



Government
of Canada

Gouvernement
du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

Benzene, 1,2-dimethoxy-4-(2-propenyl)-

Methyl eugenol

Chemical Abstracts Service Registry Number (CAS RN):
93-15-2

Environment Canada
Health Canada

September 2010

Canada

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This proposed risk management approach document builds on the previously released risk management scope document for methyl eugenol, and outlines the proposed control actions for this substance. Stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Following this consultation period, the Government of Canada will initiate the development of the specific risk management instrument(s) and/or regulation(s) where necessary. Comments received on the proposed risk management approach will be taken into consideration in developing the instrument(s) and/or regulation(s). Consultation will also take place as instrument(s) and/or regulation(s) are developed.

SUMMARY OF PROPOSED RISK MANAGEMENT

1. The Government of Canada plans to implement Significant New Activity provisions under CEPA 1999 to methyl eugenol.
2. The Government of Canada will propose a phase out plan for personal insect repellents containing citronella oil, which contains methyl eugenol, if further information to support their continued safety is not provided.

Note: This summary is an abridged list of the instruments and tools proposed to risk manage this substance. Please see section 9.1 of this document for a complete explanation of risk management.

1. ISSUE

1.1 Challenge to Industry and Other Interested Stakeholders

The substance Benzene, 1,2-dimethoxy-4-(2-propenyl)-, Chemical Abstract Service Registry Number (CAS RN)¹ 93-15-2, referred to throughout this document as “methyl eugenol”, is included in Batch 9 of the Challenge under the Chemicals Management Plan. The Ministers of the Environment and of the Health (the Ministers) have conducted an assessment under section 68 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) to assess whether the substance meets one or more of the criteria as set out in section 64 of CEPA 1999².

¹ CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society

² A determination of whether one or more of the criteria of section 64 are met and whether risk management may be required is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes exposures from ambient and indoor air, drinking water, foodstuffs and the use of consumer products. A conclusion under CEPA 1999 on the substances in the Chemicals Management Plan (CMP) Challenge Batches 1-12 is not relevant to nor does it preclude an assessment against the hazard criteria specified in the Workplace Hazardous Materials Information System [WHMIS] *Controlled Products Regulations* for products intended for workplace use.

Information-gathering authority in section 71 of CEPA 1999 is used to gather specific information where it is required. The information that is collected is used to make informed decisions and appropriately manage any risks that may be associated with these substances.

1.2 Final Assessment Report Conclusion for Methyl eugenol

A notice summarizing the scientific considerations of a final assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for methyl eugenol on September 18, 2010, under paragraphs 68(b) and 68(c) of CEPA 1999. The final report concluded that methyl eugenol is entering or may be entering the environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

The final report also concluded that methyl eugenol is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends. Methyl eugenol does not meet the criteria for persistence or bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999. The presence of methyl eugenol in the environment results primarily from human activity.

For further information on the final report conclusion for methyl eugenol, refer to the final report, available at <http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-9/index-eng.php>.

1.3 Proposed Measure

As a result of an assessment of a substance under section 68 of CEPA 1999, the substance may be found to meet one or more of the criteria under section 64 of CEPA 1999. In that case, either Minister can provide information and make recommendations respecting any matter in relation to the substance. While not subject to section 74 to section 77 the Ministers may choose to do such actions as add the substance to the Priority Substances List (PSL) for further assessment, recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act or take no further action. In this case, the Ministers proposed to recommend the addition of methyl eugenol to the List of Toxic Substances in Schedule 1. As a result, the Ministers may develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance.

Methyl eugenol is not subject to virtual elimination and may be managed using a lifecycle approach, to prevent or minimize human exposure to this substance.

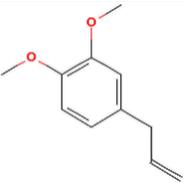
2. BACKGROUND

2.1 Substance Information

Methyl eugenol is part of the chemical grouping discrete organics and the chemical sub grouping alkoxy allylbenzene.

Table 1 presents other names, trade names, chemical groupings, the chemical formula, the chemical structure and the molecular mass for methyl eugenol.

