



Canadian Food  
Inspection Agency

Agence canadienne  
d'inspection des aliments

Canada

## Canadian Food Inspection Agency



### **Our vision:**

To excel as a science-based regulator, trusted and respected by Canadians and the international community.

### **Our mission:**

Dedicated to safeguarding food, animals and plants, which enhances the health and well-being of Canada's people, environment and economy.

## *Fertilizer Safety Program*

## *Presentation for the Alberta Biochar Initiative Technical Seminar*

*April 8, 2014*

Canada

# Outline

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1. Introduction
2. Regulation of Biochar
3. Research Authorizations
4. Future of Biochar



# Introduction



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# Canadian Food Inspection Agency (CFIA)

## Vision:

- To excel as a science-based regulator, trusted and respected by Canadians and the international community.

## Mission:

- Dedicated to safeguarding food, animals, and plants, which enhances the health and well-being of Canada's people, environment and economy.



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# Canadian Food Inspection Agency (CFIA)

The CFIA strives to:

1. Protect Canadians from preventable health risks
2. Protect consumers through a fair and effective food, animal, and plant regulatory regime that supports competitive domestic and international markets
3. Sustain the plant and animal resource base
4. Contribute to the security of Canada's food supply and agricultural base, and
5. Provide sound agency management



# Fertilizer Program

Ensures that fertilizers and supplements, imported into or sold in Canada, are:

- safe for humans
- safe for plants
- safe for animals
- safe for the environment
- farm-gate to dinner plate risk management

Regulatory authority:

- *Canadian Food Inspection Agency Act*
- *Health of Animals Regulations (for Enhanced Feed Ban)*
- *Fertilizers Act and Regulations*

Fertilizer regulation is a joint effort; other aspects of a product's lifecycle (manufacture, transport, use and disposal) are regulated by the Provincial, Territorial and Municipal partners.

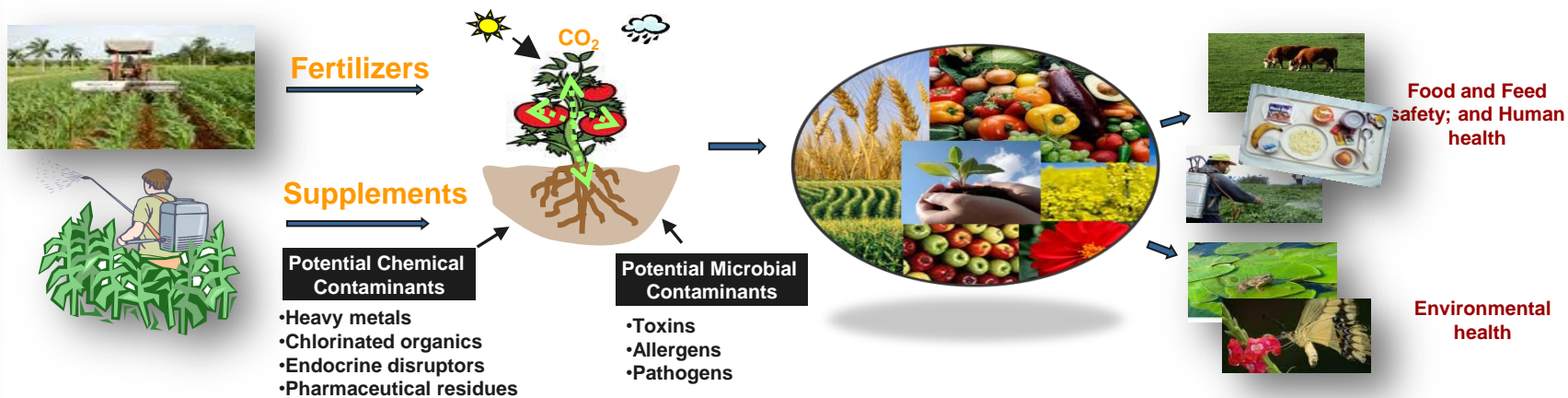




# Key Program Activities:

## 1. Health and Safety

### A. Pre-market assessment of product safety in support of registration or LONO



**B. Development of Safety policies and standards**, including allowable limits for chemical and biological contaminants.

**C. Verification** of product compliance with safety standards-heavy metals, pesticide residues and pathogens;

**D. Label reviews** for mandatory labelling of safety recommendations and precautionary statements.

**E. Verification of records** to ensure compliance of requirements of the **Enhanced Feed Ban** (joint authority under *FzR* and *Health of Animals Regulations*).

