Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Re-evaluation Decision Document RRD2004-12

Atrazine

The purpose of this Re-evaluation Decision Document (RRD) is to notify registrants, pesticide regulatory officials and the Canadian public that the re-evaluation of the human health risk assessment of atrazine is now complete. The full environmental assessment of atrazine will be communicated in a future document.

Based on a review of the available information, the Pest Management Regulatory Agency (PMRA) has determined that all uses of atrazine and its end-use products do not entail an unacceptable risk to human health, provided that the proposed mitigation measures are implemented.

This Re-evaluation Decision Document contains comments made to the PMRA in response to the Proposed Acceptability for Continuing Registration document PACR2003-13, *Re-evaluation of Atrazine*, published on 19 November 2003, the PMRA's responses to the comments and the regulatory decisions resulting from the re-evaluation of atrazine.

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1.0 Introduction

A re-evaluation of the human health risk assessment concerning the active ingredient atrazine and its end-use products has been completed by the PMRA.

2.0 Background

The re-evaluation of atrazine was first announced in June 1988, under Section 19 of the Pest Control Products (PCP) Regulations. The purpose of this RRD is to notify registrants, pesticide regulatory officials and the Canadian public that the re-evaluation of the human risk assessment of atrazine is now complete.

On 19 November 2003, the PMRA published the PACR2003-13, *Re-evaluation of Atrazine*, which presented the outcome of the assessments and the proposed risk management decision for atrazine. The PMRA received responses to PACR2003-13 from government representatives, academia, registrants of atrazine products and other interested parties.

This RRD presents a summary of the comments received by the PMRA in response to PACR2003-13 and the PMRA's response to these comments (Appendix I), and outlines the regulatory decisions resulting from the re-evaluation of atrazine.

3.0 Regulatory decision

The PMRA has reviewed the comments received in response to the Agency's proposed re-evaluation decision for atrazine as presented in PACR2003-13. A summary of the comments received and the PMRA's response to these comments is presented in Appendix I. Other than changes in use rate and number of applications incorporated into the use standard outlined in Appendix II, no information received resulted in substantive changes to the human health risk assessments as summarized in PACR2003-13.

Based on the review of the available information, the PMRA has concluded that the use of atrazine and associated end-use products does not pose an unacceptable risk to human health, provided proposed mitigation measures described in this document (Appendix II) are implemented. Further measures may be necessary at a future date pending the completion of environmental risk assessment and the outcome of the cumulative risk assessment for all triazines, which share a common mechanism of toxicity.

3.1 Conditions of continued registration

The only use pattern being supported by the registrants is corn.

Registrants of end use products are requested to submit applications to amend their registrations in accordance with Appendix II within 90 days of the decision letter. Products with existing labels can continue to be sold and distributed by the registrant within 18 months of the publication of this decision document, after which all products sold or distributed by the registrants must bear the new label requirements. Further changes may be requested upon completion of the environmental risk assessment and the cumulative risk assessment of all triazines that share a common mechanism of toxicity.

Registrants are required to develop and submit to the PMRA for approval a protocol for a drinking water monitoring program to be implemented for the 2005 use season. The protocol should include sampling of raw and finished water at treatment plants supplied by either surface or ground water sources. These monitoring data will be reviewed by the PMRA and appropriate measures will be taken, if necessary, to mitigate any concerns.

3.2 Additional data requirements

Section 8.0 of the PACR2003-13 outlined additional data requirements for continued registration of atrazine. The registrant will be informed by letter of the specific requirements and the regulatory options available in order to comply with this decision.

Appendix I Comments and responses

The PMRA received comments in response to PACR2003-13, from government representatives, academia, registrants of atrazine products and other interested parties. The PMRA has consolidated and summarized the comments received and provides responses as outlined below.

1.0 Human health assessment

1.1 Comment on toxicological assessments—safety factor

One respondent noted that the PMRA had applied an additional safety factor of 3×, in contrast to the 10× United States *Food Quality Protection Act* (FQPA) factor that was used in the United States Environmental Protection Agency (USEPA) atrazine assessment, to account for uncertainties in the toxicology and exposure database. There is concern that the additional safety factor of 3× instead of the 10× used by the USEPA does not adequately protect infants and children.

