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Proposed Re-evaluation Decision

Naptalam

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Overview

What Is the Proposed Re-evaluation Decision?

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

An evaluation of available scientific information found that the naptalam end-use product does not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of naptalam uses, new risk-reduction measures must be included on the label of the end-use product. Additional data are being requested as a result of this re-evaluation.

This proposal affects the product containing naptalam 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 naptalam 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 naptalam.

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.*

Naptalam, one of the active ingredients in the current re-evaluation cycle, has 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 (e.g. the federal Toxic Substances Management Policy (TSMP)).

Based on the health and environmental risk assessments published in the 2006 RED, the USEPA concluded that naptalam was 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 Naptalam?

Naptalam is a herbicide that is used to control weeds in cucumber, melons, squash and pumpkin. Naptalam is applied using groundboom equipment by farm workers and professional applicators.

Health Considerations

Can Approved Uses of Naptalam Affect Human Health?

Naptalam is unlikely to affect your health when used according to the revised label directions.

People could be exposed to naptalam by consuming food and water, 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 (e.g. 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 naptalam was 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.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Naptalam is currently registered in Canada for use on cucumbers, melons, squash and pumpkins, and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for naptalam in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Naptalam Is Introduced Into the Environment?

Naptalam is unlikely to affect non-target organisms when used according to the revised label directions.

Non-target organisms (e.g. birds, mammals, insects, aquatic organisms and terrestrial plants) may be exposed to naptalam in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a low risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of naptalam was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required. Furthermore, the PMRA will require Tier II data for terrestrial plants and aquatic plants to be submitted to calculate buffer zones.

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 naptalam, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect mixer/loader/applicators
- A restricted-entry interval to protect workers re-entering treated sites

Environment

- Additional use-direction and environmental-hazard statements

Next Steps

Before making a final re-evaluation decision on naptalam, 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

Naptalam is a selective, Resistance Management Group 19 herbicide that controls broadleaf weeds at germination and early growth stage. It is absorbed by the seeds and primary roots of weeds and interferes with normal growth.

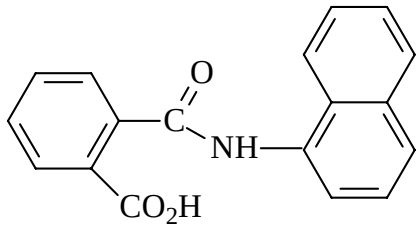
Following the re-evaluation announcement for naptalam, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the labels of the commercial end-use product in Canada.

The PMRA used recent assessments of naptalam from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for naptalam, dated 2006, as well as other information on the regulatory status of naptalam 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 Active Substance, Its Properties and Uses

2.1 Identity of Naptalam

Common name	Naptalam
Function	Herbicide
Chemical family	Phthalamate
Chemical name	
1 International Union of Pure and Applied Chemistry (IUPAC)	*N*-1-naphthylphthalamic acid
2 Chemical Abstracts Service (CAS)	2-[(1-naphthalenylamino)carbonyl]benzoic acid
CAS Registry Number	132-66-1

Molecular formula	$C_{18}H_{13}NO_3$
Structural formula	
Molecular weight	291.3

Based on the manufacturing process and a review of available chemistry information, the product is not expected to contain impurities of human health or environmental concern as identified in Regulatory Directive DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, Section 2.13.4 or Toxic Substances Management Policy (TSMP) Track-1 substances as identified in Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, Appendix II.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure	<133 Pa
Henry's law constant	$<1.94 \times 10^2$ Pa m^3 mol^{-1}
UV/Visible spectrum	N/A
Solubility in water	200 mg/L
***n*-Octanol–water partition coefficient**	**pH** — **log K_{ow}** 5 — 0.104 7 — 0.004 9 — -0.036
Dissociation constant	4.6

2.3 Comparison of Use Patterns in Canada and the United States

Naptalam is a herbicide that controls broadleaf weeds at germination and early growth stage. It is absorbed by the seeds and primary roots of weeds and interferes with normal growth. Currently, one commercial end-use product is registered in Canada. It is formulated as a liquid and contains the sodium salt of naptalam. In Canada, it is used on cucumber, melons, squash and pumpkin. Naptalam is applied to these crops as a pre-emergence spray (before the crop emerges) up to 48 hours after planting (seeding) and also applied on cucumber and melons as a post-emergence

spray, about one month after the pre-emergence spray, when the crop has emerged but weeds have not. In Canada, naptalam may be applied to cucumber and melons 1–2 times per year at a rate of 2.64 kg a.i./ha on light soil, 4.08 kg a.i./ha on medium soil and up to 2 applications of 7.2 and 5.28 kg a.i./ha, respectively, on heavy soil (i.e. the annual maximum rate is 12.48 kg a.i./ha on heavy soil). In the United States, naptalam is applied to cucumbers and melons 1–2 times per year at a rate of 2.24–3.36 kg a.i./ha on light soil and 3.36–4.48 kg a.i./ha on medium and heavy soil, with a maximum of 8.96 kg a.i./ha per year (on medium and heavy soil). The single and maximum seasonal rates applied on heavy soil in Canada are higher than those of the United States.

