

June 3, 2014

**VIA ELECTRONIC MAIL
AND COURIER**

[<Minister_Ministre@hc-sc.gc.ca>](mailto:Minister_Ministre@hc-sc.gc.ca)

[<rona.ambrose@parl.gc.ca>](mailto:rona.ambrose@parl.gc.ca)

The Honourable Rona Ambrose
Minister of Health
Health Canada
Brooke Claxton Building, Tunney's Pasture
Postal Locator: 0906C
Ottawa, Ontario K1A 0K9

Dear Minister Ambrose:

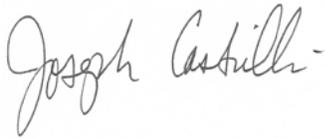
Re: Notice of Objection to Registration Decision RD2013-14 – Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides – July 23, 2013

In our September 19, 2013 and March 13, 2014 correspondence to you with respect to the above matter, we noted that the information in the section 12 notices issued under the *Pest Control Products Act* indicated that the Pest Management Regulatory Agency (“PMRA” or “Agency”) has lacked a valid study on the chronic toxicity of clothianidin to bees since 2004. The only study ever submitted in an attempt to fill this gap was “deemed unacceptable” by the Agency.

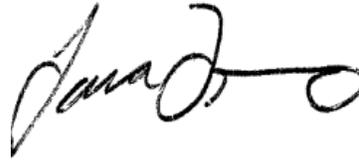
The PMRA requirements for the study referred to in the section 12 notice we provided to you in our March 13th letter were identified in DACO 9.2.4.3. At the time of our March letter to you, we did not have a copy of the PMRA terms and conditions for DACO 9.2.4.3. They have since come into our possession and are attached to this letter. You will see from the PMRA cover letter to Bayer CropScience Inc., dated May 13, 2003, that with respect to the “temporary registration” that was issued by PMRA at that time that a hive study on the “effects on honey bees from chronic/long-term exposure to clothianidin residues” was requested because these effects were described as “unknown”. Furthermore, “data on the chronic toxicity of clothianidin to hives of honey bees under field conditions” were required to be submitted to PMRA by December 1, 2004. It is this same information that remains outstanding in 2014 with respect to the conditional registrations renewed by PMRA in July 2013 referred to in our notice of objection.

We trust this information clarifies what we were referring to in our March 13, 2014 and September 19, 2013 letters to you and look forward to your decision on our notice of objection shortly.

Yours truly,



Joseph F. Castrilli
Counsel for Sierra Club Canada



Lara Tessaro
Counsel for David Suzuki Foundation,
Western Canada Wilderness Committee, and
Équiterre

Encl.

c.c. John Bennett, Sierra Club Canada
c.c. Mara Kerry, David Suzuki Foundation
c.c. Joe Foy, Western Canada Wilderness Committee
c.c. Sidney Ribaux, Équiterre

and to:

< richard.aucoin@hc-sc.gc.ca >

Richard Aucoin
Executive Director
Pest Management Regulatory Agency
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2720 Riverside Drive
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Health
Canada

Santé
Canada

Pest
Management
Regulatory
Agency

Agence de
réglementation
de la lutte
antiparasitaire

May 13, 2003

[REDACTED]
Bayer CropScience Inc.
Carleton Technology & Training Centre
Suite 3800, 1125 Colonel By Drive
Ottawa, ON K1S 5R1

Dear [REDACTED]

**Re: Poncho 600 Seed Treatment Insecticide, containing Clothianidin, EP
Submission Number: 2001-1294**

The Pest Management Regulatory Agency has carried out an assessment of available information in accordance with Section 9 of the Pest Control products (PCP) Regulations and has found it sufficient pursuant to Section 18.b, to allow a determination of the safety, merit and value of Poncho 600 Seed Treatment Insecticide for use on canola, rapeseed and corn for the control of certain insect pests. The Agency has concluded that the use of Poncho 600 Seed Treatment Insecticide in accordance with the enclosed annotated label has merit and value consistent with section 18.c of the PCP Regulations and does not entail an unacceptable risk of harm pursuant to Section 18.d.