Response

To address the potential toxicological effects of pesticides in the young, the PMRA assesses multigeneration studies in rats, developmental toxicity studies in rats and rabbits, as well as relevant published studies, for any developmental effects. In guideline reproductive and developmental toxicity studies, atrazine-related effects occurred in the offspring at or above maternally toxic doses. This indicated that there was no increased fetal/offspring sensitivity to atrazine relative to adults. Published studies reported delayed puberty (delayed preputial separation and vaginal opening) in rat offspring exposed to atrazine during the prepubertal period, suggesting that atrazine can affect the development of male and female reproductive systems. However, the male and female no adverse effect levels (NOAELs) for delayed puberty were higher than that of the most sensitive toxic endpoint that was used for risk assessment. Use of the NOAEL for the most sensitive endpoint in conjunction with a 300-fold safety factor is inherently protective of the developmental effects that were noted at higher dose levels, providing a 1000-fold margin of safety to the NOAEL for atrazine-related effects on puberty. Therefore, the additional 3-fold safety factor is considered by the PMRA to be adequately protective of infants and children. The USEPA rationale for applying a 10-fold FQPA safety factor included a 3-fold safety factor for residual concerns regarding the drinking water exposure assessment. The remaining 3-fold was for concerns regarding atrazine's neuroendocrine mode of action on the developing young, which is consistent with the rationale provided by the PMRA. Available information indicates that the levels of atrazine in community water systems in Canada do not exceed the level of concern, which will be verified with additional confirmatory data. Therefore, an additional 3-fold uncertainty factor for drinking water concerns was not warranted in the Canadian assessment.

1.2 Comment on toxicological assessment—developmental test data

The re-evaluation document for atrazine cites Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program,* as requiring particular attention to susceptibility and exposure of infants and children that may be different from that of adults during critical developmental stages. However, the toxicological risk assessment does not include specific mention of developmental test data. The USEPA does include mention of a developmental toxicity in rat and rabbit, but this is not described in any detail.

Response

The atrazine-related developmental effects are noted in Section 3.1 of PACR2003-13. These include delayed puberty (delayed preputial separation and vaginal opening) in rat pups, prostatitis in adult rat offspring that had been exposed via lactation, and increased pregnancy loss in female rats. These findings were based on standard developmental toxicity data requirements as well as on published and non-published special studies that were conducted in order to better characterize atrazine-induced developmental toxicity. It was also noted that these developmental effects are consistent with atrazine's neuroendocrine mode of action at the hypothalamus. In addition, as also indicated in Section 3.1, "there was no evidence of increased sensitivity of rat or rabbit offspring, following in utero and/or postnatal exposure to atrazine."

1.3 Comment on dietary exposure assessment—NOAEL

The USEPA NOAEL for acute dietary exposure assessment is lower than that used by the PMRA.

Response

The PMRA performs acute dietary risk assessments for food-use pesticides if toxicological studies indicate the possibility of effects occurring as a result of a one-day or single exposure event. The USEPA established an acute dietary reference dose for atrazine at 0.01 mg/kg bw/day using a NOAEL of 10 mg/kg bw/day from a developmental study in rats and applying a safety factor of 1000 (the additional 10-fold was for concerns regarding atrazine's neuroendocrine mode of action on the developing young and for residual concerns regarding the drinking water exposure assessment specific to the United States). In this study, delayed ossification of fetal cranial bones was noted at 70 mg/kg bw/day. However, the PMRA does not consider delayed ossification to result from a single-dose or one-day exposure and therefore, did not use this particular endpoint for acute dietary exposure assessment. Prostatitis, with a NOAEL of 12.5 mg/kg bw/day, was considered by the PMRA to be a more appropriate endpoint for acute dietary risk assessment because it occurred as a result of a dosing regimen that more closely approximated a single day exposure. In this study, lactating rats were given atrazine by gavage at postnatal days 1 through 4. Suckling-induced prolactin release was inhibited in the dams and an increased incidence of lateral prostatitis was later noted in the adult male

offspring from the dams that had been exposed to 25 mg/kg bw/day of atrazine. The effects reported in this study are considered to be mediated by atrazine's ability to alter hypothalamic-pituitary function, the most sensitive endpoint of concern in the atrazine toxicity database.