Table 1. Identity of methyl eugenol

| | |
|--|---|
| Chemical Abstracts Service Registry Number (CAS RN) | 93-15-2 |
| DSL name | Benzene, 1,2-dimethoxy-4-(2-propenyl)- |
| National Chemical Inventories (NCI) names¹ | <i>Benzene, 1,2-dimethoxy-4-(2-propen-1-yl)-</i> (TSCA) <i>Benzene, 1,2-dimethoxy-4-(2-propenyl)-</i> (ENCS, AICS, SWISS, PICCS, ASIA-PAC, NZIoC) <i>4-Allylveratrole</i> (EINECS) <i>1,2-Dimethoxy-4-(2-propenyl)benzene</i> (ECL) <i>EUGENYL METHYL ETHER EXTRA</i> (PICCS) <i>METHYL EUGENOL</i> (PICCS) |
| Other names | <i>1,2-Dimethoxy-4-allylbenzene; 1,3,4-Eugenol methyl ether; 1-(3,4-Dimethoxyphenyl)-2-propene; 1-Allyl-3,4-dimethoxybenzene; 3,4-Dimethoxyallylbenzene; 3-(3,4-Dimethoxyphenyl)propene; 4-Allyl-1,2-dimethoxybenzene; Benzene, 4-allyl-1,2-dimethoxy-; Chavibetol methyl ether; Ent 21040; Eugenol methyl ether; Eugenyl methyl ether; Methyl eugenol ether; Methyl eugenyl ether; Methylchavibetol; Methyl eugenol; NSC 209528; NSC 8900; O-Methyl eugenol; Veratrole methyl ether; Veratrole, 4-allyl-</i> |
| Chemical group (DSL Stream) | Discrete organics |
| Major chemical class or use | Aromatic ether |
| Major chemical sub-class | Alkoxy allylbenzene |
| Chemical formula | C ₁₁ H ₁₄ O ₂ |
| Chemical structure |  |
| SMILES² | O(c(c(OC)cc(c1)CC=C)c1)C |
| Molecular mass | 178.23 g/mol |

¹ National Chemical Inventories (NCI). 2006: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Asia-Pacific Substances Lists); ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Commercial Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); PICCS (Philippine Inventory of Chemicals and Chemical Substances); NZIoC (New Zealand Inventory of Chemicals); SWISS (Swiss Giftlist 1 and Inventory of Notified New Substances); and TSCA (Toxic Substances Control Act Chemical Substance Inventory).

² Simplified Molecular Input Line Entry System

3. WHY WE NEED ACTION

3.1 Characterization of Risk

Evaluation of risk to human health involves consideration of data relevant to estimation of exposure (non-occupational) of the general population, as well as information on health hazards.

Based principally on the weight of evidence–based assessments of international or other national agencies (European Commission 2001; NTP 2005a), a critical effect for the characterization of risk to human health for methyl eugenol is carcinogenicity. Methyl eugenol is a multisite carcinogen in male and female rats and mice at all doses tested in a 2-year NTP bioassays. In the carcinogenicity studies, methyl eugenol induced multiple types of tumours in the liver and in the glandular stomach in both males and females. The liver tumours were observed at the lowest doses tested (37 mg/kg bw per day) in both rats and mice. In male rats, tumours were also observed in the kidney, mammary gland, subcutaneous tissues and mesothelium. Methyl eugenol was genotoxic in a range of *in vivo* and *in vitro* assays, although it was not mutagenic in bacterial cells. Methyl eugenol caused gene mutation in liver of transgenic animals; mutation of β -catenin gene was observed in mouse liver tumours. Modes of action have not been fully elucidated for carcinogenicity. However, based on the weight of evidence of carcinogenicity and the positive results for genotoxicity of methyl eugenol, it is considered possible that the tumours observed in the experimental animals resulted from direct interaction with genetic material.

