List of Primary Fertilizer and Supplement Materials: Change Request Form

To initiate a change request, please complete this form and submit it along with all attachments (electronic copies ONLY) to:

Fertilizer Safety Section
c/o Pre-market Application Submissions Office (PASO)
Canadian Food Inspection Agency
cfia.paso-bpdpm.acia@inspection.gc.ca

SECTION I – APPLICANT AND CHANGE REQUEST DETAILS

Requester information	
Name of the requester	
Affiliation/company	
Email address	
Telephone number	
Date of submission (yyyy-mm-dd)	

Change request

Proposed modification

☐ Addition ☐ Deletion ☐ Amendment (term change and/or change to the definition)
Based on this response, please populate the corresponding field below.
Fields that do not apply should be left empty.

Addition: proposed new term and definition

New term
English:
French:
New definition
English:

French:

**please note that it is required to fill this field in BOTH official languages*

Deletion: term and definition proposed for deletion

Term to be deleted
English:
French:
Definition to be deleted
English:

French:

**please note that it is required to fill this field in BOTH official languages*

Amendments: current designated term, definition and proposed changes

Current term

English:

French:

Proposed changes to the current term (if no change is proposed, please indicate "no change proposed")

English:

French:

Current definition

English:

French:

Proposed changes to the current definition (if no change is proposed, please indicate "no change proposed")

English:

French:

**please note that it is required to fill this field in BOTH official languages*

Rationale for the proposed change

List of stakeholder groups that could be affected by/benefit from the change

Potential impact on consumers, trade, regulated parties, and regulators

SECTION II – INFORMATION REQUIRED FOR APPLICATION PRIORITIZATION

All applications for amendments to the List of Primary Fertilizer and Supplement Materials are given a prioritization score. The information requested in this section will be used to determine the position/priority of the change request, within a ranked processing queue. The prioritization does not affect the safety assessment of the material.

Champion information

A champion is an individual willing to support the material through the prioritization process

Name of the champion	
Email address	
Telephone number	

Agronomic value

Please describe impacts of the material (direct or indirect) in terms of improving crop yield and quality, plant growth and development and/or benefits to soil health or fertility.

Agronomic value claims for a material must be supported by research data or peer-reviewed literature, wherever possible please indicate whether data provided is peer-reviewed, whether trials have been conducted and specify who the data was generated by. Please specify if supporting data is available from other jurisdictions.

All supporting documentation must be attached to this submission and listed in the field that follows.

Supporting documentation for Agronomic Value:
Please name these AV-1, AV-2 etc, and provide a brief description of each, here.

Sustainability value
Please describe how the material supports / aligns with the development and application of fertilizers and supplements that benefit current and future generations without harmful impacts to humans or ecosystems. Criteria taken into consideration for sustainability value are: • Equity and justice, with materials designed with engagement from potentially impacted communities to help avoid negative social impacts • Transparency, with health, safety, and environmental data disclosed and easier to access • Avoiding negative impacts on climate, biodiversity, and ecosystems by using renewable and non-toxic chemical building blocks and • Circularity, with materials designed to have a lifespan appropriate to their use that also enables safe reuse and non-toxic recycling Sustainability value claims for a material must be supported by research data or peer-reviewed literature, wherever possible please indicate whether data provided is peer-reviewed, whether trials have been conducted and specify who the data was generated by. Please specify if supporting data is available from other jurisdictions. *All supporting documentation must be attached to this submission and listed in the field that follows.*
Supporting documentation for Sustainability Value: *Please name these SV-1, SV-2 etc, and provide a brief description of each, here.*

Market Value

Please describe the market value of this material.

Criteria taken into consideration for market value are:

- Market size in North America
- Market trends (historical vs potential market value)
- Number of proponents or companies interested in the material and
- Competitiveness with other jurisdictions

Market value claims for a material may be approximated via research or data, can be determined by letters of support, number of companies with the material registered and/or comparison of regulatory requirements in other countries (competitiveness).

All supporting documentation must be attached to this submission and listed in the field that follows.

Supporting documentation for Market Value:
Please name these MV-1, MV-2 etc, and provide a brief description of each, here.

