### **Regulatory Directive**

**DIR2005-02** 

# Administrative Process for a Change in a Registrant's Name or a Change in Registrant for Pest Control Products

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#### 1.0 Purpose

The purpose of this document is to communicate a revised procedure for amending the Product Register to reflect a change in a registrant's name or a change in registrant. This revised procedure replaces the provisions relating to a change in the name of a registrant and the transfer of product registration from one registrant to another outlined in Regulatory Directive <u>DIR2001-04</u>, *Notification/Non-notification*.

#### 2.0 Registrant Responsibility

"Registrant" means a person in whose name a pest control product is registered. In this context, a "person" means a person in law, that is, a natural person or a person created by law, e.g., a corporation.

The registrant must:

- be in a position to assume full legal responsibility for the pest control product registrations registered in its name;
- be able to comply with the conditions of registration for the pest control product registrations registered in its name; and
- be able to demonstrate legal entitlement to the pest control product registrations to be registered in its name.

#### 3.0 Background

The PMRA is committed to improving the efficiency of pest control product registration processes. The Agency recognizes that streamlining efforts require improved record keeping and information tracking capacity.

Under the *Pest Control Products Act* and Regulations, a product registration must be amended to reflect a registrant name that is different from the one under which the pest control product was previously registered. Regulatory Directive DIR2001-04, *Notification/Non-notification*, specifies that a change in the registrant's name may be documented through the submission of a notification letter. However, the new owner of a pest control product must submit a separate amendment application for each affected product to transfer the ownership of the registrations from one registrant to another.

With respect to the processing of applications to "transfer" ownership to a new registrant, the Agency's ability to meet the target performance standard has been compromised by the following:

- the practice of allowing other amendments to be processed in the same application, some of which require review of data and re-categorization of the application; and
- the significant workloads associated with transfers resulting from mergers, spinoffs, buyouts, product-line purchase and other complex, sequential business transactions.

For these reasons, the "transfer" of a portfolio of products has often taken two or more years to complete. Moreover, successive company mergers have resulted in an overlap of amendment submissions and difficulties in record-keeping. This, in turn, has had a negative impact on the processing of other related applications and has resulted in product labels for some registered products reflecting the names of companies that have not existed for several years.

The revised procedure described below is intended to address these issues.

#### 4.0 Scope

This policy applies to all instances where there has been:

- a change in a registrant's name, but the registrant remains the same legal entity, e.g., an Amendment to the Certificate of Incorporation and related Article of Amendment; and/or
- a change <u>in registrant</u> resulting from a business legal transaction, e.g., an amalgamation of companies, a spin-off of a new company, an acquisition of the rights to single or multiple registrations (e.g., a buyout, product-line purchase) or any other legal circumstance that entitles the new owner to have registrations placed in its name.

This policy replaces the provisions of Regulatory Directive 2001-04, *Notification/Non-notification*, that relate to a change in the name of a registrant and transfer of product registration from one registrant to another.

#### 5.0 Policy

Product-specific applications and notifications of registrant name change are no longer required. Instead, an amendment of the Product Register to reflect a change in a registrant's name or a change in the registrant will be processed through an administrative process for changing a registrant's name or changing the registrant for pest control products.

As part of this administrative process, the documentation identified in Section 6 will be required to ensure that the change may be processed as requested.

The request to change the registrant's name or change the registrant of the pest control products should be submitted to the PMRA immediately following the completion of the business legal transaction (as soon as the applicable supporting documentation is available).

Other changes to amend the Product Register will continue to require the appropriate amendment applications and/or notifications.

