CFIA WEBINAR SERIES: SAFETY STANDARDS AND ASSESSMENT LEVELS

Questions raised at the January 28, 2021 Webinar

Q1: Is the boron cautionary statement (>0.3%) required on customer-formula fertilizer labels?

A1: The boron precautionary statement "may damage fertility or the unborn child" or its equivalent is required for all products containing ≥ 0.3% boron including customer-formulated fertilizers.

Q2: Will new microbials be added to the level 1 list?

A2: The Guide for submitting applications for registration under the *Fertilizers Act* describes in detail the registration requirements. Currently, the Level 1 safety assessment includes only those microorganisms that 1) have undergone a comprehensive safety assessment based on current, publically available scientific literature and 2) have a well-established history of safe use in fertilizers and supplements. These include:

- VAMs (Vesicular Arbuscular Myccorhizae) provided the species is substantially equivalent/representative of the VAM group
- Rhizobia (species of the genera *Rhizobium*, *Bradyrhizobium*, *Mesorhizobium* and *Sinorhizobium*) provided the species is substantially equivalent/representative of the rhizobia group, and is not genetically modified.
- *Bacillus subtilis* provided the strain is representative of the species, is not genetically modified and does not produce any human enterotoxin.

Microorganisms (other than those listed above) may be considered as candidates for Level I safety assessment after they are subject to a broad-based risk assessment supported by publically available (not proprietary) information and peer-reviewed scientific literature. If such assessment of the genus, species or strain is conducted, submitted and approved by the CFIA the microorganism can be evaluated in accordance with level 1 safety requirements. It is important to bear in mind that:

1) The assessment has to be made public on request and substantiating data will not be protected as CBI
2) The basic requirements still have to be met when submitting for registration including disclosure of the source/ origin of microbial strain, the culture; manufacturing process and Quality Control/ Quality Assurance (QA/QC) procedures.
3) Taxonomic ID data verifying the identity of the strain and its substantial equivalence of the respective group
4) Results of analysis or rationale attesting to the free from pathogen contamination

Please note that genetically modified organisms are considered novel and require a level III assessment

Q3: What is the timeline for the different levels of review (1,2,3)?

A3: The Service Delivery Standards vary by application type due to the nature and complexity of the assessment required which accounts for the levels of safety assessments. The file review procedures and associated timeframes (Service Delivery Standards, SDS) for all registration related applications regulated by the Canadian Food Inspection Agency (CFIA) under the *Fertilizers Act* and regulations (new registrations, re-registrations, major and minor amendments) are described in Trade Memorandum T-4-122: Service Delivery Standards for Fertilizer and Supplement Registration.

Q4: How can someone get a copy of the presentation?

A4: The PDF copies of the presentations will be shared with all participants, in both official languages, by email after the webinar together with the transcript of the questions and answers Also, the Fertilizer and Supplement Advisory Committee (FSAC) will be posting all webinar presentations on their website.

Q5: Can you list "other" tests you may require so that time is not lost after Review Letter #1. For example, we had submitted a biochar document and we were asked to analyze PAH - and we weren't provided which ones. This slowed the process and we spent a couple of days trying to determine which PAH's we needed to test.

A5: The CFIA strives to outline all submissions requirements in the guidance material. Unfortunately there is no mechanism within the review process to identify additional requirements prior to the first review. The first review is a stage at which the contents of a submission are assessed. This assessment may identify information gaps and trigger requests for clarification, additional information, or results of analysis. The CFIA does not maintain a list of specific contaminants to be tested for – there is simply too much variability and the supplemental data requirements are based on product-specific characteristics, ingredients and their sources, hazard profile, intended use pattern etc. Please contact the safety evaluator responsible for your file to discuss details should there be a request for additional data which creates confusion.

Q6: If I have a fertilizer+ phosphite product for lawn and turf, do I need to register? Do I need to register the phosphite first with PMRA and then register the fertilizer+ phosphite product as fertilizer-pesticide?

A6: Phosphites are not plant available sources of P and as such do not meet the definition of a fertilizer and are not (alone) eligible for registration under the *Fertilizers Act*. In cases where the phosphite is used as a carrier of another plant available nutrient (e.g. K or Ca), the phosphite is considered a pesticide and as such requires registration by the Pest Management Regulatory Agency (PMRA) under the *Pest Control Products Act* (PCPA). Registration of the phosphite component must occur prior to registration of the fertilizer/phosphite combination under the *Fertilizers Act*. Please note that the use of fertilizer-pesticides on lawn and turf was disallowed by the PMRA in 2012; only single ingredient dual property products such as corn gluten meal and ferrous sulphate are permitted. This decision does not apply to farm use fertilizer-pesticides.

Q7: A continuation to the fertilizer + phosphite on lawn and turf. If we use phosphite as a carrier for nutrients, do we still need to register phosphite with PMRA?

A7: Yes, the CFIA and the PMRA consider phosphites to be a pesticides and the phosphite component needs to be registered by the PMRA first before the fertilizer-pesticide combination is registered under the *Fertilizers Act*.

Q8: How are safety standards applied to products which are exempted from registration?

Another issue we have encountered, for example on wood ash. We have been testing for various ash labels for the past 10 years according to your list of requirements. After getting a different inspector, they requested 2 tests has never been asked. We need continuity between inspectors. It has nothing to do with the time as we had 2 ash renewals submitted at the same time. One company wasn't asked for the 2 new tests and the other company was asked for new tests. This also slows it down for CFIA.