The Agency has determined that this product is eligible for temporary registration pursuant to Section 17.a, subject to the Terms and Conditions of this letter and itemized in Attachment 1. This interim position will provide opportunity for completion of these requirements.

The Agency has assigned PCP Act Registration Number 27449 to this end use product. In order to proceed with the temporary registration, you are requested to provide the following as one package **within 45 calendar days** from the date of this letter, by **June 27, 2003**:

1. Four copies of the corrected label in bilingual format. Should your product meet the criteria set out under subsection (3) of Section 39 of the PCP Regulations regarding bilingual product labelling, you must provide written confirmation of your product's eligibility for this exemption.

Canada

2720 promenade Riverside Drive, Ottawa, Ontario K1A 0K9

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2. Written confirmation of receipt and acceptance of the Terms and Conditions for temporary registration and agreement to submit the requested studies together in one package by **December 1, 2004**, described in Attachment 1 to this letter.

Your certificate of registration, temporary to December 31, 2003, will be issued when we receive and review the above information.

It should be noted that until the corrected bilingual label has been accepted by the Agency and the Certificate of Registration has been issued, this product may not be imported into, sold or used in Canada. For this purpose, the prohibition against sale of this product includes, offer for sale, expose for sale, display for sale, have in possession for sale and distribution.

Extension of Temporary Registration

Recognizing the time frame required to address the data requirements outlined in Attachment 1, the Agency is prepared to consider extending the temporary registration beyond December 31, 2003. In order to do so, you must submit an application for amended registration at least 3 months prior to December 31, 2003 consisting of:

- a covering letter explaining the purpose of the submissions and its contents;
- application form for new or amended registration - indicate "Category B Conversion/Extension of Temporary Registration";
- fee form indicating "1(b) Label..." (CAN\$262.00);
- total fees payable - \$CAN262.00;
- four (4) copies of the marketplace label.

Conversion of Temporary Registration to Full Registration

In order to convert the temporary product to full registration status, we advise you to submit an application for amended registration consisting of:

- a covering letter explaining the purpose of the submission and its contents;
- application form for new or amended registration - indicate "Category B Conversion/Extension of Temporary Registration";
- fee form indicating "1(b) Label..." (CAN\$262.00) plus any other appropriate Part and Component and their associated fees;
- 10% of the total fees payable (or 100% if total fees payable is less than CAN\$1000.00);



- four (4) copies of the marketplacelabel;
- two (2) updated product specification forms;
- two copies of any required information (eg data/studies) organized by Data Code (DACO) in correct format.
- the data requirements outlined in **Attachment 1: Terms and Conditions for Temporary Registration**, formatted as per Directive 2003-01, *Organizing and Formatting a Complete Submission for Pest Control Products*.

Please note, the formulation of Poncho 600 Seed Treatment Insecticide contains a List 2 Formulant. As a result, this product may be subject to further regulatory action.

In addition, please note that Master Product status has been denied as a result of this product receiving temporary registration.

If your written response is inadequate or is not received by the PMRA by the date specified above, this submission may be withdrawn. There will be no reminders. Further information or clarification on extension or conversion can be obtained from the Pest Management Information Service at 1-800-267-6315 inside Canada or 613-736-3799 outside Canada. Should you have any questions regarding submission of the data, please contact Susan B. Wong at (613) 736-3671 or email Susan_B_Wong@hc-sc.gc.ca. Any discussions regarding this submission should be completed before June 27, 2003.

Yours truly,

W.A. Sexsmith
Chief Registrar
PEST MANAGEMENT REGULATORY AGENCY

encl.: Terms and Conditions for Temporary Registration (Attachment 1)
Required Label Amendments (Attachment 2)
Annotated label (Poncho 600 Seed Treatment Insecticide)

**Attachment 1- Terms and Conditions for Temporary Registration
Poncho 600 Seed Treatment Insecticide, Submission No. 2001-1294**

During the temporary registration period, the following information is to be generated and must be provided to the Agency by **December 1, 2004** and should indicate the reference numbers specified below. A partial response to the outlined Terms and Conditions will not be accepted.

