RVD2007-05

Re-evaluation Decision

Atrazine
(Environmental Assessment)

(publié aussi en français)

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Foreword

The purpose of this Re-evaluation Decision document is to notify registrants, pesticide regulatory officials and the Canadian public that the re-evaluation for atrazine is now complete.

Based on the review of the available information, Health Canada's Pest Management Regulatory Agency (PMRA) has determined that the use of atrazine on corn for weed control does not entail an unacceptable risk to the environment. Continued registration of atrazine on corn is acceptable provided that the proposed mitigation measures are implemented and required data are submitted.

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1.0 Background

On 19 November 2003, Health Canada's Pest Management Regulatory Agency (PMRA) published PACR2003-13, *Re-evaluation of Atrazine*, for public consultation. That consultation document described the outcome of the human health risk assessment conducted by the PMRA. The PMRA received comments from the public and interested parties on the health risk assessments as well as limited environmental comments. The comments received and the PMRA's responses were published in the Re-evaluation Decision Document RRD2004-12 on 25 May 2004. The health assessment concluded that the use of atrazine and its end-use products on corn does not entail an unacceptable risk to human health provided that mitigation measures are implemented. The required mitigation measures described in those documents have since been implemented.

On 22 May 2007, the PMRA published the Proposed Acceptability for Continuing Registration Document (PACR2007-05), *Re-evaluation of Atrazine (Environmental Assessment)*, which presented the outcome of the environmental assessments and the proposed decision for atrazine.

The current Re-evaluation Decision document presents a summary of the comments received on the environmental assessment and the PMRA's responses to these comments (Appendix I), and outlines the regulatory decisions resulting from the re-evaluation of atrazine.

2.0 Regulatory Decision

The PMRA received several comments in response to PACR2007-05 from the public, governments, registrants and grower associations, and has considered these comments in the regulatory decision. No information received resulted in substantive changes to the environmental assessments as summarized in PACR2007-05.

Based on the review of available information, the PMRA has concluded that the use of atrazine and associated end-use products does not pose an unacceptable risk to the environment. Continued registration of atrazine on corn is acceptable provided the proposed mitigation measures described in this document (Appendix II) are implemented, and required data are submitted.

2.1 Data Requirements

A. Implementation of the Toxic Substances Management Policy

The technical grade active ingredient atrazine has been shown to be contaminated with chlorinated benzenes, which have been identified in the federal government's Toxic Substances Management Policy[1] (TSMP, 1995) as Track 1 substances. The PMRA is continuing its efforts to implement the Agency's strategy to manage Track 1 contaminants in pest control products (DIR99-03[2]). In August 2006, the technical registrants of atrazine were asked to submit data from the analysis of recent production batches of this technical grade active ingredient using sensitive and readily available analytical methods by March 2007. This information was used by the PMRA to evaluate the progress made towards the virtual elimination of chlorinated benzenes from atrazine and whether any additional measures are warranted. The current technical registrant of atrazine (Syngenta Crop Protection Canada Inc.) recently improved its manufacturing process and reports that hexachlorobenzene (HCB) concentrations in their current atrazine technical production are ~0.1 ppm, a 20-fold reduction from the ~2.5 ppm previously observed. The measures taken by the technical registrant to reduce levels of HCB in its technical product is a significant step towards the TSMP goal of virtual elimination of Track 1 substances.

B. Reproductive Effects in Amphibians

As the effects of atrazine on the reproduction and development in amphibians are inconclusive, the following data are required as a condition of continued registration of atrazine:

- Reproductive/developmental effects in amphibians (DACO 9.9)

C. Transformation Products

Transformation products were detected in aquatic habitats; however, data on acute and chronic toxicity in freshwater invertebrates and fish were not available for review. The following studies on transformation products DIA (desisopropylatrazine) and DEA (desethylatrazine) are required as a condition of continued registration of atrazine. The registrant has the option to submit scientifically based rationales to support data waivers:

- Acute toxicity test with *Daphnia magna* (DACO 9.3.2)
- Chronic toxicity test with *Daphnia magna* (DACO 9.3.3), pending results of acute toxicity test
- Acute toxicity tests with bluegill sunfish and rainbow trout (DACO 9.5.2.1)
- Early life-stage tests with fish (DACO 9.5.3.1), pending results of acute toxicity test
- Life cycle tests with fish (DACO 9.5.3.2), pending results of acute toxicity test

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[1] The federal Toxic Substances Management Policy is available through Environment Canada's website at www.ec.gc.ca/.

[2] Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, is available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or 613-736-3799 outside Canada (long distance charges apply); fax 613-736-3798; e-mail: pmra_infoserv@hc-sc.gc.ca; or through our website at www.pmra-arla.gc.ca.

D. Surface Water Monitoring Data on the East Coast

As atrazine surface water monitoring data are not available for potential freshwater salmon bearing habitat (i.e. small creeks and streams) on the East Coast (Prince Edward Island, Nova Scotia and New Brunswick) during the sensitive salmon smolt migration period, it is appropriate to conduct a monitoring study of these waterways during this period. These data are required as a condition to support continued registration of atrazine in the Atlantic provinces.

- The monitoring data should focus on "high-risk sites" (i.e. areas of high corn production adjacent to salmon habitat) and be conducted within the timeframe where high atrazine concentrations are expected. In selecting these sites, some factors to be considered include topography, proximity of waterway to treated cornfields and the intensity of atrazine use as well as meteorological conditions. The registrant is required to submit a protocol for review and approval, to ensure that the sampling locations, sampling times and procedures are sufficient to assess the risk to salmon smolts.

The registrants will be informed by letter of specific requirements. The PMRA will review these data upon submission and provide appropriate measures, if necessary, to mitigate any concerns.

