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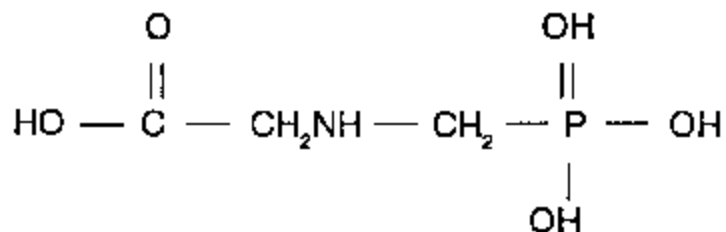
Direction des pesticides

Canada

Decision Document

E92-02

PRE-HARVEST USE OF GLYPHOSATE



HERBICIDE

PRODUCT MANAGEMENT DIVISION

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GLYPHOSATE, PREHARVEST USE

FOREWORD

As part of the ongoing effort to make regulatory information more widely available, this Decision Document has been prepared on the preharvest use of glyphosate (Roundup®) herbicide. This document reflects input from a wide variety of specialists and other interested parties. Based on the review of all available information and in consideration of the input received, a regulatory decision has been made to grant temporary registration for preharvest use of glyphosate on wheat, barley, soybeans, peas, lentils, canola and flax.

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1. INTRODUCTION

This Decision Document is the final stage in Agriculture Canada's regulatory decision-making process concerning the registration of preharvest use of glyphosate (Roundup®) herbicide on wheat, barley, soybeans, peas, lentils, canola and flax.

2. REGULATORY DECISION

Based on the considerations outlined below, Agriculture Canada has granted temporary registration for the preharvest application, by ground equipment, of glyphosate in wheat, barley, soybeans, peas, lentils, canola and flax.

The uses on malting barley and crops used for seed purposes require further assessment. The registrant, Monsanto Canada Inc., has requested a delay in a decision on these crops until this assessment is completed.

3. BACKGROUND

Agriculture Canada has been reviewing a registration submission for preharvest application of glyphosate herbicide in wheat, barley, soybeans, peas, lentils, canola, and flax. An extensive summary (Agriculture Canada Discussion Document 91-01) was distributed to a wide range of interested parties in November 1991. Agriculture Canada received forty-five responses to that Discussion Document. In addition, Health and Welfare Canada received seven comments in response to their proposed Maximum Residue Limits (MRLs) published in the Canada Gazette Part I in December 1991. These respondents also provided copies of their comments to Agriculture Canada.

4. RECENT DEVELOPMENTS

4.1 Maximum Residue Limits

Health and Welfare Canada has recently established MRLs in the Food and Drug Regulations to accommodate any glyphosate residues remaining in/on harvested crops and other agricultural commodities. Residues falling within these MRLs are not considered to pose a health hazard to consumers.

4.2 Aerial Application

Although aerial application is not being considered for registration, the subject was addressed in the Discussion Document. Canadian and provincial Aerial Applicators' Associations felt that the consideration of aerial application in the Discussion Document was superficial and revealed a bias against this method of application. However, the consensus of provincial government personnel was that the risk of damage to non-target vegetation caused by drift from aerial application was too great to allow registration of this use.

Several grower organizations also expressed this view. The label instructions for preharvest use will state "Do not apply by aircraft".

4.3 Seed Germination and Seedling Vigor

The effect of glyphosate on seed germination and seedling vigor has been reviewed. While most of the studies showed no observed effects, some studies were inconclusive. As this is an important consideration for both the seed and malting/brewing industries, both the registrant, Monsanto Canada Inc., and Agriculture Canada will be reviewing this aspect in more detail prior to making a decision with respect to registration for use on seed crops and malting barley.

5. CUSTOMER ACCEPTANCE AND TRADE CONSIDERATIONS

5.1 Milling/Baking Industry

The milling and baking industries have expressed the view that the possibility of residues of glyphosate in cereal and grain products (especially whole grain products) could result in lack of consumer confidence. The milling/baking industry commented that they could receive individual carlots from both farmers and the primary elevator system which could have been treated with glyphosate on the farm and not have been diluted through the Canadian grain handling system. MRLs in the U.S., which are currently significantly lower than those recently established in Canada, were cited as a new reason for the U.S. to reject Canadian shipments. This factor could also lead bakers to purchase U.S. rather than Canadian flour. For these reasons, this sector has strongly urged that glyphosate maximum residue limits (for wheat) should not exceed the former maximum limit of 0.1 part per million as previously stipulated in the Food and Drug Regulations.

While this represents a minority position, the views of millers/bakers are recognized, particularly in light of the importance of the grain and food sector and the complexity of the questions to be addressed in the regulatory decision-making process.

Having considered the foregoing concerns, Health and Welfare Canada has now proceeded to establish MRLs to accommodate the possibility of residues, resulting from preharvest use of glyphosate, in/on harvested crops and other agricultural commodities in Canada or other countries.

Glyphosate is already used preharvest in Europe and Australia. Registration of this use will probably be granted soon in the U.S. A decision not to register this use in Canada would deny Canadian growers the opportunity to use production technology already available to their competitors in other countries, while permitting entry into Canada of produce grown elsewhere with the benefit of this technology and containing residues up to the MRLs established by Health and Welfare Canada.

