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Re-evaluation Decision

Trifluralin

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Re-evaluation Decision

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

An evaluation of available scientific information found that products containing trifluralin do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of trifluralin uses, new risk-reduction measures must be included on the labels of all products. No additional data are required at this time.

The regulatory approach for the re-evaluation of trifluralin was first presented in Proposed Re-evaluation Decision PRVD2008-22, *Trifluralin*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of the PMRA's regulatory process for the re-evaluation of trifluralin as well as summarizes the Agency's decision and the reasons for it. Comments received during the consultation process did not result in substantial changes to the proposed regulatory decision as described in PRVD2008-22 and Appendix I summarizes the comments and provides the PMRA's response. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-22. To comply with this decision, registrants of products containing trifluralin will be informed of the specific requirements affecting their product registration(s).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Trifluralin, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- It covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions.
- It addresses the active ingredient and the main formulation types registered in Canada.
- It is relevant to registered Canadian uses.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of trifluralin. In this decision, the PMRA took into account the Canadian use pattern and issues (the federal Toxic Substances Management Policy (TSMP), for example).

The USEPA re-evaluated trifluralin and published its conclusions in a 1996 RED and a 2004 Tolerance Reassessment Eligibility Decision. Based on health and environmental risk assessments, the USEPA concluded that trifluralin was eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found that USEPA assessments were an adequate basis for the proposed Canadian re-evaluation decision with respect to human health. The PMRA's conclusions with respect to the environment and Canadian issues (TSMP) were based on an environmental risk assessment performed by the PMRA.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2008-22, *Trifluralin*.

What Is Trifluralin?

Trifluralin is a pre-emergent soil herbicide used to control annual grasses and broadleaved weeds. It is registered for use in Canada on ornamentals, shelterbelts, terrestrial food/feed crops, oil seed and fibre production crops. Trifluralin is formulated as granules or a liquid and is also impregnated into landscape fabric. Trifluralin may be applied by farmers and professional applicators using air for granules only (applied dry), with ground equipment or as landscape fabric just below the soil surface. Homeowners can apply trifluralin by hand using the shaker can provided.

Health Considerations

Can Approved Uses of Trifluralin Affect Human Health?

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

People could be exposed to trifluralin through consumption of food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (children and nursing mothers, for example). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that trifluralin was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

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

Trifluralin is currently registered in Canada for use on a variety of crops and could be used in other countries on crops that are imported into Canada. An MRL for trifluralin is established for carrots at 0.5 ppm. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Trifluralin is Introduced into the Environment?

Trifluralin poses a potential risk to terrestrial and aquatic plants and freshwater and estuarine/marine biota; therefore, additional risk-reduction measures need to be observed.

When trifluralin is released into the environment it will have a tendency to sorb to soil as well as particulate matter in surface water. It will also volatilize into the air during periods of application and could also enter the atmosphere during periods when it is not applied due to wind blown particles. Trifluralin is not mobile in soil and remains primarily in the top surface layers. Trifluralin is moderately persistent to persistent in the terrestrial environment but is non-persistent in water and air. However, trifluralin has been detected in remote regions of Canada including the Arctic; therefore, it has sufficient persistence in the air to be subject to long-range transport. Concentrations in remote regions remain very low.

When trifluralin is used for weed control in crops, there is a potential that nontarget species on land and in water may be exposed to the chemical as a result of spray drift or runoff. Some species are sensitive to the chemical and would be adversely affected.

According to a refined risk assessment, trifluralin would not pose a risk to terrestrial biota. However, trifluralin does present a risk to aquatic organisms like invertebrates, fish, plants, algae and amphibians. To reduce the effects of trifluralin in the environment, buffer zones and precautionary label statements are required to reduce the entry of spray drift into aquatic systems and to prevent volatilization into the air.

The PMRA has taken into account the federal Toxic Substance Management Policy during the review of trifluralin.

Trifluralin meets three of the four requirements for Track 1 status under the TSMP: It is persistent (in air and soil), anthropogenic[3] and toxic as defined by the *Canadian Environmental Protection Act.* After consideration of data that resulted in the publication of the proposed re-evaluation decision for trifluralin (PRVD 2008-22) and the new information submitted during the consultation period, the PMRA has concluded that trifluralin does not meet the TSMP Track 1 criterion for bioaccumulation because there is insufficient field evidence indicating that the criteria for bioaccumulation (BAF 5000) has been met (please see the PMRA's response to the bioaccumulation question in the comments section of this document, Appendix I). The PMRA reached this conclusion because the combination of low levels of trifluralin detected in the environment in remote areas (air, water, sediment) and the rapid depuration observed in fish and oysters, makes it unlikely that trifluralin will bioaccumulate to significant levels in biota.