List of Abbreviations

µg	microgram
a.i.	active ingredient
bw	body weight
C	Commercial class
CEPA	*Canadian Environmental Protection Act*
cm	centimetre(s)
DACO	data code
DACT	diaminochlorotriazine
DEA	desethylatrazine
DIA	desisopropylatrazine
DIR	Regulatory Directive
DT	disappearance time
EC	effect concentration
EEC	expected environmental concentration
EXAMS	Exposure Analysis Modeling System
FIFRA	*Federal Insecticide, Fungicide, and Rodenticide Act*
h	hour(s)
ha	hectare(s)
HA	hydroxyatrazine
kg	kilogram(s)
L	litre
LC_{50}	mean lethal concentration
LD_{50}	mean lethal dose
LIP	Label Improvement Program
m	metre(s)
mg	milligram(s)
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PACR	Proposed Acceptability for Continued Registration
PMRA	Pest Management Regulatory Agency
PRZM	Pesticide Root Zone Model
RQ	risk quotient
RRD	Re-evaluation Decision Document
SAP	Scientific Advisory Panel
SO	solid
SU	suspension
T	technical
TSMP	Toxic Substances Management Policy
USC	Use-site Category
USEPA	United States Environmental Protection Agency
WG	wettable granule
WP	wettable powder

Appendix I Comments and Responses

1.0 Comments Relevant to the Environment

1.1 Comments Pertaining to Water Monitoring Data

Comment 1.1a

- It was suggested that the PMRA's environmental review was incomplete because recent monitoring data were not considered in the risk assessment:

  Richard Y. and Giroux I., 2006. *Présence de pesticides dans l'eau au Québec, Bilan dans des cours d'eau de zones en culture de maïs et de soya en 2002, 2003 et 2004, et dans les réseaux de distribution d'eau potable*.

  Richard, Y. and Giroux I., 2004. *La présence de pesticides dans l'eau en milieu agricole au Québec*.

- In Quebec, recent sampling indicates that atrazine is still present in 99 to100% of samples taken from rivers in corn growing regions during summer. Even though the rate was decreased in the early 1990s, this herbicide often exceeds the established criteria for the protection of aquatic species. The recent published study (Giroux et al. 2006) indicates that atrazine still exceeds the criterion of 2µg/L established by the Canadian Council of Ministers of the Environment (CCME) for 6 to 13% of samples taken in summer.

- Why is a higher no observed effect concentration (NOEC) value (5µg/L) used by the PMRA to determine chronic effects on plants at the community level? Sensitive organisms are an integral part of the aquatic community; therefore, shouldn't the NOEC for the most sensitive species be used? The approach taken by the PMRA suggests that sensitive organisms are not taken into account.

Response

Given that atrazine is highly mobile and persistent, its widespread detection in waterways situated within or downstream of watersheds with corn production is expected. A considerable amount of Canadian surface water monitoring data (collected from 1994 to 2004) was available and considered in the environmental review; this data includes small tributaries such as creeks and streams located in corn-growing regions. Although atrazine concentrations have been detected above the established CCME guideline for the protection of aquatic species, these concentrations, which typically coincide with rainfall event(s) that occur shortly after spring application, are sustained at >2 µg/L for relatively short periods (day(s)).

The CCME water quality guideline for atrazine (2 µg/L), published in 1999, is based on a single model ecosystem study (Pratt et al.),[3] a study that was reviewed by the PMRA. This study reports a NOEC and lowest observed effect concentration (LOEC) of 10 and 32 µg/L based on reduced oxygen and ability of microbial communities to sequester Mg and Ca. The guideline, derived as the maximum acceptable toxicant concentration (17.9 µg/L, calculated as the geometric mean of the NOEC and LOEC) multiplied by a safety factor of 0.1), is expected to be protective of all species all of the time.

The PMRA usually considers endpoints for the most sensitive organisms in its risk assessments. However, a large number of studies were available in which the effects of atrazine were examined in mixed cultures and community level systems (microcosms, mesocosms, limnocorrals, artificial streams). As these types of studies tend to be more representative of field conditions than single organism acute toxicity tests, the aquatic risk assessment was refined by considering their results. The endpoints examined included growth, reproduction, oxygen production and changes in community structure. The lowest NOEC of 5.0 µg/L was chosen in characterizing the risk to aquatic habitats at the community level, which is a more conservative endpoint than that reported in Pratt et al.1988 and that used by the United States Environmental Protection Agency (USEPA) in its ecological risk assessment (10 to 20 µg/L). Nearly all (98%) of the ambient concentrations measured in aquatic systems are below the toxicity threshold (5.0 µg/L) for periphyton biomass, O_2 production and invertebrate community structure. Although the monitoring data indicate that peak atrazine levels may cause detrimental effects to aquatic communities, exposure at these levels is short (day(s)). Furthermore, several of the studies reviewed demonstrated full recovery from initial adverse effects at concentrations less than or equal to 5.0 µg/L that were observed within a short period (weeks). Collectively these results indicate that ambient concentrations of atrazine pose a negligible risk and are therefore not considered of concern.

The above studies were not available when PMRA completed its environmental review. The PMRA has since reviewed these publications and determined that their inclusion does not change the overall outcome of the environmental risk assessment.

Comment 1.1b
In Table 5 of PACR2007-05, the PMRA must state the monitoring data and the NOECs used in the calculation of the risk quotient for all taxonomic groups, type of exposure and habitat.

Response
The range of means and absolute maximum atrazine concentrations from the various Canadian surface water monitoring data sets reviewed is shown in Table 4 of PACR2007-05 (page 9). Acute risk was characterized using the absolute maximum concentration (26 µg/L) from monitoring data, and chronic risk was characterized using the maximum mean value (5.75 µg/L), as stated on page 13, second paragraph. All endpoints used in the calculation of risk quotients are discussed in Section 4.3, Environmental Toxicology, pages 9 to 11.

[3] Pratt J.R., N.J. Bowers, B.R. Niederlehner, and J. Cairns Jr. 1988. Effects of atrazine on freshwater microbial communities. Arch. Environ. Contam. Toxicol. 17: 449-457.

1.2 Comment on Atmospheric Deposition of Atrazine

Atrazine in the atmosphere (rainfall samples) has been detected at a maximum concentration of 40 g/L adjacent to fields where atrazine was applied (Liu, Cheuk et al. 1999, A multimedia, multiple pathway exposure assessment of atrazine: fate, transport and uncertainty analysis. *Reliability Engineering and Systems Safety*, Volume 63, pp. 169–184). The PACR fails to document that further research is needed to determine the degree of atmospheric deposition of atrazine to surface water contamination. This must be included as a monitoring requirement within the PACR.

