

US EPA ARCHIVE DOCUMENT



NAFTA Technical Working Group on Pesticides  
Grupo de Trabajo Técnico del TLCAN sobre Plaguicidas  
Le groupe de travail technique de l'ALENA sur les pesticides

# Biopesticides Registration Improvement Course

## **Non-Conventional Product Chemistry Assessment**

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Operations Directorate

Pest Management Regulatory Agency



Health  
Canada

Santé  
Canada



## Presentation Overview

- Sources of information for Non-conventional Pesticides
- Overview of Classification
- Overview of Product Chemistry Requirements
- Data Requirements:
  - Plant extracts
  - Food chemicals
  - Mixtures or blends of actives
  - Statement of Product Specification Form (SPSF)
- Problem areas



## Resources and Guidelines:

Non-conventional products registration resource webpage:

- [http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/\\_pro2010-06/pro2010-06-eng.php](http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/_pro2010-06/pro2010-06-eng.php)

### General Product Chemistry Data Requirements:

- Technical Grade of Active Ingredient and Integrated System Product (TGAI):
- [http://www.hc-sc.gc.ca/cps-spc/pubs/pest/\\_pol-guide/dir98-04/index-eng.php](http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir98-04/index-eng.php)
- Manufacturing concentrate and End-use products (MA & EP):
- [http://www.hc-sc.gc.ca/cps-spc/pubs/pest/\\_pol-guide/dir98-03/index-eng.php](http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir98-03/index-eng.php)



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## **Substances considered as non-conventional include:**

- Food items, preservatives or additives (e.g., crushed garlic, garlic powder, table salt, citric acid)
- Plant extracts and oils (e.g., vegetable and mineral oils)
- Commodity chemicals (e.g., acetic acid)
- Plant growth supplements (e.g., mineral salts)
- Inert materials (e.g., diatomaceous earth)



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## Overview of Product Chemistry Guidance / Requirements

- General requirements listed under:
  - Dir98-04 (technical grade of active ingredients and integrated system products)
  - Dir98-03 (manufacturing concentrates and end use products)
- Flexibility in data requirements
  - Products evaluated on case-by-case basis, when necessary
  - Provision of valid scientific rationale
- Presubmission consultation
  - More specific guidance on data requirements.



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## **Data Requirements:**

### **A) Technical Grade of Active Ingredient or Integrated System Product (TGAI & ISP)**

#### **i) Isolated, single known entity**

- Active ingredient identification:
  - Chemical and common names, CAS number (if applicable), physical chemical properties
- Manufacturing description
- Analytical methods
- Batch analyses
- Impurities of toxicological concern:
  - If present at any level, have to be reported



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## **A) Technical Grade of Active Ingredient or Integrated System Product (contd.)**

### **ii) Not isolated or complex mixture**

- Reduced data requirements
  - Analytical methods
  - Batch analysis
  - Specifications/certificate of analysis



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## **B) Manufacturing concentrate (MA) and End-use product (EP)**

- Product identification
  - Active constituents, formulation type
- Physical chemical properties
- Formulation process
  - Detailed description including relative quantities
- Analytical methods, if applicable
- Formulation specifications
  - All formulants and their sources



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## **Data Requirements:**

### **1. Plant extracts**

- For plant extracts and essential oils, analytical methods are required to determine the composition of the product, if applicable.
- Major and representative components in each extract/oil, if known, must be determined and quantitated.
- Standard and common methods are acceptable.
- Origin of plant (country), part (aerial, root) and method of extraction, including solvent used must be provided.



## **2. Food chemicals and food grade edibles**

- Food grade products include food grade edibles as well as the chemicals listed in the Food Chemicals Codex (FCC)\*.
- For food grade edibles:
  - A certificate from the supplier/manufacturer that the product is fit for human consumption is required.
- For food grade chemicals listed in the FCC:
  - FCC specifications must be met (certificate of analysis).
  - FCC methods or similar methods.

\*United States Pharmacopeia



### **3. Mixtures or blends of actives**

- Refers to active ingredients which have been mixed or blended deliberately
- Products containing two or more active ingredients may be registered, either:
  - Individually (separate SPSF for each active)
  - or
  - Mixture or blend (one SPSF for the active mixture)
- If the technical is registered as a mixture of active ingredients, the ratio of each of the actives in the TGAI and in the end-use product must stay the same.



## **Mixtures or blends of actives (contd.)**

- Product-specific information must be provided for each active component in the mixture.
- The information required for each active will depend on the nature of the active ingredient.
  - Case by case basis
  - Presubmission consultation recommended
- Label must have all the active ingredients listed, including respective guarantees.



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## Mixtures or blends of actives (SPSF)

- TGAI

- Box H must have the blending site as address of manufacture
- Row 1, Box 4, must have the address of the supplier for the respective actives (in subsequent rows)
- Everything else is the same as in regular products



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 Health Canada      Santé Canada  
 Pest Management Regulatory Agency      Agence de réglementation de la lutte antiparasitaire

### Statement of Product Specification Form

- Please read the instructions
- Type or print clearly in black ink
- Leave shaded areas blank

Precedent Reg #		A Page _____ of _____		Date Received
Form.	Version	B Registration #	Submission #	

C Product Name	D Formulation Type Code	E Formulation #	F Version #
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G Name of Registrant/Proposed Registrant	Row 0	H Name and address of site of Manufacture/ Formulation
I If the SPSF is confidential to a 3rd Party enter contact information: Name Address E-mail Phone      Fax		Address  Select if multiple formulation sites <input type="checkbox"/> (Multiple manufacturing sites require a separate SPSF)

<sup>1</sup> Specific Gravity/Density @ _____ °C	Units	<sup>2</sup> Flash point (°C)	<sup>3</sup> Flame Extension (cm)	<sup>4</sup> Viscosity (mPa(s))	<sup>5</sup> pH
Lower      Upper					

### COMPONENTS

Row: 1	<sup>1</sup> Trade Name	<sup>9</sup> %w/w	10 Purpose	NACT LIST ACTIONS
<input type="checkbox"/>	<sup>2</sup> Common Name		<sup>11</sup> % LCL <sup>12</sup> % Nominal <sup>13</sup> % UCL	
<input type="checkbox"/>	<sup>3</sup> Chemical Name		<sup>14A</sup> Label Guarantee	
<input type="checkbox"/>	ACT IN <sup>4</sup> Name	<sup>5</sup> Reg #	<sup>14B</sup> Value <sup>14C</sup> Units	ACT OUT
	Address	<sup>6</sup> Purity	<sup>14D</sup> LCL <sup>14E</sup> UCL	
	Multiple Suppliers? Yes: <input type="checkbox"/>	<sup>7</sup> CAS #	<sup>15</sup> Other Info	
		<sup>8</sup> List #		



## Mixtures or blends (SPSF contd.)

- MA & EP
  - Box H is site of formulation
  - Box 1, trade name of technical mixture
  - Box 4, blending site (active mixture, same as Box H of TGAI)
  - Box 6, concentration of respective active in the active mixture (TGAI)
  - Box 9, the %w/w of active mixture in the end-use product



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## Problem areas

- Data packages:
  - Description of manufacturing/formulation process
  - Certificates of analysis/certificate of product specifications
  - Scientific rationale for waivers
- Filling out the Statement of Product Specification Form (SPSF)



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# Questions