Agriculture Canada

Food Production and Inspection Branch

Direction générale, Production et inspection des aliments

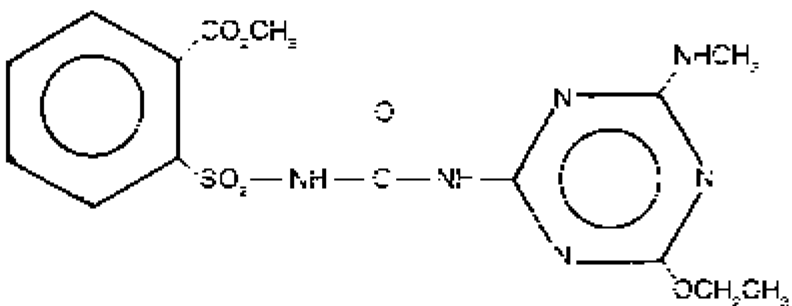
Pesticides Directorate

Direction des pesticides

Canada

Decision Document E92-01

ETHAMETSULFURON METHYL



HERBICIDE

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Publications Coordinator
Pest Management Regulatory Agency
Health Canada
2250 Riverside Drive
A.L. 6606D1
Ottawa, Ontario
K1A 0C6

Internet: pmra_publicatons@hc-sc.gc.ca
www.hc-sc.gc.ca
Facsimile: (613) 736-3798
National Pesticide Information Service:
1-800-267-6315 or (613) 736-3799

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Coordonnatrice des publications
Agence de reglementation de la lutte antiparasitaire
Sante Canada
I.A. 6606D1
2250, promenade Riverside
Ottawa (Ontario)
K1A 0C6

Internet: pmra_publications@hc-sc.gc.ca
www.hc-sc.gc.ca
Télécopieur : (613) 736-3798
Service national de renseignements sur les pesticides :
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FORWARD

Ethametsulfuron Methyl

As part of the ongoing efforts to provide a summary of the data received and to outline the regulatory action on the active ingredient ethametsulfuron methyl, a Decision Document has been prepared. This document reflects input from specialists within Agriculture Canada and from key departmental advisors. Based on the review of all available information and in consideration of the agronomic benefits, a regulatory decision has been made to grant temporary registration for ethametsulfuron methyl and the end-use product MUSTER®.

F. Montambault
Pesticides Directorate
Agriculture Canada
Ottawa, Ontario
K1A 0C6

ABBREVIATIONS USED WITHIN THIS DOCUMENT

ADI	Accepted Daily Intake
a.i.	active ingredient
ALD	Approximate Lethal Dose
b.w.	body weight
CAS (N^o)	Chemical Abstracts Service Registry Number
DT_{50}	Decline Time 50%
EC_{25}	Effective Concentration 25 (%)
EC_{50}	Effective Concentration 50 (%)
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
K_{ow}	Octanol/Water partition coefficient
LC_{50}	Lethal Concentration 50 (%)
LD_{50}	Lethal Dose 50 (%)
MRL	Maximum Residue Limit
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effect Level
NZW	New Zealand White (rabbits)
ppm	parts per million (also mg/kg, mg/L, etc.)
TDI	Theoretical Daily Intake

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1. SUMMARY

The purpose of this document is to summarize information on the risks and benefits associated with the use of ethametsulfuron methyl herbicide and to announce the formal regulatory decision on this active ingredient and its end-use product MUSTER®.

The benefits of ethametsulfuron methyl have been assessed by Agriculture Canada while the risks associated with its use have been characterized by Health and Welfare Canada, Environment Canada and the Department of Fisheries and Oceans.

Ethametsulfuron methyl has been shown to be an effective herbicide for the control of wild mustard, stinkweed and other broadleaved weeds in canola production. The product is the only herbicide on the Canadian market that controls both wild mustard and stinkweed in major canola varieties.

When the end-use product MUSTER® is applied following label directions, there is considered to be an adequate margin of safety (MOS) with respect to occupational hazard and safety. Consumer dietary exposure to canola oil extracted from canola seeds harvested from treated canola plants is not of concern.

Ethametsulfuron methyl is not expected to pose a hazard to earthworms, honeybees, and aquatic invertebrates. It is not considered to pose a direct hazard to wildlife and fish and it has a low potential for bioaccumulation. At most of the Canadian prairie and U.S. study sites, residues did not leach below the 15-cm depth. However, due to the active ingredient's toxicity to many terrestrial plants and its potential for persistence and mobility, wildlife habitat and fish habitat may be modified from off-target movement of the product. To mitigate the potential risk of such occurrences, a 15-meter buffer zone around environmentally susceptible areas has been included on the label. The appropriateness of a buffer zone will be reevaluated once additional data on off-target plant effects is made available.

Based on the identified risks associated with the use of ethametsulfuron methyl and in consideration of the economic benefits to Canadian canola production, this herbicide has been granted temporary registration until December 31, 1992. This temporary registration will allow for the submission/review of additional data, and for the consultation necessary to address unresolved concerns.

2. PESTICIDE NAME AND PROPERTIES

2.1 Pesticide Name

Common Name: ethametsulfuron methyl
Chemical Name: 2-[[[[[4-ethoxy-6-(methylamino)-1,3,5-triazin-2-yl]-amino]carbonyl]amino]sulfonyl] benzoate
Trade Name: MUSTER®
CAS Registry No: 97780-06-8

2.2 Physical and Chemical Properties

Empirical Formula:	$C_{15}H_{18}N_6O_6S$
Molecular Weight:	410.4
Physical Form:	Crystalline solid
Color:	White
Odor:	Negligible
Melting Point:	194°C
Vapor Pressure:	5.8×10^{-15} mm Hg @ 25°C
Octanol/Water partition coefficient$_{(Kow)}$:	38.7 at pH 5 0.89 at pH 7

Water solubility at controlled pH:

pH	Solubility of ethametsulfuron methyl (ppm)
5.0	1.7
6.0	50
9.0	410

Solubility in various organic solvents:

Solvent	Solubility (ppm)
Acetone	1600
Acetonitrile	830
Ethanol	170
Hexane	5
Isopropanol	74
Methanol	350
Methylene Chloride	3900
Toluene	9
Xylenes	10
Ethyl Acetate	680

Stability: At room temperature both the technical product and end-use product are stable.

3. DEVELOPMENT AND USE HISTORY

Ethametsulfuron methyl is manufactured by E.I. DuPont de Nemours & Company. DuPont Canada Inc. is the registrant for both the technical active ingredient ethametsulfuron methyl and the end-use product, MUSTER®.

Field tests with MUSTER® were initiated in western Canada in 1984 and the original submission for registration was received by Agriculture Canada in 1986.

Ethametsulfuron methyl and its end-use product MUSTER® are registered only in Canada.

4. BIOLOGICAL PROPERTIES

Ethametsulfuron methyl is one in a series of sulfonylureas whose herbicidal properties were first reported in 1966. These herbicides are inhibitors of plant growth and control a wide spectrum of broadleaved weeds. The major characteristic of ethametsulfuron methyl is the selective control of wild mustard and stinkweed in canola which are all members of the Brassicae family.