In Canada, naptalam is also registered for use on squash and pumpkin, once per year at a rate of 2.64 kg a.i./ha on light soil, 4.08 kg a.i./ha on medium soil and 7.2 kg a.i./ha on heavy soil. However, naptalam is not used on these crops in the United States.

After the USEPA decision, the maximum application rate in the United States remains at 4.48 kg a.i./ha per application, with up to 2 applications a year (maximum of 8.96 kg ai./ha per year). Discussion with the Canadian registrant revealed that heavy soils are not typical for cucumber and melons. In addition, the Canadian label requires that the soil be properly prepared, i.e. soil clods should be broken up and pulverized to give a smooth surface before application of naptalam. Therefore, the registrant has agreed to reduce the application rate on cucumbers and melons on heavy soils in Canada to match the American rate—the maximum application rate on light and medium soils are already lower than in the United States. In addition, the registrant has agreed to reduce the rate applied to squash and pumpkins on heavy soil, from 7.2 kg a.i./ha to 4.48 kg a.i./ha, to match the maximum single application rate in the United States.

The American and Canadian use patterns were compared. The American uses of naptalam, formulation and maximum application rate encompass the Canadian uses of naptalam, formulation and maximum application rate. Based on this comparison of use patterns, it was concluded that the USEPA RED for naptalam is an adequate basis for the re-evaluation of Canadian uses of naptalam.

All current uses of naptalam are being supported by the registrant and were, therefore, considered in the re-evaluation of naptalam. Appendix II lists all naptalam registered under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 2006 RED, the USEPA concluded that the end-use products formulated with naptalam met the safety standard under the American *Food Quality Protection Act* and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the amended product label.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

Exposure to naptalam may occur through consumption of food and water, through residential exposure, 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 (e.g. children and nursing mothers).

3.1.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating safety factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

Workers can be exposed to naptalam when mixing, loading or applying the pesticide and when re-entering a treated site to conduct activities such as scouting and/or handling of treated crops.

3.1.1.1 Mixer/Loader/Applicator Exposure and Risk

Both short- and intermediate-term occupational inhalation and dermal exposure was assessed. The USEPA identified four combined dermal and inhalation exposure scenarios for mixers, loaders, applicators and other handlers.

Among the scenarios assessed in the RED, the following two exposure scenarios were considered to be relevant to the Canadian situation:

- mixing/loading liquid formulation for groundboom application; and
- applying liquid sprays by open-cab groundboom equipment.

Handler exposure analyses were performed using surrogate data from the Pesticide Handlers Exposure Database (PHED), assuming baseline personal protective equipment . The short-term (1–30 days) and intermediate-term (1–6 months) inhalation and dermal risk assessments were based on a maximum naptalam application rate of 4.48 kg a.i./ha. The oral toxicological endpoint (no observed adverse effect level [NOAEL]) of 29.7 mg/kg/day was used, based on a 90-day oral toxicity study in dogs, and the assumption that the inhalation and dermal adsorption rates were 100%. Other assumptions included a default average adult body weight of 70 kg, an 8-hour work day and a daily treatment area of 32 hectares/day (80 acres/day).

An acceptable short- and intermediate- term combined dermal and inhalation MOE of 270 (i.e. >100) was reported for the scenario of mixing/loading a liquid formulation for groundboom application, with personal protective equipment for workers including baseline attire (i.e. a long-sleeved shirt, long pants, shoes, socks) plus chemical-resistant gloves. An acceptable MOE of 440 was reported for the scenario of applying liquid sprays with open-cab groundboom equipment when baseline attire was worn.

The RED adequately addressed exposure scenarios associated with the uses of products containing naptalam in Canada, and conclusions derived from the RED apply to the Canadian situation. Based on this, the PMRA requires baseline protective equipment in addition to wearing chemical resistant gloves to further protect workers. Additional instructions concerning good hygiene practices are also required on labels. The proposed label amendments are listed in Appendix IV.

