Proposed Re-evaluation Decision PRVD2010-10

Formaldehyde and Paraformaldehyde

(publié aussi en français)

15 July 2010

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

HC Pub: 100263

ISBN: 978-1-100-94745-7 (978-1-100-94746-4)
Catalogue number: H113-27/2010-10F (H113-27/2010-10F-PDF)

Table of Contents

Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the antimicrobials formaldehyde and paraformaldehyde, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing formaldehyde and paraformaldehyde in Canada.

An evaluation of available scientific information found that products containing formaldehyde or paraformaldehyde do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of formaldehyde and paraformaldehyde uses, new risk-reduction measures must be included on the labels of all products. Additional data are being requested as a result of this re-evaluation.

This proposal affects all end-use products containing formaldehyde and paraformaldehyde registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for formaldehyde and paraformaldehyde and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of formaldehyde and paraformaldehyde.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health *and* the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

Formaldehyde and paraformaldehyde, two of the active ingredients in the current re-evaluation cycle, have been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in the 2008 RED, the USEPA concluded that formaldehyde and paraformaldehyde were eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED were an adequate basis for the proposed Canadian re-evaluation decision.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What Is Formaldehyde?

Formaldehyde is an antimicrobial agent that is used as a disinfectant, fungicide and nematicide in mushroom production and agricultural buildings, as a seed treatment, and in bulb production. Formaldehyde is applied using fumigation, spray, dip or cloth/mop by farm workers.

What Is Paraformaldehyde?

Paraformaldehyde (a polymer of formaldehyde) is an antimicrobial agent that is used in alfalfa leafcutting bee (*Megachile rotundata*) production. Paraformaldehyde is applied by fumigation.

Health Considerations

Can Approved Uses of Formaldehyde and Paraformaldehyde Affect Human Health?

Formaldehyde and paraformaldehyde are unlikely to affect your health when used according to the revised label directions.

People could be exposed to formaldehyde and paraformaldehyde when working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that formaldehyde and paraformaldehyde were unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Environmental Considerations

What Happens When Formaldehyde and Paraformaldehyde are Introduced Into the Environment?

Formaldehyde and Paraformaldehyde are unlikely to affect non-target organisms when used according to the revised label directions.

The USEPA concluded that uses of formaldehyde and paraformaldehyde were unlikely to affect non-target organisms provided that additional advisory statements to further protect the environment were implemented. These conclusions apply to the Canadian situation.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of formaldehyde and paraformaldehyde, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Application limited to indoor non-producing areas free of all persons, animals, soil, produce, debris and equipment.
- Remove treatment of diseased areas on mushroom beds from label.
- Remove manual application by cloth, mop or broom from label.
- Remove control of nematodes on tools and equipment from label.

- Reduce application rates for mushroom house cleanout and general disinfection.
- Revised fumigation application requirements.
- Certification required for fumigant handlers.
- Revised paraformaldehyde storage requirements.
- Ventilation requirements prior to re-entry by unprotected persons.
- Additional personal protective equipment for handlers.

Environment

- Additional advisory label statements to reduce potential surface and groundwater contamination.

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of the formaldehyde active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix I lists all data requirements.

Next Steps

Before making a final re-evaluation decision on formaldehyde and paraformaldehyde, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

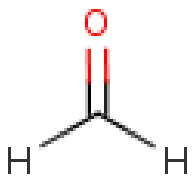
1.0 Introduction

Following the re-evaluation announcement for formaldehyde, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for certain uses included on the label of the commercial end-use product in Canada. The registrant of the paraformaldehyde technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the label of the commercial end-use product in Canada.

