



Canadian Food
Inspection Agency

Agence canadienne
d'inspection des aliments

The modernized *Fertilizers Regulations*

CFIA webinar series

► Safety standards and assessment levels ◀

January, 28, 2021



Outline



- Background and purpose
- Initial stakeholder feedback
 - November 17th Annual CFPF workshop
 - Topics of greatest interest – results of polling
- Today's webinar:
 - General prohibitions and safety objectives,
 - Safety assessments in support of registration under the *Fertilizers Act* – assessment levels,
 - Precautionary labelling,
 - Safety standards and numerical thresholds,
 - Questions,
 - Useful Links, and
 - Additional information – relevant guidance materials.

Background



- The modernized *Fertilizers Regulations* came into force on October 26, 2020 – the consolidated version of the Regulations is available:

New: <https://laws-lois.justice.gc.ca/eng/regulations/C.R.C., c. 666/FullText.html>

Old: <https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C c. 666/20150227/P1TT3xt3.html>

- The amendments to the Regulations introduced a number of substantive changes to:
 - product definitions and compositional criteria,
 - general exemptions,
 - the registration exemption scheme
 - labelling requirements
 - administrative processes
- The Regulations also contain transitional provisions that allow regulated parties to comply with either the “old” or the “new” Regulations for a period of 3 years

IMPORTANT NOTE:

Solid understanding of both sets of Regulations will facilitate your choice and ultimately promote compliance in the marketplace

General prohibition and safety objectives

General prohibition: *A person shall not manufacture, sell, import or export any fertilizer or supplement that contains a substance of mixture of substances in quantities that present a risk of harm to human, animal or plant health or the environment (except pests) when the product is used according to its directions for use or in an amount that is not in excess of the amount that is necessary to achieve its intended purposes. (section 2.1)*

Safety objectives – maintained

- **Residues** of a poisonous or harmful substance
- **Major plant nutrients, secondary nutrients or micronutrients that are present at toxic levels**
- **Proteins derived from specified risk material**
- **A pesticide** that does not comply with the requirements of the *Pest Control Products Act* in respect of the approved use and the application rate for that pesticide

★ CG II

“Commonly used amounts” = “In an amount that is not in excess of the amount that is necessary to achieve its intended purposes”



Safety assessments

- Some fertilizers and most supplements require pre-market assessment and **registration** prior to importation or sale in Canada.
- The principles of safety assessments under amended *Fertilizers Regulations* have not changed.



1. HAZARD ASSESSMENT

Identification and characterization of potential adverse effects on human, animal and plant health, and the environment.

2. EXPOSURE ASSESSMENT


Predicts the extent and duration of the exposure.

3. RISK ASSESSMENT

The risk assessment is based on the hazard, and what is known about exposure.

4. MITIGATION MEASURES

$$\text{Risk} = \text{Hazard} \times \text{Exposure}$$



Note: all ingredients (both active and inert) + potential contaminants and degradation products are considered when reviewing product safety.

Active ingredient means an ingredient of a fertilizer or supplement to which its performance as a fertilizer or supplement is attributed

Information and data requirements



Guide to submitting applications for registration under the *Fertilizers Act*

New regulations: <https://www.inspection.gc.ca/plant-health/fertilizers/registering-fertilizers-and-supplements/new-regulations-guide/eng/1601391948941/1601392244498>

Old regulations: <https://www.inspection.gc.ca/plant-health/fertilizers/registering-fertilizers-and-supplements/old-regulations-guide/eng/1456415167275/1456415380069>

Application structure and layout

Tab 1: Administrative forms and fees

Tab 2: Proposed marketplace label

Tab 3: Product specification

Tab 4: Results of analysis

Tab 5: Safety rationale and supplemental data



★ CG II

Text labels are permitted but the marketplace label is still required at the final stages of the registration process to ensure that the graphics, logos and marketing representations do not mislead the purchasers as to the approved use of the product

- **The submission layout is mandatory**, it greatly facilitates and expedites the review process
- **My CFIA:** <https://www.inspection.gc.ca/about-cfia/my-cfia/eng/1482204298243/1482204318353>

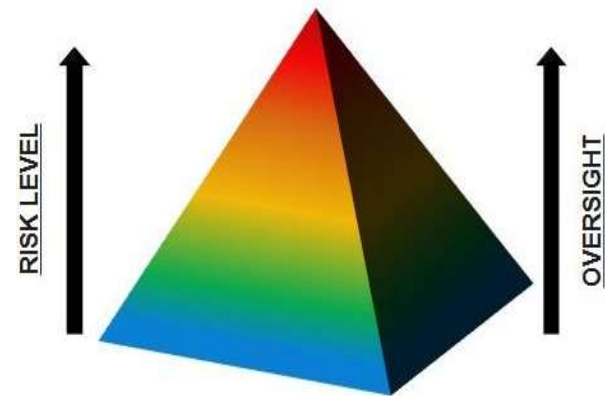
Levels of safety assessments

- Assessments are conducted on a **case-by-case basis**
- The safety data required depends on the nature of the product, associated hazards, use pattern, application rate, etc.
- To support of the amended *Fertilizers Regulations*, the CFIA implemented a tiered registration model (three levels of safety assessments) to align regulatory oversight with the risk profile of the product