The 2009 WHO/FAO report discussed the carcinogenic potential of methyl eugenol as a single component and general population exposure to methyl eugenol as part of a larger mixture in foods or essential oils. While there is evidence to suggest that methyl eugenol is a multi-site carcinogen, there is no available data to assess the toxicological potential of the mixtures most commonly found in foods or consumer products. The WHO/FAO report further suggested that the toxicity data may not relate to the presence of methyl eugenol in natural spices based on recent *in vitro* data that indicates that other components of natural spices including the essential oils extracted from these spices might modulate bioactivation and/or act as detoxifying agents. In the opinion of the WHO/FAO authors, the relevance of the critical effects observed in animal studies to the exposure scenario in humans was questionable and further assessment of methyl eugenol was recommended. While structured epidemiological research exploring possible associations between spice consumption and hepatic cancer in humans is lacking, there is an absence of any indications of human cancer associations noted in the scientific literature.

The critical non-cancer effect noted in the animal database was reductions in body weight or body weight gain noted in male rats at an oral lowest-observed-effect level (LOEL) of 10 mg/kg-bw per day following 90 days of treatment (NTP 2000a; Abdo et al 2001).

Since the predominant source of dietary exposure is from methyl eugenol's naturally-occurring presence in foods, derivation of a margin of exposure was not considered to be meaningful. The exposure and risk associated with the presence of methyl eugenol in environmental media and consumer products is considered to be low.

The use of personal care products containing essential oils results in a potential exposure to methyl eugenol of 1.5 ug/kg bw/day, resulting in a margin of exposure of 6670 to the critical

effect level (10 mg/kg bw/day). Exposure from use of a personal citronella-based insect repellent results in a potential exposure of 3.56 ug/kg /bw/day (Health Canada, 2004), resulting in a margin of exposure of 2810. With respect to non-cancer effects, these margins are considered adequate to account for uncertainty in the database on health effects and exposure.

4. CURRENT USES AND INDUSTRIAL SECTORS

In Canada, flavouring ingredients such as methyl eugenol or essential oils containing methyl eugenol can be added to any food that does not have a standard of identity and composition in the *Food and Drug Regulations* and to those foods that have a standard of identity and composition that allows for the addition of flavours to the food. Methyl eugenol is also produced synthetically in small quantities. Annual production in the United States in 1990 was estimated to be 25,000 lb (11,400 kg) (U.S. Dept. Health and Human Services 2005); in a more recent report, annual production in the United States was given as 77 kg (WHO 2009). There are currently four manufacturers of methyl eugenol in the United States and three manufacturers elsewhere, but none in Canada (2009 email from SRI Consulting to Risk Assessment Bureau, Health Canada; unreferenced). In response to the section 71 notice pursuant to CEPA 1999, no company reported the manufacture, import or use of methyl eugenol in 2006 above the reporting thresholds. There are no other data on industrial activity with respect to methyl eugenol in Canada (Environment Canada 2009).

In the United States, methyl eugenol is a permitted food additive, provided that it is used in the minimum quantity required to produce its intended effect, and otherwise in accordance with all the principles of good manufacturing practice (US FDA 2001).

In the European Union maximum limits do not apply for methyl eugenol in food provided they are flavoured with fresh, dried or frozen herbs and spices. Thus, pesto made with basil is a permitted food preparation, regardless of methyl eugenol content. The permitted maximum concentrations range from 1 mg/kg in non-alcoholic beverages up to 60 mg/kg in soups and sauces (Publications Office of the European Union 2008).

Some essential oils including citronella (*Cymbopogon* spp.), basil (*Ocimum* spp.), bay (*Laurus nobilis*) and tea tree (*Melaleuca* spp.) that may contain methyl eugenol are used in fragranced consumer products such as personal care products and household cleaners.

In Canada, citronella oil, which can contain methyl eugenol, is an active ingredient in some commercially available personal insect repellent lotions and sprays applied to the skin.

Methyl eugenol is also a component of certain fragrances present in 15 pest control products in Canada, with a resulting methyl eugenol concentration ranging from 0.00233% to 0.005 %. However, none of these pesticides are registered for use on food. (2009 email from PMRA to Risk Assessment Bureau, Health Canada; unreferenced). In the United States, methyl eugenol is used as a bait attractant for insect traps and lure products for control of fruit flies in fields and orchards (US EPA 2006).