5. REGULATORY POSITION AND RATIONALE

Ethametsulfuron methyl has low acute oral, dermal and inhalation toxicity in rats and/or rabbits. Subchronic and long-term feeding studies as well as reproduction, teratogenicity and mutagenicity studies performed on different mammals were considered favourable to the registration of ethametsulfuron methyl. The data indicate that when ethametsulfuron methyl is used on canola (and mustard), in accordance with label directions, total residues at harvest are unlikely to exceed 0.1 ppm and are not considered to pose any hazard to consumers.

Ethametsulfuron methyl is not expected to pose a direct hazard to wildlife. However its toxicity to many terrestrial plants combined with the potential for persistence and mobility have raised concerns about the possible off-target effect of ethametsulfuron methyl on flora. This possible effect could result in modifying the distribution of plants in rural habitats. Ultimately, wildlife and fish could be indirectly impaired through the destruction of niches supporting the existence of certain animal species. To minimize the risk of any significant off-target effect it was considered adequate to have the label include a 15-meter buffer zone between the last spray swath and important wildlife habitats such as shelterbelts, wetlands, sloughs and dry slough borders, woodlots, vegetated ditchbanks and other cover on the edge of fields. This 15-meter buffer zone statement will be kept on the label until additional data are submitted on the effect of ethametsulfuron methyl on off-target plant species. After submission of new studies, the appropriateness of the buffer zone will be reassessed and modified if considered necessary.

6. USE SUMMARY AND BENEFITS

6.1 Description of Market

Canola production in Canada is centered in the prairie provinces. From 1982 to 1989, an average of 2.9 million hectares per annum were grown in Canada. In 1987, canola contributed $697,257,000 to the total farm cash receipts in Canada. Canadian exports of canola in 1987 were valued at $490,554,000.

6.2 Pest Problem

Wild mustard is generally considered to be the major weed problem for which effective weed control methods are needed in canola production. Weed surveys done in the prairies in 1986 and 1988 showed that 58% of the canola fields in Manitoba, 17.8% of the canola fields in Saskatchewan, and 10% of the canola fields in Alberta were infested by wild mustard.

Wild mustard infestations are of serious concern in canola production and can be more detrimental than any other type of weed infestation. It was estimated, based on the average 1989-1990 yield figures, that low infestation levels of wild mustard in prairie canola fields resulted in a 2.3% yield reduction (i.e., 71000 metric tonnes), which would have been valued at 23 million dollars.

It should be remembered, however, that yield reductions caused by the presence of wild mustard competition do not alone account for the total loss of cash receipts at the farm gate. Because canola seeds and mustard seeds are similar in size and appearance, it is very difficult to separate them before the harvested crop is crushed for oil production. The quality of oil that can then be produced from these contaminated canola crops is easily impaired. For this reason, grade loss will occur when a canola sample contains 5-50% wild mustard seeds, which would then result in a significant drop in price.

When combined, these two negative aspects of wild mustard infestations have resulted in limiting canola production to non-infested areas. However, with the availability of an efficient wild mustard herbicide, the number of hectares of canola grown could significantly increase, depending on market demands for oil.

In the past, the significance of wild mustard and stinkweed infestations and the lack of control methods have led to the development of triazine-tolerant canola (TTC) varieties. These TTC varieties have permitted the use of atrazine, cyanazine or metribuzin in canola, traditional cultivars of which are susceptible to triazine herbicides. These varieties do, however, possess certain agronomic disadvantages (i.e., lower yields and lower oil content). These disadvantages and others have limited the popularity and expansion of the use of these varieties.

There is currently a lack of available chemical control methods to limit wild mustard infestations in major canola varieties. Benazolin was available in the past, but is no longer available on the Canadian market.

6.3 Proposed Uses

Ethametsulfuron methyl is proposed for use in canola as a systemic broadleaved weed herbicide. It is useful to control Brassicae weeds such as wild mustard, stinkweed and flixweed without causing any injury to canola which is also a member of the same family. Its effectiveness has been tested mainly in western Canada since 1985. The product has been shown to be efficacious in controlling or suppressing labelled weed species as presented in Table 1.

Table 1. Weed Spectrum for Ethametsulfuron methyl

Use Rate (g a.i/ha)	Weeds Controlled	Weeds Suppressed
15	Wild mustard Hempnettle Flixweed (spring seedlings) Green Smartweed	Stinkweed
22.5	Stinkweed pigweed	Redroot

Ethametsulfuron methyl can also be tank-mixed with sethoxydim to broaden the spectrum of weeds controlled to include a number of grassy weed species. For optimum weed control, ethametsulfuron methyl must be applied, alone or in mixture, at the cotyledon to six (6) leaf stage of the target weeds. Best results are obtained when the product is applied to the main flush of actively growing weeds. Thorough coverage of the target weeds is important to ensure good control.

6.4 Crop Rotation Intervals

Due to the persistent nature of ethametsulfuron methyl, minimum crop rotation intervals must be respected to avoid residual activity and possible phytotoxicity to susceptible rotational crops. Rotational crop studies have been performed in the prairies to develop guidelines which outline the "waiting" period for major rotational crops (refer to Table 2). For all other rotational crops a field test strip must be made 22 months after the application date.

Table 2. Interval prior to planting rotational crops

Interval (months after application)	Crop
10 months	Spring wheat Durum wheat Barley Oats Flax
22 months	Canola Lentils Peas Fababeans Tame mustard

6.5 Pre-Harvest and Grazing Intervals

The residue data submitted support a 60-day pre-harvest interval, which means that a 60-day waiting period would separate the application of ethametsulfuron methyl and swathing of the crop.

On occasion, the treated whole rapeseed plants may be fed to livestock but because no livestock feeding studies are available, the label bears a no-grazing, no-feeding period of 60 days.

7. TOXICOLOGY AND OCCUPATIONAL EXPOSURE: HEALTH AND WELFARE CANADA

A toxicology data package was submitted by the registrant, DuPont Canada Inc. The following data were considered in the assessment of potential human health hazards and the following status report prepared by Health and Welfare Canada was considered in our regulatory decision on ethametsulfuron methyl.

Background to Proposal

Ethametsulfuron methyl is one of a new group of sulfonylurea herbicides. This product is currently the only herbicide that offers control of broadleaved weeds such as wild mustard and stinkweed in oilseed crops. The manufacturer (DuPont) is proposing registration of a 75% dry flowable formulation (MUSTER®) for early season use in rapeseed (canola) on all varieties grown in Canada and in tame mustard.

Evaluation

The technical material to be manufactured has a purity of 93-99% and all major impurities have been identified and are related to the active material. The major toxicity studies used technical material containing 96-96.8% purity.

7.1 Toxicology

a) Summary of Toxicity Data

i) Acute Toxicity

Approximate lethal dose (ALD) studies in male CD(SD) rats and New Zealand White (NZW) rabbits demonstrated a very low order of oral toxicity with values exceeding 11,000 and 5000 mg/kg b.w. in the two species, respectively. The acute oral LD_{50} in CD(SD) rats of both sexes exceeded 5000 mg/kg body weight (b.w.) for both the technical material and the 75% dry flowable (MUSTER®) formulation.

The acute dermal LD_{50} in NZW rabbits for both the technical and the 75% dry flowable formulation exceeded 2000 mg/kg b.w., and the acute inhalation LC_{50} for the technical material in CD(SD) rats exceeded 5.7 mg/L.