SECTION III-SAFETY RATIONALE/DATA

Material description

Name of the material and Chemical Abstracts Service Registry Number (CAS/RN) (if available and applicable)

Source of the material

Describe the source of the material (e.g.: chemical synthesis, harvested, fermentation, etc). Please include inputs, contaminants, residuals, reaction by-products and degradation products and their associated Chemical Abstracts Service number (CAS #), if available.

Physical/chemical properties

For example: granular, liquid, pH

Safety data and rationale

The safety rationale must be supported by research data or peer-reviewed literature, wherever possible please indicate whether data provided is peer-reviewed, whether research trials have been conducted and specify who the data was generated by. Please specify if supporting data is available from other jurisdictions.

Please see Appendix 1 for Hazard Assessment templates. Safety data may not be available for all endpoints listed in the Hazard Assessment template. Provide as much data as possible/available. The safety assessment for a List of Primary Fertilizer and Supplement Materials application will assess all possible fertilizing or supplemental uses of the material. If the safety of the material cannot be substantiated, the application may be declined or additional data will be requested prior to approval of the material.

All supporting documentation must be attached to this submission and listed in the field that follows.

Human Health Hazard

Please address potential Human Health Hazards including (but not limited to) applicator, bystander, and food.

Ecological Hazard Please address potential Ecological Hazards including (but not limited to) aquatic, terrestrial, avian, soil, and plant.
Persistence and bioaccumulation Please address potential persistence and bioaccumulation of the ingredient including endpoints such as biodegradation, environmental half-life (soil, water, air), bioaccumulation factor, and bioconcentration factor.
Impact on non-target organisms Please address any potential impacts on non-target organisms including (but not limited to) soil organisms, wildlife, birds, other plant species.
Risk assessments/information available from other jurisdictions

Supporting documentation for Safety Rationale:
Please name these SR-1, SR-2 etc, and provide a brief description of each, here.

If the material is not a pure substance that is identified with a distinct CAS/RN number, the following information will also be required to support the safety rationale:

Identification of any chemical contaminants and biological/microorganisms in the raw inputs used to produce the current/proposed material

Characterization of any microorganisms (in the case of microbial material)
Please include:

- Taxonomic identification of the microorganism to the genus and species level; subspecies, and strain information may also be required depending on the nature of the microorganism)
- Relationship to known pathogens (for example phylogenetic trees)
- Origin of the microorganism (when, where and from which material it was isolated) if it is an environmental isolate; or the strain bank accession number and culture certificate if the strain has been deposited in a recognized culture collection, for example American Type Culture Collection (ATCC) or other

If any chemical contaminants and biologicals/microorganisms remain following manufacturing/treatment, determine their levels in soil based on maximum agronomically relevant application rates
Compare soil concentrations of chemical or biological contaminants against existing standards

SECTION IV - AGRONOMIC RELEVANCE
International alignment (where applicable)
Consistency with well-established history of use and application patterns
Exposure scenarios relevant to the material and its use Please consider all potential fertilizing or supplemental uses for the ingredient including maximum agronomically relevant application rates with various application methods (soil, foliar, aerial, backpack sprayer, etc.).

To be filled by CFIA Evaluator:

EXECUTIVE SUMMARY
CONCLUSION
REFERENCES

Canada

Appendix 1:

List of Materials Hazard Assessment

This form is to be used as a guide and template for the hazard assessment of candidates for addition to the List of Primary Fertilizer and Supplement Materials. Providing all listed endpoints may not be possible for the specific material and is not required. Providing sufficient hazard data to substantiate the safety of the materials is required. When specific organism endpoints are not available, similar organisms can be used in their place. There is a Pre-screening Framework at the end of the document which categorizes the material based off persistence & bioaccumulation, hazard, and exposure potential.

