



Government
of Canada

Gouvernement
du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

Methylum, [4-(dimethylamino)phenyl]bis[4-(ethylamino)-3-methylphenyl]-,
acetate

(MAPBAP acetate)

Chemical Abstracts Service Registry Number (CAS RN):
72102-55-7

Environment Canada
Health Canada

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Canada

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This proposed risk management approach document builds on the previously released risk management scope document for Methylium, [4-(dimethylamino)phenyl] bis[4-(ethylamino)-3-methylphenyl]-, acetate, 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) where necessary. Comments received on the proposed risk management approach will be taken into consideration in developing the instrument(s). Consultation will also take place as instrument(s) are developed.

SUMMARY OF RISK MANAGEMENT

1. Environmental Release Guideline to limit releases to water from facilities manufacturing, processing and using Methylium, [4-(dimethylamino)phenyl] bis[4-(ethylamino)-3-methylphenyl]-, acetate (MAPBAP acetate) or products containing MAPBAP acetate.
2. The Government of Canada plans to implement Significant New Activity provisions under CEPA 1999 MAPBAP acetate. This would require that any proposed new manufacture, import or use be subject to further assessment, and would determine if the new activity requires further risk management consideration.

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 Categorization and the Challenge to Industry and Other Interested Stakeholders

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health (the Ministers) to categorize substances on the *Domestic Substances List* (DSL). Categorization involves identifying those substances on the DSL that, in accordance with the criteria at section 73 of the Act, a) are considered to be persistent (P) or bioaccumulative (B), based on the criteria set out in the *Persistence and Bioaccumulation Regulations* (Canada, 2000), and “inherently toxic” (iT) to humans or other organisms; or b) may present, to individuals in Canada, the greatest potential for exposure (GPE). In addition, the Act requires the Ministers to conduct screening assessments of substances that meet the categorization criteria. The assessment further determines whether the substance meets one or more of the criteria set out in section 64 of the Act¹.

¹ 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.

In December 2006, the Challenge identified 193 chemical substances through categorization which became high priorities for assessment due to their hazardous properties and their potential to pose risks to human health and the environment. In February 2007, the Ministers began publishing, for industry and stakeholder comments, profiles of batches containing 12 to 19 high-priority substances. New batches are released for comments every three months.

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

The substance Methylium, [4-(dimethylamino)phenyl]bis[4-(ethylamino)-3-methylphenyl]-, acetate, Chemical Abstracts Service Registry Number (CAS RN)² 72102-55-7, referred to throughout this document as “MAPBAP acetate,” is included in Batch 8 of the Challenge under the Chemicals Management Plan.

1.2 Final Screening Assessment Report Conclusion for MAPBAP acetate

A notice summarizing the scientific considerations of a final screening assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for MAPBAP acetate on July 31, 2010, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that MAPBAP acetate is entering the environment in a quantity or a concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.

The final screening assessment report also concluded that MAPBAP acetate meets the criteria for persistence and does not meet the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999. The presence of MAPBAP acetate in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for MAPBAP acetate, refer to the final screening assessment report, available at:

<http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-8/index-eng.php>.

1.3 Proposed Measure

As a result of a screening assessment of a substance under section 74 of CEPA 1999, the substance may be found to meet one or more of the criteria under section 64 of CEPA 1999. The Ministers can propose to take no further action with respect to the substance, add the substance to the Priority Substances List (PSL) for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act. Under certain circumstances,

² 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.

the Ministers must make a specific proposal to recommend the implementation of virtual elimination. In this case, the Ministers proposed to recommend the addition of MAPBAP acetate to the List of Toxic Substances in Schedule 1. As a result, the Ministers will 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.

The final screening assessment report did not conclude that MAPBAP acetate meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, MAPBAP acetate is not subject to the virtual elimination provisions under CEPA 1999 and will be managed using a life-cycle approach, to prevent or minimize its release into the environment.