While the possibility exists of glyphosate residues appearing in Canadian cereal and grain products, there is only a remote possibility of residues occurring even in a raw agricultural commodity such as wheat, at levels approaching the tolerance (see Discussion Document p.38,39).

Consumer concern represents an intangible element that is virtually impossible to address directly. The regulatory management process followed in this particular case, i.e., presentation of science reviews followed by consultation and communication, has proven to be the most effective procedure to establish the facts and improve the level of consumer understanding and acceptance.

The possibility that individual lots of grain, which were treated preharvest with glyphosate, might enter the marketplace undiluted with grain produced by traditional agronomic practices, is highly unlikely. Even if this happened, the maximum residues that might be expected in wheat are about one half of the recently established MRL.

As indicated in the response from the milling/baking sector, differences in MRLs from country to country could result in purchasers buying raw wheat or flour from countries where this treatment is not used. However, the MRLs recently established in Canada are consistent with those established by CODEX, the internationally recognized authority in these matters. Similar tolerances are being considered in the U.S. and Japan to accommodate uses proposed in those countries as well as importation of produce grown in Europe, where this technology is already in use. Ultimately, however, these matters can only be unequivocally resolved through contractual arrangements between buyers and sellers.

5.2 Grain Handling and Trade Sector

The Canadian Grain Commission conducted an analysis of the marketing considerations associated with preharvest glyphosate use on wheat, barley, canola, lentils, soybeans and peas. This analysis was presented at length in the Discussion Document and is the basis for the Grain Commission's support of temporary registration of ground-only application.

A similar position has been taken by the Grains and Oilseeds Branch of Agriculture Canada, which represents the Canadian Wheat Board.

5.3 Growers and Grower Organizations

The Canadian Federation of Agriculture has passed a resolution in support of the registration of preharvest use of glyphosate. The Canola Council of Canada (representing producers, processors, marketers and users) responded to the Discussion Document in support of registration of ground application.

Several other grower organizations such as the Western Canadian Wheat Growers, Alberta Pulse Growers Commission, and Western Barley Growers Association, supported the temporary registration of preharvest glyphosate use, ground application. The importance of customer acceptance and trade considerations was often cited.

The validity of these views is acknowledged and every effort has been made to appropriately balance the two diametrically opposed considerations, i.e., the interest in using the technology versus any possibility of customer or trade reaction. These potential situations are virtually impossible to fully address by means of a regulatory process. The registrant has applied in the U.S. for residue tolerances to accommodate preharvest uses in that country. The registrant has also applied for import tolerances to cover cases where there may be a discrepancy between the U.S. tolerance and the Canadian or CODEX MRL.

The regulatory management process followed in this particular case, i.e., presentation of science reviews followed by consultation and communication, has proven to be the most effective procedure to establish the facts and improve the level of consumer understanding and acceptance. As stated earlier, these matters can only be unequivocally resolved through contractual arrangements between buyers and sellers.

5.4 Provincial Governments

The government of Alberta, the Prince Edward Island Pesticides Advisory Committee, and the Departments of Agriculture in Saskatchewan, Manitoba, New Brunswick, Nova Scotia and Québec supported preharvest use of glyphosate by ground application while also emphasizing the importance of customer acceptance and trade considerations. The British Columbia Pesticide Management Branch recommended that registration be granted. The P.E.I. Department of Energy and Forestry, on the other hand, was not supportive of the preharvest use of glyphosate.

These views represent an important component of the background information against which the regulatory decision on the glyphosate/preharvest registration must be made.

5.5 Environmental Considerations

Farmer and public concern about wildlife, wetlands and other natural areas associated with cropland was expressed in responses to the Discussion Document. It has been demonstrated that glyphosate will affect several plant species should drift occur on non-target areas. The preharvest use of glyphosate by ground application should not result in significant effects on fish or fish habitat provided a 15-m buffer zone is observed.

The label text for preharvest treatment which will appear on the ROUNDUP® label includes statements on: (1) avoiding contamination of water bodies; (2) keeping a 15-m

buffer zone around non-target areas; and (3) avoiding drift or overspray to non-target vegetation and wildlife habitats. The label also contains a statement prohibiting application by aircraft. The registrant, Monsanto Canada Inc., has agreed to develop farmer educational material to highlight these label restrictions.

6. PERFORMANCE

The performance aspects of the proposed use pattern include both weed control and harvest management considerations.

6.1 Weed Control

The effectiveness of preharvest glyphosate for weed control has been adequately demonstrated by traditional trials, practices and techniques. Responses to the Discussion Document from grower organizations and government agricultural experts indicated that preharvest glyphosate would be beneficial for perennial weed control. These respondents pointed out that this approach to weed control would reduce tillage and also contribute to soil and moisture conservation and reduced input costs. Some respondents also mentioned control of late germinating annual weeds.

