.)
- 6C (airblast)** The output columns in the table have been re-arranged so that they are now in the order:  
**Initial Volume / Final Volume / Volume Discharged**  
 (The final volume is subtracted from the initial volume to calculate the volume discharged, which is then used to calculate the sprayer output.)

RUN	TIME (sec)	Side(s) of sprayer calibrated (from rear of unit)								
		RIGHT			LEFT			BOTH		
		Initial volume	Final volume	Volume discharged	Initial volume	Final volume	Volume discharged	Initial volume	Final volume	Volume discharged
1										
2										
3										
Total (required)										
Average (optional)										



## Some 2013 FDB Updates

6C	<b>Was this a recheck of discharge calibration or a target output? If yes, were results within 5% of original calibration or target output? (Revised to acknowledge the acceptability of target outputs.)</b>
6G (airblast)	<b>PSI AT NOZZLES (corrected from PSI AT BOOM, which does not apply to airblast sprayers)</b>
6L1	<b>*Please list any criteria that were used in this trial that are included in the protocol but <u>are not</u> listed in the table in Part 6.L.2. (Footnote added because there may be changes to the list of options in the protocol that are made after the Field Data Books have been printed. Also, some specialty crops have protocol options that are not included in the general list in 6.L.2.)</b>
7E	<b>A prompt (<u>underlined blank space</u>) has been added for the entry of the SOP# used for freezer calibration and maintenance, if any has occurred.</b>
8A	<b><u>Use separate forms if different samples from the same trial are going to different destinations.</u> (The same form should not be used if some samples are going to one analytical laboratory and other samples are going to a different laboratory or to a processing facility.)</b>



## Some 2013 FDB Updates

8B	<b>Footnote to table: Use the rate of the last application if different applications had different rates assigned by the protocol. If there are two active ingredients (a.i.) in the test substance, enter the rate of the a.i. that is to be analyzed for that sample. (It is not necessary to enter the rate of both a.i., since the lab that receives the sample will only be analyzing for the residues of one a.i.) If the protocol does not indicate the rates for each a.i., then contact the Study Director for guidance.</b>
8B	<b>DESTINATION (do not enter more than one destination) (The same form should not be used if some samples are going to one analytical laboratory and other samples are going to a different laboratory or to a processing facility.)</b>
8C	<b>First entry prompt has been clarified to read: Laboratory ID# (from Protocol Part 24 <u>or amendment</u>)</b>



## Unused FDB Pages

- If you are not using a particular page in the FDB (for example, the speed calibration page if speed is not a factor in the applications), then please line out and initial/date the page—do not remove the page from the book. (Otherwise, we are uncertain if there is missing data.)
- For multiple applications, just one lined-out page is enough to get the message across.
- Always calculate the actual rate applied for every application.



## Why we need those corrected pages sent with your QA responses

- When the Study Director makes a revision to the raw data, the support for that change must also be in the raw data (FDB or correspondence) in accordance with Good Laboratory Practices
- QA responses are not part of the raw data
- QA audits are not made available to EPA inspectors
- If an EPA inspector comes across a change made to the raw data by a Study Director that is unsupported, we are in trouble



## Estimated Dates

- My supervisor, Dr. Debbie Carpenter, asked me to thank all of you who have submitted your estimated dates for your assigned field trials this year. These estimates allow us to plan the laboratory schedules and our targeted submission dates.
- If there will be a significant delay in completing your trial (2 months or more), please submitted revised estimates.



Thank you for your participation!