**PART 3 CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF AN
END USE PRODUCT**

DACO: 3.5.10
Title: Storage Stability Data

Deficiencies: A one year storage stability study with the product stored under ambient conditions in its commercial container for 1 year was not provided. The company has stated that the one year storage stability study is in progress and is scheduled for completion in June 2001.

Required Data: **The applicant is required to submit the one year storage stability study when completed.**

PART 5 EXPOSURE (OCCUPATIONAL AND/OR BYSTANDER)

DACO: 5.4/5.5 (OECD IIIA 7.3.3)/(OECD IIIA 5.8, IIIA 7.3.3)
Title: Mixer/Loader/Applicator - Passive Dosimetry or Biological Monitoring

Deficiency: A passive dosimetry or biological monitoring exposure study is required to document effectiveness of the required mitigation measures (ie closed mix/load systems, a product stewardship programme). The study should be representative of all job functions related to treating canola seed or corn seed with a liquid suspension including, but not limited to, estimates of exposure from relevant mix/load systems, and clean-up and repair activities.

Required Data: **Passive Dosimetry: studies that estimate the amount of a chemical depositing on the surface of the skin or clothing and the amount of the chemical available for inhalation. Refer to the *OECD Guidance Document for the Conduct of Studies of Occupational Exposure to Agricultural Pesticides* or the US/EPA's *OPPTS Test Guideline Series 875 - Occupational and Residential Exposure Test Guidelines: Group A - Applicator Exposure Monitoring Test Guidelines* (formerly Subdivision U).**

**Attachment 1- Terms and Conditions for Temporary Registration
Poncho 600 Seed Treatment Insecticide, Submission No. 2001-1294**

Biological Monitoring: Since biological monitoring uses urine or other biological matrices to measure exposure, the toxicokinetics of the compound must be well-understood prior to conducting biological monitoring studies.

The applicant is required to submit a schedule for data generation and a field study protocol for agency comment by December 2003.

DACO 5.14
Title Other - Product Stewardship Programme
Notes Risk levels for seed treatment workers are anticipated to improve with additional measures to reduce exposure potential (eg. additional Personal Protective Equipment; closed mix/load systems; product stewardship programme).

Required DATA: The applicant is required to design and implement a product-specific stewardship plan designed to mitigate exposure to Poncho 600 Seed Treatment Insecticide. The programme should be developed in consultation with the PMRA for implementation by December 2003.

PART 6 METABOLISM/TOXICOKINETICS STUDIES (OECD Annex IIA, Point 6)

DACO: 6.2 (OECD Annex IIA, Point 6.2.2/6.2.3/6.2.4)
Title: Livestock metabolism - Goat and Hen

Use expansion: For future uses with significantly higher dietary burdens, ruminant and/or poultry metabolism studies with the thiazolyl ring label will also be required.

DACO: 6.3 (OECD Annex IIA, Point 6.2.1)
Title: Plant metabolism

Use expansion: Future new uses on root crops and/or leafy vegetables will require analysis of TMG and parent in field trials. Alternatively, the registrant may submit additional metabolism data; preferably, side-by-side thiazol- and nitroimino radiolabeled studies.