**F. Research Authorization** for novel supplements

# Key Program Activities:

## 2. Market Access

- **Import Control:** Registration requirement and import inspections
- **Exports:** Although not regulated under the *Fertilizers Regulations*, Canadian approval or letter of free sale often requested by importing country prior to export

## 3. Consumer Protection

- **Label reviews:** Adequate safety information including precautionary statements to protect the consumer.
- **Guaranteed analysis:** User awareness and safe and sustainable product application (rate, frequency, target crop)
- **Product Inspection:** Field Trial Inspections; Marketplace monitoring of regulated products - label reviews, verification of registration, sampling/testing for contaminants.

## 4. Other Activities

- International Standard setting
- Stakeholder Engagement
- OGD and FPT Cooperation
- Regulatory research and oversight





# Regulated Products

The Fertilizer Program regulates a wide array of fertilizer and supplement products, imported or sold in Canada for agricultural, commercial, and home and garden purposes. These include:

- Farm fertilizers
- Micronutrients
- Lawn and garden products
- Chemical supplements and plant growth regulators
- Microbial supplements including legume inoculants
- Composts
- Waste-derived materials including processed sewage



**Fertilizer:** any substance or mixture of substances containing nitrogen, phosphorus, potassium or other plant food, manufactured, sold or represented for use as a plant nutrient.

**Supplement:** any substance or mixture of substances, other than a fertilizer, that is manufactured, sold or represented for use in the improvement of the physical condition of soils or to aid plant growth or crop yields.

# Registration vs. Regulation

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Some products are regulated and require registration (e.g. micronutrients and fertilizer-pesticides)

- Products that require registration must receive a registration number prior to product sale or import into Canada

Some products are regulated and exempt from registration (e.g. items listed in Schedule II and specialty fertilizers)

- Products that are exempt from registration can obtain a pre-market assessment and receive a Letter of No Objection (LONO).