The 75% dry flowable formulation was demonstrated to be non-irritating to the skin and eyes of NZW rabbits, and non-sensitizing upon dermal application to guinea pigs.

ii) Short-Term Toxicity

Rat: Two groups of six male CD(SD) rats treated orally by gavage with the vehicle, corn oil or ethametsulfuron methyl at 2200 mg/kg b.w./day for 10 days over a two-week period revealed treatment-related toxicity which was manifest as multifocal necrosis of epithelial cells and accumulation of protein droplets within cells of the renal proximal tubules (complete reversibility of these lesions was not evident following a 14-day recovery).

A ninety day feeding study with 10 rats/sex/group followed by a one-generation reproduction phase (additional 6 rats/sex/group) in CD(SD) rats at dietary levels of 0, 100, 1000 and 5000 ppm failed to elicit any signs of overt toxicity or any adverse effect on reproductive performance at levels as high as 5000 ppm (equivalent to 0.5% of the diet or approximately 409 mg/kg b.w./day, actual intake). Increases in the testes, and kidney-to-body weight ratios at the high dose level were of questionable significance in the absence of any collaborative clinical or pathological findings. The No Observed Adverse Effect Level (NOAEL) for this study was, therefore, set at the high dose level of 5000 ppm.

Mouse: A ninety day dietary feeding study in CD-1 mice at levels of 0, 50, 500, 2500 and 5000 ppm indicated a No Observed Effect Level (NOEL) for females and a NOAEL for males set at the high dose level of 5000 ppm (equivalent to approximate 687 mg/kg b.w./day, actual intake for males). The NOAEL in the high dose treated male mice was set based on equivocal increases in leukocytes counts and significantly increased relative kidney-to-body weights (in the absence of any supportive renal pathology).

Dog: Dietary administration of technical ethametsulfuron methyl to dogs for 90 days at levels of 0, 100, 3500 or 10000 ppm failed to reveal any evidence of treatment-related toxicity at levels as high as 10000 ppm (equivalent to 1% of the diet or approximately 386 mg/kg b.w./day, based on actual intake).

Chronic dietary administration of the test material to dogs at levels of 0, 250, 3000 and 15,000 ppm for one year indicated a NOEL of 3000 ppm, equivalent to approximately 87 mg/kg b.w./day actual intake, based on compound-related effects expressed in the 15,000 ppm treated group as decreased body weight gain and food efficiency values in the males. Significantly decreased serum sodium levels in both sexes at the high dose treated level were not associated with any evidence of renal pathology. Non-significantly ($p<0.05$) decreased erythrocyte (RBC) parameters noted in both males and females treated at 15,000 ppm were judged to be of questionable toxicological significance. In the absence of any collaborative clinical or pathological findings differences in organ weights relative to body or brain weight were considered to be of doubtful biological significance.

iii) Long-Term Toxicity

Mouse: Administration of the test material to CD-1 mice at dietary levels of 0, 25, 500 and 5000 ppm for a period of up to 78 weeks failed to reveal any overt signs of treatment-related toxicity of dietary levels of up to 5000 ppm (equivalent to 818 mg/kg b.w./day, actual intake). Although a direct effect of treatment on body weights or weight gains could not be established, overall body weight gain in the 5000 ppm treated male mice was depressed (non-significant, $p>0.05$) by 10% when compared to the corresponding controls. Overall weight gain in the treated females was comparable to the controls. There was no evidence of any treatment-related oncogenic potential.

Rat: Administration of ethametsulfuron methyl to Sprague-Dawley rats for up to 24 months at dietary levels of 0, 50, 500 and 5000 ppm revealed a NOAEL for in-life parameters of 5000 ppm (equivalent to 238.5 mg/kg b.w./day, actual intake), based on the questionable toxicological significance of decreased ($p<0.05$) serum sodium levels in both the 5000 ppm treated males and females during the first 12 months of treatment. The effects on serum sodium levels in the high dose groups were described as mild (representing a decrease of 2-6% of the control values) and occurring in the absence of any associated pathological changes in the kidney. Treatment with the test material at dietary levels as high as 5000 ppm (equivalent to 0.5% of the diet) failed to elicit any evidence of treatment-related neoplastic potential.

iv) Teratogenicity

Rat: A teratogenicity study in CD rats when administered 0(vehicle, 0.5% methyl cellulose), 60, 250, 1000 or 4000 mg/kg b.w./day of ethametsulfuron methyl orally by gavage on days 7-16 of gestation indicated a NOEL of 1000 mg/kg b.w./day with respect to maternal toxicity based on slightly decreased weight gain and significantly depressed food intake in the 4000 mg/kg b.w./day dose group. There was no evidence of any embryotoxicity. With regard to fetal toxicity, a NOEL was indicated at the mid dose level of 1000 mg/kg b.w./day based upon an increased incidence of skeletal findings at the high dose level of 4000 mg/kg b.w./day, namely wavy and calloused ribs in association with partially ossified bones in the skull, unossified hyoid and partial/incomplete ossification of the sternebra and ribs were indicative of retarded or delayed skeletal development. There was no strong evidence to support the possibility of a trend for delayed skeletal development at the lower levels of 250 and 1000 mg/kg b.w./day.

Rabbit: Artificially inseminated NZW rabbits treated orally by gavage with the test material at 0 (vehicle, 0.5% methyl cellulose), 250, 1000 or 4000 mg/kg b.w./day on gestation days 7 to 16 indicated a NOEL of 250 mg/kg b.w./day with regard to maternal toxicity. Treatment-related toxicity as manifest in the high dose dams resulted in an inadequate number of dams with viable fetuses (6/22) surviving to term. Toxicity at this level was expressed as increased mortality (36%), increased number of females aborting (7/19), decreased and discolored amounts of excreted fecal material in association with bloody discharges, decreased body weight gain, depressed food intake, increased liver weights and post mortem findings of compacted "test material hair mixtures" filling the stomachs of 11/22 females (strongly suggestive of problems with digestion or absorption of test material resulting in obstructed passage through the intestines). Maternal effects noted at the mid dose level of 1000 mg/kg b.w./day were related to a slightly higher percentage of females aborting (3/20 as opposed to 1/17 in controls), to significantly increased relative liver to body weights and to the presence of trichobezoar (hair balls) in 2/22 females at necropsy. The study did not indicate any potential for teratogenicity. Embryotoxic effects, namely increased incidence of early resorptions and decreased number of live fetuses, were noted at 4000 mg/kg b.w./day and may have occurred at 1000 mg/kg b.w./day The significance of the effects at the mid dose could not be clearly ascertained in the present study since the findings noted may have been due to pre-implantation changes, which could have resulted during a period of non-exposure to the test compound. With regard to fetal toxicity, a slightly higher (non-significant, $p>0.05$) incidence in the total number of fetuses (4/106) and litters (3/16) affected with skeletal malformations was noted at 1000 mg/kg b.w./day when compared to the zero incidence in the corresponding controls. The individual and singular findings were fused sternebra, fused vertebra, hemi and misshapen vertebra which could not alone be interpreted as evidence of developmental toxicity.