In addition to its use in personal insect repellents, citronella oil is used in outdoor candles and torches as an area insect repellent.

The tobacco of flavoured bidis and clove cigarettes has been analyzed for a number of alkenylbenzene compounds, among them methyl eugenol. The concentration of methyl eugenol found in the cigarettes in this study ranged from not detected to 61 µg/g in strawberry-flavoured tobacco (Stanfill et al 2003). The source of methyl eugenol in flavoured tobacco is presumed to be in the flavouring and not the cured tobacco. In May 2009, the Government of Canada introduced amendments to the *Tobacco Act* to prohibit the selling of cigarettes, little cigars and blunt wraps (leaf-wrapped tobacco) with flavours and additives that taste like candy (Health Canada 2009).

Essential oils are sold to individuals who choose to make their own preparations. Essential oils are used in a number of specialized applications such as aromatherapy, as ingredients of massage oils and in alternative medicine practices, among others. Methyl eugenol is a component of several essential oils which may be used in these practices.

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

There are insufficient data on which to base an estimate of releases to the environment of methyl eugenol. There are no known industrial sources of release of methyl eugenol to the Canadian environment; however, it is expected that as in the United States (Barr et al 2000), this substance is ubiquitous in air and water at low part per trillion levels. The sources of methyl eugenol in the environment have not been determined.

5.2 Exposure Sources

Methyl eugenol is a naturally occurring substance found in the essential oils of several plant species. The oils are extracted from plants by steam distillation or with organic solvents, typically for use as flavour or fragrance ingredients. The amount of methyl eugenol in an essential oil extracted from a given type of plant varies with variety, plant maturity at harvest, harvesting method, storage conditions and extraction method (Smith et al 2002).

Some examples of common culinary herbs and spices that contain methyl eugenol are basil, tarragon, lemon grass, bay leaf, nutmeg, allspice, cloves and mace. Methyl eugenol is also reported to have been found in oranges, bananas and grapefruit juice (Johnson and Abdo 2005; Smith et al 2002). Commercially prepared foods in which methyl eugenol may be found include ice cream; baked goods such as cookies, pies, pastries and buns; puddings and other gelatin-based desserts; condiments, soups and sauces, especially pesto; various meat products; candy and chewing gum; and beverages made with spices and herbs containing methyl eugenol (Council of Europe 2001).

There is not yet any epidemiological evidence associating the natural presence of methyl eugenol in spices and spice oils, which are likely to be the main sources of methyl eugenol in the diet,

with liver cancer in humans (WHO 2009). Canadians should consume a variety of foods from each food group according to *Eating Well With Canada's Food Guide*.

Methyl eugenol is a component of several essential oils sold to individuals who choose to make their own preparations for use in aromatherapy, massage oils and in alternative medicine practices (Stanfill et al 2003).

Methyl eugenol is a component of a citronella oil based personal insect repellents registered for use in Canada.

Methyl eugenol is considered ubiquitous in air and water at very low concentrations in the order of parts per trillion. Exposure to methyl eugenol is dominated by ingestion of food and beverages with smaller contributions from the use of personal care products, cosmetics, and citronella-based insect repellents. Methyl eugenol is not intended to be used as an intentional ingredient in personal care products and is present only as a naturally occurring component of essential oils which are used in the formulation of thousands of personal care products in Canada (CNS 2009).