## 6.0 Requirements and Process for a Change in a Registrant's Name or a Change in Registrant for Registered Pest Control Products

#### 6.1 Requirements for a Change in a Registrant's Name

In the case of a change in a registrant's name (where the registrant legal entity remains the same), it is the responsibility of the registrant to submit a change request, as follows:

- a) a cover letter on company letterhead
  - describing the circumstances surrounding the change
- b) a signed, completed copy of the Attestation to Accompany an Administrative Process for a Change in a Registrant's Name or a Change in Registrant for Pest Control Products (Appendix I to this Regulatory Directive)
  - confirming the contact information for the registrant
  - confirming that the marketplace label of affected marketed products will be reprinted to reflect the change in a registrant's name within one year of the date the PMRA acknowledges completion of the change request
- c) supporting legal documentation that confirms the change in a registrant's name, e.g., copies of the Articles of Amendment and the Amendment to the Certificate of Incorporation
- d) in the case of private label registration(s), a letter from the registrant of the initial product, supporting the change request for the private label registration(s)

Should the documentation submitted be insufficient to support the change in a registrant's name, the PMRA will contact the registrant to discuss the situation and the policy requirements.

#### 6.2 Requirements for a Change in Registrant

In the case of a change in registrant resulting from a business legal transaction, it is the responsibility of the proposed new registrant to submit the change request, as follows:

- a) a cover letter on company letterhead
  - describing the circumstances surrounding the change
- b) a signed, completed copy of the Attestation to Accompany an Administrative Process for a Change in a Registrant's Name or a Change in Registrant for Pest Control Products (Appendix I to this Regulatory Directive)
  - confirming the contact information for the registrant
  - confirming that the marketplace label of affected marketed products will be reprinted to reflect the new registrant's name within one year of the date the PMRA acknowledges completion of the administrative change request
  - confirming that the proposed new registrant will comply with the conditions of registration for the affected pest control product registrations and will submit any outstanding data requirements
- c) a listing of
  - affected registered products by their registration number and their corresponding product name (products that are no longer registered are not in the scope of this document)
  - affected open applications by application number and corresponding product name
- d) supporting legal documentation that confirms that the proposed new registrant
  - is in a position to assume full legal responsibility for the pest control registrations, i.e., documents confirming the proposed new registrant's status in law, e.g., Certificate of Incorporation
  - is legally entitled to the products, e.g., copy of asset purchase agreement, letter from previous registrant acknowledging the transfer of ownership of the products by specifically identifying the products by registration number and corresponding product name, letter from bankruptcy trustee, etc.

e) in the case of private label registration(s), a letter from the registrant of the initial product supporting the change request for the private label registration(s)

Should the documentation, when submitted, be insufficient to support the change in registrant, the PMRA will contact the new registrant to discuss the situation and the policy requirements.

#### **NOTE:**

- i) In the case where a registrant merger or buyout is involved, all products belonging to the parties of the merger or buyout must be accounted for in the list of registrations submitted with the administrative change request. Where registrations acquired by the proposed new registrant include those for which sales have been discontinued by the current registrant, the proposed new registrant will be responsible for complying with any conditions attached to the discontinuation until the registration expires. Any existing registrations that the proposed new registrant does not wish to support will require the submission of a notice of discontinuance.
- ii) In the case of an amalgamation of more than two companies each holding pest control product registrations, a separate change request will be required for each of the registrant companies involved in the amalgamation.

#### 6.3 Processing of Change Requests

The PMRA will proceed as follows to process change requests:

#### Within 15 days of receiving request

• verify the required documentation and inform the registrant of the acceptability or unacceptability of the supporting documentation (including the reason why the documentation has been found insufficient)

Within 15 days of verifying and finding acceptable the supporting documentation for a request

- update the Register for all affected products and, if applicable, the records for any open applications
- annotate the affected products PMRA web labels to reflect the change
- confirm, in writing, the PMRA's completion of the change request

## **NOTE:** The time taken to complete processing a request may exceed 30 days in cases where the required documentation is not found acceptable to action the request. The PMRA will work with the parties involved to clarify the requirements.

## **6.4** Fees for Administrative Process for a Change in Registrant Name or a Change in Registrant

There is no fee associated with the Administrative Process for a Change in Registrant's Name or a Change in Registrant.

## 6.5 Market Place Label Requirements Following an Administrative Process for a Change in Registrant Name or a Change in Registrant

The marketplace labels of affected marketed products must be reprinted to reflect the new registrant name within one year of the date the PMRA acknowledges completion of the change request. There is no requirement to submit copies of these reprinted labels to the PMRA at the time of reprinting.