Overall, in both rat and rabbit teratology studies there was no evidence of malformation induction.

v) Reproduction

A two generation, 4 litter reproduction study with CD rats treated at dietary levels of 0, 250, 5000, 20000 ppm of ethametsulfuron methyl failed to reveal any evidence suggestive of an adverse effect on reproductive potential. A NOEL was indicated at the mid dose level of 5000 ppm (equivalent to approx, 433 mg/kg b.w./day, actual intake based on significantly ($p<0.5$) decreased body weights in the high dose 20000 ppm treated F0 and F1 generation males. (Overall mean food consumed was decreased only in the high dose 20000 ppm treated F1 males when compared to the controls). In the absence of any associated clinical or pathological findings, differences in organ weights were considered to be of doubtful biological significance.

vi) <u>Mutagenicity</u>

A series of mutagenicity studies did not show any potential for microbial and mammalian point mutation, chromosomal aberration or any evidence of DNA damage.

vii) <u>Metabolism</u>

A metabolism study with CD(SD) rats treated orally by gavage with a single dose of 10 mg/kg/b.w. (with and without preconditioning) and 1000 mg/kg/b.w. indicated that generally over 90% of the administered radioactivity (labelled in the triazine and phenyl ring) was excreted in the urine (51%) and feces (49%) within 72 hours post dosing. (Although no sex-related differences were apparent at the low dose, females treated at the high dose excreted a slightly lower percentage of radioactivity particularly in the feces during the same time interval). Residual radioactivity in the tissues and organs was minimal, cumulatively representing 0.05-0.13% of the administered dose. The highest tissue concentrations after 5 days post-dosing were found in the kidney (0.03-0.07 ppm) and blood (0.02-0.04 µg/ml) in the low dose group, and in the kidney (1.4-8.8 ppm) and liver (0.8-7.1 ppm) in the high dose group.

Further examination of the excreta revealed that generally over 50% of the administered dose was excreted unchanged in the urine and feces. Urine and fecal extracts revealed the identity of two major metabolites (N-dimethyl and O-deethyl ethametsulfuron methyl) and a minor metabolite (free acid of ethametsulfuron methyl). (Two other very minor metabolites were not characterized but identified as P1 and T1). The predominant route of metabolism for rats administered the low dose of 10 mg/kg b.w. was N-dimethyl ethametsulfuron methyl and for the high dose of 1000 mg/kg b.w. was O-deethyl ethametsulfuron methyl (which was identified as a primary plant metabolite).

b) <u>Conclusions</u>

A comprehensive and complete battery of mammalian toxicity studies conducted with ethametsulfuron methyl has failed to illicit any deleterious effects on reproductive function in the rat, or reveal any potential for teratogenic activity as evaluated in both the rat and rabbit studies. Long-term feeding studies conducted in the rat and mouse at dietary levels as high as 5000 ppm (equivalent to 0.5% of the diet) did not reveal any evidence for treatment-related neoplastic potential. There was similarly no evidence of any mutagenic activity.

There were no definitive indications of any significant systemic toxicity following dietary administration of ethametsulfuron methyl to animals of several species at dietary levels of up to 20,000 ppm (equivalent to 2% of the diet). The toxicological significance of decreased serum sodium concentrations as noted in both rats and dogs treated with the test material for up to 12 months duration was difficult to interpret as evidenced by the mild nature of the change (from control norm) and the absence of any associated clinical or pathological changes of the kidney. (<u>N.B.</u> Possible effects on serum sodium levels in the mouse could not be ascertained, since routine blood chemistry analyses were not scheduled).

The most sensitive species, as judged on the basis of assigned no-observed-effect levels, would appear to be the dog under conditions of chronic (one-year) dietary test material administration. A NOEL of 3000 ppm (equivalent to 87 mg/kg b.w./day actual intake) was indicated based on significantly decreased serum sodium levels in both males and females treated at the high dose level of 15,000 ppm as well as decreased body weights and food efficiency values as noted in the high dose treated males. Based on the equivocal nature (absence of clear indication of an adverse or toxic response) of decreased serum sodium levels and the absence of any treatment-related potential for mutagenic, reproductive, teratogenic or carcinogenic potential; a 100-fold safety factor may be deemed to be adequate for proposal of an <u>Acceptable Daily Intake (ADI) of 0.87 mg/kg b.w./day</u>.

7.2 Food Exposure

a) Acceptable Daily Intake

An ADI of 0.87 mg/kg b.w./day has been estimated based on a NOEL of 87 mg/kg b.w./day in a 1-year dog study and use of a 100 fold safety factor.

b) Residue Levels

Metabolism studies available to us indicate that the principal route of degradation of ethametsulfuron methyl in plants involves mainly deethylation and/or demethylation of the triazine ring.

In rapeseed ethametsulfuron methyl was found to stay unchanged initially in young plants and eventually degraded to O-deethyl ethametsulfuron methyl, O-deethyl-N-demethyl ethametsulfuron methyl and other related minor metabolites in older plants and in mature seeds. In whole plant samples at harvest about 80% of the total radioactive residues were extractable and of this approximately 10% was identified as the parent compound.

In mature seeds, the detailed identification of metabolites was not successful due to low concentrations of radioactive residues. Results did indicate that approximately 66-77% of the total radioactivity found in seeds was recovered in fractions containing mainly the deethyl and/or demethyl metabolites. Assuming the proportion of the parent compound in rapeseed plant reflects that in seeds, the parent compound may account for approximately 10% of the total recovered radioactivity. The available metabolism studies indicate that total radioactive residues found in mature seeds, when rapeseed was treated at a rate equivalent to the proposed application rate, ranged from 0.008 to 0.012 ppm. These terminal residues may comprise the parent compound, O-deethyl ethametsulfuron methyl, O-deethyl-N-demethyl ethametsulfuron methyl and other minor metabolites.

Analytical methods are available to measure only the parent compound in oil seeds and oil seed processing products. Based on the available plant metabolism data it is estimated that analysis by these methods may quantitate approximately 10% of the terminal residues in treated oil seed samples.

Residue data generated using these methods have shown that residues in mature seeds and oil samples, from rapeseed plants treated at the proposed maximum (22.5 g/active ingredient/ha) or excessive (up to 60 g/active ingredient/ha) application rates, are lower than the detection limit (0.02 ppm) of the present methods.

Residues of ethametsulfuron methyl in treated tame mustard are not presently submitted but will be made available in the near future and are expected to be at similar levels to those in rapeseed.

c) Dietary Risk Assessment

The theoretical daily intake (TDI) calculated from a maximum residue level of 0.02 ppm in rapeseed oil would be 0.00001 mg/kg/b.w./day. However, as the analytical methods measure only estimated 10% of the terminal residues in oil seeds, the actual total residues may be up to 10 times greater. Considering this, if a correction factor of 10 is used, the TDI would be 0.0001 mg/kg b.w./day which is less than 0.02% of the estimated ADI. Even if a residue level of 0.1 ppm is allowed in rapeseed oil, the TDI calculated using the 10 fold factor would not exceed 0.0005 mg/kg b.w./day and is still less than 0.1% of the estimated ADI of 0.87 mg/kg b.wt/day.