1.4 Comment on carcinogenic effects

The potential of atrazine to cause cancer, and in particular prostate cancer, remains unclear. Given the serious and irreversible nature of this effect, there can be no conclusion that atrazine does not pose an unacceptable risk of harm (or that there is a reasonable certainty of no harm).

Response

The carcinogenic potential of atrazine has been investigated in a number of studies on different strains of rats and mice. The only tumorigenic response in rodent bioassays is mammary tumour formation, which is limited to one sex of one strain, the female Sprague-Dawley (SD) rat. Several mechanistic studies performed in rats indicate that atrazine's mode of action for mammary carcinogenesis is uniquely specific to the female SD rat, and that this mode of action is not relevant to humans. (This mode of action is described in more detail under Comment 1.6.) The strength, consistency and specificity of the available mode of action information for the female SD rat is further supported by data showing that other rat and mouse strains do not develop mammary tumours when treated with atrazine. Overall, experimental evidence does not indicate that the underlying mode of action for atrazine-induced mammary carcinogenesis in the SD rat is related to direct genotoxic or estrogenic activity. This conclusion was further endorsed by an independent United States Scientific Advisory Panel (SAP) that was convened by the USEPA in June 2000, which indicated that there was compelling evidence to support the conclusion that the atrazine mode of action for mammary tumour formation in SD rats is not relevant to humans (SAP Report No. 2000-05).

In July 2003, the PMRA attended the SAP that was convened by the USEPA to address the reported increased prostate cancer incidence in workers at an atrazine manufacturing plant in St. Gabriel, Louisiana. The SAP concluded that "the increase in Prostate Specific Antigen (PSA) screening at the St. Gabriel plant likely led to an increase in the detection of cases of prostate cancer," although the Panel did acknowledge several limitations in the study (small sample size, questionable exposure assessment and lack of an appropriate comparison group). According to the SAP, PSA screening may be only a "partial explanation" for the increase in prostate cancer seen in the St. Gabriel plant and that "atrazine cannot be ruled out as a potential cause."

As noted by both the PMRA and USEPA, data from animal cancer studies in conjunction with atrazine's mode of action are not consistent with those cancers that are purported by some epidemiological studies to be associated with atrazine. The USEPA has also noted that, in conjunction with the correlation between increased cancer incidence and intensive PSA screening at the St. Gabriel plant, there was no increase in advanced tumours or mortality, and proximity to the plant did not correlate with risk. In the absence of any dose-response evidence for atrazine-related carcinogenicity in humans, there is little evidence to support atrazine-induced carcinogenicity in humans.

1.5 Comment on endocrine disruption

Atrazine is an endocrine disrupting substance. It is unclear if this category of health effects has been considered by PMRA in PACR2003-13. Based on this fact alone, atrazine poses an unacceptable risk of harm and should not be dispersed into the Canadian environment, drinking water or food.

Response

The endocrine modulating effects of atrazine were presented throughout Section 3.1 of PACR2003-13 [e.g., "atrazine's primary mode of action impairs hypothalmic-pituitary function...", "...the most sensitive indicators of atrazine toxicity in the rat were inhibition of luteinizing hormone (LH) and prolactin, two hormones which play important roles in reproductive function and development..."]. Furthermore, as indicated in sections 3.2 and 3.4 of this PACR, this mode of action was used to justify the inclusion of an additional safety factor for occupational and dietary risk assessments. Several studies have shown that the neuroendocrine modulatory effects of atrazine are threshold-based, which means that a dose level can be established where no adverse effects are observed for this endpoint of concern. As indicated above, the PMRA has addressed these endocrine effects by applying a 3-fold safety factor, in addition to the standard 100-fold safety factor, to the NOAEL for the most sensitive endocrine endpoint (LH suppression) identified in the atrazine toxicology database. Furthermore, as noted in Section 3.4.3 (PACR2003-13), dietary exposure of atrazine contributed to less than 1% of either the acute or chronic reference doses, indicating that there are no health concerns related to atrazine in the diets of any population subgroup in Canada.