Response
The 40 g/L maximum atrazine concentration measured in precipitation, which is stated in Liu, Cheuk et al. 1999, was misquoted from another published study (Nations, B.K, and G.R. Hallberg 1992. Pesticides in Iowa Precipitation. *J. Environmental Quality*. 21: 486–492). The original study (Nations B.K., and G.R. Hallberg, 1992) reported the maximum concentration in rainfall as 40 µg/L. The atrazine in precipitation monitoring data presented in this study was collected from urban and agricultural areas of Iowa State from 1987 to 1990. During that time, the maximum atrazine application rate on corn in the United States was 4 lbs/acre (4.8 kg a.i./ha), more than three times the current Canadian maximum application rate (1.5 kg a.i./ha). Therefore, the PMRA did not consider the data from this study relevant to the Canadian environment.

The PMRA reviewed several Canadian monitoring studies (listed below) that indicated the presence of atrazine in the atmosphere (air and precipitation) in the low ng/L range. The data showed that atrazine can be transported in the atmosphere and deposited to areas far removed from treated sites, albeit at very low concentrations. The highest concentrations of atrazine measured in air (vapour and particulate) and rainfall were 0.09 to 0.3 ng/m^3 and 12.5 to >1000 ng/L, respectively, which coincided with the atrazine use pattern period (May to June). A large amount of quality atrazine surface water monitoring data was available for the major use areas, Ontario and Quebec, and was considered in the environmental risk assessment. Given that atrazine concentrations measured in rainfall generally appear to be 1 to 3 orders of magnitude lower than those measured in Canadian surface water, the PMRA believes that a monitoring requirement for atmospheric deposition is unwarranted.

In the PACR, only a list of those references that were directly cited in the document for discussion were provided (see also Section 1.5). The following Canadian monitoring studies were also reviewed and considered:

- Environment Canada. 1996. Occurrence and Transport of Herbicides in Precipitation from the Canadian Section of the Great Lakes Basin. Website: www.on.ec.gc.ca/glimr/data/canadian-herbicides/intro.html.

- Eisenreich, S.J. and W.M.J. Strachan. 1992. Estimating atmospheric deposition of toxic substances to the Great Lakes - an update. Workshop held at the Canada Centre for Inland Waters, Burlington, Ontario (Jan. 31–Feb. 2, 1992). The Great Lakes Protection Fund and Environment Canada.

- Muir, D. 1992. Unpublished data on atrazine in air and rain at the experimental lakes area (ELA) in northwestern Ontario. Freshwater Institute, Department of Fisheries and Oceans, Winnipeg, Manitoba.

- Rawn, D.F., T.H.J. Halldorson, and D.C.G. Muir. 1998. Atmospheric Transport and Deposition, an Additional Input Pathway for Atrazine to Surface Waters, *in* Ballantine, L.G., McFarland, J.E., and Hackett, D.S., eds., Triazine herbicides—Risk assessment: Washington, D.C., American Chemical Society Symposium Series no. 683, p. 158–176.

- Roach, C.E., L.G. Anderson and W.T. Foreman. 1997. Determination of Atmospheric Atrazine and Alachlor Concentrations By Reverse Phase Liquid Chromatography and Gas Chromatography Mass Spectrometry. For: Presentation at the Air and Waste Management Association's 90th Annual Meeting and Exhibition, June 8–13, 1997, Toronto, Ontario, Canada.

1.3 Comments on Effects of Atrazine on Fish

Comment 1.3a
In Section 4.3 of PACR2007-05 (page 11), a reference was made to salmon transferred to seawater following 5 days of continuous exposure to atrazine in freshwater. The respondent believes that the duration of exposure should be corrected to 7 days.

Response
The salmon smolt NOEC of 0.5 µg a.i./L was based on an experiment in which smolts were transferred to seawater after five days of continuous exposure to atrazine in freshwater, (Waring, C., and A. Moore. 2004. The Effect of Atrazine on Atlantic Salmon (*Salmo salar*) Smolts in Fresh Water and After Sea Water Transfer. *Aquatic Toxicology*. 66: 93–104.). This study also reported the results of another experiment in which salmon were transferred to seawater following seven days of continuous atrazine exposure in freshwater. The results of the five-day exposure experiment provided the most conservative endpoint estimate (0.5 µg a.i./L) and was therefore used in the risk assessment.

Comment 1.3b
The PMRA should consider potential effects of atrazine on fish which are demonstrated in the studies cited below for the environmental risk assessment of atrazine:

- Moore, A, C.P. Waring, 1998. Mechanistic effects of triazine pesticide on reproductive endocrine function in mature male Atlantic Salmon (*Salmo salar*) Parr, Pesticide Biochemistry and Physiology, Vol 62, No. 1, October 1998, pp 41–50.

- Giroux, I. 2000. Suivi des pesticides dans la rivière Richelieu près des sites de fraie du Chevalier cuivré, Ministère de l'Environnement, Direction du suivi de l'état de l'environnement, Quebec, pp. 2 annexes.

- Gendron A., A, Branchaud. 1997. Impact potentiel de la contamination du milieu aquatique sur la reproduction du suceur cuivré (*Moxostoma hubbsi*): Synthèse des connaissances. Québec, ministère de l'Environnement et de la Faune, Direction régionale de la Montérégie, Service de l'aménagement et de l'exploitation de la faune, Longueil. Rapport technique 16-02, xvi + 160 p.

- Steinberg, C.E.W., R. Lorenz, O.H. Spieser. 1995. Effects of atrazine on swimming behaviour of zebrafish, *Brachydanio rerio*, Wat. Res, no. 3, pp. 981–985.