2. BACKGROUND

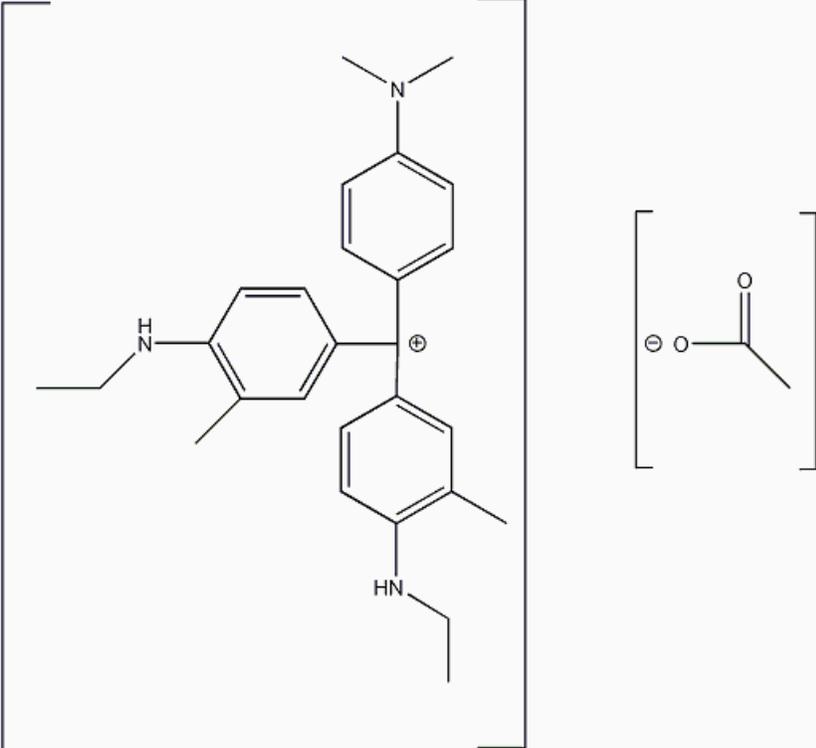
2.1 Substance Information

For the purposes of this document, this substance will be referred to as MAPBAP acetate, derived from the DSL name. MAPBAP acetate belongs to a class of dyes known as cationic triarylmethanes, and it is used in dye products (newsprint dye).

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

Table 1. Identity of MAPBAP acetate

Chemical Abstracts Service Registry Number (CAS RN)	72102-55-7
DSL name	Methylium, [4-(dimethylamino)phenyl]bis[4-(ethylamino)-3-methylphenyl]-, acetate
National Chemical Inventories (NCI) names¹	<i>Methylium, [4-(dimethylamino)phenyl]bis[4-(ethylamino)-3-methylphenyl]-, acetate (1:1) (TSCA)</i> <i>Methylium, [4-(dimethylamino)phenyl]bis[4-(ethylamino)-3-methylphenyl]-, acetate (AICS, PICCS, ASIA-PAC, NZIoC)</i>
Other names	<i>[4-(Dimethylamino)phenyl]bis[4-(ethylamino)-3-methylphenyl]methylium acetate</i>
Chemical group (DSL Stream)	Discrete organics
Major chemical class or use	Anilines; Cationic triphenylmethanes
Major chemical sub-class	Secondary aromatic amines, Secondary amines, Tertiary amines, Tertiary aromatic amines, Aliphatic amines
Chemical formula	$C_{27}H_{34}N_3 \cdot C_2H_3O_2$

<p>Chemical structure ²</p>	
<p>SMILES ³</p>	<p><chem>CN(c2ccc(cc2)C[(OC(=O)C)](c3cc(c(cc3)NCC)C)c1cc(c(cc1)NCC)C</chem></p>
<p>Molecular mass (g/mol)</p>	<p>459.64</p>

¹ National Chemical Inventories (NCI). 2006: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Asia-Pacific Substances Lists); PICCS (Philippine Inventory of Chemicals and Chemical Substances); NZIoC (New Zealand Inventory of Chemicals) and TSCA (Toxic Substances Control Act Chemical Substance Inventory).

² This substance is an organic salt, comprising a carbocation and an acetate anion.

³ Simplified Molecular Input Line Entry System. This SMILES notation was used to generate predictions. It is for the neutral form of the molecule and indicates a covalent bond between the carbocation and acetate anion. This is typically how they are shown in EPIWIN. It is not fully established what effect using this SMILES will have on the predictions. The acetate part of the SMILES is placed in square brackets here to highlight the fact that the molecule is at least partly ionic.