Note that PACR2003-13 focussed on the risks to human health. A second PACR on the environmental risk assessment of atrazine will be released for public comment at a later date.

1.6 Comment on endocrine disruption—mechanism underlying carcinogenicity

Endocrine disruption by atrazine may be the mechanism underlying carcinogenicity, that is atrazine affects sex steroid hormone levels in rodents and humans in a manner consistent with a hormonal mechanism known to influence [certain] cancers:

- atrazine exposure results in a decrease in androgen production and interferes with androgen-receptor complex formation;
- atrazine causes an increase in estrogen in rodents;
- atrazine increases aromatase (an enzyme that converts androgens to estrogens);
- atrazine affects the hypothalamus and central nervous system, which may in turn influence pituitary function.

Response

As indicated in the response to Comment 1.5, the PMRA has addressed atrazine's potential for endocrine modulating effects by applying a 3-fold safety factor, in addition to the standard 100-fold safety factor, to the NOAEL for the most sensitive endocrine endpoint (LH suppression) identified in the atrazine toxicology database. Furthermore, as indicated in the response to Comment 1.4, there is little evidence to support atrazine-induced carcinogenicity in humans.

Comment 1.6 cites a number of issues that were taken into account when assessing atrazine toxicity and its potential risks to human health. To respond to these issues, further details are provided below.

Endocrine disruption and cancer, increased estrogens in rodents and effects on the hypothalamus—Results from several carcinogenic bioassays that examined various strains of rats and mice indicated that tumour response was limited to one tumour type (mammary tumours), which occurred in one sex of one rodent strain, the female SD rat. The sequence of events associated with mammary tumour formation in the SD female specifically, include atrazine interaction with molecular targets in the hypothalamus that suppresses gonadotropin-releasing hormone (GnRH), which would normally be released during the rodent estrous cycle, thus resulting in an insufficient amount of luteinizing hormone (LH) to trigger ovulation. Ovulation failure leads to prolonged exposure to endogenous estrogen and/or prolactin, resulting in hyperstimulation of the mammary gland and tumour development. The cascade of events triggered by high doses of atrazine in female SD rats is similar to that observed in spontaneously aging female SD rats where there is significant deterioration of the hypothalamic neuroendocrine control of LH secretion. The major difference is that in atrazine-treated female SD rats, hypothalamic/pituitary failure occurs earlier in life. Conversely, Fisher 344 rats, which rely on different metabolic triggers for reproductive senescence, do not develop mammary tumours in response to atrazine. In humans, reproductive aging is less attributable to failure of the LH surge, and is characterised by episodes of lower estrogen, with failure to maintain an adequate number of maturing oocytes in the ovaries. Furthermore, when LH

is low in humans, such as in patients with hypothalamic amenorrhoea or in women who use therapeutics that inhibit gonadotropin (LH or FSH) release and ovulation, a state of low serum estrogen is found, as opposed to the elevated estrogen levels that are seen in the atrazine-treated SD female rat, and no increase in human breast cancer has been associated with the long-term use of therapeutics. Thus, although atrazine may have the potential to alter hypothalamic-pituitary function in women, the hormonal milieu conducive to mammary gland carcinogenesis (i.e., elevated and prolonged exposure to endogenous estrogen and prolactin) that occurs in atrazine-treated female SD rats, is unlikely to be established in humans.

Induction of aromatase by atrazine, suppression of androgen production and interference with androgen-receptor complex formation—Aromatase is a key enzyme in the synthesis of estrogen from androgens. A report of atrazine-induced aromatase *in vitro* (Sanderson et al. 2001, *Environmental Health Perspective*, 109:1027–1031) contrasts a recent in vivo study that reported a decrease in aromatase expression in the mammary glands of rat pups exposed to atrazine (Rayner et al. 2004, *Toxicology and Applied Pharmacology*, 195:23–34). Since increased estrogen levels occur in atrazine-treated female SD rats (due to anovulation) but not in the female Fisher 344 rats, the role of atrazine in aromatase induction in vivo remains questionable. With regard to androgen effects, there is no consistent experimental evidence to support the claim that atrazine suppresses androgen production and/or interferes with androgen-receptor complex formation.