Term:
English:

French:

Definition
English:

French:

Synonyms	**Structure**	**Formula** **Molecular Weight (g/mol)**

Physical Chemical & Environmental Properties - Modelling Inputs			
Exposure Model Inputs	**Unit**	**Value**	**Comment(s) and References**
CHEMICAL CLASS (Organic/Inorganic)			
ORGANIC CARBON PARTITIONING COEFFICIENT - Koc	(mL/g)		
LOG OCTANOL WATER PARTITIONING COEFFICIENT - Log Kow	(unitless)		
HENRY'S LAW CONSTANT AT 25°C - H'	(unitless)		
HENRY'S LAW CONSTANT AT 25°C - H	(atm-m^3/mol)		
WATER SOLUBILITY AT 25°C	(mg/L)		
DIFFUSIVITY IN AIR	(cm^2/s)		
DIFFUSIVITY IN WATER	(cm^2/s)		

VAPOUR PRESSURE AT 25ºC	(atm)		
BIODEGRADATION ADJUSTMENT FACTOR	(unitless)		
HALF-LIFE - UNSATURATED ZONE	(days)		
HALF-LIFE - SATURATED ZONE	(days)		
HALF-LIFE	(years)		

Physical Chemical & Environmental Properties - Screening Criteria			
Criteria	**Screening Criteria**	**Value**	**Comment(s) and References**
PERSISTENCE	Air ≥ 2 days		
	Water ≥ 6 months		
	Sediment ≥ 1 year		
BIO-ACCUMULATION FACTOR (BAF)	>5000		
BIO-CONCENTRATION FACTOR (BCF)	>5000 or Log K_{OW} > 5		

Human				
Exposure Route	**Term/Effect**	**Screening Criteria**	**Compound Value**	**Comment(s) and References**
ORAL	Acute	LD_{50} ≤ 500 mg/kg bw		
	Sub-chronic	LO(A)EL ≤ 90 mg/kg bw		
		NO(A)EL ≤ 30 mg/kg bw		
	Chronic	LO(A)EL ≤ 30 mg/kg bw		
		NO(A)EL ≤ 10 mg/kg bw		
	Developmental	LO(A)EL ≤ 270 mg/kg bw		
		NO(A)EL ≤ 90 mg/kg bw		
	Reproductive	LO(A)EL ≤ 30 mg/kg bw		
		NO(A)EL ≤ 10 mg/kg bw		
	Reference	LO(A)EL ≤ 90 mg/kg bw		

Human				
Exposure Route	**Term/Effect**	**Screening Criteria**	**Compound Value**	**Comment(s) and References**
DERMAL	Acute	$LD_{50} \leq 500$ mg/kg bw		
	Sub-chronic	LO(A)EL ≤ 90 mg/kg bw		
		NO(A)EL ≤ 30 mg/kg bw		
	Chronic	LO(A)EL ≤ 30 mg/kg bw		
		NO(A)EL ≤ 10 mg/kg bw		
	Developmental	LO(A)EL ≤ 270 mg/kg bw		
		NO(A)EL ≤ 90 mg/kg bw		
	Reproductive	LO(A)EL ≤ 30 mg/kg bw		
		NO(A)EL ≤ 10 mg/kg bw		
	Reference	n/a		
INHALATION	Acute	$LD_{50} \leq 1500$ mg/m^3		
	Sub-chronic	LO(A)EL ≤ 270 mg/m^3		
		NO(A)EL ≤ 90 mg/m^3		
	Chronic	LO(A)EL ≤ 90 mg/m^3		
		NO(A)EL ≤ 30 mg/m^3		
	Developmental	LO(A)EL ≤ 810 mg/m^3		
		NO(A)EL ≤ 270 mg/m^3		
	Reproductive	LO(A)EL ≤ 90 mg/m^3		
		NO(A)EL ≤ 30 mg/m^3		
	Reference	LO(A)EL ≤ 0.4 mg/m^3		
CARCINOGENICITY		Weight of Evidence Group C/Class 3 or greater		

Human				
Exposure Route	**Term/Effect**	**Screening Criteria**	**Compound Value**	**Comment(s) and References**
GENOTOXICITY		Weight of Evidence Group C/Class 3 or greater		
OTHER				

Terrestrial			
Organism	**Screening Criteria**	**Compound Value**	**Comment(s) and References**
Mallard Duck *(Anas platyrhynchos)*	Acute – LD_{50} > 2000 mg/kg practically non-toxic 501 - 2000 mg/kg slightly toxic 51 – 500 mg/kg moderately toxic 10 - 50 mg/kg highly toxic < 10 mg/kg very highly toxic Sub-Chronic – LD_{50} > 5000 mg/kg practically non-toxic 1001 - 5000 mg/kg slightly toxic 501 – 1000 mg/kg moderately toxic 50 - 500 mg/kg highly toxic < 50 mg/kg very highly toxic Chronic Lowest NO(A)EL or LO(A)EL		
Bobwhite Quail *(Colinus virginianus)*			
Rat *(Rattus)*			
Mouse *(Mus)*			