3. WHY WE NEED ACTION

3.1 Characterization of Ecological Risk

MAPBAP acetate is expected to be persistent in water, soil and sediment (half-lives in soil and water ≥ 182 days and half-life in sediment ≥ 365 days), but expected to be rapidly oxidized in air (predicted atmospheric oxidation half-life value of 0.048 days) (Canada 2010). It is also expected to have a low bioaccumulation potential.

Based on read-across data from close analogues (Ethyl Violet, CAS RN 2390-59-2; Gentian violet, CAS RN 548-62-9; and Malachite Green, CAS RN 569-64-2), MAPBAP acetate is expected to have a high potential for toxicity to aquatic organisms (Canada 2010).

Although no releases of MAPBAP acetate were reported for the 2006 calendar year in response to a survey under section 71 of CEPA, releases to the environment could occur given the substance's current use as a pulp dye. Once released into the environment, MAPBAP acetate could be found in water, soil or sediments depending on the medium of release.

A site-specific risk quotient analysis was performed for the aquatic medium at 10 industrial sites to determine whether there is potential for ecological harm in Canada. The site-specific analysis yielded a predicted environmental concentration (PEC) exceeding 0.003 mg/L for all of the sites analyzed. When these concentrations were compared to the predicted no-effect concentration (PNEC), based on experimental read-across data, the resulting risk quotients (PEC/PNEC) indicate that MAPBAP acetate could be causing ecological harm in Canada (Canada 2010).

3.2 Characterization of Risk to Human Health

No empirical data were identified for MAPBAP acetate. The potential for exposure of the general population to MAPBAP acetate from environmental media is expected to be negligible. Exposure to MAPBAP acetate from consumer products (newsprint dye) is expected to be negligible for the intended purpose of the product (negligible dermal exposure for reading activities) and low for incidental events such as mouthing exposure by toddlers.

As exposure of the general population in Canada based on the use of the substance as a paper dye is expected to be low to negligible, the risk to human health is considered to be low. However, information from analogues suggests possible flags for carcinogenicity, genotoxicity and developmental toxicity (Canada 2010).

4. CURRENT USES AND INDUSTRIAL SECTORS

MAPBAP acetate is used as a dye mainly in the production of certain paper products made from mechanical grade pulp such as newsprint (Environment Canada 2009). The concentration of the substance in dye products ranges from 30% to 60% (MSDS 2009; Environment Canada 2009). Another use for MAPBAP acetate reported in the response to the section 71 notice for 2006 was indicated as confidential business information (CBI). Quantities, uses and releases from this confidential use were considered in estimating environmental releases.

Recent information was collected through surveys conducted for the years 2005 and 2006 (Canada 2010) under *Canada Gazette* notices issued pursuant to section 71 of CEPA 1999 (Canada 2006b, 2009a) and from the Challenge questionnaire submissions. These notices requested data on the Canadian manufacture and import of MAPBAP acetate. In Canada in 2005 and 2006, no company manufactured MAPBAP acetate at quantities greater than or equal to 100 kg (Environment Canada 2006, 2009). For the 2006 calendar year, fewer than four Canadian companies reported importing a total of between 10 001 and 100 000 kg of MAPBAP acetate in a paper dye and either alone, or contained in a mixture, a product or manufactured item (confidential use) (Environment Canada 2009).

In 2006, fewer than twenty companies reported using the substance and/or were identified by importers as customers who used MAPBAP acetate (Environment Canada 2009).

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

MAPBAP acetate has not been measured in any environmental media or industrial discharge. The estimate of releases to the environment, and subsequent environmental concentrations, are based on estimates of release applied throughout the life cycle of this substance.

The releases of MAPBAP acetate via various routes during its life cycle are estimated based on survey data, industry data and data published by different organizations. Wastewater systems are the principal source of release to the environment, with an estimated 7.72% of the substance used potentially released in industrial effluents to either surface water or public/private wastewater systems. Further detail on these estimated releases is provided below.

Container Handling

To estimate the proportion of MAPBAP acetate that is released to surface water or public/private wastewater systems, assumptions concerning releases during the life cycle of the substance were used. To estimate releases due to container handling, it is assumed that empty containers could be cleaned on-site or off-site at dedicated facilities. As a worst-case scenario, it is assumed that container residues could be released in industrial wastewater effluents. It is estimated that 0.3% of the substance is released in industrial effluents as a result of container handling associated with the substance in a paper dye. The release to industrial wastewater from container handling operations associated with the confidential use is estimated to be 3% (Environment Canada 2010).

