



February 6, 2024

Via Electronic Mail

Ms. Ewa Madey, National Manager Canadian Food Inspection Agency Fertilizer Safety Section 59 Camelot Dr Ottawa ON K1A 0Y9 CANADA

SUBJECT: Section 7 of the Fertilizers Regulations, Ingredient Source Change Inquiry (ISCI) and Major

Amendments

Dear Ms. Madey:

Thank you for the opportunity to comment on the subject Ingredient Source Change Inquiry (ISCI) and Major Amendments to Section 7 of the Fertilizers Regulations. The Biological Products Industry Alliance (BPIA), Fertilizers Canada and the Fertilizer & Supplement Advisory Committee submits herewith these comments."

By way of introduction, BPIA promotes the responsible development of safe and effective biological products including biopesticides and biostimulants. These beneficial tools are used in a variety of settings, including commercial agriculture, forestry, golf courses, home gardens, horticulture, and ornamentals. BPIA also supports public health through education, outreach, and advocacy activities at the state, federal and international levels. BPIA's membership includes both large and small producers of biological pest control products and biostimulants used extensively by US farmers, including organic growers, as well as producers of pesticide inert ingredients.

BPIA understands that Section 7 of the Fertilizers Regulations states that a person shall not change the label, chemical composition or ingredients of a registered fertilizer or supplement if the change can be expected to affect its performance, safety, or use as a fertilizer or supplement, unless the registration is amended accordingly. While the New Regulations: Guide to Submitting Applications for Registration under the Fertilizers Act Fertilizer Safety, Section 2.3.1.1 provides that "Multiple sources of an ingredient may be identified at the time of product registration and used interchangeably during the manufacture of the product." it also advises that "... any changes to the ingredients, their sources or their supplier(s) or changes to the formulation after registration require a major amendment unless the CFIA first approves a submitted notification of source change."

Our members have noted challenges in efficiently meeting the requirement to provide the names and addresses of the suppliers of each inert ingredient in circumstances where the inert supplier could change due to pricing, supply chain, and or geopolitical issues. Under the current policy, if a Registrant uses a commodity formulant that can be sourced from any number of suppliers and needs to change the supplier, the registrant must submit an *Ingredient Source Change Inquiry (ISCI)* as detailed in Section 4.5 of **T-4-122 – Service delivery standards for fertilizer and supplement registration-related submissions under the Fertilizers Act and regulations** for an assessment by the CFIA to either approve the source change or submit a major amendment. While the ISCI process has a 30-day service delivery standard, the continuing challenges and risks of the global supply chain often require much quicker response and flexibility than a 30-day ISCI can afford.

Acknowledging the very high workload and demands on CFIA resources, BPIA would like to suggest another option for consideration. BPIA proposes allowing changes to suppliers of ingredients included on the *List of Primary Fertilizer* and Supplement Materials and inert ingredients for commodity chemicals (chemicals of known composition covered by a single CAS number for which there are many sources) without submission of a ISCI. Providing an exemption from notification of supplier changes for ingredients on the *List of Primary Fertilizer and Supplement Materials* and commodity chemicals is reasonable and poses little risk to human or environmental safety. These materials are manufactured globally on a large scale using standardized manufacturing methods with well-defined standards for chemical composition including allowable levels of impurities, and have a well-understood risk profile. As such, allowing a change of supplier for ingredients on the *List of Primary Fertilizer and Supplement Materials* and

Ms. Ewa Madey, CFIA-FSS

Page 2 of 2

commodity inert ingredients can be reasonably expected not to affect the performance, safety, or use of a fertilizer or supplement.

Adopting this option will reduce the regulatory and administrative burden on regulated parties due to the reduction in time and effort required to collect, process, and complete forms, and report on changes about formulant suppliers. Allowing this exemption would also be aligned with the recent November 2022 changes to the Pest Control Products Regulations that removes the requirement to provide notification to the PMRA for changing or adding suppliers of inert ingredients and requires only recording keeping of the names and addresses of the respective formulant suppliers. The PMRA notification exemption for suppliers of commodity chemicals has been in place since 2016 under Regulatory Directive DIR2016-02, Notification/Non-notification.

BPIA further proposes that this policy can be implemented through a "Notice to Industry" to allow suppliers of formulants may be changed without an ISCI provided that the registrant:

- i) Keep records of the name and address of the supplier of each formulant.
- ii) Keep copies of the supplier records for five years after the date of the product's registration, amendment, or renewal, as applicable.
- iii) Provide any supplier records to the CFIA-FSS within the period specified in the request.

We appreciate the opportunity to comment on the CFIA-FSS ISCI policy. Should you have any questions about this response, please feel free to contact me.

Sincerely,

BIOLOGICAL PRODUCTS INDUSTRY ALLIANCE

Keith J. Jones Executive Director

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