The PMRA used recent assessments of formaldehyde and paraformaldehyde from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for formaldehyde and paraformaldehyde, dated 30 June 2008, as well as other information on the regulatory status of formaldehyde and paraformaldehyde in the United States can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredients, Their Properties and Uses

2.1 Identity of the Formaldehyde Technical Grade Active Ingredient

Common name	Formaldehyde
Function	Fungicide, bactericide
Chemical family	Aldehyde
Chemical name	
1 International Union of Pure and Applied Chemistry (IUPAC)	Formaldehyde
2 Chemical Abstracts Service (CAS)	Formaldehyde
CAS Registry Number	50-00-0
Molecular formula	CH_2O
Structural formula	
Molecular weight	30.00 amu

Purity of the technical grade active ingredient	Not applicable
Registration Number	No registered technical grade active ingredient

There is no registered technical grade active ingredient for formaldehyde. The PMRA has no information to characterize the physical and chemical properties of formaldehyde used in the registered product. It could not be determined if formaldehyde would contain impurities of human health or environmental concern. The PMRA requires the registrant to submit chemistry data as a condition of continued registration under Section 12 of the *Pest Control Products Act*. Appendix I lists the data requirements.

2.2 Comparison of Formaldehyde Use Patterns in Canada and the United States

Formaldehyde is an antimicrobial agent registered in Canada as a disinfectant, fungicide and nematicide. The commercial class end-use product is formulated as a 37% active ingredient solution. The following indoor, non-food, formaldehyde uses are being supported by the registrant and were, therefore, considered in the re-evaluation of formaldehyde:

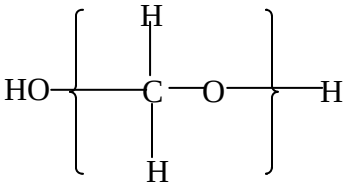
- mushroom house cleanout by manual application (spray, mop, sponge, etc);
- disinfection of mushroom equipment by dip or spray application;
- treatment of diseased areas on mushroom beds;
- general disinfection of interior surfaces by manual application (spray, mop, sponge, etc);
- control of nematodes on ornamental bulbs by dip application; and
- disinfection of poultry houses by catalyzed fumigation.

Uses of formaldehyde for mushroom casing soil, as a seed treatment, and for outdoor use are no longer supported by the registrant. Based on consultation with ornamental growers, the PMRA has determined that use of formaldehyde for control of nematodes on tools and equipment is not relevant in Canada, and therefore, is proposing this use be removed from label.

The American and supported Canadian use patterns were compared. The Canadian formulation type, application methods, and use sites are among those registered in the United States. Based on this comparison of use patterns, it was concluded that the USEPA RED for formaldehyde is an adequate basis for the re-evaluation of uses of formaldehyde in Canada. The PMRA is aware that the USEPA assessment of formaldehyde is ongoing. The PMRA may re-assess formaldehyde in the future, as required.

Appendix II lists all formaldehyde products that are registered as of 3 January 2010, under the authority of the *Pest Control Products Act*.

2.3 Identity of the Paraformaldehyde Technical Grade Active Ingredient

Common name	Paraformaldehyde
Function	Fungicide, bactericide, wood preservative
Chemical family	Formaldehyde polymer
Chemical name	
1 International Union of Pure and Applied Chemistry (IUPAC)	Polyoxymethylene glycol
2 Chemical Abstracts Service (CAS)	Paraformaldehyde
CAS Registry Number	30525-89-4
Molecular formula	$HO(CH_2O)_nH$
Structural formula	
Molecular weight	$(30.03)_n$ - average is 600
Purity of the technical grade active ingredient	92% nominal (limits: 91-93%)
Registration Number	20153

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

Physical and Chemical Properties of the Technical Grade Active Ingredient (paraformaldehyde)

Property	Result
Vapour pressure (25°C)	1.4 mm Hg
Solubility in water	Poor, slightly soluble in cold water

2.4 Comparison of Paraformaldehyde Use Patterns in Canada and the United States

Paraformaldehyde (a polymer of formaldehyde) is an antimicrobial agent registered in Canada as a sanitizer and disinfectant. It is used for control of microflora in alfalfa leafcutting bee (*Megachile rotundata*) production. The commercial class end-use product is formulated as a granule with a 92% active ingredient guarantee. Paraformaldehyde is applied by fumigation to materials provided for bee nesting (wood, plastic); and to bee cells during the pre-pupal diapause developmental bee stage (pre-emergent). Paraformaldehyde granules are heated during application resulting in the release of formaldehyde gas for fumigation.