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

- Methyl eugenol is listed on the *Cosmetic Ingredient Hotlist* (which is an administrative tool to help manufacturers satisfy the cosmetic safety provisions of section 16 of the *Food and Drugs Act*) for use as a naturally occurring component in botanical extracts at concentrations equal to or less than 0.01% in fine fragrances, 0.004% in eau de toilette, 0.002% in a fragrance cream, 0.0002% in other leave-on products and in oral hygiene products, and 0.001% in rinse-off products. Topical use of methyl eugenol present as a component of essential oils should be in accordance with the current restrictions set out on the Cosmetic Ingredient Hotlist, available at: http://www.hc-sc.gc.ca/cps-spc/person/cosmet/info-ind-prof/_hot-list-critique/hotlist-change-liste-eng.php
- Certain therapeutic products which contain methyl eugenol may be regulated as natural health products (NHPs) under the *Natural Health Products Regulations*.
- As a result of the risk management activities on methyl eugenol undertaken by the Chemicals Management Plan, the Government of Canada has changed the listing for methyl eugenol on the Natural Health Products Ingredients Database from a restricted substance to a substance which has no longer be authorized for use in natural health products. This change has now been made to the database with the following wording: "Health Canada does not authorize the use of pure methyl eugenol for either medicinal or non-medicinal purposes in oral and topical Natural Health Products."
- The Health Canada Pest Management Regulatory Agency's (PMRA) re-evaluation of citronella oil-based personal insect repellents is ongoing pending additional data to refine the proposed risk assessment published on September 17, 2004. Following the report from an "Independent Science Panel on Citronella Oil as an Insect Repellent", the PMRA required

producers of citronella oil-containing skin application products to provide confirmatory data that the levels of methyl eugenol do not exceed 0.0002% of the product formulation. If this requirement is satisfied, producers will then be required to provide additional toxicology data within a specified timeframe. Review of this data will determine the eligibility for continued registration of citronella oil-based personal insect repellents (PMRA 2008).

6.2 Existing International Risk Management

United States

- Methyl eugenol was affirmed as GRAS (Generally Recognized as Safe) by the Food and Drug Administration (FDA) as a food additive under 21 CFR §172.515.
- The Environmental Protection Agency (EPA) has registered methyl eugenol as a pesticide active ingredient to attract fruit flies to lure traps in the US.

Europe

- EC Regulation 1334/2008, which applies from January 2011, prohibits the addition of methyl eugenol to foods and restricts the concentration of methyl eugenol in compound foods that have been prepared with flavourings or food ingredients with flavouring properties.
- The European Union has conducted a risk assessment of methyl eugenol in cosmetic and non-food products. Based on the findings of this assessment methyl eugenol is permitted in cosmetics as a component of plant extracts only. The permitted concentrations are as follows: 0.01% in fine fragrances, 0.004% in eau de toilette, 0.002% in a fragrance cream, 0.0002% in other leave-on products and oral hygiene products, and 0.001% in rinse-off products. Methyl eugenol may not be added as a pure chemical to cosmetics.
- As a result of re-evaluation activities in the European Union (EU), data was requested to support the continued registration of citronella containing products, with a deadline of September 1, 2006. The citronella industry declined to provide the requested data and, therefore, all registrations in the EU were cancelled as of September 1, 2006.

Australia

- Australia permits methyl eugenol in drugs at concentrations of equal to or less than 1% (DECISION 2005/45-4, Schedule 6).

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

Pure methyl eugenol is no longer employed as a distinct chemical in Canada but is available in a mixture of essential oils derived from spices and various aromatic plants (i.e., cloves, lemon grass, tea tree, basil, bay leaf). As these oils are employed to impart a particular scent or flavour to products all alternative essential oils with a similar scent or flavour profile would also contain methyl eugenol. Therefore suitable alternatives are not readily available.

7.2 Alternative Technologies and/or Techniques

No alternative technologies and/or techniques were identified that would minimize or eliminate the use and/or release of the substance.

7.3 Socio-economic Considerations

Socio-economic factors have been considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objective(s). Socio-economic factors will also be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining Regulation* (Treasury Board of Canada Secretariat 2007) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

7.4 Children's Exposure

The Government of Canada considered, where available, risk assessment information relevant to children's exposure to this substance. As part of the Challenge, the Government asked industry and interested stakeholders to submit any information on the substance that may be used to inform risk assessment, risk management and product stewardship. In particular, stakeholders were asked through a questionnaire if any of the products containing the substance were intended for use by children. Given the information received, it is proposed that no risk management actions to specifically protect children are required for this substance at this time.

8. PROPOSED OBJECTIVES

8.1 Environmental or Human Health Objective

An environmental or human health objective is a quantitative or qualitative statement of what should be achieved to address environmental or human health concerns identified during a risk assessment.