Organism	**Screening Criteria**	**Compound Value**	**Comment(s) and References**
Honey Bee *(Apis)*	<2 µg/bee highly toxic 2-11 µg/bee moderately toxic >11 µg/bee practically non-toxic		
Earthworm *(Eisenia foetida)*	Lowest EC_{50}, NO(A)EL or LO(A)EL		

Plant				
Organism		**Screening Criteria**	**Compound Value**	**Comment(s) and References**
Lettuce	Germination			

(Latuca sativa)	Elongation	Lowest EC_{50}, NO(A)EL or LO(A)EL		
Green beans		Seedling emergence (14-21 days) & Vegetative Vigor: EC25 & NO(A)EC – emergence, height, dry weight, visual phytotoxicity		
Spinach				
Radishes				
Corn, soybeans, root crop, tomato, cucumber, lettuce, cabbage, oat, ryegrass, onion				
Endangered		EC25 & NO(A)EC – emergence, height, dry weight, visual phytotoxicity		

Aquatic			
Organism	**Screening Criteria**	**Compound Value**	**Comment(s) and References**
Rainbow trout *(Oncorhynchus mykiss)*	Acute Lowest EC_{50} or LC_{50} > 10 to 100 ppm slightly toxic > 1 to 10 ppm moderately toxic 0.1 to 1.0 ppm highly toxic < 0.1 ppm very highly toxic Chronic Lowest NO(A)EL or LO(A)EL		
Brook trout *(Salvelinaus fontinalis)*			
Fathead minnow *(Pimephales promelas)*			
Daphnids *(Daphnia sp.)* *(Ceriodaphnia dubia)*			
Green algae *(Selenastrum capricornutum)*			

Freshwater Sediment			
Organism	**Screening Criteria**	**Compound Value**	**Comment(s) and References**
Amphipod *(Hyallela azteca)*	Chronic Lowest NO(A)EL or LO(A)EL		
Midge larvae *(Chironomus tentans)* *(Chironomus riparius)*			

Marine/Estuarine			
Organism	**Screening Criteria**	**Compound Value**	**Comment(s) and References**
Bivale mollusks	Acute Lowest EC_{50} or LC_{50} > 10 to 100 ppm slightly toxic > 1 to 10 ppm moderately toxic 0.1 to 1.0 ppm highly toxic < 0.1 ppm very highly toxic Chronic		
Silverside *(Menidia beryllina)*			
Sheepshead minnow *(Cyprinodon variegates)*			
Mysid *(Mysidopsis bahia)*			
Algae *(Champia parvula)*			
Sea urchin *(Arbacia punctulata)*			

	Lowest NO(A)EL or LO(A)EL		

Microbial			
Organism	**Screening Criteria**	**Compound Value**	**Comment(s) and References**

Other Hazard or Safety Concerns (Indirect toxicity, promotes pathogen growth, etc)

Potential Contaminants (Metals, pathogens, residual monomers, etc)

Exposure Scenarios and Use Patterns

Comments

Safety Pre-screening Framework

Category	**Result (YES / NO)**
Persistence & Bioaccumulation	**YES / NO**
Hazard	**YES / NO**
Exposure Potential	**YES / NO**

Categorization Criteria.

Applicable Category	Category	Persistence & Bioaccumulation	Hazard	Exposure Potential	Action Required
	1	YES / NO	NO	NO	None
	1	YES / NO	YES	NO	None
	1	YES / NO	NO	YES	None
	2	UVCB/ UNCERTAIN	UVCB/ UNCERTAIN	UVCB/ UNCERTAIN	Further investigation to determine if risk assessment required
	3	YES / NO	YES	YES	In depth risk assessment required
	3	YES / NO	CARCINOGENICITY / GENOTOXICITY	YES / NO	In depth risk assessment required