**Attachment 1- Terms and Conditions for Temporary Registration
Poncho 600 Seed Treatment Insecticide, Submission No. 2001-1294**

**PART 7 FOOD, FEED AND TOBACCO RESIDUE STUDIES
(OECD Annex IIA, Point 4, 6)**

DACO: 7.4.4 (OECD Annex IIIA, Point 8.6)
Title: Field Crop Rotation Study

Use expansion: With respect to the nature of the residue in rotational crops, parent, TZNG, and MNG are the residues of concern for risk assessment, while parent only is needed for the enforcement of the maximum residue limit. The proposed label requires a 12-month plant-back interval for leafy, root and tuber vegetables. Additional field studies would be needed on representative vegetables to establish maximum residue limits in support of a plantback interval less than one year. A 30-day plantback interval for soybeans and dried beans are conditional upon the submission of two rotational crop field trials showing residues of clothianidin and the TZNG metabolite in mature soybeans are each less than LOQ (0.01 ppm) using the LC-MS/MS enforcement method. The petitioner should note that for future field rotational crop submissions, including the required studies for this petition, information pertaining to the weather conditions (temperature and rainfall) over the course of the study and the soil types at the field trial sites should be included in the study submission. The petitioner should analyze for parent, TZNG, and, if possible, MNG. In the absence of data for MNG, residues will be estimated using ratios from the confined study if levels are needed for dietary risk assessment.

Required data: Submission of two rotational crop field trials showing residues of clothianidin and the TZNG metabolite in mature soybeans are each less than LOQ (0.01 ppm) using the LC-MS/MS enforcement method. The petitioner should also include information pertaining to the weather conditions (temperature and rainfall) over the course of the study and the soil types at the field trial sites.

DACO: 7.5 (OECD Annex IIIA, Point 8.2/8.4.1/8.4.2/8.4.3)
Title: Livestock, Poultry, Egg and Milk

Use expansion: For poultry, with future new uses where higher residues in poultry feed items are found, parent, TZNG, TZU, TZG, and ATG-Ac are residues of concern to be analyzed in a feeding study and included in the risk assessment. Parent only is needed for the enforcement of the maximum residue limit.

**Attachment 1- Terms and Conditions for Temporary Registration
Poncho 600 Seed Treatment Insecticide, Submission No. 2001-1294**

PART 8 ENVIRONMENTAL FATE

DACO: 8.3.4
Title: Special studies of environmental fate

Required data: A prospective groundwater monitoring (PGW) study must be conducted. The applicant must submit a study protocol prior to the conduct of the study.

PART 9 ENVIRONMENTAL TOXICOLOGY

DACO: 9.2.4.3
Title: Hive study

Deficiencies: The effects on honey bee hives from chronic/long-term exposure to clothianidin residues are unknown.

Required Data: Data on the chronic toxicity of clothianidin to hives of honey bees under field conditions are required. The applicant must submit a study protocol prior to the conduct of the study.

DACO: 9.6.5
Title: Field studies

Deficiencies: The toxicity of clothianidin, when used for treatment of corn seed, to wild birds under field conditions is unknown.

Required Data: Data on the toxicity of clothianidin, when used for treatment of corn seed, to wild birds under field use conditions are required.

Attachment 2 - Required Label Amendments

Poncho 600 Seed Treatment Insecticide, Submission No. 2001-1294

- 1) The following statement should be included in the section entitled "Seed Labelling":
"Special use restriction:

This product contains no colourant. An appropriate colourant must be added when this product is applied. Regulations pertaining to the "Seeds Act" must be strictly adhered to when using this product. A baby blue colorant must be added when this product is applied to canola /rapeseed."

- 2) Based on the results of acute toxicity testing, the signal words **Warning-Poison** are required to be displayed on the primary display panel of the Poncho 600 Seed Treatment Insecticide product.

- 3) The primary label should include the statement "For use in commercial seed treatment facilities with closed transfer systems only. No open transfer."

- 4) Additional personal protective equipment are required on the label for all seed treatment workers including:

"Workers involved in treating, clean-up, or maintenance of seed treatment equipment, bagging, sewing or stacking must wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, head gear, and respiratory protection (i.e., half-mask respirator with suitable dust filter or fresh air hood).

- 5) The tags on bags of treated seed should include the following instructions:

"Wear long-sleeved shirt, long pants, and chemical-resistant gloves when handling treated seed."

- 6) Under "Environmental Precautions" the following statements should be inserted:

"This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of Poncho 600 Seed Treatment Insecticide in areas where soils are permeable, particularly where water table is shallow, may result in ground water contamination."