1.7 Comment on microcontaminants

The assessment and conclusions ignore the human health risk due to contamination of atrazine with hexachlorobenzene in both technical and formulated products and the need to eliminate this persistent and bioaccumulative substance.

Response

Hexachlorobenzene is a microcontaminant in technical grade atrazine. In re-evaluations conducted by the PMRA, impurities of toxicological concern are dealt with separately under the Toxic Substances Management Policy (TSMP), rather than on an active-by-active basis. However, it may be noted that the USEPA has estimated that, based on the daily intake for the United States population in 48 states and on the most recent refinement of anticipated residues available in the United States, assuming tolerance level residues and 100% crop treated, the cancer risk from the presence of hexachlorobenzene in atrazine is 1.5×10^{-8}, or 2.3×10^{-8}. This estimated cancer risk for hexachlorobenzene is less than 1.0×10^{-6} and, therefore, does not exceed the level of concern.

1.8 Comments pertaining to MRLs

The PMRA should consider harmonizing the MRLs with those of the USEPA in order to prevent non tariff trade barriers on commodities that have been in trade for a number of years.

Response

The PMRA is committed to harmonizing MRLs with the United States and other Codex countries. Where petitions are received requesting MRLs for imported agricultural commodities, MRLs will be established or adjusted if the PMRA determines the requested MRLs are needed and would not result in an unacceptable risks. Additional information is available in the February 2003 publication *NAFTA Guidance Document on Data Requirements for Tolerances on imported Commodities*.

2.0 Drinking water assessment

2.1. Comments on drinking water models

The use of modelling for a product like atrazine, which has been in use for so many years and for which measured concentrations are widely available is not warranted unless it is to calibrate the model. Since both the LEACHM and the PRZM-EXAMS overestimate the atrazine concentrations, the PMRA should reconsider the use of LEACHM and PRZM-EXAMS including re-calibration.

Response

In calibrating models such as LEACHM and PRZM/EXAMS, other data are required in addition to the measured concentrations. Although, the monitoring data are compared to the outputs of LEACHM and PRZM/EXAMS, additional environmental parameters that are relevant to the sites where the atrazine concentrations were sampled are required for re-calibration of the models (for leaching or surface runoff). For example, for each sampling site, the parameters would include watershed area, soil characteristics, amount of rainfall and time of sampling in relation to rainfall events. In the case of atrazine, these data were not available and, therefore, the usefulness of the monitoring data is limited to calibrating the models.

2.2 Comment on drinking water—uncertainty factor

Given that atrazine is found in 44% of water samples, and the acute and chronic concentrations exceed the USEPA maximum concentration limits (MCL) for atrazine (Section 4.1, PACR2003-13), isn’t the exposure to atrazine for children via drinking water unacceptably high? And shouldn’t an additional database uncertainty factor be applied?

Response

The acute and chronic concentrations in drinking water as obtained from model estimates, which are higher than measured concentrations in drinking water sources, did not exceed the Canadian drinking water level of comparison (DWLOC), which takes children into account. Thus, the exposure to atrazine is not unacceptably high and an additional database uncertainty factor is not required.

2.3 Comment on drinking water—data

Risk from drinking water: There is not enough data on atrazine levels in drinking water to undertake a credible exposure assessment, and the appropriate safety factor has not been applied to account for this. As such, the dietary risk from atrazine exposure via drinking water is underestimated and the conclusions are not protective of human health.

Response

The dietary risk of atrazine in drinking water was based on the outputs from the simulation models, LEACHM and PRZM/EXAMS, at the Tier I level. The estimates of drinking water concentrations at this initial assessment level (Tier I) are very conservative, thus, the dietary risk of atrazine exposure from drinking water is overestimated. Even with this overestimation of atrazine exposure from drinking water, the dietary risk was negligible.