7.3 Occupational Exposure

a) Worker Exposure

An exposure study on ethametsulfuron methyl (MUSTER®) was not submitted. Worker exposure estimates were based on an exposure study submitted by the registrant for a similar product, DPX-L5300 (EXPRESS). Both products are similar in product chemistry, both are formulated as 75% dry flowables, and both have similar use patterns employing similar application equipment. Also, the application rates employed in the EXPRESS study cover the maximum rate recommended on the MUSTER® label.

In the exposure study, 8 workers each mixed and applied DPX-L5300 using ground boom equipment to areas spanning 13-21 hectares. Seven of the workers were also monitored during cleanup of spray equipment. Each complete spray cycle (mix/load, apply, cleanup) took between 2-3 hours. Two workers employed open cab tractors; the other six utilized closed cabs. Dermal deposition and inhalation exposure were monitored. A description of the workers' clothing was not provided because the estimate of skin deposition was based on analyses of the different layers of the patches. Inhalation exposure was negligible with all samples less than the limit of detection. Little difference in exposure was noted for those workers using open or closed cab tractors. To estimate exposure to a 70 kg farmer wearing long pants, short sleeves, no gloves, and boots, and treating 48 hectares at the maximum application rate (0.05 lb active ingredient/ha) for MUSTER®, the exposure estimate from the EXPRESS study was used. This results in an estimate of exposure of 0.033 (0.008 - 0.069) mg/kg b.w./day for workers using MUSTER®. Dermal absorption was assumed to be 100% since a dermal penetration study with MUSTER® was not submitted. These figures should be viewed with caution since the total monitoring time/worker was only 2-3 hours and it is expected that the full range of exposure encountered during a work day would not be captured. Furthermore, determination of skin deposition was based on an analysis of the innermost layer of the multilayer patch as opposed to analysis of patches placed inside the workers' clothing. This may underestimate exposure occurring at seams, up cuffs, and through worn areas of clothing.

b) Risk Assessment

The range of toxicological studies on ethametsulfuron methyl failed to demonstrate any significant areas of concern. The most sensitive end-point identified was a reduction in body weight in the 1-year feeding study in dogs with a NOEL of 87 mg/kg/b.w./day. The estimated exposure for workers using MUSTER® is 0.033 (0.008-0.069) mg/kg/b.w./day based on dermal deposition and inhalation in the DPX-L5300 (EXPRESS) worker exposure study (assuming 100% dermal absorption). Based on the exposure value and the NOAEL of 87 mg/kg/b.w./day, there is a margin of safety (MOS) of approximately 2500 for workers exposed to MUSTER® which Health Protection Branch considers adequate for occupational exposure.

8. ENVIRONMENTAL ASPECTS: ENVIRONMENT CANADA

8.1 Summary

Field dissipation studies conducted under Canadian prairie field conditions indicated that ethametsulfuron methyl would be expected to persist into the next year following application at label recommended rates. Consequently, there may be a potential for residue buildups in soil following the label-recommended application every 22 months since substantial residues remained in the soil after 16 months (last sampling time). Triazine amine and triazine urea were major and persistent transformation products and accumulated over the 16 month study period. Laboratory studies indicated that ethametsulfuron methyl was mobile on the majority of the soils tested. Soil pH seemed to have an important influence on the mobility of ethametsulfuron methyl, i.e., it was less mobile at low soil pH's and more mobile at higher soil pH's. The mobility of ethametsulfuron methyl is expected to increase with increasing soil pH. Under the climatic and soil conditions (loam, silt loam and clay) at most of the Canadian prairie study sites, ethametsulfuron methyl residues were not observed to leach to soil depths below 15 cm with the exception of one site where ethametsulfuron methyl residues were found to depths of 23 cm. The mobility of ethametsulfuron methyl is expected to be higher in Eastern Canada than was observed in the field dissipation studies conducted in the Canadian prairie canola-growing regions because of the coarser-textured soils and higher rainfall of this region. Laboratory studies indicated that ethametsulfuron methyl has a low potential for bioaccumulation. The determinations for vapour pressure and dissociation constant should be repeated using accepted methodology.

Ethametsulfuron methyl is not expected to present a hazard to soil microbial processes, earthworms, honeybees, and aquatic invertebrates if applied according to label directions. The major and persistent transformation products triazine amine and triazine urea should not be hazardous to aquatic invertebrates at concentrations likely to occur in the environment.

Ethametsulfuron methyl is not expected to pose an acute and chronic hazard to birds and mammals. However ethametsulfuron methyl appears to be toxic to many terrestrial vascular plants and has, therefore, the potential to indirectly impair wildlife through destruction of habitat (food and cover) or reduction of invertebrates that live on plants. Toxicity to algae could not be assessed because of deficiencies in the study. Mitigation measures are proposed to alleviate effects on wildlife habitats: 1) more information will be provided by the company as to the effect of ethametsulfuron methyl on some aquatic vascular species, 2) a study is ongoing to assess the toxicity of the product on a battery of algae, 3) a 15 meter buffer zone is temporarily retained on the label which could become permanent pending research, 4) aerial application is contraindicated.

8.2 Environmental Chemistry and Fate

a) Physicochemical Properties

The vapour pressure of ethametsulfuron methyl was reported to be 7.7×10^{-13} Pa at 25°C. This compound would therefore be classified as relatively nonvolatile, however the appropriateness of the method used for the vapour pressure determination is questionable. The determination should be repeated using an approved method. The solubility of ethametsulfuron methyl in water ranged from low to very soluble depending on solution pH and was reported as 1.7 mg/L at pH 5, 50 mg/L at pH 7, and 410 mg/L at pH 9. Henry's Law constants calculated for ethametsulfuron methyl using the vapour pressure value, molecular weight and water solubilities provided by the proponent indicated that ethametsulfuron methyl would be classified as non-volatile from moist soil and water. The dissociation constant (pKa) of ethametsulfuron methyl, a weak acid, was reported to be 4.64. The method used to generate the dissociation constant, however, has not been adequately validated, and should be repeated using generally accepted methodology. The octanol/water partition coefficients (K_{ow}) for ethametsulfuron methyl were reported as 38.7 and 0.89 at pH 5 and 7 respectively and indicate that the compound has a low potential for bioaccumulation.

b) Transformation

Chemical hydrolysis is not expected to be an important route of ethametsulfuron methyl transformation at environmentally relevant temperatures unless the acidity of the environmental medium is fairly low (i.e., less than pH 5). Laboratory results indicated that in sterile water, ethametsulfuron methyl was hydrolyzed at pH 5 with a first order half-life of approximately 41 days. At pH 7 and pH 9, ethametsulfuron methyl was stable to hydrolysis. Phototransformation is not expected to be a significant means of transformation of ethametsulfuron methyl on soil surfaces or in water.