In the study of Moore and Waring (1998), which was not mentioned by the PMRA, the authors showed that exposure levels ranging from 2 to 20 µg/L, similar to levels found in Quebec Rivers, caused olfactory interference which significantly reduced the male response to the female priming pheromone prostaglandin in Atlantic salmon, which can compromise successful reproduction. In Quebec, these same effects are suspected to be one of the causes of reproducibility in the copper redhorse, a species unique to Quebec and also designated as a threatened species according to the Quebec Threatened or Vulnerable Species Act (Giroux 2000; Gendron and Branchaud, 1997). Moreover, a study by Steinberg et al. 1995 showed the effect of atrazine on sensory and nervous organs of certain fish species leading to behaviour modification. At concentrations as low as 5 µg/L the fish showed a preference to shady habitats. According to the authors, these behaviour modifications would increase their vulnerability to predators.

Response

The study by Moore and Waring 1998 was reviewed by the PMRA. Although the evidence presented indicates that atrazine causes sublethal impact on olfaction and reproduction in Atlantic salmon, the PMRA identified several deficiencies with the study that significantly limit the use of the data in a risk assessment. The authors claimed that the priming effect of the female pheromone prostaglandin on male milt and plasma sex steroids was reduced at environmentally relevant concentrations, at and above 0.04 µg/L. Recoveries of atrazine in water measured at the end of the five-day exposure period, however, were highly variable, ranging from 8 to 72%; the lowest concentration (0.04 µg/L) was 8% of the nominal concentration (0.5 µg/L). Because no data regarding atrazine water concentration were collected earlier in the exposure period, the actual exposure level and its consistency throughout the study was not known. In addition, based on the available atrazine monitoring data, fish are unlikely to be exposed at the concentrations used in the study that were higher than 0.5 µg/L test concentration (5–20 µg/L), for a period as long as 5 days. For the investigation of atrazine effects on the olfactory ability of mature male Atlantic salmon parr to detect prostaglandin, the electrophysiological study, the authors stated that water samples "suffered rapid degradation as the result of unavoidable delay in being analyzed." This again brings the concentrations that the salmon were exposed to into question. Based on these deficiencies, the PMRA considered the Moore and Waring 1998 study unacceptable for use in the risk assessment.

In the studies published by Giroux 2000 and Gendron and Branchaud 1997, a link between atrazine and declining copper redhorse (*Moxostoma hubbsi*) populations in Quebec waterways was postulated. The postulation was based on frequent atrazine detection in known copper redhorse habitat, the effects (olfactory and reproductive) observed in Atlantic salmon parr (Moore and Waring 1998, discussed previously in comment 2.3b) and effects observed in other

fish species (reduced recruitment, developmental) exposed at environmentally unrealistic atrazine concentrations or durations. It should be noted that neither of these two studies establishes a causal link between atrazine and copper redhorse populations. These values are therefore not used in assessing the risk of atrazine to fish.

The study by Steinberg et al. 1995, was also reviewed by the PMRA. The preliminary evidence in the study showed that atrazine altered the behaviour of zebrafish: a preference for habitats with dark substratum. Fish exposed for 1 to 4 weeks showed a significant increased preference for dark substratum at all exposure concentrations (5 to 3125 µg/L). Responses between exposure concentrations, however, were not significantly different indicating a threshold for effects less than or equal to 5 µg/L rather than a dose-response relationship. The authors state that further research is needed using more sensitive fish species to determine their behavioural response to atrazine, the threshold for effect(s), as well as the ecological implications at the population and community level. The PMRA is not aware of any subsequent related work conducted by the study authors or others.

Based on available monitoring data, fish are unlikely to be exposed to levels greater than or equal to 5 µg/L for a one-to-four-week period, a fact that the study authors conceded. Furthermore, the ecological significance of fish preference for habitats with dark substratum has not been established.

1.4 Comments on Effects of Atrazine on Amphibians

The PMRA should take into consideration the potential effects of atrazine on amphibians (such as those observed in the studies listed below) for the environmental risk assessment:

- Forson, D.F., A. Storfer, 2006. Atrazine increases Ranavirus susceptibility in the Tiger Salamander, *Ambystoma Tigrinum*, Ecological Applications, Vol 16(6): 2325–2332.

- Tavera-Mendoza, L., S. Ruby, P. Brousseau, M. Fournier, D. Cyr, D. Marcogliese, 2002a. Response of the amphibian tadpole (*Xenopus laevis*) to atrazine during sexual differentiation of the testis, Environmental Toxicology and Chemistry, Vol 21(3): 527–531.

- Tavera-Mendoza, L., S. Ruby, P. Brousseau, M. Fournier, D. Cyr, D. Marcogliese, 2002a. Response of the amphibian tadpole (*Xenopus laevis*) to atrazine during sexual differentiation of the ovary, Environmental Toxicology and Chemistry, Vol 21(6): 1264–1267.

- Rohr, J.R., Sayer T., Sesterhenn, T.M. and B.D. Palmer. 2006. Exposure, postexposure and density-mediated effects of atrazine on amphibians: breaking down net effects into their parts. Environmental Health Perspectives. Vol 114(1): 46–50.

- Hayes, T.B., Stuart A.A., Mendoza M., Collins A., Noriega N., Vonk A., Johnston G., Liu R., and Kpodzo D. 2006. Environmental Health Perspectives. Vol 114: 134–141. Suppl.

Response
The acute risk to amphibians exposed to ambient concentrations of atrazine was determined to be low within Canadian corn-growing regions. Therefore, exposure to ambient concentrations of atrazine is not expected to pose an appreciable risk to amphibians on an acute basis.

As stated in the PACR, chronic effects (i.e. reproductive/developmental) to amphibians from exposure to atrazine were considered from data reviewed and published in the USEPA public document "White Paper on Potential Development Effects of Atrazine - Eligibility Decision on Atrazine". (Website: www.epa.gov/scipoly/sap/meetings/2003/june/finaljune2002telconfreport.pdf). Subsequent to the conclusions reached by the USEPA, the studies (some of which are listed above) were re-evaluated (June 2003) by the *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA) Scientific Advisory Panel (SAP), which consisted of experts in the scientific fields of amphibian toxicology, reproduction, endocrinology, demography, and environmental risk assessment. The Scientific Advisory Panel reached a consensus that effects were attributable to atrazine, but the atrazine exposure level at which effects occurred was unclear based on differing research findings, protocols and questions about the validity of the protocols.