3.1.1.2 Postapplication Exposure and Risk

Naptalam may be applied to cucumber and melons as a broadcast application to the soil directly at planting and/or as a foliar application over-the-top of the crop early in the season before the crop begins to vine. As exposures would be limited to immature crops, the potential for exposure was considered to be low. A qualitative post-application exposure analysis was performed and post-application inhalation exposure was considered to be negligible. The potential for postapplication dermal exposure was expected to be minimal for the following reasons:

- pre-emergent and early postemergent use pattern, i.e. early season application;
- soil/early foliar application with watering-in so the product is soil incorporated;
- limited dislodgeable foliar residues, i.e. exposure limited to immature crops; and
- hand-planting or transplanting or mechanically planting, i.e. low contact activities

Based on the low potential for postapplication exposure, a restricted-entry interval of 24 hours would be adequate to protect postapplication workers. However, a restricted-entry interval of 48 hours was already on the American label at the time of the reregistration eligibility decision based on severe eye irritation. Therefore, the USEPA retained a restricted-entry interval of 48 hours.

This was considered applicable to the Canadian situation, and the PMRA requires a 48-hour restricted entry interval to further protect workers from postapplication exposure. Proposed label amendments are listed in Appendix IV.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

No residential uses of naptalam are registered in Canada.

3.1.2.2 Exposure from Food and Drinking Water

The USEPA identified no acute endpoints of concern were identified by the USEPA, and naptalam was classified as a Group "D" carcinogen (inadequate data for assessing potential human carcinogenicity). On this basis, no acute or cancer risk assessments were conducted.

Chronic dietary risk is estimated by determining how much of a pesticide residue may be ingested with the daily diet and comparing this potential exposure to an acceptable daily intake, which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. The acceptable daily intake is referred to as the ADI in Canada, and, in the RED, it is expressed as the chronic population adjusted dose (cPAD). The ADI is based on a relevant endpoint from toxicology studies and on safety factors protective of the most sensitive subpopulation (see Appendix III).

An unrefined Tier I chronic dietary risk assessment was conducted based on individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 Continuing Surveys for Food Intake by Individuals and exposure to sodium naptalam from food crops using the Dietary Exposure Evaluation Model (DEEM™). This assessment incorporated residue values based on field trial data. The amount of naptalam in each commodity (cantaloupe, fresh and pickled cucumbers and watermelon) was estimated to be 0.1 ppm. The chronic reference dose was 0.258 mg/kg/day based on a 1-year oral toxicity study in the dog (no observed adverse effect level [NOAEL] = 25.8 mg/kg/day) and a *Food Quality Protection Act* safety factor of 1-fold. Chronic dietary risk from food resulted in less than 0.1% of the chronic population adjusted dose (cPAD) for the American population and all subpopulations, including children 1–6 years old.

Drinking water risk assessments were conducted by comparing estimated drinking water concentrations (EDWCs) with drinking water levels of comparison (DWLOCs) for both groundwater and surface water sources. The DWLOC is the highest concentration of a pesticide in drinking water that would be acceptable considering the estimated exposure to that pesticide from other sources (i.e. food and residential uses). The modelled drinking water concentration estimates are compared to the DWLOC to ensure that they do not exceed this level.

The ground water concentration was estimated based on a Tier I screening-level model, SCI-GROW, at a maximum seasonal application rate of 8.96 kg a.i./ha (2 applications at 4.48 kg a.i./ha with a 14-day interval). A Tier I screening-level model, called the FQPA Index Reservoir Screening Tool (FIRST) was used to estimate naptalam in surface water sources based on two aerial applications of 4.48 kg a.i./ha per application on cucurbits (maximum seasonal application rate of 8.96 kg a.i./ha with a 14 day interval). The estimated chronic drinking water concentrations of naptalam of 3.31 ppb for ground water and 188.7 ppb for surface water were below the DWLOC of 2580 ppb and 9029 ppb, respectively, for the most sensitive population subgroup (children 1–6) and the general population.

The USEPA's assessment encompasses all Canadian registered uses of naptalam, with the exception of the use on squash and pumpkin. However, squash and pumpkin belong to the same crop group as cucumber and melon and residue levels on squash and pumpkin are expected to be non-detectable because all residues reported in the American field trials for cantaloupe, cucumbers and watermelon were <0.1 ppm. So, residue levels on squash and pumpkin at the supported revised Canadian application rates are expected to be similar (negligible) to the United States residues levels. Therefore, the USEPA assessment is considered to be applicable to the Canadian situation.

3.1.2.4 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to naptalam (i.e. from food and drinking water exposures).