Ongoing International Issues Concerning Trifluralin

Trifluralin is under discussion internationally to determine whether it meets the criteria for being considered as persistent, bioaccumulative and toxic. The PMRA is currently developing an approach for managing chemicals which do not meet all criteria for persistent, bioaccumulative and toxic. Trifluralin may be revisited once an approach has been developed.

Trifluralin is also being discussed within the United Nations Economic Commission for Europe (UNECE) Long-Range Transboundary Air Pollution Protocol on Persistent Organic Pollutants (LRTAP POP). There is concern within the UNECE that the physical/chemical properties of trifluralin make it a POP candidate. Most criteria for inclusion as a LRTAP POP are similar to Canada's TSMP criteria, with the additional criteria of evidence of long-range transboundary atmospheric transport and the existence of sufficient information to indicate the substance is likely to have significant adverse human health and/or environmental effects as a result of its long-range transboundary

[3] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

atmospheric transport. The PMRA has evidence indicating that trifluralin undergoes long-range transport. However, based on the information reviewed to date, it is unlikely there are significant environmental effects as a result of long-range transport. The PMRA will continue to be involved in discussions with the UNECE regarding trifluralin and if new data emerges the PMRA will revisit trifluralin under the POPs framework.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of trifluralin, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect mixers/loaders/applicators.
- A restricted-entry interval to protect workers re-entering treated sites.
- Skin sensitizer indication.

Environment

- Additional advisory statements to protect non-target species.
- Buffer zones for aquatic and terrestrial habitats.

Appendix II lists all required label amendments, including instructions related to basic hygiene practices.

Other Information

Any person may file a notice of objection[4] regarding this decision on trifluralin within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website, Request a Reconsideration of Decision, or contact the PMRA's Pest Management Information Service.

[4] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1.0 Comment on the Maximum Application Rate

The registrant proposed that a maximum application rate of 1700 g a.i./ha (reduction from the current rates) should be considered in the PMRA's risk assessment for asparagus and shelterbelts, and that the product label (Registration Number 23933) should be amended to reflect a strip application method for these uses.

Response

The PMRA has considered the new maximum application rate (1700 g a.i./ha) and strip application method (4464 g a.i./ha and 2016 g a.i./ha) suggested by the registrant for asparagus and shelterbelts, and no significant changes would result in the re-evaluation decision for trifluralin for the following reasons.

- Even though a strip application does not cover 100% of the target area (only sprays within the rows of plants or proposed rows of plants) the strip itself would still be receiving the rates of 4464 g a.i./ha (shelterbelts) and 2016 g a.i./ha (asparagus). Therefore, these higher application rates would still require the buffer zones previously calculated (PRVD2008-22) to protect sensitive biota against the drift from these higher application rates.
- A strip application does not negate the potential for drift of larger rates of trifluralin into sensitive areas.
- The strip width is undefined and, therefore, could be 0.5 m in width or the width of the entire field sprayer.

If the registrant wishes to amend the product label for specific use instructions, an application, adequately supported by relevant scientific data, may be submitted to the PMRA.

2.0 Comment on the Risk Assessment for Fish and Amphibians

The registrant submitted a 35-day chronic toxicity study on fathead minnow (PMRA, 1656263), as additional information to consider on the PMRA's risk assessment for fish and amphibians. The submitted static test was conducted with trifluralin applied to the water phase of a water/sediment environment. The no observed effects concentrations (NOECs) from the new study, for survival, length, body weight and radiograph (skeletal deformations) were described as 32, 32, 100 and 3.2 µg a.i./L, respectively. The NOECs in the previous study that the PMRA used for its risk assessment were 3.2, 3.2, 30 (highest dose tested) and 0.3 µg a.i./L or survival, length, body weight and skeletal deformities, respectively.

Response

The authors of this study reported the toxicity of trifluralin using the nominal concentrations instead of the measured concentrations. Measured concentrations of trifluralin decreased rapidly from 3.7, 12, 34 and 120 µg a.i./L on day 0 to 0.018, 0.059, 0.083, 0.17 µg a.i./L, respectively, by day 7. By day 14 (or earlier) there was no detectable trifluralin in the water column in any treatment. This indicates that the fish were not exposed to trifluralin in the water for much more than seven days and were definitely exposed to trifluralin at much lower concentrations than indicated by the nominal concentrations that were used to determine the NOECs.

The mean measured concentrations in the water over the 35 day period were 0.87, 2.84, 7.61 and 24.4 µg a.i./L. Using these mean measured concentrations of trifluralin to recalculate the NOECs for fathead minnows, the NOECs for survival, length, body weight and skeletal deformations (via radiograph) would be 7.6, 7.6, 24 and 0.87 µg a.i./L, respectively.