6.2 Harvest Management

As pointed out in the Discussion Document, harvest management claims are difficult to demonstrate by means of traditional small plot trials. The merits of this management technique are:

- 1) particularly difficult to demonstrate with cereal crops that naturally cease growth and undergo senescence subsequent to seed set; and
- 2) influenced by:
 - a) the indirect effect of weed growth on crop maturity, due to competition for light, moisture and nutrients; and the direct mechanical effect of weeds on the harvesting operation, e.g., clogging or winding of green plant material/foilage on harvesting machinery; and
 - b) crop maturity (seed and foliage moisture content) at the time of application.

These aspects of harvest management were reflected in the responses to the Discussion Document and were considered in the regulatory decision-making process.

a) Indeterminant Crops (e.g., Canola)

The science base indicates that preharvest treatment is more consistently useful with indeterminant crops than with determinant crops such as cereals.

In canola, for example, nine out of 12 trials in which seed moisture content was measured and four out of eight trials in which foliage drydown was measured, indicated a positive effect of the treatment. However, in three out of eight trials in which foliage drydown was measured, swathing gave better results than did the glyphosate application.

In lentils, five out of six trials in which seed moisture content was measured, and four out of four trials in which foliage drydown was measured, demonstrated a positive effect of the treatment.

In peas, two out of three trials in which seed moisture content was measured, and five out of six trials in which foliage drydown was measured, demonstrated a positive effect of the treatment.

Results were less clear on flax, where treated plots were not as good as swathed plots in four out of eight trials in which seed moisture content at harvest was measured. In the six trials where foliage drydown was reported, treated plots were better than straight-cut checks in two trials, the same in one, and worse in three.

Responses to the Discussion Document from grower organizations and government agricultural experts were consistent with the science base and emphasized the merit of harvest management with indeterminant crops such as lentils and canola.

b) Determinant Crops (Cereals)

The science base for cereals is not as conclusive. As in the case of indeterminant crops, moisture reduction (seed and foliage) was the endpoint used to measure effectiveness.

In wheat and barley, only nine out of 21 trials clearly support the effectiveness of the treatment with respect to the seed moisture content at harvest. In the other cereal trials, the treatment was only as good as the straight-cut checks, thus showing no particular effect from glyphosate. Results were similar in the smaller number of trials where foliage drydown was measured.

Overall, the glyphosate treatment often performed as well as swathing, but no better than standing checks. There were only two trials in which both types of checks were present; in one of these the glyphosate treated plot was best, while in the other the standing check was best.

6.3 Overall Assessment - Performance

The weed control claims for preharvest use of glyphosate are well demonstrated and supported in all crops. The harvest management (drydown) attribute is adequately demonstrated and supported for indeterminate crops such as canola and lentils, as measured by moisture reduction in seed and foliage.

A direct response of drydown per se, as measured by moisture reduction, has not been as well demonstrated in cereals, flax or soybeans. Nevertheless, the merits of preharvest weed control in cereals and the inherent drydown (desiccation) effect of glyphosate on green plant material, are well recognized.

The merits of cereal drydown are clearer in cool wet weather when there are actively growing perennial weeds or late germinating annual weeds, late tillering, etc. These conditions create mechanical problems in harvesting such as winding on equipment. Thus, the decision to use preharvest cereal applications will likely be based on a range of practical considerations rather than simply on crop drydown (moisture reduction).

7. LABEL TEXT

The following label text was accepted and will appear on the ROUNDUP® label:

For control of quackgrass and Canada thistle and season-long control of perennial sow thistle, Roundup® can be applied prior to harvest of wheat, barley, canola (rapeseed), flax, lentils, peas and soybeans. This treatment may also provide harvest management benefits, by drying down crop and weed vegetative growth, for example where late flushes of annual weeds, green vegetative crop growth or late tillering may interfere with harvesting operations. Roundup® should be applied preharvest at 2.5 L/ha in 50 to 100 L/ha of clean water by ground application only. Roundup® should be applied when the crop has 30% or less grain moisture content. This stage typically occurs 7 to 14 days before harvest. Consult the table "Guidelines for timing of preharvest applications" for visual indicators of this stage in each crop. For the best weed control results, apply when quackgrass is actively growing and has at least four to five green leaves. Canada thistle and perennial sow thistle should be actively growing, and at or beyond the bud stage for best results. Applications for weed control (whether or not for harvest management) must be made at the correct stage of both weed and crop growth.

Apply only during the period 7 to 14 days before harvest to ensure best weed control and to maximize harvest management benefits. Earlier application may reduce crop yield and/or quality, and may lead to excess glyphosate residues in the crop.

**DO NOT APPLY TO CROPS GROWN FOR SEED
DO NOT APPLY TO BARLEY GROWN FOR MALTING**

Avoid overspray or drift to important wildlife habitats such as bodies of water, shelterbelts, woodlots and other cover on the edges of fields frequented by wildlife. Leave a 15-meter buffer zone between the last spray swath and the edge of any of these habitats.

Do not expose or contaminate any body of water or non-target vegetation by direct application, spray drift, or when cleaning and rinsing spray equipment.

DO NOT APPLY BY AIRCRAFT