

The Cochran Fellowship Program **Residue Programs for the US crop**



We create chemistry

Field trials - Raw Agricultural Commodity (RAC)

Basic decisions



- Crops
 - ▶ Individual crops or crop groups?
 - ▶ Greenhouse use? Seed treatment?
 - ▶ Minor uses
- Application type: foliar, seed treatment, soil application
- Critical GAP or directions for use (GOAL IS GLOBAL cGAP)
- Formulation(s)
- All under GLP rules

Field trials - Raw Agricultural Commodity (RAC)

Guideline requirements

Number and location of trials



■ U. S.: Defined by Residue Chemistry Test Guidelines

OPPTS 860.1000 Background August 1996

OPPTS 860.1500 Crop Field Trials August 1996

- ▶ One season sufficient
- ▶ Seed treatment generally covered by foliar
- ▶ Greenhouse use: greenhouse trials needed (generally 4 per crop)
- ▶ Formulation comparability – usually formulation type does not matter, but there are signs of things changing by the regulators.
- ▶ Decline trials should be included if residues expected in edible crop
 - 1 if 5-12 RAC trials; 2 if 16-20 RAC trials

Field trials - Raw Agricultural Commodity (RAC)

Guideline requirements

Crop groups



- U. S. Representative crops defined for crop groups and sub groups in OPPTS 860.1500
 - ▶ If NAFTA program: allowance for reduction in number of trials by 25%, *e.g.* 8 trials to 6
 - ▶ **ALERT!** Six trials not sufficient for EU import tolerance
 - ▶ **ALERT!** Crop groups are being changed and updated –check federal register

Field trials - Raw Agricultural Commodity (RAC)

Guideline requirements

Treatment: GOAL IS GLOBAL cGAP



- Residue trials are treated according to the critical GAP
 - ▶ Maximum application rate
 - ▶ Maximum number of applications
 - ▶ Minimal interval between applications
 - ▶ Use certified formulation
 - ▶ Sample at minimum PHI
 - ▶ Extra plots might be triggered in the U. S.
 - Ultra low spray volume <2 GPA or <10 GPA (orchard) (often used in aerial applications)
 - Orchard use- dilute and concentrated spray applications must be tested (High and Low volume)

U. S. accept proportionality: residues can be adjusted based on different application rate if all other GAP parameters the same

Field trials - Raw Agricultural Commodity (RAC)

Sampling: guideline requirements

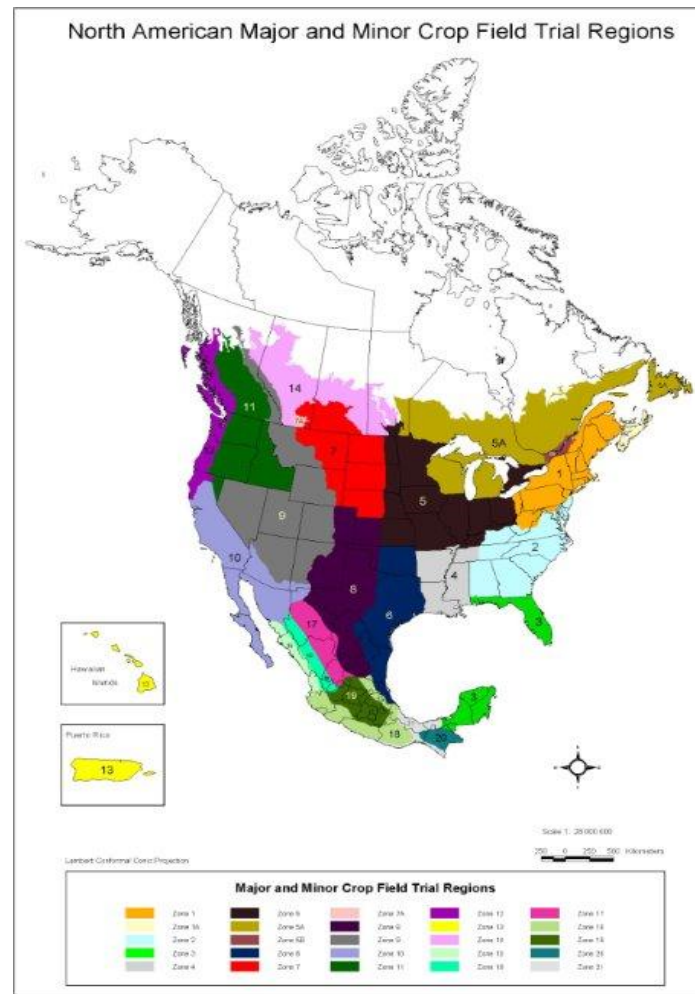
Sampling: strategic



- U. S. / Canada RAC crop commodities to be sampled defined in OPPTS 860.1000
- Need control samples (untreated) for each commodity
- U. S./Canada two independent replicates/commodity for each sampling time point
- Decline trials: sampling at multiple time points
 - ▶ Sufficient one sample/commodity for each sampling time point (however EPA still recommends 2 replicates/commodity)