Level I - products with well established history of safe use and a negligible risk profile

Level II - products with low risk profile that may be contaminated with chemical or biological agents

Level III - unknown or higher risk profile

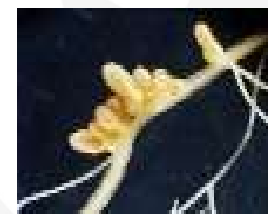
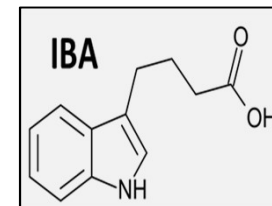


Level I

Core Information (Tabs 1, 2, 3)

Products with well established history of safe use and a negligible risk profile

- **Indole-3-butyric acid (IBA)** at a concentration not exceeding 1% of the product excluding products for spray application
- **VAMs** (Vesicular Arbuscular Mycorrhizae) provided the species is substantially equivalent/representative of 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.



Level II

Core Information + Analysis (Tabs 1, 2, 3, 4)

For products with well established history of safe use, negligible risk profile but may contain chemicals or biological agents of concern

Metals

- Silica

Metals and Dioxins and Furans

- Micronutrients*, mineral derived nutrients*, cement by-products⁺, biochar, and ash

* Dioxins and furans requirement is source dependent

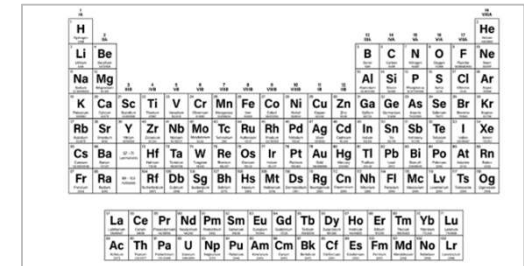
⁺ Require Thallium and Vanadium testing in addition to the analysis of the 11 standard metals

Metals, Dioxins and Furans, and Indicator Organisms

- Fertilizer and supplement products containing biosolids, and pulp and paper sludge

Metals and Indicator Organisms

- Plant extracts and residues (for example seaweed), Fertilizer and supplement products containing, compost, meals (for example seed, fish, bone), organic waste products



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K	Ca	Sc	Ti	V	Cr	Mn	Fe	Co	Ni	Cu	Zn	Ga	Ge	As	Se	Br	Kr	Rb	Sr	Y	Zr	Nb	Mo	Tc	Ru	Rh	Pd	Ag	Cd	In	Sn	Sb	Te	I	Xe	Cs	Ba	Hf	Ta	W	Re	Os	Ir	Pt	Au	Hg	Tl	Pb	Bi	Po	At	Rn	Fr	Ra	Rf	Db	Sg	Bh	Hs	Mt	Ds	Rg	Cn	Nh	Fl	Mc	Lv	Ts	Og																													
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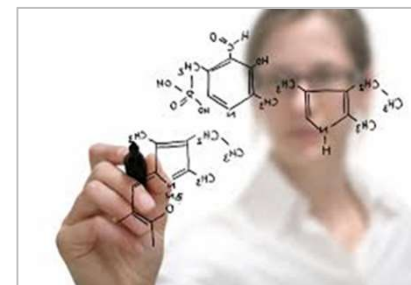
Level III

Core Information + Analysis + Safety Data (Tabs 1, 2, 3, 4, 5)

Products with a higher or unknown risk profile necessitate a full safety assessment

Safety Rationale and Supplemental Data

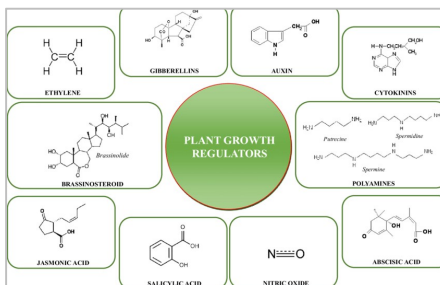
- Polymer coated fertilizers & Polymeric soil stabilizers
- Wetting agents and surfactants
- Nano-encapsulated fertilizers and nano-materials
- Plant growth regulators and Plant signalling compounds (for example Gibberellin, Cytokines, NAA, LCOs, Salicylic Acid, etc.



Metals, Dioxins and Furans and Safety Rationale and Supplemental Data

- *Registerable supplement(s) that would themselves require a full safety data package, blended with fertilizer.

