**B.7.7 Effects of Industrial Processing and/or Household Preparation**

**(Annex IIA 6.5; Annex IIIA 8.5)**

**B.7.7.1 Nature of the Residue**

 **(Annex IIA 6.5.1; Annex IIIA 8.5.1) –** *Not a data requirement in North America*

**B.7.7.2 Distribution of the Residue in Peel/Pulp**

 **(Annex IIA 6.5.2; Annex IIIA 8.5.2)**

 To be included if available.

**B.7.7.3 Magnitude of Residues on Set of Representative Processes**

 **(Annex IIA 6.5.3; Annex IIIA 8.5.3)**

B.7.7.3.1 [CROP 1]

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OECD Guideline 508 Magnitude of the Pesticide Residues in Processed Commodities (October 2008)

**GLP Compliance:** [No or Significant] deviations from regulatory requirements were reported which would have an impact on the validity of the study. [If “Significant,” then explain below the deficiencies and their impact on the acceptability of the study]

**Acceptability:** The study [is/is not] considered scientifically acceptable. [If not acceptable, then explain why below]

**Evaluator:** [Name of regulatory person who reviewed the study]

**EXECUTIVE SUMMARY**

A [crop] field trial for [active ingredient] was conducted in Canada and/or the United States during the [year] growing season. [Active ingredient, % ai, formulation type] was applied to [crop] at [rate of application lbs ai/A (xx g ai/ha)], and harvested xx days after final treatment. The [RAC samples] were processed into [processed food/feed fractions] using [simulated commercial practices].

All samples were frozen at the testing facility and remained frozen during shipping and storage prior to processing and analysis. The maximum storage interval for samples was [xx] days/months [specify period from harvest to processing and from processing to analysis]. Storage conditions and durations are supported by studies showing that residues of [active ingredient] are stable in [crops/processed commodities] for up to [xx] days under frozen conditions.

Samples in the current study were analyzed using Method [Method ID], a [describe method] method to determine residues of [list analytes]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] mg/kg (ppm), thus validating the method. The limit of quantitation (LOQ) was [xx] ppm per analyte for [matrices].

A comparison of the residues in the raw agricultural commodity (RAC) with those in each processed fraction resulted in processing factors of [processing factors] for [processed fractions], respectively. These processing factors [conform/did not conform] with the theoretical concentration factors.

[Include this section only if the "GLP Compliance" prompt above is answered "Significant deviations from regulatory requirements were reported."]

**COMPLIANCE**

The following deviations from GLP requirements were reported: [list].

[Include this section only if the "Acceptability" prompt above is answered "The study is not considered scientifically acceptable."]

**STUDY DEFICIENCIES**

Under the conditions and parameters used in the study, the data are classified as scientifically unacceptable. [Explain the deficiencies and their impact on the acceptability of the study.] The study [can or cannot] be upgraded by submission of additional information; if “can be,” then list the additional data required.

**I. Materials and Methods**

**A. Materials**

|  |
| --- |
| **Table 7.7.3.1-1. Nomenclature for [Active Ingredient] and Metabolites of Interest.** |
| **Common name** | (active ingredient) |
| **Identity** | [CAS Chemical Name] |
| **CAS no.** |  |
| **Company experimental name** |  |
| **Other synonyms (if applicable)** |  |
|  |
| **Metabolite X** | (for each analyte) |
| **Identity** | [CAS Chemical Name] |
| **CAS no.** |  |
| **Company experimental name** |  |
| **Other synonyms (if applicable)** |  |

**B. Study Design**

**1. Test Procedure**

Location and detailed use pattern for the trial is provided in Table B.7.7.3.1-2.

| **Table B.7.7.3.1-2. Study Use Pattern.** |
| --- |
| Location: City, State/Province; Year(Trial ID) | End-use Product/ Formulation (% ai) | Method of Application/ Timing of Application | Volume(gal/A)[L/ha] | Rate per Application(lbs ai/A)[g ai/ha] | Retreatment Interval (days) | Total Rate(lbs ai/A)[g ai/ha] | Surfactant/ Adjuvant |
|  |  | 1. |  |  |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |

Bulk samples (~xx lbs (kg) each) of untreated and treated [RAC] were harvested at maturity and transferred to the processing facility for preparation of [list processed commodities]. [RACs] were processed using simulated industrial practices.

**Sample Handling and Preparation**

[Briefly describe how samples were handled after harvesting (shipment, storage, etc.) and processing (storage conditions and durations) as well as any preparation that was done prior to extraction.]

**Sample Processing**

[Briefly describe how the RAC was processed into the processed commodity(ies). Include the processing flow chart if it is the clearest way to describe processing.]

**2. Description of Analytical Procedures**

Samples of [crop] were analyzed for residues of [analyte(s)] using the Analytical Method [ID# and Title]. [Indicate if the method was previously reviewed and/or validated and for what commodities.]

[Reference study summary if method is described in the B.5.2 section of this review, or provide a description similar to that below if it is a different method.]

