Health Canada Santé Canada

Subsection 16(3) **Announcement of Initiation of Re-evaluation**

Active Ingredient: Rotenone

Reference Number: 2024-0031

Date Sent: 25 January 2024

Health Canada's Pest Management Regulatory Agency (PMRA) has sent a notice to registrants as per subsection 16(3) of the *Pest Control Products Act* (PCPA). The following is a summary of the notice.

The PMRA re-evaluates older active ingredients and their uses to determine their continued acceptability in light of current regulatory standards. Rotenone is now under re-evaluation as per paragraph 16(2)(*a*) of the PCPA.

As one of the initial steps, the PMRA will consider the assessments underlying recent consultation and decision documents (for example, Evaluation Reports, Proposed Registration or Registration Decision documents) in order to determine whether these address the entire use pattern or whether any areas need to be updated to meet current standards.

Information Requested from Registrants

I. Registrants are provided with the opportunity to indicate if they wish to voluntary discontinue uses or products that they do not support for continued registration.

II. Registrants of technical grade active ingredient products who support the re-evaluation are asked to provide a list of all available studies, including ones planned or in progress relevant to the re-evaluation of rotenone and its registered uses.

III. Registrants of technical grade active ingredient products who support the re-evaluation are asked to provide:
- DACO 2.11: Manufacturing Methods
- DACO 2.12: An updated Statement of Product Specification Form

Form and Timeframe for Submission of Requested Information

- Item I: If the registrant chooses to voluntarily discontinue any uses or products, it must be provided within 30 calendar days. If no response is received following the 30-calendar day deadline, all uses and products will be considered in the re-evaluation.

- Items II and III must be submitted within 30 calendar days.

- Item II (list of available studies) must meet the requirements indicated in the template provided. If the study list submitted does not meet these requirements, registrants will be required to re-submit in the required format within 15 days. PMRA will consider the list of available studies as part of the scoping phase of the re-evaluation for establishing data requirements. If it is determined there are studies for which an executive summary is needed, registrants will be asked to provide requested executive summaries within 60 days.

- Information must be included in an electronic index. Any confidential business information (CBI, as defined in subsection 2(1) of the PCPA) should be designated and segregated according to PMRA guidance.

Registrants to whom the Notice Was Sent

WELLMARK INTERNATIONAL D.B.A. CENTRAL LIFE SCIENCES