*ingredient dependent



Level III - Continued

Core Information + Analysis + Safety Data (Tabs 1, 2, 3, 4, 5)

Indicator Organisms and Safety Rationale and Supplemental Data

- Viable microorganism(s) other than *Rhizobia* and *Bacillus subtilis*
- Microorganisms modified by molecular biological techniques
- Microbial Consortium
- Metabolites of organism(s): Supernatant

Microbial consortium means a complex community of microorganisms that is taken from a single natural environment and whose composition is **maintained without further manipulation**



Precautionary labelling

Any precautionary statement that is necessary to mitigate a risk of harm to human, animal or plant health or the environment

If any person requests a document in English or in French that lists the ingredients that are contained in a fertilizer or supplement that present a risk of harm to the health of ANY human or animal that do not appear on the label the document shall be provided by:

- a) the person who packaged it or caused to be packaged, or
- b) the person who caused it to be imported

What does that mean?

This provision is intended to protect consumers that are immunocompromised, hypersensitive or allergic from exposure risks that would result in adverse health reactions



Precautionary Statements

Precautionary statement requirements based on active ingredients in the fertilizer or supplement product

- Viable microorganisms
- Supplemental metal (such as cobalt, nickel, silicon)
- Boron, copper, iron, manganese, molybdenum or zinc
- Boron content greater than or equal to 0.3% of the final product

Precautionary statement requirement for specific materials which may be included in/as fertilizer or supplements

- Priority allergens: peanuts, tree nuts, sesame seeds, milk, eggs, fish, crustaceans and molluscs, soy, wheat and triticale, sulphites and mustard.
- Prohibited material as defined in subsection 162(1) of the *Health of Animals Regulations*

Precautionary statement is one of the preventative risk mitigation measure, along with safe handling, disposal measures, use pattern restrictions (e.g. do not use on food crops or grazing lands).



Safety Standards -Trade Memorandum T-4-93

- The results of analysis required in support of a registration vary depending on **product type** and the **source of ingredients**
- The Fertilizers Regulations (both “old” and “new”) are outcome based
- Actual standards and numerical thresholds are maintained in program policy documents (Trade Memorandum) that can be updated as new science comes to light and manufacturing practices change

T-4-93 – Safety standards for fertilizers and supplements

<https://www.inspection.gc.ca/plant-health/fertilizers/trade-memoranda/t-4-93/eng/1305611387327/1305611547479>

Note: A compliance verification tool is available upon request from cfia.paso-bpdpm.acia@canada.ca upon request.

STANDARDS

METALS

- 45 year cumulative standard
- As, Cd, Co, Cu, Cr, Hg, Mo, Ni, Pb, Se, and Zn (Cement by-products V and TI)

MICRONUTRIENT TOLERANCES

- Concentration dependent

DIOXINS AND FURANS

- 45 year cumulative standard

INDICATOR MICROORGANISMS

- *Salmonella* and Faecal coliforms

Questions



Labelling and record keeping	General labelling requirements, product-specific labelling, sample labels, record keeping option, associated definitions and guidance materials	Thursday February 4, 2021 from 11 am to 12 pm (EST) Register online
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CONTACT INFORMATION:

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USEFUL LINKS

CFIA Fertilizers

<https://www.inspection.gc.ca/plant-health/fertilizers/eng/1299165827648/1299165914316>

Fertilizer regulations

New regulations: https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._666/FullText.html

Old regulations: https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._666/20150227/P1TT3xt3.html

My CFIA

<https://www.inspection.gc.ca/about-cfia/my-cfia/eng/1482204298243/1482204318353>

Guide to submitting applications for registration under the Fertilizers Act

New regulations: <https://www.inspection.gc.ca/plant-health/fertilizers/registering-fertilizers-and-supplements/new-regulations-guide/eng/1601391948941/1601392244498>

Old regulations: <https://www.inspection.gc.ca/plant-health/fertilizers/registering-fertilizers-and-supplements/old-regulations-guide/eng/1456415167275/1456415380069>

USEFUL LINKS - continued

List of Primary Fertilizer and Supplement Materials

<https://www.inspection.gc.ca/plant-health/fertilizers/regulatory-modernization/list-of-primary-fertilizer-and-supplement-material/eng/1533213691120/1533213691867>

Trade Memorandum

<https://www.inspection.gc.ca/plant-health/fertilizers/trade-memoranda/eng/1299873703612/1299873786929>

T-4-93 – Safety standards for fertilizers and supplements

New regulations: <https://www.inspection.gc.ca/plant-health/fertilizers/trade-memoranda/t-4-93/eng/1305611387327/1305611547479>

Old regulations: <https://www.inspection.gc.ca/plant-health/fertilizers/trade-memoranda/t-4-93/eng/1305611387327/1305611547479#details-panel20>