Field trials - Raw Agricultural Commodity (RAC)

Current US Residue trial regions



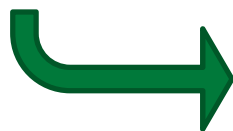
Field trials - Raw Agricultural Commodity (RAC)

Crop Groups:

<http://ir4.rutgers.edu/Other/CropGroup.htm>


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Number of trials for
a Nafta program



This document
is a guide for
number of
trials only not
crop group
changes.



Science Policy Note

SPN2017-02

Joint Canada/United States Field Trial Requirements

(publié aussi en français)

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607-D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3700
pmra.infoserv@hc-sc.gc.ca



Field trials - processing studies (PF)

Conduct study to satisfy global requirements



- U.S. /Canada trigger: Whenever residues in processed commodity might exceed residues in RAC
 - ▶ If RAC trials conducted at exaggerated rate (5x) show no residue, then processing study not needed
 - ▶ Exceptions - processing always needed for citrus and mint due to high concentration in oil

U. S. EPA Residue Chemistry Test Guideline OPPTS 860.1520 Processed Food/Feed (August 1996)
No. 96, OECD Guidance Document On Magnitude Of Pesticide Residues In Processed Commodities, ENV/JM/MONO(2008)23,
508 OECD Guideline For The Testing Of Chemicals Magnitude of the Pesticide Residues in Processed Commodities Oct. 3, 2008

Field trials - processing studies (PF)

Conduct study to satisfy global requirements



- Number of trials
 - ▶ US. One sufficient
 - ▶ BASF conducts three in the U. S.
- Treatment according to the cGAP except use exaggerated application rate 5X.
- Include all OECD & US process commodities for each RAC
 - ▶ List in U. S. EPA Residue Chemistry Test Guideline OPPTS 860.1520
 - ▶ List in OECD Guideline 508
- Include all analytes in analytical method

Field trials - processing studies (PF)

Study results

- Determine process factor (PF) also called transfer factor
 - ▶ $PF = \text{residues in the process commodity} / \text{residues in RAC}$
 - ▶ Example soybean oil $PF = 0.02 / 0.01 = 2$
- Determine PF based on residue definition for monitoring
 - ▶ U.S. & Canada determine tolerance (MRL) for processed commodities if higher than tolerance for RAC
- Determine PF based on residue definition for risk assessment
 - ▶ Use PF to adjust residues in dietary risk assessment
- U.S. calculates mean PF

Field trials – rotational crop (RotCrop)

Limited field rotational crop



- Trigger for limited field rotational crop: Analyte residues ≥ 0.01 mg/kg) in confined rotational (follow) crop study (^{14}C -study)

- Study design: Limited field rotational crop
 - ▶ U. S Two trial sites in representative growing areas for product
 - ▶ Treat bare soil or target crop at cGAP
 - ▶ Use formulation planned for target crop
 - ▶ Plant back intervals of 30, 60-120 and 360 days after last treatment
 - ▶ Three plots at each site, leafy, root and small cereal planted as rotated crops
 - ▶ Sample and analyse required RAC (also tops of root crop) with validated method

U. S. EPA Residue Chemistry TG OPPTS 860.1900 Field Accumulation in Rotational Crops (August 1996),
Appendix C Testing of Plant Protection Products in Rotational Crops, 7524/VI/95 rev.2 22/7/1997
504 OECD Guideline For The Testing Of Chemicals; Residues in Succeeding Crops (Limited Field Studies) Jan. 8, 2007

Field trials – rotational crop (RotCrop)

Limited rot. crop: study results



- U. S. No label restriction if residues <LOQ at 30 day interval; Residues ≥LOQ in follow crop: label restrictions for that follow crop
- U. S. Eliminate label restriction
 - ▶ Obtain tolerances for rotational crop. Perform # of trials equal to registration in target crop but use application to bare ground or target crop
 - or
 - ▶ Register as a target crop by performing full program

Thank you