Considering the gross deformities that were reported in fathead minnows in the new study, it is apparent that even at low concentrations in water (0.87 µg a.i./L), where trifluralin was primarily associated with the sediment phase after three days and short exposure times in water (seven days), the fish were greatly affected by trifluralin. The NOEC values from the new study cannot be used as they were based on nominal concentrations.

3.0 Comment on the Label Statement Regarding Volatilization

The registrant would like to revise the proposed label statement from:

> "To minimize the release of trifluralin into the environment due to volatilization, trifluralin should only be applied on cool mornings and evenings when air temperatures are 15°C or lower. To further reduce volatilization to the atmosphere, incorporation into the soil should occur concurrently with application."

to:

> "Incorporation into the soil should occur concurrently with application to reduce volatilization to the atmosphere. When application and incorporation into the soil do not occur concurrently, trifluralin should only be applied on cool mornings and evenings when air temperatures are 15°C or lower. Do not delay incorporation more than four hours after application."

Response

The PMRA agrees that the practice of application and incorporation occurring concurrently should be considered a best management practise for reducing volatility. However, the changes suggested by the registrant to this label statement do not alter the

previously proposed label statement. In addition, the PMRA does not have data to confirm the efficacy of the additional statement (incorporation four hours after application) that they suggest. The PMRA is attempting to standardize label statements to simplify label statements for the applicator; therefore, the label statement will remain unchanged, as previously proposed in PRVD2008-22.

4.0 Comments on the Proposed Buffer Zone Requirements

4.1 Comment on the Label Statements

The registrant would like to change the following label statement from:

> "Use of the following spray methods or equipment DO NOT require a buffer zone: handheld or backpack sprayer, inter-row hooded sprayer, spot treatment, soil drench and soil incorporation."

to:

> "Use of the following spray methods or equipment DO NOT require a buffer zone: handheld or backpack sprayer, inter-row hooded sprayer, spot treatment, soil drench and when application and incorporation into the soil occur concurrently."

Response

The PMRA does not accept the proposed change to this label statement as buffer zones are used to protect susceptible non-target areas and biota. Buffer zones are in place to prevent the potential drift of pesticides into these areas during application. Incorporation of trifluralin does not protect against the potential for drift at the time of application. Incorporation of trifluralin will only decrease the volatilization of trifluralin after application. The exemption for soil incorporation was not intended for use with broadcast sprayers (used for application of trifluralin). The revised label statements are listed in Appendix II.

4.2 Comment on the Immediate Incorporation of Trifluralin

The PMRA should allow (or require) immediate incorporation of trifluralin for buffer zone reductions.

Response

The requirement for immediate incorporation of trifluralin does not relate to mitigating drift during spraying applications. Incorporation of trifluralin is intended to reduce the volatilization of trifluralin from soil after application. In addition, a volatilization label statement has been added stating, that trifluralin should be incorporated concurrently with application.

4.3 Comment on the Use of Nozzles

The PMRA should consider the use of flood jet nozzles and other nozzle technology for buffer zone reductions.

Response

The PMRA does not specify nozzle types on labels. Spray drift is not only dependent on nozzle type; it is also dependent on pressure and flow rate. Therefore, the PMRA cannot provide guidance to the user on what nozzle should be used.

4.4 Comment on the List of Sensitive Terrestrial Habitats

The registrant would like the PMRA to consider removing shelterbelts from the list of sensitive terrestrial habitats because they are a registered use site for trifluralin products and, therefore, there is no need for a buffer zone.

Response

Buffer zones are used to protect non-target biota from indirect spray (drift). Because non-target biota may be present within shelterbelts, the buffer zones must also be in place for shelterbelts, which are not the target area of application (for example, the application of trifluralin to food crops bordered by a shelterbelt). Therefore, shelterbelts are included in the list of sensitive terrestrial habitats.

4.5 Comment on the Proposed Buffer Zone Table

The restructure of the buffer zone table is requested to allow for the grower to manage risk by rate selection as opposed to the type of crop trifluralin is applied to, as well as a reduction of buffer zones for peas, beans and lentils from 80 to 35 m.

Response

The structure of the buffer zone table is not changed as proposed (to allow the grower to manage risk by rate selection as opposed to type of crop) for a number of reasons. Most importantly, it would force the applicator to convert their product rate (L/ha) to an application rate (g a.i./ha) before they could consult the buffer zone table to determine buffer zones, which could lead to application errors. The application of trifluralin also depends on a number of variables. For example, there are different application rates for the same crop depending on the area of application (Eastern Canada versus prairie regions, for example) or timing (spring versus fall applications), as well as soil texture (light versus heavy soils or low organic matter versus high organic matter soils) would require different buffer zones. To include all of these variables in the buffer zone table would make the table exceedingly complex and subject to interpretation errors.

All buffer zones are grouped by crops. The PMRA is in the process of finalizing a labelling proposal document and will be consulting with growers and industry on the most efficient method for specifying buffer zones on pesticide labels.