Chronic aggregate risk for exposure to food and drinking water sources were estimated for two population subgroups, children 1–6 years old and for the general American population. The estimated environmental concentrations of naptalam were significantly below the drinking water level of concern (DWLOCs) for the most sensitive population subgroup and for the general population. The risks associated with food and drinking water exposures to naptalam were not of concern.

Overall, the USEPA aggregate risk assessment addressed the potential Canadian aggregate exposure scenarios. Therefore, the USEPA aggregate exposure conclusions are considered applicable to the uses of naptalam in Canada.

3.1.3 Cumulative Effects

The USEPA has not determined whether naptalam has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed that naptalam does 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

Naptalam is expected to leach into ground water and have the potential to reach surface water via runoff or spray drift. It was not found to be persistent in the environment.

To assess the ecological risk of naptalam to both terrestrial and aquatic non-target plants and animals, the USEPA calculated risk quotients (RQs) based on appropriate toxicity endpoints and expected environmental concentrations (EECs) and compared the resulting RQs to corresponding levels of concern (LOCs).

Results of acute toxicity studies suggested that naptalam is practically non-toxic to freshwater fish and invertebrates. Based on a maximum use rate of naptalam on cucumber and melon crops (2 applications at a rate of 4.48 kg a.i./ha), the acute RQ value for freshwater fish (RQ = 0.01) and invertebrates (RQ = 0.004) were below the acute endangered species level of concern (LOC = 0.05). The USEPA concluded that there would unlikely be acute adverse effects to freshwater aquatic organisms; however, they did not have adequate toxicity data to characterize the risk of chronic adverse effects to freshwater organisms. In addition, no data were available to characterize the risk to marine/estuarine fish and invertebrates and the USEPA required additional confirmatory data to be submitted.

Naptalam was categorized as slightly toxic to small mammals on an acute oral basis. It was concluded the potential for chronic reproductive effects was low. A potential for acute risk to mammals was identified based on a maximum use rate of naptalam on cucumber and melon crops (2 applications at a rate of 4.48 kg a.i./ha) and based on mean residues. The acute endangered species LOCs (0.1) was exceeded (RQ's 0.11–0.21 for 15 gram and 35 gram mammals) and the chronic LOC (1.0) was not exceeded (RQ = 0.62). Results of acute oral toxicity studies suggested to the USEPA that naptalam is practically non-toxic to birds and RQs were not calculated. Results of reproductive studies of naptalam in birds were not available, and the USEPA required data to be submitted. Based on contact lethal dose to 50% (LD_{50}) studies, naptalam was classified as practically non-toxic to the honey bee on an acute contact basis.

The USEPA's conclusions are considered relevant to the Canadian situation because the American application rate used in the assessment encompasses the Canadian application rate and all the American formulation types and methods of application encompass those in Canada.

The USEPA required label statements to minimize drift. Based on this, the PMRA requires similar label statements to reduce the potential of spray drift from ground application of naptalam. The proposed label amendments are listed in Appendix IV.

The PMRA can not determine buffer zones for naptalam as terrestrial and aquatic plant toxicological data are not available. As naptalam is a herbicide and the buffer zones are based on the most sensitive species, it is likely that the endpoints of concern will originate from the terrestrial and aquatic plant data. The PMRA, therefore, requires Tier II data for the effects of naptalam on terrestrial plants (10 crop species) and aquatic plants (4 algae and 1 vascular plant).

3.2.2 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the 1995 federal Toxic Substances Management Policy (TSMP), which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track-1 substances.

The federal Toxic Substances Management Policy and PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, were taken into account during the re-evaluation of naptalam. The PMRA has reached the following conclusions.

- Naptalam is not bioaccumulative; the *n*-octanol–water partition coefficient (log K_{ow}) is 0.104 at pH 5 , which is below the TSMP Track-1 cut-off criterion of ≥5.0. Naptalam was not found to be persistent; aerobic soil metabolism half-life is 36.7 days, which is below the TSMP Track-1 criterion of 180 days. naptalam does not meet all Track-1 criteria, and thus it is not a candidate for Track-1 classification.

- No information concerning impurities of the technical grade active ingredient was available. Based on the manufacturing process and a review of the available chemistry information (See Section 1.0), the product is not expected to contain other impurities of human health or environmental concern as identified in DIR98-04, Section 2.13.4, or TSMP Track-1 substances as identified in DIR99-03, Appendix II.

Formulant issues are being addressed through PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*, published on 31 May 2006.

4.0 Proposed Re-evaluation Decision

The PMRA has determined that naptalam is 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 product must be amended to include the label statements listed in Appendix IV. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. The registrant of the technical grade active ingredient is required to submit data as a condition of continued registration under Section 12 of the *Pest Control Products Act*. Appendix I lists details of these data requirements.