2.4 Comments on the drinking water monitoring program

Since the data reviewed by the PMRA indicates that residues in drinking water are unlikely to be of concern, the request for a water monitoring protocol should be postponed pending the review of the available data. The levels of atrazine found to date are too low to trigger a monitoring program. The water monitoring initiatives should be postponed until 2005.

Response

Upon review of the data provided by the registrant, the PMRA still concludes that a baseline concentration of atrazine in raw water from water treatment plants cannot currently be established with any degree of certainty. The need for a monitoring program, at least for one to two years, to establish this baseline remains.

The data provided by the registrant are, for the most part, the same data that were previously submitted to the PMRA by the Ontario Ministry of the Environment (MOE). A few differences were observed between the two data files. The file sent directly by MOE contains summary statistics (maximum, minimum, mean, number of samples, etc.) of sampling conducted in raw, treated and distribution water at individual water treatment plants from 1 January 1997 to 11 February 2003. In contrast, the file submitted by the registrant contains the data for the individual samples collected at each water treatment plant. The MOE file also contains more recent data, collected between 11 February 2003 to 10 June 2003. The data provided by the registrant are strictly for raw water.

The registrant also submitted monitoring data from the Regional Municipality of Waterloo in May 2003. The monitoring data in this file are for samples collected in raw, treated and distribution water, between the years 1989 and 2002.

a) Data from Ontario water treatment plants

Out of 787 samples, 420 of them (53%) were collected between April and September. The other 367 samples (47%) were collected between October and March. The detection frequency was 24.4%. It is not surprising that the majority of detections (126 out of 192 detections, or 66%) were from samples collected between April and September (when atrazine is in use). Out of the highest 25% of detections (48 samples), only 7 samples were collected between October and March. Sampling between October and March, when atrazine is not used, is very unlikely to capture maximum atrazine concentrations, if atrazine is detected at all.

The average number of samples collected per water treatment plant from 1 January 1997 to 10 June 2003 is 6.4 samples in 6.5 years (one per year, on average), with a median of 6 samples over that sample time period. This is not frequent enough to establish a baseline concentration of atrazine in raw water from water treatment plants in Ontario.

b) Data from the Regional Municipality of Waterloo

The data collected from the Regional Municipality of Waterloo break down as follows:

	Raw water samples (n = 442)	**Treated water samples (n = 821)**
October through March	284 samples (64%)	448 samples (55%)
April through September	131 samples (30%)	296 samples (36%)
Unspecified date	27 samples (6%)	77 samples (9%)

Twenty-four samples were also collected in distribution water.

Atrazine was detected in 14.7% and 4% of raw and treated water samples, respectively. No detections were observed in the 24 distribution system water samples. In interpreting the low sampling frequency of atrazine in raw and treated water from the Waterloo Region, one needs to consider that the great majority of the samples were collected during months when atrazine is not used (October to March).

2.5 Comments on drinking water—atrazine levels

The data submitted by the registrant has not been taken into consideration in setting the acute and chronic levels of atrazine at 12.4 and 3.3 µg/L respectively. The data should be analyzed before setting these values.

Response

The data set from Ontario water treatment plants and from the Regional Municipality of Waterloo have been described in Comment 2.4. Incorporating these two data sets in with all other available data sets to calculate the acute and chronic levels of atrazine in surface water does not significantly alter the estimates (acute: 12.4 µg/L would become 12.05 µg/L; chronic: 3.3 µg/L would become 3.15 µg/L). These two data sets were given the same level of importance as all other studies considered in the atrazine drinking water assessment.

2.6 Comments on omission of environmental assessment

It is inappropriate to conduct a health-only assessment when it is clear from the USEPA review that environmental endpoints are the most sensitive.

Response

The PMRA recognizes that the most sensitive endpoints are for aquatic primary producers (algae and aquatic vascular plants). The risk associated with these toxicity endpoints and exposure levels of atrazine is still under examination by the PMRA. Thus, the environmental review is still in progress. It is, however, near completion; and only upon completion of the environmental risk assessment, will the PMRA determine whether atrazine poses an unacceptable environmental risk.

2.7 Comment on buffer zones

The proposed mitigation measures concerning buffer zones around aquatic systems are unsupported by scientific data. Nor is there any indication that mitigation measures will be complied with.

