Reduced Residue Chemistry Data Requirements for Seed-Treatment Uses

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  - All crops excluding potato seed-piece treatments
  - Potato seed-piece treatments
- Overview of Changes
- Decision Tree Overview
- Case Study: Sedaxane
- Conclusions
EPA has released a memo that outlines reduced residue chemistry data requirements for seed-treatment uses

- Joint effort between EPA and the Health Canada Pest Management Regulatory Agency (PMRA)
- Performed a retrospective analysis of all seed-treatment residue data submitted to EPA and PMRA
- Developed a tiered approach for when residue data requirements for seed treatments can be reduced
  - All crops excluding potato seed-piece treatments
  - Potato seed-piece (PSP) treatments
- Conducted a case study

https://www.epa.gov/pesticide-registration/determining-number-field-trials-required-register-seed-treatment-uses
Considerations: All Crops Excluding Potato Seed-Piece Treatments

- **Maximum Theoretical Residue in Harvested Raw Agricultural Commodities (RACs)**
  - Calculated rates at which the maximum theoretical residue would equal 5 ppb (based solely on growth dilution of residues) and be considered non-food (NF) based on Table 1 of Guideline 860.1000

- **Foliar Use Also Registered (or Proposed) for the Crop**
  - If the crop has an existing foliar use (or a foliar use is being requested concurrently), then residue chemistry data specific to the seed-treatment use can generally be reduced or eliminated
  - Considers residues of concern (ROC) and application rates

- **Radiotracer Uptake Study**
  - Seed-treatment uses with no registered or applied-for foliar uses can often be classified as NF uses
  - Make determination using a 1X radiotracer uptake study

- **Seed-treatment Rate ≤ 10 g ai/100 kg seed**
  - If adequate plant metabolism data are available to determine the ROC for tolerance enforcement and the application rate is ≤ 10 g ai/100 kg seed, then a significant reduction in data requirements is appropriate
Considerations: Potato Seed-Piece Treatments

- Potato seed-piece (PSP) treatments were considered separately due to the unique nature of PSP applications

- **No Registered Potato Uses**
  - Radiotracer Uptake Study
    - Make determination using a 1X radiotracer uptake study
    - If residues of concern (ROC) are <5 ppb in potato tubers, then no further data are required, and the use is considered NF
  - Foliar or Seed-treatments Registered in Other Crops
    - The need for additional potato metabolism data may be reduced
    - PSP data are still required

- **No Other Uses Registered**
  - All residue chemistry data requirements must be fulfilled

- **In-Furrow and Foliar Uses Are Registered**
  - PSP data are still required
  - If demonstrate equivalency of residues for in-furrow and PSP treatments using bridging data, then in-furrow residue data can be used to support PSP use
  - Considers if ROC are the same for foliar and soil treatments
    - Determines if additional potato metabolism data are required
Overview of Changes

- **All crops excluding potato seed-piece treatments**
  - If the crop has an existing foliar use (or a foliar use is being requested concurrently), then data specific to the seed-treatment use can generally be reduced or eliminated.
  
  - If there are no additional metabolites of concern from soil application and the total foliar plus seed-treatment rate does not exceed 125% of the registered (or proposed) maximum seasonal foliar application rate, then additional seed-treatment field trial data are not required.
  
  - Allows for a 50% reduction in the number of seed-treatment field trials for RACs that are exclusively livestock feed items.
  
  - Allows for significant reductions in data requirements when seed-treatment application rates are low (≤10 g ai/100 kg seed).

- **Potato seed-piece treatments**
  - Allows for reductions in the number of field trials only when a 1X PSP radiotracer study indicates that ROCs are <5 ppb in potato tubers.
Decision Tree For All Crops Excluding PSP

Maximum Theoretical Residue in Harvested RACs (Food And Feed) <5 ppb?