The USEPA plans to present new data provided by Syngenta from 2005 and 2006, as well as open literature studies published since 2003 to the FIFRA Scientific Advisory Panel. The studies that the USEPA has reviewed focused on atrazine effects on amphibian gonadal development only. The USEPA announced on 4 April 2007 (www.epa.gov/fedrgstr/EPA-PEST/2007/April/Day-04/p6253.pdf) that it will be revisiting this issue. The PMRA may decide to revisit the risk to amphibians pending the outcome of discussions by the FIFRA Scientific Advisory Panel in October 2007.

1.5 Comments Pertaining to Other Studies That Were Not Considered in the Environmental Risk Assessment

The environmental review did not include the papers listed below; their information and results should be incorporated into the PACR:

- Bennett, D.H. et al., A Multimedia, Multiple Pathway Risk Assessment of Atrazine: The Impact of Age Differentiated Exposure Including Joint Uncertainty and Variability. *Reliability Engineering and Systems Safety*, Vol. 63, 1999. p. 185–198.

- Edginton, A. et al. 2005. Toxicokinetics of 14C-Atrazine and Its Metabolites in Stage 66 Xenopus laevis. *Environmental Science and Technology*, 39(20): 8083–8089

- Freeman, J. L. Aquatic herbicides and herbicide contaminants: In vitro cytotoxicity and cell-cycle analysis. *Environmental Toxicology, v 21, n 3, 2006, p. 256–26.*

- Giroux, I.. 2002. Contamination de l'Eau par les Pesticides dans les Régions de Culture de Maïs et de Soya au Québec: Résultats des campagnes d'échantillonnage 1999, 2000 et 2001, et évolution temporelle de 1992 à 2001.

- Jacomini, A. E. et al., Bioaccumulation of atrazine in freshwater bivalves Anodontites trapesialis and Corbicula fluminea, *Archives of Environmental Contamination and Toxicology*, 51, 3, October 2006, p. 387–391.

- Liu, Xin-Mei et al. Cytotoxic effects and apoptosis induction of atrazine in a grass carp (Ctenopharyngodon idellus) cell line. *Environmental Toxicology*, 21, 1, 2006, p. 80–89.
- Richard, Y., and I. Giroux. 2006. Impact de l'agriculture sur les communautés benthiques et piscicoles du ruisseau Saint-Georges (Quebec, Canada).

- Yi Hua, Wen, et al., Seasonality Effects on Pharmaceuticals and S-Triazine Herbicides in Wastewater Effluent and Surface Water from the Canadian Side of the Upper Detroit River. *Environmental Toxicology and Chemistry*, Volume 25, Issue 9, (September 2006), p. 2356–2365.

Response
In the PACR, a list of additional information regarding atrazine was provided. That list was limited to some studies directly cited in the document. It was not an exhaustive listing of all published studies on atrazine. In general, the PMRA will list those references that were considered in the risk assessment, and this reference list will be made available in the public registry. In the case of atrazine risk assessment, some of the studies reviewed for the risk assessment were found to be either irrelevant, contain insufficient information, deficient in aspects that affected the integrity of the data, or provided data that could not be used in a risk assessment context; these studies are excluded from the reference list. The published information listed above was either reviewed or simply not available when the PMRA completed its environmental review. The PMRA has since reviewed the more recent publications listed above and has determined that their inclusion does not change the overall outcome of the environmental risk assessment or regulatory decisions for atrazine.

1.6 Comment on Hexachlorobenzene (HCB) in Technical Atrazine

Information on the concentrations of the microcontaminant HCB present in technical atrazine should be included in the PACR along with the results of the data requested by the PMRA that were to be submitted by March 2007 (Section 4.8). In addition, clarity must be made within the PACR on the effects that the combination of HCB and atrazine produce or may produce, or a recommendation put forth for the requirement of further research into the effects of this combination should the reduction/elimination of HCB within technical atrazine not be able to be accomplished.

Response
Information on the concentration of HCB present in technical atrazine is presented in Section 2.1 of this document.

Once the technical has been formulated as an end-use product and then applied in the field, the levels of HCB are extremely diluted. The combined effect(s) of HCB and atrazine on wildlife had already been assessed since all toxicity studies used the technical atrazine or end-use products that contain HCB.

1.7 Comment on the Mean Aerobic Soil DT_{50} Used in the Risk Assessment

The PMRA used a mean half life of 61 days (DT_{50} = 40 to 115 days). The USEPA on page 53 of the IRED for atrazine quoted a half life of 3 to 4 months (90 to 120 days). Where did the difference between Canadian and American values come from? Taking into consideration the climate, it is unlikely that atrazine dissipation will be faster in Canadian soils compared to American. The use of American values would increase the calculated mean half life and would certainly have an impact on the level of environmental risk. Therefore, the PMRA should revise the value used for the mean half life in its risk assessment calculations.

Response
All relevant studies for atrazine reviewed by the USEPA were also reviewed by the PMRA. The DT_{50} values from the laboratory aerobic soil studies reviewed ranged from 18 to 480 days.

The PMRA found that the majority of the laboratory aerobic soil studies reported DT_{50}'s in the 40 to 115 day range (as stated on page 5 of the PACR). These studies were conducted with a variety of soil types, temperatures, pH and soil moisture contents. In fact, the mean value of 61 days (stated in the PACR) was not relevant and should not have been reported. An aerobic DT_{50} of 105 days was used in the PMRA's risk assessment calculations, a value representative of the upper 90^{th} confidence interval using the full range of DT_{50} values reviewed (18 to 480 days). This approach to calculate a DT_{50} for risk assessment modelling is the same as that used by the USEPA.

1.8 Comments on Drinking Water Monitoring Data

The PMRA report was published in 2003–2004. Syngenta started a sampling program (to sample 10 water treatment plants in Ontario and Quebec) in 2005. Results from the sampling (sampling locations, frequency and period) were therefore not presented in the PMRA report. Such results are not available in the PMRA consultation document (PACR2007-05) either, except for a few lines that mention that guidelines were not exceeded for drinking water. Detailed results should be presented for more credibility; what is currently reported is insufficient to discard the possibility of risk to human health.