Response

The mitigation measures refer to the statements currently included on all atrazine labels. Upon completion of the environmental review, the adequacy of these mitigative measures (e.g., scientifically based buffer zones) will be examined and modified as required.

3.0 Active ingredient value

3.1 Comment on application rate

What is the rationale for reducing the application rate from 1.5 to 1.2 kg/ha and restricting the number of applications per year to one?

Response

Currently, a total of 17 commercial class products are registered for use on corn (as of February 2003), among which 9 products contain only atrazine and the remaining 8 co-formulated products contain at least one other active ingredient in addition to atrazine. For products containing atrazine alone, application rates range from 0.94 to 1.5 kg a.i./ha. The higher rate is usually required for heavy weed infestations and soil types (loam and clay soils). A maximum of two applications per year is allowed when required. This results in a total maximum application rate of 3.0 kg a.i./ha per year. For co-formulated products containing atrazine and at least one other active ingredient, the rates of atrazine range from 0.039 to 1.48 kg a.i./ha.

As stated in the PACR, for most corn growers, the actual application timing is pre-emergence or early post-emergence. Based on information provided to the PMRA, almost all (over 99%) of treated corn fields in Canada receive only one application per year to help prevent the development of resistence. The typical application rate is 0.8 to 1.0 kg ai/ha. Applications to corn are most often pre-emergence (mid-April through mid-May in the major corn growing areas). Post-emergence applications can also be made until corn reaches 30 cm in height. There is some variability in timing based on geographical regions. Based on the typical application rate for atrazine, it was proposed in the PACR2003-13 to lower the rate to 1.2 kg a.i./ha.

In Canada, atrazine is often used with other herbicides in tank mixtures to reduce cost, decrease the potential for weed resistance development and broaden the spectrum of weeds controlled. Approximately 56 herbicide end-use products use atrazine as a tank mixture partner. The maximum application rate of atrazine in many of these tank mixes

[e.g. see the labels for Axiom herbicide (PCP#26233), Frontier herbicide (PCP#23462), and Dual II Magnum herbicide (PCP#25729)] is the same as the single maximum rate of atrazine (1.5 kg a.i./ha) when used alone depending on weed pressure, weed size, and environmental conditions. Only one application per year is allowed for tank mixes.

The PMRA accepts that the higher rate of 1.5 kg a.i./ha allows for certain situations such as various soil conditions and unusually high weed pressure, continued use of the co-formulated products, as well as the tank mixtures appearing on many registered product labels. In addition, two applications per season gives growers more flexibility when required, but the maximum amount of atrazine used in a year cannot exceed 1.5 kg ai/ha.

After reviewing all available information discussed above, including the comments from public, the PMRA accepts that a rate reduction to 1.5 kg a.i./ha is justified, and the number of applications can remain at two per year. The label statement should be modified as follows:

Apply atrazine at a maximum of 1.5 kg a.i./ha per year either as a pre- or post-emergent application before corn reaches 30 cm in height. Treatments can be made once or twice per year, but the maximum amount of atrazine used in a year cannot exceed 1.5 kg a.i./ha. Atrazine may be applied alone or as a registered tank mix partner. Refer to the tank mix partners for further instructions. Do not harvest within 45 days of application on sweet corn and 60 days for field corn.

3.2 Comment on alternatives to atrazine

The review gives no consideration to atrazine alternatives.

Response

It is the goal of the PMRA to reduce the risk of using pesticides to Canadians, particularly children, by mitigating risks, making lower-risk pesticides available and fostering the use of alternative approaches to pest control. While other chemical products and non-chemical methods are available, atrazine does not pose unacceptable health risks and is an effective weed control product for corn growers when used according to label directions.

4.0 Regulatory Decision

4.1 Comment on removal of uses

The proposal to remove low bush blueberries and triazine tolerant canola from the labels of products shipped after 1 January 2004 is not practical. Most labels, for use during the 2004 season, have already been printed.