The proposed human health objective for methyl eugenol is to minimize human exposure to the greatest extent practicable from non-food sources.

8.2 Risk Management Objective

A risk management objective is a target expected to be achieved for a given substance by the implementation of risk management regulations, instrument(s) and/or tool(s). The proposed risk management objective for methyl eugenol is to prevent increases in exposure.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Tools

As required by the Government of Canada's *Cabinet Directive on Streamlining Regulation*,³ and criteria identified in the Treasury Board document entitled *Assessing, Selecting, and Implementing Instruments for Government Action*, the proposed risk management tools were selected using a consistent approach, and took into consideration the information that has been received through the Challenge and other information available at the time.

In Canada, citronella oil, which can contain methyl eugenol, is an active ingredient in some commercially available personal insect repellent lotions and sprays applied to the skin. In 2004, under the *Pest Control Products Act*, Health Canada conducted a re-evaluation of the safety of citronella oil use in personal insect repellents. As a result of that review (PACR2004-36), and a review by a scientific advisory panel, Health Canada recommended adopting the methyl eugenol concentration limits proposed by the European Commission (REV2008-03). Health Canada has requested information on the levels of methyl eugenol in personal insect repellents containing citronella oil and will propose a phase out plan for personal insect repellents containing citronella oil as an active ingredient if additional information to confirm the safe use of these products is not provided.

As no Canadian data were available to estimate exposure to methyl eugenol, Health Canada's Food Directorate has recently followed up with its stakeholders to gather information about the use of methyl eugenol as a flavour and/or the use of essential oils or plant parts such as leaves, stems and seeds that naturally contain methyl eugenol as flavouring ingredients in foods offered for sale in Canada. Risk management strategies will be developed, if necessary, based on the analysis of the results.

In order to achieve the risk management objective and to work towards achieving the environmental or human health objective(s), the two risk management options being considered for methyl eugenol are as follows: **(1) The Government of Canada plans to implement Significant New Activity provisions under CEPA 1999 to this substance.** This would require that any proposed new manufacture, import or use be subject to further assessment, and would

³ Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that "Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal".

determine if the new activity requires further risk management consideration and **(2) as part of its pesticide re-evaluation program the Government of Canada will propose a phase out plan for personal insect repellents containing citronella oil, which contains methyl eugenol**, if further information to support their continued safe use is not provided.

9.2 Implementation Plan

The proposed regulation or instrument respecting preventative or control actions in relation to methyl eugenol will be published in the *Canada Gazette*, Part I, no later than September 2012, as per the timelines legislated in CEPA 1999.

10. CONSULTATION APPROACH

The risk management scope document for methyl eugenol, which summarized the proposed risk management under consideration at that time, was published on March 20, 2010. Industry and other interested stakeholders were invited to submit comments on the risk management scope document during a 60-day comment period. Comments received on the risk management scope document were taken into consideration in the development of this proposed risk management approach document.

Consultation for the proposed risk management approach document will involve publication on September 18, 2010, and a 60-day public comment period.

The primary stakeholders include

- Food industry sector
- Cosmetics and fragrance sector
- Natural Health Products sector
- Pesticide sector

11. NEXT STEPS / PROPOSED TIMELINE

| Actions | Date |
|--|---|
| Electronic consultation on proposed risk management approach document | September 18, 2010 to November 17, 2010 |
| Response to comments on the proposed risk management approach document | No later than at the time of publication of the proposed instrument |
| Consultation on the draft instrument | Summer/fall 2011 |
| Publication of the proposed instrument | No later than September 2012 |
| Formal public comment period on the proposed instrument | No later than winter 2013 |
| Publication of the final instrument | No later than March 2014 |

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Please submit comments prior to November 17, 2010, since the risk management of methyl eugenol will be moving forward after this date. During the development of regulations, instrument(s) and tool(s), there will be opportunity for consultation. Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Chemicals Management Division
 Gatineau QC K1A 0H3
 Tel: 1-888-228-0530 / 819-956-9313
 Fax: 819-953-7155
 Email: Existing.Substances.Existantes@ec.gc.ca

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