The American and Canadian use patterns were compared. The Canadian paraformaldehyde use pattern is not directly encompassed by the United States use pattern; however, the Canadian formulation and guarantee are among those of registered paraformaldehyde products in the United States, and the Canadian application method (evaporative fumigation) is encompassed by the USEPA RED assessment of formaldehyde evaporative fumigation. Since paraformaldehyde is a polymer of formaldehyde, and formaldehyde is released during use, the formaldehyde fumigation assessment is considered applicable to the Canadian situation. Based on this comparison of use patterns, it was concluded that the USEPA RED for formaldehyde and paraformaldehyde is an adequate basis for the re-evaluation of uses of paraformaldehyde in Canada.

Appendix II lists all paraformaldehyde products that are registered as of 3 January 2010, under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 2008 RED, the USEPA concluded that the end-use products formulated with formaldehyde or paraformaldehyde met the safety standard under the American *Federal Insecticide, Fungicide, and Rodenticide Act* and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the amended product labels.

3.1 Human Health

The USEPA concluded that inhalation would be the most critical route of exposure based the on high vapour pressures of formaldehyde and paraformaldehyde. No dietary, oral or dermal risk assessments were conducted.

The USEPA has classified formaldehyde as a B1 probable human carcinogen; however, is currently reviewing this position. In the interim, risk mitigation measures outlined in the RED were considered to reduce exposure such that a cancer risk would not be of concern. The USEPA's toxicological endpoint for assessing risk of formaldehyde is summarized in Appendix III.

In Canada, exposure to formaldehyde and paraformaldehyde may occur while working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

3.1.1 Occupational Exposure and Risk Assessment

3.1.1.1 Handler Exposure and Risk

Workers can be exposed to formaldehyde and paraformaldehyde when mixing, loading or applying the pesticide. The USEPA concluded that there was not sufficient exposure information available on the biocidal uses of formaldehyde and paraformaldehyde to quantitatively assess exposure. Furthermore, due the high vapour pressure, surrogate inhalation unit exposure data were not applicable. Therefore, a qualitative exposure assessment was conducted based on work practices on the United States product labels.

The USEPA identified seven occupational exposure scenarios for formaldehyde. Among the scenarios assessed in the RED, the following mixer/loader/applicator exposure scenarios were considered relevant to the Canadian uses of formaldehyde and paraformaldehyde:

- hard surface disinfection of poultry and livestock buildings and equipment;
- evaporative fumigation for disinfection of incubators; and
- catalyzed fumigation for disinfection of rooms and railcars.

Hard surface disinfection refers to the use of a formaldehyde solution applied manually by mop, sponge, spray, or soaking (dip) for disinfection of non-porous surfaces, for example, in farm buildings or on equipment. Using worst-case assumptions, the USEPA determined that handler exposure from manual application would be of concern. To protect handlers, the USEPA required the termination of cloth and mop application and required that handlers wear a full-face respirator during spray application.

Based on work practices described on the United States product labels, it was determined that exposure from evaporative fumigation uses would be low. Exposure from catalyzed fumigation might be significant depending on the time spent inside the fumigation area by a handler and the rate at which formaldehyde is released. The USEPA limited formaldehyde fumigation to animal premises, mushroom houses, citrus houses, egg facilities and rail cars.

The RED adequately addressed the potential exposure scenarios associated with the uses of products containing formaldehyde and paraformaldehyde in Canada, and conclusions apply to the Canadian situation. Due to higher application rates in Canada, exposure from mushroom house cleanout and general disinfection uses is expected to be higher than hard surface disinfection uses assessed in the RED. Therefore, in addition to mitigation measures required by the USEPA, the PMRA also requires a rate reduction for mushroom house cleanout and general disinfection uses. Catalyzed formaldehyde fumigation of poultry houses could result in brief handler exposure; however, the risk is expected to be acceptable provided handlers wear

personal protective equipment, including a full-face respirator. Evaporative paraformaldehyde fumigation in designated fumigation chambers is expected to result in low exposure as handlers remain outside the fumigation chamber during application. In the United States, formaldehyde application is limited to indoor areas free of all produce. Based on this, the PMRA requires use for treatment of diseased areas on mushroom beds to be removed from product label.