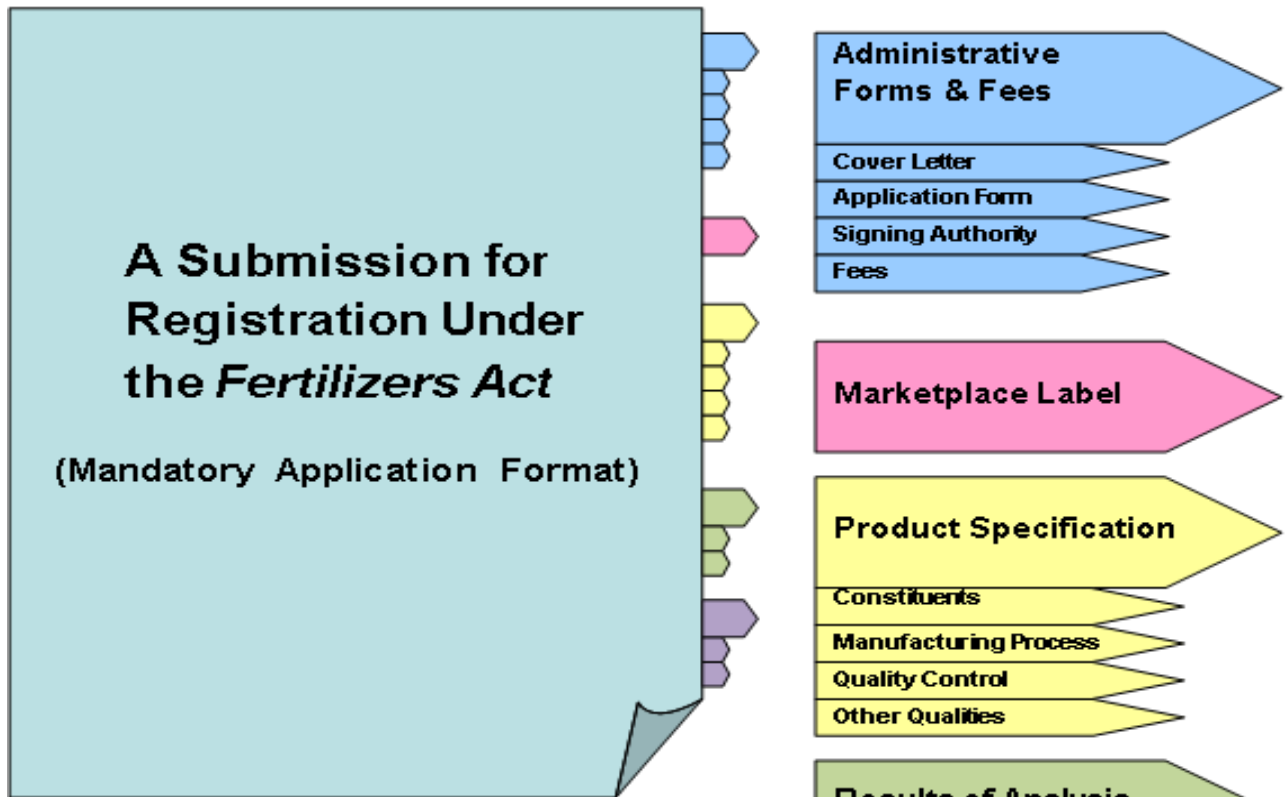
# Regulation of Biochar



# Registration

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- Under the federal *Fertilizers Act and Regulations*, biochar is considered a supplement and requires **registration** prior to importation or sale in Canada.
- Everything requires registration unless exempted in the *Regulations* and Biochar **does not** meet any existing exemptions.
- In order to obtain registration, applicants must demonstrate that the product is safe with respect to human, animal, plant health and the environment, and properly labelled to avoid misrepresentation in the marketplace.
- To register your product, please follow the Tab Submission Format available at [www.inspection.gc.ca](http://www.inspection.gc.ca). Please click on “Plants” “Fertilizers” “Guidance Document for Tab Submission”.



All products require mandatory submission of information in TAB 1, 2, and 3.

TAB 4 and 5 depend on the nature of the product and its risk profile.

# Registration Requirements for Biochar

(not a comprehensive list)

Due to the safety concerns associated with Biochar (to be discussed) it requires a Full Safety Data Package including Results of Analysis and a Rationale that the product is safe to use as directed.

➤ **Metals Analyses**

*4 sets required*

➤ **Dioxins and Furans Analysis**

*1 set*

➤ **Product Characterization**

*NPK, ash and carbon content*

➤ **Production Specifications**

- residence time
- combustion temperature
- combustion chamber design
- QA/QC to ensure combustion optimisation

➤ **Carbon Source Specifications**

- source type (hard/soft wood, hay, straw, biosolids, manure)
- name of vendor; place of origin



# Reference Materials

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These are the references available for more information on the registration process:

- Tab Submission Format Document (contains list of relevant T-memos: T-4-93; T-4-113; T-4-118; T-4-119)
- T-4-122: Service Delivery Standards
- Submission Checklists
- Guide to the Canadian Federal Regulatory Requirements for Fertilizers and Supplements
- *Fertilizers Act and Regulations*
- Inquiry
- Pre-Submission Consultation

*All reference material is available through the CFIA website:  
[www.inspection.gc.ca](http://www.inspection.gc.ca)*

# Research Authorizations



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# Research Authorization (RA)

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Research Authorizations exempt supplement products used for experimental purposes from registration under the *Fertilizers Act and Regulations*.

Research Authorizations must be obtained prior to the import into Canada or environmental release of all novel supplements (i.e. supplements that are not registered and not exempt from registration or that contain a novel trait).

# Documentation Required for Field Trials

## Documentation required for all trials categorized : A, B, or C

Application form

Signing authority

Research label

Trial maps

## Documentation required for trials categorized: A or B

Description of trial design

Constituent materials – list of all ingredients and their source

For microorganisms – source and method of identification

Method of crop disposal

A - no safety data required; B - safety data required; C - renewal

# Documentation Required for Field Trials

## Documentation required for trials categorized: B

Method of manufacture and quality control procedures

Rationale for product safety supported by data or literature

Monitoring plan of the spread and establishment of the supplement in the environment

Confinement procedures – i.e. description of packaging during shipment and storage, buffer zones, entry restrictions, equipment cleanup and sterilization etc.

Contingency plan – description of cleanup and disposal procedures in cases of accidental spill or release of the product

A - no safety data required; B - safety data required; C - renewal



# Biochar Field Trial Requirements

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- Biochar is categorized a Category B field trial, and requires a full safety assessment.
- In addition to submitting the requirements for a Category B field trial, 1 set of metals analyses are required, and depending on the source and manufacturing process of the biochar, 1 set of dioxins and furans analyses may be required.