Laboratory studies conducted under aerobic conditions using an Alberta black loam soil (pH 5.6) demonstrated that the average half-life of ethametsulfuron methyl under nonsterile conditions at 70% field capacity and 25°C was 2.3 months which would categorize the compound as moderately persistent according to Goring et al. (1975) and Rao and Davidson (1980). However, approximately 10% of the applied radioactivity persisted after 12 months. The reported half-life was calculated by the proponent assuming first-order kinetics, but the transformation of ethametsulfuron methyl under the various conditions in the experiment did not follow first-order kinetics for the 12 month period of the study. Consequently, the reported half-lives may not be representative because actual concentrations of ethametsulfuron methyl would be expected to be greater than those predicted by the calculation. Transformation was attributed to chemical hydrolysis and to microbial activity. In soils of pH higher than 5.6, ethametsulfuron methyl could be more persistent because it would be stable to hydrolysis. Triazine amine {6-ethoxy-N-methy1-1,3,5-triazine2,4-diamine} was the major transformation product in nonsterile soil arising from the triazine ring portion of the molecule and it accumulated over the 12 month period of the experiment. The phenyl ring portion of the molecule as not labeled for study, but, studies with other compounds having the same phenyl ring structure as ethametsulfuron methyl have indicated that this portion of the molecule is transformed to ester sulfonamide {methyl 2-(aminosulfonyl)-benzoate} which undergoes hydrolysis to acid sulfonamide {2-(aminosulfonyl) benzoic acid} and then is transformed further to saccharin {1,2-benzisothiazo1-3(2H)-one, l,l-dioxide} and CO_2.

Laboratory studies examining the aerobic aquatic biotransformation of ethametsulfuron methyl using Canadian prairie slough water (pH 8.0) demonstrated that the average first-order half-life of ethametsulfuron methyl under nonsterile conditions at 29°C and 5°C was 6.1 and 86.5 months, respectively. From these reported half-lives ethametsulfuron methyl would be categorized as persistent under these conditions. Triazine amine, saccharin and D-demethyl triazine amine were the major transformation products observed in nonsterile Saskatchewan slough water at 29°C and they accumulated over the 12 month period of the study.

Laboratory studies examining the transformation of ethametsulfuron methyl under anaerobic aquatic conditions indicated that the first order half-life of ethametsulfuron methyl in sediments of pH 5.6 and pH 9.3 averaged 2 and 9 months, respectively. From these results ethametsulfuron methyl would be categorized as being moderately persistent in sediments of acidic pH and persistent in sediments of neutral to alkaline pH. A significant amount of ethametsulfuron methyl residue (32-38% of applied radioactivity) was observed to persist after a period of 12 months in the sediment of pH 9.3. Both chemical hydrolysis and microbial transformation are believed to contribute to the transformation of ethametsulfuron methyl under anaerobic water/sediment conditions. Major transformation products under these conditions included triazine amine, saccharin, and ethametsulfuron methyl acid {2-[[[[(4-ethoxy-6-methylamino-1,3,5-triazin-2-yl) amino] carbonyl] amino] sulfonyl]benzoic acid}. All of these products accumulated over the 12 month study period. The minor amounts of CO_2 detected after 12 months in the non-sterile treated pond water/sediment systems indicated that mineralization of ethametsulfuron methyl is minimal under anaerobic aquatic conditions.

In field studies conducted on four soils of pH's ranging from 6.1-7.9 at sites in the Canadian prairies, the reported half-lives of ethametsulfuron methyl ranged between 1.9-3.0 months after application at the maximum label-recommended rate. From these results, ethametsulfuron methyl would be classified as moderately persistent under these conditions, according to Goring et al. (1975). The proponent used first-order kinetics to describe the dissipation of ethametsulfuron methyl over the first 2 to 4 months of the studies. However, it was evident that the first-order half-lives reported by the applicant could not be used to describe ethametsulfuron methyl dissipation over the entire study period because the rate of dissipation decreased after the first 2 to 4 month period and it persisted at all the sites with 5.3-34.6% of the applied radioactivity remaining after 16 months. Collectively, these results indicate that under Canadian prairie field conditions, ethametsulfuron methyl will persist into the next year following one application at label-recommended rates. Consequently, there is a potential for residue buildup following application every 22 months as a substantial amount of ethametsulfuron methyl would remain in the soil after a period of 16 months (last sampling time), and the period between 16 and 22 months following a spring application of ethametsulfuron methyl would be in the fall and winter months when the colder temperatures would reduce the rate of biotransformation. Major transformation products in these studies included triazine amine, triazine urea {[4-ethoxy-6-(methyl-amine)-1,3,5-triazin-2-yl] urea}, ester sulfonamide, and saccharin. Triazine amine and triazine urea were major and persistent transformation products, and accumulated at all of the sites during the studies.

c) Mobility

Laboratory soil adsorption/desorption, soil TLC, and soil column leaching studies indicated that ethametsulfuron methyl was mobile in the majority of the soils tested. Generally, mobility was highest on the sandy loam soils. These studies indicated a negative correlation between organic matter content and mobility, i.e., reduced mobility with increasing organic matter content. Soil pH seemed to have an important influence on the mobility of ethametsulfuron methyl, i.e., less mobile at low soil pH's and more mobile at higher soil pH's, probably because it is a weak acid and the dissociated form of the molecule (neg actively charged) is predominant at soil pH's above the reported pKa of ethametsulfuron methyl (4.64). Mobility of ethametsulfuron methyl is expected to increase with increasing pH. This expectation is supported by the fact that the solubility of ethametsulfuron methyl in water also increases dramatically with an increase in pH. Under the climatic and soil conditions (loam, silt loam and clay) at most of the Canadian prairie and American study sites, ethametsulfuron methyl residues were not observed to leach to soil depths below 15 cm to a notable extent. The exception was at the Indian Head Saskatchewan site, where ethametsulfuron methyl residues were found to depths of 23 cm. A combination of low % soil organic matter and a high soil pH at this site may be a possible explanation for the observed behaviour of ethametsulfuron methyl residues.

The mobility of ethametsulfuron methyl is expected to be higher in Eastern Canada than was observed in the field dissipation studies conducted in the Canadian prairie canola-growing regions because of the coarser-textured soils and higher rainfall of this region.

Cohen et al. (1984) identified several pesticide characteristics which provide an indication of a chemical's potential for leaching and contamination of ground water. A comparison of these characteristics with those shown by ethametsulfuron methyl indicate that this chemical has all of the characteristics of a chemical with a high leaching potential.

8.3 Environmental Toxicology

a) Wild Birds

Birds (Horned Lark, Savannah Sparrow, Clay-coloured Sparrow, Wren species, etc.) foraging in canola fields or adjacent fencerows, could potentially be exposed to ethametsulfuron methyl residues by the ingestion of seeds, fruits, or insects contaminated with residues from direct spray or spray drift. In canola fields associated with Aspen stand and wetland, the species diversity is high with, among others, the Lesser Yellowlegs, American Coot, Clay-coloured Sparrow, Red-winged Blackbird, Yellow-headed Blackbird, Wrens, Mallard, Pintail, Lesser scaup, etc. Exposure could also occur by ingesting residues absorbed from the soil by plants or soil invertebrates. Aquatic birds could be exposed by ingesting aquatic plants or invertebrates contaminated by spray drift or by the leaching of ethametsulfuron methyl into the water.