The registrant noted that buffer zones for peas, beans and lentils (and all other crops) could be reduced, if based on the range of application rates rather than the maximum allowable rate. The PMRA does not currently specify buffer zone sizes based on the application range; however, the labelling proposal document will seek stakeholder input regarding the usability of this approach.

The buffer zone table and directions will remain unchanged as previously proposed (PRVD2008-22), with a deletion of the exemption for soil incorporation. The label amendments are listed in Appendix II.

5.0 Comment on the Toxic Substances Management Policy Data Requirements

In the PRVD2008-22, data were requested as a condition of continuing registration, in order for the PMRA to make a final determination of the status of trifluralin under the TSMP. The required data consisted of the following:

- field data addressing the bioaccumulation of trifluralin in biota inhabiting the areas of use; and
- analytical data of air, water and biota in remote areas (the Arctic, for example), to determine if long-range transport of trifluralin is occurring.

The registrant submitted a report along with supporting studies to address these areas of concern and suggests: 1) that bioaccumulation in some studies are below the TSMP criteria for bioaccumulation (5000) and 2) that a constant exposure scenario must be maintained for bioaccumulation to take place, which they state is unlikely considering the rapid sorption from water to sediment and rapid transformation in sediment.

Response

1) Bioaccumulation

The registrant referred to a new study on bluegill sunfish that were exposed to treated sediment under static conditions for eight days and showed steady state bioconcentration factors (BCFs) ranging from 1087 to 1838. Even though this study was only eight days in length, the fish were still able to accumulate trifluralin. The PMRA does not have this study and cannot make a judgement on the its validity. It should be noted that it was a laboratory study and the PMRA specifically asked for field data from areas of use and remote areas. They also provided a BCF value of 5674 in bluegill sunfish from a 28-day exposure/14-day depuration laboratory study (Graper and Rainey, 1988).[5] A depuration

[5] Graper, L.K. and Rainey, D.P. (1988): Laboratory Studies of ^{14}C Trifluralin Accumulation in Bluegill Sunfish. Dow AgroSciences, unpublished report No. ABC-0372 & ABC-0376, 8 June 1988. This study was not submitted to the PMRA by the registrant, but only discussed in the comment to the PRVD 2008-22.

half-life of 4.7 days was found in this laboratory study. This study was not submitted to the PMRA.

The registrant also provided a summary from a four-year monitoring study conducted on predator and bottom dwelling fish, from various locations across the contiguous United States. The summary provided to PMRA shows low detection frequencies in fish tissues (10%, 3%, 0.9% and 0.7% in 2000, 2001, 2002 and 2003, respectively) and a maximum concentration of 36 µg/kg. Only one predatory fish was found to contain trifluralin (11.3 µg/kg). The PMRA does not have information for Canada; however, this information does indicate that trifluralin may not accumulate in the higher trophic levels of food chains.

In addition, the registrant provided information on trifluralin in air and/or water in Canadian provinces. All of these studies showed that trifluralin has been detected to varying degrees in Canada. The registrant's reports that as the concentrations were low, it is not expected that trifluralin would accumulate in biota. However, there was no data in any of these studies on trifluralin residues in biota in areas of use. The low level of detections of trifluralin in water is not surprising, considering its tendency to adsorb organic matter (high K_{oc}) and its rapid phototransformation rate in water and volatilization.

The registrant stated that the 2005 OSPAR report indicated that there was no concern for fish-eating predators (birds or mammals) or secondary poisonings as shown by their estimation methods. The PMRA agrees that the OSPAR report does indicate this fact. However OSPAR states that "trifluralin is clearly a PBT (Persistent, Bioaccumulative, Toxic) substance."

Summary

The new information that the registrant provided and that was taken into consideration during the initial re-evaluation of trifluralin provides sufficient information to determine that trifluralin does not meet the TSMP criteria for bioaccumulation. Although the PMRA has some information indicating that BCF values are above the criteria threshold, the weight of evidence at this time does not support it being considered bioaccumulative.

Those studies/reports that showed BCFs above the criteria include the USEPA RED (1996), Graper and Rainey (1988) and Spacie and Hamelink (1979). The USEPA RED found that BCF values were 2041, 9586 and 5674 in edible, non-edible and whole fish tissues, respectively. However, it was also observed that 86 to 88% of the trifluralin was depurated after 14 days in trifluralin free water. Graper and Rainey found a BCF of 5674 in bluegill sunfish in the lab with 50% clearance times of 4.7 days. Spacie and Hamelink found a BCF value of 5800 in sauger downstream of a chemical plant that manufactured trifluralin and other chemicals and an experimental value of 6000 in fathead minnow. Depuration rates ($t_{1/2}$s) were 22–31 days in the sauger and 3 days in the fathead minnow. In total, the PMRA has four BCF values that are above the threshold criteria for bioaccumulation. One of these values was from a study conducted downstream of a chemical manufacturing plant in 1979 and the remaining three were from laboratory

studies. All studies traced depuration and observed rapid loss of trifluralin from fish tissues.