# Crop Destruct Waivers (CDW)

Applicants have the option of requesting a crop destruct waiver which allows you to:

- conduct farm size trials
- use farmer fields as opposed to research facilities
- use or sell the treated crop

*CDW do NOT authorize the sale and/or distribution of the supplement product itself*

The crop destruct requirement may be waived by the FSS if:

- an appropriate safety assessment has been conducted;
- the supplement has been deemed safe when used according to directions;
- the request is submitted prior to an application for a RA

# Submission Deadlines

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All application packages must be submitted at least 90 days prior to the trial start date.

If submissions are received past the specified deadline, the Fertilizer Safety Section cannot guarantee that the review of the information will be completed in time for the planting season.

# Reference Materials

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These are the references available for more information on the field trial submission process:

- T-4-103: Guidelines for Research Authorizations for Testing of Novel Supplements
- *Fertilizers Act and Regulations*

*All reference material is available through the CFIA website:  
[www.inspection.gc.ca](http://www.inspection.gc.ca)*

# Future of Biochar



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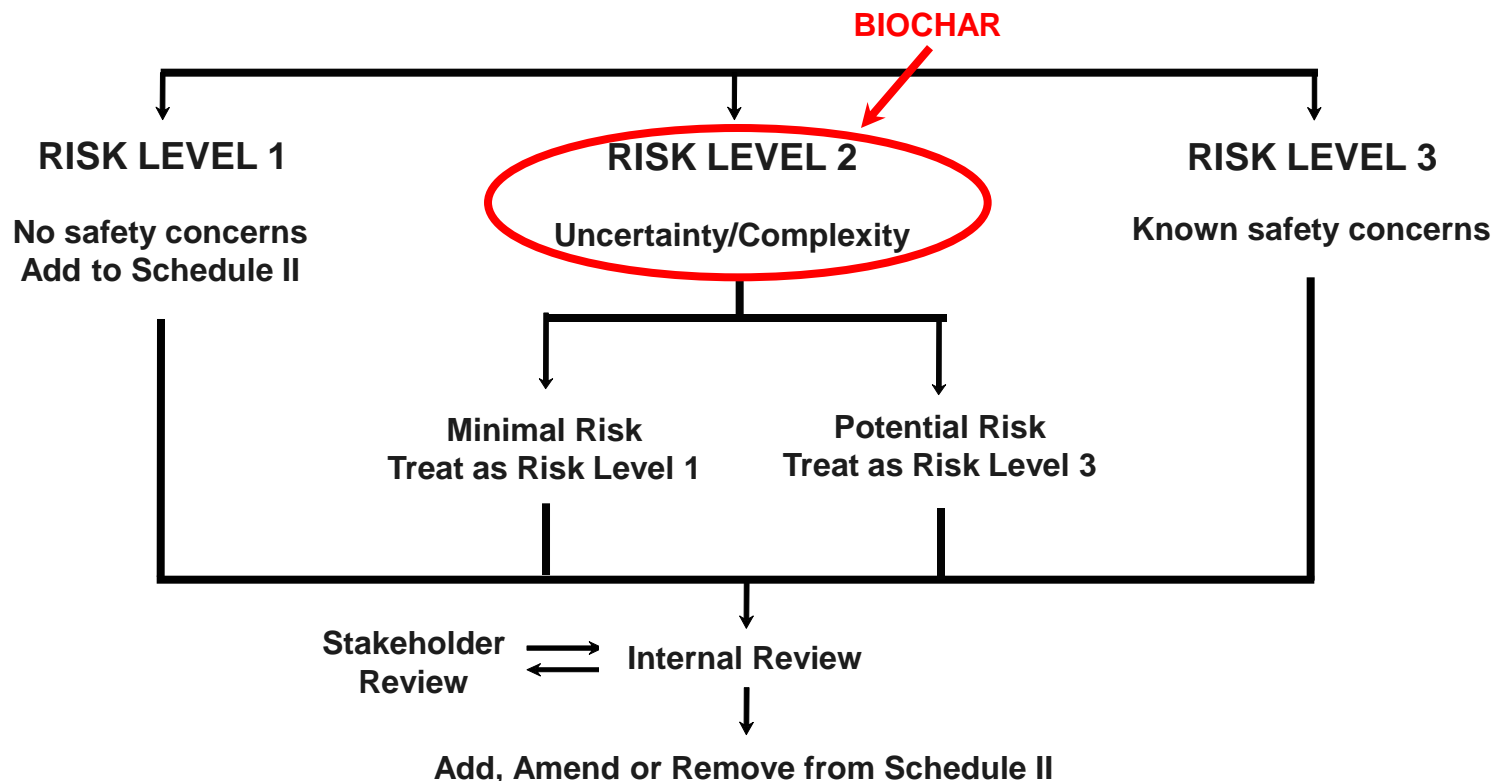
# Safety Concerns Associated with Biochar