Briefly, samples were extracted with [solvent system]. Extracts were cleaned up using [SPE column, partitioning, etc.] and a portion of this extract was analyzed for residues of [list analytes] using [describe instrument/detector system]. The LOQ was xx ppm for each analyte. [State the LOD if available and how the LOQ and LOD were determined.]

**II. RESULTS AND DISCUSSION**

Method performance was evaluated [during method validation and] by use of concurrent recovery samples by fortifying [matrix] at [xx] and [yy] ppm. [n] samples of [crop matrix] were fortified at [xx] ppm and individual recoveries ranged from [xx]% to [yy]% with a standard deviation of [xx]%. [n] samples of [crop matrix] were fortified at [yy] ppm and individual recoveries ranged from [xx]% to [yy]% with a standard deviation of [xx]%. All recoveries were within the acceptable range of 70% to 120%; therefore, the method was considered valid for the analysis of [active ingredient and metabolites] residues in [crop] matrices (Table B.7.7.3.1-3)). [Note Table B.7.7.3.1-3 should only be included if recoveries are outside the acceptable range.] The fortification levels [did/did not] bracket the measured residues.

The detector response was linear (coefficient of determination, r2 >[xx]) within the range of [concentrations]. Representative chromatograms of control samples, fortified samples and treated samples were provided. The control chromatograms generally had no peaks of interest above the chromatographic background. [The fortified sample chromatograms contained only the analyte of interest, and peaks were symmetrical and well defined.] or [Residues in controls were ≤xx ppm. The reported residue values [were/were not] corrected for apparent residues in controls.]

|  |
| --- |
| **Table B.7.7.3.1-3. Summary of Procedural/Concurrent Recoveries of [Active Ingredient] from [Matrix]1.** |
| Matrix | Fortification Level (ppm) | Recoveries(%) | Mean ± Std. Dev.(%) |
| [Analyte] |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1 This table should be included only if recoveries are consistently outside the acceptable range.

The processed samples were stored frozen a maximum of [xx days/months] from harvest to analysis [may need to specify between harvest and processing and processing and analysis] (Table B.7.7.3.1-4). [Table B.7.7.3.1-4 should only be included if storage stability data are not included in B.7.6.2, if it is included elsewhere in the document, then just cite location in monograph.]

The available freezer storage stability data indicate that residues of [active ingredient and metabolites (if applicable)] were stable when stored frozen at ≤-20°C in [crop(s)/processed commodities] for up to [demonstrated period]. [Indicate if the freezer storage stability data were previously reviewed and report the demonstrated storage intervals for each matrix/analyte]; or

Freezer storage stability data were generated concurrently with the [crop] processing study. [Note: A summary table of these results should be inserted here.] Data showed that [active ingredient and metabolites (if applicable)] residues were stable in [matrices] under frozen storage for the duration of the storage period.

|  |
| --- |
| **Table B.7.7.3.1-4. Summary of Storage Conditions1.** |
| Matrix(RAC or Extract) | Storage Temperature (°C) | Actual Storage Duration(days/months) | Interval of Demonstrated Storage Stability[specify crop/matrix if different](days/months) |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1 Delete this table if storage stability addressed in B.7.6.2.

Residues found in samples and processing factors are given in Table B.7.7.3.1-5.

|  |
| --- |
| **Table B.7.7.3.1-5. Residue Data from [RAC] Processing Study with [Active Ingredient].** |
| Commodity | Analyte | Residues (ppm) | Processing Factor1 | Median Processing Factor2 |
| RAC |  | Rep 1 | -- | -- |
| Rep 2 |
| Processed Fraction 1 |  | Rep 1 |  |  |
| Rep 2 |
| Processed Fraction 2 |  | Rep 1 |  |  |
| Rep 2 |

1 Note to evaluator/reviewer: Always calculate a separate processing factor for each analyte and processed commodity.

2 Calculate in cases where multiple samples of RAC are processed independently.

**III. CONCLUSIONS**

The [crop] processing study is considered scientifically [acceptable or unacceptable]. [Note: adjust the following statement as appropriate.] A comparison of the residues in [RAC] with those in each processed [crop] fraction indicated that residues of [active ingredient] concentrate in [processed fraction] (average processing factor of x), but do not concentrate in any of the other processed commodities of [crop]. [Also, specify for metabolites if applicable.] Adequate storage stability data are available to support sample storage durations and conditions.

[Note: Also, address the following question - How do the empirical processing factors compare to theoretical factors based on loss of water or separation into components?]

**REFERENCES**

[Cite references for analytical methods and freezer storage stability studies. Include the EPA MRID# and the PMRA# of both the study and the review (if available)].

B.7.7.3.2 [CROP 2]

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**Acceptability:** The study [is/is not] considered scientifically acceptable. [If not acceptable, then explain why below]

**Evaluator:** [Name of regulatory person who reviewed the study]

**[Repeat previous sections, modify as appropriate.]**

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