The BCF values that were below the bioaccumulation criteria include Spacie and Hamelink (shorthead redhorse and golden redhorse: 2800 and 1800, respectively), Kearney et al. (1977) (algae, snails, daphnids and fish: 521, 208, 188 and 42, respectively), Muir (personal communication, NWRI, Hamilton, Ontario) (zooplankton: 255 and 4200) and PMRA 1656263 (Bluegill sunfish: ranged from 1087 to 1838).

Other data that indicated trifluralin was rarely detected in biota and, therefore, not bioaccumulating include PMRA 1656264—where the USEPA found 37 fish out of 1003 with detectable trifluralin in fish tissues from various lakes across the contiguous U.S.A. between the years 2000 and 2003—and Evenset et al. (2004)—where trifluralin was never detected in zooplankton. Vague statements in Evenset et al. on the presence of trifluralin in chironomids ("The concentration pattern (of all chemicals) in chironomid samples mirrored the pattern observed in zooplankton…") and arctic char ("Concentrations of chlordane, heptachlor, aldrin and trifluralin were below detection limits in almost all the fish samples…") preclude the discussion of whether trifluralin was actually detected or not in these two biotic groups in the two remote lakes sampled.

The most significant studies in support of the PMRA's decision that trifluralin is not bioaccumulative are the three field studies. BCFs in zooplankton in Ontario (Muir, personal communication) were below the threshold; PMRA 1656264 found that trifluralin was rarely detected in fish across the contiguous U.S.A. and Evenset et al. (PMRA 1656267) who found that trifluralin was never detected in zooplankton and was rarely detected, if at all, in chironomids and fish in remote areas. The available data also indicate that trifluralin is depurated rapidly from fish tissue, also precluding the constant accumulation of trifluralin that would lead to bioaccumulation.

2) Persistence

The registrant does not agree that trifluralin is persistent in soil. In the re-evaluation of trifluralin conducted by PMRA, the $t_{1/2}$s for aerobic biotransformation studies ranged from 81–356 days with losses from volatilization in these studies of 21.7%, which contributed to the perceived biotransformation or loss of trifluralin. The registrant states that the longer aerobic biotransformation value $t_{1/2}$ (356 days) is "anomalous." There is no valid scientific argument offered, and the PMRA cannot arbitrarily decide that this value is less credible than the lowest $t_{1/2}$ of 81 days.

The registrant provided two studies (that the PMRA had already included in their re-evaluation) showing that trifluralin is not persistent in water. The first study in the OSPAR report (2005) showed that the $t_{1/2}$ of trifluralin in water and sediment could not be determined in the water, due to rapid sorption to the sediment and was 4–6 days in the sediment. However, it must be noted that in this study, 53 to 77% of the applied trifluralin volatilized from the system. The PMRA had determined earlier that this study did not provide an accurate depiction of the aerobic transformation of trifluralin in a water/sediment system due to the high volatilization. In the other study, trifluralin was

not found in the water phase "during the 17 day incubation period." The PMRA review of this study showed that the water phase was not analyzed for trifluralin because the percent radioactivity was <10% of applied in the water phase. However, the DT_{50} of trifluralin in the sediment was 17 days and would thus be classified as slightly persistent. The registrant provided information on a UK field study to determine potential accumulation of trifluralin in soil over a period of five years. The study indicated that trifluralin residues in soil one year after each application did not increase over the course of the five-year study. However, in the re-evaluation of trifluralin, the PMRA found that annual carry over in Canadian field studies ranged from 6 to 40%, which indicated that there was carry over of trifluralin residues.

The registrant wanted clarification of the statement that trifluralin is persistent in air based on the fact that trifluralin has been detected in remote areas away from areas of use, even though the phototransformation $t_{1/2}$ in air is 5.3 hours. In the re-evaluation of trifluralin, the PMRA determined that the detection of trifluralin in remote areas may indicate it is bound to airborne particulates, which prevents phototransformation from taking place. The sorbed trifluralin is then dry or wet deposited to the remote areas. The registrant indicates that "information on the atmospheric loading form of trifluralin (volatile or adsorbed onto dust) and possible route and distance of dispersal, are unknown." Although the information regarding dispersal may not be adequate, the available evidence shows that trifluralin is subject to long-range transport and has been detected in remote areas.

The PMRA does not agree with the registrant that trifluralin is not persistent in soil. Please note that the OSPAR report (2005), European Food Safety Authority (2005) and USEPA (1996) also agree that trifluralin is persistent in soil.