***Variability in carbon source material and manufacturing processes warrant regulatory oversight, given resultant variability in composition and potential for hazardous by-products and contaminants***

- **Metals**
- **Dioxins and Furans**  
*Higher level of concern associated with sea-transported wood, biosolids*
- **Polycyclic Aromatic Hydrocarbons (PAHs)**
- **Polychlorinated Biphenyls (PCBs), Hexachlorobenzene (HCB) and Emerging Substances of Concern (ESOCs) (e.g. pharmaceuticals) in biosolids**
- **Treated and/or Contaminated Carbon Sources**  
*e.g. treated railway ties*
- **Undeclared NPK Content of Manure and Biosolids**  
*environmental concerns with over-application*
- **Inhalation Exposure via Dust**

# Safety Categorization for Schedule II Amendment

Owing to uncertainty surrounding its safety, exacerbated by complexity associated with the wide range of carbon sources, biochar falls under Risk Level 2, which may lead to categorization as Risk Level 1 (addition to Schedule II) or Risk Level 3 (requirement of product-specific risk assessment)





# Safety Requirements for Proposed Addition of Biochar to Schedule II

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## ➤ Definition of proposed addition

- Source material  
*hard/soft wood, hay, straw, biosolids, manure*
- Ash content
- Carbon content
- Incineration temperature
- Incineration holding time
- NPK content

## ➤ Human Health Toxicity

## ➤ Ecotoxicity

## ➤ Persistence and Bioaccumulation Potential

## ➤ Environmental Fate

## ➤ Manufacturing Practices

## ➤ Application Rates and Frequencies

# Safety Requirements for Proposed Addition of Biochar to Schedule II

This is part of the safety standard against which all products on Schedule II are assessed - Human Health Hazard Component

Criterion	Element(s)	Threshold(s)	Value(s)	
			1	2
i <sub>H</sub> (Inherently Toxic to Humans)	Carcinogenicity Genotoxicity	<i>Weight of Evidence</i> <i>Weight of Evidence</i>		
	Regulatory Reference Values	Oral: ≤ 0.1 mg / kg bw / day Inhalation: ≤ 0.4 mg / m <sup>3</sup> Dermal: N/A		
	Developmental Toxicity	Oral/Dermal: LO(A)EL ≤ 270 mg / kg bw / day NO(A)EL ≤ 90 mg / kg bw / day Inhalation: LO(A)EC ≤ 810 mg / m <sup>3</sup> NO(A)EC ≤ 270 mg / m <sup>3</sup>		
	Reproductive Toxicity	Oral/Dermal: LO(A)EL ≤ 30 mg / kg bw / day NO(A)EL ≤ 10 mg / kg bw / day Inhalation :LO(A)EC ≤ 90 mg / m <sup>3</sup> NO(A)EC ≤ 30 mg / m <sup>3</sup>		
	Long Term Toxicity	Oral/Dermal: LO(A)EL ≤ 30 mg / kg bw / day NOEL ≤ 10 mg / kg bw / day Inhalation: LO(A)EC ≤ 90 mg / m <sup>3</sup> NO(A)EC ≤ 30 mg / m <sup>3</sup>		
	Short Term Toxicity	Oral/Dermal: LO(A)EL ≤ 90 mg / kg bw / day NO(A)EL ≤ 30 mg / kg bw / day Inhalation: LO(A)EC ≤ 270 mg / m <sup>3</sup> NO(A)EC ≤ 90 mg / m <sup>3</sup>		
	Acute Toxicity	Oral/Dermal LD <sub>50</sub> ≤ 500 mg / kg bw Inhalation LD <sub>50</sub> ≤ 1500 mg / m <sup>3</sup>		

For a copy of the full safety evaluation criteria for amendment of Schedule II, please contact [fertilizer@inspection.gc.ca](mailto:fertilizer@inspection.gc.ca)



# Questions ??



## **Contact information:**

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