"This product is toxic to wild birds and wild mammals when used as a seed treatment. Do not expose treated seeds on soil surface. Any spilled or exposed seeds should be incorporated into the soil or otherwise cleaned-up from soil surface."

Attachment 2 - Required Label Amendments
Poncho 600 Seed Treatment Insecticide, Submission No. 2001-1294

7) The approved application rates must replace the proposed application rates (see the following tables for the approved rates).

Crop	Pest	Rate Poncho 600 Seed Treatment Insecticide	Remarks
Canola Rapeseed	Flea beetle	250 mL or 666 mL per 100 kg seed	250 ml/100 kg seed: For use under low to moderate flea beetle pressure. 666 ml/100 kg seed: For use under high to extreme flea beetle pressure where extended control is required.

Crop	Pest	Rate Poncho 600 Seed Treatment Insecticide		Remarks
		mg AI/KERNEL	80,000 UNIT of SEED	
Corn (including field, sweet, and pop)	Corn rootworm (including Northern, Western)	1.25	166.7 mL	The application rate recommended for control of corn rootworm also provides control of other listed corn pests. If corn rootworm is not a target pest, use appropriate lower application rates for control of other listed corn pests.
	Corn flea beetle Cut worm, black Seed corn maggot Wireworm	0.25-0.5	33.3-66.6 mL	
	White grub (larvae of European chafer, May/June beetle Japanese beetle)	0.25	33.3 mL	

Label statements in the column of "Remarks" for "Canola Rapeseed" under RECOMMENDED APPLICATIONS in GENERAL INFORMATION must be changed from "250 ml /100 kg seed: For ... 333 ml /100 kg seed: For ... 666 ml /100 kg seed: For ... 1000 ml /100 kg seed: For ..." to "250 ml/100 kg seed: For use under low to moderate flea beetle pressure. 666 ml/100 kg seed: For use under high to extreme flea beetle pressure where extended control is required".

Attachment 2 - Required Label Amendments

Poncho 600 Seed Treatment Insecticide, Submission No. 2001-1294

Add an additional column "Remarks" in the "Corn" table under RECOMMENDED APPLICATIONS in GENERAL INFORMATION. The following sentence is required to be added to the label statement in the column of "Remarks": "**The application rate recommended for control of corn rootworm also provides control of other listed corn pests. If corn rootworm is not a target pest, use appropriate lower application rates for control of other listed corn pests.**"

- 8) Add to the label the **site of action identification symbol** and the **Resistance-Management Statement** according to the Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance Management Labelling Based on Target Site/Mode of Action*, (see 7.5.3), as follows:

GROUP	4	INSECTICIDE
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Resistance management recommendations

For resistance management, PONCHO 600 Seed Treatment Insecticide contains a Group 4 insecticide. Any insect population may contain individuals naturally resistant to PONCHO 600 FS and other Group 4 insecticides. The resistant biotypes may dominate the insect population if these insecticides are used repeatedly in the same field. Other resistance mechanisms that are not linked to site of action, but specific for individual chemicals, such as enhanced metabolism, may also exist. Appropriate resistance-management strategies should be followed.

To delay insecticide resistance:

- Where possible, rotate the use of PONCHO 600 Seed Treatment Insecticide or other Group 4 insecticides with different groups that control the same pests in a field.
- Insecticide use should be based on an integrated pest management (IPM) program that includes scouting and record keeping and considers cultural, biological, and other chemical control practices.
- Monitor treated pest populations for resistance development.
- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance-management and IPM recommendations for the specific site and pest problems in the area.
- For further information or to report suspected resistance, contact (company representatives) at (toll free number) or at (Internet site).

- 9) Directions for Use - Rotational crop restrictions: Corn and canola may be replanted at any time. A one year plantback interval is required for leafy, root and tuber vegetables. A 30-day plantback on cereal grains, grasses, nongrass animal feeds, and soybean and dried beans is required.