In terms of groundwater, two Canadian studies have demonstrated that atrazine was present in the water table in maximum concentrations of 1.2 µg/L in 44% of the samples, i.e. 10-times the concentration that is considered unacceptable in terms of human health by the European Union (0.1 µg/L). The PMRA completed their analysis with data from the US Geological Survey to fill data gaps. Studies performed in Canadian soil, either Québec or Ontario, are critical and should be submitted by companies in order to determine actual atrazine concentrations.

Response
The 2005 drinking water monitoring study conducted by Syngenta, at the PMRA's request, measured atrazine and its associated metabolites in 10 municipal water supplies located in the corn-growing region of Ontario and Quebec. The sampling sites included both surface and groundwater sources and were identified as potentially having a risk of water contamination. As stated in PACR2007-05, the total chlorotriazine residues detected do not exceed the Canadian guideline for atrazine residues in drinking water (5 µg/L) or the chronic water level of comparison for the most sensitive populations (41.9 µg/L). The drinking water monitoring data submitted by the technical registrant will be made available in the PMRA reading room for viewing.

The European Union adopted a level of 0.1 µg/L as the maximum acceptable concentration in groundwater for individual pesticides in 1998 (Annex I of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1998). This is a legislated value that applies to all pesticides regardless of their toxicity to humans. The PMRA follows a scientific approach in determining the risk of pesticides in drinking water to human health.

1.9 Comments Pertaining to Label Statements

Comment 1.9a
The PMRA demonstrated that the potential for water contamination via runoff is very high. In the PACR2007-05, Table 3 shows that the potential contamination from surface runoff in the province of Quebec represents more than 98% of the total loss. It should be noted that the PMRA requires that a 10-m buffer zone be respected to prevent contamination from drift. However, this route of contamination represents less than 2% of total loss.

In the document, no buffer zone is proposed to reduce the risk of runoff. It is stated that "no method is currently available to reduce the impact of pesticide transport via runoff." Before such methods become available, the PMRA should impose a buffer zone (vegetative strip) between the treated area and the water body in order to reduce as much as possible the risk of water contamination from atrazine. The PMRA has considered this approach when re-evaluating endosulfan and prescribes a 10-metre grassy strip (PACR2004-21).

The USEPA prescribes buffer zones for atrazine (see the IRED for atrazine published in 2006). In Table 29 entitled Summary of Labelling Changes for Atrazine, the following is stated:

> "Product must not be applied within 66 feet of points where field surface water runoff enters perennial or intermittent streams and rivers or within 200 feet of natural or impounded lakes and reservoirs. If this product is applied to highly erodable land, the 66 foot buffer or setback from runoff entry points must be planted to crop, or seeded with grass or other suitable crop."

Other mitigation methods about the type of agricultural method or the type of field are also stated:

> "One of the following restrictions must be used in applying atrazine to tile outletted fields containing standpipes:
> - Do not apply within 66 feet of standpipes in tile-outletted fields.
> - Apply this product to the entire tile-outletted field and immediately incorporate it to a depth of 2–3 inches in the entire field.
> - Apply this product to the entire tile outletted field under a no-till practice only when a high crop residue management practice is practiced. High crop residue management is described as a crop management practice where little or no crop residue is removed from the field during and after crop harvest."

The respondent believes that a similar vegetative strip should be imposed in Canada as a temporary mitigative measure to prevent the contamination of water from runoff. The efficacy of this mitigative measure could be validated by tracking atrazine concentrations in surface waters; this could be financed by atrazine registrants.

Response

There is currently no information available on the effectiveness of vegetative strips in reducing pesticide levels in runoff. The interim mitigation measure of a 10-m vegetative buffer strip between areas treated with endosulfan and sensitive aquatic habitats (PACR2004-21) remains a recommendation rather than a mandatory requirement for endosulfan labels. Environment Canada and Agriculture and Agri-Food Canada are both currently investigating the effectiveness of vegetation filter strips (i.e. types of vegetation, land slope). In the interim, the following statement will appear in the DIRECTIONS FOR USE section of the label under surface runoff:

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

The buffer zones (setbacks) on the U.S. label were determined from a previous generation of assessment; the USEPA imposed these buffer zones in 1992 as a mitigative measure against surface water contamination from atrazine in runoff. The buffer zones for the Canadian label were determined by the PMRA using modern risk assessment methods. The PMRA considers these buffer zones to be sufficiently protective for both aquatic and terrestrial habitats to mitigate against spray drift.

Label restrictions for tile-outletted fields containing standpipes were added to the US label in 1996 in order to further reduce atrazine runoff that could contaminate surface water sources. The PMRA did not include these statements on the Canadian label for the following reasons:

- Although tile outletted fields are found in some areas of Canada where corn is grown, the presence of standpipes directly within corn fields is considered to be uncommon. Therefore, Canadian atrazine product labels do not include specific mitigative directions to reduce runoff from tile outletted fields with standpipes.

- Soil incorporation up to 5-cm soil depth is recommended for pre-plant applications on Canadian labels.
- It is not uncommon for Canadian corn producers to operate under a no-till practice unless they are implementing a crop rotation. Most growers realize that leaving crop residue on the surface of the field greatly reduces soil erosion from wind and water. Therefore, significant atrazine loss from the soil surface is not expected under no-till farming practices. The PMRA also provides recommendations for minimizing off-site transport of pesticides from surface runoff on all Canadian product labels for broadcast pesticides (Appendix II of this document).

Given that the maximum Canadian single application rate is roughly half of that registered in the U.S., the potential contamination of surface waters from atrazine in runoff would be expected to be far lower than in the U.S. The PMRA therefore believes that current statements and directions on Canadian atrazine product labels offer a similar level of protection against surface water contamination compared to the U.S. label in terms of applications made to tile-outletted fields.

Comment 1.9b
The label recommendation regarding leaching, included in Appendix II of PACR2007-05, is enormously inadequate. The label must be revised under *leaching* to reflect the following information:

> "The soil–water distribution coefficient Kd is low, ranging between 0.4 for sands and 8 for other soils. Atrazine was therefore considered to be a Priority A chemical for potential groundwater contamination by the U.S. Environmental Protection Agency (EPA) and was ranked highest of 83 pesticides in the Agriculture Canada priority scheme for potential groundwater contaminants."

Response
The information in quotations is far too technical to include as a label statement (e.g. most users would not know what a Kd is). In addition, this information does not add anything new to the information in PMRA's label statement (Appendix II of this document). The label is simply meant to advise the user that atrazine may contaminate groundwater if used under certain conditions.

Comment 1.9c
The PMRA should ask registrants to include directions for band application on product labels or any other practices that would reduce atrazine use in the field.

Response
The users are given the choice of ground application as an overall spray or band application, as stated on the atrazine label. Because differences exist between applicator equipment and its configuration as well as with site-specific aspects (e.g. field size, row width), a higher level of detail for product application cannot be included on the label.

Pesticide applicators must be certified in order to apply pesticides in Canada. Certification programs are the responsibility of the provincial and territorial governments and are based on the Standard for Pesticide Education, Training and Certification in Canada. This training includes awareness of calibration procedures for specific application equipment and sources of information on specific calibration procedures.

Comment 1.9d
Both PMRA documents PACR2003-13 (p.26) and RRD2004-12 (p.19) state that atrazine end-use product labels must stipulate that products should not be mixed/loaded or used within a 30-metre distance from wells, lakes, streams, ponds or sink holes in order to avoid potential well or surface water contamination. There is no mention of this requirement in PACR2007-05. Will this requirement be maintained on product labels?

Response
The 30-metre buffer zone between areas of mixing/loading and wells and surface waters shall remain on all atrazine end-use product labels.

Comment 1.9e
In Appendix II of PACR2007-05 (Label Amendments for Commercial Class Products Containing Atrazine), the PMRA proposes the best management practices on the label to minimize surface runoff and leaching of atrazine. As the label is a legal document, how does the PMRA ensure that these good management practices are applied in the field?

Response
Label statements that explain good agricultural practices are meant to promote, encourage and facilitate the safe and proper use of pesticides through good stewardship. They are not the same as statements intended to be enforceable. The PMRA supports and promotes voluntary good stewardship through many means, only one of which is a National Pesticides Compliance Program. Inspections by the PMRA not only serve as a deterrent, but can educate applicators so they can avoid mistakes and remain compliant. The need to educate users increases as pesticide labels and uses become more complex.

1.10 Comment on Buffer Zones

PACR2007-05 (page 28) states that “contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip (buffer zone) between the treated area and the edge of the water body.” However, the document also states they need a 10 m buffer zone from terrestrial habitats. Thus corn producers would need to leave a 20 m buffer zone as the vegetative strip will need to be buffered. Producers will not be encouraged to plant a vegetative strip if it causes them to double the size of the buffer zone to 20 m instead of 10 m. Please reconsider how the buffer zone requirement is worded so as not to discourage the planting of vegetative strips along water bodies.

Response
Vegetative strips adjacent to water bodies (also referred to as riparian habitat) serve vital ecological functions such as shoreline stabilization, nutrient and contaminant removal and wildlife habitat reserves, which can enhance farm productivity by minimizing soil erosion and providing refugia for beneficial species. Mature vegetative strips may also help trap pesticide spray drift before it can enter a water course. Due to the importance of its ecological function, riparian habitat is considered a "sensitive terrestrial habitat" by the PMRA, and therefore terrestrial buffer zones are required for products that demonstrate a risk to non-target plants.

The PMRA acknowledges that there is a potential disincentive for farmers to maintain a vegetative buffer strip between the cultivated sections of their fields and adjacent water courses if terrestrial buffer zones are required to protect these areas. However, vegetative buffer strips provide substantial benefits to farmers, and in some provinces (e.g. Prince Edward Island), they are also required under provincial legislation. Currently, the PMRA does make the distinction between "managed" and "natural" terrestrial habitats, and therefore cannot exempt vegetative buffer strips established by farmers. The PMRA does not, however, want to discourage environmental farm management practices and is therefore in the process of reviewing its terrestrial buffer zone processes to ensure that buffer zones will be useable by farmers while remaining protective of biodiversity.

1.11 Comment Pertaining to Translation Error in the French PACR

"Buse à jet conique" should read "buse munie d'un écran conique," as indicated below the table on page 29.

Response
The PMRA found the error in 4.9.2 and the text on page 24 has been corrected. "Buse à jet conique" has therefore been replaced by "buse munie d'un écran conique," as specified below the table on page 29.

1.12 Comments Pertaining to Risk Assessment Methodology

Comment 1.12a
In order to determine risk to non-target vegetation, the PMRA should use native plant species that live close to agricultural fields rather than cultivated crop species.

Response
A list of possible native plant species for toxicity testing was recently included in Annex 3 of the revised OECD Guidelines 208 and 227 for testing of terrestrial plants. Although this list is now available, at the time of the data submission for atrazine, this list of native species was not available. The Annex also outlines the test conditions for each non-crop species which was previously not available. In addition, the PMRA is not aware of any open literature studies investigating the effects of atrazine on native plants.

Comment 1.12b
Pesticides are currently re-evaluated individually. However, atrazine is used concurrently with other pesticides to maintain good control of herbicides. Also, this herbicide is found in surface waters along with other herbicides and transformation products. According to Giroux (2006), it is not uncommon to find six or seven pesticides at a time in rivers. Considering possible synergistic effects of pesticides on living organisms, shouldn't the PMRA be more conservative when evaluating the environmental risk of atrazine?

Response
While it is known that pesticides often occur as mixtures of residues in the environment and that synergistic or antagonistic effects can thus be expected, knowledge on the nature and extent of such effects is currently very limited. Determining a quantitative relationship between the toxicity of mixture components and observed effects is extremely complicated because the pesticides in the environment often differ in their mechanism of action in exposed organisms. There is no generally agreed upon framework/approach yet for combined risk assessment of pesticides at the international level. There are not many studies on the nature of interactions between constituents in a mixture. In view of the varying modes of action, it is unlikely that a single approach would be suitable for application to the risk assessment of all chemical mixtures.

