

# Anything New with Regulation of Biopesticides in Canada?

**BPIA Annual Meeting  
February 22, 2023  
Reno, NV**

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Health Canada

YOUR HEALTH AND SAFETY... OUR PRIORITY.



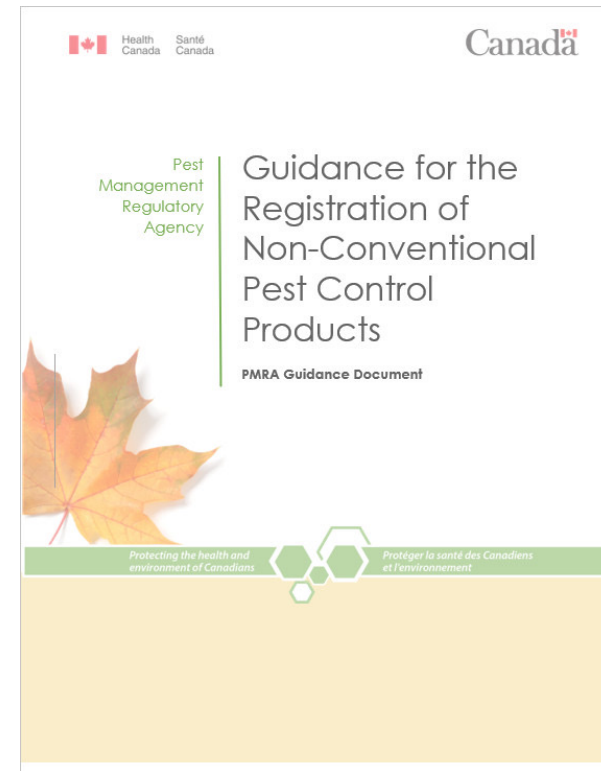
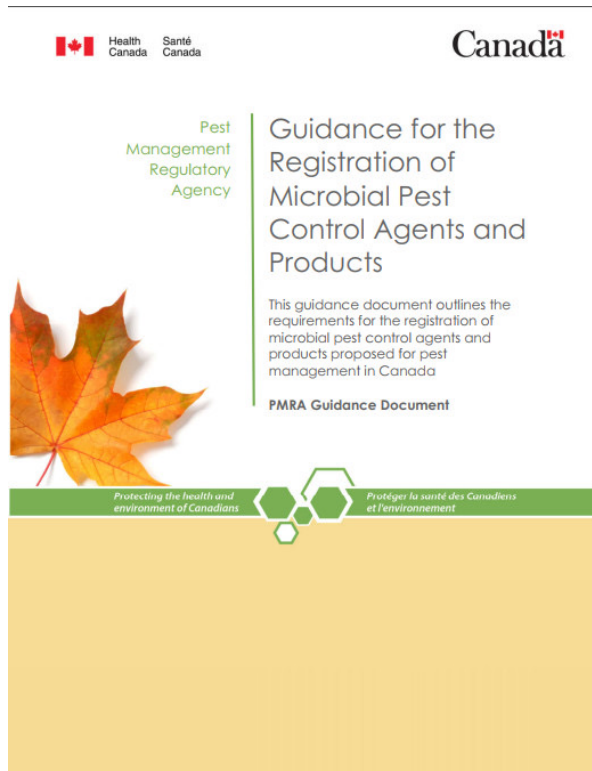
# Outline

- New guidance documents
- Food Grade Edible chemistry attestation forms
- Limits for residual solvents in Technical Grade Active Ingredients (TGAIs)
- Data requirements for biopesticides applied to cannabis and hemp
- Vertical farming
- OECD activities



# Updated Guidance documents

**\*COMING SOON\***



# Food Grade Edible (FGE) Attestation Form

## Attestation Forms

- PMRA has developed attestation forms to be completed by applicants for **FGE products**. The forms can be obtained during the pre-submission consultation or ordered by contacting the PMRA info line.

## Required DACOs

- Attestation form under data code (DACO) 2.16 for the TGAI and DACO 3.7 for the end-use product (EP).
- Certificate confirming Food Grade Edible classification submitted under DACO 0.8.8.
- Statement of Product Specification Form (SPSF) submitted under DACO 0.1.6003.

## Chemistry Requirements

Since FGE products are fit for human consumption, PMRA requests the following:

- For TGAI: Physical-Chemical properties and levels of methyl eugenol and mycotoxins, if applicable.
- For EP: Physical-Chemical properties, Storage Stability and Corrosion Characteristics study.