Based on the RED, the PMRA requires the following mitigation measures to address potential risk to handlers:

- Application is limited to indoor non-producing areas that are free of all persons, animals, soil, produce, equipment, debris, etc. Application is prohibited on surfaces that may have either direct or indirect contact with food or feed.
- Remove use for treatment of diseased areas on mushroom beds.
- Remove application by cloth, mop or broom from label.
- Reduce application rate for general surface disinfection from 4.0 g a.i./L to 0.19 g a.i./L.
- Reduce application rate for mushroom house cleanout from 16.0 g a.i./L to 0.19 g a.i./L.
- Fumigant handlers must hold an appropriate pesticide applicator certificate or licence recognized by the provincial/territorial pesticide regulatory agency where the pesticide application is to occur.
- Prior to fumigation, warning signs must be posted at all entrances, and an 8 meter prohibited entry zone must be established surrounding the fumigated building/chamber.
- Premises must be securely locked during all stages of fumigation including application, fumigation, and ventilation.
- Surfaces must be washed with soap or detergent prior to use of formaldehyde. Surfaces that might come in contact with animal feed or water should be washed with soap or detergent post application.
- Additional label amendments are required to limit off-gassing during paraformaldehyde storage.
- All handlers and persons inside the prohibited entry zone must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves and footwear, chemical-resistant headgear (during overhead application) and a full face respirator. During cleaning of equipment or mixing/loading product a chemical-resistant apron must also be worn.

The proposed label amendments for formaldehyde are listed in Appendix IV. The proposed label amendments for paraformaldehyde are listed in Appendix V.

Data is required to ensure the reduced application rates for general surface disinfection and mushroom house cleanout are effective. The PMRA requires the registrant to submit data as a condition of continued registration under Section 12 of the *Pest Control Products Act*. Appendix I lists the data requirements.

3.1.1.2 Post-application Exposure and Risk

Workers or bystanders could be exposed to formaldehyde or paraformaldehyde residues post-application when entering sites where the products have been used.

The USEPA used the Multi-Chamber Concentration and Exposure Model (MCCEM v1.2) to estimate the peak indoor formaldehyde air concentration during fumigation. Based on this, the USEPA determined that ventilation achieving 12 air-changes would be required to reduce the formaldehyde interior air concentration to below the 0.1 ppm no observed adverse effect level (NOAEL).

The RED adequately addressed exposure scenarios associated with the Canadian uses of formaldehyde and paraformaldehyde, and conclusions derived from the RED are considered to be applicable to the Canadian situation. The existing Canadian formaldehyde and paraformaldehyde labels require ventilation; however, no detailed requirements are specified for ventilation capacity. Based on this, the PMRA requires ventilation achieving 12 air changes before re-entry by unprotected persons after any form of formaldehyde or paraformaldehyde application. The proposed label amendments for formaldehyde are listed in Appendix IV. The proposed label amendments for paraformaldehyde are listed in Appendix V.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

No residential formaldehyde or paraformaldehyde uses are registered in Canada. Based on this, the PMRA requires no further mitigation measures with respect to residential exposure.

3.1.2.2 Exposure From Food and Drinking Water

The USEPA determined that based on the antimicrobial use pattern of formaldehyde and paraformaldehyde, dietary exposure would be negligible. Based on the environmental fate properties of formaldehyde (and paraformaldehyde), the active ingredients would be unlikely to persists in water. Based on this, it was concluded that there were no dietary or drinking water concerns from the antimicrobial uses of formaldehyde and paraformaldehyde; therefore no risk assessment was required.

The Canadian formaldehyde uses are encompassed by the USEPA RED; therefore, conclusions described in the RED are considered relevant to the Canadian formaldehyde use pattern. The Canadian paraformaldehyde use in alfalfa leafcutting bee production occurs (21-28 days) prior to bee emergence (hatching) in designated fumigation chambers (indoor application). The alfalfa leafcutting bee does not produce honey; it is used solely as a pollinator. Based on this, the PMRA does not expect dietary or drinking water concerns from uses of formaldehyde or paraformaldehyde in Canada and no further mitigation measures are required.

3.1.2.3 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure (i.e. from food, water and residential exposures). There are no residential uses of formaldehyde or paraformaldehyde in Canada, and exposure through food and drinking water is expected to be limited. Based on this, aggregate exposure to these chemicals is not expected, and therefore, an aggregate risk assessment is not required.