3) Long-Range Transport

Based on the re-evaluation of trifluralin, the PMRA determined that this herbicide was transported away from the area of application to remote sites such as Baie St. Francis, Waskesiu, Saskatchewan, the Canadian Arctic, Greenland and in the Bering and Chukchi (north of the Bering Straight) marine ecosystems. The concentrations were shown to be comparable across the Arctic, indicating a uniformity of the contamination in the arctic atmosphere (Skov et al. 2005). The registrant provided further documentation of long-range transport with the submission of a poster by Jantunen (PMRA 1656259) that showed detectable concentrations of trifluralin in air in the Canadian Arctic in all 11 samples at 0.2 to 0.91 pg/m^3. This submitted study is scant on details; however, it does show that trifluralin is found in the Canadian Arctic. Water samples were also taken by the authors; however, there was no information on the analyses of the samples in this poster.

Overall Conclusions

Although the PMRA agrees that trifluralin is non-persistent in water/sediment systems under static conditions and states in PRVD2008-22 that "trifluralin is classified as non-persistent in laboratory aquatic aerobic biotransformation studies," the PMRA has

information showing that trifluralin is subject to long-range transport and is persistent in soil.

Reviewed Data

1. Field data addressing the bioaccumulation of trifluralin in biota inhabiting the areas of use.

a) USEPA. National Study of Chemical Residues in Lake Fish Tissue. www.epa.gov/waterscience/fish/study/ Validated 20 August 2008.

This report was limited to a USEPA Fact Sheet (PMRA number 1656264) describing this American study and a summary of the trifluralin data from this report. The report provided information on the accumulation of trifluralin in biota, from areas of use as well as from remote areas. The results indicated that biomagnification through the food chain had not occurred. Combined with the low levels of trifluralin detected in abiotic media in remote areas and the rapid depuration observed in fish, it is unlikely that trifluralin will bioaccumulate to significant levels in biota from remote areas (Arctic).

b) Hoberg, J.H. 2006. *Trifluralin – 35-Day Exposure of Fathead Minnow (*Pimephales promelas*) in a Sediment:Water Exposure System Under Static Conditions*. Unpublished study of Dow AgroSciences Number 050055. 15 May 2006. PMRA 1656263.

This is a laboratory chronic toxicity study and does not fulfill the data requirement for field data addressing accumulation of trifluralin in biota in areas of use.

2. Analysis of air, water and biota in remote areas (for example, the Arctic), to provide additional and more recent data on long-range transport and bioaccumulation of trifluralin.

a) Donald, D. B., A. J. Cessna, E. Sverko and N. Glozier. 2007. Pesticides in Surface-Water Supplies in the Northern Great Plains. *Environmental Health Perspectives*. 115:8: 1183–1191. Canadian Arctic Contaminants Assessment Report II. Verified 20 August 2008. PMRA 1656257.

The report on water monitoring provided information on concentrations of pesticides in reservoirs and water treatment plants in Manitoba, Saskatchewan and Alberta. Trifluralin was rarely detected in these waters within areas of use. It did not provide any information on the concentrations of trifluralin in biota in remote areas. The study did not include an analysis of sediment and biota for trifluralin residues.

b) Evenset, A., G. N. Christensen, T. Skotvold, E. Fjeld, M. Schlabach, E. Wartena and D. Gregor. 2004. A Comparison of Organic Contaminants in two High Arctic Lake Ecosystems, Bjørnøya (Bear Island), Norway. *Science of the Total Environment*. 318:125–141. PMRA 1656267.

The report indicated that trifluralin was detected in sediment in one of two remote lakes in Bear Island Norway, at concentrations of 0.04 ng/g sediment. Trifluralin was not detected in zooplankton from either lake and was "below detection limit in almost all fish samples." There was no other information in this article on trifluralin or the actual levels in the fish that they sampled.

c) Jantunen, L. M., F. Wong, T. F. Bidleman and G. Stern. *Occurrence and Levels of Current-Use and Legacy Pesticides in Air: Leg 1 of ArcticNet 2007*. http://www.arcticnet-ulaval.ca/pdf/posters_2007/jantunen_et_al.pdf. Verified 20 August 2008. PMRA 1656259.