The application of MUSTER® at the recommended application rates is not expected to pose an acute risk to birds ingesting ethametsulfuron methyl residues. Ethametsulfuron methyl was practically non-toxic to the Mallard Duck and Bobwhite Quail when administered orally or in the diet on a short-term basis. No dose-related mortalities occurred in the studies submitted. A sublethal no observable effect level (NOEL) of 810 mg active ingredient (a.i.)/kg body weight (b.wt.) established in the duck LD_{50} study was based on a decrease in weight gain in the high-dosed birds. In the risk assessment, a conservative NOEL of 173 mg a.i./kg b.wt. was used based on the possibility of a decrease in weight gain and food consumption evident in the low dose group in the dietary quail study. This effect was not evident in the higher dose groups. Since behaviourial abnormalities were not associated with the weight loss, this effect would not likely be critical to the survival of bird species, providing recovery occurred. The worst-case risk factors (ratio of expected exposure over the level causing toxicity) estimated for five bird species range from 0.6×10^{-4} to 0.02.

The risk to birds from the long-term exposure to ethametsulfuron methyl and the risk to avian reproduction could not be estimated. Based on the mammalian data, ethametsulfuron methyl is not expected to pose a risk when ingested on a long-term basis or to avian reproduction; however, information on the metabolism of ethametsulfuron methyl in birds is not available to confirm this assumption.

b) Wild Mammals

Wild mammals could be exposed to ethametsulfuron methyl residues by ingesting plants in the canola fields, adjacent fencerows, and woodlots that have been contaminated by spray drift. Mammals could also be exposed by ingesting plants that have absorbed residues from the soil. Carnivores could be exposed to ethametsulfuron methyl residues by ingesting several smaller herbivores that have been feeding on contaminated vegetation, or, in the case of insectivores, by ingesting residues on the surface of their prey.

Twenty-two mammals have been inventoried either living or foraging in grainfields within the Prairie ecozone, plus an additional eleven species that could be found in adjacent fencerows. These include game species, carnivores, and the vulnerable Plains Pocket Gopher. Additional species, such as the vulnerable Grey Fox and the rare Red-tailed Chipmunk, are found in woods adjacent to the fields.

Both ethametsulfuron methyl and the 75 DF formulation are practically nontoxic to rats and rabbits when administered as a single oral dose. No mortalities occurred in the studies submitted. A sublethal NOEL could not be established in the acute oral toxicity studies because decreases in weight gain or stained perineum occurred at the lowest dose levels. In two of the four acute mammalian studies, there appeared to be a sexual difference in response to ethametsulfuron methyl: the females being more sensitive than the males.

The toxicity of ethametsulfuron methyl to mammals did not increase significantly when administered in the diet on a long-term basis. The NOEL used in the risk assessments was taken from the one-year dietary study using the dog and was 3000 mg a.i./kg diet, which was equivalent to approximately 87 mg a.i./kg body weight.

Based on the available mammalian toxicity data and the estimated environmental concentrations of ethametsulfuron methyl, the application of ethametsulfuron methyl at the recommended application rates is not expected to pose an acute or chronic risk to mammals or mammalian reproduction from the ingestion of contaminated material. The worst-case estimated risk factors for eight representative mammalian species ranged from 0.0006 to 0.048.

c) Amphibians and Reptiles

Information was not available on the impact of ethametsulfuron methyl on reptiles and amphibians. These organisms could be exposed by direct dermal exposure from spray drift or by the ingestion of contaminated invertebrates.

d) Fish

Laboratory data indicated that ethametsulfuron methyl was of low acute toxicity to bluegill sunfish (*Lepomis macrochirus*) and rainbow trout (*Oncorhynchus mykiss*). Our colleagues at the Department of Fisheries and Oceans will comment further on the toxicity to and effects of ethametsulfuron methyl on fish.

e) Aquatic Invertebrates

The 48-h EC_{50}s for ethametsulfuron methyl to unfed and fed *Daphnia magna* in static laboratory tests were reported to be 34 and >200 mg/L, respectively. The (NOEL) for *Daphnia magna* exposed to ethametsulfuron methyl for 21 days was reported to be 30 mg/L. The theoretical water concentration in a shallow water body 0.1-0.5 meters in depth resulting from a direct overspray of ethametsulfuron methyl at the maximum label-recommended rate of 30 g a.i./ha would be 6-30 µg/L. ethametsulfuron methyl is, therefore, not expected to be acutely or chronically toxic to aquatic invertebrates at label-recommended rates, even in a direct-overspray, worst-case scenario.

The 48-h EC_{50}s for the major and persistent transformation products, triazine amine and triazine urea, to *Daphnia magna* were reported to be greater than 3.0 mg/L. These results indicate that these major transformation products are not expected to be acutely toxic to *Daphnia magna* at concentrations likely to occur in the environment following an application of ethametsulfuron methyl at the maximum label rate.

f) Terrestrial Invertebrates

The acute LD_{50} for ethametsulfuron methyl to honeybees (Apis mellifera) was estimated to be greater than 12.5 µg/bee in laboratory topical application tests. From this result, ethametsulfuron methyl would be considered to be relatively nontoxic to the honey bee.

The LC_{50} for ethametsulfuron methyl to earthworms (Eisenia foetida) was estimated to be greater than 1000 mg/kg, the highest rate used in laboratory studies. From this result, ethametsulfuron methyl residues are expected to be non-toxic to earthworms under conditions of operational use.

g) Soil Microorganisms and Microbial Processes

There was no indication from the data that an application of ethametsulfuron methyl in accordance with label directions would result in any lasting detrimental effects on CO_2-evolution (respiration), N_2-fixation, ammonification, and nitrification in soil.

h) Wildlife Habitat Considerations

Wildlife living in the vicinity of cultivated fields, particularly breeding waterfowl, could be affected by a shortage of food invertebrates or reduction of cover through damage and destruction of plants. Furthermore, herbicides may affect wildlife via a destruction of macrophytes on which invertebrates subsist. However when used at the recommended application rate, ethametsulfuron methyl is not expected to pose an acute risk to aquatic or terrestrial invertebrates.

Direct effects of ethametsulfuron methyl and MUSTER® on plants were evaluated, using the plant screening data routinely generated by the company during product development. According to the label, MUSTER® provides control or suppression of Wild Mustard (Sinapis arvensis), Green Smartweed (Polygonum lapatifolium), Hempnettle (Galeopsis tetrahit), Redroot Pigweed (Amaranthus retroflexus), Flixweed (Descurainia Sophia) and Stinkweed (Thlaspi arvense). The mode of toxic action of sulfonyl ureas in general is by inhibiting acetolactate synthase, an enzyme found only in plants. One to three weeks are needed after application before symptoms of phytotoxicity (discoloration) are evident.

A very conservative scenario is adopted that 10% of the amount of pesticide applied will reach non-target environments via spray drift (=2.25 g a.i./ha); a level of 25% detrimental effect (EC25) for terrestrial plants is considered permanent damage by EPA. The plant screening data submitted for terrestrial vascular species indicated that, at 10% maximum label rate, ethametsulfuron methyl will cause a 25% detrimental effect to 42% of the species tested in the greenhouse, from 10 out of 14 families tested. In field trials with the formulated product, 28% of the species from 9 families, out of 18 tested, had an EC_{25} <10% maximum label rate. However in this latter efficacy test, data were very variable. If overspray occurred at 100% maximum label rate, 70% to 95% of the plants tested would be damaged at the 25% detrimental effect. In addition, results show that toxicity could not generally be predicted for a whole family.

This is of course anticipated since MUSTER® is expected to control wild mustard in canola fields, both species from the Brassicae family. However this also occurs in the grass family as well as in the Compositae and Leguminosae families.