3.1.3 Cumulative Effects

The USEPA has not determined whether formaldehyde and or paraformaldehyde have a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed formaldehyde and paraformaldehyde do not share a common mechanism of toxicity with other substances and a cumulative risk assessment was not required.

3.2 Environment

3.2.1 Environmental Risk Assessment

The USEPA determined that based on the primarily indoor use pattern, the potential for formaldehyde or paraformaldehyde to be released into the environment at exposure levels of concern would be minimal. In the event of release, formaldehyde and paraformaldehyde are not likely to persist or bioaccumulate in the environment. An environmental hazard assessment was conducted for all uses, including oil fields, and it was determined that formaldehyde is highly toxic to oysters. Based on the ecological hazard assessment, the USEPA required confirmatory data to establish acute toxicity to freshwater invertebrates and hazard labelling pertaining to disposal of wastewaters and oyster toxicity.

In Canada, all formaldehyde and paraformaldehyde uses are indoors, therefore, the potential for environmental exposure is lower than in the United States. Based on the RED, and in consideration of the Canadian situation, the PMRA requires additional advisory label statements on formaldehyde labels to further protect the environment from discharge. The proposed label amendments for formaldehyde are listed in Appendix IV. No additional labelling is required for paraformaldehyde labels.

3.3 Pest Control Product Policy Considerations

3.3.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy, i.e., *Canadian Environmental Protection Act*-toxic or equivalent, predominantly anthropogenic, persistent and bio-accumulative.

During the re-evaluation process, formaldehyde and paraformaldehyde were assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy,* and evaluated against the Track 1 criteria for persistence and bioaccumulation. In order for formaldehyde or paraformaldehyde or their transformation products to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one media) must be met.

The log *n*-octanol-water partition coefficient (log K_{ow}) of formaldehyde is 0.7, which is below the TSMP Track 1 cut-off criterion for log K_{ow} of 5.0. As well, formaldehyde does not meet the criteria for persistence as its half-life value in soil (14 days) is below the TSMP Track 1 cut-off criteria of 182 days. The environmental fate properties of paraformaldehyde are considered equivalent to formaldehyde. On this basis, it is concluded that the uses of formaldehyde or paraformaldehyde are not expected to result in the entry of Track 1 substances into the environment.

3.3.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of formaldehyde and paraformaldehyde contaminants in the technical are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[3]. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

- The PMRA has no information to characterize the physical and chemical properties of formaldehyde. It could not be determined if formaldehyde would contain impurities of human health or environmental concern. The PMRA requires the registrant to submit chemistry data as a condition of continued registration under Section 12 of the *Pest Control Products Act*. Appendix I lists data requirements.

- Technical grade paraformaldehyde does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

[3] *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette,* Part II, Volume 142, Number 13, pages 1611-1613*. Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

4.0 Incidence reports

Starting April 26, 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame.

- There were no incident reports submitted for formaldehyde as of 3 January 2010.

- There is one incident report on file for paraformaldehyde as of 3 January 2010. The incident involved a packaging failure. There were no reports of injury or exposure from workers. There was no environmental release.

5.0 Organisation for Economic Co-operation and Development Status of Formaldehyde and Paraformaldehyde

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 30 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies. They compare experiences, share information and analyses, seek answers to common problems, and work to co-ordinate domestic and international policies to allow for consistency in practices across nations.

Based on the available information, formaldehyde is permitted/registered for use as an antimicrobial agent in the United States, European Union, New Zealand, and Australia.

As described earlier in this document, the United States, also an OECD member, assessed the registration of all uses of formaldehyde and paraformaldehyde in 2008 and concluded that use as a pesticide does not result in unreasonable adverse effects to human health or the environment provided the risk-reduction measures recommended in the RED document were implemented.

The Canadian re-evaluation of formaldehyde and paraformaldehyde is largely based on the 2008 USEPA assessments. As described in Section 3.1 and 3.2 above, the PMRA has found the USEPA human health and environmental risk conclusions to be relevant to the use of formaldehyde and paraformaldehyde in Canada and requires measures to mitigate risk to further protect workers, bystanders, and the environment.