A8: We are sorry to hear that but thank you for bringing it to our attention. The CFIA has a marketplace monitoring programs in place, to verify product compliance with prescribed safety and labelling standards. The monitoring inspections include :

- a review of a product's label to ensure it conforms with the labelling requirements,
- a product sampling and analysis to assess compliance with the appropriate safety standards, and
- review of records (list of ingredients, manufacturing method, results of analysis etc).

The CFIA strives to ensure that submission requirements are consistent across products and sectors. Similarly, efforts are being invested to ensure that inspectors across the various regions across Canada are provided with coordinated and comprehensive guidance and training to avoid situations that you just described. Should you observe such inconsistencies please bring them to our attention and we will action accordingly

Q9: How long does it take to obtain a response on a product Inquiry?

A9: The Information Request IQ can assist product applicants in generating appropriate data and information in support of product registration. When a product specific inquiry is received by the Fertilizer Safety Section, an applicant can expect to obtain a response from an evaluator within **30 working days**. The response provided will explain the categorization of the product under the *Fertilizers Act* and Regulations, as well as the requirements specific to that product type.

Q10: Maybe a question for the labeling session next week, but do you have a guide/memo on how you want certain precautionary statements worded? I know the USA is very specific on what words or series of words are used.

A10: The trade memoranda that an applicant can consult to obtain information regarding labelling requirements for fertilizers and supplements regulated under the *Fertilizers Act* and Regulations is T-4-130 – Labeling requirements for fertilizers and supplements. However, as indicated during the webinar presentations, the *Fertilizers Regulations* are largely outcome based which means that the goal or objective of mitigating risks of harm is outlined but the specific means to achieve the outcome are up to the product proponent and the Fertilizer Safety Section. The only specific word sets are prescribed for products containing Prohibited Material (in the

context of the Enhanced Feed Ban Regulation). Otherwise the exact wording is not mandated. Examples of precautionary statements were provided during the Labelling webinar (February 4th). However, the final text may vary between labels and products as long as it adequately and effectively delivers the message to the user.

Q11: Is there a tool/webpage, where we can find the microorganism safety level or the new compliance tool has that feature?

A11: A compliance verification tool that includes the functionality to verify compliance with pathogen limits is available from cfia.paso-bpdpm.acia@canada.ca upon request. It provides information regarding maximum acceptable level of indicator organisms in fertilizers and supplements, however, it does not include a feature that can indicate the biosafety level of the microorganism.

An applicant can consult the PHAC biological agent search tool, ePATHogen, which contains a searchable list of biological agents with their associated human and animal risk group classifications, as well as the applicable containment levels (CL), Security Sensitive Biological Agent (SSBA) status, regulatory authority, and containment considerations.

Another source that an applicant can consult is Organisms on the Domestic Substances List (DSL), maintained under the *Canadian Environmental Protection Act, 1999* (CEPA 1999) by the Government of Canada where hazard characteristics is used to rank the microorganism strains into various groups.

Among international resources American Type Culture Collection (ATCC) is a well-recognized culture collections where microorganisms are classified in various Biosafety Level (BSL) based on the associated risks. If a microorganism is obtained from ATCC, the Fertilizer Safety Section accepts product sheet provided by the ATCC as part of the safety assessment. The product sheet contains information about the taxonomic identity, origin, Biosafety Level (BSL), growth requirements and characteristics.

Q12: Based on section 9 (a)(ii) of the Fertilizers Regulations, would it be allowed to use in a fertilizer a bone meal source containing specified risk material that was treated in a manner approved by the Minister (in accordance with a permit issued under section 160 of the Health of animal regulations)?

A12: According to *Fertilizers Regulations* Section 16(1)(i), any fertilizers and supplements containing certain animal proteins known as prohibited material (described in the PART XIV (162) (1) of the *Health of Animals Regulations*) must be appropriately labelled, recorded and controlled. The details of the precautionary statements can be found in Guide for submitting applications for registration under the *Fertilizers Act*.

However, in accordance with PART XIV (162)(2) of the *Health of Animals Regulations* prohibited material that has been treated in a manner approved by the Minister to inactivate the agents that cause transmissible spongiform encephalopathies is no longer prohibited material. The output obtained as a result of using treatment method approved by the Minister (in accordance with permit issued under section 160 of the *Health of Animals Regulations*) is no longer considered either Specified Risk Material (SRM) or Prohibited Material (PM), therefore,

can be used in a fertilizer/ supplement. Such material is not required to meet labelling requirements as outlined in Section 16(1)(i) of *Fertilizers Regulations*

Q13: What testing methodology is required for testing dioxins and furans? Is there a CFIA resource which can help labs understand which methodologies to use and what detection limits are required?

A13: The new Guide to submitting applications for registration under the *Fertilizers Act* and the updated T-4-93 – Safety standards for fertilizers and supplements outline the compounds required to be tested for when performing analysis for dioxins and furans. The CFIA laboratory uses modified AAOC methodologies. If a stakeholder wishes to obtain a copy of the CFIA methodology, please submit a request to PASO at cfia.paso-bpdpm.acia@canada.ca.

The CFIA accepts equivalent methodologies and most frequently see results generated using EPA equivalent methodologies. Please ensure that the QA/QC are provided with the results of analysis as well as the detection limits.

The CFIA does not have specific standards for limits of detection or quantification for dioxins and furans. Similar to metals, the CFIA does require that the analysis be sensitive enough to demonstrate compliance with the CFIA safety/contaminant standards.

Q14: Is there a contact at the CFIA laboratories? I previously asked and they told me they were not able to share.

A14: We request that questions regarding methodologies or analytical procedures be directed to the Fertilizer Safety Section via PASO at cfia.paso-bpdpm.acia@canada.ca. We will coordinate the response and send it back to the requester.