From these results it appears that this herbicide could potentially indirectly impair wildlife through destruction or modification of many plant species in their habitats. MUSTER® is expected to be persistent in soils and in anaerobic aquatic sediments and is predicted to be mobile; MUSTER® has therefore the potential to contaminate non-target areas via run-off, wash-off and leaching, especially in the prairies where the product will mainly be used. Overspray of field margins and sloughs would definitely cause important damage to wildlife habitats.

The toxicity of ethametsulfuron methyl to the green algal species Selenastrum capricornutum could not be assessed because of deficiencies in the study. This information is essential to evaluate the toxicity of ethametsulfuron methyl to algae which are basic components of aquatic ecosystems.

As for animals, known species are used as indicator species from which an extrapolation to non-target organisms can be made. Data submitted on crop and weed terrestrial plants indicated a high toxicity of ethametsulfuron methyl and MUSTER® to many species, unpredictably from several families. These results suggest that ecologically important plants are likely to be sensitive to MUSTER®, and that wildlife habitats in the prairies could be seriously threatened by frequent use of the compound. Herbicides have been shown to cause changes in vegetation of slough margins and hedgerows, which affect the nesting success, predator avoidance and foraging of avian species. Canola is mainly grown in the Northern prairies with a high pothole density which accommodates a large diversity of waterfowl and wildlife in general. Two studies are ongoing that will provide more information concerning the impact of MUSTER® on important aquatic species (algae and vascular plants) that may be affected off-sites of canola fields.

A 15 meter buffer zone retained as a permanent requirement on the label as well as strict contraindication of aerial delivery are possible compromise to the Canadian Wildlife Service concerns with MUSTER®. The Canadian Wildlife Service also sees a need to sensitize growers in Prairie Canada about the potential impacts of herbicides on wildlife habitats. These mitigation measures would reduce damage to wildlife habitats around canola fields and help preserve wildlife in agricultural lands in general.

9. EFFECTS ON FISH, FISH HABITAT AND FISHERIES RESOURCES: DEPARTMENT OF FISHERIES AND OCEANS

9.1 Fish

No significant adverse effects, attributable to ethametsulfuron methyl, were observed in rainbow trout (Oncorhynchus mykiss) and bluegill sunfish (Lepomis macrochirus) exposed for 96 h to ethametsulfuron methyl at concentrations up to 600 mg/L.

Chronic studies of effects on fish were not requested because environmental concentrations are expected to be several orders of magnitude less than the no effect concentrations for acute toxic effect.

The reported low K_{ow} for ethametsulfuron methyl (0.89 & .39 at pH7 & pH5 respectively) and the reported lack of significant bioconcentration of other similar compounds (sulfonylureas) in fish indicated that ethametsulfuron methyl does not have a significant potential to bioconcentrate in fish.

9.2 Fish Food and Habitat

In a 48 h test, ethametsulfuron methyl was toxic (80-100% mortality) to daphnids (Daphnia magna) at nominal concentrations of 40 mg/L or greater, but was not toxic at 20 mg/L. In another 48 h test, no significant toxic effects were observed in daphnids when they were exposed to ethametsulfuron methyl at nominal concentrations ranging up to 200 mg/L.

Daphnid reproduction and growth were reduced when they were exposed for 21 days to measured concentrations of ethametsulfuron methyl greater than 30 mg/L.

The only direct indication of the phytotoxicity of ethametsulfuron methyl was a non-definitive algal growth inhibition study which indicated a 120 h EC_{50} of 2.5 to 2.7 mg/L.

9.3 Movement Onto and Transformation in Aquatic Environments

Since ethametsulfuron methyl formulated as MUSTER® will be applied to agricultural fields by ground operated equipment only, substantial oversprays of aquatic areas should not occur. The possibility of input to aquatic habitats is further limited by the use precautions listed on the label which prohibit the use of MUSTER® on fields draining into irrigation water and in irrigation systems. Although the precautions also include a 15 m buffer zone to be maintained between application sites and some types of wildlife habitat, they do not mention specifically the types of water bodies used by fish. To avoid confusion, reference to habitats in the precautions should include all water bodies supporting fish or draining into aquatic systems inhabited by fish.

Ethametsulfuron methyl will not readily dissipate in aquatic environments. It does not readily hydrolyse, particularly at neutral or alkaline pH, and it does not readily transform when exposed to sunlight. It transformed very slowly (DT_{50} typically 1.9 to 9.9 months at 25°C) in aerobic and anaerobic water/sediment studies. At cold temperatures (5°C) its estimated half-life was 86 months in natural slough water.

Since ethametsulfuron methyl is likely to persist in aquatic environments and since it is moderately soluble at the pH of many prairie waters, it is likely to remain available in the water column once it enters aquatic systems.

Because of its persistence and availability in aquatic environments and because similar compounds are extremely toxic to some common aquatic plants, accurate information on spray drift is needed to estimate the potential exposure of fish habitat to ethametsulfuron methyl. Therefore, information to support the adequacy of a 15 m buffer zone to protect riparian and aquatic vegetation is required.

Runoff of ethametsulfuron methyl into aquatic systems is likely to occur since ethametsulfuron methyl will persist on soil for many months and it is relatively mobile on soils of the pH and texture found in many areas of the regions in which MUSTER® may be used. Empirical runoff data specific to ethametsulfuron methyl may be required when the phytotoxicity of this compound to aquatic vegetation is established.

9.4 Impact Assessment

Ethametsulfuron methyl is unlikely to have a direct adverse effect on fish and aquatic invertebrates when used according to the MUSTER® label directions and precautions. This conclusion is based on the limited application rate, the assumption that the labelled use precautions will be heeded and the demonstrated lack of toxicity of ethametsulfuron methyl to aquatic fauna at expected environmental concentrations.

However, the potential for adverse effects on riparian and aquatic vegetation which are essential for the maintenance of fish habitat could not be assessed due to lack of information. The results of the algal study, or any other phytotoxicity study using a single species, is inadequate to assess the phytotoxicity of sulfonylurea compounds because there is a wide range in species sensitivity to these compounds (Beyer et al., 1988). This range can be as much as 20,000 fold (Hageman and Behrens, 1984). This is illustrated for ethametsulfuron methyl by its intended use to control wild mustard (Brassica kaber) in crops of closely related canola species (Brassica napa or Brassica campestris). Since it is not known where Selenastrum capricornutum fits in this wide range of sensitivity, conclusions concerning the phytotoxic potential of ethametsulfuron methyl may be in error by several orders of magnitude if based on this test with a single species. Therefore a study using a variety of common aquatic plant species is required to indicate the potential toxicity of ethametsulfuron methyl to aquatic vegetation and algae.

The need for definitive information on the potential of ethametsulfuron methyl to adversely affect riparian and aquatic vegetation is enhanced by its apparently slow dissipation at application sites, its persistence under aquatic conditions and its bioavailability. Therefore, in order for DFO to complete an assessment of ethametsulfuron methyl's effects on fish habitat, definitive information is required on:

1. the toxicity of ethametsulfuron methyl to common riparian and aquatic macrophyte and algal species, and

2. the potential exposure of vegetation and water bodies to spray drift beyond the buffer zone.

9.5 References

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