6.0 Proposed Re-evaluation Decision

The PMRA has determined that formaldehyde and paraformaldehyde are acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment. The labels of Canadian end-use products must be amended to include the label statements listed in Appendix IV and V. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. The registrant of the formaldehyde product will be required to submit data as a condition of continued registration under Section 12 of the *Pest Control Products Act*. Appendix I lists data requirements.

7.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and data code (DACO) tables can be found on our website at www.healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for formaldehyde and paraformaldehyde is available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

List of Abbreviations

a.i.	active ingredient
CAS	Chemical Abstracts Service
DACO	data code
g	gram(s)
IUPAC	International Union of Pure and Applied Chemistry
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
m	metre(s)
m^3	metre(s) cubed
MCCEM	Multi-Chamber Concentration and Exposure Model
mm Hg	millimetre mercury
MRL	maximum residue limit
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PCPA	*Pest Control Products Act*
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
RED	Reregistration Eligibility Decision
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency

Appendix I Additional Data Requirements

The following data are required as a condition of continued registration under Section 12 of the Pest Control Products Act. The registrants of this active ingredient are required to provide these data or an acceptable scientific rationale within the timeline specified in the decision letter that will be sent to the registrant by the PMRA.

- DACO 2: The entire Part 2 chemistry data for the formaldehyde technical product are required.

  This study must be conducted with the relevant technical grade active ingredient.

- DACO 10.2.3.2 Laboratory Trials:
  The new lower formaldehyde rate of 0.19 g a.i./L must be tested to ensure it is effective. Testing may be carried out using protocols derived from EPA DIS-TSS 01 (Disinfectants for Use on Hard Surfaces), or DIS-TSS 10 (Sanitizer Test for Inanimate Surfaces), or ASTM E-2192-02 (Standard Quantitative Disk Carrier Test Method for Determining the Bactericidal, Virucidal, Fungicidal, Mycobactericidal and Sporocidal Activities of Liquid Chemical Germicide). The microorganisms being used in the tests must be relevant to the use pattern (e.g., mushroom pathogens for mushroom houses disinfection).

Appendix II

Registered Products Containing Formaldehyde as of 3 January 2010

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
6998	Commercial	United Agri Products Canada Inc.	Formalin Fungicide	Solution	37%

Registered Products Containing Paraformaldehyde as of 3 January 2010

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
20153	Technical	Saskatchewan Alfalfa Seed Producers Association	Paraformaldehyde Technical	Granular	92%
27853	Commercial	Saskatchewan Alfalfa Seed Producers Association	Paraformaldehyde	Granular	92%

Appendix III Toxicological Endpoints for Formaldehyde and Paraformaldehyde Health Risk Assessments

Exposure Scenario	NOAEL (ppm)	Study
Inhalation (all durations)	0.1 (human)	Horvath, E.P. *et al*. 1986. Based on complaints of eye, nose, and throat irritation in particle board workers at concentrations of formaldehyde from 0.4 - 1.0 ppm. JAMA 259(5): 701-707.
Cancer	B1, Probable human carcinogen, Currently under review by the USEPA.	

Appendix IV Label Amendments for Products Containing Formaldehyde

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

The label of the end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following uses are not eligible for continued registration and must be removed from end-use product labels:

Mushroom casing soil, diseased areas on mushroom beds, mushroom composting yards and concrete slabs, potato diseases, smuts in grain, nematode control on tools and equipment.

Manual application of formaldehyde by cloth, broom or mop application.

II) The end-use product labels must be amended to indicate a maximum application rate

Mushroom house cleanout: 0.19 g a.i./L.

General disinfection: 0.19 g a.i./L.

III) The following statements must be included on the primary display panel.

DANGER POISON

DANGER – CORROSIVE TO EYES

DANGER SKIN IRRITANT

POTENTIAL SKIN SENSITIZER

The following statements must be included on the secondary display panel

Fatal or Poisonous if swallowed.
Extremely hazardous by skin contact. DO NOT get on skin.
CORROSIVE to the eye. DO NOT get in eyes.
CORROSIVE to the skin. DO NOT get on skin.
Potential skin sensitizer

IV) The following must be included in a section entitled **DIRECTIONS FOR USE**.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

All handlers and persons inside the prohibited entry zone must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves and footwear, chemical-resistant headgear (during overhead application) and a full face respirator. During cleaning of equipment or mixing/loading product a chemical-resistant apron must also be worn.