There was limited information on the presence of trifluralin in air at three sites: St. Lawrence Seaway, Labrador Coast and Hudson Bay. Trifluralin was detected in all 11 air samples that were taken at concentrations of 0.2 to 0.91 pg/m^3. A full report was not available. This information, although of limited value due to its brevity, confirms that trifluralin is detected in air at remote sites. Concentrations of trifluralin in these sites are comparable to those found in the literature in other remote sites (0.03 to 2.92 pg/m^3) and reported in our re-evaluation. The data does provide information on the long-range transport of trifluralin.

d) Muir, D., C. Teixeira, and X. Wang. 2005. Atmospheric Deposition and Bioaccumulation of Current Use Pesticides in Remote Lakes in Ontario, Canada. *SETAC abstract*. http://abstracts.co.allenpress.com/pweb/setac2005/document/56956. Verified 21 August 2008. PMRA 1656260

This submission was an abstract from the Society of Environmental Toxicology and Chemistry meeting. There was very little information on bioaccumulation of trifluralin that could be gleaned from this abstract.

e) OSPAR Commission. 2005. *OSPAR Background Document on Trifluralin*. The Convention for the Protection of the Marine Environment of the North-East Atlantic (the "OSPAR Convention"). ISBN 1-904426-37-9. Publication Number 2005/203. 32 pp. PMRA 1656261.

This report was already used by the PMRA in its re-evaluation of trifluralin. In it, the authors conclude that trifluralin is clearly a persistent, bioaccumulative and toxic substance. There was no information on the presence of trifluralin in biota in remote sites.

f) Su, Y., H. Hung, P. Blanchard, G. W. Patton, R. Kallenborn, A. Konoplev, P. Fellin, H.Li, C. Geen, G. Stern, B. Rosenberg, and L. A. Barrie. 2008. A Circumpolar Perspective of Atmospheric Organochlorine Pesticides (OCPs): Results from six Arctic Monitoring Stations in 2000-2003. *Atmospheric Environment*. 42:4682–4698. PMRA 1656262.

This article provided only the following limited information in regards to the levels of trifluralin detected in air from six arctic sites "...trifluralin (concentrations) were quite low and mostly below MDLs." There was no data as to what the range of levels at which and what sort of detection frequency was observed. The report did not provide any credible information.

6.0 Comment on Other Submitted Documents

The registrant requested that the PMRA review three additional documents as follows:

1) Muir, D.C.G., and J. Zheng. 2007. Environmental trends monitoring of new chemical contaminants in the Canadian high Arctic via ice and snow cores. In: *Synopsis of research conducted under the 2006–2007, Northern Contaminants program*, Indian and Northern Affairs Canada.

2) Muir, D.C.G. 2006. *Spatial/Temporal trends of current use pesticides in surface waters and precipitation in Ontario, 2003–2005*. Environment Canada Pesticide Science Fund (PSF) project summary report.

3) Environment Canada. 2005. *Presence, Levels and Relative Risks of Priority Pesticides in Selected Canadian Aquatic Ecosystems*. An Environment Canada Pesticides Fund Project. Project Progress Report for 2005. National Water Research Institute, Environment Canada.

Response

The PMRA reviewed the three additional documents.

1) Muir and Zheng (2007)

In 2005 and 2006, snow/ice samples were collected from a snow pit from the Devon Island Ice cap. Duplicate samples were taken horizontally at 25 cm or 20 cm intervals to a depth of 4.5 m (2005) and 6.8 m (2006). The samples were pooled according to annual deposition. The samples were screened for 45 current use pesticides using GC-low resolution MS; however, the 2006 samples were analyzed by GC-electron capture detection for a limited number of currently used pesticides, which did not include trifluralin. Only 12 of 45 currently used pesticides were detected from the 2005 snow pit, seven of which were detectable in all "recent horizons." Trifluralin was among those that were detected in "almost all recent horizons." Trifluralin was "less than detection limits

in surface and near surface layers" of the snow pit. In the 2005 samples, the flux of trifluralin was determined to be 0.22 ng • m^2/yr in the horizons determined to be from the years 2000–2001 and was 0.16 ng • m^2/yr in the horizons determined to be from the years 2004–2005.

This information further confirms the presence of trifluralin in the Canadian Arctic at a remote site and that trifluralin is subject to long-range transport, away from areas of use.

2) Muir, D.C.G. (2006)

Current use pesticides were analyzed in surface (1–4 m) and subsurface (4.5–50 m) waters from three lakes in southwestern Ontario (areas of trifluralin use) and seven lakes in north/central Ontario (remote sites) from May to July in 2003 and 2004 and five lakes (southern and central Ontario) in 2005. Precipitation was also collected at three southern sites and two north/central locations between April and the end of August in 2003 and 2004 as well as at four locations in 2005. Passive air samples were taken from the precipitation sampling sites in 2004 and 2005. Zooplankton samples were also obtained during lake water sampling times.

Trifluralin was detected in >80% of lake water and precipitation samples in the southern sites with lower frequency of detection (data not provided) in the more northerly lakes. In southern, central and northern lakes concentrations of trifluralin were approximately 0.015, 0.0014 and 0.007 ng/L, respectively. Flux of trifluralin in precipitation at Grand Bend (area of use) ranged from less than detection limit to 0.42 μg/m^2 and showed increasing flux from 2003 to 2005. Concentrations of trifluralin in air in the southern (area of use) and central/northern (remote) lakes was approximately 1.2 ng/m^3 and approximately 0.0013 ng/m^3, respectively. The concentrations were estimated from available figures as no data were provided. There was no report of trifluralin being detected in zooplankton.