After reprinting marketplace labels to reflect the changed registrant name or new registrant, with regard to products already in the distribution chain bearing labels, the registrant must either:

- over sticker or over label product already in the marketplace; or
- advise retailers and users of the new contact information.

## 6.6 Requirement for New E-PRS Legal Agreement Following an Administrative Process for a Change in Registrant Name or a Change in Registrant

The PMRA, as part of the processing of change requests, will work with registrants enrolled in e-PRS to determine the effect of the change on the current e-PRS legal agreement and to assist them in submitting new legal agreements as necessary.

#### 7.0 Implementation

Given that this approach represents reduced regulatory burden for industry and the PMRA, and given that a similar approach has been piloted successfully with numerous registrants during the past two years, formal consultation is not deemed necessary. Consequently, the effective date of implementation is the date of publication of this Regulatory Directive.

Before submitting a change request, registrants or proposed new registrants are strongly encouraged to contact the PMRA to clarify the **parties** and **products** involved as well as determine in advance any other issues that may arise as a result of the change.

To obtain additional information on the Administrative Process for a Change in Registrant's Name or a Change in Registrant, the proposed new registrant should contact the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or

(613) 736-3799 outside Canada (long distance charges apply); Fax: (613) 736-3798; E-mail: <a href="mailto:pmra">pmra</a> infosery@hc-sc.gc.ca</a>; or through our website at <a href="www.pmra-arla.gc.ca">www.pmra-arla.gc.ca</a>.

#### 7.1 Transition

The PMRA will work with registrants who have current applications in progress for change in a registrant's under the pilot project, referred to in Section 7.0, to finalize the applications in as expeditious a manner as possible.

## Appendix I Attestation to Accompany an Administrative Process for a Change in a Registrant's Name or a Change in Registrant for Pest Control Products

In accordance with the accompanying legal documentation, please update administratively the Register to reflect the registrant's new name / new registrant for the attached list of pest control product registrations and open applications to register a new product or to amend a registration submitted under the name of the current registrant.

(Current registrant name and address on record with PMRA)

A:

From:

Registrant Name	
Mailing Address	
City	
Province / State	
Country	
Postal Code / ZIP	
B: To: (Registrant's	new name / proposed new registrant's name and contact information)
Registrant Name	
	ness address provided is complete and capable of receiving postal mail delivery. This headquarters' address. In addition, please provide the contact information for the is address.
Mailing Address	
City / Town	
Province / State	
Country	
Postal Code / ZIP	
Principal contact at th	nis address
Name	
Title	

Phone	
Fax	
E-mail	

## C: Regulatory mailing address for registrant following completion of administrative change:

(Canadian resident representative for non-Canadian registrants, as identified in B)<sup>1</sup> Same as B above  $\square$  ("Same as B" may not be selected for non-Canadian registrants)

<b>Business Name</b>		
Mailing Address		
City / Town		
City / Town		
Province		
Country	CANADA	
Postal Code		
Principal contact at this address		
Name		
Title		
Phone		
Fax		
E-mail		

In requesting this change, the registrant identified in B above, assumes full responsibility for the registrations (and any open applications) and undertakes to comply with the conditions of registration and any outstanding data requirements. The registrant identified in B above, also confirms that the marketplace label of affected marketed products will be reprinted to reflect the new registrant name and contact information within one year of the date the PMRA acknowledges completion of the change request.

**NOTE:** 

This attestation must be signed by an officer of the registrant company that has changed its name, or by an officer of the proposed new registrant in the case of a change in registrant.

Non-Canadian registrants identified in Section B of this attestation must provide a Canadian address for receiving postal mail delivery, to which the PMRA will send all of the registrant's regulatory mail. This will be the registrant's Canadian Resident Representative. Operational and system requirements dictate that the regulatory mailing address must be the same for all products registered to the registrant identified in B.

Signing officer:		
Name		
Position		
Phone		
Fax		
E-mail		

Signature of signing officer: