

**Section 12 Notice                      Additional Information Required to Fulfill the Terms and Conditions for Conditional Registration**

***Product Name:***                      *Scala SC Fungicide*  
***Registration Number:***            *28011*  
***Application Number:***            *2007-1409*  
***PMRA #***                                *1590453*

During the temporary registration period, the following information is to be generated and must be provided to the Agency by **December 1, 2008**. Data submitted should indicate the reference numbers specified below. A partial response to the outlined Terms and Conditions will not be accepted.

**PART 7                      FOOD, FEED AND TOBACCO RESIDUE STUDIES**

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**DACO:**                                7.2.2  
**Title:**                                Enforcement Analytical Methodology - Livestock Matrices

**Deficiency:**                        Method RAM AN/0101 Version 2 is not very robust with recoveries above the acceptable range of 70 - 120% in milk and muscle and below the acceptable range in kidney. Based on the submitted recovery data, Method RAM AN/01/01 Version 2 (or RAM AN/01/02) is considered **conditionally acceptable** in livestock matrices.

**Required Data:**                    **For Method RAM AN/0101 Version 2 (or RAM AN/01/02) to be considered as the enforcement method in livestock matrices, the registrant must provide the following:**

**1) Information describing the various conditions that may be implemented to optimize Method RAM AN/01/01 Version 2 (or RAM AN/01/02) recoveries in livestock matrices.**

**2) New recovery data validating the implemented changes to the method in livestock matrices.**

**DACO:** 7.2.5  
**Title:** Storage Stability of Working Solutions

**Deficiency:** The rationale to waive the requirement for additional storage stability of working solutions under DACO 7.2.5 to satisfy the Canadian requirements (as per DIR98-02) **is considered unacceptable** as the supporting data provided by the registrant could not be found in the following referenced report: Dacus, S.C. (2001), “*Radio-Validation of the Analytical Method DGM C05/98-0 for the Determination of Pyrimethanil in Fruits and Vegetables Using Lettuce Treated with <sup>14</sup>C Labelled Pyrimethanil*”, Aventis CropScience, Residue Chemistry Department, Study No. AN00R002, Document No. B003142, April 18, 2001.

**Required Data:** **Data illustrating the storage stability of working solutions must be submitted.**

**DACO:** 7.3  
**Title:** Freezer Storage Stability - Processed Commodities

**Deficiency:** The freezer storage stability of pyrimethanil residues in apple processed commodities was not demonstrated over the freezer storage interval of 200 days.

**Required Data:** **Freezer storage stability data demonstrating the stability of pyrimethanil residues in apple processed fractions must be submitted to validate the freezer storage intervals of the processed samples.**

**DACO:** 7.3  
**Title:** Freezer Storage Stability - Livestock Matrices

**Deficiency:** Storage stability data depicting the freezer storage stability of pyrimethanil and the two metabolites AN2 (AE C614276) and AN3 (AE C614277) in milk and livestock tissues as per DIR98-02 for samples that were stored for more than 30 days were not demonstrated.

**Required Data:** **Freezer storage stability data demonstrating the stability of pyrimethanil and the two metabolites AN2 and AN3 residues in milk and livestock tissues.**

**DACO:** 7.4.1  
**Title:** Supervised Residue Trials - Apples

**Deficiency:** To support the regional registration of Scala SC Fungicide in/on apples in Quebec and Ontario for the combination of an early season application and a late season application (2.4 kg a.i./ha/season) with a PHI of 14 days, four trials in Zone 5 and three trials in Zone 5B are required as per DIR98-02. Only three trials in Zone 5 and three trials in Zone 5B were submitted.

**Required Data:** **One supervised residue trial in/on apples conducted in Zone 5 according to label directions.**