It is difficult to make many conclusions from this report as it is an interim report and contains no actual data for trifluralin or any other compound (only figures were provided). However, it can be shown that trifluralin is detected in lake water, precipitation and air in areas of use and also in remote areas albeit at lower concentrations and with a lower detection frequencies.

3) Environment Canada (2005)

This report includes information already discussed above (Muir 2006).

Appendix II Revised Label Amendments for Products Containing Trifluralin

The label amendments presented below do not include all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of the **commercial** end-use products in Canada must be amended to include the following statements, to further protect workers and the environment.

I) Under "**PRECAUTIONS"**:

For all commercial end-use products with the exception of the product with Registration Number 19521, the following label statement is required:

> All handlers must wear a long-sleeved shirt and long pants. In addition, wear chemical-resistant gloves during mixing/loading, repair and clean-up activities.

For the product with Registration Number 19521, the following label statement is required:

> All handlers must wear a long-sleeved shirt and long pants. In addition, wear chemical-resistant gloves, during mixing/loading, repair and clean up activities. Aerial mixers/loaders must also wear coveralls.

For all commercial end-use products, the following label statements are required:

> DO NOT enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.
>
> POTENTIAL SKIN SENSITIZER

The statement regarding skin sensitization is also required on the primary panel of the label.

II) Under "**ENVIRONMENTAL HAZARDS"**:

For all commercial products formulated as emulsifiable concentrate, the following label statement is required:

> TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

For all commercial end-use products, the following label statements are required:

> To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil or clay.
>
> Avoid application of the product when heavy rain is forecast.
>
> Contamination of aquatic areas as a result of runoff may be reduced, by including a vegetative strip between the treated area and the edge of the water body.

Under "**DIRECTIONS FOR USE"**:

For all commercial end-use products, the following label statements are required:

> DO NOT apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.
>
> Discard clothing or other absorbent materials that have been heavily contaminated with this product. DO NOT reuse them.
>
> Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
>
> DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats.
>
> DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.
>
> To minimize the release of trifluralin into the environment due to volatilization, trifluralin should only be applied on cool mornings and evenings when air temperatures are 15°C or lower. To further reduce volatilization to the atmosphere, incorporation into the soil should occur concurrently with application.

For all commercial products formulated as emulsifiable concentrate, the following label statements are required:

> Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.
>
> DO NOT apply by air.
>
> Use of the following methods or equipment DO NOT require a buffer zone: handheld or backpack sprayer, inter-row hooded sprayer, spot treatment and soil drench.
>
> 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, shelterbelts, woodlots, hedgerows, rangelands, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of Application	Crop	Buffer Zones (Metres) Required for the Protection of:				
		Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial Habitat
		Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer*	Fall-seeded wheat, rye and triticale grown in rotation with tobacco	35	4	3	1	0
	Rutabaga, forage legumes, Saskatoon berries, carrots, peppers, strawberries, tomatoes, summer fallow followed by spring or durum wheat, white turnips, forage kale, forage rape, white lupins and first year apple, apricot, cherry, peach, plum and pear trees	55	5	4	2	1
	Brussels sprouts, cauliflower and crambe, sainfoin and sweet clover	70	10	5	2	1
	Alfalfa, beans (common, dry, kidney, black, Lima), fababeans, snapbeans, peas, soybeans, sunflowers, lentils, barley and wheat, canola/rapeseed, triazine tolerant canola/rapeseed, flax, mustard and safflower	80	10	5	3	1
	Asparagus, broccoli and cabbage.	90	10	5	3	1
	Woody and perennial ornamental planting and nursery stock (field and container grown), shelterbelts (American elm, caragana, green ash, Scotch pine, Siberian elm)	120	20	15	5	1

* 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, 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, the labelled buffer zone can be reduced by 30%.

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.

The labels of **domestic** end-use products in Canada must include the following statement in the "**PRECAUTIONS"** section to further protect residential handlers:

POTENTIAL SKIN SENSITIZER

The statement regarding skin sensitization is also required on the primary panel of the label.

References

Published References

PMRA Document Number 1346402
Reference EFSA 2005. Final addendum to the Draft Assessment Report (DAR) - public version -Initial risk assessment provided by the rapporteur Member State Greece for the existing active substance TRIFLURALIN of the second stage of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC. 208 pp.

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Reference USEPA. 1996. Reregistration Eligibility Decision (RED) Trifluralin. United States Office of Prevention, Pesticides EPA Environmental Protection And Toxic Substances April 1996 Agency (7508W) 738-R-95-040. 240 pp.

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