Response

The registrants of atrazine have volunteered to remove the uses of atrazine on triazine tolerant canola and lowbush berries from the labels. Within 90 days of the publication of this document, registrants must submit applications to amend their registrations. Products with existing labels can continue to be sold and distributed by the registrant within 18 months of the publication of this decision document, after which all products sold or distributed by the registrants must bear the new label requirements.

Appendix II Use standard for commercial class products containing atrazine

(**NOTE:** The information in this appendix summarizes the acceptable uses, limitations and minimum Personal Protective Equipment (PPE) for commercial class products containing atrazine resulting from this re-evaluation. This use standard does not identify all label requirements for individual end-use products such as first aid statements, and supplementary PPEs that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in this use standard.)

COMMON NAME: Atrazine

CHEMICAL NAME: 6-chloro-N^2-ethyl-N^4-ethyl-N^4-isopropyl-1,3,5-triazine-2,4-diamine

FORMULATION TYPE: WP: Wettable powder
EC: Emulsifiable concentrate
WG: Wettable granules
SU: Suspension
GR: Granular

SITE CATEGORIES: USC 13: Terrestrial Feed Crops (Silage, field and seed corn)
USC 14: Terrestrial Food Crops (Sweet corn, popcorn and seed corn)

PERSONAL PROTECTIVE EQUIPMENT (PPE):
See Engineering controls for additional requirements.

During application, wear chemical-resistant gloves and coveralls over a long-sleeved shirt and long pants. During mixing and loading, wear a face shield in addition to chemical-resistant gloves, and coveralls over a long-sleeved shirt and long pants.

For workers incorporating atrazine into dry bulk fertilizers, the following conditions must be met:

- This activity is restricted to commercial facilities (to prohibit on-farm impregnation).
- The facilities must employ a closed mix/load system.
- A maximum of 1500 kg active ingredient can be incorporated per day.
- This activity must occur for no more than 30 days per year.

ENGINEERING CONTROLS:
Wettable powder (WP) and wettable granule (WG) formulations are permitted only when marketed in water-soluble packages. Water-soluble packets qualify as a closed mixing/loading system when used correctly. Mixers and loaders using water-soluble packets must wear the PPE required above for mixers/loaders.

Mixing of atrazine with dry bulk fertilizers must be restricted to commercial facilities.
SPRAY DRIFT MANAGEMENT FOR GROUND APPLICATIONS:

GENERAL INFORMATION
Use good pesticide practices and apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and parks is minimal. Take into consideration wind speed, wind direction, temperature, application equipment and sprayer settings used for application.

For the protection of non-target habitats, over-spray or drift to any body of water or other environmentally sensitive habitat must be avoided. The interaction of equipment and weather-related factors determines the potential for spray drift. The applicator is responsible for considering all these factors when making application decisions.

GROUND APPLICATION
Avoid over-spray or drift to sensitive aquatic habitats. An appropriate buffer zone is required between the downwind point of direct application and the closest edge of sensitive aquatic habitats including sloughs, coulees, ponds, prairie potholes, lakes, rivers, streams, reservoirs and wetlands that are situated on the periphery of the treated area. Do not apply during periods of dead calm or when winds are gusty.

For ground spray booms, a buffer zone of 30 m is required for protection of aquatic habitats (as indicated above) when mixing or loading, and 10 m when spraying.

AERIAL APPLICATION
Do not apply by air.

SPRAYING:
Protect sprayer operators from drift or mist. Additional information on spray drift management for GROUND APPLICATION is provided in the section “SPRAY DRIFT MANAGEMENT FOR GROUND APPLICATIONS.” When low volumes of spray are applied, complete coverage and thorough application are essential for the most effective results. Schedule applications in accordance with local conditions. Consult your local agricultural authorities for specific use information.

DIRECTIONS FOR USE:

Apply atrazine at a maximum of 1.5 kg a.i./ha per year either as a pre- or post-emergent application before corn reaches 30 cm in height. Treatments can be made once or twice per year, but the maximum amount of atrazine used in a year cannot exceed 1.5 kg a.i./ha. Atrazine may be applied alone or as a registered tank mix partner. Refer to the tank mix partners for further instructions. Do not harvest within 45 days of application on sweet corn and 60 days for field corn.