- Yes: NF, No Data Required
- No: Foliar Use Also Registered or Proposed?
  - Yes: ROC Same for Foliar And Soil Treatment? (Compare Foliar Metabolism Data with Confined Rotational Crop Data)
    - Yes: Total Foliar + Seed Rate ≤125% Foliar Rate (Label Restriction On the Foliar End-Use Product May Be Required)
    - No: Additional Data May Be Required On A Case-By-Case Basis (E.G., Residue Data for Soil Metabolites, Residue Data For Seed + Foliar Application)
  - No: Radiotracer Study Available?
    - Yes: Are Adequate Plant Metabolism Data Available to Determine ROC?
      - Yes: Rate >10 g a/100 kg Seed?
        - Yes: Conduct Radiotracer Study
        - No: For Human Foods, No Field Trial Data Are Required and A LOQ Level Tolerance Is Set. For RACs That Are Only Livestock Feed Items, A 50% Reduction In The Number Of Trials Can Be Applied.
      - No: Conduct Radiotracer Study
        - OR: Conduct FTIs for Tolerance Setting
    - No: TRR/ROC <5 ppb in All RACs (food and feed) In 1X Radiotracer Study?
      - Yes: NF, No Additional Data Required. No Tolerances Required.
      - No: OPTIONAL for Both Food/Feed Items: ROC <LOQ in Three 5X Field Trials? (Assumes Adequate Plant Metabolism Data Available to Determine ROC)

For Food Use, Field Trial Data (1X) Required For All RACs In Which ROC ≥5 ppb in the Radiotracer Study. Tolerances Set (LOQ Level for RACs in Which ROC <5 ppb). For RACs that are Only Livestock Feed Items, a 50% Reduction in the Number of Trials can be Applied. Note that Livestock Metabolism (and Possibly Feeding) Studies Will Be Required and that Adequate Plant Metabolism Should Be Available.

Food Use, No Additional Data Required. Tolerances Set at LOQ Level for All RACs.

Definitions:
- NF: Non-Food
- LOQ: Limit of Quantification
- ROC: Residues of Concern
- Note that if there is no characterization/identification of the TRR (total radioactive residues), then the ROC = TRR.

Notes:
1) For highly toxic chemicals, the 5 ppb ROC threshold value may be reduced.
2) If the ROC are <5 ppb in radiotracer studies conducted on five representative crops (small grain, radish or garden beets (analyse both root and tops), leaf lettuce, soybeans, and a short season fruiting or crucifer vegetable), then seed treatment uses on all crops will be considered NF; 3) if the ROC in wheat forage, hay, grain, and straw are all <5 ppb, then the seed treatment can be considered nonfood for the following crops: wheat, barley, oats, rye, triticale, buckwheat, sorghum, rice, and millet. Also, if the ROC is <5 ppb in all wheat and corn RACs, then uses on all cereal grains can be classified as NF; 4) For uses on soybeans and peanuts (or other legumes that are not grown as livestock feeds) where ROC >5 ppb in soybean forage/hay and peanut hay, but <5 ppb in seeds or nuts/muts, the uses are classified as food uses and field trials required unless the petitioner chooses to restrict feeding of the foliage parts of these crops. This restriction would eliminate the need for crop field trials on the foliage, but a LOQ-level tolerance would still be needed for the seeds or nuts/muts; 5) if tolerances are needed, then a validated enforcement method will always be required; 6) A minimum of three trials are required for tolerance setting; 7) In cases where field trials are waived for a human food RAC, a processing study will also not be required.
Conducted case study to illustrate potential savings resulting from use of the decision trees

Considered three different seed-treatment petitions for the chemical sedaxane

The following savings were estimated based on the application of the decision trees

- 109 field trials waived
- 40 field trials with reduced data requirements
- Five processing studies waived
EPA has released a memo that outlines reduced residue chemistry data requirements for seed-treatment uses:
- All crops excluding potato seed-piece treatments
- Potato seed-piece treatments

The reduced seed-treatment data requirements are now in effect.

The changes in seed-treatment residue chemistry data requirements will save both petitioners and the Agency considerable resources while still obtaining the data necessary to support pesticide registrations and conduct human health risk assessments.
Useful Links

- Reduced Residue Chemistry Data Requirements for Seed-Treatment Uses Memo
  - [https://www.epa.gov/pesticide-registration/determining-number-field-trials-required-register-seed-treatment-uses#reduced-residue](https://www.epa.gov/pesticide-registration/determining-number-field-trials-required-register-seed-treatment-uses#reduced-residue)

- Series 860 Residue Chemistry Test Guidelines
Questions?