5.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and data code (DACO) tables can be found on our website at www.pmra-arla.gc.ca. 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 naptalam is available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

List of Abbreviations

ADI	acceptable daily intake
a.i.	active ingredient
bw	body weight
CAS	Chemical Abstracts Service
cPAD	chronic population adjusted dose
DACO	data code
DEEM	Dietary Exposure Evaluation Model
DWLOC	drinking water level of comparison
EDWC	estimated drinking water concentration
EEC	expected environmental concentration
FIRST	FQPA Index Reservoir Screening Tool
FQPA	*Food Quality Protection Act*
g	gram(s)
ha	hectare
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LD_{50}	lethal dose to 50%
LOC	level of concern
mg	milligram(s)
mm	millimetre(s)
MOE	margin of exposure
MRL	maximum residue limit
nm	nanometre
NOAEL	no observed adverse effect level
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
p*K*a	-log10 acid dissociation constant
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
ppm	parts per million
RED	Reregistration Eligibility Decision
RQ	risk quotient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

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:

- Part 2 chemistry data as described in Regulatory Directive DIR98-03, *Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products*, must be submitted to register the technical grade active ingredient.

- For the PMRA to determine an appropriate buffer zone, the registrant of naptalam is required to provide Tier II data for effects of naptalam on terrestrial plants (10 crop species) and aquatic plants (4 algae and 1 vascular plant). If data are not submitted or the data are deemed inadequate, then conservative buffer zones will be applicable to the end-use product containing naptalam. These studies must be conducted according to the appropriate USEPA Office of Prevention, Pesticides and Toxic Substances (OPPTS) guidelines.

Appendix II Registered Naptalam Products as of 28 February 2007

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
16244	Commercial	Chemtura Canada Co./cie	ALANAP 3 Liquid Herbicide	Solution	240 g/L

Appendix III Toxicological Endpoints Selected by the USEPA for Naptalam Health Risk Assessments

Exposure Scenario (route and period of exposure)	Dose (mg/kg bw/day)	Study	Target UF/SF or MOE[a]
Short- and intermediate-term dermal	Oral NOAEL = 29.7	90- day: oral toxicity (dog)	100
short- and intermediate-term inhalation	Oral NOAEL = 29.7	90- day: oral toxicity (dog)	100
Chronic dietary	Oral NOAEL = 25.8	Chronic study in the (1 year) dog	100
	cPAD = 0.258 mg/kg/day (i.e. acceptable daily intake)		

[a] UF/SF refers to total of uncertainty and/or safety factors for dietary assessments. MOE refers to desired margin of exposure for occupational or residential assessments.

Appendix IV Label Amendments for Products Containing Naptalam

The Canadian end-use product label must be amended to include the following statements to further protect workers and the environment.

I) The following statement should be included on the **PRIMARY DISPLAY PANEL**.

POTENTIAL SKIN SENSITIZER

II) The following statements must be included in a section entitled **PRECAUTIONS**.

May cause skin sensitization. Avoid contact with skin, eyes or clothing.

Wear long-sleeved shirt, long pants, shoes and socks when handling this product. In addition, wear chemical-resistant gloves during mixing, loading, clean-up and repair activities.

DO NOT apply this product in a way that this product will contact workers or other persons, either directly or through drift. Only handlers (mixers, loaders and applicators) wearing personal protective equipment may be in the area being treated during application.

DO NOT enter or allow worker entry into treated areas for 48 hours following application.

III) The following good hygiene recommendations must be included on the label in the **DIRECTIONS FOR USE**.

Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

Users should remove clothing/personal protective equipment immediately if pesticide comes in contact with skin through soaked clothing or spills. Then wash skin thoroughly and put on clean clothing. Wash contaminated clothing before reuse.

Users should remove personal protective equipment immediately after handling this product. Wash the outside of the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

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

DO NOT apply through any type of irrigation system.

DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats.

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

DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty.

DO NOT apply with spray droplets smaller than the ASAE medium or coarse classification.

DO NOT apply by air.

Not for use in greenhouses.

Release spray no more than 4 feet above the ground.

V) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS**.

To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to, heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g. soils that are compacted, fine textured or low in organic matter such as clay)."

Avoid application of this product when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

VI) The label of the end-use product must be amended to reflect the following information:

- Naptalam may be applied to cucumbers and melons 1–2 times per year (one pre-emergence and/or one post-emergence to the crop) with a maximum single application rate of 4.48 kg a.i./ha; and to squash and pumpkins only once per year with a maximum single (pre-emergence to the crop) application rate of 4.48 kg a.i./ha.