Application is limited to indoor non-producing areas that are free of all persons, animals, soil, produce, equipment, debris, etc. Application is prohibited on surfaces that may have either direct or indirect contact with food or feed.

Fumigant handlers must hold an appropriate pesticide applicator certificate or licence recognized by the provincial/territorial pesticide regulatory agency where the pesticide application is to occur.

Warning signs must be posted on, or in the vicinity, of all entrances prior to fumigation. Signs must state “DANGER – FUMIGATION” and “FORMALDEHYDE” with skull and crossbones symbol, date and time fumigant introduced, and contact information of applicator performing fumigation. Signs may not be removed until fumigation, ventilation is complete and the premise is safe for re-entry.

An 8 meter prohibited entry zone must be established extending from, and surrounding, the building being fumigated. The prohibited entry zone must be clearly identified with cones and cautionary tape. No persons except for properly equipped handlers are permitted within the prohibited entry zone.

Premises must be securely locked during all stages of fumigation including: application, fumigation, and ventilation.

All surfaces must be washed with soap or detergent prior to use of formaldehyde. Surfaces that might come in contact with animal feed or water, should be washed with soap or detergent post application.

Ventilation must achieve a total of 12 air-changes prior to re-entry by unprotected persons.

Appendix V Label Amendments for Products Containing Paraformaldehyde

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

The label of the end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statement must be added to the primary display panel.

POTENTIAL SKIN SENSITIZER

The following statements must be included on the secondary display panel.

Harmful is swallowed.
Extremely hazardous by skin contact. DO NOT get on skin.
Harmful if inhaled.
CORROSIVE to the eye. DO NOT get in eyes.
Potential skin sensitizer.

II) The following must be included in a section entitled **DIRECTIONS FOR USE**.

All handlers and persons inside the prohibited entry zone must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves and footwear and a full face respirator. During cleaning of equipment or mixing/loading product a chemical-resistant apron must also be worn.

Fumigant handlers must hold an appropriate pesticide applicator certificate or licence recognized by the provincial/territorial pesticide regulatory agency where the pesticide application is to occur.

Paraformaldehyde fumigation is limited to designated fumigation chambers used exclusively for fumigation of alfalfa leafcutting bee cells and/or nest material.

Warning signs must be placed on fumigation chambers and the surrounding area before fumigation begins. Signs must state: “DANGER – FUMIGATION” and “PARAFORMALDEHYDE” with skull and crossbones symbol, date and time fumigant introduced, and contact information of applicator performing fumigation. Warning signs may not be removed until ventilation is complete and the premise is safe for re-entry.

An 8 meter prohibited entry zone must be established extending from, and surrounding, the building being fumigated. Prohibited entry zone must be clearly identified with cones and cautionary tape. No persons except for properly equipped handlers are permitted within the prohibited entry zone.

Fumigation chambers must be securely locked during all stages of fumigation including: application, fumigation, and ventilation.

Ventilation must achieve a total of 12 air-changes prior to re-entry by unprotected persons.

After transfer of bee cells to the hatching incubator, ventilation of the incubator must continue for 5-7 days to capture residual formaldehyde vapour.

Bags of paraformaldehyde granules not completely used in fumigation operations must be tightly folded and taped shut, placed in single or double plastic bagging, placed in a solid plastic container with snap-top lid, and locked in the fumigation chamber for storage until the next fumigation operation.

References

Studies Considered in the Chemistry Assessment

List of Studies/Information Submitted by Registrant

PMRA Document Number 1631606
Reference: PFH-CZJ-1 Confidential Business Information of Celanese Chemical Company, Inc. Manufacturing Process, formation of impurities, analysis, Data Numbering Code: 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.10, 2.11, 2.12, 2.13, 2.14, 2.15, 2.16.

PMRA Document Number 1631595
Reference: PFH-CZJ-1 2004-08-24 Request for clarification for Paraformaldehyde Technical, Data Numbering Code: 2.13.1,2.13.3