Product Manufacturing

A site-specific exposure analysis was conducted for the aquatic compartment at a total of 10 sites where MAPBAP acetate was used as a dye in the production of paper products (Canada 2010). The quantity of the substance used at each site was in the range of 1000 to 10 000 kg/year (Environment Canada 2009). Two scenarios were developed: a worst-case scenario that assumes a fixation rate of 80% and a low degree of closure (recycling of white-water within the mill); and a best-case scenario that assumes a fixation rate of 90% and a high degree of closure. The fixation rates (80 and 90% respectively) are taken from the OECD Emission Scenario Document (ESD) on non-integrated pulp mills (OECD 2006). After accounting for the influence of water reuse on the overall fixation rate and the container residue at 0.3% expected from the on-site cleaning of totes (OECD 2009), the maximum fraction lost from the production processes to wastewater prior to any wastewater treatment was estimated to be 8.3%. The wastewater containing MAPBAP acetate was then treated by either on-site or off-site secondary wastewater treatment systems with a conservative (for the release to water scenario) model-predicted removal rate of 3.4% (Canada 2010).

Consumer Use

No releases of MAPBAP acetate are expected during use of the products containing it (paper and confidential use).

Disposal and Recycling

According to the Forest Products Association of Canada, 58% of papers consumed in Canada were recycled in 2007 (FPAC 2010). The other part, 42%, will be considered to be disposed of in waste sites or incinerated at the end of its life cycle. MAPBAP acetate in paper disposed of in a landfill will largely remain there because of its low vapour pressure (Canada 2010). Due to uncertainties in the fate of MAPBAP acetate during the recycling process, releases due to paper recycling have not been estimated (Environment Canada 2010).

MAPBAP acetate is expected to be used mainly in paper. Although no information is available on the quantity of manufactured items containing MAPBAP acetate that are imported into Canada, it is anticipated that the quantities of the substance estimated to be disposed of as waste would be higher if importation of these items were taken into consideration. However, available information is currently not sufficient to derive a quantitative estimate for these quantities (Canada 2010).

5.2 Exposure Sources

MAPBAP acetate is not reported to be naturally produced in the environment. No environmental monitoring data for MAPBAP acetate from Canada or elsewhere have been identified (Canada 2010).

Ecological Exposure

Most of MAPBAP acetate may be released to water during paper manufacturing activities. When MAPBAP acetate is released into a water body, it partitions into suspended particulate matter and to bottom sediments, where sediment-dwelling organisms would be exposed to the substance (Canada 2010). Based on the available experimental evidence, MAPBAP acetate is expected to cause harm to aquatic organisms at relatively low concentrations (Canada 2010). The modelled evidence supports the analogue data used to show that MAPBAP acetate is potentially highly hazardous to aquatic organisms (Canada 2010).

MAPBAP acetate may enter soil through land application of sludge from wastewater treatment plants or through disposal of sludges and coloured papers in landfills. It is unknown whether harm to soil-dwelling organisms is likely to occur; effects data for terrestrial organisms were not available for MAPBAP acetate and could not be reliably estimated. It is not expected to be significantly present in air (Canada 2010).

Human Exposure

The evaluation of risk to human health involves consideration of data relevant to the estimation of exposure (non-occupational) of the general population, as well as information on health hazards. The screening assessment concluded that the potential for exposure of the general population to MAPBAP acetate from environmental media is expected to be negligible. Exposure to MAPBAP acetate from consumer products (newsprint) is expected to be negligible for the intended purpose of the product and low for incidental events such as mouthing exposure by toddlers (Canada 2010).

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

Currently, there are no known risk management measures related specifically to MAPBAP acetate in Canada.

Effluents from pulp and paper mills are regulated by the *Pulp and Paper Effluent Regulations* (PPER) of the *Fisheries Act* (Canada 2009b). These regulations establish effluent release limits for biochemical oxygen demand (BOD) and total suspended solids (TSS), and prohibit the discharge of acutely lethal effluent. Although MAPBAP acetate is not within the scope of the PPER, the level of wastewater treatment required to meet the PPER requirements may also remove substances such as MAPBAP acetate.