# PMRA limits for residual solvents in TGAs

| Residual solvent       | Maximum PMRA general limit (ppm) | Required limit of quantitation (LOQ) (ppm) |
|------------------------|----------------------------------|--|
| carbon tetrachloride   | --- (to be avoided)              | 1  |
| 1,2-dichloroethane     | --- (to be avoided)              | 1  |
| benzene                | --- (to be avoided)              | 1  |
| 1,4-dioxane            | 4                                | 1  |
| chloroform             | 10                               | 1  |
| tetrahydrofuran        | 100                              | 10   |
| pyridine               | 200                              | 100  |
| hexane                 | 290                              | 100  |
| dichloromethane        | 300                              | 100  |
| acetonitrile           | 410                              | 100  |
| N,N-dimethylformamide  | 500                              | 100  |
| N-methyl-2-pyrrolidone | 530                              | 100  |
| chlorobenzene          | 600                              | 100  |
| cyclohexane            | 710                              | 500  |
| methylcyclohexane      | 1000                             | 500  |
| N,N-dimethylacetamide  | 1090                             | 500  |
| xylene                 | 2170                             | 1000                                       |
| methanol               | 3000                             | 1000                                       |
| toluene                | 15000                            | 1000                                       |

# Biopesticides Used On Cannabis And Hemp

- To-date, mainly biopesticides have been registered for use on cannabis and industrial hemp grown for flowers
- Potential consumer exposure could include ingestion of edible oils or extracts, inhalation by smoking and vaping.
- Additional data/information required
  - **DACO 5.2 (Use Pattern/ Exposure Scenario):** The specific use pattern for cannabis and/or industrial hemp crops must be described in sufficient detail as well as the intended end use(s) of the harvested industrial hemp crop
  - **DACO 7.4.1 (Supervised Residue Trial Study):** The assessment of biopesticides will consider active ingredients, formulants, and any potential metabolites or reactive by-products of human health concern that may remain on consumable portions of the harvested crop. Alternatively, an acceptable scientific rationale to waive this data requirement may be provided.
  - **DACO 7.8.1 (Pyrolysis Study):** Required when there is potential for crop to be consumed through smoking/vaping. Alternatively, an acceptable scientific rationale to waive this data requirement may be provided.

# Vertical Farming

- Vertical farm produces crops grown:
  - In appropriate media (hydroponically, aeroponically or in soil);
  - Indoors on vertically stacked or inclined layers and/or integrated in other vertical structures; and
  - Relying solely or largely on artificial lighting
  - This differs from greenhouse growing, for which there are registered pest control products. In a greenhouse, plants are generally grown in a single layer on horizontal benches, containers or troughs placed on the ground or suspended, relying largely on natural sunlight.
- Currently the use of pest control products in vertical farming (including those registered for use in greenhouses) in Canada is not permitted under the Pest Control Products Act
- PMRA is engaging with stakeholders to gain a better understanding of practices employed in vertical farming and considerations in assessing risk to human health and the environment

# OECD Projects

- PMRA participates in various activities at the OECD level through membership in the Expert Group on Biopesticides and the Ad Hoc Expert Group on RNAi-based Pesticides
- Bacteriophage and baculovirus guidance documents coming soon
  - General guidance on considerations for preparing regulatory submissions
- Contaminants in microbial pest control products
  - The methodology section of the OECD Series on Pesticides No. 65, *Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products* (ENV/JM/MONO(2011)43) is being updated to include methods such as quantitative polymerase chain reaction (qPCR)
  - No change proposed to the list of pathogens or levels of detection



# OECD Projects cont'd.

- RNAi-based pesticides
  - Ad Hoc Expert Group has published a document on environmental considerations; document on human health considerations nearing completion (aiming end of 2023)
  - In Canada, data requirements determined on a case by case basis
    - Pre-submission consultation required
    - Research authorizations required for any research conducted outside of laboratory

# Challenges regulating biopesticides in Canada



# Resources

Guidance for the Registration of Microbial Pest Control Agents and Products

(<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/guidance-registration-microbial-pest-control-agent-products.html>)

Information Note: Vertical farming and pest control products (<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/vertical-farming-pest-control-products.html>)

OECD Working Document on Considerations for the Environmental Risk Assessment of the Application of Sprayed or Externally Applied ds-RNA-based Pesticides, Series on Pesticides No. 104 [ENV/JM/MONO (2020)26]

([https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2020\)26&doclanguage=en](https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2020)26&doclanguage=en))

PMRA info line [pmra.info-arla@hc-sc.gc.ca](mailto:pmra.info-arla@hc-sc.gc.ca)





THANK  
YOU!

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