The assessment of environmental risk of atrazine to non-target aquatic organisms was conservative, as the most sensitive toxicity endpoints were chosen for use in the assessment. Furthermore, the derivation of the toxicity endpoints was based on the use of safety factors. The chosen LC_{50} values were divided by 2 for aquatic plants and aquatic invertebrates and 10 for fish and amphibians. The computer-model-generated numbers on residue concentrations in water tend to be conservative as they generally exceed numbers from actual water monitoring.

Comment 1.12c
The PMRA typically uses the earthworm as an indication of toxicity for terrestrial invertebrates. For the re-evaluation of the herbicide 2,4-D, the earthworm was used as a indicator species. Why was this species not used to evaluate the risk to terrestrial invertebrates in the case of atrazine? Should the PMRA not ask the registrant to provide data on the toxicity of atrazine to earthworms?

Response
The data for the environmental risk assessment was primarily obtained from reviews conducted by the USEPA. The USEPA's IRED did not include reviews for atrazine toxicity to earthworms. The PMRA acknowledges that earthworm toxicity to atrazine should have been included in the environmental assessment. The UK Pesticide Safety Directorate (1993) reported an acute toxicity of earthworms (*Eisenia foetida*) LC_{50} value of 78 and 79 mg a.i./kg soil for 7 and 14 days respectively. The expected environmental concentration of atrazine in soil (based on a soil density of 1.5 g/cm^3, soil depth of 15 cm) was 0.67 mg a.i./kg. The PMRA therefore does not consider earthworms exposed to atrazine to be at risk (RQ = 0.004; risk quotient was divided by a safety factor of 2).

2.0 Comments Pertaining to Regulatory Decision

2.1 Comment on the Removal of Use of Atrazine from British Columbia

The rationale for removing the use of atrazine in BC was not provided.

Response
As stated in the PACR, the technical registrant of atrazine—Syngenta Crop Protection Inc.— is the data provider for atrazine re-evaluation and had voluntarily withdrawn the use of atrazine in British Columbia. Once the re-evaluation of any chemical is initiated, the technical registrants are required to inform the PMRA what uses or use sites they intend to support and for which they are willing to provide any data required to complete the assessments. The technical registrants make their own decision and the PMRA only conducts risk assessments on uses that are supported by the technical registrants.

2.2 Comment on the Ban of Atrazine in European Union (EU) Countries

There was no mention in the PACR that at least six EU countries have banned the use of atrazine.

Response
The PMRA is aware of the fact that atrazine is prohibited in four OECD member countries and the EU based on its potential to contaminate groundwater and drinking water. The EU prohibits any chemical that may be found in groundwater at concentrations greater than 0.1 µg/L. The PMRA drinking water assessment is risk-based and is summarized in Comment 1.8 of this document.

2.3 Comment on Alternatives to Atrazine for British Columbia

Other than planting glyphosate-ready corn in BC, there are very few alternative products left for BC growers to use to control weeds. Consideration should be given to the possibility that herbicide-resistant weeds could develop sooner than expected.

Response
The PMRA aims to reduce the risk to Canadians and the environment from the use of pesticides by mitigating risks, making lower-risk pesticides available and fostering alternative approaches to pest control. While the PMRA has recognized that there are fewer products available for BC growers, minor use programs are available to register other products that are available to other areas in Canada. In the meantime, there are other products registered for use on corn in BC, such as products containing bromoxynil, EPTC and glyphosate. These products are also listed in the BC crop profile publication for sweet corn.

2.4 Comments on the USEPA Registration Process

Did the PMRA take into account that the USEPA evaluation was publicly contested in a published article in the *International Journal of Occupational Environment Health* (Sass and Colangelo, 2006, European Union bans atrazine, while the United States negotiates continued use, Int. J. Occup. Environ. Health 12:260-267)?

Response
The PMRA's risk assessment and decision are science based and the Agency considered both the USEPA and EU evaluations, and the Canadian context.

Appendix II Label Amendments for Commercial Class Products Containing Atrazine

(**NOTE:** This is a summary of label statements for Commercial Class products containing atrazine resulting from the re-evaluation on environmental risks of atrazine. This attachment does not identify all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements and supplementary personal protective equipment that may be required. Additional information on labels of currently registered products should not be removed unless it contradicts information indicated below.)

All Canadian end-use product labels containing atrazine must be amended as follows.

On the primary display panel,- As per the registrant request, the following statement must be added immediately below the product name:

- **DO NOT USE IN THE PROVINCE OF BRITISH COLUMBIA**

The following statements must be added to end-use product labels containing atrazine, under **ENVIRONMENTAL HAZARDS**:

- Toxic to non-target terrestrial plants and aquatic organisms. Observe the buffer zones and precautionary measures specified under Directions for Use.

Because terrestrial field accumulation/dissipation studies have shown that more than 30% of the atrazine is remaining after one use season (e.g. at the beginning of the following use season), the following statement on the label is required:

- Atrazine is persistent and will carry over. It is recommended that any products containing atrazine not be used in areas treated with this product during the previous season.

The following statements must be added to end-use product labels containing atrazine under **DIRECTIONS FOR USE**:

- Do NOT apply by air.
- Do NOT apply during periods of dead calm or when winds are gusty.
- Do NOT overspray non-target terrestrial or aquatic habitats.
- Do NOT contaminate aquatic habitats when cleaning and rinsing spray equipment or containers.

- When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

Buffer Zones

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, pastures, rangelands and shrublands) or aquatic habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, wetlands and estuarine/marine habitats).

Application Method	Buffer Zone for Protection of:	
	Terrestrial Habitats (m)	Aquatic Habitats (m)
Groundboom sprayer[a]	10	10

[a] For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy or ground, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy or ground, the labelled buffer zone can be reduced by 30%.

Surface Runoff

- 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 and poorly draining soil (e.g. soils that are compacted, fine textured or low in organic matter such as clay).

- Avoid applying this product when heavy rain is forecast.

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

Leaching

- The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g. sand, loamy sand and sandy loam soils) and/or the depth of the water table is shallow.

- Avoid applying this product when heavy rain is forecast.