6.2 Existing International Risk Management

Although not used in pesticides in Canada, in the United States, MAPBAP acetate is listed in the U. S. Environmental Protection Agency's "Inert Ingredients Permitted for Use in Nonfood Use Pesticide Products" (US EPA 2010a) and in the U.S. EPA's *Toxic Substances Control Act* (TSCA) chemical inventory (US EPA 2010b).

MAPBAP acetate was added to the New Zealand Inventory of Chemicals in 2006. The inventory states that MAPBAP may be used as a component in a product covered by a group standard but that it is not approved for use as a chemical in its own right (NZIoC 2006). This group standard limits the use of the substance to 28 categories of substances, including surface coatings and colorants. These categories are predominantly based on the use of a product (ERMA New Zealand 2006).

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

Dye products with MAPBAP acetate are used as an alternative to dye products containing another substance that was also deemed hazardous.

Otherwise, there may be other dye blends or processes that could be used to achieve the desired results.

7.2 Alternative Technologies and/or Techniques

Paper machines recycle their water streams multiple times as part of the normal papermaking process, allowing even further fixation of any free dyestuff.

Furthermore, paper mills in Canada employ wastewater treatment systems for the papermaking process that could result in a high removal rate.

7.3 Socio-economic Considerations

Socio-economic factors will be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining Regulation* (TBS 2007) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

MAPBAP acetate is not manufactured in Canada.

Socio-economic considerations for MAPBAP acetate include a significant decrease in demand over the past five years resulting from decline of newsprint production. The paper manufacturing subsector consists of these industry groups:

- Mechanical Pulp Mills (NAICS 322111)
- Newsprint Mills (NAICS 322122)

Canada is a major newsprint exporter. Declines in North American newsprint demand are expected to persist through 2011 (NRCan 2010).

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 and Human Health Objectives

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 environmental objective for MAPBAP acetate is to reduce releases of the substance to soil and water.

The proposed human health objective for MAPBAP acetate is to minimize human exposure to the greatest extent practicable.

8.2 Risk Management Objectives

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 objectives for MAPBAP acetate is to limit industrial releases from facilities manufacturing, processing, or using MAPBAP acetate or products containing MAPBAP acetate, and, as the current exposures of Canadians to MAPBAP acetate were considered to be low under the current use conditions, prevent increases in exposure.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Instrument and Tool

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 instrument and tool were selected using a consistent approach, and took into consideration the information that was received through the Challenge and other information available at the time.

In order to achieve the risk management objective and to work towards achieving the environmental objective, the risk management being considered for MAPBAP acetate is an environmental release guideline (ERG) to limit releases to water from facilities manufacturing, processing and using MAPBAP acetate or products containing MAPBAP acetate. Effluent from pulp and paper mills is already subject to the *Pulp and Paper Effluent Regulations* under the *Fisheries Act*. A CEPA ERG will assist pulp and paper facilities using MAPBAP acetate or products containing MAPBAP acetate in predicting when their concentrations in effluent to water may have an effect on the receiving waters, and allow them to adjust their supplies and processes accordingly.

In addition, as a human health precaution, the Government of Canada plans to implement the 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 determine if the new activity requires further risk management consideration.

Furthermore, and where relevant, research and monitoring will support verification of assumptions used during the screening assessment.

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".

9.2 Implementation Plan

The proposed measures respecting preventative or control actions in relation to MAPBAP acetate will be published in the *Canada Gazette*, Part I, no later than July 2012, as per the timelines legislated in CEPA 1999.

10. CONSULTATION APPROACH

The risk management scope document for MAPBAP acetate, which summarized the proposed risk management under consideration at that time, was published on January 30, 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 July 31, 2010, and a 60-day public comment period.

The primary stakeholders include

- dye and pigment importers
- pulp and paper manufacturers
- non-governmental organizations

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on the proposed risk management approach document	July 31, 2010 to September 29, 2010
Response to comments on the proposed risk management approach document	No later than the time of publication of the proposed instrument
Consultation on the draft instrument	Spring/summer 2011
Publication of the proposed instrument	No later than July 2012
Formal public comment period on the proposed instrument	No later than fall 2012
Publication of the final instrument	No later than January 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 September, 29, 2010, since the risk management of MAPBAP acetate 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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